出國報告

(類別:其他:研討會)

參加世界動物衛生組織動物用藥品業務窗口之區域性 ANIMUSE 培訓研討會

服務機關:行政院農業委員會動植物防疫檢疫局

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派赴國家:泰國曼谷

報告日期:112年4月17日

出國期間:112年2月21日至2月25日

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# 一、緣起及目的

於細菌抗藥性(Antimicrobial Resistance, AMR)全球行動計畫框架下,世界動物衛生組織(World Organisation for Animal Health, WOAH,前身為 OIE)已建立動物用抗菌劑使用量(Antimicrobial Use, AMU)全球資料庫,收集 AMU 資料。自 2016 年發布第一份 AMU 年度報告以來,參與國家逐漸增加,至第七年度資料收集時已增加至 157 個國家。為響應 WOAH 於 2018 年 10 月第二次全球細菌抗藥性會議上提出之建議,進一步優化 AMU 資料收集,WOAH 於 2022 年9 月推出全新之線上 AMU 報告工具,即 <u>AN</u>imal ant <u>IM</u>icrobial <u>USE</u>(ANIMUSE) 全球資料庫。此舉旨在進一步強化對動物用藥之監管。

於此框架下,WOAH 籌劃區域性 ANIMUSE 培訓研討會,受眾對象為 WOAH 國家動物用藥品業務聯繫窗口,該研討會安排 2023 年 2 月 22 日至 24 日於泰國 曼谷舉辦。此培訓由日本政府透過日本信託基金與英國弗萊明基金資助,並於泰國政府支持下進行。

此次培訓旨在向參與者提供實務面知識與技巧,讓會員國開始使用 ANIMUSE全球資料庫,並為會員國提供機會與不同利害相關者合作,分享其於 AMU 資料收集、資訊視覺化與其他 AMU 相關活動中之經驗。培訓結束後, WOAH業務聯繫窗口應將所獲得之知識與其他方之利益關係者分享。

# 二、行程及會議議程

■ 2023年2月21日(二):臺北往曼谷。

■ 2023年2月22日(三):

時間	主題	主持人/主講人	
時間 9:00~ 9:45	開幕式與引言	王持人/王講人  1. Dr. Chantanee Buranathai(防疫一體協調員,WOAH -東南亞區域代表處One Health Coordinator,WOAH RR-SEA)  2. Dr. Hirofumi Kugita(區域代表,WOAH - 亞太地區辦事處,Regional Representative,WOAH RRAP)  3. Dr. Ronello Abila(WOAH -東南亞區域代表,Sub-Regional Representative,WOAH RRAP)  4. Dr. Morgan Jeannin(WOAH總部 - 數據資訊管理主任,Data Information Management Officer,	
9:45 ~ 10:00	與會者簡短自我介紹 本研討會目標	WOAH HQ)  所有與會者  Dr. Ronello Abila (WOAH -南亞東南亞分區域代表處,WOAH SRR-SEA)	
10:00 ~ 10:15	WOAH 之 AMR 與謹慎使用抗菌劑策略	WOAH -亞太區域代表處AMR區 域 專 案 主 任 Nahoko Ieda (Regional Representation for Asia and the Pacific, RRAP, AMR Regional Project Officer)	

時間	主題	主持人/主講人	
10:15~	     國家級動物用抗菌劑使用量及其使用	WOAH細菌抗藥性暨動物用藥產	
10:30	型態監測之重要性	品部門 (AMR&VPD) Dr. Morgan	
	空恐血,	Jeannin	
10:30~	WOAH 之 AMU 資料收集歷程	WOAH亞太區域代表處/東南亞分	
10:45	WOAII 之 AWO 真附収未庭住	區代表處(RRAP/SRR-SEA)	
10:45~	提問與回答 (Session for Q&A)	所有與會者	
11:00	元向央回告 (Bession for Quit)	777月六日日	
11:00~	 		
11:30	/八// [五	<b>小</b> 次在7次	
11:30~		WOAH細菌抗藥性暨動物用藥產	
11:50	ANIMUSE 及其主要功能介紹	品部門(AMR&VPD)Dr. Idrissa	
11 - 50		Savadogo	
11:50~	ANIMUSE – AMU 問卷之線上與非線上送件	WOAH細菌抗藥性暨動物用藥產	
12:10		品部門 (AMR&VPD) Dr. Morgan	
12 * 10		Jeannin	
12:10~	ANIMUSE –	WOAH細菌抗藥性暨動物用藥產	
12:30	AMU 問卷填報與常見錯誤	品部門(AMR&VPD)Dr. Delfy	
		Góchez	
12:30~	提問與回答 (Session for Q&A)	所有與會者	
13:00	THE CONTROL OF COLUMN 1 (See 1)	加有 <del>與</del> 首有	
13:00~	午餐		
14:00	十食		
14:00~	WOAH會員國測試使用ANIMUSE之	我國行政院農業委員會動植物防	
14:15	經驗分享	疫檢疫局 黃怡銘技士	
14:15~	ANIMUSE之AMU問卷實作練習	● 所有與會者	
16:00	1. 回答AMU問卷疑義(包括線上與	● 輔導員:WOAH細菌抗藥性	
10 . 00	非線上問卷)	暨動物用藥產品部門	

時間	主題	主持人/主講人		
	2. 回應WOAH之提問	( AMR&VPD ) Dr. Morgan		
		Jeannin 與 Dr. Andrés García		
		Campos °		
16:00~	+.+ ^/			
16:30	茶敘			
16 : 20		WOAH細菌抗藥性暨動物用藥產		
16:30~	ANIMUSE其他功能介紹	品部門(AMR&VPD) Idrissa		
16:50		Savadogo		
		● 所有與會者		
		● 輔導員:WOAH細菌抗藥性		
16:50~		暨動物用藥產品部門		
17:20	ANIMUSE功能探索(實作練習) 	( AMR&VPD ) Dr. Morgan		
		Jeannin 與 Dr. Andrés García		
		Campos °		
17:20~	THERETIZAN ( G	rr + rei A +v		
18:00	提問與回答 (Session for Q&A)	所有與會者		
19:00	晚宴			

# ■ 2023年2月23日(四):

時間	主題	主持人/主講人	
8:30 ~ 8:45	從亞太區看第六年度 AMU 報告	WOAH 亞太區域代表處 AMR 區域 專案主任 Nahoko Ieda (Regional Representation for Asia and the Pacific, RRAP, AMR Regional Project Officer)	
8:45 ~ 9:00	以總動物體重分析AMU資料(Using Animal Biomass to analyze AMU data)	WOAH細菌抗藥性暨動物用藥產 品部門(AMR&VPD)Dr. Morgan Jeannin	
9:00 ~ 9:20	AMU資料收集之製藥產業角色	全球動物衛生協會 Rick Clayton	
9:20 ~ 9:40	提問與回答 (Session for Q&A)	所有與會者	
9:40 ~ 10:10	茶紋		
10:10 ~ 10:30	運算式分子之計算:藥品主成份重量 ( Calculation of the numerator: kilograms of active ingredients )	WOAH細菌抗藥性暨動物用藥產 品部門(AMR&VPD)Dr. Delfy Góchez	
10:30 ~ 10:45	ANIMUSE計算工具與 日本AMU國家報告	日本農林水產省國家獸醫檢驗實 驗室研究主任 Dr Mari Matsuda	
10:45 ~	ANIMUSE計算工具之實作練習	<ul><li>● 所有與會者</li><li>● 輔導員</li></ul>	
12:30 ~ 13:30	午餐		
13:30 ~ 13:45	馬來西亞之AMU國家監測經驗	馬來西亞獸醫局 Dr. Rohaya Mohd Ali ( Department of veterinary services)	

時間	主題	主持人/主講人			
	柬埔寨之AMU國家監測經驗	柬埔寨動物衛生與生產總局之動			
		物衛生暨獸醫公共衛生處副處長			
		Dr. Tep Bengthay			
13:45 ~ 15:00	小組討論:  1. 定義執行AMU監測系統之原因與 目標  2. 於AMU監測系統中,定義利益關 係者之角色定位  3. AMU監測系統之資料公布	● 所有與會者			
15:00 ~ 15:30	小組報告 報告者				
15:30~					
16:00	茶敘				
16:00~	法國AMU資訊視覺化經驗	法國動物用藥管理局-抗菌劑使用專案經理 Anne Chevance (Antimicrobial Use Project Manager, French Agency for			
16:25	印尼AMU資訊視覺化經驗	Veterinary Medicinal Products)  印尼農業部動物衛生署動物用藥 監管處 Dr. Ni Made Ria Isrlyanthi			
16:25 ~ 16:40	ANIMUSE之AMU資訊視覺化	WOAH 細菌抗藥性暨動物用藥產品部門(AMR&VPD)Dr. Morgan Jeannin			
16:40 ~ 17:40	ANIMUSE資訊視覺化實作練習	<ul><li>所有與會者</li><li>輔導員</li></ul>			
17:40~	WOAH全球計畫介紹:動物用藥品之	WOAH 細菌抗藥性暨動物用藥產			

時間	主題 主持人/主講人		
18:00	偽藥、劣藥通報系統	品部門(AMR&VPD)Dr. Andrés	
		García Campos	

# ■ 2023 年 2 月 24 日 (五):

時間	主題	主持人/主講人	
8:30~	AND OLICE 李州兴 中 帝 hr 体羽	● 所有與會者	
10:30	ANIMUSE 資料送件之實作練習	● 輔導員	
10:30~	唐田ANIMUSE 文 F 碑	公子(4) 本书.	
10:45	使用ANIMUSE之反饋	所有與會者	
10:45 ~	·女·Ar		
11:15	茶敘		
11:15~		WOAH細菌抗藥性暨動物用藥	
11:13~	WOAH之畜牧場端AMU資料收集	產品部門(AMR&VPD)Dr.	
11 · 30		Morgan Jeannin	
11:30~	供茶明甘 <u>会</u> 社妻之西湖 <b>AM</b> T资料收集	Mott MaDonald≥Manisha Bista	
11:45	佛萊明基金計畫之亞洲AMU資料收集 	與Darunee Tuntasuvan	
		法國動物用藥管理局-抗菌劑使	
		用專案經理 Anne Chevance	
		( Antimicrobial Use Project	
	法國獸醫師與農民之AMU工作	Manager, French Agency for	
		Veterinary Medicinal Products )	
11:45 ~			
12:20			
	巴基斯坦觀點:獸醫師與農民AMU收	巴基斯坦國家食品安全與研究	
	集工作	部門-副動物畜牧委員會助理委	
		員/動物健康防疫及疾病控制計	
		畫北部與東部負責人	
		Riasat Wasee Ullah	
12:20~		or Loke A de	
12:30	提問與回答 (Overall Q&A)	所有與會者	
12:30~	午餐		

時間	主題	主持人/主講人		
13:30				
13:30~	日日 ナケ ケーナンエ CE1 ハエ マケ ブル・キャ	WOAH 南亞東南亞分區域代表		
13:55	閉幕結語與頒發證書	處(WOAH SRR-SEA)		
ANIMUSE 培訓研討會結束				
14:00~       動物用藥品偽藥、劣藥通報系統實作練         15:30       習		WOAH 細菌抗藥性暨動物用藥 產品部門(AMR&VPD)Dr. Andrés García Campos		

■ 2023年2月25日(六):曼谷返回臺北。

## 三、過程及會議內容

#### (一) 開幕式及引言

於世界動物衛生組織(WOAH)八個業務聯繫窗口(Focal Points)之中,動物用藥品(Veterinary Products)併同動物疾病通報業務聯繫窗口(Animal Disease Notification Focal Points)成為近年最活躍之業務窗口,此最主要原因為全球細菌抗藥性行動方案。細菌抗藥性(Antimicrobial Resistance, AMR)議題對人類與動物均相當重要。WOAH於 2016年11月啟動 AMR 與謹慎使用抗菌劑策略,並不斷致力於建立與管理動物用抗菌劑使用量(Antimicrobial Use, AMU)全球資料庫。國際上已有國家執行AMU資料收集與監測,並透過銷售供應鏈進行分析,包括動物用抗菌劑之法規、製造、銷售與使用,該等工作對每個國家而言並非易事。

迄今為止,WOAH 已公布第六年度 AMU 報告,第七年度報告刻正作業中,該報告係以洲級別顯示區域性之總和數據。此外,WOAH 鼓勵所有會員國將收集之數據發布至自己國家平臺上,並強化會員國數據收集與分析能力。WOAH 於 2022 年啟用 AMU 全球資料庫資訊系統,稱為 ANIMUSE。WOAH 舉辦為期三天之 ANIMUSE 培訓,主要係邀請 WOAH 國家動物用藥品業務聯繫窗口,分享 AMU 資料收集之經驗與提供 AMU 相關之實務面知識與技巧。WOAH 正與聯合國世界糧農組織(FAO)持續合作。

WOAH 勉勵國家動物用藥品業務聯繫窗口(Veterinary Products Focal Points),與該國之同事、工作夥伴建立良好之橫向連結與合作,為人類與環境健康而努力。

WOAH 於 2020 年 4 月即規劃辦理 AMU 資料收集實體會議,然而因 COVID-19 疫情而取消,並轉以視訊會議方式進行,會員國亦提出許多 AMU 資料收集與分析之功能需求,該等需求對 WOAH 至關重要。過去十年已有不同之政治領域提高人民對 AMR 之關注,而使 AMR 成為迫切處理之議題。2022 年 11 月於阿曼馬斯喀特舉辦第三屆細菌抗藥性全球高層部長級會議( Third Global High-level Ministerial Conference on Antimicrobial

Resistance [AMR] in Muscat, Oman. 24-25 November 2022),所有與會成員均承諾強化國家監測系統,包括改善資料管理、私營部門之參與、因應收集資料採取對應措施;與透過 WOAH 動物用抗菌劑使用量全球資料庫系統(即 ANIMUSE)向 WOAH 送交 AMU 資料。自 2015 年以來,WOAH已開始進行全球 AMU 資料收集。自 2018 年起,WOAH一直致力於將 AMU資料收集轉化自動化、高效率與安全之資訊系統線上作業(即 ANIMUSE),並協助會員國進行分析、報告;最重要的是協助會員國進行 AMU 資料溝通交流。ANIMUSE系統已於 2022 年 9 月 19 日啟用並與第八年度之 AMU資料收集同步進行。WOAH提醒,ANIMUSE創建宗旨係提供會員國所有必要之 AMU 收集與分析相關工具。於本次培訓研討會,會員國學習如何使用 ANIMUSE 及其效益,亦討論國家層級可能需要之數據視覺化功能,WOAH希望 ANUMUSE 有助於會員國 AMU 之相關決策並成為該國對抗AMR 之工具。

## (二)WOAH 之AMR 與謹慎使用抗菌劑策略

由 WOAH 亞太區域代表處(Regional Representation for Asia and the Pacific, RRAP)之 Dr. Nahoko Ieda 簡報「WOAH 之 AMR 與謹慎使用抗菌劑策略」(WOAH's strategy on AMU and prudent use of antimicrobials)。《決議案 26》為 2015 年世界衛生大會(World Health Assembly)通過一項決議,標題為「打擊細菌抗藥性與促進動物合理使用抗菌劑(Combating antimicrobial resistance(AMR)and promoting the prudent use of antimicrobial agents in animals)」。該決議強調迫切需要應對不斷增長之細菌抗藥性威脅,此為全球公共衛生問題。該決議承認合理使用抗菌劑對於防止細菌抗藥性之發展與傳播,對人類與動物均非常重要,並呼籲採取「防疫一體策略(One Health approach)」,進行人類、動物與環境之跨部門合作,以應對細菌抗藥性問題。另呼籲制定與實施國家行動計畫(National action plans),與進行國際合作,打擊細菌抗藥性。

第 36 號決議係由 WOAH 通過之決議,著重於透過防疫一體策略對抗細菌抗藥性(AMR)。該決議承認,動物謹慎使用抗菌劑可降低細菌抗藥性出現與擴散之風險,並強調需要跨部門合作,包括人類衛生、動物衛生與環境衛生,以有效解決細菌抗藥性問題。該決議包括多項行動與策略以對抗細菌抗藥性,包括強化獸醫服務體系,促進動物謹慎使用抗菌劑,改善細菌抗藥性之監測與監控系統,提高公眾對抗藥性之認識與教育(Increasing awareness and advocacy),促進國際合作與夥伴關係。WOAH 另制定防疫一體應對細菌抗藥性之策略,包括強化國家與區域技術能力、制定基於科學證據之政策與指南、促進研究與創新,以及提高對細菌抗藥性之認識與宣導。

WOAH 已制定了一套程序與標準,確保每年能從會員國收集產食動物 之抗菌劑使用量,並建立成全球資料庫。



#### RESOLUTION No. 26

Combating Antimicrobial Resistance and Promoting the Prudent Use of Antimicrobial Agents in Animals

#### CONSIDERING

- 1 That antimicrobial agents are essential tools for protecting animal health and welfare and also contribute to meeting the increasing global domand for safe meat, milk, fish and oggs, and other products of animal origin.
- That antimicrobial resistance (AMR) is a significant global animal and human health threat that is influenced by the use of antimicrobial agents in some conditions.
- 3 That during the 77th General Session 2009, the World Assembly of Delegates (the Assembly) adopted Resolution No. 25 on Veterinary Products, which considered previous Resolutions on harmonisation of registration requirements for veterinary drugs, their responsible and prudent use and monitoring of resistance.
- 4 The recommendations of the DIE Global Conference on the responsible and prudent use of artimicrobial agents in summis, held in March 2013 in Paris, France, including recommondation No.7 to collect harsements quantitative data on the use of antimicrobial agents in animals with the view to establishing a global database.
- 5 The recent update and development of OIR standards and gain/alinea related to antimierchial resistance, which include references to the relevant standards developed by Codex Alimentaries.
- 6 The tripartite agreement between FAO, OIE and WHO to address as a priority antimicrobial resistance and the important contribution of the OIE to the development and achievement of the WHO global action plan on antimicrobial resistance.
- The network of GIE National Pocal Points for Veterinary Products and its rele in supporting
  the global implementation of the OIE standards regarding seterinary products.
- 8. The importance of the PVS yathway in supporting compliance of notional veterinary services with OIE standards including legislation, as a prerequisite to ensuring good governance sovering production, registration, distribution and use of antimicrobial agents at the national level.
- The importance of appropriate Veterinary Education and Veterinary Statutery Bedies in the promotion of voterinary oversight to ensure responsible use of antimicrobial agents in arimale.

#### THE ASSEMBLY

#### RECOMMENDS THAT

 The OIE continue to develop and update standards and guidelines related to antimicrobial resistance and the prudent use of antimicrobial agents including updating regularly the OIE

#### RESOLUTION No. 36

ombating Antimicrobial Resistance through a One Health Approach:
Actions and OIE Strategy

#### CONSIDERING

- That astimizabial resistance (AMR) is both an animal and human health threat of growing encorn which has been significantly considered by the OUE through the development and adoption of relevant and important standards and guidelines.
- 2. That during the 77th General Session (May 2009), the World Assembly of Belogates (the Assembly) adopted Berobation No. 25 on Veterianry Medicinal Products, which also considered previous Resolutions on the harmonising of registration requirements for veerianty drugs, their responsible and pradect use and the monitoring of resistance including recommended actions to be implemented.
- 3. The recommendations of the OIE Global Conference on the responsible and prudent use of antimerobidal agents in animals, sheld in March 2013 in Parts, Peares, including Recommendation No. 7 to other thermonised quantitative that as the use of antimicrobial agents in animals with the view to establishing a global database, which was subsequently formally endersed by the Assembly at the Bird General Session (May 2015) through the adoption of Recontaints No. 8.
- 4. The contribution of the OIE to the development of the World Health Organization's (WHO) Global Action Plan on Antimerobial Besistance, under the framework of the Tripursite agreement between the Food and Agriculture Organization of the United Nations (FAO), the WHO and the OIE which was adopted by the World Health Assembly of the WHO in May 2015.
- The recommendation to Member Countries, to follow the guidance of the WHO Glebal Action Planen Antimicrobial Resistance, in particular by developing authoral action plans, in respect of the use of antimicrobial agents in animals and ensuring close collaboration with public health officials, adopted through Resistance No. 26 of the 38rd Georgia Bession on Countaining Antimicrobial Resistance and Promoting the Prodect Use of Antimicrobial Agents in Animals.
- 6. The importance of the capacities of the national Votorinary Services to comply with the relevant standards and the particular bounds of the OIE PVS Pathway in supporting the Member Countries to tupdate their legislation, which is a preventiant to ensure good governance overing registration production, distribution, prescription and use as well as mortral and curvatilance of ontimiorabilal agents at the sational level.
- The role of the network of the OIE National Focal Points for Voterinary Products in supporting the global implementation of the OIE standards regarding reterinary products.
- 8. The importance of appropriate veterinary and veterinary pare-prefessional education in the



WOAH 於 2016 年 11 月公布因應細菌抗藥性與謹慎使用抗菌劑之策略(WOAH Strategy on AMR and the Prudent Use of Antimicrobials)(如附件 1)。該策略與 2015 年世界衛生組織之全球細菌抗藥性行動計畫(WHO Global Action Plan on AMR)一致,且為三方國際共同合作。目標為:1. 提高對細菌抗藥性之認識與瞭解(Improve awareness and understanding)。2. 透過監測和研究強化相關知識(Strengthen knowledge through surveillance and research)。3.支援良好之管理措施並建立相關技術能力(Support good governance and capacity building)。4. 鼓勵實施國際標準(Encourage implementation of international standards)。

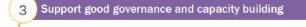




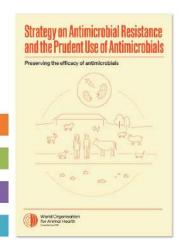
- Launched in November 2016
- Aligned with WHO Global Action Plan on AMR in 2015 and the Tripartite Partnership

# 1 Improve awareness and understanding 2 Strengthen knowledge through surve









第一大目標:提高對細菌抗藥性之認識與瞭解(Improve awareness and understanding):

遵循五個使用抗菌劑之原則:

- 1. 只於有良好動物衛生照護時,才使用抗菌劑。
- 2. 抗菌劑無法治療所有感染,僅於需要時才使用抗菌劑。
- 3. 只於獸醫師開處方時,才使用抗菌劑。
- 4. 只按處方箋劑量、治療天數與停藥期使用抗菌劑。
- 5. 只從合法販賣業者與來源取得抗菌劑。

## **5 ONLY Rules**



全球四方合作(Global Quadripartite)係指世界衛生組織(WHO)、聯合國糧食及農業組織(FAO)、世界動物衛生組織(WOAH)與聯合國世界糧食計畫署(World Food Programme, WFP)等四個國際組織之合作。他們致力於提升全球防疫、健康與營養安全,其中包括對抗細菌抗藥性活動。

全球四方合作(Global Quadripartite)主辦之「世界抗藥性警覺週」(或翻譯為世界抗菌劑認識週)(World Antimicrobial Awareness Week,WAAW)固定於每年 11 月 18 日至 24 日舉辦。活動口號為「抗菌劑:謹慎使用」(Antimicrobials: Handle with Care)。活動跨多領域,主題為全球共通:

● 2021 年:提升覺察意識、遏制細菌抗藥性。

● 2022 年: 齊心預防細菌抗藥性

2023年: 待於年中公布。

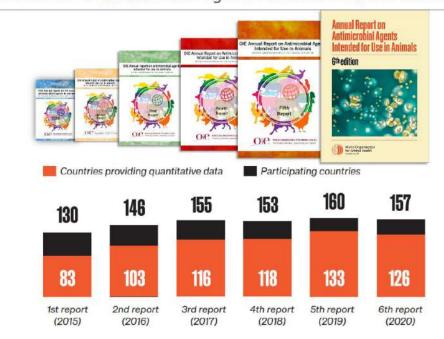
以下照片為 WOAH 與某些國家合作舉辦之「世界抗藥性警覺週」(或翻譯為世界抗菌劑認識週),例如於孟加拉國,WOAH 合作舉辦研討會與提高對細菌抗藥性認識之活動。於斐濟,WOAH 亦有定期研討會,WOAH 另為兒童發表一篇期刊文章,創作一幅彩色圖片,如下列照片,係由斐濟提出非常好的活動。因此,如果會員國有興趣與 WOAH 合作,提高您國家人民對細菌抗藥性與抗菌劑之認識,請與 WOAH 聯絡。



第二大目標:透過監測和研究強化相關知識(Strengthen knowledge through surveillance and research):

透過監測和研究強化相關知識為本次培訓研討會重點關注目標,建立全球動物用抗菌劑使用量資料庫。自 2015 年起, WOAH 每年發布 AMU 報告, WOAH 刻正努力擴大參與 AMU 報告之國家。從最初之 130 個國家到目前最新一次報告達到 157 個國家。

Global database on antimicrobial agents intended for use in animals (AMU)



於國內舉辦監測抗菌劑使用量與使用模式之研討會方面,自 2018 年以來,WOAH 與寮國、菲律賓、柬埔寨、緬甸、孟加拉國、不丹、蒙古、尼泊爾、斯里蘭卡、越南、印度尼西亞、馬來西亞、巴基斯坦舉辦相關研討會,2020 年為最後一次研討會,因 COVID-19 疫情,而使 WOAH 暫停這類型實體研討會,2021 年只有一個印度視訊研討會,WOAH 希望從 2023 年開始或從某個時間點開始,可恢復這類型研討會活動。因此,若會員國尚未舉辦這類型 AMU 研討會,可與WOAH 討論舉辦之可能性。



# In-country workshops on monitoring of the quantities and usage patterns of AMU

2018: Lao PDR, Philippines, Cambodia, Myanmar

2019: Bangladesh, Bhutan, Mongolia, Nepal, Sri Lanka, Viet Nam,

2020: Indonesia, Malaysia, Pakistan

2021: India (virtual)





第三大目標為支援良好之管理措施並建立相關技術能力(Support good governance and capacity building):

WOAH 每年都會進行業務聯繫窗口培訓研討會,上一次培訓為 2022 年 4 月份以視訊會議進行,WOAH 希望能於明年進行第八屆培訓,屆時 WOAH 總部將會通知大家。WOAH 動物用藥品業務聯繫窗口負責處理細菌抗藥性與抗菌劑使用問題。每兩年舉辦一次培訓研討會,旨在推廣 WOAH 活動。第一屆:2011 年 暹粒(Siem Reap)、第二屆:2012 年曼谷、第三屆:2014 年東京、第四屆:2016 年東京、第五屆:2018 年曼谷、第六屆:2020 年吉隆坡、第七屆:2022 年視訊會議。



# **Training series for Focal Points**

WOAH's Focal Points for Veterinary Products (appointed by WOAH Delegates in our counterpart ministry) are the officers in charge of AMR issues and AMU

Biannual training seminars aiming to promote WOAH's activities

1st Cycle: Siem Reap, 2011

2<sup>nd</sup> Cycle: Bangkok, 2012

3<sup>rd</sup> Cycle: Tokyo, 2014

4<sup>th</sup> Cycle: Tokyo, 2016

5<sup>th</sup> Cycle: Bangkok, 2018

• 6th Cycle: Kuala Lumpur, 2020

· 7th Cycle: Virtual, 2022

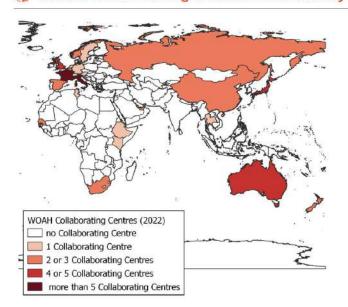


WOAH 於世界各地擁有許多合作中心與實驗室網絡,負責不同主題領域, 本次研討會強調 WOAH 之兩個合作中心。

第一、動物疾病與動物醫藥產品評估之合作中心(CollaboratingCenters for Animal Disease & Veterinary Products Assessment):由日本的兩個實驗室組成,分別為國家動物衛生研究所,國家獸醫實驗室。

第二、食品安全合作中心,包括日本兩個(羅久能學園大學獸醫學院;食品安全研究中心)、新加坡一個研究中心(國家食品安全中心)。這些研究中心為WOAH 區域性抗藥性監測與抗菌劑使用之專家,他們提供培訓與指導。例如,如下圖所示,他們與日本國家獸醫實驗室合作,邀請來自亞洲各國之抗藥性技術人員進行實作培訓,讓他們學習最新之抗藥性監測知識與技能。

#### (III) WOAH Collaborating Centers & Laboratory Network



#### CC for Animal Disease & Veterinary Products Assessment (JAPAN)

- National Institute for Animal Health
- · National Veterinary Assay Laboratory

#### CC for Food Safety

- School of Veterinary Medicine, Rakuno Gakuen University (JAPAN)
- Research Center for Food Safety (JAPAN)
- National Centre for Food Safety (SINGAPORE)



Hands-on training for AMR technicians in Asia

#### 第四大目標為鼓勵實施國際標準:

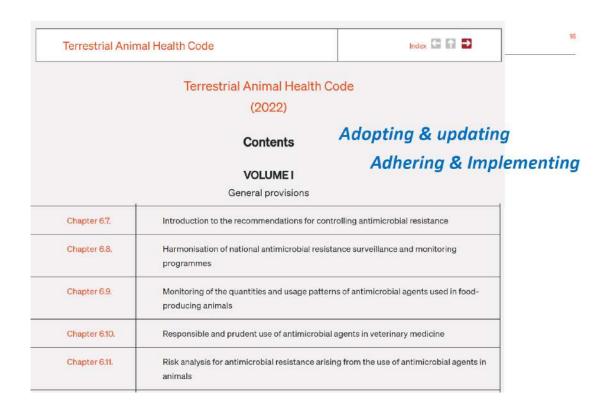
動物衛生為世界貿易組織中,食品安全檢驗及動植物防疫檢疫(Sanitary and Phyto Sanitary, SPS)協議之一部分,計三部分組成,分別為動物衛生(WOAH 標準與手冊)、食品安全(國際糧食法典)與植物衛生(國際植物保護公約)。對於活體動物及其相關產品之動物衛生,WOAH 國際標準獲得世界貿易組織認可。WOAH 國際標準旨在提高動物健康、福利與獸醫公共衛生,該國際標準係由WOAH 會員國於每年 5 月之常規會議上一致同意採納。因此,WOAH 目標係確保動物及其產品貿易之衛生標準。WOAH 已制定動物及其產品貿易的衛生標準,



另訂定診斷試驗與疫苗生物學標準手冊,以供診斷檢測與疫苗使用,其中亦包括 AMR 議題。



以下為陸生動物衛生法典、AMR、抗菌劑使用之相關章節,WOAH 鼓勵會 員國遵守與實施這些法典與手冊之標準,並持續與會員國合作。



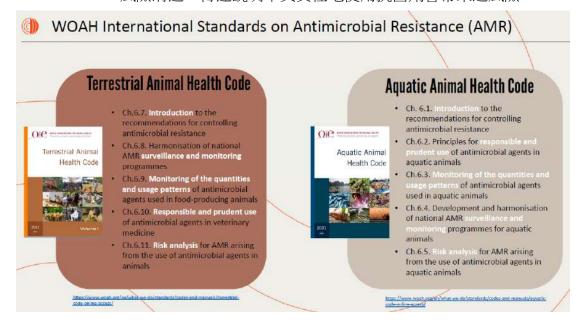
#### (三)國家級動物用抗菌劑使用量及其使用型態監測之重要性

由 WOAH 細菌抗藥性暨動物用藥產品部門(Antimicrobial Resistance and Veterinary Products Department, AMR&VPD)之 Dr. Morgan Jeannin 簡報「國家級動物用抗菌劑使用量及其使用型態監測之重要性」(Importance of monitoring quantities and usage patterns of antimicrobial agents in animals at a national level)。

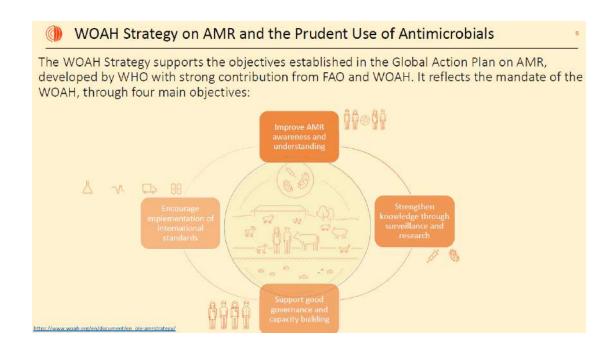
WAHO 陸生與水生動物衛生法典中,有一個專門講解 AMR 之章節, 即第六章。陸生動物衛生法典第 6.9 章與水生動物衛生法典第 6.3 章係說明 動物用抗菌劑使用量(AMU)資料收集。該等章節說明 AMU 監測之四項 目標及其重要性:

- 判讀: AMU 資料可協助 AMR 監測數據之判讀,以更精確與針對性之方式應對 AMR 問題。
- 2. 趨勢演變與相關性:隨著時間之推移,所取得不同時間點之 AMR 與 AMU 資料,可協助瞭解 AMR 與 AMU 趨勢演變與相關性。

- 3. 評估:透過上述分析資料,有助於國家進行風險管理,該評估資料與助於瞭解其努力與因應策略之有效性。
- 4. 溝通: 若國家之 AMR 與 AMU 資料係屬公開透明,則有助於進行 風險溝通,傳達說明不負責任地使用抗菌劑會帶來之風險。



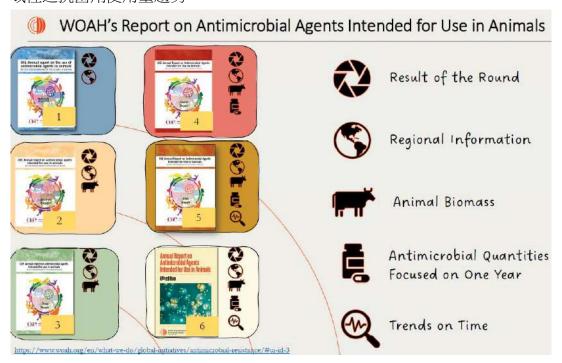
WOAH 對抗細菌抗藥性與謹慎使用抗菌劑之策略係支持世界衛生組織因應 細菌抗藥性全球行動方案計畫(Global Action Plan on AMR)制定之目標,該行動計畫獲聯合國糧食及農業組織(FAO)、WOAH 大力支持。其反映 WOAH 使命,主要目標為:1. 提高對 AMR 認知與理解。2. 透過監測與研究強化相關知識。3. 支援良好之管理措施並建立相關技術能力。4. 鼓勵實施國際標準。而本次培訓研討會之抗菌劑使用量資料收集屬於第二大目標:「透過監測和研究強化相關知識」。



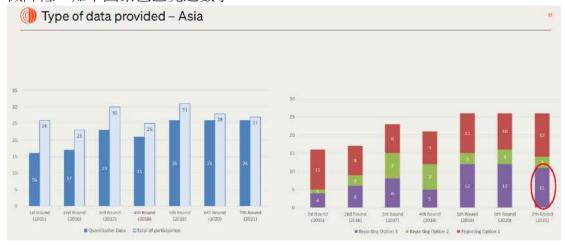
WOAH 任務係透過「WOAH 細菌抗藥性與合理使用抗菌劑策略」,建立、 收集產食動物與伴侶動物之抗菌劑使用量資料庫,並進行相關分析與年度報告。 WOAH 之 AMU 年度報告已持續六年,目前刻正編寫第七年度 AMU 報告。從這 些報告中,我們可從區域性或全球性視角觀察到抗菌劑使用量與細菌抗藥性趨勢; 出現具抗藥性特徵之微生物體。WOAH 動物用抗菌劑使用量全球資料庫旨在: 1.監測抗菌劑產品類型與使用情況。2.測量隨時間變化之 AMU 趨勢。3.追蹤全球 循環與使用模式。4.評估使用中之抗菌劑品質與真偽。



WOAH 使用全球與區域性之總動物體重(Animal Biomass)分析 AMU。於 過去兩年期間,WOAH 已有足夠可靠之 AMU 資料,因此能夠產出全球性與區 域性之抗菌劑使用量趨勢。



於歷次 WOAH 之 AMU 報告可觀察到,亞洲區國家之參與率一直很高,此外,填報動物種類與給藥途徑之 AMU 資料參與率亦創新高,惟於最後一年度略 微降低,如下圖紫色區塊之數字。



WOAH 短期願景係希望增加會員國 AMU 報告之參與度。透過 ANIMUSE 資訊系統計算工具,可更容易計算藥品使用種類、給藥途徑與;陸生、水生或伴 侶動物分群資料。長期願景: 1. 可產出每個動物種類之相關資訊。2. 透過世界動物衛生資訊系統(WAHIS)優化畜牧場之動物數量資料。3. 探索小範圍收集畜牧場端 AMU 資料之可行性。

## (四) WOAH 資料收集歷程

由 WOAH 亞太區域代表處/東南亞次區域代表處簡報「WOAH 之 AMU 資料收集歷程」(Journey of the AMU data collection)。

AMR 與 AMU 工作起源: AMR 工作最早起源於 1952 年 WOAH 第二十次會議。動物用藥品業務聯繫窗口(Focal point for veterinary products)係於 2008 年成立。



年份	事件			
2012	對陸生動物衛生法典第 6.9 章之實施進行調查,該章標題為「監測產食動物抗菌劑使用量與使用模式」,調查目標:  1. 確定需要採取哪些行動,並幫助 WOAH 制定相關之抗菌劑使用策略。  2. 為第 1 屆 WOAH 全球 AMR 會議做準備。			
	● 結果於 2013 年第 1 屆全球 AMR 會議上發表。			
2013	第 1 屆全球 AMR 會議:WOAH 會員國同意收集動物之抗菌劑使用			
2013	量,並提交給 WOAH 建立全球資料庫。			
	● 抗菌劑使用量(AMU)問卷範本:係由 WOAH AMR 臨時小組			
2014	(ad hoc Group on AMR)之專家依據《陸生動物衛生法典》第			
	6.9 章與《水生動物衛生法典》第 6.3 章·制定 AMU 問卷範本。			

	● WOAH 與美洲、歐洲、亞洲、遠東與大洋洲 地區國家動物用藥品業務聯繫窗口 (National Focal Points for Veterinary Products, FPVP)討論動物用藥產品之相關 文件;而非洲則係透過電子郵件詢問。
	● 「WOAH 第 83 屆全體會議」第 26 號決議「細菌抗藥性與促進
	動物合理使用抗菌劑」:由 WOAH 設計程序與國際標準以確保
	資料品質,收集會員國之抗菌劑使用量資料,以建立 WOAH 全
	球資料庫。
2015	● WOAH 國際標準:依據《陸生動物衛生法典》第 6.9 章與《水生
	動物衛生法典》第 6.3 章,制定陸生與水生產食動物之抗菌劑使
	用量與使用模式之問卷。
	● 首次推出第一個版本之 AMU 問卷(Excel),並正式啟用 (即
	第一年度 AMU 問卷)。
	「WOAH 第 84 屆全體會議」第 36 號決議「透過防疫一體策略對抗
2016	AMR」: 將 WOAH 採取之行動編制與整合於 WOAH 之 AMR 策略,
	包括建立與管理收集動物抗菌劑使用量資料庫、設計判讀指標。
	第 2 屆 WOAH 全球 AMR 大會第 4 號建議:將標準付諸實踐,進一
2018	步優化 WOAH 動物抗菌劑使用量資料收集·將電子檔格式轉換為線
	上資料庫系統,該資料庫能容納各個動物種別之資料,並與世界動物
	衛生資訊系統(WAHIS)連接·同時可用於未來畜牧場端 AMU 資料
	收集之研究。

動物抗菌劑使用量資料問卷分兩大部分,並以文獻報告同儕審查方法學收集 與分析資料:

- 1. 定性數據(基本資料,旨在讓所有國家均能填報)。
- 2. 定量數據(此部分依資料詳細程度,分為三種選項)
  - (1) 有抗菌劑之大類使用量與使用類型資料。

- (2) 有抗菌劑之大類使用量與使用類型資料。尚有對應之動物分群類別。
- (3) 有抗菌劑之大類使用量與使用類型資料、有對應之動物分群類別。 尚有對應之給藥途徑資料。

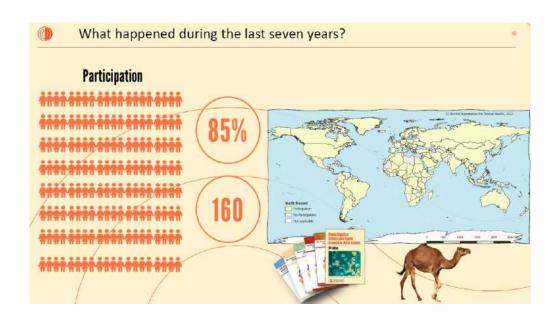
#### 名詞定義:

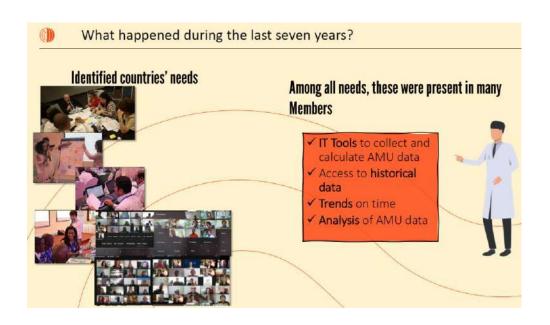
- \* 使用類型:分為「動物醫療用」或「生長促進用」。
- \*\* 動物分群類別:分為「陸生產食動物」、「水生產食動物」或「伴侶動物」。



## 過去七年期間,發生之事件:

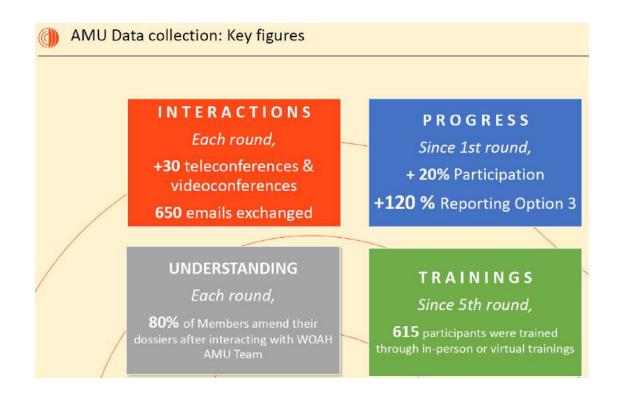
- 1. WOAH 之 AMU 問卷共 160 個會員國參與,參與率達 85%。
- 2. 確認會員國之需求。
- 3. 會員國之需求包括:
  - (1) 需要有一個收集與計算抗菌劑使用量之資訊技術(IT)工具。
  - (2) 可查看過去之歷史數據。
  - (3) 可分析抗菌劑使用量資料之趨勢。





#### AMU 資料收集歷程:

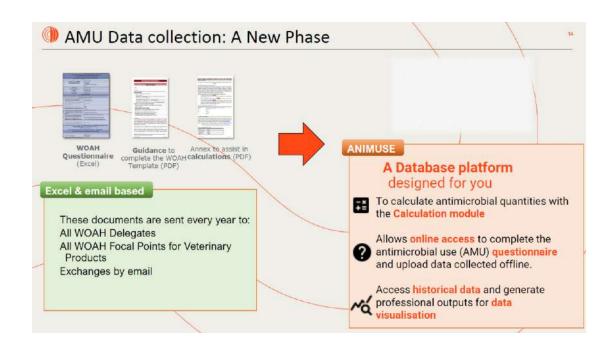
- 1. 與會員國互動:於每次 AMU 問卷調查,進行 30 次以上電話與視訊會議。往返 650 封電子郵件。
- 2. 增加對問卷之理解:於每次 AMU 問卷調查,有 80%會員國與 WOAH AMU 團隊討論後,修改其送交之檔案資料。
- 3. 進展: 自第 1 年度以來, AMU 調查參與率增加超過 20%。填報 3 號問 卷者增加超過 120%。
- 4. 培訓:自第5年度起,透過實體或視訊培訓計615名參與者。



AMU 資料收集已邁入新階段,起初係使用 Excel 檔案與電子郵件填寫 AMU 調查問卷,這些文件每年會電郵寄送給所有 WOAH 會員國代表與所有 WOAH 國家動物用藥品業務聯繫窗口。

目前已升級至使用 ANIMUSE 資訊系統填報 AMU 資料,其功能包括:

- 1. 使用系統計算工具,計算抗菌劑量。
- 2. 可線上填寫 AMU 問卷並上傳收集到之 AMU 數據。
- 3. 可查看過去歷史數據,並產出專業之視覺化圖表。



#### (五) ANIMUSE 及其主要功能介紹

WOAH 賦予 AMU 全球資料庫一個全新名字,稱為 ANIMUSE。其為 <u>An</u>imal Antimicrobial Use Global Database 之縮寫。



# ANIMUSE 大事紀時間軸如下:

日期		
— ///		

#### ANIMUSE 主要活動

2022/09/19	ANIMUSE 上線‧超過 200 名參與者‧至少 65 名成員代表出席。
2022/09/21	邀請函已發送至各國進行第八年度 AMU 資料收集。
	邀請會員國創建該國 ANIMUSE 帳號。
2023/02/15	亞洲 ANIMUSE 成功登錄率為達 63%,而全球為 64%。
2022/11/2~4	非洲培訓(英語):於南非為非洲國家進行 ANIMUSE 實體培訓。
2022/11/30~12/2	非洲培訓(法語):於突尼斯為非洲國家進行 ANIMUSE 實體培訓。
2023/02/22~24	亞洲培訓:於曼谷為亞洲國家進行 ANIMUSE 實體培訓。
2023/05/02~04	中東培訓:規劃於中東 ANIMUSE 實體培訓。

備註:歐洲和美洲國家之培訓將安排於往後幾個月。

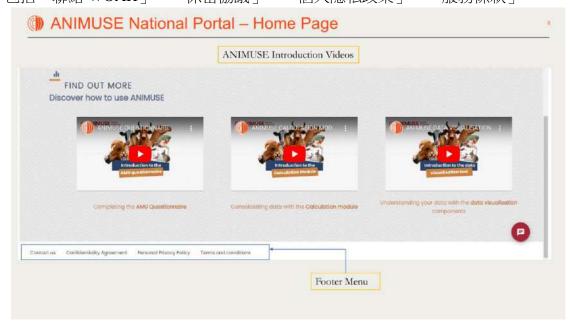
有關 ANIMUSE 登入權限方面,每個會員國僅開放 4 名,分別為會員國代表 (Delegate)、動物用藥品業務聯繫窗口、其他主管機關 (2 名)。會員國代表 之專屬權限為「定義資料之機密程度」、「創建其他主管機關基本資料」。



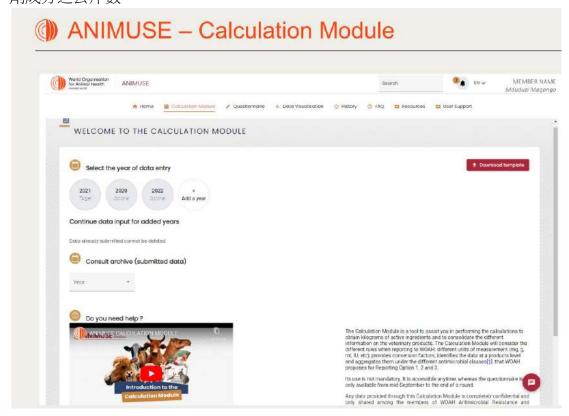
ANIMUSE 登入後之首頁畫面如下。右上角有訊息通知(Notifications)、語言選擇(英語、法語、西班牙語)、使用者名稱。上方第一排為網頁導覽選單(Top Navigation Menu),於其下方為 AMU 問卷填報與辦理進度(Tracker)。Calculation Module 為計算工具。下方為數據儀表板(Data Dashboard)、右下角為聊天室(Chat),可與 WOAH 之 AMU 團隊聯絡。



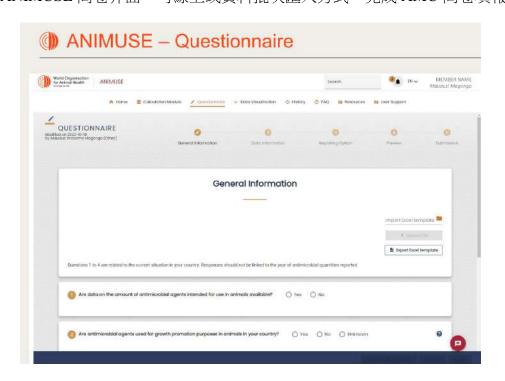
ANIMUSE 首頁最下方為 ANIMSUE 介紹影片。網站底部選單(Footer Menu)包括「聯絡 WOAH」、「保密協議」、「個人隱私政策」、「服務條款」。



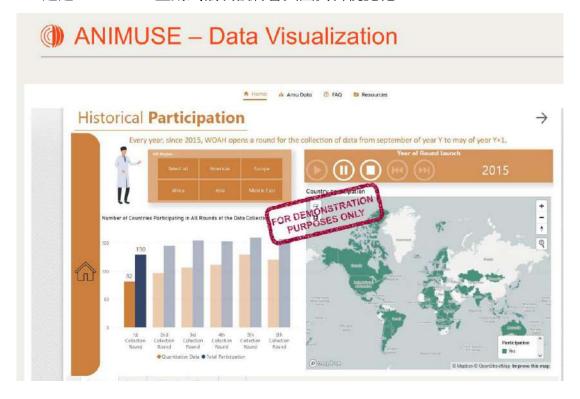
ANIMUSE 之計畫工具(Calculation Module)介面,可協助會員國計算抗菌劑成分之公斤數。



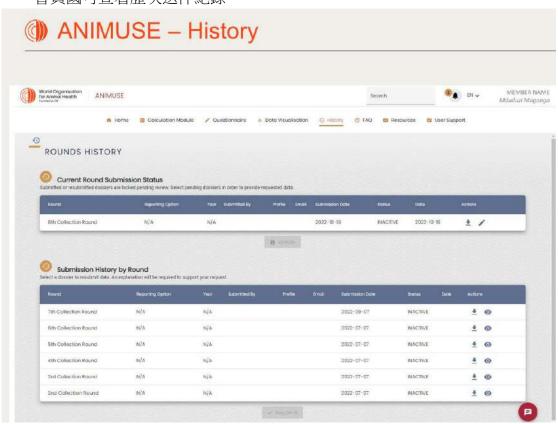
於 ANIMUSE 問卷介面,可線上或資料批次匯入方式,完成 AMU 問卷填報。



## 透過 ANIMUSE 互動式儀表板將會員國資料視覺化。

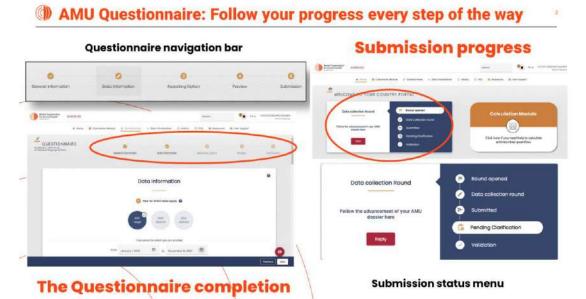


#### 會員國可查看歷次送件紀錄。

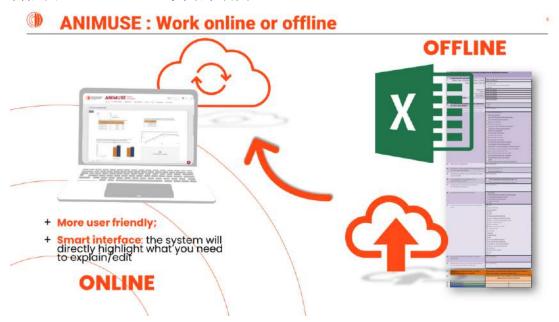


#### (六) ANIMUSE - AMU 問卷之線上與非線上送件

由 WOAH 細菌抗藥性暨動物用藥產品部門(AMR&VPD)Dr. Morgan Jeannin 簡報「ANIMUSE – AMU 問卷之線上與非線上送件」。ANIMUSE 之 AMU 問卷介面可查看問卷填報進度與送件進度。

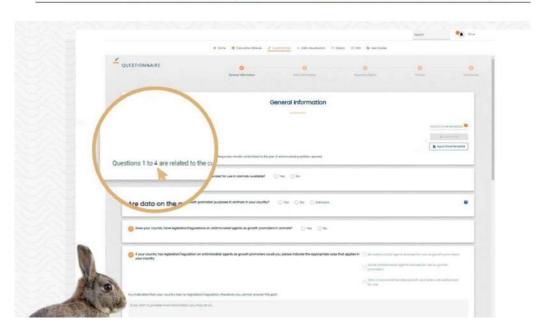


AMU 問卷數據除了可於 ANIMUSE 線上填報,亦可將離線之 Excel 檔案資料批次匯入 ANIMUSE 資訊系統內。

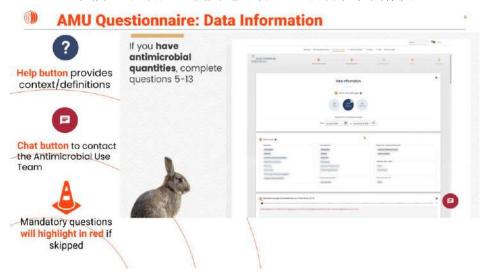


AMU 問卷調查第一部分為「一般資訊」。旨在讓所有參與者均能回答,即 使該國無收集抗菌劑使用量資料亦可回答。根據會員國之回答,系統可能會要求 會員國提供相關資訊。

# M AMU Questionnaire: General Information

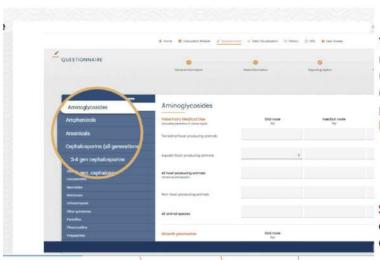


AMU 問卷第二部分為「數據資料」:若會員國有抗菌劑使用量資料,需填寫問卷第 5-13 題。「問號圖示」提供背景說明、定義說明。「聊天室圖示」可聯繫 WOAH 之 AMU 團隊。若跳過必填問題,將以紅色顯示未填報處。



AMU 問卷之報告選項:會員國可依「數據資訊」所提供之答案,選擇填報1號、2號或3號 AMU 問卷。可於 ANIMUSE 資訊系統暫儲填報之問卷內容。





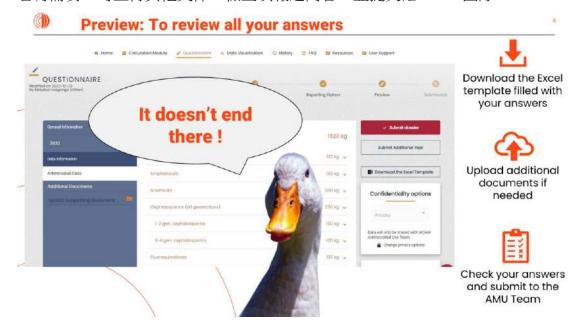


You have the possibility to report antimicrobial quantities using reporting option 1,2 or 3 depending on the answers provided in the Data Information section.

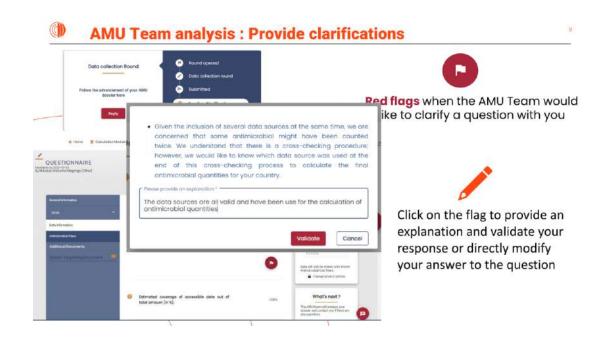


Save your questionnaire and complete it at the most convenient time

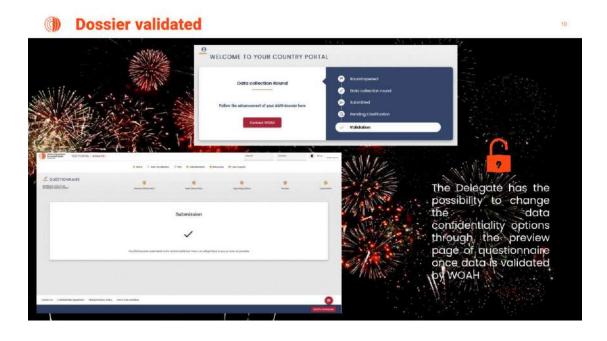
預覽:於 ANIMUSE 檢閱所有填報之內容,可下載填有答案之 Excel 模板。若有需要,可上傳其他文件。檢查填報之內容,並提交給 AMU 團隊。



AMU 團隊分析: 若 AMU 團隊希望與會員國釐清問題時,會出現紅色旗幟(如下圖)。點擊旗幟以提供解釋說明並驗證回答之內容;或直接修改回答內容。



最後會顯示「檔案已驗證」,一旦 AMU 資料被 WOAH 驗證後,會員國代表可以透過問卷預覽頁面,修改資料保密選項。

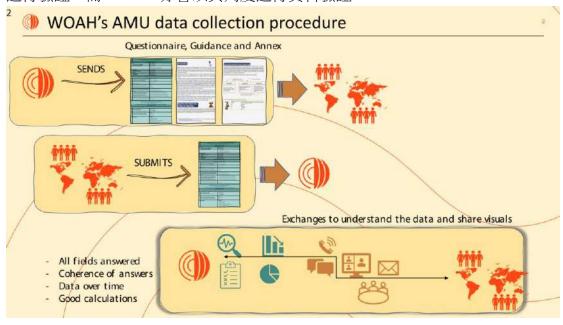


# (七) ANIMUSE - AMU 問卷填報與常見錯誤

由 WOAH 細菌抗藥性暨動物用藥產品部門(AMR&VPD)Dr. Delfy Góchez 以預錄影片簡報「ANIMUSE – AMU 問卷填報與常見錯誤」。

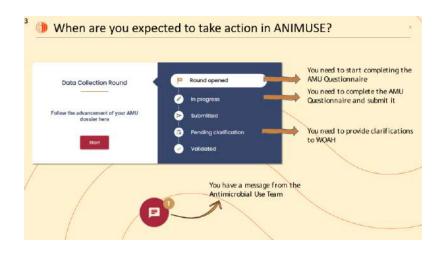
有關 WOAH 收集 AMU 資料之流程方面,以往係由 WOAH 電郵寄送 AMU

問卷(Excel 檔案)與指引說明給會員國。會員國將資料填畢後,電郵寄送給WOAH。為確保資料正確性、完整性與一致性,WOAH 會檢查問卷填報內容,並針對有疑義部分向會員國討論,可能係以電話、視訊會議、電子郵件或實體會議等方式進行,以確保WOAH提供適當之資訊與視覺化內容,會員國以其角度進行驗證,而WOAH亦會以其角度進行資料驗證。

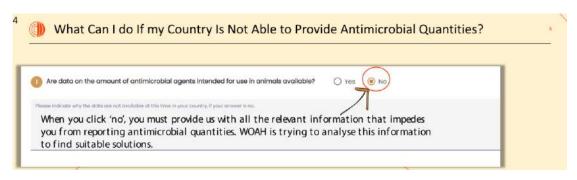


# 會員國何時要至 ANIMUSE 作業?

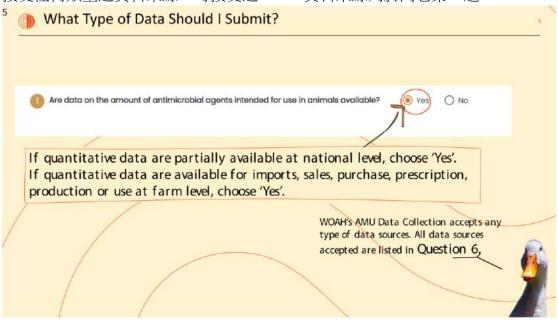
- 1. WOAH 開放填寫 AMU 問券時。
- 2. 填完 AMU 問卷並要提交給 WOAH 時。
- 3. 需要向 WOAH 釐清問卷填報內容時
- 4. 收到 WOAH 之 AMU 團隊訊息時。



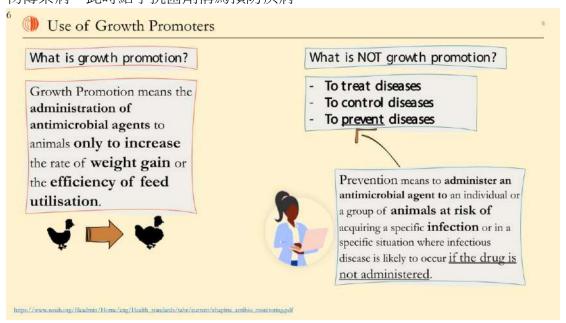
如果會員國無法提供抗菌劑使用量,則能做些什麼?於 AMU 問卷第一題點選「否」時,會員國必須向 WOAH 提供所有阻礙其收集抗菌劑使用量資料之相關訊息。WOAH 正試圖分析該等訊息以找到合適之解決方案。某些會員國反映有計算問題與缺乏協助數據收集之資統系統,故 WOAH 為解決此問題而創建ANIMUSE 計算工具。自 AMU 問卷創建以來,WOAH 之 AMU 問卷一直係設計供每個會員國可參與。



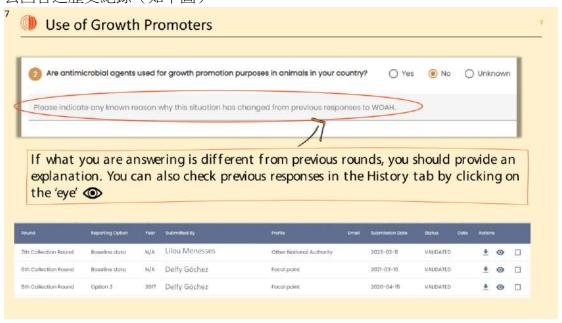
會員國應該提交哪種資料?若會員國有該國部份(即非全國性)之抗菌劑使用量資料,請點選「是」。若會員國有抗菌劑之進口量、銷售量、購買量、處方箋、製造量或畜牧場端使用量之資料,請點選「是」。WOAH之 AMU 資料收集接受任何類型之資料來源。可接受之 AMU 資料來源列於問卷第 6 題。



什麼是生長促進劑?生長促進劑係指將抗菌劑用於動物身上,僅用於提高體 重增長速率或提高飼料利用效率。什麼不是生長促進劑?用於治療、控制與預防 疾病均非為生長促進劑。所謂「預防疾病」係指個體或一群動物有受感染動物傳 染病之風險;或於可能發生動物傳染病之特定情況下,若不投藥,則可能發生動物傳染病,此時給予抗菌劑稱為預防疾病。

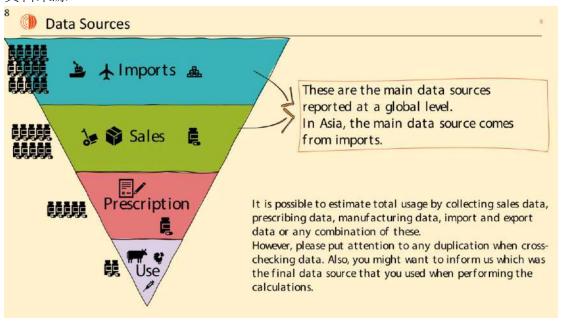


會員國是否有使用促進生長劑?若會員國回答之內容與前一次不同,則會員國應提供解釋說明。會員國亦可於 ANIMUSE 問卷點選「眼睛」之圖示,查看過去回答之歷史紀錄(如下圖)。

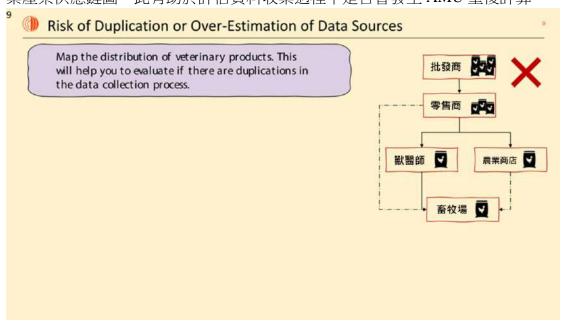


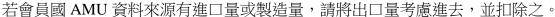
抗菌劑「進口量」與「銷售量」為全球 AMU 報告之主要資料來源。亞洲 AMU 主要資料來源為進口。可透過收集抗菌劑銷售量、處方箋資料、製造量、進口量、

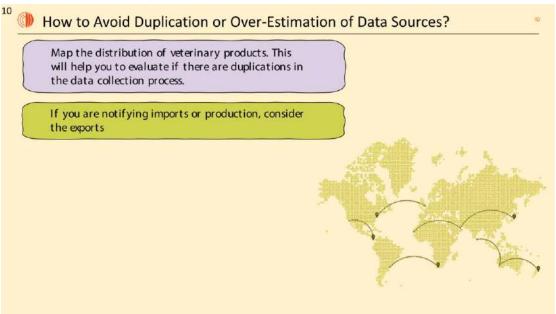
出口量或任何組合方式來估計總使用量。但是勾稽資料數據時,請注意是否有重複計算之處。同時,會員國需告知 WOAH,其計算 AMU 時,係使用哪種或哪些資料來源。



如何避免 AMU 資料來源重複或超估 AMU 之風險?建議會員國繪製動物用藥產業供應鏈圖,此有助於評估資料收集過程中是否會發生 AMU 重複計算。







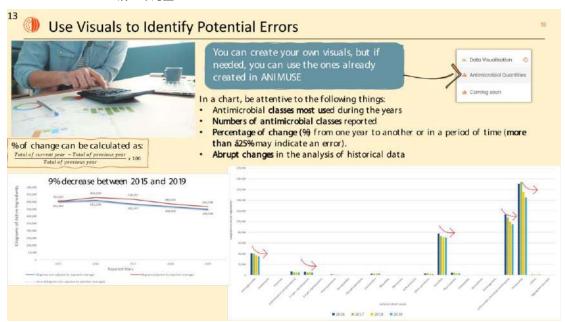
會員國可以為不同之動物種類,使用不同之資料來源(此取決於該動物種類最適合之資料來源為何),例如一個國家之抗菌劑使用量資料 = 家禽抗菌劑使用量(資料源自抗菌劑進口量)+伴侶動物抗菌劑使用量(資料源自抗菌劑銷售量)+水生動物抗菌劑使用量(資料源自用提供實際使用量)(加下層)。



可使用視覺化工具找出潛在之錯誤資料,會員國若有需求,則可創建自己之 視覺化工具,亦可直接使用 ANIMUSE 內建視覺化工具。於圖表判讀時,需注意 以下事項:

- 1. 每年最常使用之抗菌劑類別。
- 2. 報告中抗菌劑大類別之統計量。
- 3. 從一年至另一年;或一段時間內之變化率(25%以上可能表示有誤)。
- 4. 分析時發現過去數據之驟變。

變化率 =  $\frac{\text{當年總量 - }\hat{n} - \text{年總量}}{\hat{n} - \text{年總量}} \times 100\%$ 



### 計算時避免錯誤的方法:

- 1. 核對 WOAH 之計算建議。
- 2. 確保於適當時機使用換算參數。
- 3. 不計算包裝箱之重量,而係計算出抗菌劑活性成分之公斤數。
- 4. 一個國家之主管機關應可以查看按動物用藥產品之個別主成分資料。主管機關需確保能驗證不同利益關係者所提交之抗菌劑資料。

# (八) 我國測試使用ANIMUSE 之經驗分享

由行政院農業委員會動植物防疫檢疫局黃怡銘技士簡報「我國測試使用

# ANIMUSE 之經驗分享」。

# 背景說明:

AMR 議題已成為全球性重要問題,因此許多國家已開始實施對抗 AMR 行動計畫。為有效監測,瞭解過去與現況,故亟需一個自動化且高效率之 AMU 作業系統,協助 AMU 計算、發現錯誤、減輕耗時之工作量、並進行相關分析與產出報告。

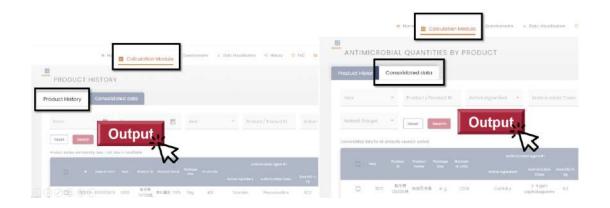
我國目前已建立動物用抗菌劑銷售量資訊系統,以收集動物用藥品製造商與輸入商之抗菌劑銷售量資料。再將該原始資料批次匯入 ANIMUSE 資訊系統中,該系統即可計算 AMU 並完成報告 WOAH 問卷。

# 給 WOAH 之建議:

測試使用 ANIMUSE 後,我國以使用者角度給予相關建議。於計算工具中有一個功能可以搜索「產品歷史紀錄」與「總合數據」。我國希望此兩種計算數據可以輸出為 Excel 檔案,此有助於我國對該等資料做進一步相關分析(如下圖)。



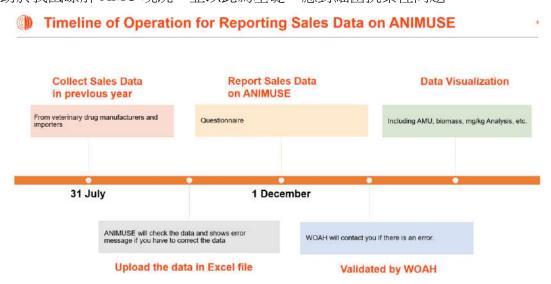
· Would be helpful for us to analyse the data



### 我國抗菌劑銷售量資料收集時程:

我國於每年7月31日會完成前一年度動物用藥製造商與進口商之抗菌劑資料收集與確認。收集之原始資料將以 ANIMUSE 標準化之 Excel 檔,上傳至

ANIMUSE 資訊系統,該系統會進行資料檢查,若資料有誤,則會顯示錯誤訊息。一般而言,WOAH之 AMU 問卷調查必須於每年 12 月 1 日前完成前一年度資料送件。送件後,資料由 WOAH 進行驗證。若發現有異常,則 WOAH 會與會員國聯繫並協助其修正錯誤。最後,我國上傳之 AMU 數據可透過 ANIMUSE 資訊系統進行視覺化分析,包括年度 AMU 折線圖、總動物體重、mg/kg 分析等。此有助於我國瞭解 AMU 現況,並以此為基礎,應對細菌抗藥性問題。



# (九) ANIMUSE 之AMU 問卷實作練習

ANIMUSE 資訊系統實作練習步驟如附件 2,供參考。

# (十) ANIMUSE 其他功能介紹

由 WOAH 細菌抗藥性暨動物用藥產品部門(AMR&VPD)Idrissa Savadogo 以預錄影片簡報「ANIMUSE 其他功能介紹」。

### 資訊安全:

# ANIMUSE 具多重安全層:

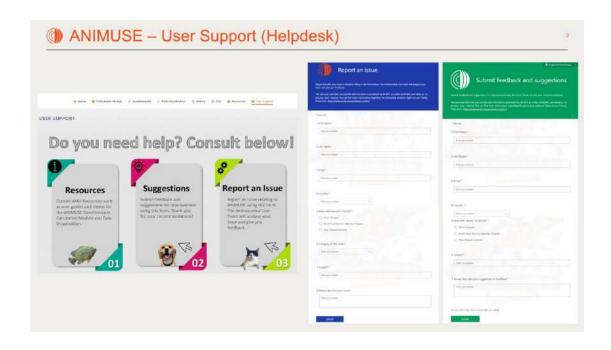
 認證: ANIMUSE 使用 Azure Active Directory (Azure AD) 多重認證,
 透過提供第二層認證,例如簡訊、驗證器應用程式等,協助保護系統之 登入權限。

- 2. 資料加密: ANIMUSE 使用 256 位元 AES (先進加密標準)對資料進行加密,此為目前可用最強之區塊加密之一。
- 3. 系統稽核:ANIMUSE 定期進行程式碼和效能稽核,以識別漏洞與效能問題。
- 4. 威脅偵測與監控: ANIMUSE 伺服器使用威脅偵測與監控工具,透過不 斷監控惡意活動以識別威脅,並提供相關發現,以便進行視覺化與修正。



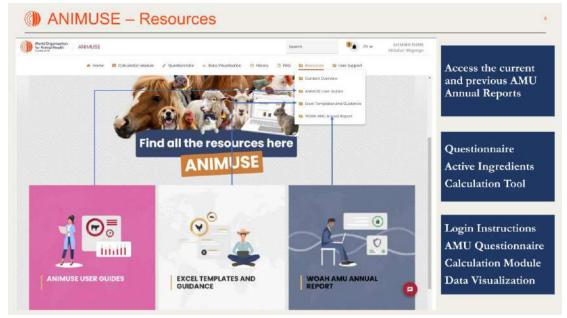
# 協助 ANIMUSE 系統使用者(點選 User Support):

- 資源:使用者可查閱 AMU 資源,如 ANIMUSE 問卷、計算工具與資料視覺
   化之使用者指南與教學影片。
- 2. 建議:使用者可填寫建議表單,給予系統工程師反饋與建議。
- 3. 報告問題:使用者可填寫問題表單。AMU 團隊會分析使用者提供之問題並 給予反饋。



# ANIMUSE 資源 (點選 Resources):

- 1. ANIMUSE 使用者指南:登入說明、AMU 問卷、計算工具、資料視覺化。
- 2. Excel 計算工具檔與指引:計算抗菌劑主成分公斤數。
- 3. WOAH 之 AMU 年報:可取得歷次 AMU 年報。





點選 Resources,可取得歷次 WOAH 之 AMU 年報(如下圖)。

# ANIMUSE 使用者指引:

- 保護資料安全性,界定資料查看者之權限:依據使用者指引步驟登入 ANIMUSE。請注意,獲 WOAH 邀請者或由會員國代表指定創建之帳號,才 有權限登入 ANIMUSE。
- 2. 全新問券調查智慧介面,該指南可協助會員國 WOAH 之 AMU 問券調查。
- 3. 協助計算、減少錯誤:此指南協助會員國使用計算工具時面臨之困難,以產 出抗菌劑主成分之公斤數,並整合動物用藥品之不同資訊。
- 4. 透過 Microsoft Power BI 儀表板,將資料視覺化:此指南協助會員國透過儀表板,將資料視覺化。圖表資料來源為歷年收集之 AMU 資料,並由 AMU 團隊管理。視覺化圖表係使用微軟之 Power BI 應用程式創建。

# ANIMUSE - Excel 版 AMU 問卷與指引:

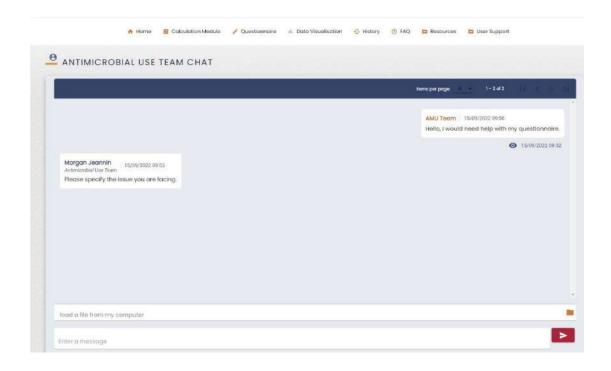
- 1. AMU 問卷(Excel 檔):使用者可自行選擇要使用 Excel 版 AMU 問卷離線填報,再將該檔案上傳至 ANIMUSE;或直接於 ANIMUSE 線上填報 AMU 問卷。如果想使用 Excel 版本問卷,可至 ANIMUSE 下載 Excel 版問卷,並依據指引完成問卷填報。
- 2. 抗菌劑成分(Excel 檔):依據抗菌劑類別填寫。

3. 計算工具(Excel 檔):協助計算抗菌劑成分之公斤數與整合不同動物用藥 產品之資訊。

ANIMUSE 之 FAQ 專區提供常見問題與說明,如下圖:

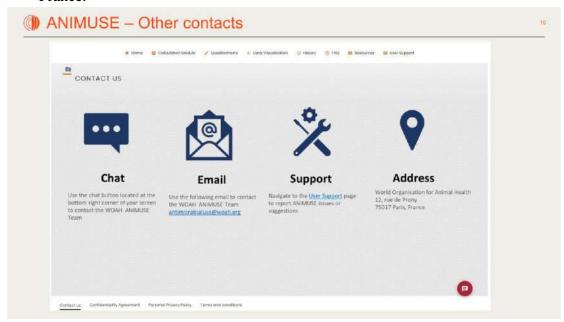


ANIMUSE 提供聊天室功能,可與 WOAH 之 AMU 團隊討論問題,亦可上傳檔案,檔案上傳容量最大限制為 10 MBs。聊天室之所有訊息均可被該 WOAH會員國看到(如下圖)。



# ANIMUSE 團隊之聯絡方式:

- 1. 聊天室:位於 ANIMUSE 介面右下角之聊天按鈕。
- 2. 電子郵件: <u>antimicrobialuse@woah.org</u>。
- 3. 支援:前往使用者支援頁面,回報 ANIMUSE 問題或給予建議。
- 4. 聯絡地址: World Organization for Animal Health 12, rue de Prony 75017 Paris, France.

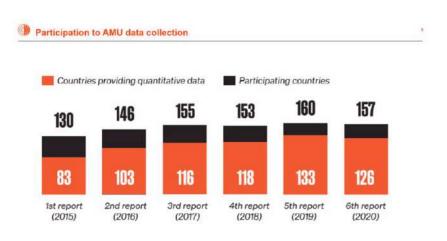


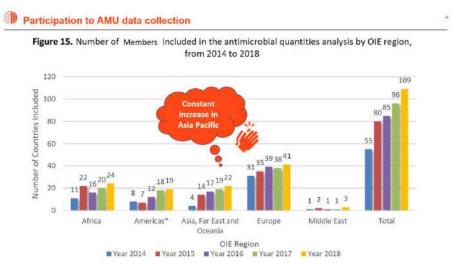
# (十一) ANIMUSE 功能探索(實作練習)

ANIMUSE 資訊系統實作練習步驟如附件 3,供參考。

# (十二)從亞太區看第六年度AMU 報告

由 WOAH 亞太區域代表處之 Dr. Nahoko Ieda 簡報「從亞太區看第六年度 AMU 報告」(Update from 6<sup>th</sup> AMU Report From Asia-Pacific Perspective)。參與 AMU 資料收集之國家數量,自 2015 年至 2020 年,由 130 個增加至 157 個國家。亞太區參加 AMU 資料收集之國家持續增加,自 2014 年至 2018 年,由 4 個增加至 22 個國家。





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若要比較不同區域及不同年度之 AMU 資料,前經 WOAH 之 AMR 專案小組同意,需將 AMU 除以總動物體重估計值(estimated animal biomass),始得進行比較。總動物體計算方式係依據 WOAH 之 WAHIS(World Animal Health Information System)資訊系統之該國動物數量普查資料,並由 WOAH 進行驗證。必要時,則使用 FAOSTAT 資料彌補不足之處。

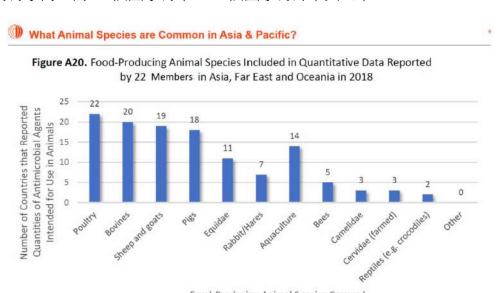


(...) previous ad-hoc group on AMR agreed to analyze the antimicrobial quantities using the estimated animal biomass as a dominator.



Animal biomass is calculated based on the census data reported to WOAH WAHIS interface (reported by VS via Delegates) and validated by WOAH staff. FAOSTAT data was also used only to complement it and when necessary.

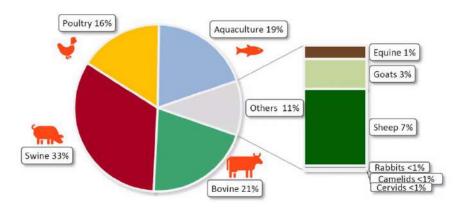
依據 2018 年亞太區 22 個國家之 AMU 資料,報告之產食動物類別以家禽為最大宗,牛為次之,綿羊與山羊為第三,即 22 個國家之 AMU 報告均有家禽,而 20 個國家有牛,19 個國家有綿羊與山羊。



依據 2018 年亞太區 22 個國家之總動物體重資料(Animal biomass), 以豬總體重佔最大宗(33%),牛為次之(21%),家禽為第三(21%)。

What Animal Species are Common in Asia & Pacific?

Figure A22. Species Composition of Animal Biomass for the 21 Members in Asia, Far East and Oceania Included in 2018 Quantitative Data Analysis



依據 2018 年 WOAH 會員國之總動物體重報告顯示,全球有 50%之總動物體重未納入計算,此顯示各區域於總動物體重之統計仍有很大之進步空間,並需要以校正方式調整數據。



3% 7%

12%

Africa - estimated coverage

Not covered

Americas - estimated coverage

Not covered

Asia, Far East and Oceania - estimated coverage

Not covered

Europe - estimated coverage

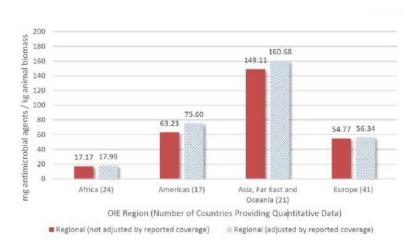
Not covered

Figure 32. Regional percentages of estimated biomass covered by Countries reporting quantitative data for 2018\*

The Middle East was not included in the visual, but the region's coverage is included at the global level.

2018 年洲級 AMU(mg)除以該洲之總動物體重(kg)進行比較(如下圖),紅色柱條表示未經過該區域 AMU 統計覆蓋率校正之數據、灰色柱調表示經該區域 AMU 覆蓋率校正之數據。有關 AMU 統計覆蓋率定義,以案例說明,例如某國統計其國內 AMU 時,未統計觀賞魚之抗菌劑使用量,則經該國評估,觀賞魚抗菌劑使用量佔比約為 2%。則該國之 AMU 統計覆蓋率為 98%,該 AMU 統計需經過運算式校正調整至覆蓋率 100%。依據 AMU 統計校正後之數據,亞太區數據最高(160.68 mg/kg)、美洲次之(75.60 mg/kg)、歐洲第三(56.34 mg/kg)。

Figure 37. Quantities of antimicrobial agents intended for use in animals adjusted by animal biomass, 2018 regional comparison (mg/kg)



於 2018 年 AMU 報告顯示,亞太區 22 個會員國使用頻率最高之抗菌劑為 Tetracyclines (40.0%), Penicillins 次之(14.0%), Macrolides 為第三(9.6%)。 歐洲區 41 個會員國使用頻率最高之抗菌劑為 Tetracyclines (31.1%), Penicillins 次之(14.0%), Sulfonamides(包括 Trimethoprim)為第三(9.6%)。

# Which Class of Antimicrobials are Frequently Used?

% of Reported Quantities of Antimicrobial Agents Used in Animals by 22 Countries

Figure A19. Proportion of Antimicrobial Classes Reported for Use in Animals by 22 Members in Asia, Far East and Oceania in 2018 by 41 European Members in 2018 Aggregated class data 1.0.4% Aggregated class data | 0.1% Others = 1.7% Others 0.9% Tetracyclines Tetracyclines nides (including trimethoprim) Sulfonamides (including trimethoprim) Streptogramins Streptogramins Quinoxalines 3.3% Quinoxalines 0.0% Polypeptides Polypeptides 3.1% Pleuromutilins Pleuromutilins 2.8% 2.6% Penicillins Penicillins 14.0% Antimicrobial Classes Other quinolones Other quinolones Orthosomycins 0.1% Nitrofurans 0.0% Nitrofurans 0.0% Macrolides Macrolides Lincosamides Lincosamides . 1.6% Glycophospholipids Glycophospholipids 1 0.2% Glycopeptides 0.0% Glycopeptides Huoroquinolones Fluoroquinolones 3-4 gen cephalosporins 3-4 gen cephalosporins 🕒 0.7% 0.2% 1-2 gen. cephalosporins 0.3% 1-2 gen, cephalosporins 0.1% ephalosporins (all generations) Cephalosporins (all generations) . 1.0% Arsenicals 0.0% Arsenicals 0.2% Amphenicals Aminogivcosides Aminoglycosides 5.0% 10.0% 15.0% 20.0% 25.0% 30.0% 35.0% 0.0% 5.0% 10.0% 15.0% 20.0% 25.0% 30.0% 35.0% 40.0% 45.0% % of Reported Quantities of Antimicrobial Agents Used in Animals by 41 Countries

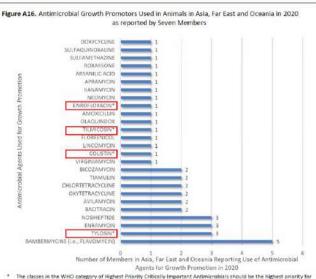
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依據 WOAH 之 2020 年 AMU 報告,統計 157 個國家,69%之國家已不將抗菌劑用於生長促進,25%之國家仍將抗菌劑用於生長促進,6%之國家資料不明。若以洲別區分,非洲計 43 個國家,有 27 個國家已不將抗菌劑用於生長促進,有 11 個國家仍將抗菌劑用於生長促進,5 個國家資料不明。美洲計 28 個國家,有 11 個國家已不將抗菌劑用於生長促進,有 17 個國家仍將抗菌劑用於生長促進,5 個國家資料不明。亞太區計 28 個國家,有 16 個國家已不將抗菌劑用於生長促進,5 個國家資料不明。亞太區計 28 個國家,有 16 個國家已不將抗菌劑用於生長促進,有 10 個國家仍將抗菌劑用於生長促進,2 個國家資料不明。歐洲計 48 個國家,有 44 個國家已不將抗菌劑用於生長促進,有 2 個國家仍將抗菌劑用於生長促進,2 個國家資料不明。歐洲計 48 個國家,有 44 個國家已不將抗菌劑用於生長促進,有 2 個國家仍將抗菌劑用於生長促進。

亞太區 28 個提送 AMU 報告之國家中,有 7 個會員國使用抗菌劑類生長促進劑(Antimicrobial growth promoters, AGPs)。其中以 Bambermycin(或稱Flavomycin)使用頻率最高。此外,WOAH 提醒,亞太區報告之 AGPs 中,Enrofloxacin、Tilmicosin、Colistin 與 Tylosin 為世界衛生組織分類表中,人類醫療高度優先重要抗菌劑(Highest Priority Critically Important Antimicrobials, HPCIAs),會員國應優先考量將這些品項自 AGPs 刪除。



- 7 Members out of 28 who reported the use of AGPs listed the agents utilized regarding 2020
- High frequency in the use of Bambermycins
- Indicated in red: The classes in the WHO category of Highest Priority Critically Important Antimicrobials (in human medicine) should be the highest priority for Countries when phasing out the use of antimicrobial agents as growth promoters.

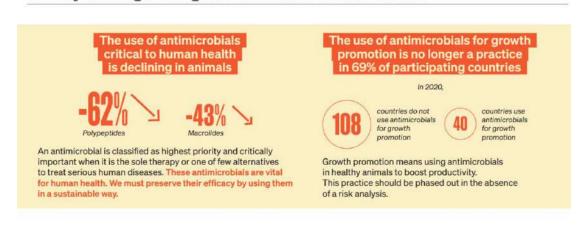


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若一種抗菌劑係用於治療人類嚴重疾病之單一療法或替代療法稀少,則該抗菌劑被歸類為人類醫療高度優先重要抗菌劑(HPCIAs),包括 Polypeptides 與 Macrolides。該等類別之抗菌劑為人類醫療高度至關重要抗菌劑,因此我們必須以永續方式,確保其療效。此外,基於動物醫療(動物健康與動物福利)考量與保護農民生計,保留抗菌劑之有效性亦相當重要。依據 WOAH 之 AMU 報告資料顯示,用於動物之 Polypeptides 使用量減少 62%, Macrolides 使用量減少 43%。

按WOAH 之 2020 年 AMU 報告,計 108 個國家不再使用抗菌劑類生長促進劑(佔所有參與 AMU 報告之國家數量的 69%),計 40 個國家有使用抗菌劑類生長促進劑(AGPs)。生長促進(growth promotion)之定義為將抗菌劑(Antimicrobials)用於健康動物,以提高生產力。若缺乏相關風險分析,則應停止此種使用方式。

# Key findings: Progress in Animal Health Sector





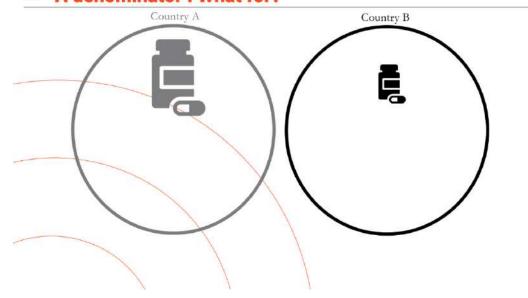
It's also important to preserve the antimicrobials efficiency from the perspective of veterinary medicine (animal health & welfare) and for protecting farmers livelihoods.

# (十三)以總動物體重分析AMU 資料

由 WOAH 細菌抗藥性暨動物用藥產品部門(AMR&VPD)Dr. Morgan Jeannin 簡報「以總動物體重分析 AMU 資料(Using Animal Biomass to analyze AMU data)」。 首先說明為何需要將 AMU 資料除以總動物體重,以下圖為例,將 A 國家與 B 國家進行抗菌劑使用量比較時,乍看之下會認為 A 國家抗菌劑使用量較多。

17

# A denominator : What for?

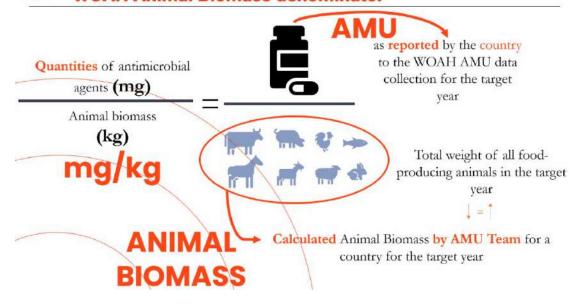


然而,若將兩國家之總動物體重考量進去,作為分母計算,則可發現,實際 上係 B 國家之抗菌劑使用量較多,而非 A 國家。

# A denominator: What for? Country B mg kg kg

為解決此問題,WOAH 於評估抗菌劑使用量之增減或多寡時,係以每公斤動物體重使用多少毫克之抗菌劑作為評估指標,即 AMU (mg)/Animal biomass (kg)。分子 = 由 WOAH 會員國填報給目標年度之 AMU 數據。分母 = 目標年度之總產食動物體重。該總體重係由 WOAH 之 AMU 團隊計算該國目標年度之總動物體重而得。

# **WOAH Animal Biomass denominator**



總動物體重分母之方法學係由 WOAH 之 AMR 專案小組研發,該小組瞭解每個國家之動物種群數量、週期因素和平均體重均具變異性。依據陸生動物衛生法點第 6.9 章與水生動物衛生法典第 6.3 章,當比較不同時間之 AMU 數據時,應考慮動物族群數量與組成之變化。

透過將 AMU 數據按總動物體重進行調整,可以將動物群體數量變化納入考量,則適用於不同時間之 AMU 比較,調整後,亦適用於比較不同區域之 AMU 數據,因為此調整已將不同區域之不同產食動物種類與不同養殖系統納入考量。

總動物體重計算需要之資料為該國在養之動物數量、不同動物種類之各年齡層數量及其平均體重。目前可使用之全球資料庫為 WAHIS 普查不同動物種類於某一時間之活體動物數量(年齡層分類可能有或無)。另一個全球資料庫為 FAO 之生產資料庫,包括該國於一整年不同動物種類之動物屠宰數量、屠體重量與普查數據。因此,WOAH 需要會員國協助該國動物數量與動物種類平均體重之資料驗證。

有關總動物體重計算方法學有三項一般性原則。第一、若動物之生命期限小於1年,則使用年度生產數據計算總動物體重。第二、若動物之生命週期大於1年,則使用動物普查數據,並與國家(或次區域)之動物平均體重估算值合併計算。第三、儘可能優先使用動物普查數據,因為生產數據可能無法呈現後院式屠宰作業資料。

總動物體重之計算係使用一個國家不同動物別之動物數量、國家與次區域之平均體重估算值與短生命期動物別之平均繁殖率(週期因子)。最後,將總動物體重置於數學運算式之分母,將抗菌劑使用量置於分子,計算出 AMU (mg)/動物體重 (kg)。有關總重物體重之方法學,WOAH 已有發表相關文獻,供有興趣者參考,包括「OIE Annual Report on Antimicrobial Agents Intended for Use in Animals: Methods Used」、「From OIE standards to responsible and prudent use of antimicrobials: supporting stewardship for the use of antimicrobial agents in animals」、「Comparison of different biomass methodologies to adjust sales data on veterinary antimicrobials in the USA」。

不同國家之 AMU 監測計畫係採用不同動物體重計算方法。加拿大、歐盟與泰國係採用治療時之動物體重。美國與日本係依生產類型區分不同之平均動物體重。WOAH 所研發之平均動物體重估算值可適用於全球任何一個國家。若總動物體重資料來源為生產數據(Production data),則屠體重量(Carcass weight)計算式為動物別屠宰重量除以動物別屠宰頭數。再將屠體重量除以轉換係數,計算出活體動物於屠宰時之體重(Live weight at slaughter)。

# Methodology: Estimation of average animal weights for any country in the world

Different AMU surveillance programs > Different weight calculation methodologies



- o Canada, ESVAC (EU), Thailand: weight at time of treatment
- USA, Japan: average weight by production category

# From production data → carcass weight



$$carcass\ weight\ (kg) = \frac{weight\ of\ species\ slaughtered\ (kg)}{number\ of\ species\ slaughtered\ (heads)}$$

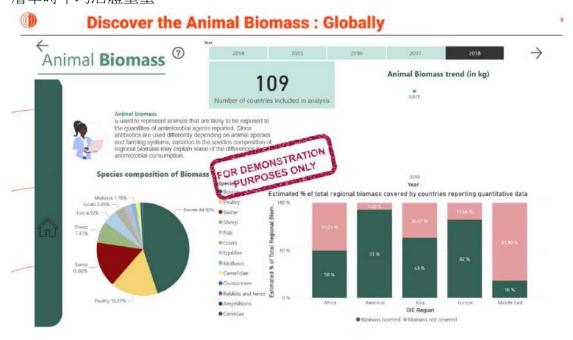
From carcass weight → live weight at time of slaughter



live weight at slaughter (kg) = 
$$\frac{\text{carcass weight (kg)}}{\text{conversion coef ficient (k)}}$$

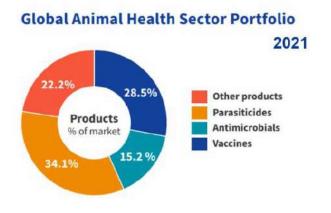
為了優化總動物體重(Animal biomass)之計算,則應考慮區域/國家之特殊性。會員國需持續合作研究與驗證動物數量、平均體重、屠宰轉換係數、動物別之年齡分布、週期因子等數據。因此,會員國履行其動物數量報告之承諾,則顯

相當重要。WAHIS 資訊系統優化,包括動物種類及其年齡層分類、週期因素、 屠宰時平均活體重量。



# (十四)AMU 資料收集之製藥產業角色

由全球動物衛生協會(Global animal health association)Rick Clayton 以預錄影片,簡報「AMU 資料收集之製藥產業角色」(Role of the pharmaceutical industry

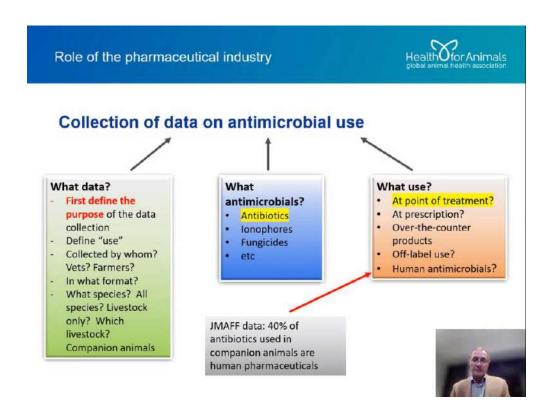


to support the collection on AMU data)。全球動物衛生協會代表動物製藥商,該協會計 29 個區域與國家協會作為會員,包括企業會員,例如 Zoetis、Virbac、Elanco、Boehringer Ingelheim、IDEXX等。這些公司提供一系列產品,包括疫苗、抗寄生蟲藥、抗微生物藥品、其他產品等。

對於 AMR 之立場方面,全球動物衛生協會表態以下幾點之動物製藥產業立場:

- 1. 支持健全之 AMU 資料收集系統,因為良好品質資料係做出良好決策之基礎。
- 2. 協助維護現有抗菌劑產品之效力,因為很少有新的抗菌劑問世。
- 3. 將抗菌劑產品銷售資料公開透明化。
- 4. 積極溝通交流負責任使用抗菌劑之原則。
- 5. 推廣疫苗接種與其他措施,以減少抗菌劑之使用需求。
- 6. 投資新產品之研發
- 7. 分享全球動物衛生協會之經驗與專業知識

總結上述立場,全球動物衛生協會主要角色功能為領導動物製藥產業界。有關抗菌劑使用量(AMU)資料收集方面,定義目的非常重要,此將決定你要收集哪些數據?係要從獸醫師、農民收集資料嗎?或從處方箋收集?係要收集銷售量或使用量資料?抗菌劑使用之定義為何?係指治療時?開藥時?包括標籤外使用?包括人醫用抗菌劑?此定義相當重要,因為某些國家與地區將相當高比例之人醫用藥,用於寵物治療。依據日本農林水產省(JMAFF)資料,用於治療寵物之抗菌劑有40%為人醫用抗菌劑。



由於良好品質之資料為做出良好決策之基礎。因此,第一、必須精確定義資料收集之目的,因為此會影響你要收集什麼資料與最終結果。AMU資料收集之目的是要找出抗菌劑大量使用區(Identify hotspots in use)嗎?或係只要進行不同國家之 AMU 分級比較(Benchmarking between countries)?而最終目的必須為減少細菌抗藥性(同時需要有 AMR 資料)。第二、清楚說明你 AMU 資料收集之限制與範圍。對外溝通時此點特別重要,因為你的資料可能被別人拿去使用。你的資料詳細程度是否可區別動物種類?你的資料為抗菌劑使用量或為銷售量?這些都必須說明清楚。第三、收集資料可聚焦於受最大影響之處,例如找出細菌抗藥性之主要原因。收集的資料僅為使用嗎?或係針對負責任之藥品使用?包括違法用藥與誤用藥嗎?

良好品質之資料能幫助我們找到細菌抗藥性(Antimicrobial resistance, AMR)背後之主要原因,此點至關重要,因為其可幫助我們避免執行錯誤介入措施之風險。良好之資料可幫助我們追蹤情況之進展或根據情況之進展調整介入措施。為了說明這此點重要性,全球動物衛生協會說明,也許於幾十年前,因動物醫療產業被認為係造成人類醫療細菌抗藥性增加之原因,而被放大關注。但近期科學證據顯示,人類醫療細菌抗藥性之增加主要係因為人

類使用抗菌劑所致,而非動物使用抗菌劑所致。全球動物衛生協會分享兩份報告資料說明,第一、英國政府五年期抗菌劑策略報告指出:「愈來愈多科學證據指出,人類醫療所面臨之細菌抗藥性臨床議題,主要係人類使用抗生素所致,而非動物使用抗生素所致。」。第二、於一項具里程碑意義之研究中,歐洲疾病預防與控制中心(the European Centre for Disease Prevention and Control)發現:「75%之抗藥性細菌相關疾病係由醫源性照護相關感染症所致。」該等資料助於確保介入措施可運用至正確地方。

Role of the pharmaceutical industry



# Good data - Identification of main causes of AMR

- Risk of mis-directed interventions
- Adaptation of interventions as situation evolves





The UK Government in a five-year antimicrobial strategy reported that "Increasing scientific evidence suggests that the clinical issues with antimicrobial resistance that we face in human medicine are primarily the result of antibiotic use in people, rather than the use of antibiotics in animals"

Source: UK Department of Pealth & DEFRA, https://assets.publishing.service.gov.uk/government/uploeds/system/uploads/attachment\_clata



In a landmark study, the European Centre for Disease Prevention and Control found that "75% of disease linked to resistant bacteria is due to healthcare-associated infections"

Source: ECDC, https://www.ecdc.europa.eu/in/news-events/ocdc-calls-continued-action-address-antimicrobial-resistance-healthca

全球動物衛生協會分享歐洲、澳大利亞等地 AMU 收集之經驗和專業知識,並整理成下列幾點原則:

- 1. 以簡單為宗旨,從小範圍開始執行 AMU 資料收集。
- 2. 界定 AMU 資料收集範圍。
- 3. 從收集 AMU 總量開始,先不要急著收集動物別之 AMU,待 AMU 收集系統建置完備與通過測試後,再開始收集動物別之 AMU。
- 4. 不同單位有不同之使用目的,因此資料之使用必須經過報告單位之同意。

- 5. 建立所有登記產品或許可進口產品之國家資料庫相當重要,因為你需要該等資料為依據,記錄藥品之使用。
- 6. WOAH 資料收集應協助會員國有更完善之 AMU 收集方法,以避免 發生資料重複計算與錯誤。
- 7. 資料之保密性對產業界至關重要,應以總數據出報告,去除識別性。

全球動物衛生協會強調,需要特別說明抗菌劑使用量和銷售量兩者之差異性 (如下表),因為有時評論者會錯誤解讀資料。雖然我們最終目標係要收集抗菌劑使用量,但實際上難以收集到使用量數據。收集使用量數據之優點包括有確定 之用藥動物別。因此,你可深入研析目標動物種類及其藥品使用。抗菌劑使用量資料之另一個特點為,可收集到藥品標籤外使用之狀況,包括使用人醫用藥。因此,最佳之資料收集方式係在治療時收集。

抗菌劑使用量資料 (Use data)	抗菌劑銷售量資料 (Sales data)
難以收集	較容易收集
可確定用藥之動物別	無法完全確定用藥之動物別
可挑選目標動物別及其使用進行深入研析	無法收集到標籤外使用之資料
可收集到標籤外使用之資料(例如人醫用	影響資料結果之干擾因子包括非法貿
抗生素)	易、仿冒品和非法進口
影響資料結果之干擾因子包括違法用藥	影響資料結果之干擾因子包括產品銷售
	後因廢棄或過期而未使用
容易避免重複計算抗菌劑使用量	可能重複計算抗菌劑使用量
可真實反映投予動物之抗菌劑使用量,且	~ 计专家 C In 小 Z 科 M 之 计 共
與 AMR 變化程度具相關性	無法真實反映投予動物之抗菌劑使用量

動物製藥產業中最重要之一項工作為投資研發領域(Research and development),研發所需產品與適當之使用情況。包括研發改善動物健康之新技術與替代物質,以減少動物之抗生素使用需求,例如疫苗、營養配方可以提高動物健康;早期診斷之技術。新劑型藥品可能於對抗 AMR 具效益,因某些給藥途

徑產生細菌抗藥性之風險較低。最後,動物製藥產業可投資開發動物專用之抗菌劑,以減少與人醫共用抗生素之使用需求。上述許多產品均屬於預防醫學,而預防勝於治療。而針對最一點,即研發動物專用抗菌劑方面,屬於高難度挑戰,需要高昂之成本,商業風險亦相當高。因此,保護現有抗菌劑之療效即非常重要。

動物製藥產業一直在投資研發領域,並支持一項研究計畫,該計畫已執行多年,分析了 53 種動物疾病並將之歸類。透過該研究可找出許多重大動物傳染病缺乏疾病防治工具(如下圖),該缺口可為動物製藥研發提供方向。該研究報告已發表於《柳葉刀》期刊,網址為 https://www.thelancet.com/journals/lanplh/article/PIIS2542-5196 (22) 00147-4/fulltext。

# Invest in R&D New research identifies lack of DISCONTOOLS 53 diseases needed control categorised, tools for many ranked and major infectious prioritised animal diseases Disease knowledge Impact on animal health and welfare Available at: https://www.thelancet.com/jou rnals/lanplh/article/PIIS2542-5196(22)00147-4/fulltext

全球動物衛生協會關鍵角色功能為領導製藥產業,該協會建立專業知識資料並分享之,以實現產業領導力。全球動物衛生協會發布 2019 年《減少對抗生素需求路線圖》(詳如附件 4),鼓勵其會員公司承諾執行相關措施,以改善抗菌劑負責任之使用,並制定了 25 項承諾或行動計畫,為了於 2025 年之前完成。因此,該協會製作一份《減少對抗生素需求路線圖之 2021 年追蹤報告》(詳如附

件 5)。所有會員公司之承諾均在進行中,包括新疫苗、投資培訓與獸醫師獎學 金等。

# Role of the pharmaceutical industry



# Provide leadership

Significant actions and commitments by companies are helping reduce the need for antibiotics



# 2019 - Roadmap to reducing the need for antibiotics

- · Vision for improving responsible use
- · List of 25 commitments
  - > 25 measurable actions to be completed by 2025



2021 - Roadmap progress report

All 25 commitments on track

- 49 new vaccines
- ☐ Training 650,000 veterinary professionals
- Donating \$7 million vet scholarships



全球動物衛生協會最近亦發布其他報告,一份係有關疫苗接種趨勢之報告,另一份為全球動物抗生素使用趨勢報告。若有興趣,可至該協會網站查看該等報告(網址:https://www.healthforanimals.org/resources/publications/)。於全球抗生素使用趨勢報告中,已確定四種最成功減少抗菌劑使用之方法,分別為增加疫苗接種、改善生物安全、改善動物健康與改善動物疾病檢測。

全球動物衛生協會已製作一份推廣負責任使用抗菌劑手冊,共五項原則(詳如附件6):

- 1. 透過防疫一體策略保護動物健康及福祉
- 2. 謹慎並負責任地使用抗生素
- 3. 推廣疾病預防;增加農民取得動物醫藥專業知識之管道
- 4. 投資預防及治療疾病之產品
- 5. 增加專業知識、資訊透明度與溝通交流

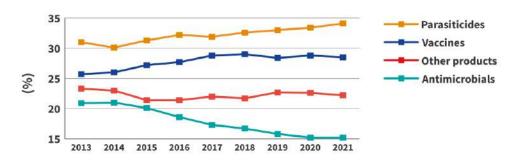
同時,全球動物衛生協會亦製作一份全球動物抗生素使用趨勢報告(詳如附件7),並於2022年9月發布。該報告總結五項全球趨勢:

- 動物抗生素使用量正在下降:全球使用量下降近三分之一,而在許多國家,動物抗生素之需求亦顯著下降,有時為驟降。
- 2. 預防性措施已發揮功效: 抗生素銷售量之減少與預防產品之增加相呼應。 以全球而言,動物保健產品中抗生素之銷售相對佔比下降 28%,而疫苗 之銷售則增加。因此值得投資預防性產品。
- 3. 抗生素仍然是至關重要的工具:許多已開發國家已達成動物抗生素顯著下降趨勢,並穩定維持於一定水平。此常反映了一種「抗生素使用最佳化」之狀態,因為已最大化使用預防措施,然而,一旦有疾病侵入養殖場,抗生素仍為治療疾病之必要工具。
- 4. 若無防疫一體行動計畫(One Health Action),則無法有所進展:歐洲疾病預防與控制中心(ECDC)發現,大多數人類細菌抗藥性轉移源於人類醫療單位,而先導研究(Leading studies)顯示人類抗生素使用量正在增加。研究結論指出,若人類醫療方面無相對因應措施,對於減少細菌抗藥性方面,單靠動物領域之努力,則影響力相當有限。
- 5. 動物醫療為全球領導者:政府當局已注意到,動物抗生素使用需求顯著減少,取得重大進展。動物醫療公司正透過相關行動措施,推動此進展,例如《減少對抗生素需求路線圖》(詳如附件4),該路線圖提供25項可量化之承諾,以幫助解決細菌抗藥性與負責任使用抗生素等問題,所有這些承諾均有望於2025年前完成。

預防措施可減少抗生素使用需求:依據動物醫療企業龍頭(Leading animal health companies)之銷售數據顯示(如下圖),由於全球轉向預防措施,使全球對抗菌劑(Antimicrobials)之需求減少。自 2013 年以來,動物醫療企業龍頭之產品組合中,疫苗和抗寄生蟲藥(Parasiticides)之比例已從 56.7%增長至 62.6%,而抗菌劑(Antimicrobials)之比例從 20.9%降至 15.2%(相對減少了 28%)。

# Prevention can reduce the need for antibiotics

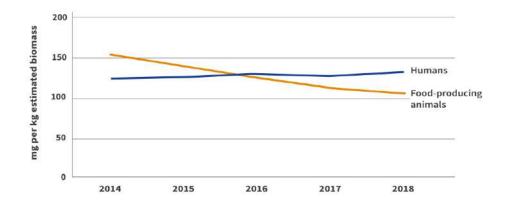
### Sales per product category (%) (2013-2021)



最近歐洲藥品管理局(EMA)、歐洲食品安全局(EFSA)、歐洲疾病預防控制中心(ECDC)與OECD聯合發布一份歐盟抗菌劑使用情況報告,該報告顯示:「關於抗生素使用量方面,農業領域之進展比人類領域優異」(如下圖)。自 2016年起,「人類使用抗生素之平均量已高於產食動物之平均用量」。然而,某些市場可見動物用與人用抗生素同時減少。該報告指出,歐盟內人類使用抗生素之總量有所下降,但若檢視個別種類之抗生素,人類使用廣效抗生素之量仍在上升中。

### "More progress in agriculture than in the human sector"

### Antibiotics consumption in the EU/EEA, 2014-2018

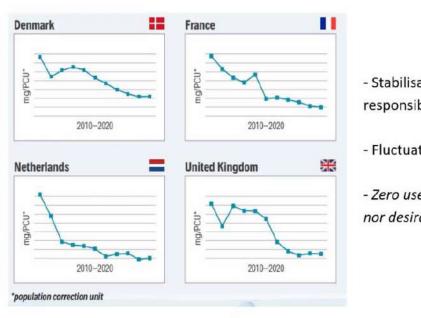


全球動物抗生素使用趨勢報告可見各個國家之數據(如下圖),依據該數據顯示,你可以將動物抗生素使用量降低至一定水平,之後趨於穩定。我們希望此穩定水平為負責任使用抗生素之平衡線,此平衡線為動物生病需要治療,同時最大限度地減少抗生素之使用,只在必要時使用抗生素。該報告亦顯示,動物抗菌

劑銷售量曲線會有些波動,這些波動是正常的,取決於不斷變化之疾病狀況與主 流疾病之程度。最後該協會強調,想要將動物抗生素使用量降至零是不可能的, 因為一旦動物生病,基於動物健康與福祉,則有治療疾病、使用抗生素之需求。

# Animal antimicrobial sales trends





- Stabilisation at responsible use

- Fluctuations normal

- Zero use not possible nor desirable



防疫一體(One Health)策略架構致力於對抗細菌抗藥性,並由多個國際組 織進行合作,推動防疫一體策略。



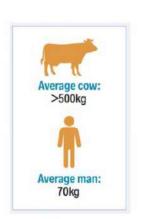
若要解讀與使用數據時,必須考量情境背景,因單純銷售數據報告並無太多價值。例如,動物與人類於體重與治療劑量具很大之差異性,平均一頭牛體重大於 500 公斤;而人類平均體重約為 70 公斤,使治療劑量極具差異性。此外,尚需考量抗生素效力之差異。獸醫師主要係使用較老之抗生素,而較老之抗生素可能需要較高使用劑量。

### Role of the pharmaceutical industry



### Use data must be put in context

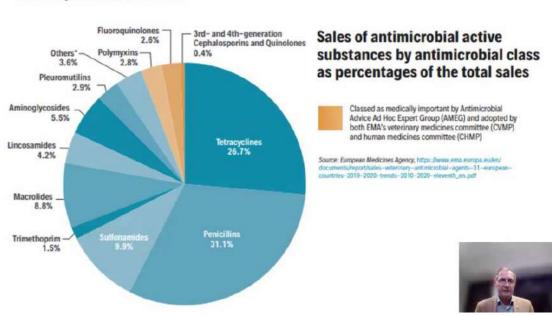
- · Many more animals than humans
- · Big differences in
  - · body weight
  - biomass
  - · therapeutic doses
- · Differences in antibiotic potencies
  - · Veterinary: primarily using older antibiotics
  - · Older antibiotics need higher doses
- · Disease pressure



依據歐洲藥品管理局(EMA)資料顯示(如下圖),土黃色區塊為人類醫療高度優先重要抗菌劑(Highest Priority Critically Important Antimicrobials, HPCIAs),於獸醫使用係受到限制或未使用,使用佔比極低,偶爾用於治療某些動物之特定細菌感染,因為該細菌感染症無替代用藥,但許多藥品不能用於動物。獸醫師主要係使用較老之抗生素,以 Tetracyclines 使用佔比最高, Penicillins 次之, Sulfonamides 第三。



### Europe sales data



### 全球動物衛生協會最後總結本次簡報重點:

- 1. 良好品質之資料有助於決定良好決策,所以需要有投資者收集這些數據。
- 2. 目標係可收集到治療時之抗菌劑使用量資料。
- 3. 釐清目標為何,可幫助我們決定應收集哪些數據。
- 4. 防疫一體(One Health)至關重要,所有利益關係者必須盡其職責與合作。
- 5. 疾病預防措施已發揮功效:動物抗生素使用量正在減少。
- 6. 抗生素仍為重要工具,我們必須保護現有抗生素之功效,不可能不使用抗生素。 素。
- 7. 投資產品研發相當重要。

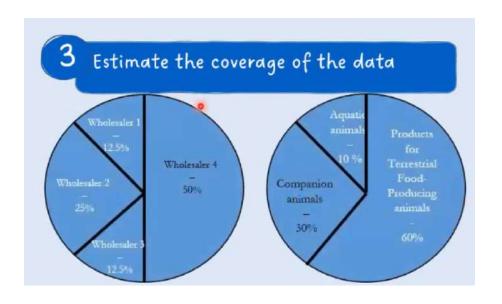
### (十五) 運算式分子之計算:藥品主成份重量

由 WOAH 細菌抗藥性暨動物用藥產品部門(AMR&VPD)Dr. Delfy Góchez 簡報「運算式分子之計算:藥品主成份重量」(Calculation of the numerator: kilograms of active ingredients)。

### 1. 如何開始?

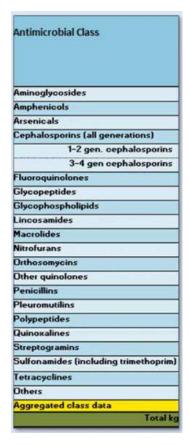
在收集與計算 AMU 資料前,有三點注意事項:

- (1) 建立國家級動物用藥產品銷售系統之分布圖,以避免數據資料重複或不完整。
- (2) 若你係要求不同利害相關者提供數據資料,請確保他們接受過培訓並可 以讓你有權限查閱其計算。
- (3) 評估 AMU 資料之覆蓋範圍,此點相當重要。於 WOAH 問卷調查中,即會詢問你填報之 AMU 總量佔你國家總量之百分比為何,再推估 100%覆蓋率之 AMU 數據為何。估計覆蓋範圍需要考慮不同的因素,可能很主觀的,但也不完全是主觀,視該國情況而定。估計涵蓋範圍時需考慮以下不同因素:(A)提供數據之業者數佔總體業者數之百分比。(B)抗菌劑產品所涵蓋之動物種類。(C)所涵蓋之產品劑型(通常以口服劑型為主)。例如若你的國家總共有 10 個利益關係者,但只有其中 5 個回復你調查數據,則可說該國填 AMU 數據佔該國 50%覆蓋率(如下圖之左方圓餅圖)。但實際上,可能未必如此,因為若該國可能有 1 家製藥公司壟斷市場,或者其中三家製藥公司或利害相關者已佔全國抗菌劑銷售量(或 AMU)之 80%,而其他者可能只佔全國總銷售量之 5%。因此,你所調查取得之抗菌劑銷售量(或 AMU)佔全國 85%覆蓋率。另一個要考慮 AMU 資料之覆蓋範圍之因素為產品所涵蓋之動物種類(如下圖之



右方圓餅圖)。有時伴侶動物之抗菌劑銷售量(或 AMU)佔比較陸生產 食動物低。

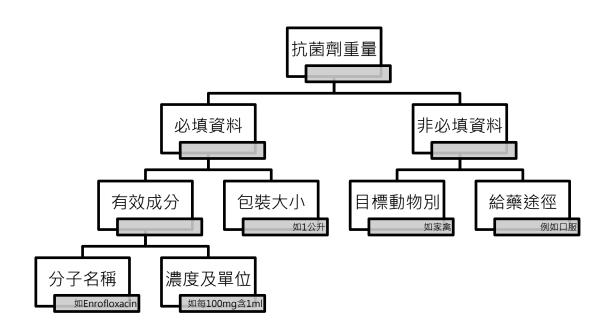
WOAH 之 AMU 問卷將抗菌劑分成 23 種類別(如下左圖)。其他類抗菌劑(Others)係指未列出之抗菌劑類別,例如 novobiocin、fusidic acid、kirromycins,fosfomycin、rifamycins 等。統合類抗菌劑數據(Aggregated class data)欄位僅限保密目的時合併填報,此非指抗菌劑複方。若在你的國家,有某個抗菌劑類別銷售量資料需要被保密,則將該數據填報於「統合類抗菌劑數據」欄位。以Aminoglycoside類抗菌劑為例,若在你的國家僅有一家廠商銷售 Aminoglycoside類抗菌劑,國家會考量不能揭露 Aminoglycoside類抗菌劑銷售量,因為每個人都知道係誰在銷售 Aminoglycoside類抗菌劑,此可能造成商業衝突。一般而言,國家於立法時都非常清楚何種資訊需要保密。於填報 ANIMUSE 系統時,則將要保密之抗菌劑類別勾選統合類抗菌劑數據(Aggregated class data)方塊,該類抗菌劑之銷售量即被列為保密資訊(如下右圖)。



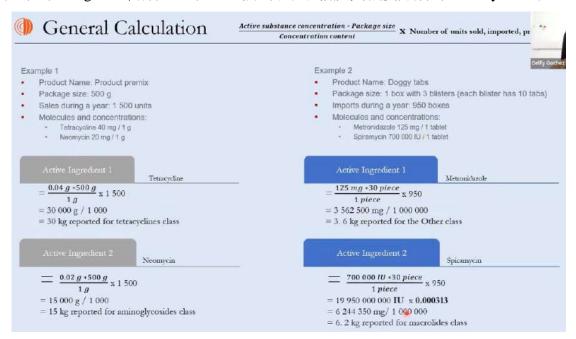


### 2. 需要取得哪些資料以計算抗菌劑有效成分重量?

必要資料包括有效成分、包裝大小、分子名稱、濃度及其單位,必須要有這 些資料,才能計算出抗菌劑重量。非必填資料包括目標動物別與給藥途徑(如下 圖)。



以下提供兩個抗菌劑重量計算案例,案例一產品名為 Product premix,包裝大小為  $500\,\mathrm{g}$ ,一年銷售量為  $1500\,\mathrm{d}$ 。分子名稱及其濃度分別為 Tetracycline (  $40\,\mathrm{d}$ 



mg/lg) 與 Neomycin(20 mg/lg)。案例二產品名為 Doggy tabs,包裝大小為 l 盒有 3 片,每片有 10 顆藥。一年進口量為 950 盒。分子名稱及其濃度分別為 Metronidazole(125 mg/l tablet)與 Spiramycin(700,000 IU/l tablet)。

### 3. 抗菌劑有效成分重量之轉換係數

Oxytetracycline Paromomycin

Polymyxin B

Rifamycin

Spiramycin

Streptomycin

Tetracycline

Tobramycin

Tylosin

某些抗菌劑係以國際單位(International Uints, IU)表示,這類抗菌劑必須要使用轉換係數計算重量(如下圖)。

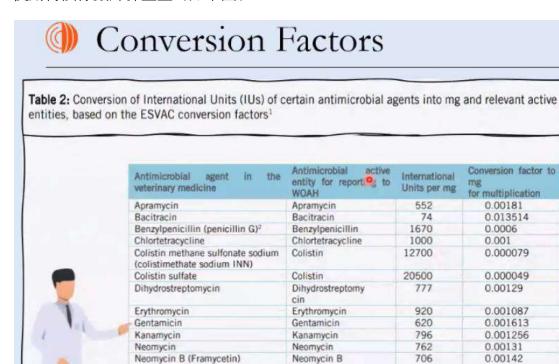


Table 3: Conversion of content stated in mg, g or kg of derivates/compounds of antimicrobial agents in the veterinary product into corresponding mg, g or kg antimicrobial active entity for reporting to WOAH, based on the ESVAC conversion factors<sup>3</sup>

(Framycetin)

Paromomycin

Polymyxin B

Rifamycin

Spiramycin

Streptomycin

Tetracycline

Tobramycin

Tylosin

Oxytetracycline

Derivate or compound	Active entity	Conversion factor for multiplication
Benethamine benzylpenicillin	Benzylpenicillin	0.61
Benzathine benzylpenicillin5	Benzylpenicillin	0.68
Cefapirin benzathine <sup>6</sup>	Cefapirin	0.78
Cefalexin benzathine <sup>7</sup>	Cefalexin	0.74
Cloxacillin benzathine8	Cloxacillin	0.78
Oxacillin benzathine9	Oxacillin	0.77
Penethamate hydriodide 10	Benzylpenicillin	0.60
Procaine benzylpenicillin <sup>11</sup>	Benzylpenicillin	0.57

0.00114

0.00133

0.000119

0.001127

0.000313 0.00132

0.00102

0.001143

0.001

750

8403

887

3200

760

982

875

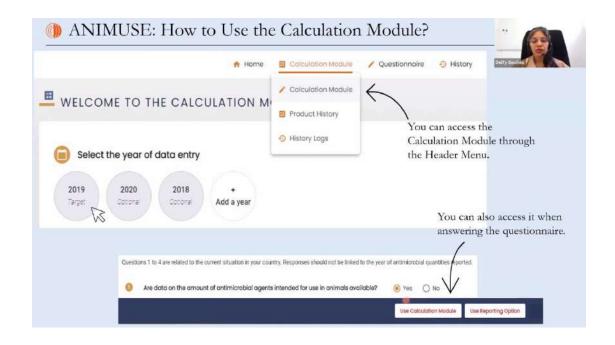
1000

### 4. ANIMUSE 資訊系統之計算工具(Calculation Module)

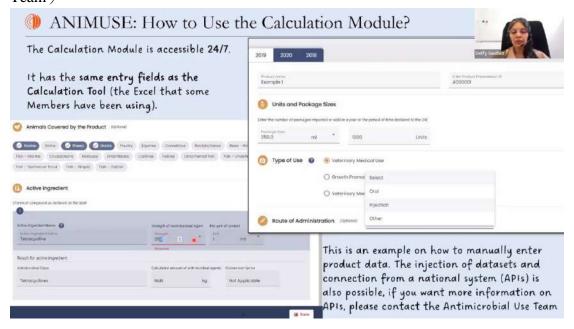
ANIMUSE 資訊系統內建計算工具(Calculation Module),該計算工具內容 非必填項目。此內建計算工具主要係協助會員國收集動物用抗菌劑資料時,可使 用該計算工具計算出抗菌劑有效成分之公斤數。填寫於計算工具內之任何數據, 均列為保密狀態。有關何時使用「ANIMUSE 資訊系統計算工具」,WOAH 整理 以下說明:

- (1) 24 小時全年無休,任何時間皆可使用。
- (2) 因抗菌劑產品數量龐大而需要計算協助時。
- (3) 若會員國無動物用藥產品資料庫,可供資料收集時(使用線上輸入)。
- (4) 會員國雖有動物用藥產品資料庫可供資料收集,但該國家資訊系統卻無計算功能時(可將資料批次匯入 ANIMUSE 計算工具)。
- (5) 想檢查計算結果是否正確時。
- (6) 想針對效成分或動物用藥產品進行深入之數據分析時。

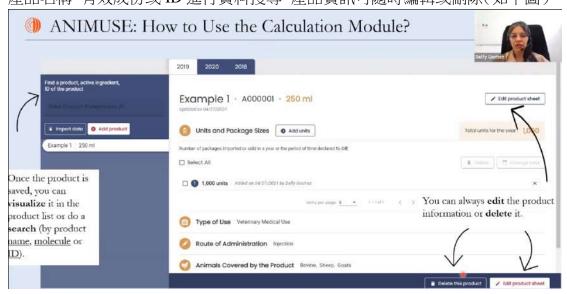
進入至 ANIMUSE 資訊系統之介面後,點選最上方之計算工具(Calculation Module),即可以進入「計算工具」介面,可以手動方式輸入數據或批次匯入數據,接著點選要匯入與計算資料之年份(如下圖)。於 ANIMUSE 資訊系統填報問卷之介面,於問題 4「是否有動物用抗菌劑用量之資料?」,可點選「使用計算工具(Use Calculation Module)」,可使用該計算工具計算之數據,填報問卷。



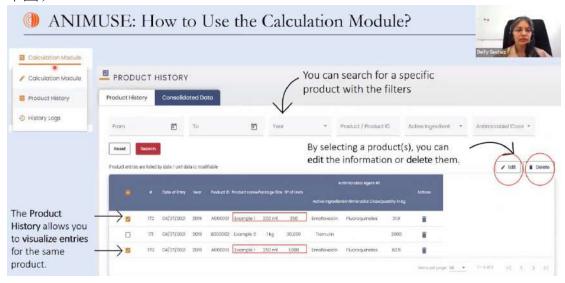
ANIMUSE 計算工具為 24 小時全年無休,隨時可用。計算工具之欄位與 WOAH 之前提供給會員國之 Excel 計算工具相同。下圖範例為以手動方式輸入產品數據。若會員國有需要將國家動物用藥產品資料庫與 WOAH 之 ANIMUSE 資訊系統,以 API 方式介接,請聯絡 WOAH 之 AMU 團隊 (the Antimicrobial Use Team)。



一旦將動物用藥產品資訊保存後,可於左方深藍色區塊查看產品列表,或按 產品名稱、有效成份或 ID 進行資料搜尋。產品資訊可隨時編輯或刪除(如下圖)。

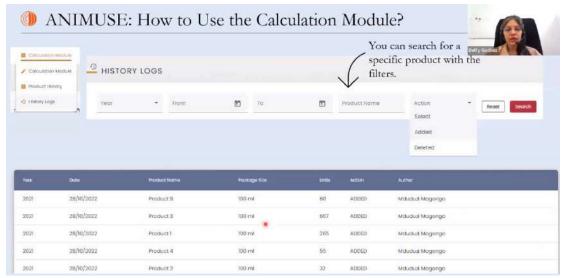


點選「計算工具(Calculation Module)」,再點選「產品過往紀錄(Product History)」,於此介面可使用篩選功能,篩選特定產品,以查看同一產品之所有輸入資料。亦可勾選一個產品或一個以上之產品,編輯該產品資訊或將之刪除(如下圖)。



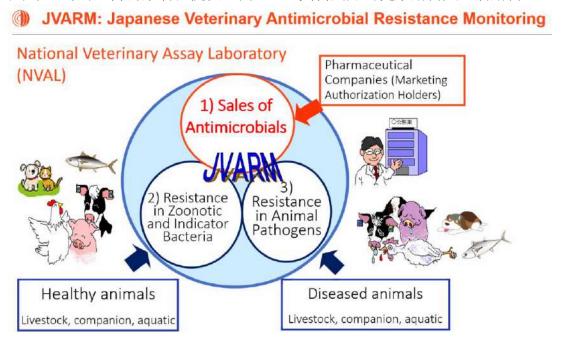
「過往操作紀錄(History logs)」係指記錄資訊系統內所有之操作紀錄,包括新增、修改、刪除等。歷史紀錄可以用於追蹤資料庫之使用情況、追蹤資料庫

中數據之變更情況。其通常用於保障資料庫之安全性和完整性,亦可用於溯源和 監測資料庫中之操作。於「過往操作紀錄(History logs)」,可使用篩選功能搜 尋特定產品(如下圖)。



### (十六) ANIMUSE 計算工具與日本AMU 國家報告

由日本農林水產省國家獸醫檢驗實驗室研究主任 Dr. Mari Matsuda 簡報「ANIMUSE計算工具與日本 AMU 國家報告」。日本 AMU 資料係由製藥公司(即藥品許可證持有業者)提供;而 AMR 資料則分為健康動物與生病動物。



日本政府依據「藥品與醫療器材法(Pharmaceutical and Medical Device Act)」,要求製藥公司必須將 AMU 報告送交給「國家獸醫檢驗實驗室(National Veterinary Assay Laboratory, NVAL)」,資料需包括抗微生物藥品銷售量、抗微生物藥品名稱、有效成分每單位之重量、給藥途徑、估算每種動物別之銷售百分比。由日本「國家獸醫檢驗實驗室」將資料彙整、分析與評估,並將 AMU 報告發布於「國家獸醫檢驗實驗室」網站,以提高公眾對於動物用藥之認識與理解。

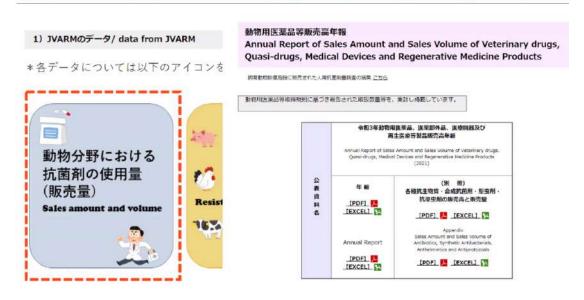
() JVARM: Japanese Veterinary Antimicrobial Resistance Monitoring

Under the Pharmaceutical and Medical Device Act



日本於 JVARM 網站(<a href="https://www.maff.go.jp/nval/yakuzai/yakuzai\_p3.html">https://www.maff.go.jp/nval/yakuzai/yakuzai\_p3.html</a>)公開動物用抗微生物藥品銷售量與細菌抗藥性資訊,包括「動物用藥品、衛生或保健產品、醫療器材及再生醫學產品銷售金額及銷售量年報(Annual report of Sales Amount and Sales Volume of Veterinary drugs, Quasi-drugs, Medical Devices and Regenerative Medicine Products)」、「抗生素、合成抗菌劑、驅蟲藥和抗原蟲藥之銷售金額與銷售量(Sales Amount and Sales Volume of Antibiotics, Synthetic Antibacterials, Anthelmintics and Antiprotozoals)」年報(pdf 檔與 excel 檔供下載)(如下圖)。

## JVARM HP (https://www.maff.go.jp/nval/yakuzai/yakuzai\_p3.html)



下表為日本 2021 年抗微生物藥品銷售量報告,該表依據藥品類別、動物別、 給藥途徑進行分類統計,包括肉用牛、乳用牛、馬、豬、肉用雞、蛋雞、犬/貓、 淡水魚、海水魚、觀賞魚與其他。給藥途徑分為口服、注射、灌注(Infusion)與 其他。該表可見,日本政府除了有收集抗微生物藥品銷售量之有效成分重量,亦 收集產品銷售金額。

#### 各種抗生物質・合成抗菌剤・駆虫剤・抗原虫剤の販売高と販売量

日性ガビエ初発・ロルガル製剤・美工用・ガルデエ門の構造に同じ扱うと単 Sales Amounts and Sales Volumes (Active Substance) of Antibiotics, Synthetic Antibacterials, Anthelmintics and Antiprotozoals

R3(2021)							対象動物別推定割合 Estimated Percentages of Sales for Each Animals Species										
系統名		区分 Active substance		投与経路	販売高金額 (千円) Sales amount (¥1,000)	原末換算量 (Kg) Amount of pure active substance (Kg)	肉用牛 pure Beef tange Cattle	of Dairy	Dairy Horse	R¥ Pig	肉用鶏 Broiler	採卵類 Layer	犬·猫 Dog/Cat	水産用 (淡水) Fish (Freshwater)	水産用 (海水) Fish (Seamater)	観賞魚 Ornamental Fish	その他 Others
抗生物質 Antibiotics	アミノグリコシド系 Aminoglycosides	硫酸アプラマイシン	Apramycin sulfate	経口 Oral	77,872	1,565.2	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0
	S. Const. M. A. Directonico			成分・計 Total	77.872	1,565.2											
		統敵カナマイシン	Kanamyoin sulfate	経口 Oral	71,241	4,309.2	0.0%	0.0%	0.0%	50.0%	50.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0
				注射 Injection	195,341	3,218.4	16.7%	43.3%	0.5%	15.9%	18.7%	3.9%	1.0%	0.0%	0.0%	0.0%	0.0
				注入·排入 Infusion	55,991	131.3	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0
				その他 Others	3,845	32.0	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0
				株分·計 Total	326,418	7,691.0											
		硫酸ゲンタマイシン Gentamion sufate	経口 Oral	50,112	13.6	50.0%	50.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0	
			IEST Injection	12,962	3.1	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0	
			程皮 Cutaneous	210,017	8.0	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	0.0	0.0	
				その他 Others	110,687	6.2	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0
				成分・計 Total	383,778	30.9	- 4		0 1				- "		a		
		破骸ジヒドロストレプトマイシン Dihydrostreptomycin	注射 Injection	91,946	2,761.3	31.7%	31.7%	13.4%	20.0%	1.9%	0.0%	1.2%	0.0%	0.0%	0.0%	0.0	
		N. 1009 See - C. 151 GH		注入·挿入 Infusion	90,284	407.2	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0
				成分-計 Total	182,230	3,168,6	- 1			- 1							
		硫酸ストレプトマイシン	Streptomycin sulfate	経口 Oral	162,612	17,268.0	0.3%	0.3%	0.0%	65.9%	33.6%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0
				成分・計 Total	162,612	17,268.0											
		統領フラジオマイシン	A STATE OF THE PARTY OF T	経口 Oral	14,280	73.5	40.0%	60.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0
				注入·排入 Infusion	11,647	36.6	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0
				程皮 Cutaneous	133,177	10.8	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0
				成分·計 Total	159,104	120.9	22002	2,3524	2. 2000 B	0.000		100001			N. N		
		*	統名・計 Class Tota	d	1.292.014	29.845											

依據動物用抗微生物藥品抗藥性監測系統之日本報告,以堆疊柱狀圖呈現不同製藥公司在 2001 年至 2017 年間之動物用抗微生物藥品(以活性成分公噸計算)之銷售量,基於商業保密考量,故將公司名稱去識別性(如下圖)。

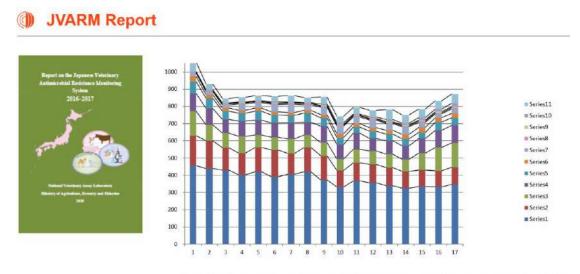
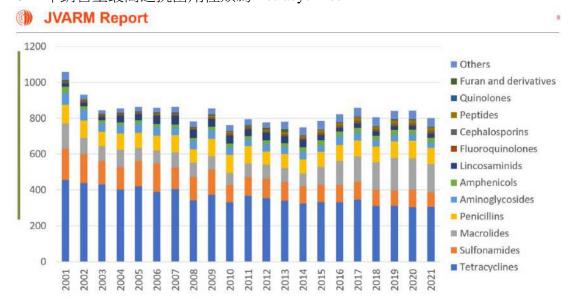
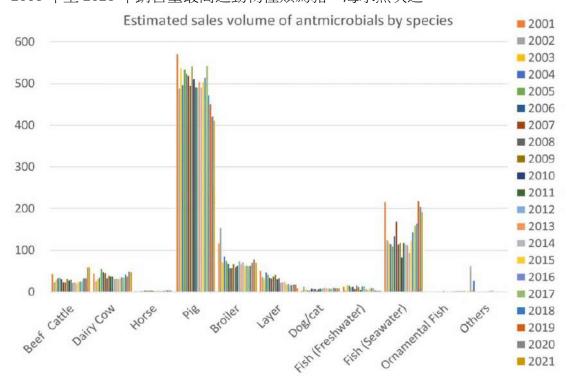


Fig. 3.2 Volumes of veterinary antimicrobials (in tons of active ingredient) sold by pharmaceutical companies in Japan between 2001 and 2017

下圖為依據抗菌劑類別分類統計之堆疊圖,該資料顯示日本於 2001 年至 2021 年銷售量最高之抗菌劑種類為 Tetracyclines。



下圖為依據抗菌劑銷售之對象動物分類統計之柱狀圖,該資料顯示日本於 2001年至 2021年銷售量最高之動物種類為豬,海水魚次之。



Nippon 為日本之意,以日語發音命名。日本每年會發布一次 AMR 防疫一體報告(Nippon AMR One Health Report, NAOR),包括人類與動物等,有日文與英文版本供下載。



### Nippon AMR One Health Report (NAOR)



- National Action Plan on Antimicrobial Resistance 2016-
- NAOR 2017- annually report
- AMR
  - Human
  - Animal (livestock animal, companion animal, aquatic, wild animal)
  - Foods
  - Environment
- · AMU
  - Livestock
  - Aquatic
  - Companion animal
  - Human
  - · Agriculture

Animal Total

下表為日本 2013 年至 2020 年不同動物用抗菌劑之銷售量分類統計(以公噸 為單位)。



# Nippon AMR One Health Report (NAOR)

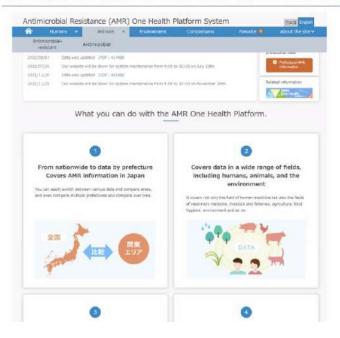
### Amount of veterinary antimicrobials in active gradient by class (t)

Class	2013	2014	2015	2016	2017	2018	2019	2020
Penicillins	78.2	78.0	83.7	90.0	88.1	89.0	92.4	97.0
Cephalosporins (total)	5.6	5.5	5.9	6.5	6.6	7.1	8.0	7.7
(1st generation cephalosporins)	4.7	4.5	5.0	5.4	5.5	5.7	6.6	5.4
(2nd generation cephalosporins)	0.2	0.2	0.1	0.2	0.2	0.2	0.1	0.2
(3rd generation cephalosporins)	0.7	0.7	0.8	0.9	1.0	1.2	1.3	1.2
Aminoglycosides	39.5	40.6	35.5	47.9	44.8	35.6	35.2	36.9
Macrolides	77.7	70.4	98.4	134.1	140.8	154.7	180.7	173.7
Lincosamides	39.0	43.3	28.7	21.9	25.3	22.8	21.3	21.5
Tetracyclines	340.5	324.8	333.9	331.5	347.1	311.2	313.0	304.4
Peptides	11.8	10.0	14.5	14.0	20.0	12.3	19.6	19.1
Other antibacterials	26.0	28.8	32.4	32.0	36.2	37.5	36.0	36.3
Sulfonamides	103.9	97.6	96.7	95.8	99.1	88.8	84.7	98.5
Quinolones	1.0	1.9	1.7	1.7	1.8	1.5	2.6	2.3
Fluoroquinolones	5.5	5.6	7.3	6.1	6.8	6.6	7.5	7.1
Thiamphenicol and derivateives	21.5	26.1	29.7	26.5	27.1	24.8	27.4	25.6
Furan and derivatives	14.5	1.8	1.2	1.6	1.4	1.3	1.4	1.2
Other synthetic antibacterials	15.0	14.0	13.3	12.1	13.1	12.0	11.7	11.7
Total	779.7	748.4	783.0	821.7	858.1	805.2	841.4	842.9

NAOR 2022(https://www.mhlw.go.jp/content/10900000/001045158.pdf)

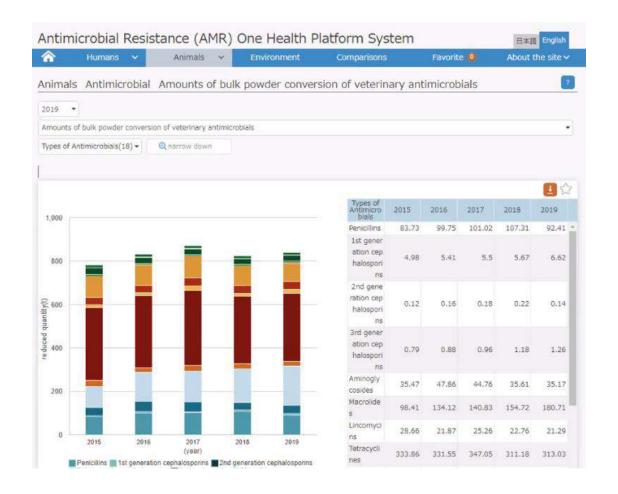
日本設有 AMR 防疫一體平台網站( https://amr-onehealthplatform.ncgm.go.jp/home),供資料上傳、彙整與分析。

# Nippon AMR One Health Report (NAOR)



· Website: AMR One Health **Platform** 

https://amr-onehealthplatform.ncgm.go.jp/home



總結:日本 AMU 資料係依據藥品許可證持有業者之抗菌劑銷售量,並以三種報告形式發布,分別為 NVAL HP 報告、JVARM 報告與 AMR One Health 報告。然而,日本目前 AMU 報告缺乏總動物體重之變因,若將總動物體重納入計算變因,則可針對每個國家或地區之抗菌劑使用量進行比較。ANIMUSE 資訊系統工具已將總動物體重納入計算變因,協助會員國進行運算。日本考慮未來要收集畜牧場端之 AMU 資料。

### (十七) ANIMUSE 計算工具之實作練習

本節提供 ANIMUSE 練習題與操作步驟截圖說明(如附件 8)。練習題分別 為

- 1. 進入 ANIMUSE 計算工具介面與將產品銷售量相關資訊輸入。
- 2. 將 Excel 檔之產品銷售量相關資訊批次匯入。

- 3. 查看「產品過往紀錄(Product History)」與「過往操作紀錄(History logs)」。編輯與刪除「產品過往紀錄」。
- 4. 使用 ANIMUSE 計算工具產出 AMU 問卷資訊。

### (十八)馬來西亞之AMU 國家監測經驗

#### 1. 背景說明:

馬來西亞獸醫局(Department of veterinary services) Dr. Rohaya Mohd Ali 簡報「馬來西亞經驗之 AMU 國家監測」。動物用抗菌劑之使用主要分為四類,分別為生長促進、預防、控制與治療。



馬來西亞之動物用藥相關法規與指引包括 1952 年有毒物質法(Poison Act 1952)、2009 年飼料管理法 (Feed Act 2009)、1974 年除蟲藥法 (Pesticides Act 1974)、2011 年檢疫及檢驗服務法 (MAQIS Act 2011)、馬來西亞細菌抗藥性行動方案(2017-2021, 2022-2026)、馬來西亞 2021 年動物用抗菌劑指引(Malaysian Veterinary Antimicrobials Guidelines, MVAG 2021)、2021 年獸醫師處方箋。

### 2. 馬來西亞之動物用抗菌劑使用量監測:

量化抗菌劑使用量相當複雜且具挑戰性。馬來西亞過去並無有效或適當之抗 菌劑使用量監測系統,並於 2020 年建立該新監測系統。馬國 AMU 監測系統主 要目標為:

- (1) 估算高風險畜禽族群(肉雞和豬)之抗菌劑使用量。
- (2) 取得指定抗菌劑之基本資料與數量,並於不久將來與國際數據進行比較。
- (3) 建立馬來西亞家禽與豬的之抗菌劑使用量模式與趨勢。

馬來西亞 AMU 監測方法分為四個步驟,分別為資料收集、資料分析、資料統合、資料報告與分享。馬來西亞 AMU 資料收集方式,整理如下表:

序號	資料來源	監測地點	負責單位	監測頻率
1	進口之抗菌劑	海關入口處	衛生部 藥事組	每年一次
2	家禽產業公司 (Poultry integrators)	家禽諮詢會議	獸醫局	每年一次
3	進口飼料	進出口服務部門	獸醫局	每年一次
4	馬來西亞優良農業規範(MyGAP)養畜禽場	養畜禽場 認證查核	獸醫局	每年一次
5	具許可證之	發新照與換照	獸醫局	每年一次
6	動物用藥品許可證持 有者(MAH)	動物用藥品許可證持有者或紀錄	獸醫局	每年一次

以下為馬來西亞監測畜禽抗菌劑使用量之流程圖,從「抗菌劑進口資料」、「家禽產業公司」、「飼料進口資料(含藥飼料與飼料添加物)」、「優良農業規範(MyGAP)養畜禽場」、「具許可證之養禽場與豬場」、「抗菌劑批發商資料」收集資料,由 TWG4 動物衛生秘書處(Seretariat TWG4 Animal Health)進行資料彙整,彙整資料由「國家細菌抗藥性委員會-動物衛生協調處/秘書處」進行驗證,並取得獸醫局局長(Department of Veterianry Services, Director General)同意後,再將報告送交給國家細菌抗藥性委員會(National Antimicrobial Resistance Committee, NARC)。

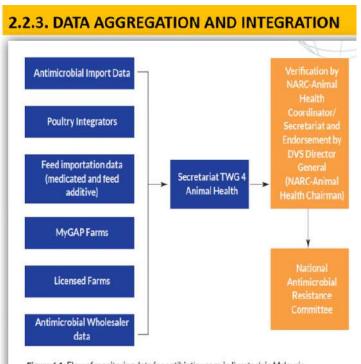
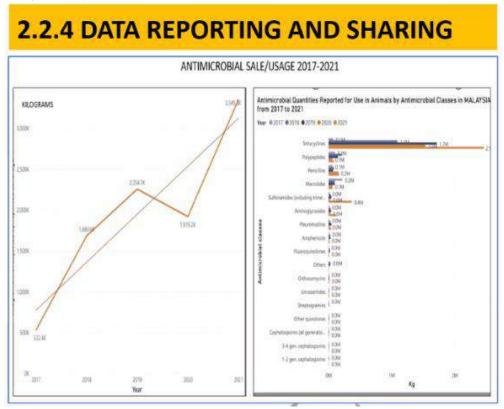


Figure 6.1: Flow of monitoring data for antibiotic usage in livestock in Malaysia

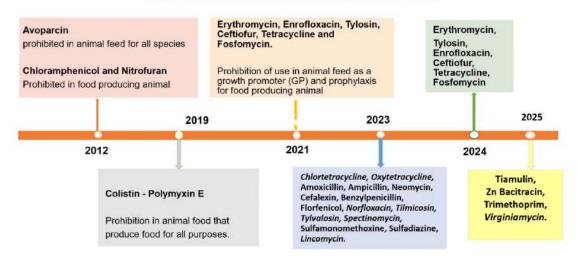
馬來西亞 2017 年至 2021 年 AMU 趨勢圖如下,其中以 Tetracycline 類 抗菌劑使用量最高。



### 3. 刪除抗菌劑作為生長促進與預防使用之馬來西亞時間軸:

馬來西亞 2021 年禁止所有動物使用 Avoparcin 與禁止產食動物使用 Chloramphenicol 與 Nitrofuran。2019 年禁止產食動物使用 Colistin。2021 年 起禁止產食動物將下列抗菌劑用於產食動物之生長促進與疾病預防: Erythoromycin、Enrofloxacin、Tylosin、Ceftiofur、Tetracycline 與 Fosfomycin。

# 3.0 PHASE OUT OF ANTIMICROBIAL USAGE AS GROWTH PROMOTERS & PROPHYLAXIS.



### 4. 馬來西亞之政策與指引:

以下為馬來西亞細菌抗藥性行動方案之相關手冊與動物用藥品之法規。

# 4.0 POLICY AND GUIDELINES



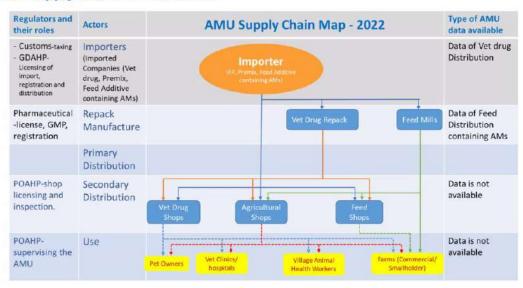
### (十九)柬埔寨之AMU 國家監測經驗

由動物衛生與生產總局之動物衛生暨獸醫公共衛生處副處長(Deputy Director, Department of Animal Health and Veterinary Public Health, General Directorate of Animal Health and Production)Dr. Tep Bengthay 簡報「柬埔寨之 AMU 國家監測經驗」。

柬埔寨動物數量:牛為 295 萬頭,其中 90%為家庭式養殖(back yard production);水牛為 43 萬頭,其中 90%為家庭式養殖;豬為 125 萬頭,其中 41%為家庭式養殖;家禽為 3,189 萬隻,其中 60%為家庭式養殖。柬埔寨為了維持動物健康與提高生產力,會使用抗菌劑。柬埔寨農業林業漁牧部之動物衛生暨生產總局(The General Directorate of Animal Health and Production [GDAHP], Ministry of Agriculture, Forestry and Fisheries)負責監管動物用抗菌劑產品登記、進口、分銷與監測。動物 AMU 資料係由 GDAHP 每年向動物用藥進口商與飼料生產商收集。下圖為柬埔寨 AMU 供應鏈示意圖。

### AMU Supply Chain

### 2. AMU Supply Chain in Cambodia:



有關柬埔寨 AMU 資料收集與報告方面,柬埔寨已依據 WOAH 模板,建置 AMU 資料模板,並將該模板以電子檔發送給藥品進口商與飼料製造公司。每家 公司每年均要依抗菌劑活性成分報告銷售量,並以電子檔或紙本寄送至 GDAHP。 國家動物用藥品業務聯繫窗口將所有公司提供之抗菌劑銷售量資料,填入

WOAH 之 AMU 資料模板。必要時,會請提供資料之公司說明與釐清。AMU 報告會先經過柬埔寨代表(WOAH Delegate)同意後,始送交給 WOAH 之 AMU 團隊。柬埔寨未來將與藥品進口商和飼料製造公司召開研討會。建立國家資料庫系統,將該系統與 GDAHP 所管理之動物用藥產品登記系統串聯。

### (二十)分組討論AMU 監測系統並進行小組報告

針對下列議題,分7小組討論,再進行小組報告:

- 1. 定義執行 AMU 監測系統之原因與目標。
- 2. 於 AMU 監測系統中,定義不同利益關係者之角色定位
- 3. 不同利益關係者之 AMU 資料傳播。

### 各小組報告資料彙整如下:

- 1. 定義執行 AMU 監測系統之原因:
  - (1) 以證據為基礎,制定國家政策,確保該國謹慎使用抗菌劑。
  - (2) 為了促進謹慎使用動物用抗菌劑。
  - (3) 為了瞭解動物族群中 AMR 程度。
  - (4) 量化與管理抗菌劑之使用,使 AMR 風險降至最低。
  - (5) 建立國家 AMU 基礎值資料(baseline data of AMU at national level),並 瞭解該國 AMU 狀態。
  - (6) 提升對抗菌劑使用之認知,能夠有目標性採取行動,減少抗菌劑不當使 用和濫用,降低 AMR 風險。
  - (7) 建立以科學為基礎之抗菌劑使用量資料庫,以制定有目標性之行動計畫, 鼓勵謹慎使用抗菌劑。
- 2. 定義執行 AMU 監測系統之目標:
  - (1) 進行 AMU 趨勢分析。
  - (2) 提供利益關係者(例如農民、獸醫師、獸醫助理等)之 AMR 警覺性。
  - (3) 監測動物抗菌劑使用之模式與趨勢。
  - (4) 產出準確之 AMU 資料,以便與相關利害相關者進行有效溝通。

- (5) 從畜牧場端與獸醫師收集 AMU 資料,進行實驗室分析(AMR 檢驗)、動物用藥產品之品質檢驗。
- (6) 強化現有技術能力。
- (7) 傳遞所獲得之資訊。
- (8) 收集 AMU 資料,以支持政策制定者對抗 AMR。
- (9) 促推謹慎使用動物用抗菌劑。
- (10) 提高該國對其抗菌劑使用狀況之瞭解,並提供證據以制定適當之抗菌劑使用策略。
- (11) 能夠追蹤 AMU 趨勢,並與其他區域或全球進行比較。
- (12) 建立國家 AMU 基礎值。
- (13) 建立或修改抗菌劑使用之相關政策。
- (14) 提高公眾對於 AMU 和 AMR 之警覺性。
- (15) 保留獸醫學上重要抗菌劑之效力,以供未來有具效力之藥品可用。
- 3. 不同利益關係者與 AMU 監測系統之角色定位,7 組票數統計結果如下,括號 內數字表示認同之組數統計:
  - (1) AMU 資料提供者:製藥業者(7)、民間獸醫師(7)、公共衛生部門(4)、 獸醫服務暨流行病學部門(4)、畜牧業(4)、飼料廠(1)、相關食品 業(1)。
  - (2) 受益者:製藥業者(5)、一般大眾(5)、公共衛生部門(5)、民間獸醫師(5)、獸醫服務暨流行病學部門(4)、媒體(4)、畜牧業(4)、學術研究單位(2)、政治領導(2)、飼料廠(1)、相關食品業(1)。
  - (3) 分析與知識管理: 獸醫服務暨流行病學部門(7)、公共衛生部門(6)、 民間獸醫師(4)、政治領導(2)、媒體(2)、製藥業者(1)、學術研 究單位(1)、畜牧業(1)、飼料廠(1)。
  - (4) 決策者:政治領導(7)、獸醫服務暨流行病學部門(5)、公共衛生部門(4)、媒體(1)、民間獸醫師(1)
  - (5) 就 AMU 監測結果有所因應:公共衛生部門(7)、一般大眾(5)、民間 獸醫師(5)、獸醫服務暨流行病學部門(5)、媒體(5)、政治領導(4)、

製藥業者(4)、畜牧業(4)、學術研究單位(2)、相關食品業(1)、 飼料廠(1)。

# 4. 不同利益關係者之 AMU 資料傳播,以下為各組報告:

組別	利益關係者	他 們 多 久 要 收 到 一 次反饋?	決定反饋頻 率之原因	溝通形式	傳播方式	分享數據之類 型(圖/表格)	此為公開 或內部溝 通管道		
1	製藥業者	每年一次	此為年度計 畫,資料分 析具挑戰性	年度會議	官方通知並進行數據比較	全國 AMU 資料彙整	公開		
2	一般大眾	每年一次	按年度計畫 之報告	書面、會議	社群媒體、網站、手冊、看板、研討會、警 覺性活動	圖表	公開		
3	公共衛生部門	每年一次	收集完整 AMU資料所需時間為一年	視訊或實體會議	電子郵件、實體會議、年度報告	AMU 趨勢圖	內部溝通		
4	政治領導	每年一次	需要足夠資 料以確認下 一年度之行 動計畫	圖表報告	會議	AMU 資料與 趨勢	內部溝通		
5	民間獸醫師	   每季一次 	監測與保持 警覺性	視訊與實 體會議、 媒體	官方與非官方	圖表	公開與內部		
6	獸醫服務暨流 行病學部門	每年一次	收集完整 AMU資料所 需時間為一 年	圖表與資 料分析	公布、電子郵件、部門網站	圖表	公開		
7	媒體	每季一次	因每 3 個月 有一次進度 報告	記者會	透過傳單、社 群 媒 體 提 供 AMU 對 於 AMR 之重要 性資訊	資訊視覺化	公開		

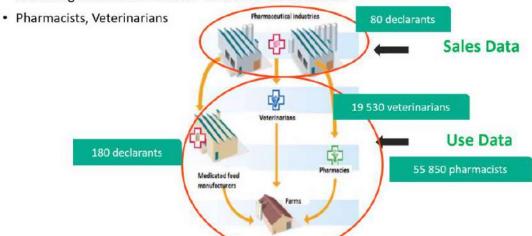
### (二十一) 法國AMU 資訊視覺化經驗

由法國動物用藥管理局-抗菌劑使用專案經理 Anne Chevance 簡報「法國 AMU 資訊視覺化經驗」。法國法規要求申報抗菌劑之銷售量及其運輸。須申報 者包括動物用藥品上市許可證持有業者(計 80 名申報者)、飼料製造商(計 180 名申報者)。截至 2023 年 2 月為止,法國目前尚無收集藥師(計 55,850 名)與 獸醫師(計 19,530 名)之抗菌劑銷售量資料(如下圖)。



# What data are we collecting in France?

- Mandatory declaration of sales and delivery of antimicrobials
- · Who should declare?
  - · Marketing Autorisation Holders -Feed mills manufacturers

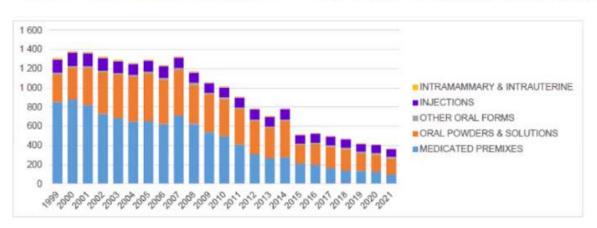


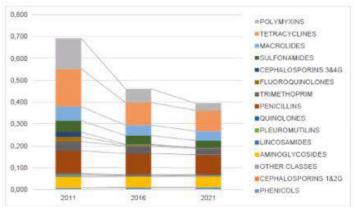
向各申報者收集之抗菌劑銷售量資料會與其他資訊串接,包括抗菌劑種類、 劑型與成份。抗菌劑銷售量收集係依據不同動物種別、不同年度區分,惟仍面臨 幾項問題,包括如何處理這麼大量之資料?如何驗證資料之正確性?如何以最佳 之方式判讀資料?因此,需要透過圖表使資料具有意義且使報告易於閱讀。法國 目前使用 Excel 軟體功能、免費軟體 (R、QGIS) 與商用智慧工具進行分析 (經 費由農業部支出)。為了確保抗菌劑銷售量之資料品質,法國以資料視覺化(Data visualization)之方式進行銷售量資料驗證。使用 Excel 軟體「設定格式化的條件」 功能,將過去之銷售紀錄與當年度銷售量資料進行比對(如下圖),若兩者具顯 著差異性,則會聯繫申報者,以確認資料之正確性。

Package	ID VMP	Veterinary Medicinal Product	Sales 2021	Sales 2020	Absolute Difference in sales
Boite de 1 flacon de 250 mL	298886	PRODUCT 3	0	28984	-2898
Boite de 1 flacon de 250 mL	298886	PRODUCT 3	0	28984	-2898
Boîte de 3 plaquettes thermoformées de 10 comprimés	267086	PRODUCT 5	27398	30489	-309
Boîte de 3 plaquettes thermoformées de 10 comprimés	267086	PRODUCT 5	27398	30489	-309
Boîte de 1 plaquette thermoformée de 20 comprimés	252806	PRODUCT 5	139830	133843	598
Boîte de 1 plaquette thermoformée de 20 comprimés	252806	PRODUCT 5	139830	133843	598
Boîte de 1 flacon de lyophilisat et de 1 flacon de solvant de 5 mL et 1 bouchon compte-goutte	252446	PRODUCT 9	281740	256460	2528
Boîte de 1 tube de 5 g	252326	PRODUCT 9	416962	391882	2508
Pot de 1 kg	248606	PRODUCT 4	2829	2991	-16
Pot de 1 kg	248606	PRODUCT 4	2829	2991	-16
Pot de 500 g	248606	PRODUCT 4	4635	5341	-70
Pot de 500 g	248606	PRODUCT 4	4635	5341	-70
Boîte de 1 flacon de lyophilisat, 1 flacon de solvant de 5 mL et 1 bouchon compte-gouttes	248366	PRODUCT 4	262440	224489	3795
Boîte de 1 flacon de lyophilisat, 1 flacon de solvant de 5 mL et 1 bouchon compte-gouttes	248366	PRODUCT 4	262440	224489	3795

進行抗菌劑銷售量資料分析與製作報告時,應避免將所有細節放入資訊儀表板或圖表中,圖表呈現應簡單化,主要目標為使資料具有意義且易於閱讀。不論係抗菌劑銷售量或其他指標,結果均可按不同年份、不同抗菌劑類別、不同劑型與不同動物別呈現。

# > The aim: make the data meaningful and the report easy to read

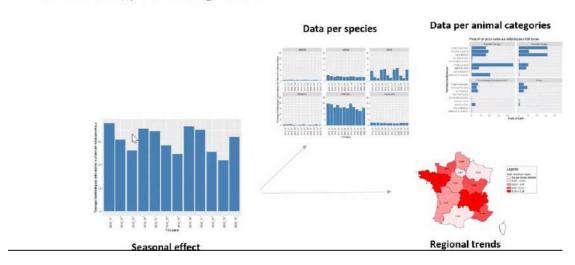




AMU 資訊視覺化分析包括季節性銷售量、按動物別分類、按法國地區之 AMU 多寡進行色層分類(如下圖)。

# Data analysis / Report

### > For use data, possible to go further



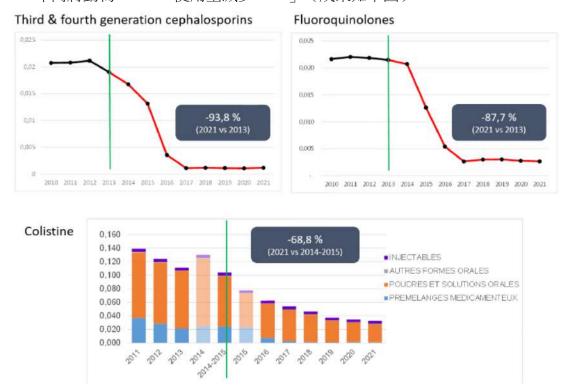
法國以資訊視覺化評估抗菌劑管理效能, Ecoantibio 第一期計畫目標為「於5年內(2012~2016年),降低25%之動物用抗菌劑使用量」。Ecoantibio 第二期(2017~2021年)計畫目標為「維持趨勢:維持動物減少使用抗菌劑之趨勢」。就5年內降低25%之抗菌劑使用量目標,法國成功達標(如下圖)。

### Exposure to antimicrobials (ALEA)



The target of reducing exposure by 25 % in 5 years has been achieved

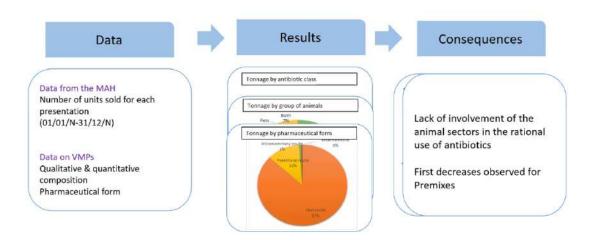
法國追加目標: 2014 年 10 月 13 日頒布 2014-1170 號法律,關於農業、食品與林業之未來展望,以 2013 年數據為基準,於 3 年內將動物 Fluoroquinolones 與第三、第四代 Cephalosporins 使用量減少 25%。 Ecoantibio 第二期計畫目標為:「5 年內將動物 Colistin 使用量減少 50%」(成果如下圖)。



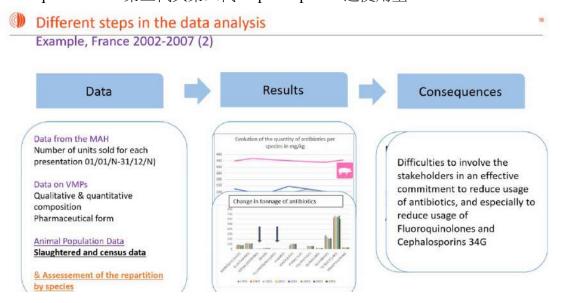
有關資料分析之限制與溝通交流方面,法國於資料分析共經歷三個階段,第一階段(1999~2001年)係向動物用藥品許可證持有業者(Marketing Authorization Holder, MAH)收集資料,收集每個抗菌劑產品之每年銷售量。抗菌劑產品資料需包括質性、量性資料、成份、劑型。結果報告係按抗菌劑種類、動物種類分群(例如寵物類)、藥品劑型製銷售量圓餅圖百分比進行分析(如下圖)。該報告結論指出,Fluoroquinolones、第三代與第四代 Cephalosporins 幾乎不被使用。產食動物中,老舊類別抗菌劑(Tetracyclines、Sulfamides)之使用非常重要,特別係在預混料(Premixes)中。該報告指出所面臨限制為,動物產業於抗菌劑合理使用方面參與不足。



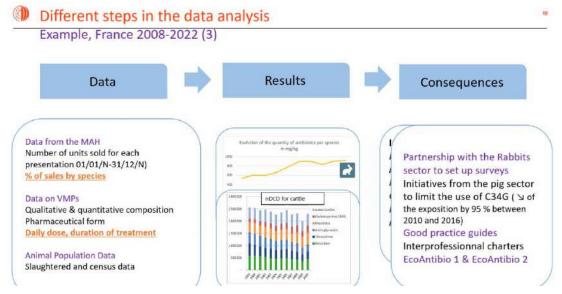
Example, France 1999-2001 (1)



法國第二階段(2002~2007年)如同第一階段,係向動物用藥品許可證持有 業者(MAH)收集資料,收集每個抗菌劑產品之每年銷售量。另外增加動物數量 資料,該資料源自屠宰數量與畜牧場在養數普查,並按動物種類對數據進行分類 和評估。結果報告係按動物種類於不同年度之每公斤體重用藥量(mg/kg)呈現 趨勢圖,可見豬隻中 Tetracyclines 使用量很大,特別係預混料之使用。另一張為 柱狀圖,係按抗菌劑種類統計歷年抗菌劑銷售量,可見 Fluoroquinolones、第三代 與第四代 Cephalosporins 之使用量增加並不明顯(如下圖)。該報告指出所面臨 限制為,難以讓利益關係者有效承諾減少抗菌劑之使用,尤其是減少 Fluoroquinolones、第三代與第四代 Cephalosporins 之使用量。



法國第三階段(2008~2022年)如同第一階段,係向動物用藥品許可證持有業者(MAH)收集資料,收集每個抗菌劑產品之每年銷售量。另外增加依動物種類之抗菌劑銷售量比例資料、每日劑量(Daily dose)、治療天數(Duration of treatment)。結果報告係按動物種類於不同年度之每公斤體重用藥量(mg/kg)呈現趨勢圖,可見兔子使用抗菌劑比例很高(如下圖)。於獸醫學中,Fluoroquinolones、第三代與第四代 Cephalosporins 之使用易不可忽視。該報告指出,除透過與兔肉業建立調查合作,亦對豬肉業採取措施限制第三、四代 Cephalosporins 之使用(2010~2016年減少95%之使用)。制定良好作業指南(Good practice guides),制定「跨產業協議」,並推行 EcoAntibio 1 與 EcoAntibio 2。所謂「跨產業協議」係一份由特定產業或產業不同角色間達成共識,一起朝向共同目標努力之協議書。於動物養殖業使用抗菌劑情況下,跨產業協議可集結獸醫師、農民、飼料製造商與其他相關人士,就最佳作業與標準達成共識,以降低抗菌劑使用量。該協議有助於促進協作與承諾,朝著更負責任使用抗菌劑之方向前進。



### 結論:

資料圖像化對於追蹤時間、區域趨勢等方面非常有用,可幫助確定目標並評估管理措施之有效性。透過更詳細之分析,結果會更具有意義。公眾意見通常只會關注有限數量之資訊信息,故要注意於報告中需要強調哪些關鍵結果。此為敏感性議題,需依賴溝通發揮影響力。透過不同角度觀察數據,可突顯不同之結果。同時需要注意我們的數據管理與分析係有其局限性。

### (二十二)印尼AMU 資訊視覺化經驗

由印尼農業部動物衛生署動物用藥監管處 Dr. Ni Made Ria Isrlyanthi 簡報「印尼 AMU 資訊視覺化經驗」。

### 背景說明:

印尼法規禁止使用抗生素類生長促進劑(Antibiotic Growth Promoter, AGP), 僅限動物醫療用,避免於產食動物預防性使用抗生素。政府法規第 18 號法案 (2009 年)與第 41 號法案(2014 年)禁止使用抗生素類生長促進劑。農業部 (MoA)2017 年修訂第 14 號法規之動物用藥分類。農業部(MoA)2019 年第 3 號法令規定獸醫服務相關事項,並規範於動物/使用抗生素之責任,此為總統就 獸醫主管機關之第 3 號法令後續措施。

第二期印尼之國家細菌抗藥性行動計畫(2020-2024)以家禽業為管理標的:

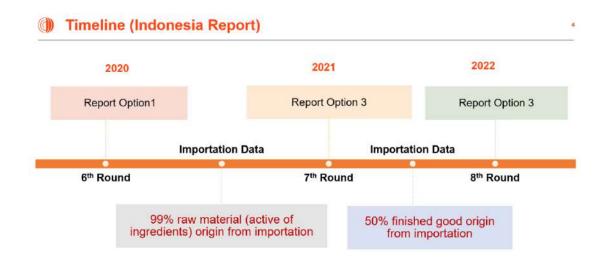
- 透過監控抗菌劑之使用,以減少肉雞場預防性使用抗菌劑(2024 年抗菌劑使用比例從80%降至50%)。
- 2. 改善蛋雞產業之生物安全措施與抗菌劑使用管理,並取得獸醫管理認證認證 (2024年認證比例從 4.4%提高至 20%)。

### 印尼之國家細菌抗藥性行動計畫主要有六大主軸:

- 1. 提高對細菌抗藥性之認識與瞭解 (Raising awareness and understanding regarding AMR)。
- 2. 透國監測與研究,強化專業知(Strengthening Knowledge through surveillance and research)。
- 3. 透過有效之衛生與預防感染措施,減少疾病感染發生率 (Reducing the incidence of infection through effective sanitation, hygiene and infection prevention)。
- 4. 於人類與動物衛生方面,優化抗菌劑之使用 (Optimizing the use of antimicrobial drugs in human and animal health)。
- 5. 增加對動物醫療技術之研發投資,並實施控制措施。(Increase investment for research and development [R&D] and implementation of control measures)。

6. 建立跨部會或跨機關之整合管理和協調 (Build integrated governance and coordination between ministries/agencies)。

下圖為印尼 AMU 報告之時間軸,印尼 2020 年報告僅能統計各類抗菌劑之總量,2021 年透過 WOAH 之 Excel 工具表,已可統計至陸生動物、水生動物、伴侶動物及其劑型。印尼 99%之原料藥源自進口。50%藥品製劑源自國外進口。



### 抗菌劑進口之限制與優先順序:

印尼法規就抗菌劑產品及其活性成份有進口之限制與優先順序原則(包括用途、抗菌劑進口數量之合理性、銷售途徑等)。進口之原料藥僅限銷售給製藥廠進行生產,藥品進口程序必須符合農業部規定。

### 印尼 AMU 資訊視覺化:

印尼 AMU 圖表均為 WOAH 開發之 ANIMUSE 資訊系統內建置之視覺化圖表功能。印尼 2021 年抗菌劑銷售量為 8,754,951 公斤,而於 2022 年抗菌劑銷售量縣降至 686,834.70 公斤,降幅高達 92.1%。此原因可能係印尼之「國家細菌抗藥性行動計畫」發揮功效所致。

### 結論:

- 印尼已禁止使用抗生素類生長促進劑,僅限動物醫療用,並避免於產食動物 預防性使用抗生素。
- 2. 印尼自 2020 ~ 2022 年(第 6 ~ 8 年度 AMU 報告)已提交 AMU 問卷報告給 WOAH。
- 3. 2020~2023年期間,印尼使用最廣泛之抗菌劑類別為 Polypeptides。
- 4. 產食動物與寵物使用抗菌劑之給藥途徑中,以口服與注射佔了大多數。
- 5. 印尼於 2020 年禁止動物使用 Colistin (人醫後線治療用藥)。

### (二十三) ANIMUSE 之AMU 資訊視覺化

由 WOAH 細菌抗藥性暨動物用藥產品部門(AMR&VPD)Dr. Morgan Jeannin 簡報「ANIMUSE 之 AMU 資訊視覺化」。

本簡報重點在於瞭解我們已經收集數據後,如何能夠溝通,如何處理該數據。因此,ANIMUSE 目標為讓會員國可查看該國過去提供給 WOAH 之所有歷史數據,並且會員國可使用 ANIMUSE 工具,進行數據分析。這些工具於未來幾年,將會根據會員國提出之需要不斷增加。我們可透過蓋房之概念,解釋何謂資料視覺化(Data visualization)。資料視覺化係將資訊(Information)與資料(Data)以圖像化方式呈現。透過圖表與地圖等視覺元素,使資料更易看出趨勢、極端值及其模式。數據資料為蓋房之地基,其本身並無太大意義。必須將資料(Data)

置於某情境中,以提供資訊(Information)。瞭解是否有疾病存在等情況,從中 獲取相關知識,並依據該知識做出決策,付諸行動。

● 資料:為沒有獨立意義之離散、客觀事實。

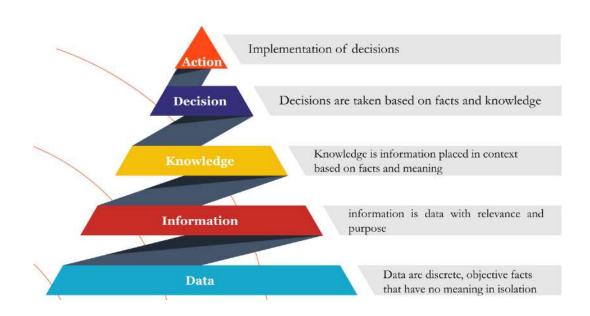
● 資訊:為具有相關性與目的之資料。

● 知識:為根據事實與含義放置於情境中之資訊。

● 決策:為基於事實與知識做出之決策。

● 行動:實施決策。

截至今日,WOAH 目標一直專注於收集資料與嘗試優化資料之品質,因為資料為資料視覺化分析之基礎,若資料(Data)地基不牢固,則資訊、知識、決策與行動將會整個崩塌。ANIMUSE計算工具可幫助會員國強化此資料基礎。



### 資料視覺化之主要優點:

- 找出資料模式與新興趨勢。例如用量最大抗菌劑種類由一種轉換成另一種; 或發現資料錯誤。
- 2. 協助理解資料與優化資料分析。
- 3. 以視覺化圖表處理大量數據。

- 4. 有助於聚焦於重要觀點;並發現需關注之處。
- 5. 顯示出過去未被注意之關鍵點。
- 6. 促進資料溝通交流。



### ANIMUSE 儀表板:

在 ANIMUSE 數據儀表板係使用 Microsoft Power BI 應用程式製作而成。其最大優勢為互動式、動態圖表,進行資料探勘,查看有興趣標的之所有相關資料及其相關細節。例如,查看某一日期區間,指定抗菌劑種類、動物種類、給藥途徑等,產出視覺化圖表。WOAH 會依據會員國提出更多之視覺化圖表需求,再創建更多圖表,以滿足會員國之需求。因此,若發現 ANIMUSE 缺乏某種功能,請與 WOAH 聯絡。ANIMUSE 數據儀表板分為公開介面與會員國專屬介面。

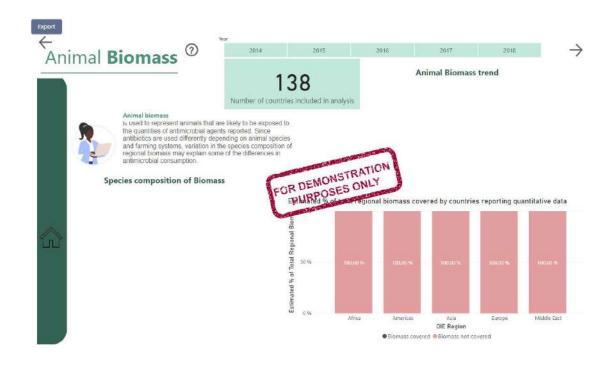
- 1. 公開介面:任何人均有權限查看。
  - (1) 公布全球性與區域性之 AMU 資料。
  - (2) 每會員國代表可決定是否公布該國 AMU 資料。
- 2. 會員國專屬介面:僅 AMU 團隊與 WOAH 會員有權限查看。
  - (1) 會員國代表有權限杳看該國所有數據資料。
  - (2) WOAH 動物用藥品業務聯繫窗口有權限查看該國所有數據資料。
  - (3) 非必要帳號:每個會員國有額外兩個帳號名額,供該國其他主管機關有 查看之權限,該權限僅能由會員國代表授權與建立帳號。

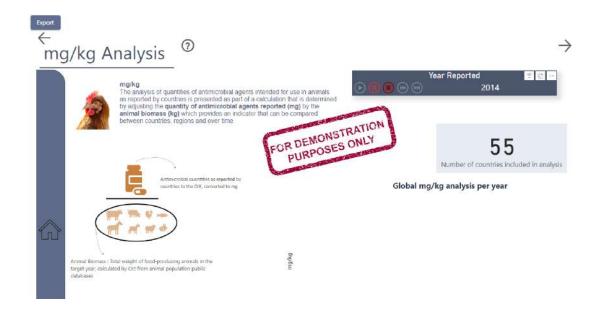


### (二十四) ANIMUSE 資訊視覺化實作練習

與會人員登入 ANIMUSE 資訊系統,瞭解資訊視覺化相關功能。包括各類抗 菌劑銷售量橫條圖、國家總動物體重、每公斤動物體重使用多少毫克抗菌劑之分 析圖 (mg/kg) 等。







# (二十五) WOAH 全球計畫介紹:動物用藥品之偽藥、劣藥通報系統

由 WOAH 細菌抗藥性暨動物用藥產品部門 (AMR&VPD) Dr. Andrés García Campos 簡報「WOAH 全球計畫介紹:動物用藥品之偽藥、劣藥通報系統」。

依據 2017 年相關報告估計,全球動物用藥產品有 3%為違法動物用藥或劣藥。另依據 2020 年相關研究指出,亞洲與非洲上市之動物用藥品,有 52%為偽

藥與劣藥(Substandard and Falsified Veterinary Products, SFVDs)。下圖為原廠藥 與偽藥之樣本對比圖。



這些偽藥、劣藥將打擊我們的獸醫服務體系,除了影響農民或寵物飼主外,亦使其對獸醫師失去信任。偽藥、劣藥於毒理學方面具高危險性。另就細菌抗藥性而言,若我們使用這些有效成分含量低於標籤標示之產品來治療動物,則冒著低劑量治療帶來之細菌抗藥性風險。



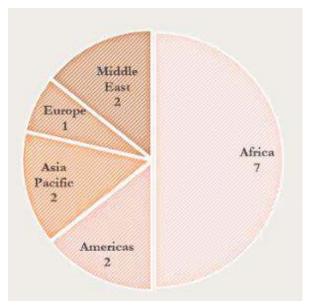
2015 年全球抗微生物抗藥性行動計畫(Global Action Plan on AMR in 2015) 第四個目標:優化人類和動物健康領域中的抗微生物藥物使用。而促進細菌抗藥 性發展之相關因素即包括人醫與動物用藥之劣藥盛行。 第 5 屆動物用藥品業務聯繫窗口培訓研討會(2017-2018),與會者即提出 偽藥、劣藥為重要議題。

2018年第二屆 WOAH 全球細菌抗藥性與謹慎使用抗菌劑會議之第 6 項建議為:研析建立一個資訊系統之可能性,以監測國與國之間非法流通之動物偽藥、劣藥,並借鑒世界衛生組織之人類用藥監測系統,採取「防疫一體策略(One Health approach)」。WOAH 第三年度 AMU 資料收集,即有 20 個會員國報告有違法或非官方核准之動物用藥。

第一期試驗階段(Pilot phase 1)目標為從 WOAH 會員國中,挑選自願國家試用劣藥與偽藥資訊警報系統,收集國內動物用藥品質情況、並對該資料收集工具給予反饋意見,以便將其改進為一個線上工具。偽藥與劣藥資料來源可以為製造商(Manufacturers)、分銷商(Distributors)、批發商(Wholesalers)、寵物飼主(Pet owners)、農民(Farmers)和獸醫師(Veterinarians)。若他們懷疑有偽藥與劣藥產品,即可向國家主管機關通報。國家主管機關將會知道發生什麼事與該國狀況。當國家主管機關瞭解偽藥與劣藥案件後,其要把這些資訊通報給WOAH,以便WOAH 能瞭解全球偽藥與劣藥之情況。經過評估和分析後,WOAH可同區域其他會員通報該區域有偽藥與劣藥存在,WOAH可提供建議,包括如何應對這些情況,同時國家主管機關亦執行其認為必要的措施。



以此為基礎, WOAH 於 2021 年開始第一期試驗階段, 並持續至 2022 年底。 於此試驗, WOAH 分析此試驗之資料,以測試該系統之可行性與永續性, 並要求各會員國提供有關該國處理偽藥與劣藥產品之資訊與反饋。目前 WOAH 有 14 個參加國(如下圖),其中亞太地區有 2 個參加國。WOAH 非常感謝他們參與試驗並提供意見。

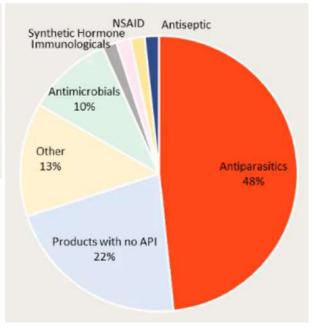


下圖框線區強調三個重點,第一、WOAH 詢問參與試驗之會員國,是否有與其他國家就動物用藥品質問題進行合作或協作,經調查結果顯示只有3個參與國有進行某種形式之合作。因此,WOAH 想要解決之問題為是否要共同合作。第二、於14個參加國中,有7個參加國有實驗室檢驗以執行監測與監控系統(Monitoring and Surveillance System),此表示只有50%之參加國能夠確認產品是否為劣藥,一旦該國有疑似產品時,大多數情況均無法確認。第三、於14個參加國中,僅4個參加國擁有藥品溯源系統,此將造成動物用藥產品之製造商或藥品許可證持有業者之記錄困難。此可作為WOAH制訂會員國指引之依據,以試圖改善這些國家中所有藥品監測系統之品質。

#### WOAH之動物偽藥與劣藥計畫 (Project on SFVPs) 有 無 未回覆 與其他國家合作或協作,以管理可疑之偽藥與劣藥產品 1 3 10 14 執行動物用藥產品登記核准之主管機關 13 1 執行動物用藥品質監控之主管機關 登記核准動物用藥產品之國家資料庫 11 抽驗市面上動物用藥產品之法規 10 召回動物用藥產品之法規 10 動物用藥品質監控系統 10 7 以實驗室檢驗執行動物用藥品質監控系統 11 3 有實驗室可檢驗動物用藥品質 動物用藥溯源系統 4 10

WOAH 總共收到 38 起案件,涉及 59 種動物偽藥與劣藥產品(如下圖)。 這些藥品有將近一半為抗寄生蟲藥,10%為抗菌劑。因此,WOAH強調,我們必 須要意識到偽藥與劣藥會引發抗藥性問題。

	Number incidents	Number products	
Classification		Suspect	Confirmed
Substandard	22	20	17
Falsified	10	0	12
Unregistered	0	0	0
Unknown	5	10	0
TOTAL	38	30	29



下圖顯示發現偽藥與劣藥之地點為動物用藥產品之整個產業鏈,此表示偽藥與劣藥可於產業鏈中任何一地點進入市場。於檢查與監控期間產生之懷疑,多數時係值得重視,此亦突顯監控之重要性。



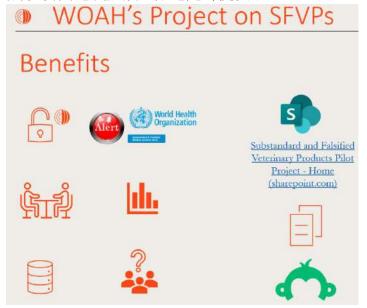
WOAH 偽劣動物用藥計畫徵求會員國合作,該計畫具包容性、不評判、不 指責。WOAH 於 2022 年進行第一階段動物偽劣藥通報系統試驗,並於 2023 年 1月15日開始第二階段試驗,為期1年。基於第一期試驗階段之會員國反饋, WOAH 已進行優化,包括將偽劣藥通報系統數位化,並使之更易於收集資料與 操作。WOAH 已開始定義試驗範圍、專有名詞、參考資料、如何發送警報資訊 給會員國,與如何加強與其他組織之合作。WOAH 目前於試驗階段僅有 14 個國 家參與,規模很小,WOAH 希望能夠更加瞭解參加國之需求,並徵求會員國合 作與參與此試驗。WOAH 希望該試驗具包容性,不希望讓會員國感到更好或更 糟,因為 WOAH 認為沒有更好或更糟,只是提供不同服務。WOAH 不做任何評 判,亦不是為了羞辱或顯示哪個國家更好或更糟,只是為了瞭解會員國之通報需 求,並瞭解未來幾年中 WOAH 想開發之系統需如何建置。



對於參與試驗階段之國家而言,效益說明如下:

1. 参加之國家能查看區域警報。WAOH強調,WAOH收到動物偽劣藥產品通報時,參加國可決定其要以何種方式分享資訊,可選擇揭露地點資訊之程度為發生國家或區域(例如亞洲)。參加國亦可選擇是否與其他國際組織合作,例如國際反偽劣藥組織等。WAOH不強迫任何參加國揭露其不想公開之資訊。

- 2. 参加國可查看 WHO 發送之警報,該等警報為公開可供使用,供大眾瞭解。 WAOH 希望以微生物抗藥性角度切入,執行動物偽劣藥通報相關作業。
- 3. 若對產品有疑慮時, WAOH 會請該國評估需要進行哪種實驗室技術,以確認該產品是否為偽藥或劣藥。
- 4. 参加國擁有自己國家之數據資料,持續執行幾年後,於 ANIMUSE 即可查看相關資訊,該資訊將以視覺化圖表呈現,此為 WAOH 未來需努力方向。参加國可查看會員國於系統中提供之指南或公開資料庫。
- 5. 若參加國有任何問題或反饋,歡迎隨時提供給 WAOH。



關於如何參加動物偽劣藥通報試驗,WOAH為此試驗創建 SharePoint 管道,並提供此管道之網址連結,以便希望參加之國家。WOAH已訂定相關《職責範圍》與三種問卷,用於收集資料。第一份問卷為基本報告表,每年填寫一次。該份問卷旨在瞭解會員國是否擁有監控與監測系統(Monitoring and Surveillance System),是否有執行實驗室檢驗,是否有藥品溯源系統等。該等資訊有助 WOAH瞭解會員國需求並作為制訂後市場藥品監控指引(Post-marketing surveillance guidelines)依據。

第二份問卷為即時通報表,內容較詳細,但不需全部填寫,只要有懷疑即可提供相關訊息。第三份問卷僅用於監測目的(Monitoring purposes),每個月填報

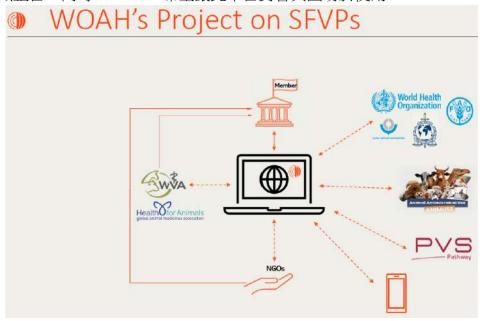
一次。若會員國於一個月內並無發現動物偽劣藥產品或可疑產品,僅需一分鐘時間,即可完成問卷填報。

WOAH Baseline Reporting Form (Blue Form)

WOAH Immediate Notification Form (Green Form)

WOAH Monthly Declaration Form (Pink Form)

WOAH 希望有一個數位平台, 能整合 WOAH 現有其他工具, 亦能與所有國際組織整合。同時, WOAH 希望讓此平台對會員國易於使用。



除了此建立一個動物偽劣藥資訊與警報系統之外,WOAH 未來尚有三大面項工作,第一,制定動物用藥品後期市場監控指南。成立專家小組,成員包括動物用藥品許可證持有業者、海關、批發商與經銷商、法規主管機關、獸醫師協會與國際組織。第二、發展區域性實驗室網絡:WOAH 需要參加國家之間建立實驗室網絡,以瞭解何時可檢驗樣本、如何進行檢驗。第三、提供現場監測之指南與工具:WOHA 希望與所有國際組織合作,進行現場監測,瞭解目前已在使用之偽劣藥檢驗方法。

# WOAH's Project on SFVPs



WOAH 強調,此平台不是為了 WOAH 建立,而是 WOAH 為了符合會員國之需求與目而建立之平台。因此,WOAH 需要會員國之協助與合作。參與此平台方式相當容易,第一、每年填寫 WOAH 基本報告表。第二、及早填寫 WOAH 即時通報表,即使資訊不完整也沒關係。第三、只有在前一個月沒有發現任何動物偽劣藥案件時,才填寫 WOAH 每月聲明表。

有關同意完全分享動物偽劣藥資料或僅分享部分資料方面,WOAH 強烈鼓勵但並非強制會員國分享與將資訊透明化。如此,WOAH 即能協助會員國解決減少偽劣藥產品之情況。若有任何問題或疑慮,請發送電子郵件至 sfvp@woah.org,或於 SharePoint 網站張貼相關問題。

若會員國有興趣參加,WOAH 已發送給與會者使用平台之權限。本研討會第三天結束後,與會者會收到 SharePoint 系統鏈接。請注意,該系統權限係開放給動物用藥品業務聯繫窗口、會員國代表、一名經會員國代表同意之提名者。

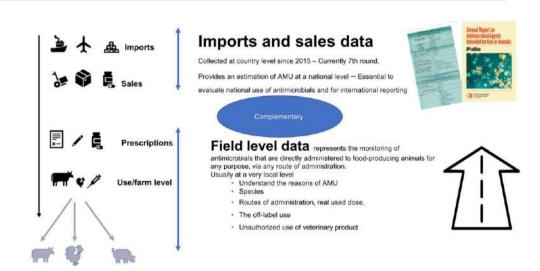
WOAH 之所以這樣做,係基於第一次參加者提供之反饋意見,主要係為了避免 重複報告與減少行政負擔。第三天研討會,請與會者填寫虛構之偽劣藥事件報告, 以熟悉 WOAH 問卷。

# (二十六) WOAH 之畜牧場端AMU 資料收集

由 WOAH 細菌抗藥性暨動物用藥產品部門(AMR&VPD ) Dr. Morgan Jeannin 簡報「WOAH 之畜牧場端 AMU 資料收集」。

抗菌劑使用量(AMU)資料來源分為兩種,一種為銷售量資料(Sales data);另一種為畜牧場端資料(Field level data),兩種資料具互補性,WOAH並非要以畜牧場端資料取代銷售量資料。自 2015 年以來,由國家收集之 AMU 資料來源通常為進口商與批發商。國家級 AMU 估算數據有助於評估國內抗菌劑使用情形並提供國際報告。畜牧場端資料表示監測之抗菌劑使用量係直接投予至產食動物,可能基於任何原因給藥,透過任何給藥途徑。畜牧場端資料通常係於非常小範圍收集資料,以瞭解抗菌劑使用原因、使用動物種類、給藥途徑、實際使用劑量、標籤外使用(The off-label use)、未核准藥品使用(Unauthorized use of veterinary product)。

# Field level AMU data collection: Understanding



# 瞭解畜牧場端AMU資料收集

	進口量與銷售量資料(自 2015年起之WOAH全球抗 菌劑使用量資料收集)	畜牧場端資料收集 (刻正進行之地方性獨立專案計畫)
規模 (Scale)	全國性 (National level)	地方性或抽樣 (Local /Sampling)
目標 (Objective)	進行全球性比較·比較國與國 之間;或區域之間	抗菌劑使用之原因、抗菌劑使用之模式
目標動物別 (Targeted species)	資料為該國之所有動物	一般而言·資料為某一個時間點·某一動物別之特定生產類型 (例如肉用雞)
資料提供者 (Data providers)	國家主管機關、進口商、批發 商等	現場獸醫師、農民等

### 畜牧場端 AMU 資料收集之背景說明:

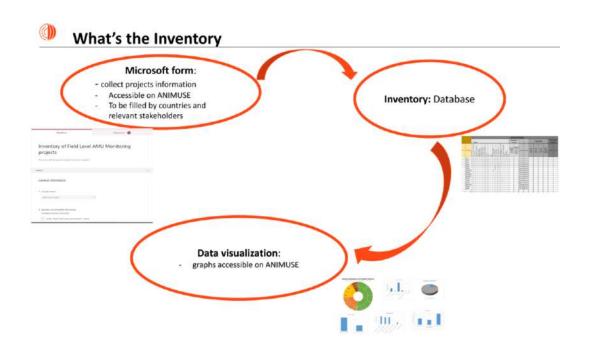
2018年10月第二次OIE全球細菌會議之第4號建議為:優化OIE之AMU收集,將電子檔格式轉換為資料庫系統(本項工作已完成,即ANIMUSE資訊系統),且能收取動物種類資料,並連接世界動物衛生資訊系統(WAHIS),亦可增加畜牧場端之研究資料。關於畜牧場端研究資料之收集方面,WOAH目前遇到困難,尚無法瞭解如何將畜牧場端研究資料,增加至國家AMU資料庫,故WOHA目前想法為開始找出哪些國家已有相關計畫執行畜牧場端AMU資料收集,並確認該資料研究結果是否可被該國WOAH動物用藥品業務聯繫窗口查看。因為這個畜牧場端AMU資料收集計畫可能係由大學、協會或專門之外部贊助商主導與執行,WOAH希望該等計畫結果內回饋至該國WOAH動物用藥品業務聯繫窗口,因為某些國家之動物用藥品業務聯繫窗口並不知道其國內學術或民間單位已在進行畜牧場端AMU資料收集,此相當可惜。

爰此,WOAH 擬建立一個已有或正在執行之畜牧端 AMU 資料收集計畫清單。WOAH 強調,其只是要確認該國有畜牧場端 AMU 資料收集計畫存在而已,並建立已有或正在執行之計畫清單,而並非要收集該計畫結果之資料,以確保該國家主管機關知悉其國內有此計畫存在。如此,國家主管機關可透過其所收集之抗菌劑銷售量與其國內已有之畜牧場端 AMU 資料進行比對檢查,並確認收集資料是否正確。對 WOAH 而言,WOAH 可更加瞭解不同 AMU 收集之方法學,以

利於 AMU 資料收集方面可提供更好之協助。WOAH 亦能更加瞭解全球畜牧端 AMU 資料收集計畫之情況。

目前建立畜牧場端 AMU 計畫清單只是一個探索性階段,只要填寫一個簡單之微軟表單,WOAH 會問 20 個問題,瞭解計畫是什麼?誰負責出資?誰負責該計畫?針對哪些動物別?以及正在收集哪些數據。WOAH 強調,其不會收集該計畫結果數據。

WOAH 目前正在收集資訊,希望於幾個月後,可透過 ANIMUSE 向會員國提供不同國家、不同計畫之清單。Inventory 是一個資料庫,目的係收集畜牧場端 AMU 資料收集計畫之相關資訊,以便國家主管機關能夠取得其國家內進行之畜牧場端 AMU 資料收集計畫資訊,彌補進口與銷售資料不足之處,強化國家主管機關之決策能力,並更加瞭解其國內收集資料計畫之方法,以提供更好之支援。另外,亦能更加瞭解全球畜牧場端監控計畫之情況。該資料庫可透過 ANIMUSE 受入,相關國家與利益關係者需填寫表格。資料可透過 ANIMUSE 取得,並提供資料視覺化圖像化。



### Inventory 資料庫內容將包含:

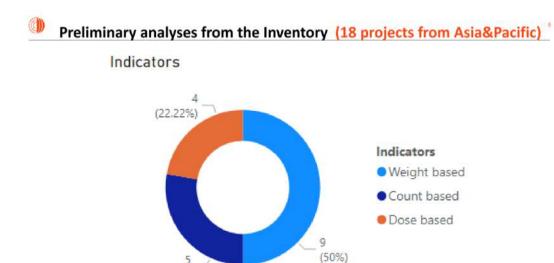
- 1. 由大學、研究人員等進行與發表之計畫文獻
- 2. 由其他組織與利害相關者收集之計畫資訊

### 3. 由動物用藥品業務聯繫窗口添加之計畫項目訊息。

WOAH 已對所有可找到之畜牧場端 AMU 計畫專案進行文獻回顧,並與不同組織、利害相關者討論這些計畫。若會員國正在進行一個畜牧場端 AMU 計畫且希望讓 WOAH 知道,則可透過該微軟表單,將訊息發送給 WOAH。

就亞太地區而言,WOAH 已確定至少有 18 個正在進行之畜牧場端 AMU 計畫,主要集中於家禽、牛、水產養殖與豬。AMU 資料提供者大多數為農民,而計畫負責人多數為大學。

於多數情況下,畜牧場端 AMU 係通過行政管道與治療目的收集,這些訊息對於會員國相當有幫助。多數分析數據所使用之指標類型有一半以上係依據重量制定之指標,例如每公斤(Per kilogram)或總動物體重(Animal biomass)。WOAH 希望確保此清單能滿足會員國之需求,因為有愈來愈多人對 WOAH 提出問題,問 WOAH 對於畜牧場端 AMU 收集可提供什麼幫助。

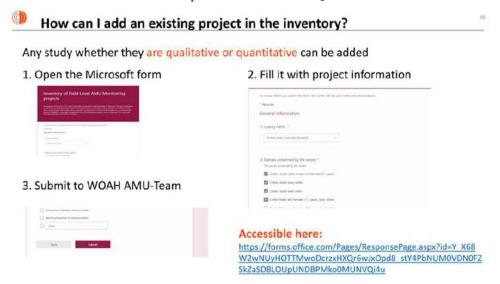


(27.78%)

此僅為 WOAH 探索與瞭解有哪些畜牧場端 AMU 計畫,以更加瞭解不同之 AMU 收集方法學。WOAH 將持續透過文獻回顧、培訓、討論、與利害相關者之 合作,盡可能收集更多數據。並期望很快能於 ANIMUSE 之會員國介面展示不同 之畜牧場端 AMU 收集計畫清單。

會員國如何於計畫清單中增添現有之畜牧場端 AMU 計畫?無論為定性或定量研究均可納入,定性資料包括使用抗菌劑之原因。首先打開 Microsoft 表單,填寫計畫訊息,線上提送給 WOAH 之 AMU 團隊。表單網址為:

https://forms.office.com/Pages/ResponsePage.aspx?id=Y\_X68W2wNUyHOTTMwoDcrzxHXQr6wJx
Opd8\_stY4PbNUM0VDN0FZSkZaSDBLOUpUNDBPMko0MUNVQi4u



該表單只是填寫簡單之訊息,主要係瞭解計畫在做什麼,而不是要收集 AMU 數據,WOAH 並沒有要用畜牧場端 AMU 計畫清單取代會員國 7 年來收集 AMU 資料之成果。WOAH 只是想瞭解某些國家已經開始做什麼。WOAH 強調此工作 主要係回應會員國之需求,而非強制性,WOAH 只是想幫助會員國瞭解自己國 家或地區之 AMU 收集計畫。此平台只是為了促進討論,並建立一個合作網絡。

# (二十七) 佛萊明基金計畫之亞洲AMU 資料收集

由 Mott MaDonald 的 Manisha Bista 與 Darunee Tuntasuvan 簡報「佛萊明基金計畫之亞洲 AMU 資料收集」。

#### 背景說明:

1. 弗萊明基金(Fleming Fund)係由英國政府成立之一個基金,旨在支持開發中國家建立與強化細菌抗藥性之監測與控制系統。弗萊明基金主要目標為減少

細菌抗藥性於開發中國家造成之威脅;並提高這些國家對抗菌劑之合理使用與管理抗菌劑之能力。

- 2. Mott MacDonald 為 Fleming Fund 合作夥伴之一,負責管理與實施該基金於南亞、東南亞與非洲之工作計畫。Mott MacDonald 為 Fleming Fund 提供技術支持、管理與協調工作計畫之執行,並與當地政府、利益關係者合作,推動 AMR 監測與管理系統之發展。
- 3. 透過「防疫一體策略 (One Health approach)」,提高實驗室量能、診斷能力、AMR 監測能力。
- 4. 透過全球細菌抗藥性監控系統(Global AMR Surveillance System, GLASS), 優化細菌抗藥性定期報告,包括地區性、全國性與全球性使用資料。

# 弗萊明基金資助計畫:

弗萊明基金透過國家資助、獎學金與區域資助進行工作,所有工作均包括追 蹤抗菌劑之使用與支爰 AMU 資料收集。

- 1. 弗萊明基金(國家資助計畫):以針對目標國家以「防疫一體策略(One Health Approach)」為基礎,優化 AMR 與 AMU 資料收集與應用。
- 2. 弗萊明基金(研究員計畫): 為每個國家 4~8 名研究員提供高階專業與領導力培訓,並透過國家與區域性資助計畫進行投資。
- 3. 弗萊明基金(區域資助計畫):支援區域性「防疫一體策略(One Health Approach)」,以優化 AMR 監測。

以下為佛萊明基金資助之東南亞與南亞國家,Mott MacDonald 為佛萊明基金之亞洲管理方,實施方為佛萊明基金受助機構,例如於越南由 FHI 360 實施、於巴基斯坦由發展聯合國際公司實施;於蒙古由 Menzies 衛生研究學院實施。於南亞,佛萊明基金支助孟加拉國、不丹、印尼、尼泊爾、斯里蘭卡等五國。不過基於某些原因,緬甸只能資助兩年,即不再繼續資助。



# 佛萊明基金計畫成果(東南亞與南亞):

- 1. 透過提供軟體、IT 設備和/或模板(越南、東帝汶和巴基斯坦),建立進口藥 品資料收集系統。
- 2. 草擬畜牧場端 AMU 監測計畫(東帝汶、巴基斯坦)。
- 3. 提供技術諮詢與培訓,特別係針對提交給 WOAH 支 AMU 報告。
- 4. 參加 AMR 會議或研討會。
- 5. 巴基斯坦:透過國家 AMU 監測系統策略,以確定聯邦至省級政府之作業步驟。
- 6. 寮國:農業進行國家 AMU 情勢分析(尤其係畜牧業與水產養殖業)。
- 7. 東帝汶:提供動物 AMU 監測系統資料輸入與報告之指引與培訓:
  - (1) AMU 紀錄系統係依據 WOAH 模板。
  - (2) 實地採樣資料收集工具係依據 REDCap 軟體。
- 8. 越南:評估畜牧場端、動物用藥儲存端、區域性動物醫療站與動物衛生副部 門之 AMU 資料管理報告。越南已啟用國家動物用藥資訊管理與報告系統, 由畜牧動物衛生部執行。
- 9. 寮國:國家農業之 AMU 情況分析(畜牧與水產養殖)。
- 10. 巴布亞新幾內亞:已開發進口動物抗菌劑與含藥飼料之 AMU 監控系統。

11. 佛萊明基金計畫不僅向 WOAH 提交報告與目標,尚將相關成果發表期刊,如下圖。



# 佛萊明基金計畫成果(南非):

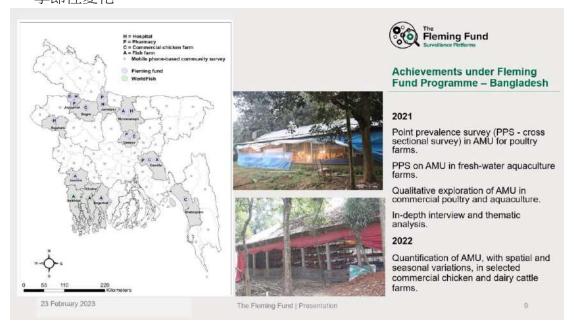
建立跨部門(人類健康和動物健康)功能性 AMU 技術工作小組:

- 1. 制定畜牧場端 AMU 監控計畫。
- 2. 開發或更新現有軟體、IT系統與數位資料之記錄機制,以收集全國 AMU 資料。
- 3. 提供培訓與技術協助,以收集、整理與分析 AMU 資料。
- 4. 就提交給 WOAH 之 AMU 資料報告,提供技術諮詢。
- 5. 於內部、地方性、全國與國際之 AMR 平台, 進行資料傳播與知識共享。

# 佛萊明基金計畫成果(孟加拉):

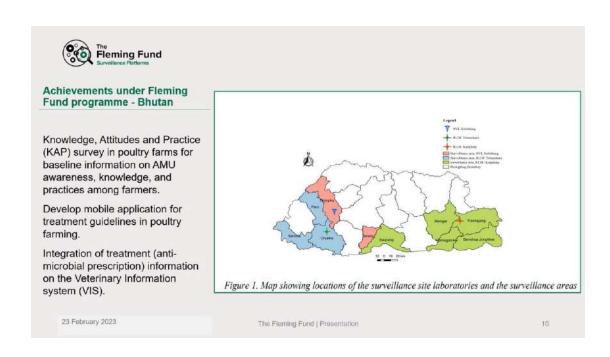
- 1. 2021年:
  - (1) 對家禽場進行 AMU 點盛行率調查(橫斷調查法 [cross-sectional survey])。
  - (2) 對淡水之水產養殖場 AMU 點盛行率調查。
  - (3) 商業化家禽與水產養殖之 AMU 質性探查。
  - (4) 深入性訪談與主題分析

2. 2022 年:對選定之商業化肉雞與乳牛場進行 AMU 量化,並研究其空間性與季節性變化。



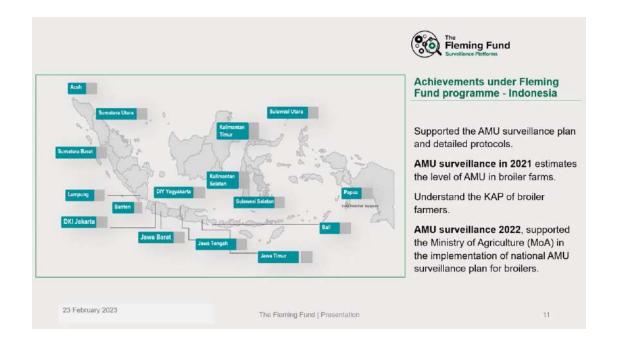
# 佛萊明基金計畫成果(不丹):

- 於家禽養殖場進行知識、態度與實踐(Knowledge, Attitudes and Practice, KAP)
   調查,以瞭解農民對抗菌劑使用之知識、態度與實踐之基礎資訊。
- 2. 開發行動應用程式作為家禽養殖之治療指南。
- 3. 整合治療(抗菌劑處方箋)資訊至獸醫資訊系統(Veterinary information system, VIS)。



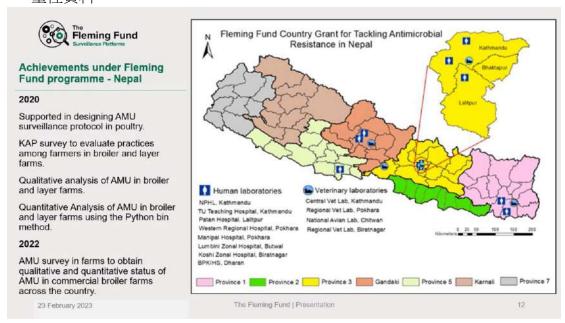
# 佛萊明基金計畫成果(印尼):

- 1. 支援 AMU 監測計畫與細節流程。
- 2. 2021 年監控估算肉雞養殖場 AMU。
- 3. 瞭解肉雞養殖戶之 KAP (知識、態度與實踐)。
- 4. 2022 年支援農業部實施國家肉雞 AMU 監測計畫。



# 佛萊明基金計畫成果(尼泊爾):

- 1. 2020年:
  - (1) 支援家禽 AMU 監測流程之規劃。
  - (2) 進行 KAP (知識、態度與實踐)調查,評估肉雞與蛋雞農民作業情形。
  - (3) 對肉雞和蛋雞農場 AMU 進行質性分析。
  - (4) 以 Python bin 方法對肉雞與蛋雞場 AMU 進行定量分析。
- 2. 2022 年:於畜牧場端進行 AMU 調查,取得全國商業化肉雞場 AMU 質性與量性資料。



以下表格整理佛萊明基金計畫如何直接與間接對 WOAH 之 AMU 報告做出 貢獻,協助國家取得與增加 AMU 質性與量性資料。下表可見東帝汶與尼泊爾均 可提交 AMU 三號問卷報告資料 (即提供各大類抗菌劑使用量、給藥途徑、動 物分群 [陸生、水生產食動物、伴侶動物] 資料)。但佛萊明基金計畫初期,尼 泊爾僅能提交 AMU 一號問卷報告資料 (僅有各大類抗菌劑使用量資料)。



#### Achievements under Fleming Fund programme (SA)

Country	FF support for WOAH reporting in Asia	AMU reporting to WOAH (option)	
Laos	Developed national AMU surveillance and increased the quality and quantity of data.	2	
Vietnam	Established national AMU data collection system and provided training on data analysis.	1	
Pakistan	Training and TAs on AMU survey at farm level.	1	
Timor-Leste	Established national AMU surveillance and increased quality and quantity of data.	3	
PNG	Developed national AMU data collection system.	1	
Bangladesh	Increased quality and quantity of data; PPS survey and data analysis training.	1	
Bhutan	Increased quality and quantity of data; AMU survey and data analysis training.	1	
Indonesia	Increased quality and quantity of data; AMU survey and data analysis.	1	
Nepal	Increased quality and quantity of AMU data; AMU survey, data collection and analysis.	3	
23 February 20		13	

在實施或進行 Fleming Fund Grant 時,本計畫從受助國和受助者那裡得到了 反饋,亦遇到許多挑戰。首先,大多數國家的 AMU 監測計畫並不普遍,即使有, 也缺乏指南。另一個挑戰是缺乏高技能的人才來領導這項研究,即使有,但於時 限內很難找到。全球大流行病導致國家的優先事項發生了變化,進而延遲或犧牲 了研究質量。有時,由於家禽場的疾病爆發,必須縮減調查範圍。而最大的挑戰 可能是由於政策制定者或技術人員缺乏對數據的需求,導致 AMU 數據之收集相 對較少。

# 取得 AMU 資料面臨之挑戰:

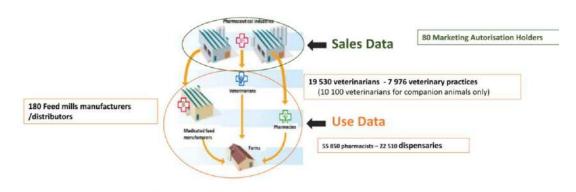
- 1. 缺乏 AMU 監測計畫
- 2. 缺乏作業指引。
- 3. 缺乏技術人才領導 AMU 監測計畫。
- 4. 國家重要優先工作改變。
- 5. 全球疫情大流行。
- 6. 畜牧場爆發動物傳染病。
- 7. 人才流動。
- 8. 最大的挑戰可能為政策制定者或技術人員缺乏對數據之需求,導致 AMU 資料收集相對較少。

# (二十八) 法國獸醫師與農民之AMU 工作

由法國動物用藥管理局之抗菌劑使用專案經理 Anne Chevance 簡報「法國獸醫師與農民之 AMU 工作」

法國已建立一個系統,從動物用藥品許可證持有業者(計 80 名)收集抗菌劑銷售量資料,該系統自 1999 年以來一直運作良好。但使用該系統幾年後,法國需要進一步瞭解抗菌劑使用資料。因此,法國首先嘗試從畜牧場端向農民收集資料,而目前有法規要求從藥師、獸醫師與含藥飼料製造商收集 AMU 資料。法國計 180 名飼料商或分銷商、19,530 名獸醫師(7,976 個獸醫診所,10,100 名寵物獸醫師)、55,850 名藥師(22,510 個藥局)。一個良好之 AMU 資料收集系統係相當龐大之系統,需要多方相關者與申報者參與,需要有許多軟體供獸醫師使用,以自動化取得 AMU 資料。最後所取得之龐大數據量可進行資料交流。

# Antimicrobial monitoring systems in France



#### Huge system to be built!

- Numerous actors / declarants
- Numerous sofwares used by Veterinarians
- Big volume of data and various flows of exchange

抗菌劑使用量(AMU)資料可從整個產業鏈不同階段之業者收集(如下圖)。 愈接近抗菌劑使用端之資料來源所估算之 AMU,愈能符合實際情況之抗菌劑消 耗量,且愈能提供動物別、劑量、治療天數、適應症等精確資料。

# (III) AMU可能之不同資料來源

#### Consumption data can be collected at different levels.

Data sources close to the use of antimicrobials will provide the most reliable estimates of Antimicrobial consumption and will be more likely to provide precise data on the animal, dose, duration of treatment, indications ...

		動物		
資料來源範例	評語	有全部動物 別總計資料	有依動物種 類區分	有依動物生 產類型區分
進口資料	數量與進口週期相符·而非與抗菌劑消耗 模式相符	有	無	無
動物用藥品許可證持有業者	可能無法於區域性·地方性·廠房或開立 處方者端檢查這些數據	有	無	無
批發商	分銷與供應數據可能比購買數據更接近抗 菌劑實際消耗量	有	有	無
飼料製造商	針對含藥飼料	煮	疽	有
畜牧場端	可能有詳細資訊·包括診斷·劑量、治療 天數、治療動物之數量。	有	有	有
處方箋	可能有詳細資訊 · 例如診斷 · 劑量 · 用藥 天數 · 同時開處方之藥品	有	有	有

藍色區塊表示法國現有或正在開發中之系統

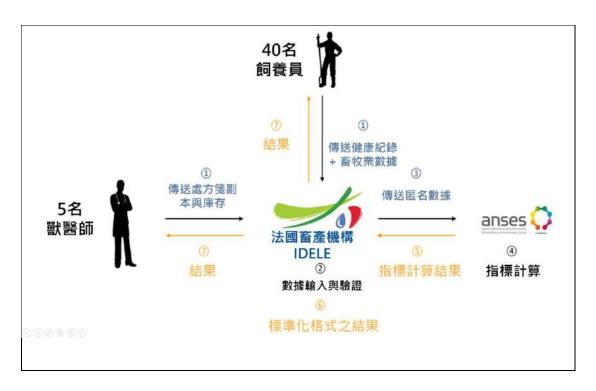
AMU 資料收集之第一步為向動物用藥品許可證持有業者收集抗菌劑銷售量。全國 AMU 估算值有助於提高對 AMR 之警覺性。案例分享:肉用仔牛產業:法國於 2011 年公布之抗菌劑銷售量國家報告中,首次估算仔牛抗菌劑銷售量於牛隻佔比,資料來源為動物用藥品許可證持有業者銷售量。結果顯示抗菌劑銷售給仔牛量為成牛量之 18 倍。法國於 2013~2014 年透過一項現場調查,證實肉用仔牛產業大量使用抗菌劑。2015 年發起 AMU 警覺性活動,透過簽署「跨產業協議」,律定肉用仔牛產業有良好健康管控,並適當使用藥品治療。

	X 18	
		1
Sales in mg/kg	19,55	350,32
Tonnage sold	183,46	75,62
	Cattle	Calves

# 畜牧場端肉用仔牛之 AMU 監測:

- 1. ANSES-ANMV 與法國畜產機構 (IDELE ) 決定成立一個肉用仔牛畜牧場觀測站,用以監控抗菌劑使用情況。
- 2. 2016 年啟動 AMU 資料收集工作,並與一組志願飼養者合作。
- 3. 法國開發一套專門之軟體工具,以進行分析數據。
- 4. 該觀測站供農民、畜牧技術人員與獸醫師共同評估其抗菌劑使用作業,為畜牧場提供適當之溝通管道。





# 畜牧場端肉用仔牛之 AMU 監測(續2):

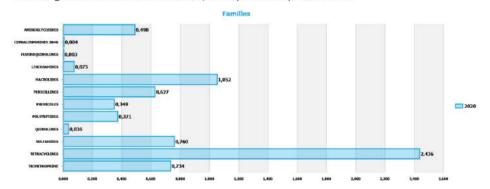
- 5. 計40個肉用仔牛飼養場參與,每年收集資料。
- 6. 收集畜牧場端抗菌劑使用量資料;收集農民藥品室於每批動物進出前與後之 資料。
- 7. 同時收集獸醫師處方箋。
- 8. 必須有資料驗證程序。
- 9. 農民紀錄與獸醫師紀錄存在落差:
  - (1) 農民報告之所有治療方法均會保存下來。
  - (2) 農民報告之治療天數有時會經過修改。
  - (3) 補充填寫農民漏記資料,農民有時會漏記獸醫師開立之處方藥品。

# 10. 肉用仔牛治療量統計:

- (1) 88% 為口服治療; 12% 為注射治療。
- (2) 於所有抗菌劑類別中,其中以 Tetracyclines 使用量最高(如下圖)。

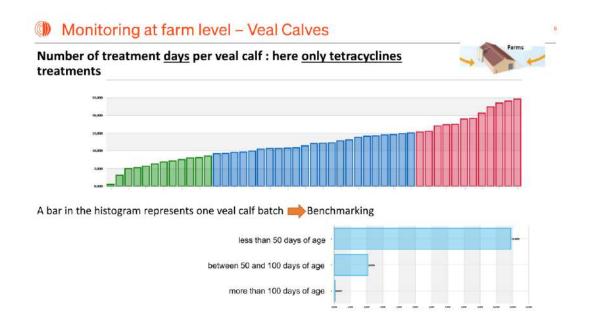
# Monitoring at farm level – Veal Calves

- · Number of treatments per veal calf
- 88% oral treatments + 12% injectables
- Among the antimicrobial classes used, tetracyclines are predominant.



# 畜牧場端肉用仔牛之 AMU 監測(續3):

- 11. 每頭仔牛治療天數:下圖僅列出 Tetracyclines,一個條形代表一批仔牛,進行使用量分級比較。
- 12. 有不同計算指標,選擇貼近抗菌劑實際使用、容易計算與對飼養者有意義者 為主:
  - (1) 每頭動物使用藥品次數。
  - (2) 每頭動物接受藥品治療天數。



歐盟通過一項新法,要求每個成員國需建立一個連續性系統,收集該國 AMU 資料,送交給歐洲藥品管理局(European Medicines Agency)。法國規劃於 2024年,向歐洲藥品管理局提供豬、家禽與牛之 AMU 資料;於 2027年提供其他產食動物 AMU 資料。

# 優化抗菌劑監測系統

# 歐盟新法規:按動物別或動物生產類型之抗菌劑使用量資料收集系統



# 抗菌劑使用量資料:

- 1. Calypso 為法國建置之大型複雜資訊系統,用於收集 AMU 資料。
- 2. AMU 資料收集之工作優先順序
  - (1) 自 2014 年以來一直討論 Calypso 資訊系統之規劃。
  - (2) 自 2017 年以來開始準備, Calypso 至今仍未啟用。
  - (3) 由法國農業部官方授權給法國獸醫師理事會(French Veterinary Council) 負責管理。
- 3. 規劃從畜牧場、獸醫診所、藥局與飼料廠等相關單位之軟體或管理系統中直接檢索相關數據,以提供更準確的分析和管理,促進管理機構與獸醫師之間的數據共享。
- 4. 所有動物種類均納入考量
- 5. 個別提交報告內容包括自我評估與後續改進。
- 6. Calypso 資訊系統要求非常嚴格,確保資料具完整性,確保資料品質,且可連續性收集資料。
- 7. 系統複雜性。需要考慮各種情況以建立作業流程,例如:
  - (1) 在法國只有獸醫師可開處方藥,但獸醫師、藥師與飼料廠均可銷售供應 抗菌劑。

- (2) 建立處方箋與銷售供應抗菌劑數據之關聯。
- (3) 藥品重新分裝 (Fractioning of the delivery): 例如一個藥品包裝內含有 10 碇藥片,但獸醫師只開具 2 碇處方,此時藥局需將藥品進行分裝,取出兩碇後重新包裝,此過程稱為 Fractioning of the delivery。
- (4) 資料收集範疇除涵蓋動物用藥品,亦須需涵蓋使用人用藥之標籤外使用。
- (5) 管理重複申報,缺乏申報等問題。.

#### 8. 機會:

- (1) 需要所有利害相關者參與。
- (2) 可協助獸醫師進行自我評估。

# 結論:

- 1. 抗菌劑使用量監測工作至關重要。
- 2. AMU 資料有助於促進抗菌劑謹慎使用。
- 3. 更精確之數據資料有助於管理單位針對關鍵目標對象動物種類執行介入措施。
- 4. AMU 資料能夠按動物種類評估管理措施成效。
- 5. AMU 資料為 AMR 管理重要關鍵元素。

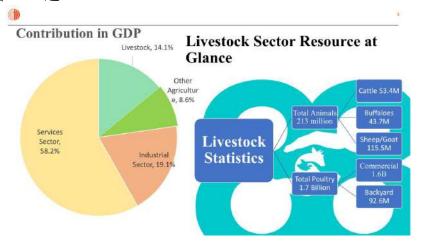
# (二十九) 巴基斯坦觀點:獸醫師與農民AMU 收集工作

由巴基斯坦國家食品安全與研究部門-副動物畜牧委員會助理委員/動物健康防疫及疾病控制計畫北部與東部負責人 Dr. Riasat Wasee Ullah 簡報「巴基斯坦觀點:獸醫師與農民 AMU 收集工作」。

儘管巴基斯坦沒有任何畜牧場端 AMR 與 AMU 監測系統,但該國仍努力缺補缺口中。巴基斯坦以三項工作進行說明,分別為抗菌劑足跡、抗菌劑使用知識、態度與實踐調查(Knowledge, Attitude, and Practice Surveys on AMU);家禽業與乳業之抽樣點盛行率調查研究(Point Prevalence Survey Studies, PPS Studies)。



巴基斯坦擁有 2.13 億頭家畜,包括牛、羊和山羊,還有大約 17 億家禽。畜牧業佔該國 GDP 之 14.1%。



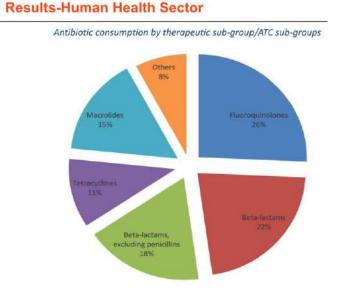
抗菌劑使用量(AMU)或稱抗菌劑消耗量(Antimicrobial Consumption, AMC)資料收集:

- 1. 人類衛生部門 AMU 資料收集:有3個資料來源
  - (1) 藥品銷售量資料源自 IQVIA 公司之製造端與經銷端,其藥品銷售量佔巴基斯坦市場 85%。
  - (2) 國際機構於巴基斯坦之垂直專案進口抗菌劑。
  - (3) 針對剩餘 15%藥品銷售量資料,由 IQVIA 公司進行調查。

# 2. 動物衛生部門 AMU 資料收集:

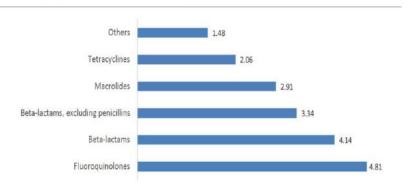
- (1) AMU 資料來源為巴基斯坦進出口資料庫,該資料庫由海關管理。
- (2) 使用 5 個來源資料以識別、驗證與擷取所有用於動物之抗菌劑產品。
  - A. 已知之動物用抗菌劑製造商名單。
  - B. WHO/WOAH 重要醫藥抗菌劑清單:125種主成分。
  - C. DRAP(巴基斯坦藥品監管局)列出當年核准之藥品許可證製造商名單(包括人類與動物部門)。
  - D. 線上藥品資訊系統:內含巴基斯人用藥許可證與製造商資料。
  - E. 使用製造商網站產品目錄或其他網路資源,包括社交媒體(Facebook; LinkedIn)資訊,識別與驗證動物衛生部門與抗菌劑資料,並與人類 衛生部門資料相結合。

下圖為人類衛生部門 AMU 調查結果,結果顯示使用最多為 Fluoroquinolone 類抗菌劑。



人類衛生部門 AMU 調查結果顯示,於定義每日劑量(Defined Daily Dose, DID)計算中,可見 Fluoroquinolone 類抗菌劑消耗量最高,為 4.81 個 DID,而活性藥品成分(Active Pharmaceutical Ingredient, API)總使用量約為 1600 萬噸(如下圖)。

# Results-Human Health Sector

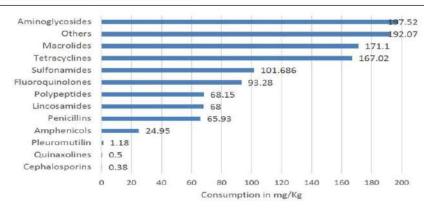


DID: The total consumption of systemic antibiotics in humans was 18.60 DID.

Kg of API: The total estimated antibiotic consumption was 1,651,908.96 kg (1,652 MT).

依據動物衛生部門 AMU 調查結果顯示, Aminoglycoside 類抗菌劑使用量最高。動物用藥與含藥飼料之總消耗量為 1,481.78 公斤。總消耗量包括 1,253.52 公斤之 API 與 228.46 公斤之含藥飼料。經動物總體重調整之單位(Population Correction Unit, PCU)之總消耗量為 22.94 毫克/公斤。

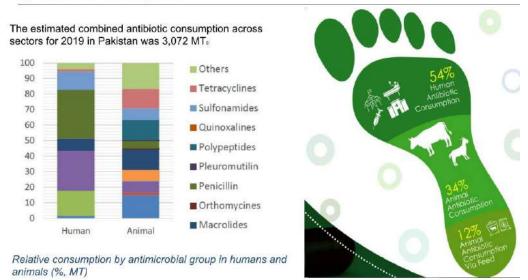
# Results-Animal Health Sector



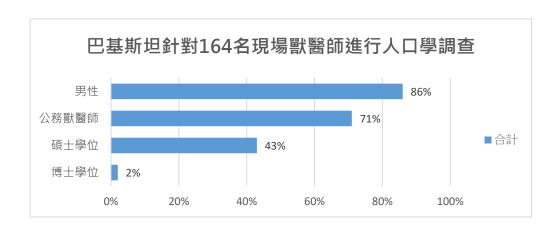
- The estimated total consumption of medicines and medicated feed in the veterinary sector was 1,481.78 kg.
- Total consumption comprised of 1,253.52 kg as APIs and 228.46 kg of medicated feed.
- · Total consumption in mg/PCU, or biomass, was estimated at 22.94 mg/Kg

巴基斯坦 2019 年人用藥與動物用藥領域估算之抗菌劑總消耗量為 3,072 公噸。各大類抗菌劑消耗量佔比如下圖。

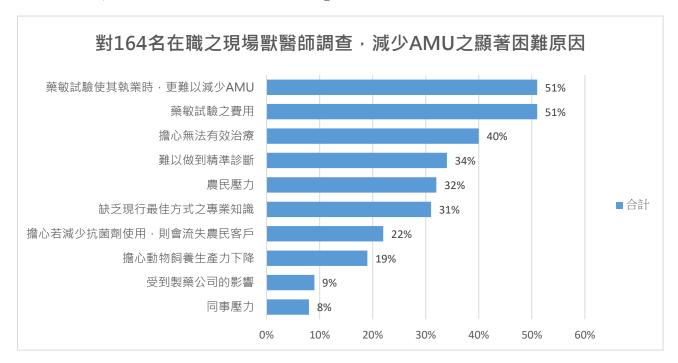
# Antibiotic Footprint



KAP 係指知識、態度與實踐(Knowledge, Attitudes, Practices),於醫學、公共衛生等領域中常用於評估人群對於某個主題之認知、態度與行為等方面的狀況。 巴基斯坦針對 164 名在職之現場獸醫師進行知識、態度與實踐(KAP)調查,結果顯示如下三張統計圖:針對問卷針對 164 名獸醫師進行調查,其中 86%為男性,71%為公務獸醫師(worked as Veterinary Officer)。

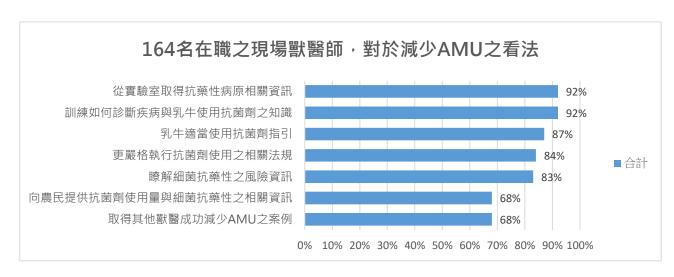


為瞭解減少 AMU 之顯著障礙原因,164 名獸醫師中,51%之獸醫師認為「藥 敏試驗使其執業時,更難以減少 AMU」、51%之獸醫師認為係「藥敏試驗之費



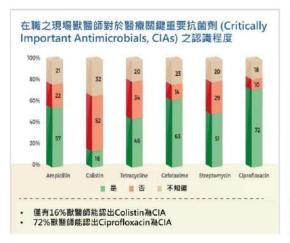
用」。31%獸醫師表示「缺乏現行最佳方式之專業知識」。32%之獸醫師表示「有來自於農民之壓力」。22%之獸醫師「擔心若減少抗菌劑使用,則會流失農民客戶」。

巴基斯坦另針對 164 名在職之現場獸醫師進行問卷調查,詢問對於減少 AMU 之看法,92%獸醫師希望從從實驗室取得抗藥性病原相關資訊。92%獸醫師希望有訓練如何診斷疾病與乳牛使用抗菌劑之知識。87%獸醫師希望有乳牛適當使用抗菌劑指引。84%獸醫師認為應更嚴格執行抗菌劑使用之相關法規。



有關認識醫療關鍵重要抗菌劑(CIA)方面,KAP 調查發現僅有 16%獸醫師 能認出 Colistin 為 CIA。72%獸醫師能認出 Ciprofloxacin 為 CIA。

# 知識、態度與實踐調查 (Knowledge, Attitudes, and Practices Surveys, KAP surveys)





#### 就 AMR 與 AMU 管理,巴基斯坦提出以下建議:

- 1. 透過培訓和進修課程來解決發現之缺口。
- 2. 於「防疫一體」框架下評估動物性食品生產之風險因素。
- 3. 引入之抗菌劑管理措施需包含 AMR。
- 4. 建立抗菌劑處方箋指引並確保遵循該指引。
- 5. 強化動物傳染病預防、控制與通報系統。
- 6. 強化實驗室監測系統、快速診斷工具;建立現場獸醫師與實驗室之聯繫機制。
- 7. 強化法規架構以確保不會有無處方箋即購買抗菌劑。
- 8. 於法定之獸醫公立機關或民間組織中進行宣傳,推動獸醫課程之更新與修訂。

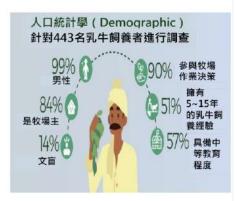
依據巴基斯坦對 164 名獸醫師之 KAP 調查,影響在職之現場獸醫師抗菌劑藥品選用之因素中:79%獸醫師認為抗菌劑之抗菌範圍「很大程度上」影響他們選用哪種抗菌劑。77%獸醫師認為,前次使用相同抗菌劑之治療結果「很大程度上」影響他們選用哪種抗菌劑。

# 知識、態度與實踐調查 (Knowledge, Attitudes, and Practices Surveys, KAP surveys)

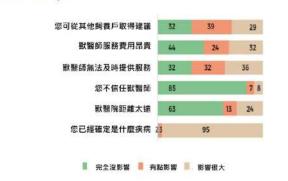


依據巴基斯坦對 326 名乳牛飼養戶進行 KAP 調查,就影響乳牛飼養戶未經 獸醫師諮詢即購買抗菌劑的因素:95%飼養戶於購買抗菌劑時沒有諮詢獸醫師, 是因為他們對自己的判斷很有信心。36%飼養戶提到獸醫師無法及時提供服務。

# 飼養戶之知識、態度與實踐調查 (KAP surveys of farmers)



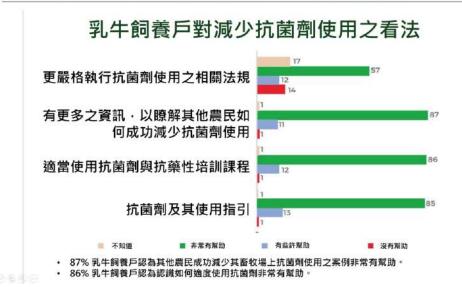
# 影響乳牛飼養戶未經獸醫諮詢即購買抗菌劑的因素 (n = 326)%



- 95%飼養戶於購買抗菌劑時沒有諮詢獸醫師,是因為他們對自己的判斷 很有信心。
- 36%飼養戶提到獸醫師無法及時提供服務

乳牛飼養戶對減少抗菌劑使用之看法方面,87% 乳牛飼養戶認為其他農民 成功減少其畜牧場上抗菌劑使用之案例非常有幫助。86% 乳牛飼養戶認為認識 如何適度使用抗菌劑非常有幫助。

#### 间 飼養戶之知識、態度與實踐調查 (KAP surveys of farmers)



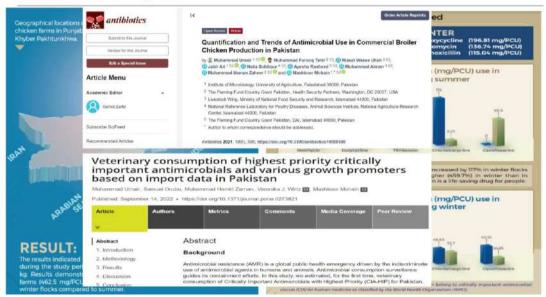
依據「在巴基斯坦商業肉雞生產中,抗微生物使用的數量和趨勢的量化研究(Quantification and Trends of Antimicrobial Use in Commercial Broiler Chicken Production in Pakistan)」文獻報告,該研究進行肉雞場端 AMU 調查,於 2020-2021年夏季與冬季,進行橫斷面研究法,量化了 12 個商業肉雞場之 AMU 並檢查季節性變化。大多數抗菌劑使用量,冬季比夏季增加。夏季使用最多之三種抗菌劑為 Neomycin(111.39 mg/PCU),Doxycycline(91.91 mg/PCU)和 Tilmicosin(77.22 mg/PCU),而冬季使用的三種抗微生物藥物則為 Doxycycline(196.81 mg/PCU)、Neomycin(136.74 mg/PCU)和 Amoxicillin(115.04 mg/PCU)。整體而言,肉雞中使用之 60%抗菌劑為 WHO 定義的對人類醫療重要之抗菌劑類別(CIA)。該研究結果顯示肉雞生產過程中 AMU 很高,並呼籲巴基斯坦採取緊急措施來監管產食動物中 CIA 之使用。

有關文獻報告「依據巴基斯坦進出口資料調查動物醫療中,使用醫療最高優先級別抗菌劑之使用量與各種生長促進劑之消耗量(Veterinary consumption of highest priority critically important antimicrobials and various growth promoters based on import data in Pakistan)」,本研究使用出口與進口資料庫,該資料庫提供了巴基斯坦海關收集的進口數據,調查來自巴基斯坦旁遮普省 10 個家禽與乳業畜牧場之調查。抗菌劑之消耗量以國家總動物體重為分母,估算抗菌劑消耗量以mg/kg 為單位。

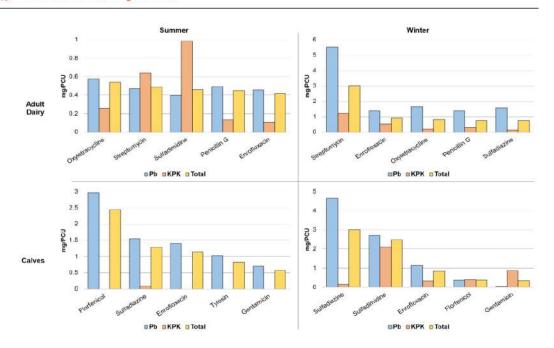
依據該文獻報告結果顯示,2017~2019 年 7 種醫療最重要抗菌劑進口量為: Tylosin 240.84 公噸、Enrofloxacin 235.14 公噸、Colistin 219.73 公噸、Tilmicosin 97.32 公噸、Spiramycin 5.79 公噸、Norfloxacin 5.55 公噸、Ceftiofur 1.02 公噸,總計 805.39 公噸。依國家總動物體重之抗菌劑消耗量為 10.05mg/kg。家禽飼料添加生長促進劑包含:Zinc bacitracin、Enramycin、Bacitracin methylene disalicylate、Tylosin、Tiamulin、Colistin、Lincomycin、Streptomycin、Flavophospholipol、Tilmicosin 與 Penicillin,2017 年至 2019 年總抗菌劑進口量為 577.18 公噸,家禽依國家總動物體重之抗菌劑消耗量為 96.53mg/kg。

本研究報告說明,巴基斯坦動物醫藥產業正大量進口具有醫療最高優先級別抗菌劑,這些抗菌劑主要用於產食動物,包括家禽和乳業畜牧場。此外,生長促進類抗菌劑所使用之醫療重要抗菌劑級別包括最高級別,並用於家禽,且目前尚未受到監管。不幸的是,目前沒有任何議會或任何政府機構監測這些產品進口與使用之法規,可能會使細菌抗藥性問題變得更加嚴重。

### ( AMU in Poultry-PPS



### AMU in Dairy-PPS

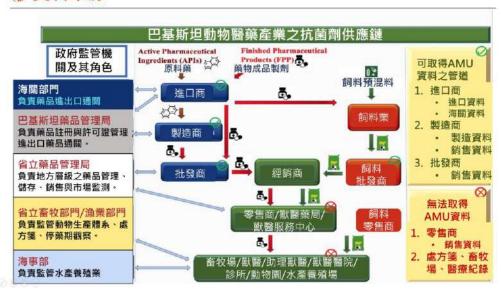


為提高巴基斯坦畜牧場主對於細菌抗藥性之認知(Farmers awareness),爰 針對目標受眾辦理相關知識教育訓練,期望透過相關知識傳達,改變畜牧場主用 藥行為,以減少細菌抗藥性之發生。



下圖為巴基斯坦動物醫藥產業之抗菌劑供應鏈,可取得 AMU 資料來源分別 為進口商之進口資料、海關資料;製造商之製造資料與銷售資料;批發商之銷售 資料。無法取得 AMU 資料來源為零售商之銷售資料、處方箋、畜牧場與醫療紀 錄。

#### @ 資料來源



#### (三十) 閉幕結語與頒發證書

ANIMUSE 培訓正式落幕,WOAH 東南亞次區域代表處表示若會員國需要更多幫助,東京與曼谷辦事處會給予協助,進一步協助優化會員國之 AMU 資料。WOAH 有機會與某些國家進行更多之研討會,展示該國優化之資料品質,並向利益害相關者展示。WOAH 樂見 ANIMUSE 儀表板之數據能應用於會員國之報告,並向衛生部門、其他利害相關者展示這些來自動物衛生方面之數據。

有些人說人類衛生方面並沒有 AMU 年度報告,那是因為他們不使用抗菌劑使用量(Antimicrobial use)這個專有名詞,WHO稱之為抗菌劑消耗量(Antimicrobial consumption)。人類衛生領域亦在監測,並且大部分係從醫院與其他機構進行監測。WOHA希望繼續幫助會員國使用 ANIMUSE 這項新工具。

#### (三十一)動物用藥品偽藥、劣藥通報系統實作練習

動物用藥品偽藥、劣藥通報系統實作練習題目,請參閱附件9。

### 四、心得與建議

- 一、綜觀 WOAH 與國外舉辦之提升抗菌劑認知活動(或翻譯為抗藥性警覺週活動),其精神與形式在於精準對到目標受眾,傳遞 AMR 重要知識,並實地深入產業界。所有 AMR 利益關係者包括藥商、飼料廠、農民、獸醫師。透過實地走訪與深入民間辦理抗菌劑認知提升並提供相關教育知識,使受眾認識負責任使用抗菌劑對養殖產業、人醫與動物醫藥界而言極具重要性,藉此改變目標對象之行為,使之步入負責任地販賣與使用抗菌劑之正軌,延緩與減少 AMR 發生。
- 二、巴基斯坦於執行對抗 AMR 行動方案方面,初步對農民與獸醫師進行 KAP (Knowledge, Attitudes, Practices 知識、態度與實踐)調查,調查詢問 AMU 減少之困難原因及其對於 AMU 減少之想法或意見。此調查結果極具價值性,透過產業界第一線人員提出之困難與解決方案,將有助於規劃及推動國家 AMR 行動方案,並融入抗菌劑認識活動,此可為我國借鏡之參考。
- 三、對抗 AMR 並非要將抗菌劑使用量降至不合理之低或不使用抗菌劑,而係期 望透過獸醫師專業與藥商、飼料廠、農民產業界之配合,將動物抗菌劑使用 量達負責任與謹慎使用之平衡線,此平衡線為動物生病需要治療,同時最大 限度地減少抗菌劑之使用,僅於必要時使用抗菌劑。而動物抗菌劑使用量曲 線可能會有些波動,此為正常現象,波動取決於不斷變化之動物疾病狀況與 主流疾病之程度。想要將動物抗菌劑使用量降至零是不可能的,因為一旦動 物生病,基於動物健康與福祉,則有治療疾病、使用抗菌劑之需求。
- 四、對抗 AMR 目標可能帶來結果為抗菌劑使用量降低,首當其衝為藥商利潤減少。為解決藥商之擔憂並使動物醫藥產業永續經營,若對藥商進行 KAP 調查與抗菌劑認識活動,將有助於與藥商產業達成共識,推動國家 AMR 行動方案。全球動物衛生協會為藥商產業界之代表,該協會透過提出各種策略,包括謹慎並負責任使用抗菌劑、推廣疾病預防;增加農民取得動物醫藥專業知識之管道;投資預防與治療疾病之產品;增加專業知識、資訊透明度與溝通交流等,其全力配合全球 AMR 行動方案之際,未見 AMU 減少之國家發生動物醫藥產業衰退,因為國家目標並非要將動物抗菌劑使用量降至不合理

- 低,一旦有動物疾病醫療需求,仍需使用抗菌劑,國家目標係取得負責任與 謹慎使用抗菌劑之平衡線。此外,動物醫藥產業仍可透過投資與研發其他預 防與治療疾病之產品(例如疫苗)而為藥商利益與防疫一體(人類與動物醫 療之細菌抗藥性議題)共創雙贏。
- 五、國內動物醫藥商、飼料廠、養殖業者對於抗菌劑認識與負責任使用抗菌劑之認知仍有進步之空間,係我國未來努力之目標。我國目前對於國家 AMR 行動方案之推行,國內藥商、飼料廠、養殖業者會認為此為政府的事,無關產業界。也許可邀請相關產業界,參與提升抗菌劑認識活動(World Antimicrobial Awareness Week 或翻譯為世界抗藥性警覺週活動),並邀請相關產業界(包括獸醫師)依據 AMR 行動方案之框架,自行訂定目標與行動計畫,並定期檢視達標狀態,進而培養相關產業界當責之態度,負責任地銷售與使用抗菌劑,把 AMR 行動方案當成產業界的事,而非僅限於政府的事。
- 六、為維護人醫與動物醫療界之醫療重要抗菌劑療效,我國自 2000 年起,即逐步刪減各先進國家皆不使用、人畜共通使用且影響人體健康風險較高,以及與治療人體疾病重要藥物具有交叉細菌抗藥性之「含藥物飼料添加物」品目,並將於 2024 年達 43 刪減品項,僅存 5 項動物專用且非人類醫療重要抗菌劑品項(Avilamycin、Enramycin、Flavomycin [Bambermycin]、Nosiheptide、Tiamulin)。
- 七、為使抗菌劑謹慎與負責任使用,抗菌劑使用前必須有相對應措施,以預防動物傳染病發生,包括落實養殖場生物安全、良好生產及飼養管理、免疫接種計畫等,此涉及多部門、機關及單位之業管,需跨各產、官、學界共同合作推動。

### 五、附圖



ANIMUSE 培訓研討會與會成員



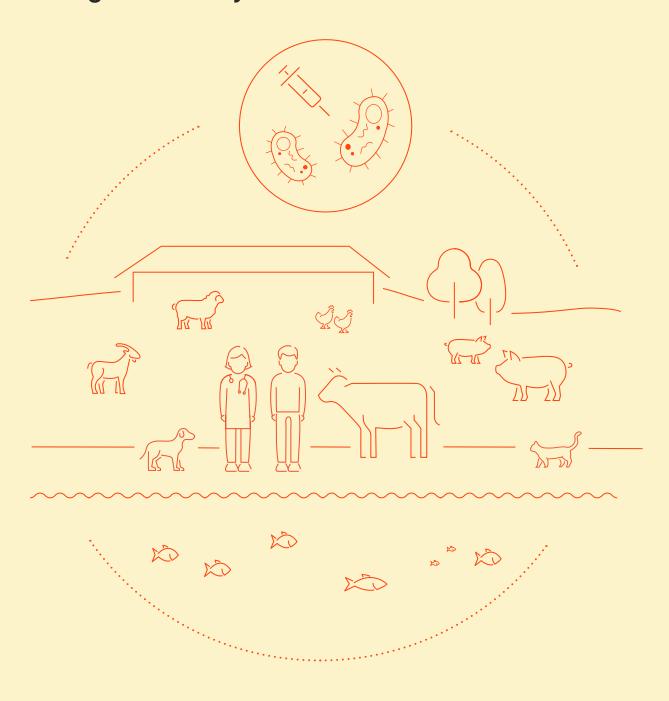
WOAH 工作人員指導會員國使用 ANIMSUE 資訊系統

### 六、附件

- (一)附件 1:WOAH 為保留抗菌劑之療效,制定之「抗菌劑謹慎使用與 細菌抗藥性策略」。
- (二)附件2:線上填報 WOAH 之 AMU 問卷練習題1。
- (三)附件3:線上填報 WOAH 之 AMU 問卷練習題2。
- (四)附件4:全球動物衛生協會發布2019年《減少對抗生素需求路線圖》
- (五)附件 5:全球動物衛生協會《減少對抗生素需求路線圖之 2021 年追 蹤報告》。
- (六)附件6:全球動物衛生協會「負責任使用抗菌劑手冊五項原則」。
- (七)附件7:全球動物抗生素使用趨勢報告。
- (八)附件8:ANIMUSE計算工具練習題。
- (九)附件9:動物用藥品偽藥、劣藥通報系統實作練習題目。
- (十)附件10:ANIMUSE培訓研討會議程。
- (十一) 附件 11: ANIMUSE 培訓研討會之與會名單。
- (十二)附件12:ANIMUSE培訓研討會之講者簡報。

# Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials

### Preserving the efficacy of antimicrobials





# **Foreword**

Antimicrobial medicines have transformed the practice of human and animal medicine. Infections that were once lethal are now treatable. The use of antimicrobial drugs has advanced global public health, animal health, and food safety and security. However, the overuse and misuse of antimicrobial products in humans, animals and plants has dramatically contributed to the emergence and spread of antimicrobial-resistant microorganisms, which pose an extraordinary threat to human and animal health, and to the world ecosystem.

On September 21, 2016, I had the honour and privilege of representing the World Organisation for Animal Health (WOAH, founded as OIE) and addressing the 71st United Nations General Assembly regarding the global threat that antimicrobial resistance (AMR) poses to human and animal health. My voice was among many others, including Directors General of the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO), speaking out about AMR and shining a light on the severe threat it presents.

The international community has started to come together to take steps to combat antimicrobial resistance.

As the reference organisation for standards related to animal health and zoonoses, WOAH is committed to supporting its Members as we confront the shared global threat of AMR in animals and humans. Our Standards and guidelines provide a framework for responsible and prudent use of antimicrobial products in animals, and for surveillance of use of antimicrobials and antimicrobial resistance. Our communication and advocacy materials foster understanding of the risks of AMR and encourage the adoption of measures that slow its spread. Science drives the development of tools and policies that support Veterinary Services and enhance animal health and welfare.







At our 83rd General Assembly in 2015, all 180 Members made a commitment to support the WHO Global Action Plan on Antimicrobial Resistance, and support the development of National Action Plans. This shared commitment highlights the increasing awareness of the threat posed by resistant pathogens and the need for action. In 2016, WOAH's 84th General Assembly unanimously adopted Resolution 36, which mandated WOAH to compile AMR activities into a strategy.

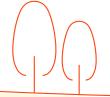
Our Strategy on Antimicrobial Resistance is aligned with the WHO Global Action Plan and recognises the importance of a "One Health" approach – involving human and animal health, agricultural and environmental needs. It outlines the goals and tactics we have in place to support our Members and to encourage the national ownership and implementation. Time is of the essence. As the saying goes, "an ounce of prevention is worth a pound of cure."

I urge our Members to actively move forward on developing and implementing cross sectoral National Action Plans. WOAH is at your service, wherever you are in the process of building and implementing a strategy to combat AMR in animals.

# "Alongside our Quadripartite partners - FAO, UNEP and WHO - we move towards a common objective: to control AMR for the benefit of all."



Dr Monique Eloit, Director General, World Organisation for Animal Health



# It's everyone health

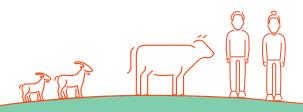
The availability and use of antimicrobial medicines has transformed the practice of human and animal medicine. Infections that were once lethal are now treatable, and the use of antimicrobial drugs has advanced global health as well as animal health, which is a key component of policies to improve animal welfare, food security and food safety.

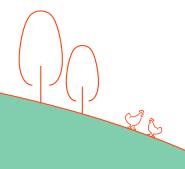
Preserving the efficacy of these life-saving medications, as well as their availability for both human and veterinary use, is therefore essential to preserve our future. The development of antimicrobial resistance (AMR) compromises this dual objective and impacts our ability to successfully treat infectious diseases.

AMR occurs when bacteria, viruses, fungi and parasites no longer respond to antimicrobial agents. As a result of drug resistance, antibiotics and other antimicrobial agents become ineffective and infections become difficult or impossible to treat, increasing the risk of disease spread, severe illness and death. AMR may occur naturally as organisms adapt to their environments. However, **overuse** and misuse of antimicrobial agents in humans, animals and plants sectors has dramatically accelerated the emergence of AMR. Consequently, minimising the emergence and spread of AMR requires a coordinated, focused multi-sectorial and multinational effort.

Animal health and welfare depend on the availability, effectiveness and appropriate use of quality veterinary medicines, including antimicrobials. To continue to progress in disease control management and in improving animal welfare, we as international, regional, national and local animal sector leaders, need to encourage and achieve a sustainable change in behaviour so that antimicrobial use in animals closely respects WOAH international Standards on responsible and prudent use of antimicrobials.

In particular, Veterinary Services including veterinarians and veterinary paraprofessionals have a key part to play in this, through our role in regulating and supervising use of antimicrobials and offering professional advice on their use to farmers and animal owners.





# Our role in the fight against AMR

We have been working on AMR for a long time. In undertaking our role as a standard-setting organisation\* for animal health, including zoonoses, we have developed a wide range of international standards on antimicrobial agents, in particular on responsible and prudent use as well as on surveillance of antimicrobial use and resistance.

These standards are regularly reviewed and updated through the transparent and inclusive process of expert advice and member consultation before presentation for adoption to the World Assembly of Delegates each year. We also work with our Members in a comprehensive and continuous capacity building process for their Veterinary Services.

# "WOAH has developed a wide range of international standards on antimicrobial agents."

# FAO, UNEP, WHO and WOAH: A Quadripartite Partnership

The rise of AMR is a shared responsibility between human, animal, environmental and plant sectors, which therefore requires a multi-sectoral, global and coordinated approach.

The Quadripartite partnership reflects the "One Health" nature of the AMR challenge, and has been proven as a mean of successfully addressing animal and public health risks associated with zoonoses and animal diseases. Recognising the needs and challenges of each sector, the Quadripartite relationship drives the development of policies and tools that support the investments of Members to combat AMR and enhance biosecurity at every level.

In this context, in 2015 the World Health Organization (WHO) issued a Global Action Plan on AMR<sup>2</sup> developed in collaboration with WOAH and FAO. The Global Action Plan recognises the need to address the challenge of AMR through a "One Health" approach. This approach emphasises the interconnectedness of the health of humans, animals, plants and the environment. Issues and solutions are viewed through the lens of multi-sectorial collaboration between stakeholders in all sectors.

On 21 September 2016, the United Nations General Assembly adopted a political declaration aimed at combating the global threat posed by AMR and confirmed the "One Health" approach in line with the Global Action Plan. The Directors General of FAO, WHO and WOAH were present and addressed the General Assembly to support this declaration.

<sup>\*</sup> The World Trade Organization's (WTO) Sanitary and Phytosanitary Agreement (SPS), signed in 1994, established WOAH as the reference organisation for standards related to animal health, including zoonoses<sup>1</sup>.

# Our Strategy on AMR and the Prudent Use of Antimicrobials

In 2015, in addition to a full review of the standards related to AMR, our Members officially committed during the 83rd General Session to combat AMR and promote the prudent use of antimicrobials in animals<sup>3</sup>. WOAH World Assembly of Delegates stated its full support for the Global Action Plan on AMR. One year later, during the 84th General Session, the World Assembly of Delegates directed WOAH to compile and consolidate all the actions to combat AMR into a global Strategy<sup>4</sup>.

The structure of this strategy supports the objectives established in the Global Action Plan, and reflects our mandate as described in our Basic Texts and Strategic Plans, through four main objectives:

- Improve awareness and understanding;
- Strengthen knowledge through surveillance and research;
- Support good governance and capacity building;
- Encourage implementation of international standards.

Since 2022, we have set a monitoring and evaluation system to assess the delivery of our strategy. In parallel, WOAH contributes to the monitoring and evaluation of the overall Global Action Plan, in collaboration with the Quadripartite partners.

"We, sectors and countries, all share responsibility in the development of antimicrobial resistance. It is by addressing this global threat together that we will manage to protect human and animal health, and therefore, our future."

Dr Monique Eloit, Director General, World Organisation for Animal Health







# **Objectives**

### **Objective 1: Improve awareness and understanding**

AMR is a global threat, and the emergence of antimicrobial-resistant pathogens threatens decades of progress against infectious diseases in animals and humans. Veterinary Services play a critical role in building awareness of AMR and encouraging the prudent use and management of antimicrobial medicines in animals. **Our initiatives seek to increase awareness and understanding among Members, veterinarians, farmers, animal owners, stakeholders and citizens**, and in doing so, support the development and implementation of tools and policies that enhance animal health and welfare.

- Support Members through the development of targeted communications and advocacy
  materials designed to foster understanding of the risks of AMR in a large range of actors
  and encourage the adoption of measures that reduce the use of antimicrobials and slow
  the emergence and spread of resistant microorganisms.
- Promote awareness of AMR more especially through Veterinary Statutory Bodies and Veterinary Education Establishments to encourage a professional culture that supports the responsible and ethical use of antimicrobial products in animals.
- Continue to support professional development goals by organising and conducting workshops, conferences and symposia that promote the prudent use of antimicrobials and address the issue of AMR at global, regional and national levels.
- Expand the portfolio of WOAH guidance, educational and scientific reference materials
   associated with combatting the emergence and spread of AMR microorganisms in
   animals while promoting good animal husbandry, vaccination and biosecurity measures to
   prevent diseases and limit the need for antimicrobial treatments, in collaboration with
   partner organisations and stakeholders.
- Collaborate with FAO, UNEP and WHO to ensure the alignment and coordination of policy and advocacy initiatives aimed at combatting AMR.



# Objective 2: Strengthen knowledge through surveillance and research

In many countries, WOAH Performance of Veterinary Services (PVS) evaluation missions<sup>5</sup> have found that antimicrobial drugs are widely available and their distribution and use is largely uncontrolled and unmonitored. Despite Members adopting standards on antimicrobial use and on monitoring and surveillance for resistance, the current lack of implementation in many countries constrains our ability to fully understand the risks, to target interventions and to monitor progress.

Since 2015, the World Assembly of Delegates has set as a priority the development of a global database on the use of antimicrobials in animals. This project, supported by FAO and WHO as part of the Global Action Plan, started in 2015 and will allow countries, regions and the global community to establish baseline information using a harmonised approach, to measure trends over time and to evaluate effectiveness of actions taken to ensure responsible and prudent use of antimicrobial agents.

This global database will be linked to the our World Animal Health Information System (WAHIS)<sup>6</sup>, a web-based reporting system that collects, processes and avails online information about animal populations and diseases in real time, providing notifications to Members of sanitary events in animals.

WOAH and its Reference Centers are also supporting coordinated national and international surveillance systems for microorganisms with acquired AMR traits across animal production and along the food chain.

- Support Members in developing and implementing monitoring and surveillance systems to detect and report antimicrobial use and the emergence of organisms with AMR characteristics.
- Build and maintain a database for collecting and holding data from Members on the use of antimicrobial agents in food-producing and companion animals, with associated analysis and annual reporting.
- Enhance the development, use and functionality of WAHIS to ultimately allow analysis of data on antimicrobial use taking into account animal populations of each country and region.
- Guide and support research into alternatives to antibiotics by working alongside partner
  organisations to encourage the development and uptake of new tools, products and
  methodologies that will reduce the dependence of animal sectors on antimicrobials and slow
  the emergence and spread of AMR.
- Identify and pursue opportunities for public-private partnerships in AMR research and risk management, working alongside and in conjunction with FAO, UNEP and WHO efforts.

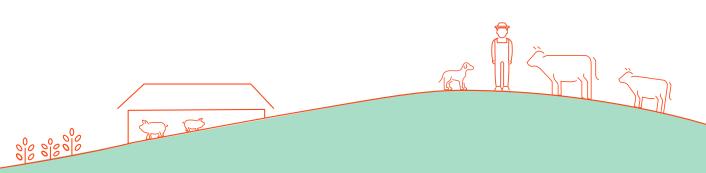
<sup>\*</sup>The PVS Evaluation Tools for Terrestrial and Aquatic Animals, respectively, specifically explore the technical authority and capability of the Veterinary Service with respect to the regulation of veterinary medicines and biologicals, including residue monitoring, as well as other more general competencies and capacities related to regulatory systems, resourcing, laboratories and competencies of veterinarians and veterinary paraprofessionals<sup>5</sup>.

### Objective 3: Support good governance and capacity building

WOAH is committed to supporting Veterinary Services of Members to build their capacity as well as to develop and implement National Action Plans for AMR, to regulate and promote responsible and prudent use of antimicrobial agents, and to implement monitoring and surveillance. Many Members need support to develop policies and legislation to govern the importation, manufacture, marketing authorisation, distribution and use of quality veterinary medicines, including antimicrobials.

We work alongside international partners and stakeholders to improve Members' capacity to build robust plans and policies to control AMR, to promote responsible and prudent use and good animal husbandry and disease prevention and control practices. International cooperation and exchange of experience is critical as the global community seeks ways to combat AMR, and funding is necessary to assist countries when needed as they adopt policies and guidelines that support animal health and welfare.

- Provide assistance and leadership to Members as they develop and implement National
  Action Plans and policies governing the use of antimicrobials in animals, promoting the
  "One Health" approach and the interconnectedness of the health of humans, animals,
  plants and ecosystems.
- Provide tools and guidance to assist Members in their AMR risk-assessment initiatives associated with antimicrobial agents and use in animals.
- Work alongside Members to ensure Veterinary Services have the capacity to implement WOAH Standards, taking advantage of their engagement in the PVS Pathway<sup>7</sup>.
- Support Members to develop and modernise legislation governing the manufacture, marketing authorisation, importation, distribution and use of veterinary products.
- Engage Members through regular training of Focal Points on Veterinary Products, establishing direct links and support processes.
- Ensure that well-trained veterinarians and veterinary paraprofessionals are at the forefront of national and regional efforts to improve animal health and welfare and the stewardship of antimicrobial products through training initiatives at international, regional and national workshops and conferences.



### **Objective 4: Encourage implementation of international Standards**

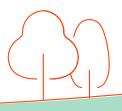
WOAH Standards and guidelines reflect the best available science and provide a global benchmark for consistent regulation of antimicrobials, for promoting responsible and prudent use, for risk analysis, surveillance and monitoring, and for reporting<sup>8</sup>. These activities are critical to building trust and confidence in livestock sectors and to achieving the objective of slowing the emergence and spread of AMR.

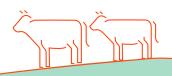
Our Standards provide a framework to achieve consistent outcomes using equivalent methodologies adapted to local contexts. The adoption of WOAH Standards and their implementation enables Members to improve biosecurity, to support animal health and welfare, and to support public health. Further, this enables Members to participate in safe international trade for economic and food security benefits.

Harmonisation between sectors, countries and regions ensures we generate comparable data, are able to turn it into information that improves our understanding of risks and opportunities, and can report progress towards the objectives of the Global Action Plan.

- Support individual Members in their efforts to implement WOAH international Standards for responsible and prudent use of antimicrobials and to combat AMR in animals taking into account their respective social, economic and cultural circumstances.
- Disseminate and encourage adoption of the recommendations in the WOAH List of Antimicrobials of Veterinary Importance<sup>9</sup>.
- Strengthen multilateral support for implementation of WOAH Standards among policymakers, our cooperation partners and donors to contribute to a well-coordinated international effort in the fight against AMR.
- Build on the success of the WOAH Standards development work programme to continue to advance for the animal sectors our comprehensive framework of quality, science-based standards that support the Global Action Plan on AMR.
- Collaborate with FAO, UNEP and WHO to support the development of a comprehensive and aligned framework of international standards and guidelines across human health, animal health, agriculture and the food chain.







# WOAH Statregy on Antimicrobial Resistance (AMR) and the Prudent Use of Antimicrobials

Protecting animal health and welfare by supporting global efforts to combat antimicrobial resistance

# Improve AMR awareness and understanding



Targeted communication











# Strenghten knowledge through surveillance and research

**AMR National Action Plans** 



Monitoring and surveillance systems



Report trends in antimicrobial use and AMR



Emergence of organisms with AMR traits

### **Antimicrobial Resistance**











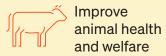
Veterinary Services play a critical role

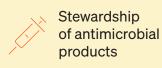
### **WOAH Strategy**

# Support good governance and capacity building



Well trained veterinarians and veterinary paraprofessionals





# **Encourage implementatin** of international standards

#### **WOAH International Standards**

Science-based and adopted by our Members



Improving worldwide









Production

Monitoring

Circulation

Use in animals

of antrimicrobials

### **Antimicrobial Resistance**



www.woah.org

#### References

- 1. WTO and WOAH (formerly OIE) Mandate. 1998; Available from: <a href="https://www.wto.org/english/thewto\_e/coher\_e/wto\_oie\_e.htm">https://www.wto.org/english/thewto\_e/coher\_e/wto\_oie\_e.htm</a>
- 2. Global Action Plan on Antimicrobial Resistance. 2015; Available from: https://www.who.int/publications/i/item/9789241509763
- 3. Resolutions of the 83rd WOAH General Session, Resolution No.26. 2015. Available from: goo.gl/KwaM84
- 4. Resolutions of the 83rd WOAH General Session, Resolution No.36. 2016. Available from: goo.gl/PFKWJo
- $5. \ PVS \ Evaluation \ Tools; Available \ from: \underline{https://www.woah.org/app/uploads/2021/03/2019-pvs-tool-final.pdf}$
- 6. WAHIS Portal; Available from: <u>goo.gl/1yaaEU</u>
- $7. \ PVS\ Pathway.\ Available\ from: \underline{https://www.woah.org/en/what-we-offer/improving-veterinary-services/pvs-pathway/2006.}$
- 8. Terrestrial Animal Health Code: Chapters 6.6 to 6.10. Available from: <a href="https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/">https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/</a>
  - Aquatic Animal Health Code: Chapters 6.1 to 6.5. Available from: <a href="https://www.woah.org/en/what-we-do/standards/codes-and-manuals/aquatic-code-online-access/">https://www.woah.org/en/what-we-do/standards/codes-and-manuals/aquatic-code-online-access/</a>

    Manual of Diagnostic Tests and Vaccines for Terrestrial Animals: Chapter 3.1. Available from: <a href="https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-manual-online-access/">https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-manual-online-access/</a>
- 9. List of Antimicrobials of Veterinary Importance. Available from: https://www.woah.org/app/uploads/2021/06/a-oie-list-antimicrobials-june2021.pdf





### **INSTRUCTIONS**

- 1. This workshop exercise is divided into 3 mandatory sections:
  - 1. Manual response of the questionnaire in ANIMUSE
  - 2. Responding to the Antimicrobial Use Team's requests
  - 3. Uploading an Excel version into ANIMUSE



- 2. Make sure you <u>ONLY</u> use the **training/testing environment** for this exercise which is accessible through the link <a href="https://test-amu.woah.org/">https://test-amu.woah.org/</a>
- 3. Login to your national portal using your **email** and **password** you have previously created to access ANIMUSE.
- 4. You are **required to provide fake responses** based on <u>testing scenarios</u> that WOAH have created. They are not considered as real submissions of national data and will be erased during the training.
- 5. Use this guide as a general reference if required.
- 6. The total time to complete all sections is **90 minutes.**
- 7. If you find any difficulty, please contact WOAH staff.

### **SECTION 1 – ONLINE SUBMISSION**

**X** [35 Minutes]

In this section, you are required to submit your answers online using the printed version that WOAH has provided you.

You are **required to provide fake responses** based on <u>testing scenarios</u> that WOAH have created. They are not considered as real submissions of national data and will be **erased** during the training.

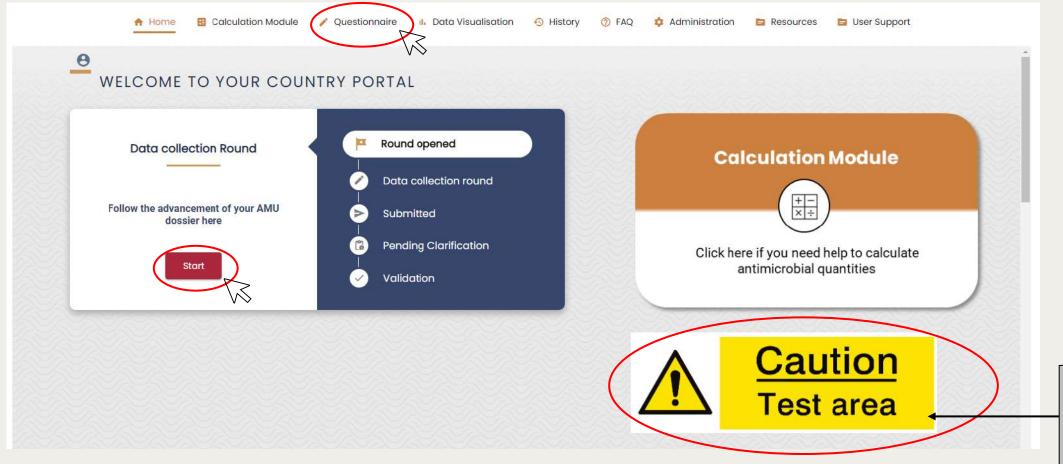
Do not answer with your real data, all participants should follow the same steps.

Only in certain cases (responses related to growth promoters – Questions 2, 3 and 4), ANIMUSE might detect differences in your historical responses, and you will be asked to provide a clarification of the change(s). For the purpose of this training reply: **testing ANIMUSE**.



### **SECTION 1 – ONLINE SUBMISSION ▼ [35 Minutes]**

Access the AMU Questionnaire on the **Home page** by using the button 'Start' or by selecting 'Questionnaire' from the menu.

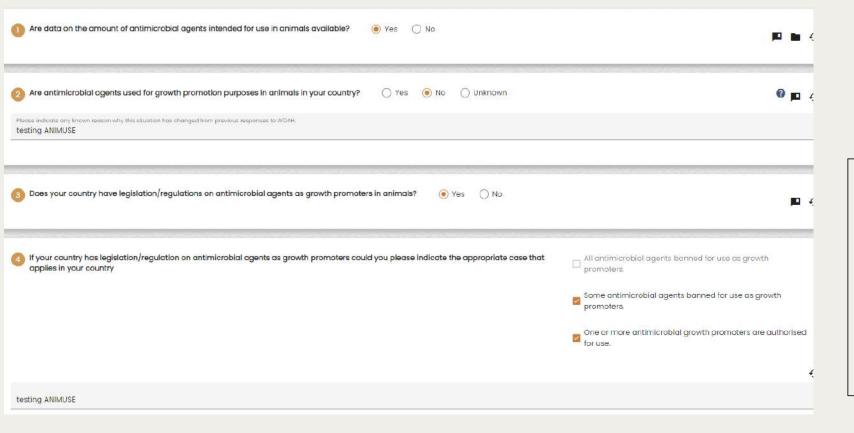


**NB:** Make sure you are in the test area



You are now in the 'General information' section. Please respond to the first four questions as stated in printed version that you have.

Only after you have provided all the responses, ANIMUSE will propose you to pass to the next section ('Data information').



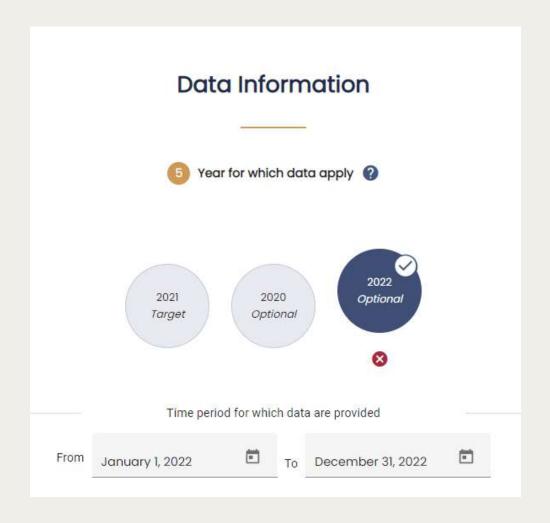
Please answer as stated on the printed version that has been provided to you.

Only once you have answered all the necessary fields, ANIMUSE will display two buttons at the bottom of the page. For this training scenario, choose 'No data in the Calculation Module'.





Answer the Data Information section (**Questions 5-13**). Depending on your responses, the system may ask you for more information or clarification.

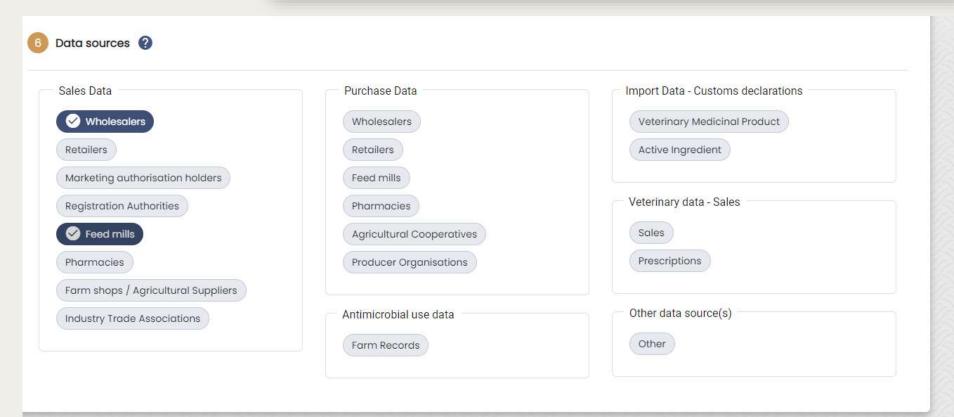


**NB:** For the purpose of this exercise please select **2022.** 

ANIMUSE will propose only the years that you can submit for this round. If previous years have been already submitted, they will not appear.





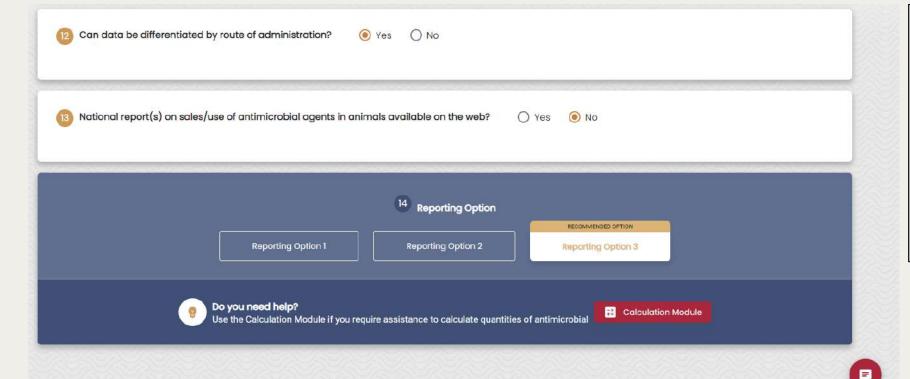


You can always access this button in case you would like to modify previous questions.

Previous



Once you reach the end of the **Data Information** section (**Question 13**) and ANIMUSE considers that ALL questions have been answered correctly, only in this case you will be proposed a Reporting Option (highlighted in yellow) based on your answers. Click on the proposed **Reporting Option** or click **Next** to go the next section.



NB: In a real scenario, if you wish to provide data in a different Reporting Option, you need modify Question 9 and/or Question 12. For the purpose of this exercise, your responses should guide you to Reporting Option 3

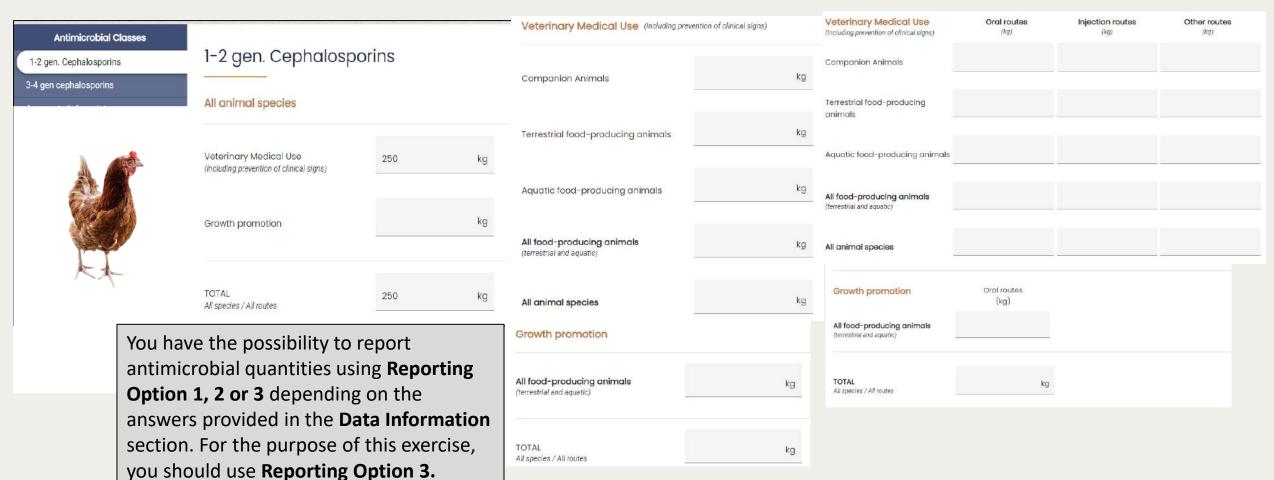




### **Reporting Option 1**

### **Reporting Option 2**

### **Reporting Option 3**

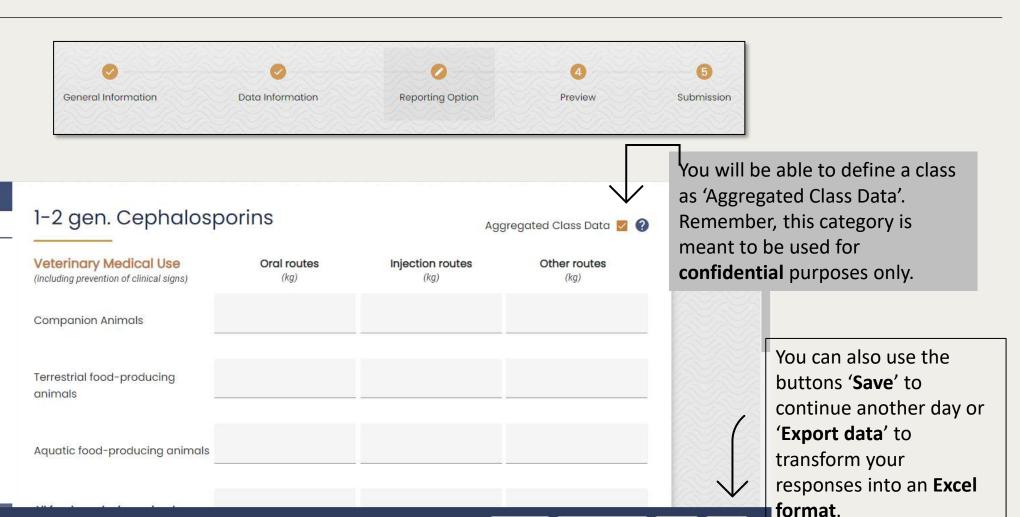




**Antimicrobial Classes** 

1-2 gen. Cephalosporins

# Online Questionnaire Submission



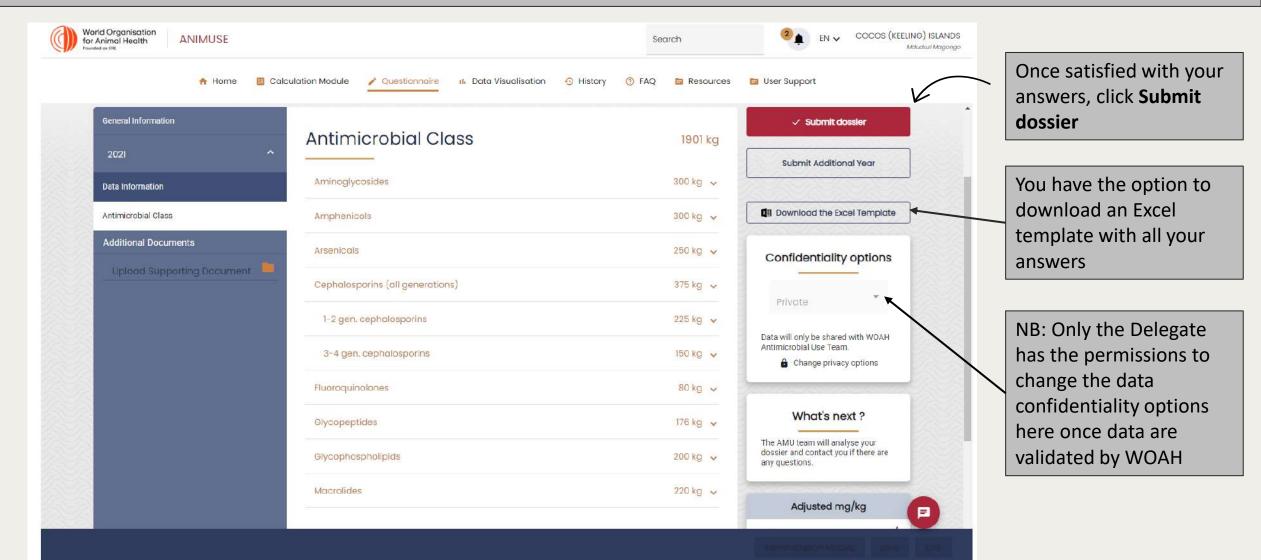
Previous

Save

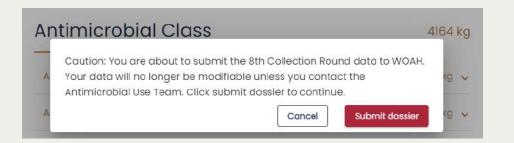
Next



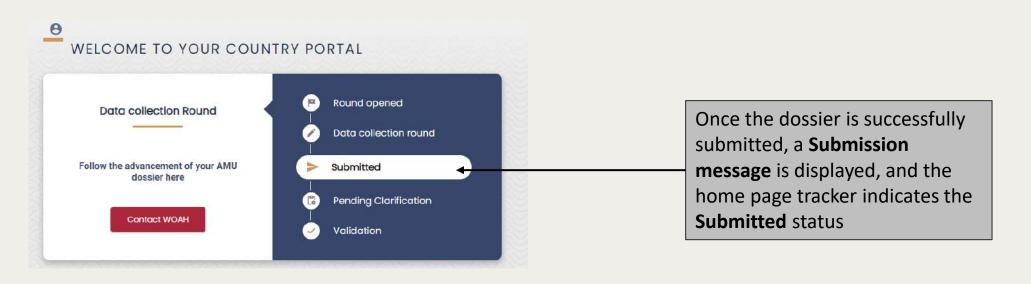
Preview all the answers you have provided in all previous sections, including the antimicrobial quantities before submission. Use the left navigation bar to move between the sections (General Information, Data Information and Antimicrobial Class). You can also upload additional support documents.







A caution message appears before dossier submission



Please indicate to the AMU Team when you have submitted your dossier

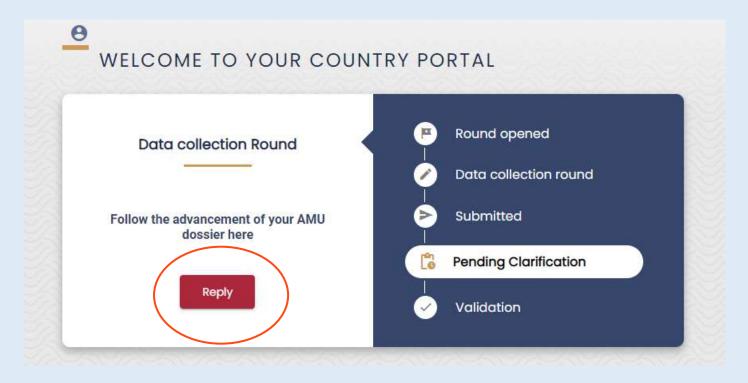


# Responding to WOAH queries

# 

In this section, you are required to provide clarifications to the AMU Team, based on the submission you just did. You will be able to see questions that need further clarification with a **red flag**.

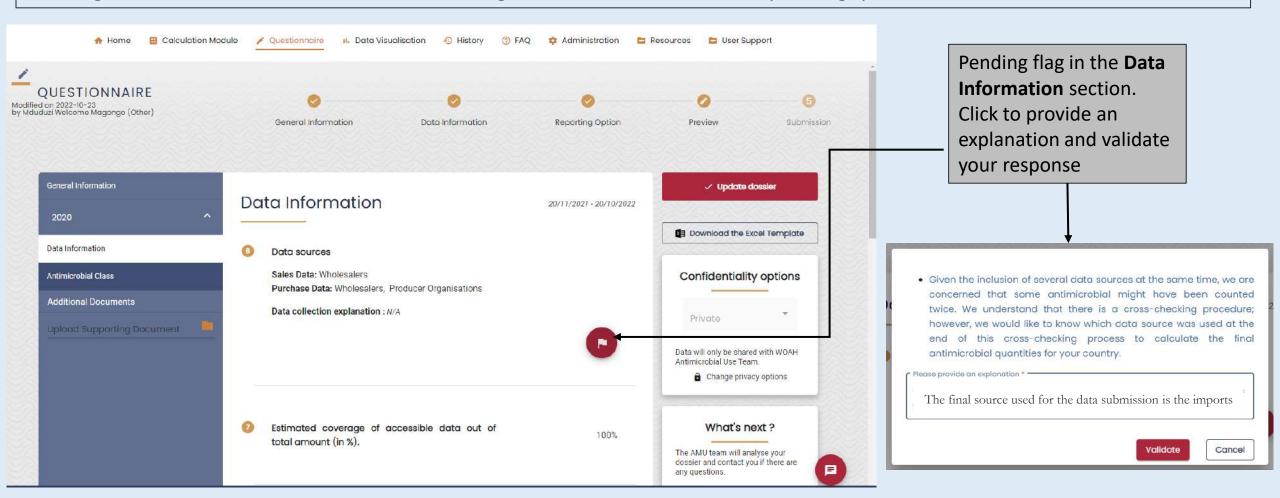
Your data have been submitted and have now been reviewed by the AMU Team. You are required to provide further explanation to **Question 7 and Question 11.** These questions have been flagged so that they are easily recognisable. Click **Reply** button to provide clarifications.





# Responding to WOAH queries

- 2. Once you click reply, you will be taken directly to the **preview screen** where you will be able to view all questions with pending flags. Navigate all sections to view all questions with pending flags and provide explanations or change your responses.
- 3. Navigate to the **Data Information** section using the left side bar to review pending questions



# Responding to WOAH queries

4. Once all pending questions have been provided, click **Update dossier** to submit your responses to the AMU Team



Please indicate to the AMU Team when you have updated your dossier



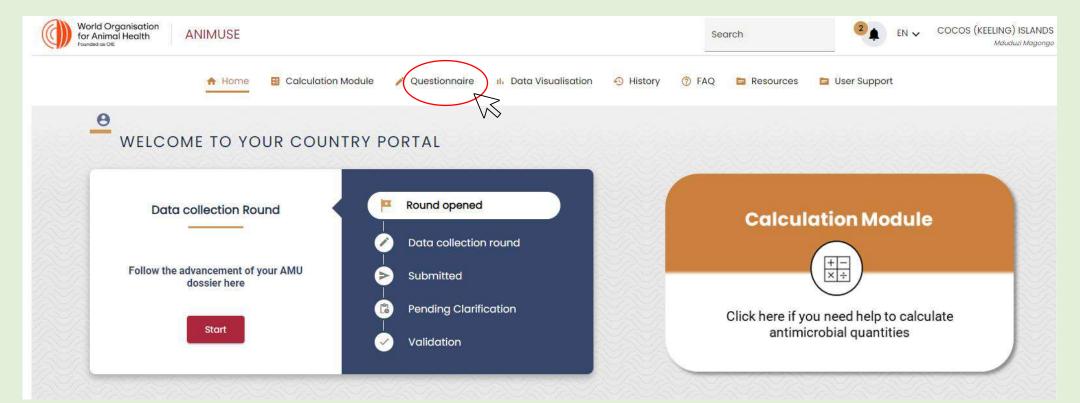


# **SECTION 3 – OFFLINE SUBMISSION ▼** [20 Minutes]

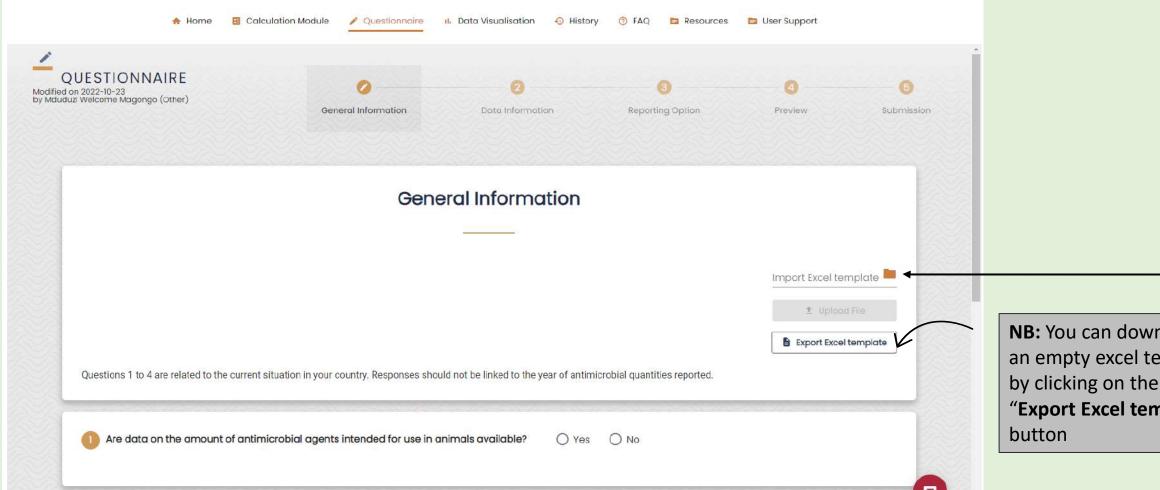
In this section, you are required to submit your answers by uploading the **Questionnaire Template** completed offline. Please follow the instructions provided in this guide to inject your file.

**NB:** You might need to correct some of your answers before successfully submitting your answers to WOAH.

The data collection <u>round is open</u>. You can access the AMU Questionnaire on the **Home page** by using the button **'Start'** or by selecting **'Questionnaire**' from the menu.



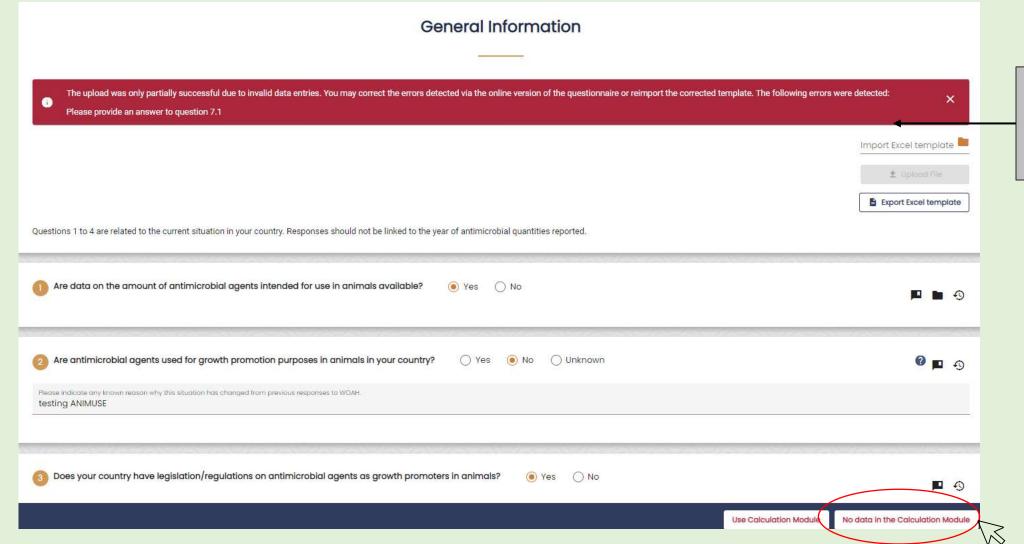
1. Upload (inject) the completed questionnaire template named 1.3.Injection\_questionnaire - error through the "Import Excel Template" button. Locate your file in your computer and click "Upload File"



**NB:** You can download an empty excel template by clicking on the "Export Excel template"

## Offline Questionnaire Submission

2. The file will be partially uploaded with some errors indicated on the screen. You have the option to fix the error on the Excel template and re-upload the file again or to click "Continue" and fix the error(s) on the system. For the purposes of this exercise, click continue

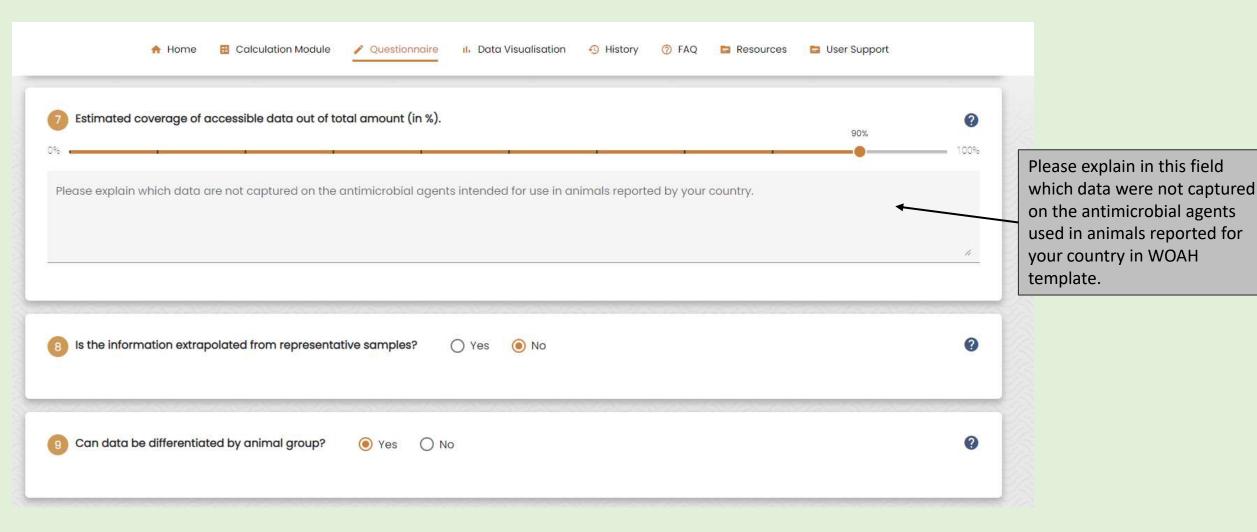




Error message indicating exactly where the error is coming from the excel template i.e., Question 7.1

## Offline Questionnaire Submission

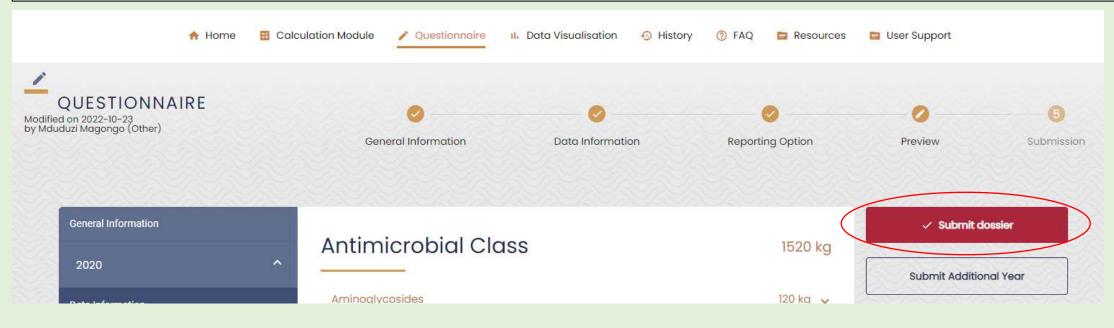
3. Provide an explanation for **Question 7**. Currently the estimated coverage of accessible data is less than 100% but no explanation is given, hence the error.





## Offline Questionnaire Submission

#### 4. Preview all data recorded and click **Submit dossier**



Please indicate to the AMU Team when you have updated your dossier











## Regional ANIMUSE Training for Asia and the Pacific

Bangkok, Thailand, 22-24 February 2023

# Training Material

Q *** This sheet of the WOAH template should be completed by all countries *** Please refer to the Guidance document for further instructions.			Questions in <b>bold</b> are mendatory. Please provide this information as requested.  Questions in <i>grey italics</i> are optional.	
		Information - Part A	Please provide the contact information of the	
	Title	<free field="" text=""></free>	person completing this template. He/she will be contacted by WOAH in case any darifications on	
	Name (First name, SURMAME)	free text field>		
	Role with respect to WOAH	□ WOAH Delegate	data are needed.	
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		☐ Other National Competent Authority	the WOAH' from the list.	
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_		Information - Part B		
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_		ntities reported.	1	
1	Are data on the amount of antimicrobial agents	☑ Amountsavailable - Yes		
•	intended for use in animals available?	☐ Amountsavailable - No		
	Please indicate why the data are not available at this			
La	time in your country, if the answer to Question 1 is	<pre><free field="" text=""></free></pre>		
_	'No'	□ Yes	Growth Promotion means the administration of	
2	Are antimicrobial agents used for growth promotion	□ No	antimicrobial agents to enimals only to increase the	
4	purposes in animals in your country?		rate of weight gain or the efficiency of feed	
		E3 Unknown	utilisation.	
	Does your country have legislation/regulations on	☑ Legislation/regulation exists - Yes		
3	antimicrobial agents as growth promoters in	L		
	animals?	☐ Legislation/regulation does not exist - No	4	
	If your country has legislation/regulation on	El All antimicrobial agents banned for use as growth promoters		
	antimicrobial agents as growth promoters in animals,			
4	could you please indicate the appropriate case that	Some antimicrobial agents banned for use as growth promoters		
	applies in your country?			
		One or more antimicrobial growth promoters are authorised for use	<b>-</b>	
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ij	Delegate in copy, to	the Antimicrobial Use Team at:		
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5	Delegate in copy, to antimic if your response to Question 1 is "Yes".  Data in  *** Please provide data for 2021 if you have data to  Yearfor which data apply  (Please select only one year per template)  Time period for which data are provided  (e.g., from 1 January to 31 December 2021)	the Antimicrobial Use Team at:  tobial use (through complete Section C * Data Collection* .  formation - Part C  for another year, please select the year from the list below * * * *    2020 (optional)     2021 (target year)     2022 (optional)     1/Jan/2022     1/Jan/2022     5ales data	another year, please select the year from the list will accept data for other years (2020 or 2022), is not from before 2020. If you would like to providate for additional years, please fill out one temper year of data.  If you have found calculation errors in data alresubmitted to WOAH for previous years, we ask you please send en updated data template to the Antimicrobial Use Team.  From the list of options, indicate the data source from which the information on the amount of antimicrobial agents for use in animals was obtained. Multiple selections are possible. In each you use multiple sources, please be aware of the volume of the please be aware of the selections.	

		Other data source(s)		
6,2	Ciarification of the data source, if your response to Question 6 is 'Other'	<pre></pre> <pre></pre> <pre> <pre>free text field&gt;</pre></pre>	Please provide an estimate of the extent to which the quantitative data you report is representative of the overall antimicrobial agents intended for use in animals.	
7	Estimated coverage of accessible data out of total amount (in %)	95%		
7.a	Explanation of estimated coverage	illegal product entry of product represents 5%	Please explain which data <u>are not captured</u> on the antimicrobial agents intended for use in animals reported by your country.	
8	Is the information extrapolated from representative samples?			
8.a	Explanation of extrapolations carned out, if your response to Question S is "Yes"	<pre></pre> <pre><pre></pre> <pre></pre> <pre> <pre>free text field&gt;</pre> </pre></pre>		
9	Can data be differentiated by animal group?	Date differentiated by animal group - Yes     These differentiated by animal group - No.	For the purposes of the database, animal group means: 'Terrestrial food-producing animals', 'Aquatic food-producing animals' or 'Companion animals'. If your data is differentiated by any of these	
10	Animal groups <u>covered by the data</u>	Data with no differentiation (all animats combined) Data for terrestrial and equatic food animals (all food-producing animals combined) Data for terrestrial food-producing animals and non-food-producing animals (combined)	groups, please select 'Yes'.  Please indicate which animal groups are covered by your data. Multiple selections are possible.	
		Data for terrestrial lood-producing animals Data for equatic food-producing animals Dista for non-lood-producing animals		
11	Food-producing animal species <u>covered by the information on antimicrobial quantities</u>	Tetrestrial food-producing animals  Cattle  Pigs - commercial  Pigs - badyard  Sheep  Goals	Please indicate which food-producing animals are covered by the data. Multiple selections are possible.  For the purpose of this database, the following terms are defined:	
		□ Sheep and goats (mixed flocks) □ Layets - commercial production for eggs □ Broilers - commercial production for mest □ Other commercial poultry □ Poultry - boddyard □ Buffaloes (excluding Syncerus called) □ Carvidae (farmed) □ Carvidae (farmed) □ Equidae □ Rabbits □ Ress - honey □ Reptiles (e.g. crocodiles) □ Other □ All terrestrial food-producing animals	1. Terrestrial food-producing animels Pigs – commercial: pigs including piglets, fattening pigs and breeding pigs. Shoep/goast (mixed flocks): use this option only if there are mixed flocks and you cannot differentiate between sheep and goats in your country. Other commercial poultry: it includes turkey, duck, geese, quali, guinea foovi, pheasant, pigeon, ostrich, etc. in commercial production. Poultry – backyard; poultry including chickens and hers in backyard or village flocks. Equidace horses, donkeys and their crosses. All – terrestrial food-producing animals: use this option only if all terrestrial food-producing animals listed in question 11 (e.g. cattle, pig-commercial, pigs- backyard, etc.) were included in the information on antimicrobial quantities.  2. Aquatic food-producing animals (equaculture) Fish – Cyprinidee: carp, etc. Fish – Salmonidee: salmon, trout, etc. Fish – Schonidee: salmon, trout, etc.	
		□ All - terrestrial food-producing animals (aquaculture)  □ Fish - Cyprinidae □ Fish - Salmonidae □ Fish - Salmonidae □ Fish - Salmonidae □ Fish - Salmonidae □ Cish	Fish – Siluriformes: caffish, etc. Crustaceans – Penseidee: marine shrimp/ prawn. All – squetic food-producing enimels (equaculture): use this option only if all aquatic food-producing animals listed in question 12 (e.g. Fish - Cyprinidee, Fish – Salmonidae, Crustaceans - Penseidae, Molluses etc.) were included in the information on antimicrobial quantities.	
		Ciber All aquatic food producing animals (aquacultura)  All aquatic food-producing animals (aquacultura)	When 'Other commercial poultry' or 'Other' is	
11.a	Clarification of other species considered to be food- producing, if your response to Question 11 is 'Other commercial poultry' or 'Other'	Ducks and turkeys	selected in Question 11, please dainly the other animal species that are raised for food production that are covered by the data.	
11,b	Non-food-producing animal species <u>covered by</u> <u>antimicrobial quantities,</u> if any	☐ Canines ☐ felines E☐ Équidae ☐ Consequental (Est)	Please indicate which non-food-producing animals are covered by the data. Multiple selections are possible.	

	Clarification of other species considered to be non- food-producing animals, if your response to Question 11.b is 'Other'	spec text field>
12	Can data be differentiated by route of administration?	☐ Data differentialled by muse of administration - Yes
13	National report(s) on sales/use of antimicrobial agents is animals available on the web?	☐ Cata differentiated by route of administration - No ☐ Report available on the web - Yes
	Please provide the link to the report, if the answer to Question 13 is 'Yes'	☐ Report available on the web - No space text field>

According to your responses to the questions abo	According to your responses to the questions above, you are invited to fill in the following Reporting Option:		
REPORTING OPTION	Appropiate for your Country		
Option 1	<u>NO</u>	If you answered 'No' to Question 9, then Reporting Option 1 may be the best adapted Reporting Option for the data you can report.	
Option 2	NO	If you answered 'Yes' to Question 9, then Reporting Option 2 may be the best adapted Reporting Option for the data you can report.	
Option 3	YES, PLEASE CLICK HERE	If you answered 'Yes' to Question 9 and Question 12, then Reporting Option 3 may be the best adapted Reporting Option for the data you can report.	



## Working Group Session 3: CALCULATION MODULE [30 min]



#### SECTION 1 - ONLINE DATA ENTRY

Objective: Add products online using the Calculation Module

#### Product 1

#### A. NAME OF THE VETERINARY MEDICINAL PRODUCT

**EROXYSTREP FARM 1 KG** 

#### **B. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each gram contains: Active substance:

Erythromycin thiocyanate: 35 mg Oxytetracycline hydrochloride: 50 mg

Streptomycin sulphate: 35 mg

**Excipient:** 

Lactose monohydrate 50 mg

#### C. PHARMECEUTICAL FORM

Powder for oral use

**D. TARGET SPECIES** 

Poultry, calves, sheep and goats.

**E. PACKAGE SIZES APPROVED** 

1 KG

F. INFORMATION ON THE SALES

800 units sold.



#### Product 2

#### A. NAME OF THE VETERINARY MEDICINAL PRODUCT

#### PRODUCT VETFIELD

#### **B. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each ml contains: Active substance:

Procaine penicillin G: 200 000 IU Dihydrostreptomycin sulphate: 200 mg

Excipient:

Monothioglycerol 1 mg

#### C. PHARMECEUTICAL FORM

Solution for injection

#### **D. TARGET SPECIES**

Cattle, sheep, goats and pigs.

#### **E. PACKAGE SIZES APPROVED**

50 ML 100 ML 500 ML

#### F. INFORMATION ON THE SALES

467 products sold for the presentation of 100 ml. 25 products sold for the presentation of 500 ml.

#### **G. MARKETING AUTHORISATION NUMBER**

ANIMUSE02-334-PS5



#### Product 3

#### A. NAME OF THE VETERINARY MEDICINAL PRODUCT

#### **CHICKEN FEED WSP**

#### **B. QUALITATIVE AND QUANTITATIVE COMPOSITION**

100 grams contain:
Active substance:
Oxytetracycline 10 g
Colistin sulfate 7 000 000 IU
Excipient:

Lactose monohydrate 50 mg

#### C. PHARMECEUTICAL FORM

Powder for oral use

D. TARGET SPECIES

Poultry.

**E. PACKAGE SIZES APPROVED** 

100 G 1 KG 2 KG

#### F. INFORMATION ON THE SALES

69 boxes containing 10 bags of 100 g were sold during the year

#### H. MARKETING AUTHORISATION NUMBER

ANIMUSE02-367-PS7



#### Product 4

#### A. NAME OF THE VETERINARY MEDICINAL PRODUCT

BOVI-MASTITIS. INJ.

#### **B. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each applicator contains:

Active substance:

Lincomycin 330mg

Neomycin 100 mg

**Excipient:** 

Citric acid 0.2 ml

Water for injectable preparation 2 ml

#### PHARMECEUTICAL FORM

Intra-mammary suspension

#### C. TARGET SPECIES

Cattle.

#### **D. PACKAGE SIZES APPROVED**

Intramammary applicators of 5 ml Box of 30 pieces of applicators with a leaflet.

#### **E. INFORMATION ON THE SALES**

9 boxes sold.

#### I. MARKETING AUTHORISATION NUMBER

ANIMUSE02-264-PS1



Working Group Session 5: Visualising and using AMU data ANIMUSE Training, Bangkok, 22-24 Feb. 2023

#### Working Group Session 5: Visualising and using AMU data

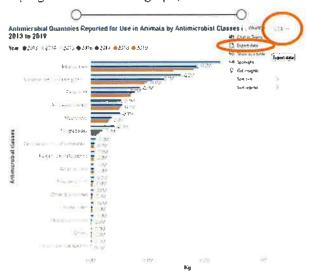
#### Objective:

- Exploring ANIMUSE Data Dashboards
- Sharing experiences on data reporting and communication.
- Need gathering workshop Understanding the data visualisation needs from users.

Additional information: Data visualisation User Guide

#### I. Exploring ANIMUSE data dashboards (individually)

- ⇒ Simultaneously to presentation: 12. Data visualisation
  - 1. Access Public Data dashboard
  - A. Either disconnect if you are logged in or <u>use a private navigation window</u> of your internet browser to see <u>ANIMUSE</u> as a **non-connected/public user**.
  - B. Navigate on the **Public Home page data dashboard**, there are currently 5 pages within that single data dashboard.
    - 2. Access Country portal Private Data dashboards
  - A. Login to your country portal to see <u>ANIMUSE</u> as a **country user**, by clicking login at the top right corner of ANIMUSE screen.
  - B. Navigate on the **Country Portal Home page data dashboard**, there are currently 5 pages within that single data dashboard.
  - C. Remember each graph are **dynamic** within one page: You can **filter**, **click** on the variables of the **graphs themselves** (i.e. Click on one antimicrobial class in the AMU page to see the trends on time of that particular class)
  - D. **Download** the data in excel behind one particular graph by clicking on the " located at the top right corner of each graph/table



E. From the top menu bar, click on "Data Visualisation" to access and visit an additional data dashboard "antimicrobial quantities"



#### Working Group Session 5: Visualising and using AMU data ANIMUSE Training, Bangkok, 22-24 Feb. 2023



#### Communicating and reporting on AMU data [30 min] 11.

Has your country used the AMU data that you report to WOAH for any national activity/report/decision?

- a. Write your country name on a post it note and stick it in the right box "Yes" or "No" in the dedicated area
- b. For what activity are you using your AMU data? If your answer is "Yes" or "No" yet you are planning to use this data, write on another Post-it note your country name + some details on the reporting activity and stick in the right category of the dedicated area - if you are using the AMU data in multiple activities do not hesitate to use several different Post-it notes.
- c. What kind of data are you using and how are you presenting it? Write your country name + quickly explain on your Post-it and stick it in the right category.



Feedback to the group facilitated by AMU Team

### [In groups of 5] Identify further data visualisation needs $\bowtie$ [ 30 min] III.



#### What are your needs?

- a. In groups, evaluate from the existing dashboards you have explored, which ones are more relevant for your needs in terms of data visualisation. Do not hesitate to annotate the provided dashboards in paper format.
- b. Brainstorm and create the graphs/tables that you would want to see in data visualisation dashboards:

On the paper board draw or describe the variables, axis, columns etc...



Feedback to the group facilitated by AMU Team



## **ROADMAP**

TO REDUCING THE NEED FOR

## **ANTIBIOTICS**



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## Contents

1	Introduction.	3
	Our Vision for Reducing the Need for Antibiotics	
	Our Contribution.	
4	Call to Action	14
5	Fulfilling our Commitment	18

This document was produced by HealthforAnimals, the global animal medicines association. HealthforAnimals represents the animal health sector: manufacturers of veterinary pharmaceuticals, vaccines and other animal health products throughout the world, as well as the associations that represent companies at national and regional levels.



## 1. Introduction

#### Antibiotics are a cornerstone of modern medicine and public health.

Their importance to human and animal health cannot be understated, which is why antimicrobial resistance (AMR) is such an important global threat. When bacteria develop tolerance or resistance to antibiotics, we risk returning to a time when animals – and people – fell seriously ill or even died from simple, treatable infections.

## Antibiotics are the only way to treat a bacterial disease. There is currently no alternative.

As the producers of animal medicines and other health products, our industry equips veterinarians with the tools to manage animal disease. Reducing antibiotic use without first tackling disease rates would mean sick animals go untreated, causing unnecessary suffering and mortality while increasing risk of transfer to other animals and people.

## However, we can exploit the full spectrum of animal health tools to reduce the need for antibiotics.

By better protecting animals from the threat of disease, identifying health issues earlier and treating them quickly and responsibly, we can decrease disease levels and with it, the need for antibiotics. This requires maximising the long-term and preventative health benefits of tools such as vaccination, nutrition, antiparasitics, biosecurity, disease surveillance, diagnostics, husbandry and other animal health technologies.

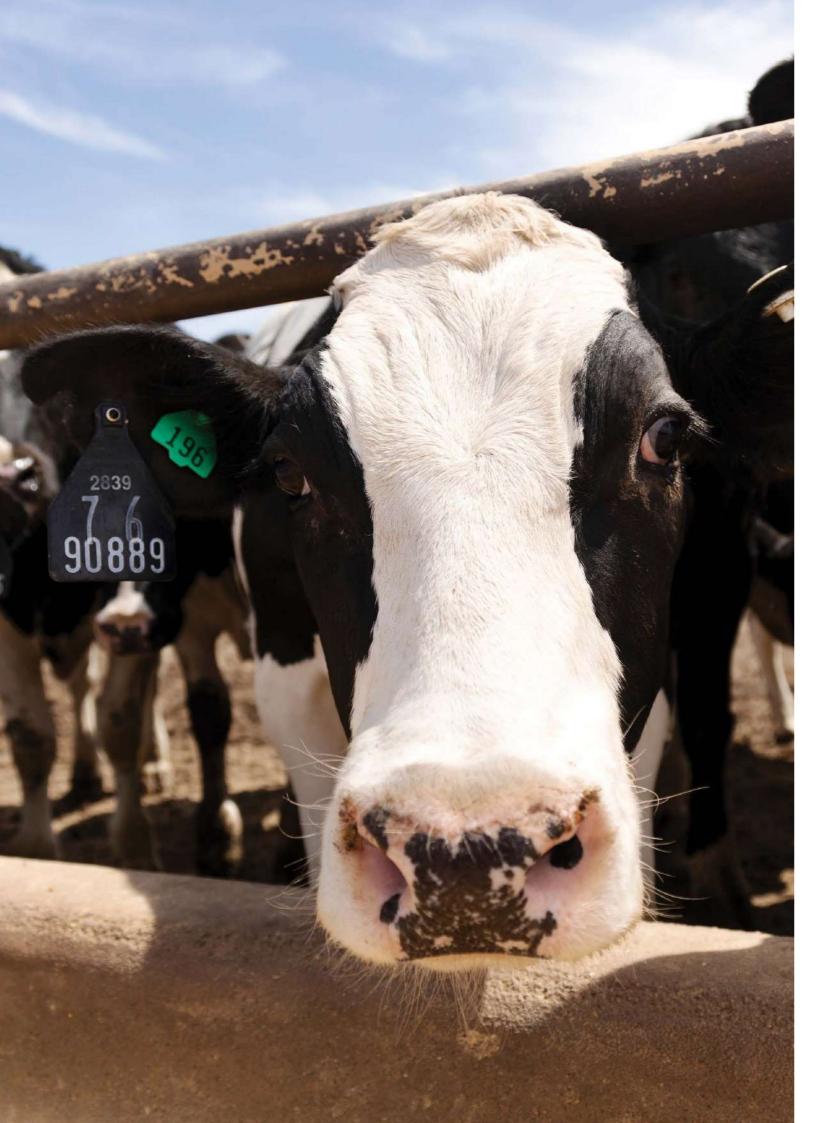
## Together, these tools can improve the prevention, detection and treatment of animal disease. This is our roadmap to reducing the need for antibiotics.

The ability to manage and control animal disease has profound consequences for human health and development, from ensuring the safety of meat, milk, fish and eggs to reducing the risk to people of bacterial animal-borne diseases. And while the relationship between using antibiotics in animals and growing levels of resistance in people remains complex and not well understood, AMR affects us all.

Our industry has worked on this challenge for many years, and our 2017 Antibiotics Commitment defined our core principles in approaching AMR. Activities we have undertaken in line with these principles can be seen in Section Five of this Roadmap. But we see more opportunities to reduce the need for antibiotics while also improving animal health.

Our Roadmap to Reducing the Need for Antibiotics offers a clear vision for improving global animal health both in the steps HealthforAnimals and our Members pledge to undertake by 2025, and in the areas where we call on others to take action and support this goal.





## 2. Our Vision for Reducing the Need for Antibiotics

To preserve antibiotic effectiveness, the animal health industry believes the whole animal health sector – both public and private – must devote more investment, research and energy into three priority areas:



Prevention



Detection



Treatment



## **Prevention**

Disease prevention is our first line of defence and the best way to reduce the need for antibiotics.

Preventing disease outbreaks involves three key elements: vaccination, biosecurity, and overall health and wellbeing. Vaccines are one of the most effective forms of prevention available while biosecurity measures, such as sanitizing equipment or indoor rearing of certain species, can limit bacteria exposure. Strengthening the overall health of an animal also improves their natural resilience against infection and ability to fight off disease, reducing the need for antibiotics.

Improving prevention requires commitments to:



#### Vaccination

- Improve access to veterinarians and/or paraprofessionals, especially in low- and middle-income countries (LMICs), who can administer vaccinations
- Make government funds for vaccination available to farms, especially in LMICs
- Improve vaccine availability in underserved markets
- Improve the regulatory route for existing vaccines, especially in LMICs
- Enact clear regulations for new types of vaccines
- Deliver new vaccines
- Improve the acceptance of GM/biotech vaccinations
- Strengthen cold chain transportation and the availability of heat-resistant vaccines



### **Biosecurity**

- Increase government funding for farm facilities
- Train animal handlers on good biosecurity practices
- Improve consumer understanding of biosecurity benefits
- Train animal handlers on the cost/benefit of various biosecurity measures
- Increase funding for research on biosecurity practices and adoption



## Overall health and wellbeing

- Develop and improve access to in-feed nutritional products
- Develop and improve access to immunostimulants
- Increase research into animal genetics
- Increase public funding for animal nutrition research

## **Detection**

Disease threats and veterinary access vary around the world but sharing information can help treat and contain an outbreak before it spreads.

Early detection of disease can make all the difference in treatment success, allowing for selection of the most appropriate antibiotic from the outset and reducing the risk of the illness spreading throughout herds or flocks.

This relies on two important elements: monitoring and diagnostics. Monitoring can help identify disease threats before an outbreak takes hold and track any emergence of antibiotic resistance, while swift and accurate diagnostics can help ensure appropriate treatment is given at the earliest possible opportunity.

Improving detection levels will require commitments to:



#### **Monitoring**

- Improve disease tracking and data collection
- Increase training of veterinarians and/or paraprofessionals on disease identification
- Improve access to veterinarians and/or paraprofessionals in LMICs
- Increase public funding for disease monitoring
- Continue to share antibiotic sales volume data in markets where it is required
- Monitor antibiotic use levels where appropriate
- Monitor AMR levels in food and animals
- Increase research on AMR transfer pathways and the role of the environment



#### **Diagnostics**

- Bring new diagnostics to market that can identify disease more rapidly and accurately
- Define legal requirements for farm data protection
- Increase training of veterinarians and/or paraprofessonals on diagnostics tools
- Integrate diagnostics with treatments to allow for rapid identification and care







## **Treatment**

When an animal contracts a bacterial infection, there is currently no viable alternative to antibiotics.

For the times when antibiotic use is necessary, we must support responsible use. This means the right antibiotic, at the right time, at the right dose, administered through the right route.

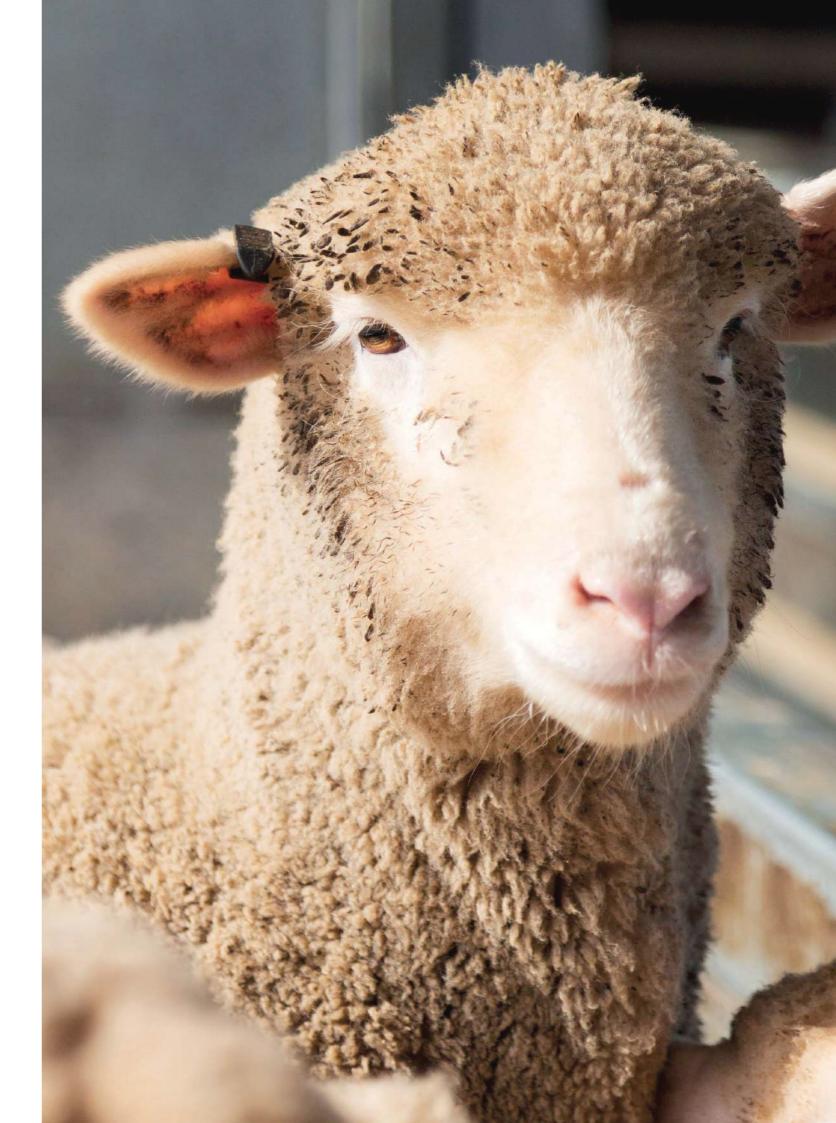
Improving treatment requires commitments to:

#### Responsible antibiotic use

- Increase training of veterinarians and/or paraprofessionals on responsible antibiotic use
- Improve access to veterinarians and/or paraprofessionals in LMICs
- Increase veterinary supervision of antibiotic use in LMICs
- Improve understanding of the role of antibiotics in animal care
- Strict enforcement of existing antibiotic use requirements, especially in LMICs
- Foster greater dialogue across the value chain (e.g. suppliers, farmers, vets) on responsible use

Achieving progress under the three pillars of this vision will require dedicated action both by the animal medicines industry and the wider animal and public health sector, which includes governments, international authorities and the private sector.

Read on to **sections 3 and 4**, Our Commitments and Call to Action, to learn about the actions each of these groups can undertake.





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## 3. Our Contribution

Building on our 2017 Antibiotics Commitment, which outlined five key principles to improve animal health and responsible antibiotic use, we see a way forward that addresses AMR through reducing the need for antibiotics.

This Roadmap focuses on the actions the public and private sectors can undertake to reduce the need for antibiotics in animals. This includes better prevention, earlier diagnostics, increased access to innovative treatments, and more.

In this section are the cumulative actions that HealthforAnimals and our Members, will undertake between now and 2025. HealthforAnimals will regularly survey our Members to track progress on the Roadmap and release updates.

However, we cannot achieve this alone. **Read on to section 4** to see how policymakers and international organizations can also take action that can help reduce the need for antibiotics in animals.

### **Our Actions**

Addressing AMR is a difficult, global challenge. But we believe reducing the need for antibiotics is an essential part, and this will require strong action and accountability.

HealthforAnimals and our Members, representing more than 85 percent of the animal medicines industry, pledge to collaboratively undertake the following clear, measurable actions to improve the three areas of our vision – prevention, detection and treatment – by 2025:

### Research & development

If we are to continue to maintain and improve animal health as well as reduce the need for antibiotics, we will need new innovations that help keep animals healthier, preserve welfare, diagnose disease earlier and treat illness more accurately. To help achieve this, we will:

- Invest at least \$10 billion in research and development
- Deliver at least 100 new vaccines
- Deliver at least 20 new diagnostics tools
- Deliver at least 20 new nutritional enhancement products
- Deliver at least 30 other products that can reduce the need for an antimicrobial by reducing animal stress or boosting the natural immune system (ex. parasiticides, immunostimulants, anthelmintic, etc.)

#### One Health

In addressing issues such as AMR, we must recognize that this is not an issue limited by species or location. AMR affects animals, people and the planet, and can only be addressed through working across these disciplines. To help achieve this, we will:

- Deliver new tools that reduce the likelihood of human exposure to a resistant pathogen such as *Salmonella*, *Campylobacter*, or *E. coli*
- Conduct an AMR risk analysis for every new antibiotic brought to market

#### Communications

Reducing the need for antibiotics can only be possible when the importance, benefits, scientific basis, and methods are properly communicated. To help achieve this, we will:

- Strengthen communications on benefits of biosecurity, in-feed supplements, vaccinations, and products that support good animal health
- Participate in forums and public dialogues to help build understanding of risks, benefits, and actions that different stakeholders can take to improve public health outcomes in the fight against AMR
- Issue regular report(s) and/or white paper(s) identifying barriers to adoption of prevention tools (e.g. vaccination, biosecurity, etc) and how they can be addressed
- Issue Roadmap Updates in 2021 and 2023

#### Veterinary training & access

Veterinarians and veterinary paraprofessionals are on the frontline of the battle against AMR, using their expertise and knowledge to make a difference. They are trained to use antibiotics in a responsible manner that reduces animal suffering while limiting the emergence of resistance. Contributing to greater veterinary training and access can make all the difference in upholding animal health. To do this, we will:

- Provide clear labels on every, single product
- Make technical guidance available to all product users
- Train more than 100,000 veterinarians in responsible use of medicines
- Undertake at least 15 veterinary training partnerships
- Invest at least \$5 million in veterinary education scholarships and grants
- Deliver a white paper on opportunities in telemedicine for improving access to veterinarians in high-income and low and middle income nations

### Cooperation

The animal medicines industry does not work in a vacuum and we cannot address animal health alone. We will redouble efforts to build partnerships and work across disciplines to reduce the need for antibiotics. To do this, we will:

- Participate in responsible use coalitions in major markets
- Share sales data in every market where it is required
- Undertake five new partnerships that deliver products that help to reduce the need for antibiotics in underserved markets
- Conduct at least 50 audits of active ingredient suppliers to ensure they are meeting appropriate standards
- Encourage medicine users to submit efficacy reports into pharmacovigilance monitoring systems





## Knowledge

Addressing AMR will be more successful with greater knowledge and understanding about its origins, development, movement and contributory factors. To support this, we will:

- Provide research grants of at least \$1 million
- Publish new, scientific research within peer-reviewed publications which improves understanding of veterinary pathogens or antimicrobial resistance
- Provide data and support to help improve disease tracking to organizations such as the World Organisation for Animal Health (OIE)

HealthforAnimals and our Members commit to undertaking the above actions between now and 2025.

We will issue updates in 2021 and 2023 that evaluate our progress.





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## 4. Call to Action

The animal medicines industry cannot reduce the need for antibiotics alone. Alongside our industry commitments, we also call upon the public sector and international organisations to join us in this effort to reduce the need for antibiotics by improving prevention, detection and treatment of animal disease.

Supportive public policies can drastically change farmer access to new treatments, preventative tools and veterinary expertise, which will allow them to improve animal health and reduce the need for antibiotics.

This will require decisive policy action across the following four areas:

Regulation	<u> </u>	Consumer acceptance
Funding for livestock	\$	Access to veterinary expertise

#### Regulation

Farmers are facing continually evolving animal health threats, with new diseases spreading faster than ever due to natural disasters and global trade. As the animal medicines industry works to deliver new technologies to tackle emerging threats swiftly and effectively, the accompanying regulatory process must also adapt, otherwise the opportunity to respond to a health threat could be lost.

Delivering products into smaller regional markets such as East Africa or South Asia, for example, poses a unique financial challenge. Having a medicine approved for use through the regulatory process and ensuring the infrastructure is in place to deliver it to the market often costs more than a company can recoup. This makes it financially unviable to deliver the newest technologies to many farmers in developing countries who need it the most.

At the other end of the spectrum, animal medicines are advancing faster than ever before with tools like modern vaccinations, stem cell therapies, monoclonal antibodies and more, opening up a world of new prevention and control treatments. Regulations must keep up to allow new products and technologies to be assessed and licensed in a timely manner. Delays can mean veterinarians, livestock farmers and animals must wait longer for an appropriate treatment or product, which could increase disease risk and the need for antibiotics.

Strengthening the regulatory process requires:

Regulatory convergence: Policymakers should support greater regional
regulatory harmonization and convergence. This could enable a company to submit
a product to one, unified regulatory system and receive a market authorization for
multiple countries in a region. This would significantly increase the amount of tools
available to veterinarians and farmers, particularly in smaller markets.

- Modern, flexible regulatory systems: Ground-breaking products are in the
  animal medicines pipeline but some may not fit into the current regulatory framework.
   Regulators must prepare for these situations by offering flexible, collaborative
  processes that ensure product safety while avoiding unnecessary delay.
- Controls on illegal medicines: Policymakers and authorities must crack down
  on illegal medicines, including counterfeits. Illegal medicines are a \$2 billion a year
  market that threatens farmers, veterinarians, animal safety, and even consumer
  safety. Actions to improve control could include strengthening enforcement
  agencies, improving data collection and analysis, facilitating identification of
  medicine authenticity, and improving general awareness.
- Support for OIE Standards: The World Organisation for Animal Health (OIE)
  offers science-based standards that countries can use to improve prevention and
  control of disease. Greater adoption of OIE standards can better protect the health
  and welfare of animals and promote responsible use of medicines.

#### Consumer acceptance

Consumers are increasingly interested in the provenance and production of their food. The food chain, from retailers to farmers, are working to provide more detail, but there remains a disconnect between marketing campaigns promoting sustainably sourced foods and the threat of disease risk among livestock. This creates confusion for consumers.

For example, indoor rearing of poultry as a biosecurity measure can be an effective way to limit exposure to disease, but consumers are increasingly expecting birds to be raised primarily outdoors. This can significantly increase disease risk as seen in the 2016 outbreak of bird flu in Europe, which was spread by wild birds who swiftly infected outdoor poultry. Policymakers must support public awareness and understanding of animal disease risks, and the necessary measures to prevent outbreaks.

Strengthening this awareness requires:

- Better public education on biosecurity: Consumers need to understand that farm
  conditions and husbandry play an enormous role in preventing disease outbreaks,
  which affect animals as well as people, their food supplies and their livelihoods.
- Improved understanding about responsible use and the role of antibiotics in animal care: The public must understand that, just as in humans, antibiotics are the only way to treat bacterial infections in animals. We can reduce the need for antibiotics, but, they will remain crucial to animal welfare.
- Greater education about the safety and importance of vaccines:
   Consumers should be reassured that vaccines can safely and effectively prevent disease, reducing the need for antibiotics.

## Funding for livestock

Livestock contributes 40 percent of global agricultural output, according to the UN's Food and Agriculture Organisation (FAO), yet the percentage of development spending devoted to livestock is less than 0.25 percent. With 1.3 billion people worldwide relying on livestock for their livelihoods and food security, the funding available to support the health of livestock must increase.





Financial assistance is vital to encourage smallholder farmers to invest in preventative medicine such as vaccines. Effective, international disease monitoring also needs crucial funds to limit the risk of a disease emerging that requires antibiotics for treatment.

Finally, investment is also needed for research and development to allow scientists to keep up with emerging disease threats. Strengthening livestock funding requires:

- Livestock vaccination support: Investing in preventative medicine is the
  best way we can reduce the need for antibiotics. Subsidies or other farm-level
  support is essential for improving uptake of vaccination, especially in low- and
  middle-income countries.
- **Investment in research and development:** Forming public-private partnerships can be a helpful way of sharing the cost of innovation while investing in health.
- Funding for disease monitoring across borders: Disease knows no borders
  and vigilant surveillance and shared information can help countries limit an outbreak
  and stop it from spreading, reducing the need for subsequent treatment.
- Best practice training of farmers: Livestock producers are on the frontline of animal health. By investing in best practices like good nutrition, husbandry and biosecurity, we can help them reduce the likelihood of disease and the need for antibiotics.

#### Access to veterinary expertise

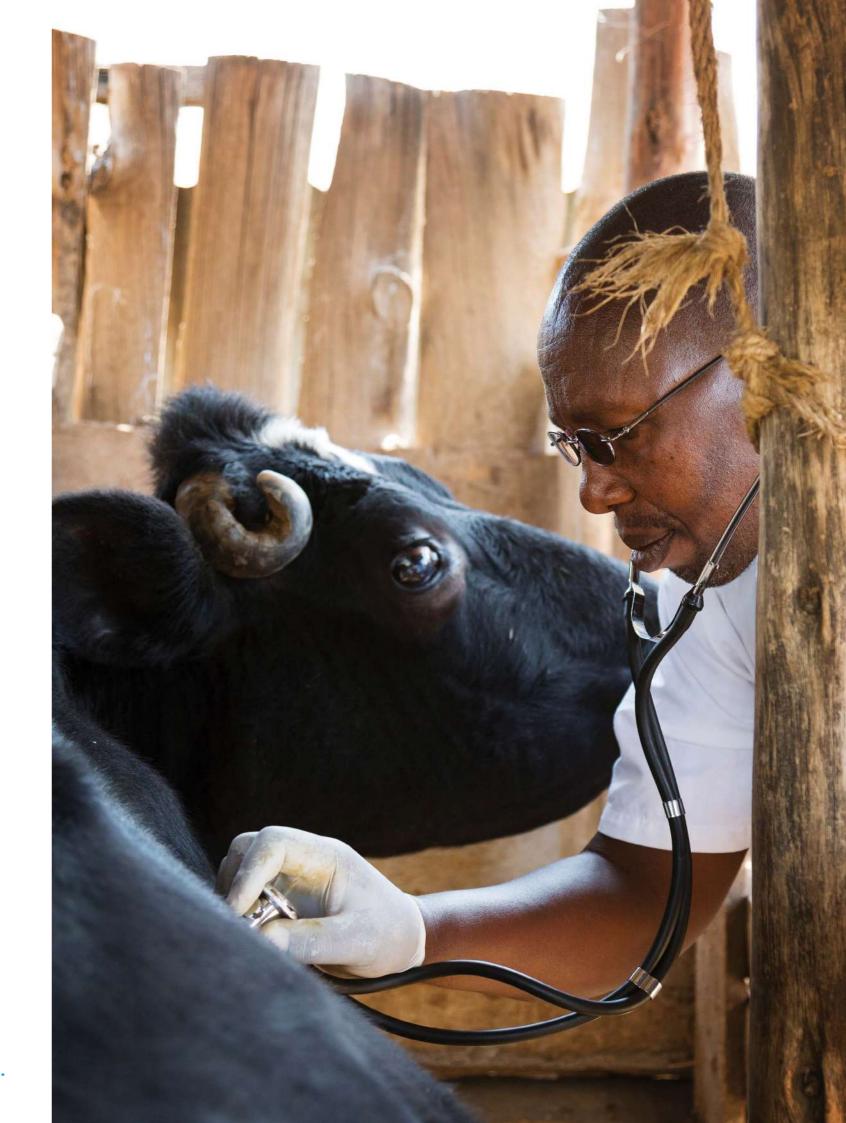
It is impossible to reduce the need for antibiotics and tackle AMR without proper access to veterinary expertise. Only with the right expertise can livestock producers improve the prevention, detection and treatment of animal disease.

However we simply do not have enough veterinarians nor veterinary paraprofessionals. This is especially acute in low- and middle-income countries where many animals will never see a veterinarian in their lifetime. This puts farmers in the challenging position where they must make medical decisions for their livestock without adequate training. Increasing access to veterinary expertise must be at the top of the global agenda.

Strengthening access to veterinary expertise requires:

- Increasing investment in veterinary education: Veterinarians must be equipped to respond to emerging disease threats and responsibly use antibiotics.
- **Promoting the veterinary profession:** To fill the global shortage of veterinarians, we must redouble efforts to make this an attractive, rewarding career.
- Investing in veterinary paraprofessionals: There are simply not enough veterinarians available. Paraprofessionals with some training can make an enormous difference to animal health.
- Encouraging livestock farmers to seek out veterinary expertise: This requires
  promoting trust in the veterinary profession and in the efficacy of animal health products.

Actions by the public sector and international organizations across these four areas can help improve prevention, detection and treatment of animal disease on a national and international scale, reducing the need for antibiotics on farms across the globe. Combined with the actions of our industry, this can make a significant impact in the fight against AMR and improve responsible antibiotic use for all our benefit.





## 5. Fulfilling our Commitment

Our Roadmap to Reducing the Need for Antibiotics is the product of our experiences and efforts to address AMR, improve responsible use, and bolster the health of animals.

It is also the next step in a process that began in 2017 with the release of our 'Antibiotics Commitment'. This pledge outlined the five guiding principles for HealthforAnimals and our Members when approaching responsible use and AMR:

13	Principle 1:	Protect animal health and welfare in a unified One Health approach
	Principle 2:	Use antibiotics judiciously and responsibly
AYA.	Principle 3:	Promote disease prevention and increased access to products and expertise
<b>(\$</b>	Principle 4:	Invest in development of products for prevention and treatment
(A)	Principle 5:	Increase knowledge, transparency and communication

These principles, and the actions we have undertaken to meet them, have informed our vision and helped guide our way forward. Since our Antibiotics Commitment is the foundation of our Roadmap to Reducing the Need for Antibiotics, it's essential that we demonstrate how we embody this Commitment.

Activities in this section have been provided by HealthforAnimals Members, which includes 10 company members and associations around the world:





















The activities demonstrate how our industry is fulfilling the principles of our Commitment and provided us with the learnings necessary to develop this Roadmap. This list not exhaustive, but demonstrates the wide breadth of work we undertake to address AMR and responsible use.







## Principle 1:

## Protect animal health and welfare in a unified One Health approach

Selection of activities by HealthforAnimals Members

#### Memorandum of Understanding with World Organization for Animal Health (OIE)

In 2017, HealthforAnimals officially renewed their Memorandum of Understanding with the OIE. This agreement calls for both organizations to work together towards common goals in "responsible and prudent use of antimicrobials and anthelmintics with the aim of tackling resistance," alongside other areas including regulatory frameworks, information sharing and development of new medicines.

#### How does this address AMR and responsible use?

The OIE is the premier global body for animal health and a leader on AMR and responsible antibiotic use. With 182 Member Countries, OIE's ability to affect change across the world is unprecedented. Working with OIE is essential to tackling the global challenge of antibiotic resistance, and this cooperation agreement enables HealthforAnimals and our industry to directly contribute to their efforts.

#### Global responsible use coalitions

Around the world, HealthforAnimals and our Member Companies and Associations participate in value chain coalitions that work to improve responsible use of antibiotics, such as RUMA (Responsible use of Medicines in Agriculture) in the UK, EPRUMA (the European Platform the Responsible Use of Medicines in Animals) across Europe, ALIANÇA in Brazil, and others. These coalitions allow the entire value chain - from producer to medicine developer to retailer - to work together towards responsible use. Each is an essential collaborative platform that offers a unified approach to the challenge.

#### How does this address AMR and responsible use?

Resistance cannot be solved by just one link in the value chain. Working together means the effort of each link (whether the developer, producer, retailer, etc.) builds upon one another to become greater than the sum of their parts. In addition, close collaboration ensures the efforts of the animal health sector remain focused, working towards a common goal.

#### HealthforAnimals' Antibiotics Commitment

Ten of the largest animal health companies in the world are united through the global association, HealthforAnimals. Members of the Association work together on common issues affecting veterinary medicine and the wider public health sector. In 2017, HealthforAnimals and its Members agreed to an industry-wide Antibiotics Commitment, outlining the five principles that underpin their work on responsible use and AMR.

#### How does this address AMR and responsible use?

The Commitment publicly sets out the industry's ability and responsibility to support the responsible use of antibiotics and provides principles against which it can be measured.

#### Online training for farmers to support responsible use of antibiotics on UK farms

The National Office for Animal Health (NOAH), RUMA, the Veterinary Medicines Directorate (VMD), the British Retail Consortium (BRC) and leading academics developed a robust and trusted online training programme for all those working in the sheep, dairy, beef and pig sectors in the UK. The Animal Medicines Best Practice (AMBP) Programme gives farmers and vets access to new resources, enabling a coordinated and consistent approach to farmer training in the responsible use of antibiotics.

#### How does this address AMR and responsible use?

The programme aims to raise awareness, knowledge and understanding of AMR and helps drive best practice in a consistent manner across UK farms when it comes to using antibiotics. Training modules are available for farmers via the NOAH website or directly through an online Lantra e-learning platform. Veterinarians can also access resource materials, enabling them to deliver training directly to their farmer clients.

#### Participation in global veterinary associations

HealthforAnimals is an official Member of the World Veterinary Association (WVA) and World Small Animal Veterinary Association (WSAVA), which represent a combined 700,000 veterinarians in over 100 nations worldwide. The two associations set clear defined standards and guidelines for proper animal treatment, including how to use antimicrobials responsibly. HealthforAnimals is an active contributor to working groups in each association and strongly supports their efforts to encourage responsible use and improve access to veterinarians.

#### How does this address AMR and responsible use?

By working with global veterinary associations, we can support the efforts of veterinarians to tackle AMR and improve responsible use. HealthforAnimals has done this by offering technical expertise, forming partnerships, and participating in working groups with each association.

#### Training veterinarians on responsible use of antibiotics in Spain

Spanish veterinary medicines association Veterindustria hosted a web seminar on responsible use of antimicrobials for over 1000 veterinarians at the 2018 launch of their product compendium Gui@Vet. The compendium is renewed every two years and these responsible use webinars are organized for each publication.

In collaboration with the Spanish Medicines Agency and the Board of Deans of Spanish Veterinary Faculties, Veterindustria provides further training on responsible use of animal medicines at all veterinary faculties across Spain, including veterinary university hospitals.

#### How does this address AMR and responsible use?

Providing clear guidance for the correct use of antibiotics directly to those entrusted to use these products, the veterinarians, is one of the best ways to ensure their responsible use. Raising awareness through training sessions at student level and practicing veterinarian level, and furthering knowledge about the challenges of antibiotic resistance helps to ensure better understanding of what is at stake and what role the veterinarians play in addressing the challenge of AMR.





#### Surveillance of disease outbreaks

Launched on 27 January 2016, the STAR-IDAZ International Research Consortium (IRC) aims to maximize funding for coordinated animal health research strategies for at least 30 priority diseases, infections and issues. HealthforAnimals and several Members are partner members of the IRC, while AnimalhealthEurope, the association for animal medicines companies in Europe, is a secretariat member.

#### How does this address AMR and responsible use?

Among the outcomes of international research are candidate vaccines, diagnostics or other therapeutic health products, all of which help to prevent or better control disease and reduce the need for antibiotics.

#### **VICH** support

VICH is a trilateral (EU-Japan-USA) program aimed at harmonizing technical requirements for veterinary product registration. This makes bringing products to market more efficient and predictable, which puts innovative products that can reduce the need for antibiotics in the hands of users quicker. Through its Members, observers and outreach forum participants, VICH represents approximately 100 countries. HealthforAnimals has been an active member of VICH for many years.

#### How does this address AMR and responsible use?

VICH activities help products that can reduce the need for antibiotics in animals reach users in a quicker, more efficient manner. This helps tackle challenges earlier and more effectively.







## Principle 2:

#### Use antibiotics judiciously and responsibly

Selection of activities by HealthforAnimals Members

#### Promoting best practices to companion animal veterinarians in Europe

Vetoquinol recently launched a campaign to educate veterinary clinics about the prudent use of antibiotics. Vetoquinol provided an electronic sales aid for all company territory managers to help explain best practices to veterinarians. Brochure and webinars outlined to veterinarians the prudent use approach in areas such as dermatology, respiratory infections and urinary tract infections.

In-clinic meetings with practising veterinarians shared methods in the field of prudent use and "lunch & learn" training sessions were organized.

#### How does this address AMR and responsible use?

These types of campaigns raise awareness on AMR, responsible use, and antibiotic stewardship for veterinarians and pet owners.

#### 'Cevolution'

With increasing global concern about the impact of antibiotic resistance on health and welfare of people and animals, Ceva Santé Animale undertook an extensive, companywide change called 'Cevolution.' Ceva's aim was to make a wide portfolio of antibiotics available, encouraging veterinarians to make the right diagnosis, prescribe the right antibiotic, at the right time and only for individual infected animals. This includes extensive education and training program for vets and farmers. A comprehensive library of high-quality, authoritative print and online resources, produced in partnership with international opinion leaders, and a regular newsletter are freely available to veterinary practitioners.

#### How does this address AMR and responsible use?

'Cevolution' helps veterinarians to choose the most appropriate antibiotic for the diagnosed infection. Extensive education, training and information ensures vets and farmers are aware of best practice and latest developments in the control of AMR.

#### Eight-point antibiotic stewardship plan

Elanco Animal Health has committed to an eight-step antibiotic stewardship plan that promotes responsible use of antibiotics and greater research into new treatment technologies. One year after launching the plan, Elanco convened more than 200 global animal protein industry leaders, intergovernmental organizations, NGOs, and experts at a One Health Antibiotic Stewardship Summit to address critical challenges and establish pathways forward.

In 2018, Elanco further refined the eight-point plan with commitments in three key areas of stewardship: combating antimicrobial resistance through responsible antibiotic use, reducing the need for medically important antibiotics in livestock, and significantly investing in new research.

#### How does this address AMR and responsible use?

The eight-point plan promotes responsible use practices, reducing the need for antibiotics, and development of alternatives. These actions can improve use of existing antibiotics and spur development of new treatment or prevention tools.

#### Promoting best practices to livestock veterinarians in Europe

Vetoquinol recently launched a communications campaign to promote best practices in antibiotic use, which included materials such as a in-depth brochure outlining the differences among the four categories of antibiotics and the varying needs for prescription.

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Vetoquinol also ran workshops, in cooperation with universities, for veterinarians to explain the relevant legislation and prudent use of antibiotics.

This was supported by a farmer case study on mastitis prevention, which showed how to reduce the need for antibiotics through targeted mastitis treatments, rapid diagnostics, and sensitivity testing methods.

The company also developed sanitary audits, performed by Service Implementation Consultants, and worked with digital partners to help practices understand their current antibiotic usage and discuss appropriate usage.

Vetoquinol territory managers have also received specific training about the National Plan about Antibiotic Resistance and the company position on the topic.

#### How does this address AMR and responsible use?

The Vetoquinol campaign helps European users better understand and fundamentally improve their use of antibiotics in livestock. This means more effective animal care that ultimately reduces the need for antibiotics.

#### Guidance for the rational use of antimicrobials (GRAM)

Several years ago, Ceva Santé Animale began work to address the veterinarian's need for a pragmatic guide to rational prescribing, which can be used under the time pressure of a consultation. This resulted in the 2016-2017 launch of Ceva's 'Guidance for the rational use of antimicrobials' (GRAM), a comprehensive practical and easy-to-use guide to help reduce the development of antimicrobial resistance in pets.

Since its launch, GRAM has been released in various languages and is freely available to veterinary practitioners. With over 500 pages, it was developed over six months by an independent panel of 10 experts from seven European countries, all recognised leaders in antibiotherapy.

GRAM aims to synthesise what already exists, reach consensus and simplify the material so as to provide clear, practical answers to the questions in relation to rational use of antimicrobials in canine and feline surgery and medicine. It includes 37 disease factsheets, 29 detailed recommendations and six synopses dealing with major topics, e.g. 'key questions before initiating any antibiotherapy'.





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#### How does this address AMR and responsible use?

GRAM emphasises proper diagnosis before treatment and the use of options other than antibiotics; e.g. use of suitable topical antiseptics as initial choices for the treatment of superficial dermatological conditions.

#### Digital support for treatment of BRD

In 2016, a meta-analysis comparing antibiotic options for treating bovine respiratory disease (BRD) was published in Preventative Veterinary Medicine. In 2017, Bayer Animal Health's technical veterinary team in conjunction with IT programmers began the creation of a web application to present the results of this study in a clear, concise and useable format. The goal was to support practitioners searching for data on BRD treatment options by providing them with data from this meta-analysis.

The iCOWNT web application allows practitioners to compare the relative risk of retreatment between two products and view a ranking of products based on efficacy (from highly efficacious to not efficacious) based on the published data. This assists practitioners in antimicrobial selection for BRD treatment and helps prevent them from choosing products that have a low likelihood of success.

#### How does this address AMR and responsible use?

Practitioners using the iCOWNT web application and underlying data to support BRD treatment protocols can reduce their retreatment rate as well as their likelihood of selection of inappropriate antimicrobials for BRD treatment. This can result in a reduction in overall antibiotic use and assist in preventing the selection of antimicrobials that could lead to the selection of resistant BRD pathogens.

#### Increasing veterinary supervision of use

As part of efforts to improve the responsible use of antibiotics, Elanco Animal Health has committed to new partnerships in countries with limited resources that aim to increase veterinary and professional oversight of antibiotic use.

In addition, Elanco has completed submission of 67 labels for five shared-class molecules that moves products from over-the-counter use to under the oversight of a veterinarian in all countries where over-the-counter uses remained and veterinary infrastructure exists. Unfortunately, veterinary infrastructure doesn't exist in all parts of the globe to allow for this move completely. In places where veterinarian oversight is not available, Elanco is working to educate farmers and others on the responsible use and administration of antibiotics.

#### How does this address AMR and responsible use?

Increasing access to veterinarians promotes preventative medicine which improves overall animal health and reduces the need for antibiotics. In situations where antibiotics are needed, veterinarians are best positioned to use antibiotics correctly and responsibly. Increasing access to their expertise promotes better use of antibiotics at the right time, in the right amount, for the right duration. Where veterinary expertise is unavailable, increasing farmer education promotes better use of antibiotics.

#### Individual Pig Care program

Individual Pig Care from Zoetis is an educational, in-barn training program that helps caregivers assess pig populations and support farmers antibiotic use. The program can help producers spot sickness sooner. When illness is addressed sooner, treatment success and well-being can be improved.

The program also helps personalize health protocols and reduce treatments. By using the classification system, caregivers can communicate a pig's condition to managers and veterinarians. This helps veterinarians prescribe the correct product for the pig's condition.

#### How does this address AMR and responsible use?

When illness is spotted and treated sooner, pigs can return to full health sooner. This reduces the need for additional antibiotic treatments and stops the illness from spreading to more animals, who may then require treatment.

## Raising awareness of responsible use through non-product advertising materials

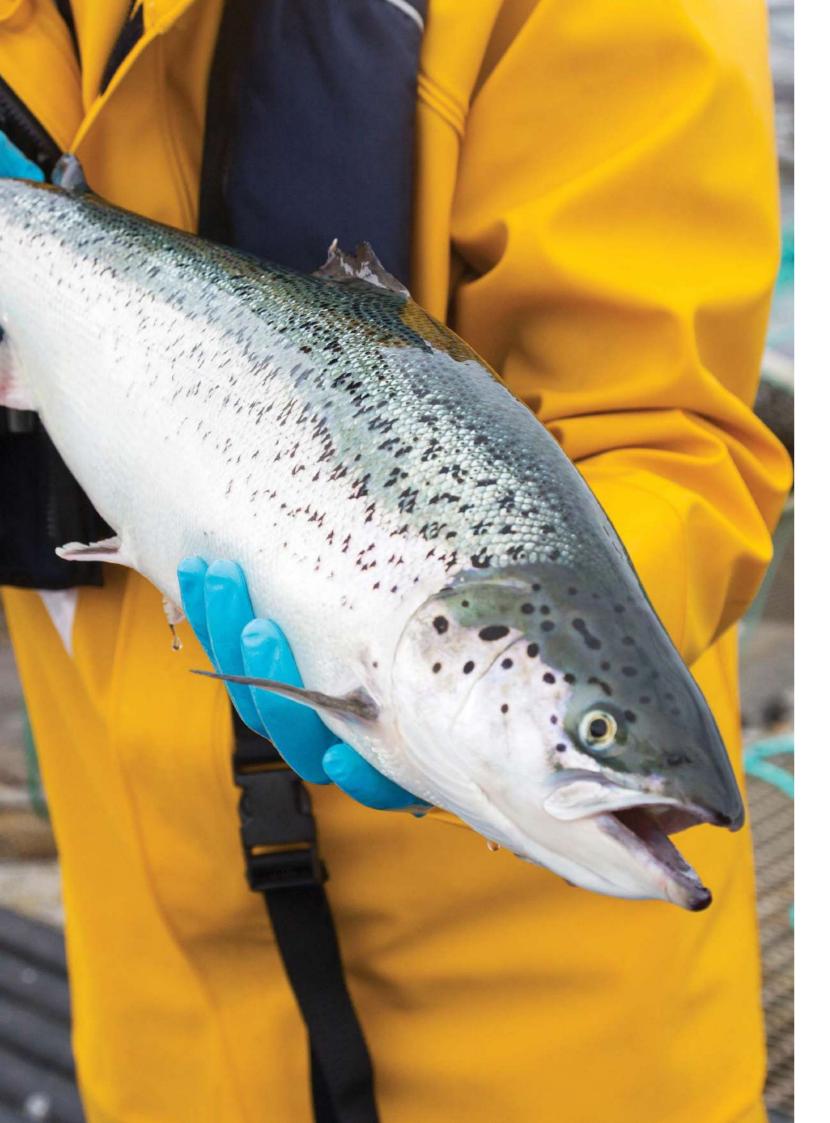
To help educate veterinarians on the implication of antimicrobial resistance and responsible use of antibiotics, Zoetis developed microsite and webinar series for veterinarians. The objective was to provide a proactive campaign to raise awareness about the responsible use of antibiotics. Over 4,000 veterinarians engaged in the campaign on sites multiple languages, including English, Dutch, French, German, Portuguese and Spanish.

#### How does this address AMR and responsible use?

Proactively promoting the responsible use of antibiotics as a topic under the slogan "As much as necessary, as little as possible" supports overall awareness of this topic to the wider veterinary audience and greater adoption of best practices.









## Principle 3:

Promote disease prevention and increased access to products and expertise

Selection of activities by HealthforAnimals Members

## Advancing accessibility of quality medicines, knowledge and education in Sub-Saharan Africa

The Zoetis ALPHA initiative, sponsored by the Bill & Melinda Gates Foundation, aims to advance livestock health and productivity in Sub-Saharan Africa through the increased availability of veterinary medicines, services and education.

Expected results include increase availability of veterinary medicines, services and education; implementation of disease diagnostics infrastructure; and development of veterinary laboratory networks and outreach services into business hubs in Ethiopia, Nigeria, Tanzania and Uganda.

#### How does this address AMR and responsible use?

Better access to medicines and expertise can significantly improve livestock management. Veterinarians and farmers will be able to better prevent and manage health problems, which can reduce disease risk and the need for antibiotic treatments. This is especially needed in areas of Africa that lack veterinary capacity.

#### **CEVA Lung Program**

In 2014, the Ceva Lung Program was launched in Asia and has been subsequently rolled out worldwide. The Program, which runs as a user-friendly app on Android and iPad mobile devices in multiple languages, assists in the correct diagnosis of respiratory diseases by providing a methodology and guidelines for scoring lesions at slaughter. The Program calculates the incidence, severity and impact of enzootic pneumonia and pleuropneumonia and reveals the presence of subclinical infections. The results can be used to evaluate the efficacy of control measures, including vaccination protocols, flag changes in disease dynamics and benchmark effectiveness of respiratory disease management in comparison to other farms.

Use of the Program has grown rapidly. In 2018, data was collected and analysed from more than 500,000 lungs. In addition to being useful as a strategic tool on individual farms, this unique, 'big data' set is being used to identify factors associated with high or low prevalence of respiratory disease to help design better preventive programs.

#### How does this address AMR and responsible use?

By providing vets and farmers with a simple but effective tool to help them improve the management of respiratory diseases through more effective vaccination regimes, use of antibiotics can be reduced to a minimum, while enhancing productivity and welfare. This reduces the chance of AMR strains developing in the animal population.

#### Convenience program evaluation for poultry

The 'Convenience Program Evaluation' is an initiative by Merck Animal Health, known as MSD Animal Health outside the US and Canada, designed to help poultry producers



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protect chickens against various diseases while achieving optimal vaccination standards, bird quality and performance goals.

Through the Convenience Program suite, producers receive vaccination support in the form of laboratory services and field visits, and also staff training and scientific seminars. These services enable them to remain highly proficient in poultry health practices.

#### How does this address AMR and responsible use?

This suite of services empowers poultry producers to protect their birds from disease and decrease the need for antimicrobials for disease treatment.

#### Disease prevention and control for profitable livestock production in Nigeria

In January 2019, the Veterinary Teaching Hospital of the University of Ibadan hosted a seminar on disease prevention and control. Several topics were discussed, ranging from biosecurity, disease symptoms, identification and also disease reporting.

The Nigeria Zoetis/ALPHA Initiative supported this seminar with writing materials and learning resources. The Initiative also officially launched a Learn & Grow microsite at the event, which provides free educational modules on livestock health and business courses on the microsite. 300 people attended, ranging from students, veterinarians from both public and private sectors, veterinary students, lecturers and paravets.

#### How does this address AMR and responsible use?

Veterinary oversight of antibiotics can improve responsible use. By improving access to veterinary expertise in areas like Nigeria where it is lacking, we can subsequently improve responsible use of antibiotics.

#### **Educational scholarships**

Each year, Zoetis provides USD\$500,000 in educational scholarships to over 200 veterinary students around the world. These are offered to students focused on species, diseases or regions which may be underserved in animal agriculture or pet heath.

#### How does this address AMR and responsible use?

More veterinarians and greater access to veterinary care improves responsible use.

#### Farmer and veterinary training academies

Boehringer Ingelheim organizes training academies on all continents, open to both internal and external professionals to be trained on the impact of diseases and how to prevent them. These academies are developed by universities or experts in the field. These training sessions provide the knowledge and support that producers and veterinarians require to identify and understand the dynamics of diseases, minimize disease transmission and maximize immune response while still running a profitable farm.

An example is the Boehringer Ingelheim Swine Academy (BISA®), organized in collaboration with international experts, such as the Iowa State University of Science and Technology and the University of Illinois, for Boehringer Ingelheim employees and

practitioners. It provides the participants with hands-on training run by scientists and industry professionals.

For our customers in the ruminant segment, Boehringer Ingelheim organizes the Milk Quality Academy, focusing on mastitis prevention, through useful advice and guidance.

#### How does this address AMR and responsible use?

Increased knowledge and support for prevention helps animal health practitioners avoid diseases, which can ultimately reduce the need for antibiotics. In addition, demonstrating that prevention works without compromising on profit offers an important business case for practitioners.

#### Handling and treatment practices in Mexico

Bayer recently collaborated with cattle farmers in Mexico to improve on-farm handling and treatment practices. This led to a reduction in the overall rate of morbidity, mortality and improved weight gain in cattle.

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#### How does this address AMR and responsible use?

Improvements in handling and treatment practices reduced respiratory morbidity without the need for antibiotic treatments.

#### Leptospirosis vaccine

In 2019, Merck Animal Health, known as MSD Animal Health outside the US and Canada, released a leptospirosis vaccine effective for dogs against four of the five known serovars that cause canine leptospirosis infection, Nobivac EDGE LEPTO4. Leptospira bacteria are widespread in the environment and are zoonotic, with up to 10 million people infected every year and a fatality rate in humans of up to five per cent. In dogs, leptospira infections cause serious damage to the liver and kidneys and can cause fever, loss of appetite, shivering, muscle pain, weakness, and urinary symptoms.

#### How does this address AMR and responsible use?

By limiting the spread of leptospirosis among dogs and in turn reducing the chance of human infection, the vaccine ultimately reduces the need for antimicrobials to treat leptospira infections.

#### Innovation in vaccination devices

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Ease of administration can be a significant factor in the adoption of a vaccine by veterinarians and animal caretakers. In 2018, Merck Animal Health, known as MSD Animal Health outside the US and Canada, developed a needle-free vaccination device for pigs, the IDAL 3G.

The device aims to help professionals administer vaccinations more quickly and at greater scale because they are more easily maintained and cleaned, are capable of injecting into multiple injection sites, allow for comprehensive record-keeping, and ensure the proper dose is administered during each injection.

#### How does this address AMR and responsible use?

Increasing the ease of vaccination for pigs and their handlers can improve the adoption of robust vaccine protocols, allowing for more pigs to be vaccinated, and encourage more handlers to vaccinate. This can decrease the need to use antimicrobials treat disease over the lifetime of the pig, and reduce the possibility of AMR developing in swine bacteria.

#### Developing new vaccines and delivery systems

Phibro Animal Health has had 77 new vaccine licences granted in 18 different countries over the last three years. Examples of new products include a live virus vaccine in an effervescent tablet, sealed in sterile aluminium blister packaging. The user-friendly tablet is convenient and safe to handle so it allows vaccines to be used in locations without access to equipment or refrigeration.

Phibro has also invested in autogenous animal vaccines, which are herd-specific vaccines (also referred to as custom vaccines) and can be effective against illnesses such as BRD, Pinkeye (IBK), and enteric diseases like Salmonellosis. Animal death rates from these diseases are well documented, and the use of autogenous vaccines to combat these conditions can be effective.

#### How does this address AMR and responsible use?

Vaccination and herd immunity are key parts of antimicrobial stewardship and two principle ways to reduce the need for antimicrobials, reducing the chance of AMR pathogens strains developing in the population.

#### Prevention and diagnostic toolbox

Effective vaccination programs help keep livestock healthy and productive, which helps reduce the need for antibiotics. Availability of vaccines is not a guarantee for success though. Perfect management may not always avoid exposure to pathogens and a vaccine may not prevent every outbreak from occurring. This is why Boehringer Ingelheim offers a full suite of tools that can work alongside vaccination, such as early warning tools can help to identify the dynamics of a disease and enable initiation of the correct treatment.

For example, the 'SoundTalks' tool can measure coughing in a pig barn as an early indicator of Mycoplasma infections. This will be followed by an onsite diagnostics tool which can help obtain a fast detection of pathogens and diseases. This promotes quicker detection and more accurate treatment selection.

#### How does this address AMR and responsible use?

Prevention is key to reducing the need for antibiotics. When a bacterial disease is avoided, the need for antibiotic treatment falls. However, disease cannot always be prevented. Early detection tools can help stop bacterial disease before it spreads widely and increases the need for antibiotic treatments across a herd.

#### 'Time to Vaccinate' Campaign

The 'Time to Vaccinate' campaign is an initiative by Merck Animal Health, known as MSD Animal Health outside the US and Canada, intended to provide farmers with information and shared experiences about vaccination as a preventive tool. 'Time to Vaccinate' connects beef and dairy farmers who want to learn about vaccination for preventable diseases with farmers who've already adopted a preventive approach to managing their herds. The objective is to increase awareness and ultimately vaccination rates.

Time to Vaccinate is expected to increase the number of farmers and veterinarians who implement a preventative vaccination protocol on their farm which could lead to continuous improvement in overall animal health, well-being and productivity.

#### How does this address AMR and responsible use?

Increased implementation of vaccination programs, in conjunction with other farm management best practices such as quality nutrition, biosecurity, and animal handling, will help to prevent infectious diseases from negatively impacting ruminant health and productivity. Quality implementation of vaccination protocols may result in less bacterial infectious bacterial disease on farms and enhance antimicrobial stewardship.

#### Developing a vaccine against ileitis in swine

lleitis is a bacterial disease that infects the intestines of an animal. Once an animal is infected, an antibiotic is the only treatment. If untreated, ileitis can cause pain, suffering and even death for an animal.

In 2000, Boehringer Ingelheim developed a vaccine that could prevent ileitis. In the 20 years since then, more than 700 million pigs have been vaccinated against ileitis. Researchers have tracked field use of the ileitis vaccine and found evidence it reduces the need for antibiotics.

#### How does this address AMR and responsible use?

Vaccines against ileitis can reduce the need for antibiotic treatment in swine production by preventing the disease, while also increasing awareness of the need of preventive care.

#### Vaccines in Norwegian aquaculture

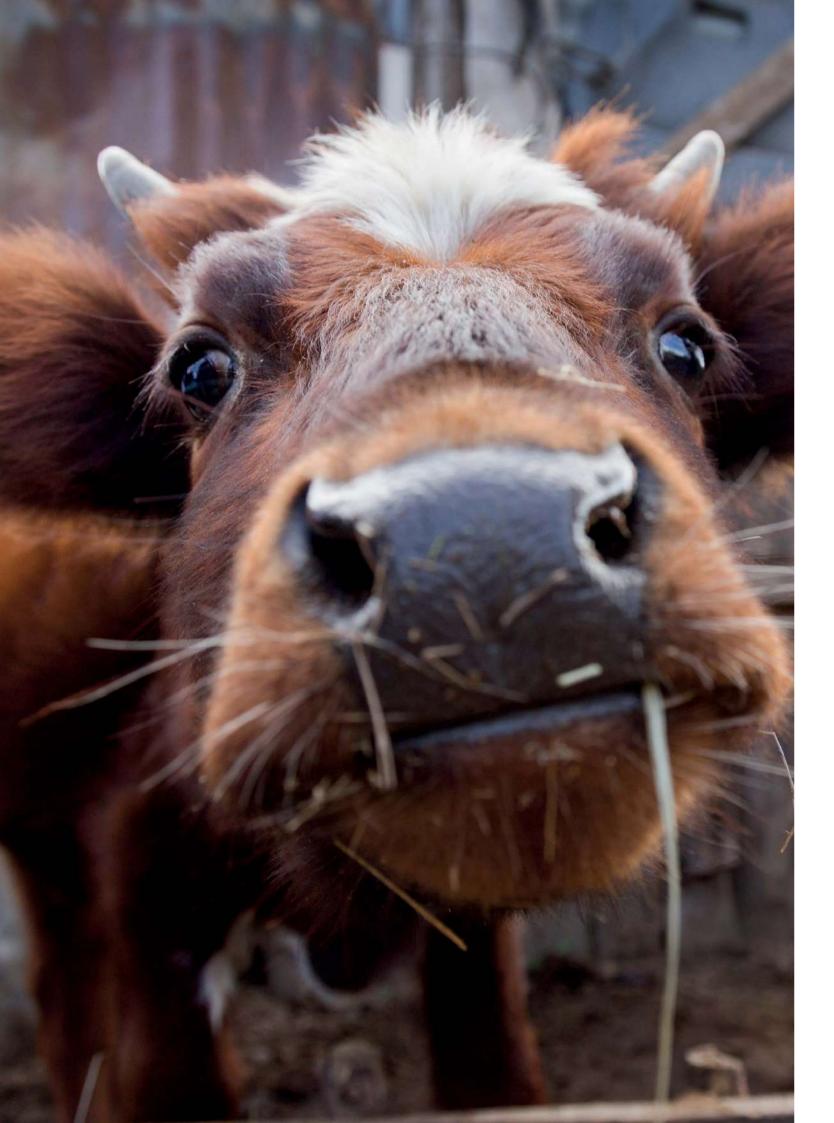
In the early 1990s, a vaccine against furunculosis – a salmon skin disease – was released by Pharmag. Later it was made effective against three types of vibriosis infections in addition to furunculosis. The vaccine enabled the aquaculture industry to shift from antibiotic treatments to prevention through routine vaccination.

#### How does this address AMR and responsible use?

Through the introduction of predictable vaccines, the Norwegian aquaculture industry has reduced its use of antibiotics by 99.8 percent per ton of trout and salmon produced, compared to 1987 level. Norwegian aquaculture also grew from 57,000 tons in 1987 to 1.25m tons in 2012.









## Principle 4:

## Invest in development of products for prevention and treatment

Selection of activities by HealthforAnimals Members

#### Alternative topical solutions to support innate immune system in dogs

Virbac recently developed a new technology based on plant extracts, (boldo and meadowsweet) which promotes natural secretion of antimicrobial peptides (AMPs) by keratinocytes (a cell type in the skin) that can treat bacterial infections, especially in atopic dogs. These AMPs naturally produced by the body were shown to also successfully treat resistant bacteria.

#### How does this address AMR and responsible use?

The use of topical therapies, especially in the case of superficial skin infections, can stimulate natural defences for treatment, which reduce the need for an antibiotic.

#### Developing diagnostics and monitoring tools

Boehringer Ingelheim has recently introduced two platforms that give farmers and veterinarians additional information to improve preventive healthcare.

SoundTalks is technology designed to detect early symptoms of respiratory disease. The system includes devices that continuously and objectively monitor the herd via automated analysis of sound. The devices are the 'ears – continuously listening to the pigs – and algorithms are the 'brain' – interpreting what is heard.

Mobinostics is a point-of-care system that can be operated on farm, from a veterinarian's vehicle or in clinic – reducing the need to ship samples to a central testing laboratory. Mobinostics is simple to use – no need for a trained lab technician – and will allow testing of various types of samples (e.g. nasal swabs, blood, oral fluids) for targeted diseases in less than 60 minutes.

#### How does this address AMR and responsible use?

Earlier detection of disease and rapid diagnosis mean farmers and veterinarians can intervene sooner, enabling an improved treatment response with the potential to shorten and reduce the number of treatments, including antibiotics.

#### **Education and Digital Tools**

Bayer encourages taking a practical and holistic approach to mitigating infectious diseases. Ongoing scientific and educational outreach to livestock professionals encompasses topics such as good biosecurity and the importance of detecting diseases early. Digital tools such as BCS Cowdition and BCS SowDition smartphone applications can help simplify accuracy and tracking of body condition scores for dairy cows and sows, respectively.

#### How does this address AMR and responsible use?

Better livestock management improves detection, control and treatment of bacterial disease, which can lead to fewer and more targeted antibiotic treatments.



#### Integrated Health Ecosystems for Precision Livestock Farming

Boehringer Ingelheim has recently launched an 'Integrated Health Ecosystem' central data-management platform that integrates technologies and tools within and across swine farms into one ecosystem. This system can provide better insights and decision-ready information to veterinarians and producers enabling them to take more informed decisions that increase health, performance and profitability. This approach brings together multiple technologies that can enable more effective monitoring and detection of diseases, fast diagnosis of causative agents, and precise intervention.

#### How does this address AMR and responsible use?

Effective utilisation of precision livestock farming enables earlier and more precise intervention and disease prevention plans, which can reduce the need for antibiotics. It also improves responsible use through improved effectiveness and continuous accountability where antibiotic use is needed for the well-being of animals.

#### Investment in new prevention and treatment tools

In its 2017/22 strategic plan, Vetoquinol plans to invest up to 20 percent of its R&D pot in tools that can reduce the need for antibiotics.

.....

This can include solutions that span across genetics, prevention, hygiene and biosafety, vaccines, immunostimulants and efficient diagnostics. This will target the use of antiinfectives still available for animal health and new targeted treatments that do not crossreact with critical antibiotics.

#### How does this address AMR and responsible use?

The innovations produced will either substitute or reduce the use of antibiotics.

#### Proteobiotic use in pigs and poultry

In 2018, Bio Agri Mix, a member of the Canadian Animal Health Institute (CAHI is an Association Member of HealthforAnimals), launched a novel proteobiotic for the Canadian livestock industry. Proteobiotics represent a new class of anti-virulent products providing an alternative to conventional antimicrobial preventative programs. More than 300,000 pigs have received preventative therapy with NUVIO to control E. coli K88 and the poultry sector has recorded rapid uptake for Necrotic Enteritis control.

.....

#### How does this address AMR and responsible use?

Through reducing the prevalence of animal disease and providing an alternative to antimicrobial use in the Canadian livestock industry, proteobiotics can reduce the need for antimicrobial use and the chance subsequent AMR strains emerge.

.....

#### Maintaining intestinal integrity in poultry flocks

With the growing consumer demand for lean protein that is produced without the use of antibiotics, Phibro Animal Health has worked to address gut health challenges in poultry raised without antibiotics. Such gut health problems are a major concern, as they often have an impact on animal welfare, product quality, and affordability.

Phibro's Magni-Phi helps maintain overall intestinal health in poultry, which may lead to a reduction in diseases and decrease the need for antibiotics. This natural product is made from quillaja extract and yucca powder and is listed by the Organic Materials Review Institute (OMRI).

#### How does this address AMR and responsible use?

Protecting and improving overall animal health bolsters an animal's natural defences against illness. When an animal can naturally fight off an infection, it reduces the need for animal antibiotics in the future.

#### Targeting improved nutritional health

In 2016, Elanco announced the creation of a nutritional health division, which focuses on functional nutrition products, including enzymes, probiotics and prebiotics, which impact animal microbiomes and other dietary factors to reduce disease incidence, improve gut health and enhance feed digestibility. The organization recently launched Correlink – a novel direct-fed microbial (probiotic) product outside the U.S - and announced a global, exclusive in-licensing agreement to launch an in-feed antibody product focused on reducing and controlling coccidiosis.

#### How does this address AMR and responsible use?

Improving nutrition bolsters an animal's natural defences against illness. When an animal can naturally fight off an infection, it reduces the need for animal antibiotics in the future.

#### Poultry immunostimulants to reduce E. coli incidence

Bayer's Victrio is an immunostimulant that stimulates the innate immune system in poultry, providing a rapid, nonspecific, protective response to infectious agents. This offers a non-antibiotic option to help reduce mortality associated with E. coli in embryonated eggs and newborn chicks. The treatment is registered in a number of countries including USA and Canada.

#### How does this address AMR and responsible use?

As a non-antibiotic option, Victrio can help poultry producers reduce the need for antibiotics when addressing the challenge of mortality associated with E. coli, especially in the early stages of life when chicks are highly susceptible to E. coli infections. Reducing antibiotic use at hatchery is an important step in reducing AMR in chickens.

#### R&D into new treatment options

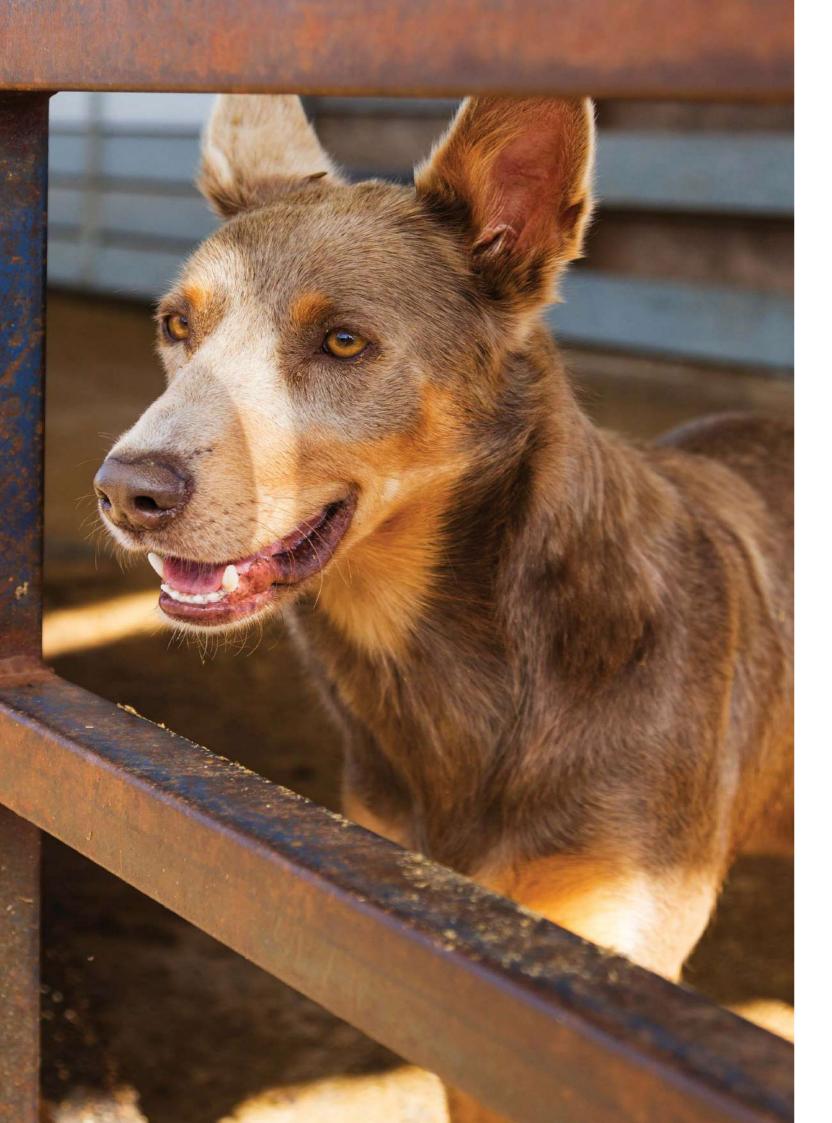
In 2018, Elanco Animal Health announced it was investing at least half of its food animal research and development budget in projects dedicated to developing alternatives to shared-class antibiotics. This builds off Elanco's 2015 'Eight-Point Antibiotic Stewardship Plan,' which restructured its work in this area, creating two new research and development teams focused on advancing antibiotic alternatives.

#### How does this address AMR and responsible use?

Providing alternative treatment options for farmers can help limit development of resistance in existing antibiotic treatments.









## Principle 5:

## Increase knowledge, transparency and communication

Selection of activities by HealthforAnimals Members

#### Educating consumers with ExploreAnimalHealth.org

Created by Phibro Animal Health, ExploreAnimalHealth.org is a website intended for consumers that delivers clear, credible and easily understood information about animal antibiotic use, vaccines, nutritional products and the One Health approach. The site features shareable content for use on websites and social media channels, infographics, blogs, resource links, and a video library.

#### How does this address AMR and responsible use?

Improving consumer understanding of animal antibiotic use and the challenges we face in tackling AMR helps them become advocates for responsible use.

#### Horizontal AMR transfer research

In 2018, Bio Agri Mix, a member of the Canadian Animal Health Institute (CAHI is an Association Member of HealthforAnimals), completed an initial AMR gene study in litter samples from 10 poultry production systems. Results are being used in follow-up research to further develop AMR gene PCR panels and create a pilot study in conjunction with the Chicken Farmers of Canada (CFC). While the project is still underway, initial results provided encouraging signs that the final research could assist veterinarians in making prudent antimicrobial decisions.

#### How does this address AMR and responsible use?

Monitoring AMR and transfer genes will enable veterinarians to make prudent antimicrobial use decisions without hampering animal welfare, thus reducing the potential for AMR strains developing in animals.

#### Monitoring antibiotic sensitivity in New Zealand

In 2017, Bayer introduced DairyAntibiogram, an antibiotic sensitivity test for mastitis bacteria on dairy farms, in New Zealand. The test is performed on bulk milk samples obtained directly from the milk processors. Armed with results of the DairyAntibiogram, dairy professionals have knowledge of the antibiotic resistance status of a herd, enabling them to better select the most effective, responsible and sustainable antibiotic treatment. The test now includes 10 antibiotics and a website for enhanced tracking and results management.

#### How does this address AMR and responsible use?

DairyAntibiogram equips dairy professionals with knowledge of the antibiotic sensitivity status of a herd and enables them to better select effective, responsible and sustainable antibiotic treatment for mastitis. This helps veterinarians ensure that they are using antibiotics in the most responsible and effective way possible, when needed. This subsequently reduces the risk of new AMR strains emerging in the animal population.



#### 'One Health Antibiotic Stewardship Summit'

In 2016, Elanco organized a 'One Health Antibiotic Stewardship Summit', convening more than 200 global animal protein industry leaders, including company chief executives and livestock owners, intergovernmental organizations, NGOs, and experts to discuss critical challenges. Topics included increasing global veterinary training and capacity, enhancing metrics and monitoring of responsible use globally increasing incentives for innovation and working to enhance predictability of regulatory pathways.

#### How does this address AMR and responsible use

Building momentum for One Health approaches to responsible use and AMR helps promote long-term, sustainable solutions. These issues cannot be solved by one sector, it requires communication across the full livestock value chain as well as with human health.

#### One Health education series on AMR

In 2018, Merck Animal Health, known as MSD Animal Health outside the US and Canada, in partnership with the National Institute for Animal Agriculture (NIAA), initiated the One Health educational series. This is a video series that explores AMR and the collaborative efforts between ranchers, animal health and human health experts to address the issue. The series continues in 2019.

#### How does this address AMR and responsible use?

Through education and increased understanding of the challenges producers face related to the prevention and treatment of animals, the proper use of antibiotics can be better implemented.

#### Pradofloxacin sensitivity discs

Since 2015, Bayer Inc. has provided Pradofloxacin sensitivity discs free of charge to any Canadian diagnostic laboratory or veterinary clinic conducting culture and sensitivity testing.

#### How does this address AMR and responsible use?

Accurate culture and sensitivity testing helps ensure the selection of the most effective antimicrobial for the pathogen being tested. This improves treatment outcomes, reduces the chance of relapses and reduces the potential for selecting resistant bacteria.

#### PROHEALTH Consortium

The PROHEALTH Consortium was a collaboration between 22 academic, industry and private enterprise organisations - including HealthforAnimals Members - from 11 countries to explore new ways to ensure the sustainability of modern animal production.

The project focused on disease threats associated with the intensity of production in swine herds and poultry flocks. It recommended innovative prediction, prevention and detection solutions to improve animal health and increase productivity, while limiting environmental impact and preserving profitability for livestock farmers.

The project presented scientific evidence about the multifactorial dimension of animal pathologies linked to modern farming.

The findings of PROHEALTH's research addressed these issues and provided the foundations for practical guidelines to help farmers.

#### How does this address AMR and responsible use?

Through comprehensive research on pressing issues pertaining to farming practices, antimicrobial usage, and AMR, the PROHEALTH Consortium provided steps that policymakers, researchers, and farmers could undertake to mitigate the development of AMR strains and promote responsible use of antimicrobials.

#### Research antibiotic treatments in canines

Otitis externa is an inflammation of the ear canal and/or pinnae, and can represent up to 20 percent of consultations in dogs. Acute otitis externa management is often handled through topical treatments which comprise a mixture of corticosteroids, antibiotics and antifungal molecules.

Frequent recurrences and use of antibiotics to treat it may lead to resistance, so, identification of the underlying cause is key to decrease frequencies of flare ups.

Virbac has collaborated with ONIRIS veterinary school to gather recent epidemiologic data regarding microbial identification and their sensitivity to antibiotics in otitis externa cases. This will result in academic papers and clinical studies, which will explore if an ear cleanser - either alone or coupled with the right antimicrobia - could better treat, cure and prevent recurrence of otitis with Pseudomanas spp.

#### How does this address AMR and responsible use?

Reducing the recurrence of chronic otitis externa may decrease the use of antibiotics to treat those otitis cases, which is cases frequently associated with resistant Pseudomonas aeruginosa

#### Monitoring antibiotic susceptibility of pathogens in livestock.

The antibiotic susceptibility monitoring programs of CEESA are an ongoing collaboration among veterinary pharmaceutical companies for twenty years.

CEESA conducts two types of monitoring: the EASSA program, which collects zoonotic and commensal bacteria at slaughter from healthy food-producing animals, and the target pathogen programs (VetPath, MycoPath and ComPath), which collect bacterial isolates from diseased animals prior to antibiotic treatment.

The latter programs are the only long-standing pan-European projects in veterinary medicine where antibiotic susceptibility data for a large variety of target pathogens are generated.

Through valuable support by external laboratories and veterinary practitioners, CEESA has meanwhile generated a collection of more than 55,000 non-duplicate bacterial isolates.





#### How does this address AMR and responsible use?

Understanding the evolution of pathogens and their susceptibility to treatment is essential to the long term efficacy of antibiotics. It allows veterinarians, farmers and medicine manufacturers to adapt protocols to limit resistance development.

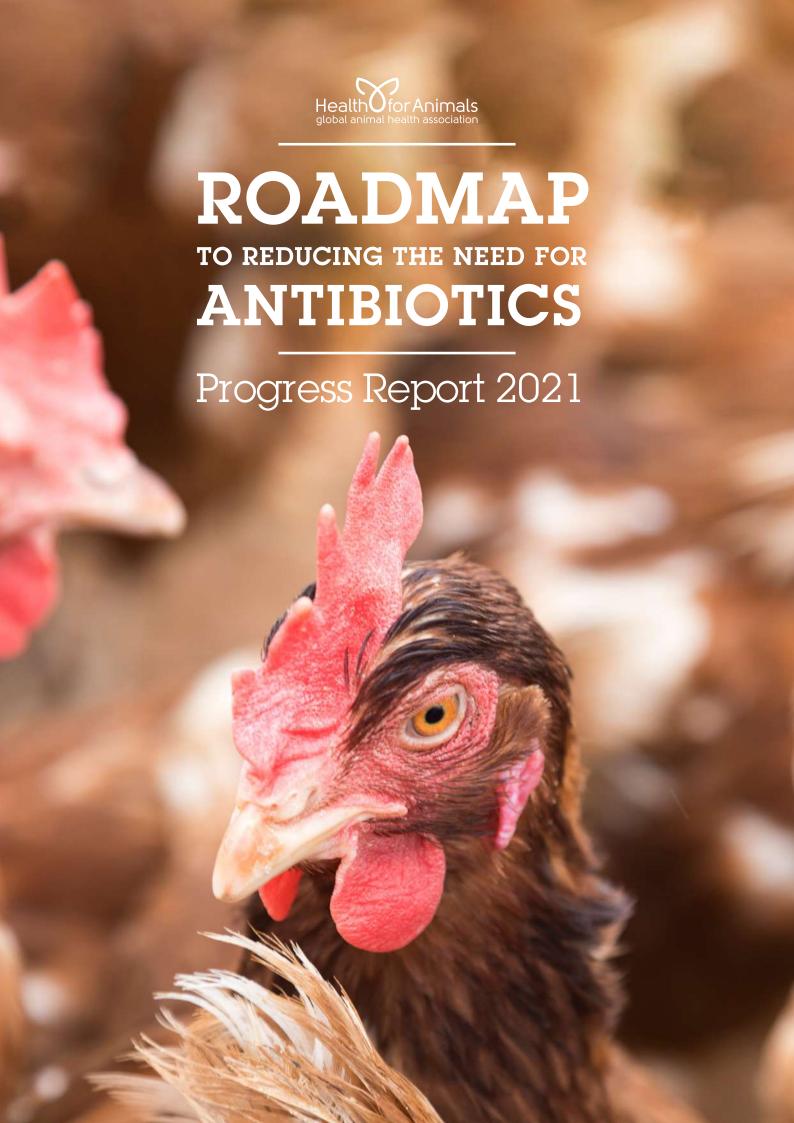
The list of activities in this section are only a selection of the work by HealthforAnimals members.

To discover more materials, such as our Antibiotics Commitment, or request information about a specific activity listed above visit **HealthforAnimals.org** or contact us at **info@HealthforAnimals.org** 









#### Introduction

In August 2019, HealthforAnimals published the 'Roadmap to Reducing the Need for Antibiotics', a strategy for addressing antimicrobial resistance and improving responsible use. It was undersigned by the world's largest animal health companies and demonstrated a unified approach to a global challenge.

The Roadmap offered a vision for decreasing disease levels, reducing the need for antibiotics and preserving welfare by fundamentally improving how we care for animals. It called for greater commitments to veterinary access, farmer training, AMR monitoring, vaccine development and more.

The objective was to build upon actions seen in recent years, such as:

- Sales Reductions: Antimicrobial sales declined by 34% in the EU<sup>1</sup> since 2011, 38% in the U.S.<sup>2</sup> since 2015 and over 50% in the UK<sup>3</sup> since 2014. However, sales are a flawed mechanism for surveillance. It is essential to also track how this affects actual human resistance levels and recognize it will only be effective with complementary actions in human health.
- **Increased Training:** HealthforAnimals Members have created major programs to educate veterinarians in responsible medicine use, such as a new collaboration between HealthforAnimals, the World Veterinary Association and the UNFAO's EUFmD Program to train para-professionals in Africa.
- Coordinated Action: Coalitions such as the UK's Responsible Use of Medicines in Agriculture Alliance or the EU's Platform for Responsible Use of Medicines in Agriculture have been in place for decades. These coalitions bring together farmers, veterinarians, research, retail, etc. to deliver improvements in responsible use, a unique approach that has not been replicated in human health.
- **Greater Prevention:** Adoption of prevention technologies like vaccines, nutrition supplements and more have been significantly rising in recent years. For instance, the market share for vaccines rose 22.5% in the EU from 2015-2020.4

The Roadmap offered four areas for public sector action (Regulation, Consumer Acceptance, Funding for Livestock and Access to Veterinary Expertise), and a list of 25 actions the Animal Health sector committed to completing by 2025. This Progress Report outlines the Animal Health sector's success and work to-date on our Roadmap Commitments.

Overall, all Commitments are on track for completion by 2025 and some are well ahead of schedule. As a result, the sector is evaluating how it can push itself and expand these Commitments even further in coming years.

In 2019, HealthforAnimals Members set 25 Commitments for the sector to undertake by 2025 to help improve responsible use and address AMR. All but one are either on track, ahead of schedule or already completed. These include results like, at least:



**49** out of **100** new vaccines delivered



657,000 veterinary professionals indirectly trained



**US\$6.7M** in veterinary scholarships, exceeding our US\$5M goal

This Progress Report provides an update on all 25 Commitments. Another version will be published in 2023.

<sup>4</sup> European Animal Medicines Industry in Figures, https://figures.animalhealtheurope.eu/



<sup>1</sup> Sales of veterinary antimicrobial agents in 31 European countries in 2018, European Medicines Agend

<sup>2 2019</sup> Summary Report On Antimicrobials Sold or Distributed for Use in Food-Producing Animals, U.S. Food and Drug Administration

<sup>3</sup> UK VARSS 2019, UK Veterinary Medicines Directorate

#### Our commitments to

## Research & Development

If we are to continue to maintain and improve animal health as well as reduce the need for antibiotics, we will need new innovation. HealthforAnimals Members made the following five commitments in our Roadmap to Reducing the Need for Antibiotics to advance our R&D between 2019 and 2025.

Invest at least \$10 billion in research and development<sup>1</sup>

Progress: at least 3.17B has been invested to-date

\$3.17B

On track

Deliver at least 100 new vaccines<sup>2</sup>

Progress: 49 vaccines delivered to-date

49 out of 100

Ahead of schedule

Deliver at least 20 new diagnostics tools

Progress: 17 delivered to-date

17 out of 20

Ahead of schedule

Deliver at least 20 new nutritional enhancement products

Progress: 7 delivered to-date

7 out of 20

On track

8 out of 30

Deliver at least 30 other products that can reduce the need for an antimicrobial by reducing animal stress or boosting the natural immune system

On track

▶ Progress: 8 delivered to-date

<sup>1</sup> This figure represents only R&D investment in traditional medicines (pharmaceutical and biologics) and is likely an underrepresentation. Future progress reports will seek to capture new non-traditional areas such as products and services.

<sup>2 22</sup> specifically address bacterial disease while others address other issues like viral illness that can lead to or exacerbate secondary bacterial infections.

Deliver new tools that reduce the likelihood of human exposure to a resistant pathogen such as Salmonella, Campylobacter, or E. Coli

▶ Progress: HealthforAnimals Members offer a wide range of tools that can help protect the public against exposure to resistant bacteria from animals.

#### On track

#### Tools offered by HealthforAnimals Members included:

- Animal vaccines against zoonotic public health threats like salmonella, e.coli and campylobacter;
- Nutritional products that help reduce the presence of clostridia in the gut;
- Sensitivity tests that reduce chances of resistance development when antibiotics are needed;
- Diagnostic tests to accurately detect bacterial infection and support swift treatment.

Conduct an AMR risk analysis for every new antibiotic brought to market

On track

▶ Progress: HealthforAnimals Members introduced three new antibiotics to the market in the past two years.³ Each received an AMR risk analysis prior to market introduction.

<sup>3</sup> This does not include generics as these are not new antibiotic formulations or APIs.

Strengthen communications on benefits of biosecurity, in-feed supplements, vaccinations, and products that support good animal health

▶ Progress: All HealthforAnimals Members offered robust communications campaigns and materials on the value of preventative care in animal health over the past two years.

#### On track

#### Types of HealthforAnimals Member Communications included:

- Boehringer Ingelheim's ADVANCE study on the value of vaccination to increased production
- Ceva's series on the value of vaccination at TogetherBeyondAnimalHealth.com
- Elanco's 8-point antibiotic stewardship plan
- IDEXX's social media toolkits and opinion articles
- Merck Animal Health's 'Time to Vaccinate' program

- Phibro's robust 'Phibro Academy Program' that provides guidance on prevention
- Virbac's 2020 Annual Report highlighting work on alternatives to antimicrobials
- Zenoaq's analysis of the value of biosecurity
- Zoetis' 2020 Sustainability Report outlining a preventive approach to animal health and AMR.

Participate in forums and public dialogues to help build understanding of risks, benefits, and actions that different stakeholders can take to improve public health outcomes in the fight against AMR

▶ Progress: HealthforAnimals Members have been active and vocal in forums across the globe, even during the pandemic, promoting the need for One Health collaboration, antibiotic stewardship, strategies for reducing antibiotic need in animals.

#### On track

#### Major forums where HealthforAnimals Members spoke included:

- 2020 World Health Summit
- French government's One Health Forum
- U.S. Presidential Advisory Council for Combatting Antibiotic Resistance
- World AMR Congress

- United Nations One Health Global Leaders Group
- AMR Action Fund
- Forbes AgTech Summit



Issue regular report(s) and/or white paper(s) identifying barriers to adoption of prevention tools (e.g. vaccination, biosecurity, etc) and how they can be addressed

#### On track

#### Progress:

- In November 2019, HealthforAnimals published a comprehensive report entitled "How to Increase Animal Vaccination," outlining the systemic economic, political, technical, regulatory, practical, and social barriers facing greater adoption of these medicines.
- In 2021, HealthforAnimals published "New Frontiers in Animal Care: The Innovations Shaping the Future". The report explained how new technologies like digital innovation could improve veterinary care and the steps necessary to accelerate adoption.



#### Issue Roadmap Updates in 2021 and 2023

#### On track

▶ Progress: This Progress Report offers a valuable update for stakeholders and a second version is still planned in 2023. Furthermore, HealthforAnimals published French and Spanish translations of the original Roadmap in 2020.







#### Provide clear labels on every, single product

#### On track

▶ Progress: All HealthforAnimals Members provide comprehensive labels on every medicine sold. Labels will differ depending upon the market and regulatory requirements, but the common goal is to provide clear information to the end user.

## Information on labels provided by HealthforAnimals Members include information such as:

- 'Indications of use': The situations and diseases where the medicine is approved for use.
- Dosage and Administration:
   Detailed instructions for how to administer the medicine effectively.
- 'Adverse Reactions': List of possible side effects from a medicine that should be monitored.
- Withdrawal Periods: Amount of time a farmer must wait after administering the medicine before slaughter.

- Pharmacology: Clinical explanation of how the medicine functions, efficacy levels, etc.
- Precautions/Warnings: Cautions for the user (e.g. Not for Human Use) and information on what to do in case of an accident (e.g. accidental human injection).
- Contact: Contact information for the manufacturer to report adverse events or other issues.

Note: this is not an exhaustive list and product labels may include other details.

#### Make technical guidance available to all product users

#### On track

▶ Progress: All medicines sold by HealthforAnimals Members include detailed guidance on the label and accompanying materials. Furthermore, contact information is available on the label to seek additional detail as needed. Other animal health products such as diagnostics and monitoring technologies also include clear instructions on proper use of the product for accurate results.

## Train more than 100,000 veterinarians in responsible use of medicines

▶ Progress: HealthforAnimals Members directly trained over 37,000 veterinarians in the past two years through various partnerships and initiatives. Through 'Train the Trainer' style programs, an additional 650,000+ veterinarians have received valuable instruction on disease control and responsible medicine use.

Direct Training 37,000 out of 100,000

Indirect Training

657,000 veterinary professionals

On track

## Undertake at least 15 veterinary training partnerships

▶ Progress: HealthforAnimals Members undertook at least 25 veterinary training partnerships in the past two years. These activities spanned geographies as diverse as China, USA, Bangladesh, Ethiopia, Spain, Australia and more. Partnerships delivered on-the-ground results in regions where veterinary expertise is often lacking.

25 veterinary training partnerships undertaken, exceeding our target of 15

Ahead of schedule

## Invest at least \$5 million in veterinary education scholarships and grants

▶ Progress: HealthforAnimals members provided over US\$6.7 Million in scholarships and grants in 2020 and 2021.

#### \$6.7 Million

Ahead of schedule

Deliver a white paper on opportunities in telemedicine for improving access to veterinarians in high-income and low- and middle-income nations

#### On track

▶ Progress: HealthforAnimals published new data on the use of telemedicine during the pandemic in 2020 and expects to further research this topic in the coming years.





## Participate in responsible use coalitions in major markets

#### On track

Progress: HealthforAnimals Members continue to be active in coalitions such as the UK's Responsible Use of Medicines in Agriculture Alliance (RUMA), the European Platform for the Responsible Use of Medicines in Animals (EPRUMA), and Brazil's Aliança. In markets without a formal coalition, Members often still work closely with the value chain through direct relationships and informal working groups.







## Share sales data in every market where it is required

#### On track

▶ Progress: HealthforAnimals Members continue to meet their regulatory requirement to supply sales data in various markets. These show sharp reductions in recent years such as:

UK: 50% reduction since 2014

USA: 38% since 2015EU: 34% since 2011France: 53% since 2011

Sales data is a flawed mechanism for surveillance though. HealthforAnimals and Members support tracking resistance itself to provide more actionable data.

#### Recent Antibiotic Sales Reductions by Market

50%

38

34%

53%

The Animal Health sector is taking valuable action to promote responsible use of antibiotics. However, sales data does not indicate whether AMR is rising or falling; only testing for resistance itself can achieve this. Actions by Animal Health can also only be truly impactful if accompanied by complementary steps in human health.



Undertake five new partnerships that deliver products that help to reduce the need for antibiotics in underserved markets

#### On track

Progress: HealthforAnimals

Members have undertaken at least
5 new partnerships in the past two
years that are delivering products to
underserved markets.

#### Partnerships undertaken by HealthforAnimals Members include:

- 'Village Poultry Project', offering tools and training to smallholders in East Africa.
- ALPHA Initiative, which aims to improve access to quality veterinary medicines and services in Africa.
- Partnership with Cowtribe, a Ghana startup that distributes medicines in rural regions.
- PREVENT Project, a partnership to provide vaccinated chicks to hatcheries across eight African countries.
- East Africa Growth Accelerator, helping farms in East Africa access quality medicines tailored to smallholders.

## Conduct at least 50 audits of active ingredient suppliers to ensure they are meeting appropriate standards

#### Ahead of schedule

▶ Progress: HealthforAnimals Members have undertaken at least 206 audits of active ingredient suppliers in the past two years.



## Encourage medicine users to submit efficacy reports into pharmacovigilance monitoring systems

#### On track

▶ Progress: All HealthforAnimals Members operate pharmacovigilance monitoring systems, which include details information on how users can submit reports.





## Provide research grants of at least \$1 million

▶ Progress: HealthforAnimals Members have provided at least US\$7.9 million in research grants over the past two years, well exceeding our Commitment. This has funded research into antibiotic alternatives, resistance surveillance, antimicrobial susceptibility monitoring, medicine effectiveness and more.

**\$7.9M** in research grants provided, exceeding our **\$1M** goal

Ahead of schedule

Publish new, scientific research within peer-reviewed publications which improves understanding of veterinary pathogens or antimicrobial resistance

#### On track

▶ Progress: HealthforAnimals Members published at least 29 articles over the past two years across a variety of peer-reviewed publications such as Journal of Livestock Medicine, Viruses, Microbiome, and Scientific Reports. Topics included new methods of bacterial infection diagnosis, antimicrobial susceptibility, antimicrobial alternatives and more. A full list of publications is available upon request.

Provide data and support to help improve disease tracking to organizations such as the World Organisation for Animal Health (OIE)

#### On track

▶ Progress: HealthforAnimals is an active supporter of the World Organisation for Animal Health and maintains an ongoing Memorandum of Understanding (MoU) that calls for collaboration on "responsible and prudent use of antimicrobials...with the aim of tackling resistance and maintain efficacy." HealthforAnimals Members also support national, regional and global surveillance efforts. For example, one Member currently operates the longest continuous AMR surveillance program in North America, while many Members contribute to CEESA resistance monitoring programs.



#### Looking Ahead

Our Roadmap to Reducing the Need for Antibiotics offers a clear vision for improving global animal health both in the steps HealthforAnimals and our Members pledge to undertake, and in the areas where we call on others to take action and support this goal. HealthforAnimals Members have made significant progress on the Commitments we made within the Roadmap and are determined to fulfil or exceed all by 2025.

We encourage others in the public sector, international organisations, human health sector, or any other institution that can affect positive change to join us by making measurable One Health commitments to tackling AMR and improving responsible use. Together, we can ensure antibiotics remain a powerful tool in global human and animal health for years to come.





















#### **Data Notes**

Information in this report was collected in summer 2021. It reflects HealthforAnimals Member Company activities between November 2019 (the original Roadmap Launch) and this collection date. Data was submitted confidentially by HealthforAnimals Member Companies to the Association for aggregation and presentation fully in accordance with data privacy and anti-trust considerations.

#### 全球動物衛生協會負責任使用抗生素之五大原則

- 原則1:透過防疫一體策略保護動物健康及福祉
  - 1. 行動措施:協會將透過提供等同人用之高品質動物健康醫療產品,以保護動物及符合道德條件要求。在處理 AMR 議題方面,協會將強化動物健康醫療公司、農戶及獸醫師、零售商、主管機關及協會之間的合作。協會將找尋新方案及想法,並公開給其他人,以加入此行動措施。

#### 2. 協會會員的工作:

- (1)與泛美衛生組織基金會 (Pan American Health Organization Foundation)合作,支持拉丁美洲國家建立行動方案以對抗 AMR,符合世界衛生組織 (World Health Organization)重要的工作目標。
- (2)建立「負責任使用動物用藥品」之歐洲平台,以串聯農戶、 獸醫師、藥劑師及藥品製造業者等共同發展合作方案。
- (3)直接與超過 130 個國家的動物用藥品使用者合作,以建立 關係及提供專業指引。
- 原則2:謹慎並負責任地使用抗生素
  - 1. 行動措施:推廣使用治療用抗生素的方式,套句諺語「儘可能少用、必要時才用(As little as possible, as much as necessary)」,協會將持續透過明確標示及良好的技術意見,推廣謹慎並負責任使用抗生素。協會建議抗生素應在獸醫師的監督下使用及取得。針對獸醫師人力不足的國家,處理此問題之前,強制執行此措施,以免動物受苦。協會將鼓勵投資以提供更好的動物醫療照護。協會主動參與推廣負責任使用抗生素的原則及措施。

#### 2. 協會會員的工作:

(1) 訂定「合理使用抗微生物藥品指引」(Guidance for the Rational use of AntiMicrobials, GRAM),由獨立的專家學者 訂定一份全球指引資料。在管理抗藥性議題方面,此指引提供重要意見,改善診斷及治療。

- (2)透過產品標示用法用量、停藥期等注意事項,訓練動物用 藥品使用者負責任使用抗生素。
- (3)透過學術研究及補助計畫投資數百萬美金於下一個世代 獸醫師,包含美國、非洲、中國及其他國家/區域。
- 原則3:推廣疾病預防;增加農民取得動物醫藥專業知識之管道。
  - 1. 行動措施:透過分享專業知識給養殖生產者,協會推廣涉 及疾病預防的畜牧產業技術。協會承諾持續改善疫苗的取 得性。協會將尋找價格平易近人、容易取得的產品,以對 抗違法、品質低劣及偽造之產品,並持續教育宣導使用這 些產品的危險性。協會提倡增加開發中國家之獸醫師人力。

#### 2. 協會會員的工作:

- (1)推動新的應用軟體,幫助任何區域的養殖生產者優化 其牧場的免疫注射、疾病辨別及建立預防策略。
- (1)與比爾與美琳達·蓋茲基金會 (Bill & Melinda Gates Foundation)合作,於非洲及東南亞訓練新進獸醫師、 研發診斷網絡及增加基礎建設。
- (2)為對抗偽藥,與政府單位合作制定新包裝,以警告養殖生產者使用違反藥品的風險。
- 原則 4:投資預防及治療疾病之產品
  - 1. 行動措施:協會將投資新產品,以減少對抗生素的依賴。身為動物健康醫療公司,協會將每年營收的 6~9%,投資於新型產品、診斷劑、基因學產品及已存在產品的運作管理。全球每年動物健康醫療領域的收入估計約為 300 億美元。假設非為協會成員公司亦投資類似的比例,則等同於每年投資 18~28 億美元,用於食用動物及伴侶動物之疾病預防及治療技術。協會鼓勵政府機關:(1)增加新技術發展的誘因。(2)推動法規適用所有產品(3) 鼓勵增加疫苗接種率(Uptake of vaccination)(4)支持獸醫師人力資源。

#### 2. 協會會員的工作:

- (1)首次建立一種新型技術,係針對特定動物族群的客製化疫苗(Herd-specific custom vaccines for animals)。此針對特定動物的疫苗可提供有效保護。
- (2)研發營養補給品,增強動物的先天性免疫系統,以降低疾 病發生及抗生素需求。
- (3)引進新型,僅動物用之抗生素,供獸醫師處理疾病,並且 不會造成人類疾病抗藥性的風險。
- 原則 5:增加專業知識、資訊透明度與溝通交流
  - 1. 行動措施:協會支持以科學實證為基礎的解決方案。許多動物 健康醫療公司已著手進行 AMR 研究,而協會支持其研究。協 會將持續參與國家及國際抗生素使用量資料收集。協會將鼓勵 養殖生產者及藥品販賣業者,使無抗生素飼養生產對動物健康 及福利的影響透明化。協會將針對負責任使用抗生素、疫苗免 疫及其他預防措施,努力進行溝通交流,並持續提供疾病管理 方面的意見給消費者。

#### 2. 協會會員工作:

- (1)持續進行抗生素調查,例如歐洲藥品管理局(EMA)的 ESVAC 報告 (European Surveillance of Veterinary Antimicrobial Consumption Report, ESVAC report)。
- (2)建立網站工具及訓練第一線代表協會之人員整合分析預 測疾病之風險、改善預防措施及針對特定牧場設計永續方 案。
- (3)與研究組織及大學合作,以更加瞭解 AMR,另經費資助 AMR 食媒病原研究計畫。





**Principle 1:** Protect animal health and welfare in a unified One Health approach.

Actions: We will meet the ethical requirement of protecting animals by providing animal health products of the same high quality as products developed for people. In addressing antimicrobial resistance, we will take a One Health approach to cooperation, equally considering human and animal health, and environmental impact. To address AMR, we will strengthen partnerships between animal health companies, farmers, veterinarians, retailers, authorities and associations. We will reach out to seek new solutions and ideas and are open to explore joint actions with others.



**Principle 2:** Use antibiotics judiciously and responsibly.

Actions: We promote the use of antibiotics for therapeutic reasons. Under the adage "as little as possible, as much as necessary", we will continue to promote responsible/judicious use by providing clear labels and good technical advice. We recommend antibiotics be used under veterinary supervision where available. In countries that lack veterinary capabilities, imposing this requirement before addressing the shortage of veterinarians condemns animals to unnecessary suffering. We will increase our efforts to encourage investment in better access to veterinary care. We actively contribute to the promotion of responsible use principles and practices in national responsible use coalitions.



**Principle 3:** Promote disease prevention and increased access to products and expertise.

Actions: We promote animal husbandry techniques that contribute to disease prevention by sharing our knowledge with producers. We commit to continuing to improve availability of vaccination. We will seek maximum access and affordability of legitimate products to counter the use of illegal, low quality and fake products in some markets, and contribute to education and training on the dangers of their use. We will advocate for programs to increase the number of veterinarians in developing countries.



**Principle 4:** Invest in development of products for prevention and treatment.

Actions: We will invest in new products that reduce reliance on antibiotics. As animal health companies we will invest between 6%-9% of our annual turnover in the development of new products, diagnostics, genetics and life-cycle management of existing products. Global annual animal health sector revenues are estimated at US\$30 billion. Assuming companies not part of HealthforAnimals also invest a similar percentage, this equates to an annual investment of US\$1.8 - 2.7 billion for prevention and treatment options for food and companion animals. Investment at these levels for new solutions is commercially viable only if rising cost factors like regulatory cost are reduced. We encourage governments to: increase incentives for new technological advances, facilitate regulatory pathways for all types of products, encourage increased uptake of vaccination, and support availability and access to veterinarians.



**Principle 5:** Increase knowledge, transparency and communication.

Actions: We support science and evidence-based solutions. Many animal health companies undertake scientific research into AMR pathways, and we support other groups in their research. We will continue to contribute to the collection of national and international antibiotic use data. We will encourage producers and retailers to be transparent about animal health and welfare impacts resulting from antibiotic-free production practices. We will increase our communications efforts about responsible use, vaccination and other prevention methods, while continuing to provide data and advice to our customers on managing diseases.

This Commitment is managed by HealthforAnimals, the global animal medicines association, and our Members. Other organizations or companies are encouraged to join us in affirming these principles.

Contact info@HealthforAnimals.org to learn how to join the Commitment and become a signatory.



#### HealthforAnimals Member Companies:



















#### HealthforAnimals Member Associations:



Argentina:	Caprava	
Australia:	Caprove	
	Animal Medicines Australia	
Belgium:	PHARMA.BE	
Brazil:	Sindicato Nacional da Industria de Produtos Para Saude Animal (SINDAN)	
Canada:	Canadian Animal Health Institute	
Chile:	Association Gremial de Laboratorios de productos Veterinarios	
Denmark:	Danish Association for the Veterinary Pharmaceutical Industry	
France:	Syndicat de L'industrie Du Médicaments et Reactif Veterinaires (SIMV)	
Germany:	Bundesverband Für Tiergesundheit (BfT)	
Europe:	AnimalhealthEurope	
India:	Indian Federation of Animal Health Companies (INFAH)	
Indonesia:	Indonesian Veterinary Drugs Association	
Ireland:	Animal and Plant Health Association (APHA)	
Italy:	Italian Animal Health Association (AISA)	
Japan:	Japan Veterinary Products Association (JVPA)	
Korea:	Korean Animal Health Products Association (KAHPA)	
Mexico:	Industria Farmaceutica Veterinaria, Canifarma	
Netherlands:	Fabrikanten en Importeurs van Diergeneesmiddelen (FIDIN)	
New Zealand:	Association for Animal Health and Crop Protection (AGCARM)	
Paraguay:	Cámara de Especialidades Veterinarias del Paraguay	
Portugal:	Apifarma	
South Africa:	South African Animal Health Association	
Asia:	Asian Animal Health Association	
Spain:	Veterindustria	
Sweden:	Läkemedelsindustriföreningen (LIF)	
Switzerland:	Scienceindustries	
Thailand:	Thai Animal Health Products Association	
United Kingdom:	National Office of Animal Health (NOAH)	
United States:	Animal Health Institute (AHI)	

#### **Other Animal Medicines Associations:**

Greece:	HAVEPHARM	
Finland:	Finnish Veterinary Pharma Association (FVPA)	
Poland:	Polish Association of Producers and Importers of Veterinary Medicinal Products	
Czech Republic:	Czech and Slovak Association of Veterinary Pharmaceutical Companies (CSAVP)	
Slovakia:	Czech and Slovak Association of Veterinary Pharmaceutical Companies (CSAVP	
Hungary:	HAIVPMR	
Norway:	Norwegian Association of Pharmaceutical Manufacturers (LMI)	

#### Other Companies and Organizations:

Biogenesis	
Colorado Serum Company	
Coveli	
Des-Vet Productos Vet	
Dopharma	
IDT BIOLOGIKA	
Jurox	
Kyoritsu Seiyaku	
Laboratorio Bio-Vet	
LABORATÓRIO Productos Vet	
Nippon Zenyaku Kogyo (Zenoaq)	
Pharmaxim	
Orion	
Ourofino	
UZINAS CHIMICAS BRASILEIRAS	
\/ata:I	

#### Support from the Veterinary Community:



Statement from World Veterinary Association:

The World Veterinary Association (WVA) represents around 500,000 veterinarians around the world. WVA commends HealthforAnimals for the development and launch of the Global Animal Health Sector Antibiotic Commitment WVA supports the initiatives and actions set out in the Commitment; they are in line with the WVA position on responsible use of medicines. WVA wishes HealthforAnimals much success in its endeavors to decrease the development of antimicrobial resistance.

Veterinarians play a primary role in assessing animal health, making a diagnosis, and recommending effective care programs including the use of antimicrobials which must be under veterinary care with a valid veterinarian-client-patient relationship.

#### The WVA position highlights the global basic principles of antimicrobial use such as:

- Therapeutic antimicrobials are licensed or registered for the purposes of disease treatment, control, and prevention.
- The availability of antimicrobials should be based on risk/benefit analysis that considers the importance of the antimicrobial to both veterinary and human medicine.
- Codes of good veterinary practice, quality assurance programs, herd health control and surveillance programs, and education programs should promote the responsible and prudent use of antimicrobials.
- Therapeutic antimicrobials should be used for as long as needed but for the shortest duration necessary, and at the appropriate dosage.



Statement from the World Small Animal Veterinary Association (WSAVA):

The World Small Veterinary Association (WSAVA) represents 200,000 veterinarians worldwide. Based on our active involvement in One Health and the recognition that AMR is very much a One Health issue within which companion animal practice shares responsibility for proper antimicrobial stewardship, the WSAVA endorses the HealthforAnimals antibiotic commitment, and looks forward to working collaboratively to realize its goals.





The Animal Health sector's 'Commitments and Actions on Antibiotics Use' lays out our five key principles for responsible use of antibiotics. However, a Commitment is only as effective as the work behind it.

For each principle, our Members are taking clear, concrete steps to ensure we are living up to the standards set out in our commitment.



**Principle 1:** Protect animal health and welfare in a unified One Health approach.

#### **Our Members' Work:**

- Partnering with the Pan American Health Organization Foundation to support countries in Latin America in creating action plans to combat AMR in line with the World Health Organization's key pillars.
- Building a 'European Platform for Responsible Use of Medicines in Animals' that brings together farmers, veterinarians, pharmacists, manufacturers and more to develop collaborative solutions.
- Working directly with users of veterinary medicines in over 130 countriesto build strong relationships and provide professional guidance.



**Principle 2:** Use antibiotics judiciously and responsibly.

#### **Our Members' Work:**

- Creating GRAM (Guidance for the Rational use of AntiMicrobials), a comprehensive, 500-page global guide to responsible use created by independent experts. The guide improves diagnosis and treatments while providing key advice on managing resistance.
- Training veterinary medicines users in responsible antibiotic use supported by detailed product labels outlining dose, withdrawal periods, and more.
- Investing millions in the next generation of responsible veterinarians through scholarships and grant programs in the U.S., Africa, China and elsewhere.



**Principle 3:** Promote disease prevention and increased access to products and expertise.

#### **Our Members' Work:**

- Launching new apps that help producers in any region optimize vaccinations, identify disease and create prevention strategies specific to their farm.
- Partnering with the Bill and Melinda Gates Foundation to train new veterinarians, develop diagnostic networks and bolster infrastructure in Africa and Southeast Asia.
- Creating new packaging to thwart counterfeiters and working with national governments to warn producers of the risks of illegal medicines.



**Principle 4:** Invest in development of products for prevention and treatment.

#### **Our Members' Work:**

- Creating first-of-its kind, new technologies that allow for herd-specific custom vaccines for animals. These provide effective care targeted to specific animals.
- Developing nutritional supplements that bolster an animal's natural immune system, which can reduce disease and decrease the need for antibiotics.
- Introducing new, animal-only antibiotics that offer veterinarians a way
  to tackle disease that pose virtually no risk of contributing to resistance
  in humans.



**Principle 5:** Increase knowledge, transparency and communication.

#### **Our Members' Work:**

- Contributing to antibiotics surveys like the European Medicines Agency's ESVAC report (European Surveillance of Veterinary Antimicrobial Consumption Report).
- Creating web-based tools and training front-line representatives to us integrated analytics to predict disease risk, improve prevention and design sustainable solutions specific to individual farms.
- Collaborating with research organisations and universities to better understand antimicrobial resistance; funding research on AMR in foodborne pathogens.

his work is only a sample of what signatories to the nimal Health ector ommitments and ctions on ntibiotic Use are doing to support responsible antibiotic use. or more information or to learn about other work being done, contact **nfo HealthforAnimals or** 

iew the full nimal Health ector ommitments and actions on ntibiotic Use at

HealthforAnimals or urCommitment

## **Global Trends in Animal Antibiotic Use**

Antibiotics are a cornerstone of modern medicine. These medicines are the only way to treat a bacterial disease; there is no alternative. Their importance to human and animal health cannot be understated, which is why the animal health sector recognizes antimicrobial resistance (AMR) as a significant global threat.

Since the United Nations issued their 'Political Declaration on AMR' in 2016, countries across the globe have implemented national action plans to address the threat of resistance. As developers of medicines, the Animal Health sector recognizes that it *must* be part of the solution and has been at the forefront of these efforts. The sector has set measurable targets for increasing prevention, worked with governments to implement responsible use strategies, and strengthened global cooperation.

However, AMR cannot be solved alone. Animal health companies and institutions will be ready to work together and share our knowledge to help strengthen the actions of others.

At the same time, researchers from leading institutions have undertaken robust analysis to better understand how AMR develops and transfers between people and across species. This essential work helps the world better target efforts in minimizing the threat of resistance and preserving antibiotics.

Six years on from the United Nations Political Declaration, this report analyzes global data to understand how efforts are progressing to better understand and tackle AMR. The key findings show:



1. Animal antibiotic use is falling: Globally, use is down by nearly 1/3rd, while in many countries there have been significant and sometimes dramatic declines in the need for antibiotics in animals.



2. **Prevention works:** Reductions in antibiotic sales are mirrored by a rise in prevention products. Globally, antibiotics relative share of the animal health product portfolio has declined 28% while vaccines sales increased.



**3. Antibiotics remain a critical tool:** Many developed nations have achieved drastic declines that level off to a consistent level. This often reflects a state of 'optimized use' where prevention is maximized, but antibiotics remain necessary for treatment of disease that evades a farm's defenses.



**4. Progress cannot be achieved without One Health action:** Authorities like the European Centre for Disease Prevention and Control (ECDC) have found that the majority of human AMR transfer stem from human health care settings, while leading studies show human antibiotic use is growing. Research concludes that without corresponding action in human health, actions within the animal domain will have little impact.



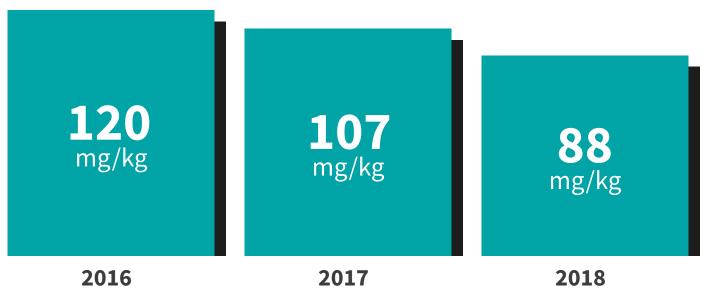
**5. Animal health is a global leader:** Authorities have recognized the significant progress made in reducing the need for antibiotics in animals. Animal health companies are building on this progress with actions such as the Roadmap to Reducing the Need for Antibiotics, which provided 25 measurable commitments to help address AMR and responsible use, all of which are on track for completion by 2025.

## Animal antibiotics use has fallen across the world

Countries are reducing their need for antibiotics and continuing to support responsible use.

#### Global antimicrobial use is declining

The World Organisation for Animal Health collects global antimicrobial use data from countries across the globe. They have found that "global antimicrobial use in animals has declined by 27% in 3 years" and provided the following figures.



Source: World Organisation for Animal Health, Annual report on Antimicrobial Agents Intended for Use in Animals, 6th Edition

#### Critically important antimicrobials have seen the largest reductions



#### Antimicrobial sales have fallen up to 65% in major markets



Although sales can offer an indicator of trends in antimicrobial use, it cannot measure whether AMR is rising or falling. Only testing for resistance itself can achieve this, which is why sales reporting must be accompanied by AMR surveillance.

Sources: UK Veterinary Medicines Directorate, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_data/file/1126450/FOR\_PUBLICATION\_-\_UK-VARSS\_2021\_Main\_Report\_\_Final\_v3\_-accessible.pdf

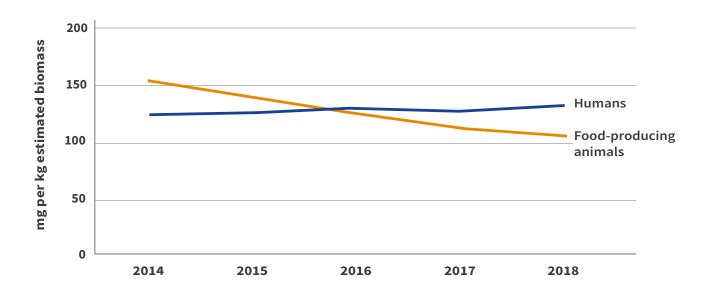
 ${\it USFDA}, https://www.fda.gov/animal-veterinary/cvm-updates/fda-releases-annual-summary-report-antimicrobials-sold-or-distributed-2021-use-food-producing and the summary-report-antimicrobials-sold-or-distributed-2021-use-food-producing and$ 

European Medicines Agency, https://www.ema.europa.eu/en/news/sales-antibiotics-animal-use-have-almost-halved-between-2011-2021

German Office of Consumer Protection and Food Safety, https://www.bvl.bund.de/SharedDocs/Pressemitteilungen/05\_tierarzneimittel/2022/2022\_PM\_Abgabemengen\_Antibiotika\_ Tiermedizin.html

#### "More progress in agriculture than in the human sector"

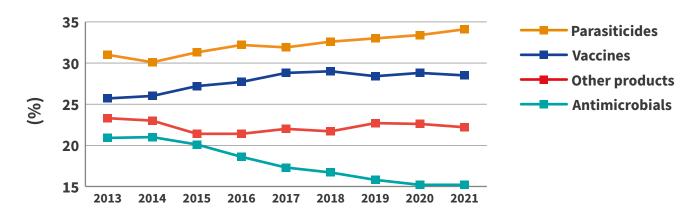
#### Antibiotics consumption in the EU/EEA, 2014-2018



A recent report on antimicrobial use in the EU from the European Medicines Agency (EMA), European Food Safety Authority (EFSA), European Centre for Disease Control (ECDC) and OECD found there was "more progress in agriculture than in the human sector" and since 2016, "average consumption of antibiotics in humans is now higher than in food-producing animals". However, some markets have decreased human consumption of antibiotics alongside animal reductions. The report found that overall human antibiotic use in the EU had fallen, although when looking at specific classes, broad-spectrum antibiotic use in humans was still rising.

#### **Prevention can reduce the need for antibiotics**

#### Sales per product category (%) (2013-2021)



Sales data from leading animal health companies demonstrate how global shifts towards prevention are reducing the need for antimicrobials worldwide. Since 2013, vaccines and parasiticides have grown from 56.7% to 62.6% of the product portfolio of the leading animal health companies, while antimicrobials fell from 20.9% to 15.2% (a relative reduction of 28%).

Source: HealthforAnimals, Global Trends in the Animal Health Sector, https://www.healthforanimals.org/reports/global-trends-in-the-animal-health-sector/

#### One Health action is necessary for minimizing AMR risk

#### **Recent changes in human use of antibiotics**

46% increase in antibiotic use

90% increase in 'watch' antibiotic use

From 2000 to 2018 according to a Lancet study

From 2000 to 2016. 'Watch' antibiotics have 'higher resistance potential' according to the WHO

Source: The Lancet, https://www.thelancet.com/journals/lanplh/article/ PIIS2542-5196(21)00280-1/fulltext#gr5 Source: The Lancet, https://www.thelancet.com/journals/laninf/article/ PIIS1473-3099%2820%2930332-7/fulltext

Although global human antibiotic consumption may be rising, some markets have decreased use. An EU report, *Antimicrobial Resistance in the EU/EEA: A One Health Response*, found that overall human antibiotic use in the EU had fallen, although when looking at specific classes, broad-spectrum antibiotic use in humans has risen.

AMR is a 'One Health' challenge, meaning it requires complementary action across humans, animals and environment. This means reducing the need for antibiotics, researching transfer pathways, strengthening surveillance across all three domains. A University of Edinburgh study found that reducing antibiotic use only in animals but not in people has "little impact on the level of resistance in humans."

#### Markets are achieving steady, 'optimal' levels of use

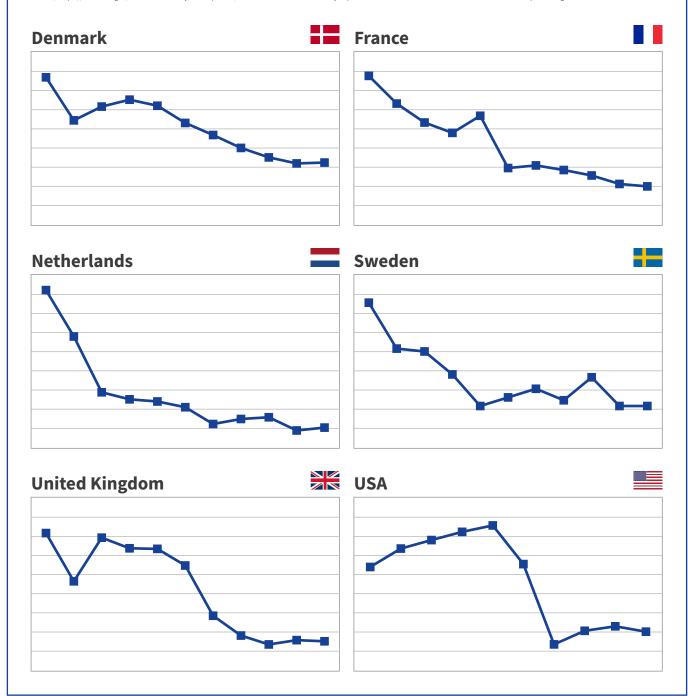
#### **Animal antimicrobial Sales Trends (2010–2020)**

The below charts show how animal antimicrobial sales have changed for six nations. The sales levels differ for each (see source below for the underlying numbers), however the trend lines are similar for all.

These drastic declines leveling off to a consistent level often reflect a state of 'optimized use' where prevention is maximized, but antibiotics remain necessary for treatment of disease that evades a farm's defenses. It is a reminder that not all illness can be prevented, and these medicines remain the only way to treat bacterial disease.

Source: European Medicines Agency, https://www.ema.europa.eu/en/documents/report/sales-veterinary-antimicrobial-agents-31-european-countries-2019-2020-trends-2010-2020-eleventh\_en.pdf

US FDA, https://www.fda.gov/animal-veterinary/cvm-updates/fda-releases-annual-summary-report-antimicrobials-sold-or-distributed-2020-use-food-producing



# Antimicrobial use and AMR can be vastly different between humans and animals

Understanding these differences enables complementary, One Health actions.

In the US, at least 72% of animal antibiotics

are an animal-only class or tetracyclines.

#### Types of antibiotics used in animals

The types of antimicrobials used in humans and animals are very different. According to the World Organisation for Animal Health, tetracyclines and pen-

icillins represent about 55% of global animal antibiotic use, and neither of these classes are on the WHO list of highest priority critically important antimicrobials for humans. Furthermore, WOAH does not include 'animal only' antibiotics in their measurements. These are antibiotics that are *only* authorized for use in animals and not considered contributors to human AMR. In the U.S., at least 72% of animal antibiotics are an animal-only class or tetracyclines.<sup>1</sup>

Antibiotics used in both humans and animals are known as 'shared classes.' Fluoroquinolones and cephalosporins are typically considered the most important to human health, and both account for less than 3% of the antibiotics used in animals. Cephalosporins are only used for individual animal treatment via injection. Veterinary fluoroquinolones make up less than 1% of all antibiotic use in U.S. agriculture and around 1.9% in Europe, which are only available through a veterinarian's prescription.<sup>2</sup>

#### Comparing use levels between people and animals

Developing a clear, reliable comparison between antimicrobial use in humans and animals is challenging. 1-to-1 comparison in volumes used is often misleading since a beef cattle weighing over 500 kilos will naturally require a different type and dosage of medicine compared to a 65 kg person. Therefore, when comparing quantities, it is important to consider:

- There are many more animals than humans, and there are differences in physiology and weight between humans and animals.
- Different species metabolize antimicrobials differently, meaning that some species may require more product to be effective, or may need to be treated for a longer period.
- Different antibiotics have different potencies. Older antibiotics such as tetracyclines the largest group used in animal care – tend to have much higher doses than newer antibiotics such as fluoroquinolones.

Global authorities such as the World Organisation for Animal Health (WOAH) and leading markets have developed systems to measure the amount of antibiotics used per kilogram of biomass. These provide a greater standardization that better illustrates trends in antibiotic use and enables comparisons.

<sup>1</sup> Sources: WOAH, https://www.fda.gov/media/154820/download, FDA, https://www.woah.org/app/uploads/2022/06/a-sixth-annual-report-amu-final.pdf

#### **Understanding pathways for AMR development and transfer**

Potential actions for tackling AMR are endless, but funding, time and manpower are not. Strategies must focus on actions that provide the greatest potential impact. This is why public authorities and international institutions have invested in better understanding where AMR transfer occurs, what actions can be most effective, and when it may originate in animals.



In a landmark study, the European Centre for Disease Prevention and Control found that "75% of disease linked to resistant bacteria is due to healthcare-associated infections"

 $\textit{Source: ECDC}, \ \text{https://www.ecdc.europa.eu/en/news-events/ecdc-calls-continued-action-address-antimicrobial-resistance-healthcare-settings}$ 



In 2019, the U.S. CDC published a report on 'Antibiotic Resistance Threats' that identified 18 bacteria and fungi that are a resistance concern for humans. Two (Campylobacter spp. and Salmonella spp.) of the 18 can originate in food animals.

Source U.S. CDC, https://www.cdc.gov/drugresistance/biggest-threats.html



An OECD analysis of antimicrobial resistance found that "three out of four deaths could be averted by spending just USD 2 per person a year on measures as simple as handwashing and more prudent prescription of antibiotics"

 $\textit{Source: OECD}, \ \text{https://www.oecd.org/health/stopping-antimicrobial-resistance-would-cost-just-usd-2-per-person-a-year.htm}$ 





The UK Government in a five-year antimicrobial strategy reported that "Increasing scientific evidence suggests that the clinical issues with antimicrobial resistance that we face in human medicine are primarily the result of antibiotic use in people, rather than the use of antibiotics in animals"

 $Source: \textit{UK Department of Health \& DEFRA}, \\ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_data/file/244058/20130902\_UK\_5\_year\_AMR\_strategy.pdf$ 

Together, these reports indicate that animals can play a role in AMR development in humans, which is why the work outlined in the previous section have been so critical, but complementary action in human health is needed to make significant gains in the years ahead. AMR can only be managed through a One Health approach that works across human, animal and environmental health.

## Animal health sector is leading the way

## Significant actions and commitments by companies are helping reduce the need for antibiotics.

Animal health companies recognize the importance of reducing the need for antibiotics in animals and support greater shifts towards prevention. The sector has taken action for years to support this goal.



#### **Clear Commitments**

The 'Roadmap to Reducing the Need for Antibiotics' was launched by leading animal health companies in 2019. The Roadmap offered a vision for improving responsible use and outlined a list of 25 measurable actions the sector would complete by 2025.

#### **Measurable progress**

In 2021, the animal health sector released its Roadmap Progress Report showing that all 25 commitments made in the Roadmap were on track for completion. This included delivering 49 new vaccines, training 650,000+ veterinary professionals and donating nearly \$7 million in veterinary scholarships in just two years.



#### **Coordinated Approach**



Coalitions such as the UK's Responsible Use of Medicines in Agriculture Alliance or the EU's Platform for Responsible Use of Medicines in Agriculture have been in place for decades. These coalitions bring together farmers, veterinarians, research, retail, etc. to deliver improvements in responsible use, a unique approach that has not been replicated in human health.

#### **Training and Data Collection**

HealthforAnimals Members have created major programs to educate veterinarians in responsible medicine use, such as a new collaboration between HealthforAnimals, the World Veterinary Association and the UNFAO's EUFmD Program to train para-professionals in Africa.

International institutions are also stepping up effort to improve data collection around antimicrobial use worldwide. The World Organisation for Animal Health's Annual Report on Antimicrobial Agents Intended for Use in Animals provides invaluable data that is helping



to better target efforts. The United Nations Food and Agriculture Organization (UNFAO) is also supporting capacity building to help nations more effectively implement their national action plans.

Altogether, this work has made animal health the global leader in tackling antimicrobial resistance and our strong, collective action will continue in the coming years. However, AMR cannot be solved alone. Animal health companies and institutions will be ready to work together and share our knowledge to help strengthen the actions of others.



## **Calculation Module**

#### **INSTRUCTIONS**

- 1. This workshop exercise is divided into 4 mandatory sections:
  - 1. Manual product entry
  - 2. Uploading an Excel version into the Calculation Module
  - 3. Product History and History logs
- A
- 4. Generating a Reporting Option
- 2. Make sure you <u>ONLY</u> use the **training/testing environment** for this exercise which is accessible through the link <a href="https://test-amu.woah.org/">https://test-amu.woah.org/</a>
- 3. Login to your national portal using your **email** and **password** you have previously created to access ANIMUSE.
- 4. You are **required to provide fake responses** based on <u>testing scenarios</u> that WOAH have created. **They are not considered as real submissions** of national data and will be **erased** during the training.
- 5. Use this guide as a general reference if required.
- 6. The total time to complete all sections is **80 minutes.**

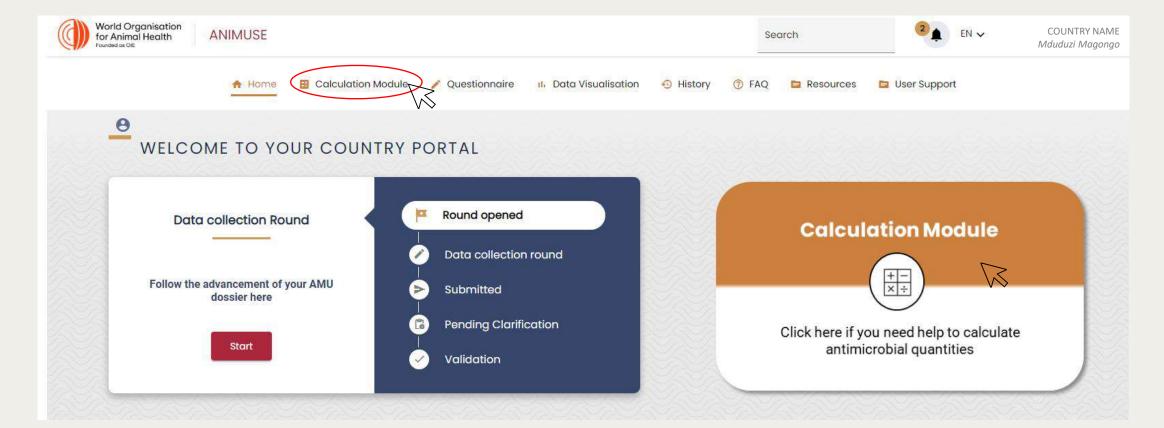


### **SECTION 1 – ONLINE DATA ENTRY** $\overline{\mathbb{X}}$ [30 Minutes]



In this section, you are required to add fake veterinary products using the Calculation Module. Use the information that WOAH has provided you.

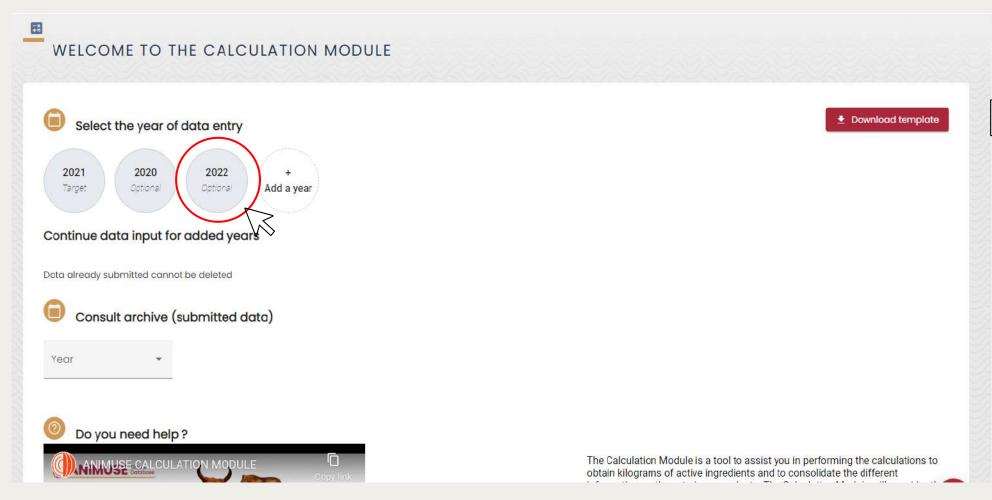
You can access the Calculation Module on the **Home page** by clicking the **'Calculation Module'** button or by selecting 'Calculation Module' from the top navigation menu.





## Calculation Module – Online Functions

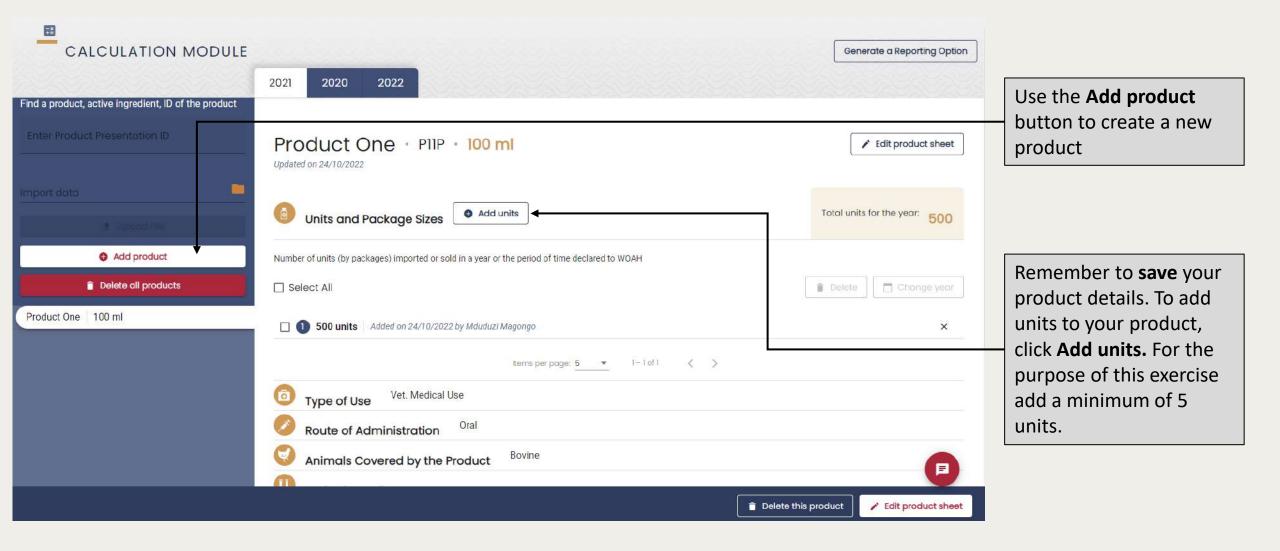
1. Select a **2022** for which you want to add a product



NB: Select 2022

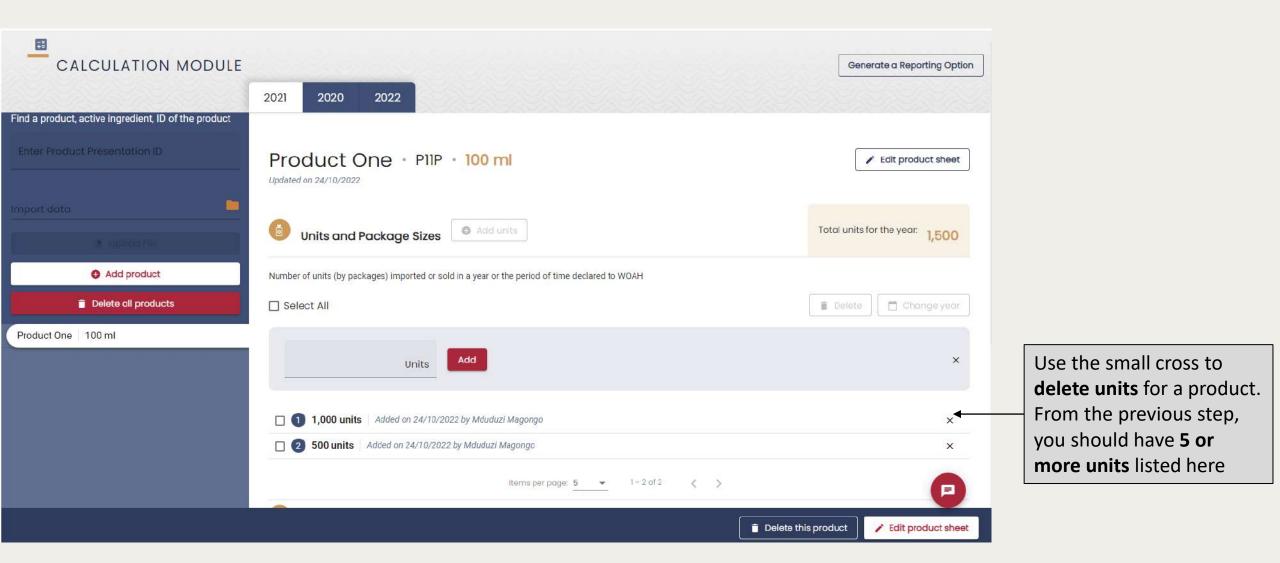


2. **Add** new products with different product details, including the number of units. Repeat this for 5 different products. Please use the printed document which will be provided to you.



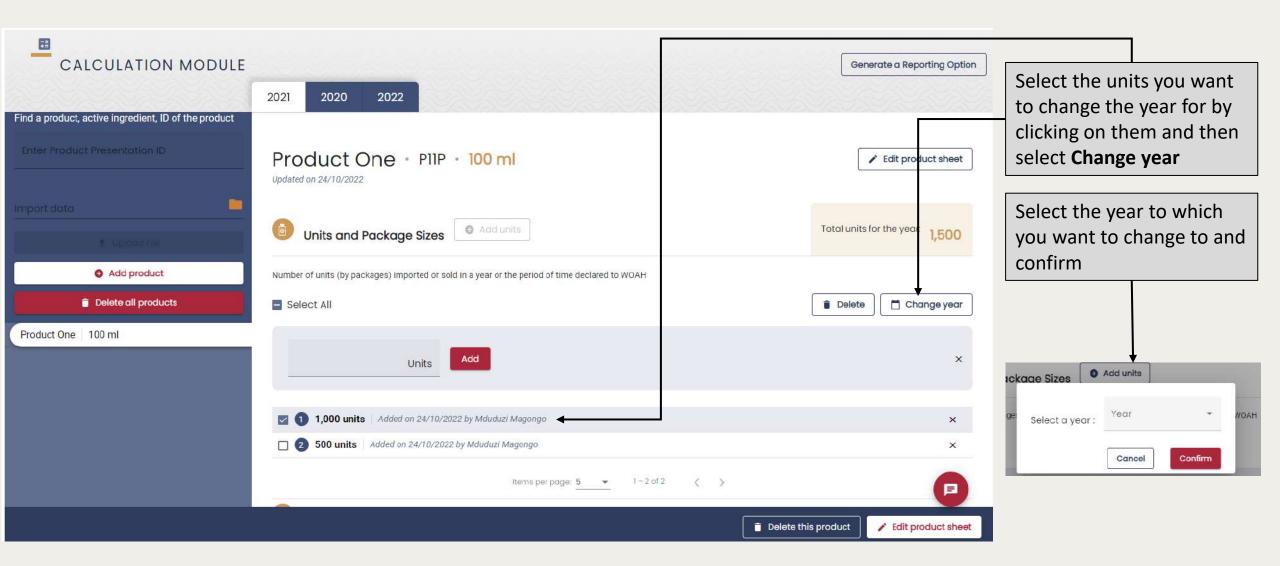


3. Delete the number of units for 1 product



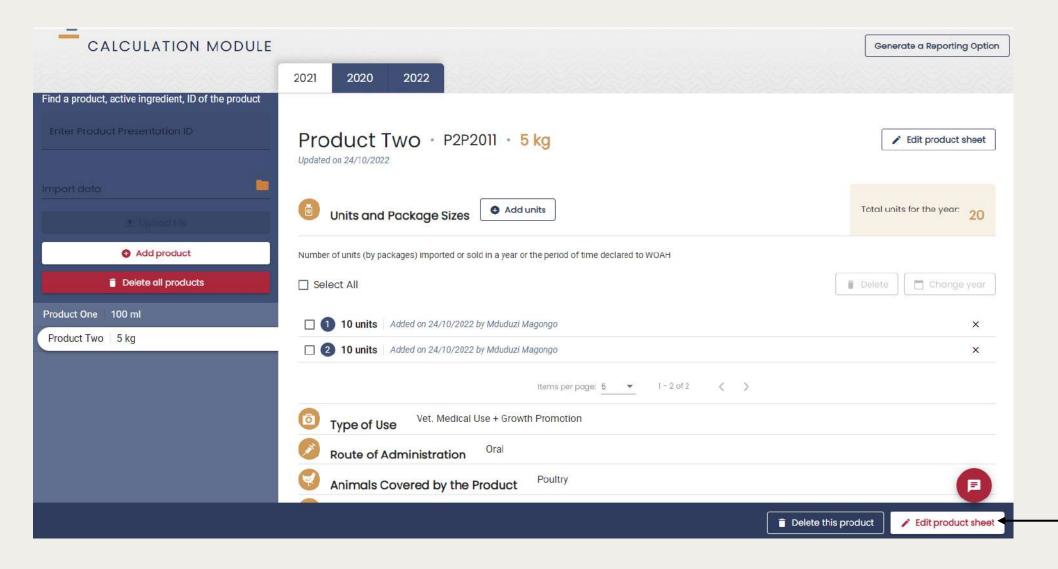


4. **Change year** for the units of a product





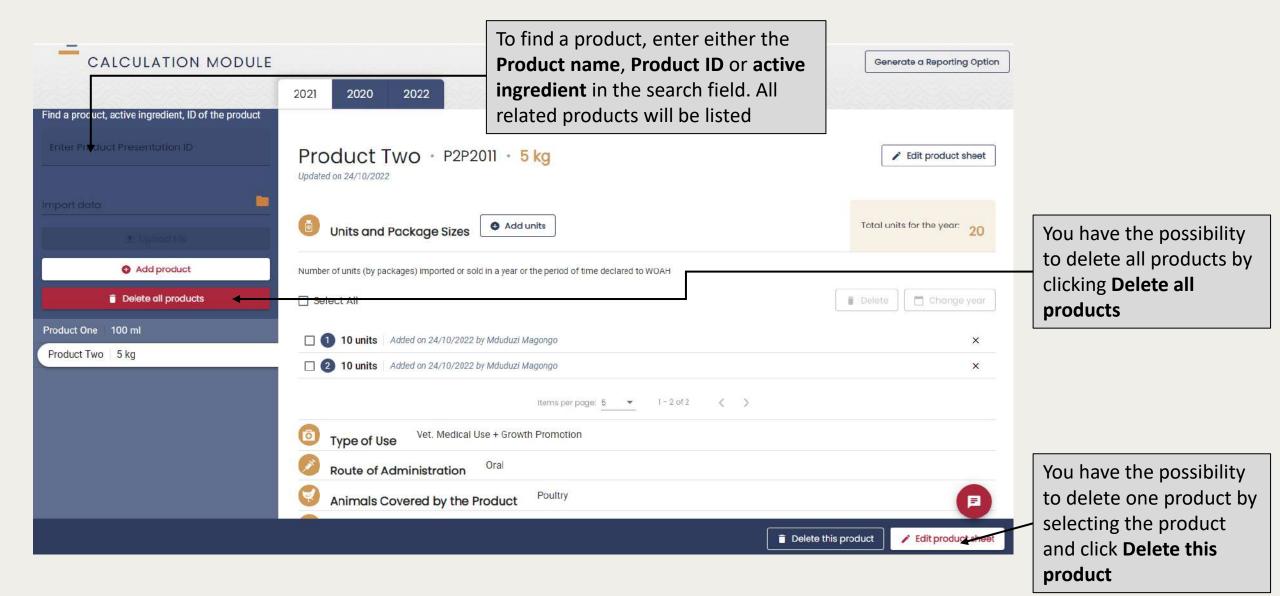
#### 5. **Edit** an existing product



Click *Edit product*sheet to modify an existing product



#### 6. **Find** a product, delete a product or **all products**





## Calculation Module - Offline Data Injection

#### 

In this section, you are required to download an empty calculation Excel template and inject a completed one. NB: For the purpose of this exercise, you will be provided with a pre-populated calculation Excel template named 3.3. Module Injection - error

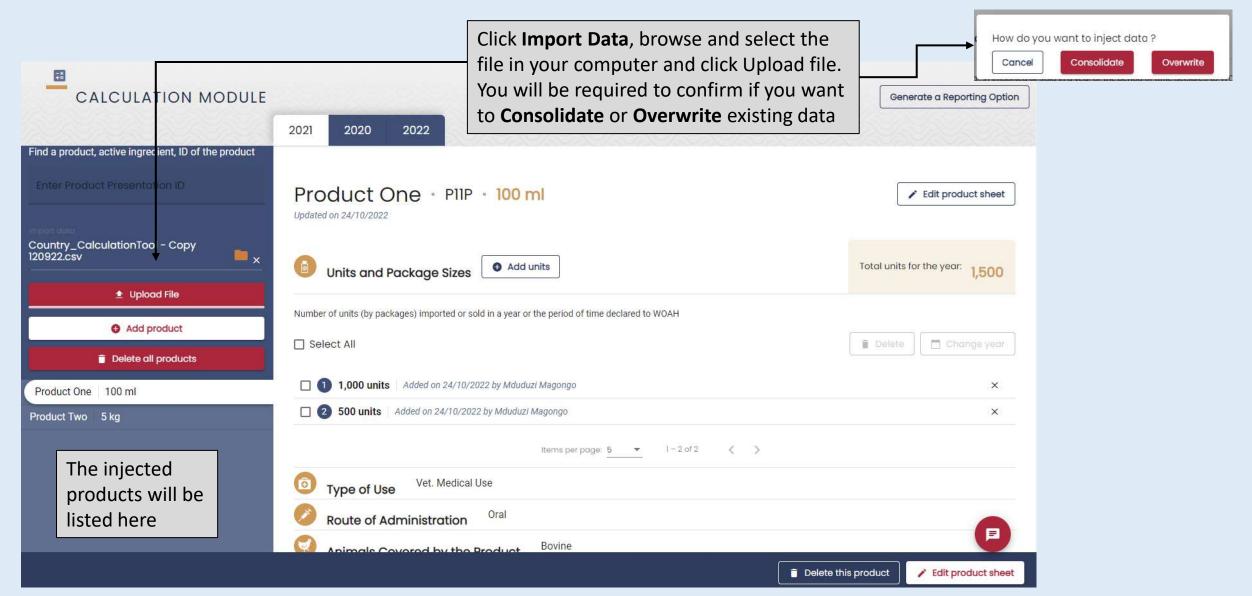
1. Access the Calculation Module on the **Home page** by clicking the **'Calculation Module'** button or by selecting **'Calculation Module'** from the top navigation menu. On the home page of the Calculation Module, click **Download template** 





## Calculation Module - Offline Data Injection

2. Inject or import the provided Calculation Module Excel template

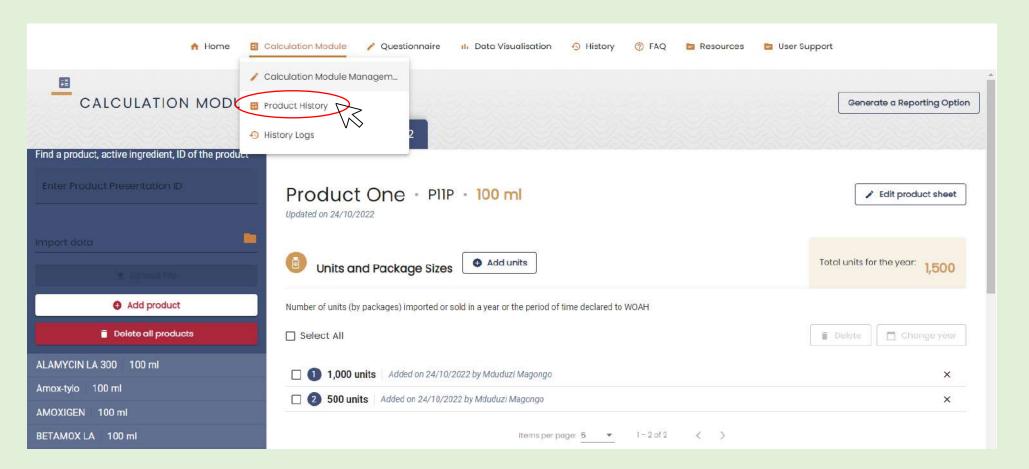




## **SECTION 3 – PRODUCT HISTORY ▼** [10 Minutes]

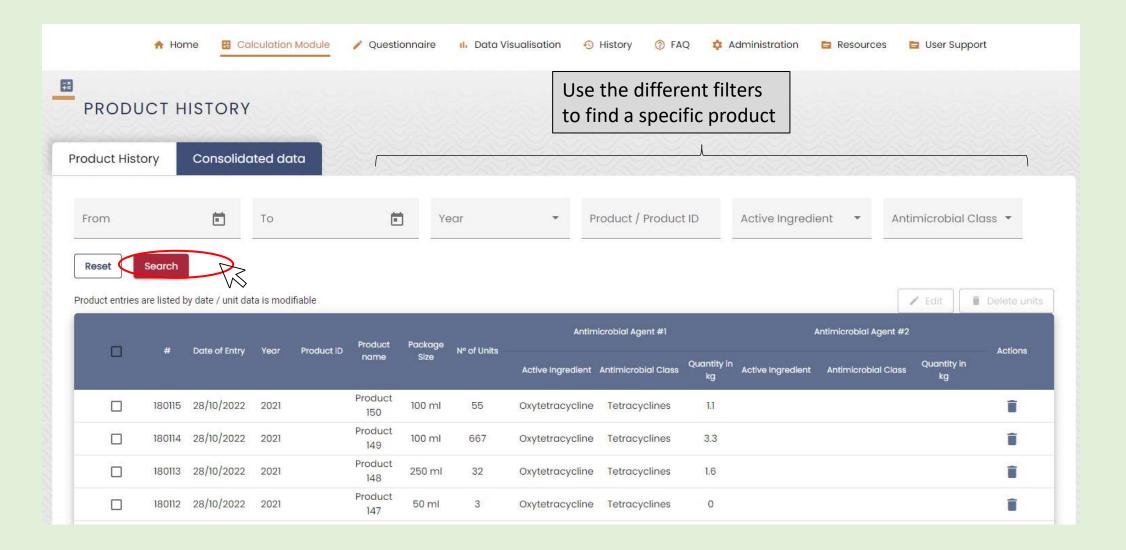
In this section, you are required to **consult** the *Product History* page of the Calculation Module. You will **filter/find products**, **edit** a product and **delete** units via the *Product History* page.

1. Access the Calculation Module *Product History* page from top navigation menu as highlighted below.



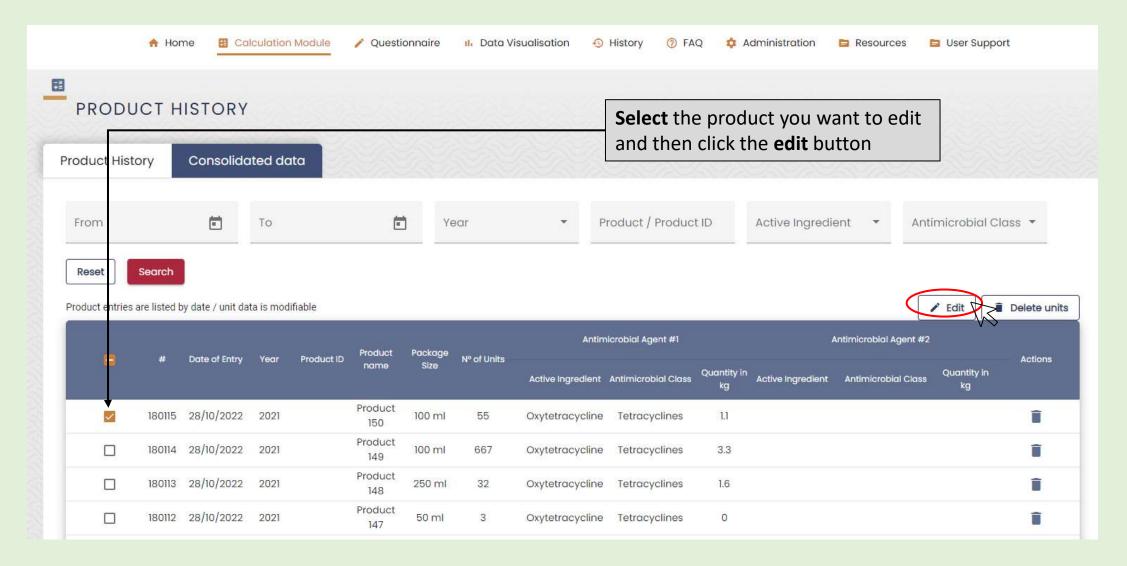


#### 2. Consult the *Product History* and find products



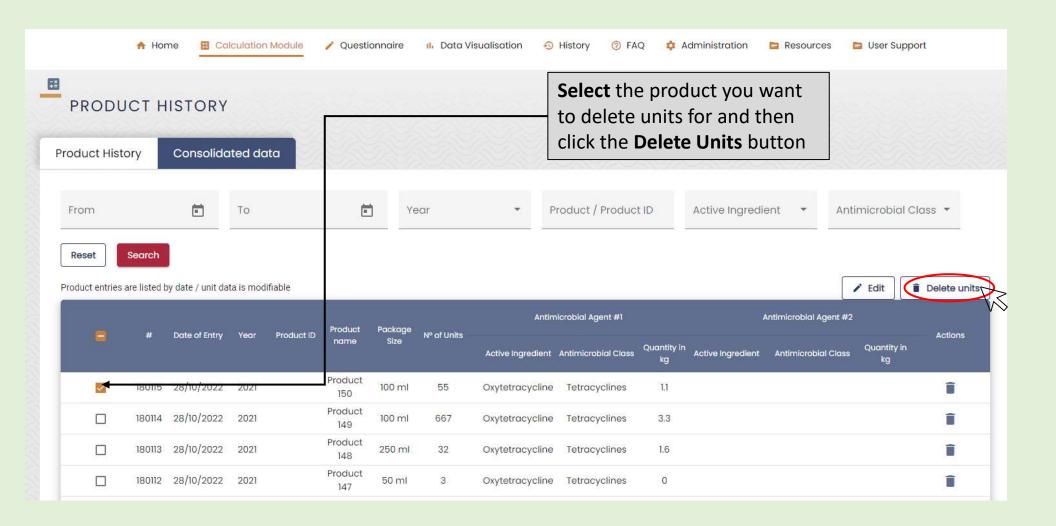


#### 3. Edit a product





#### 4. Delete units via the product history page

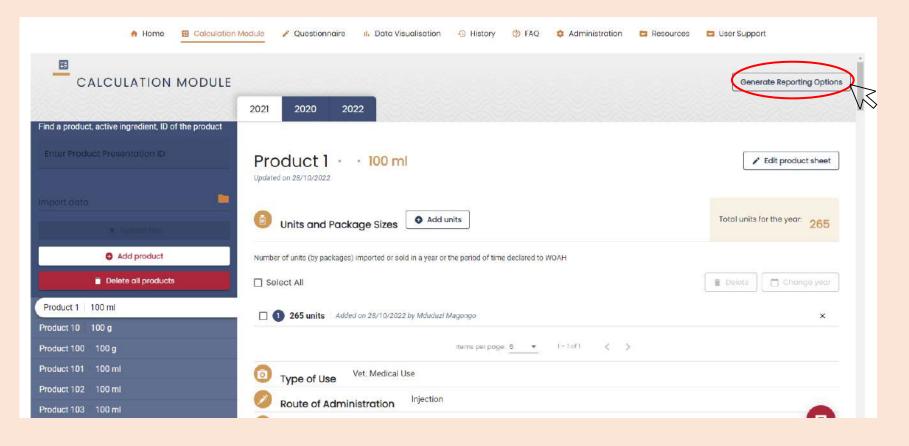


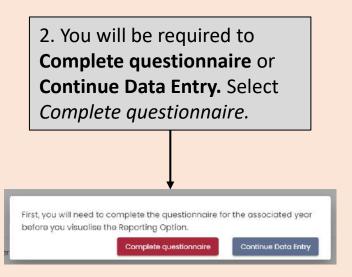


## **SECTION 4– GENERATE A REPORTING OPTION ▼** [30 Minutes]

In this section, you are required to **generate a Reporting Option** using the products created in the Calculation Module. This step is done only when you have declared all the concerned products and you are ready to notify the quantities to WOAH.

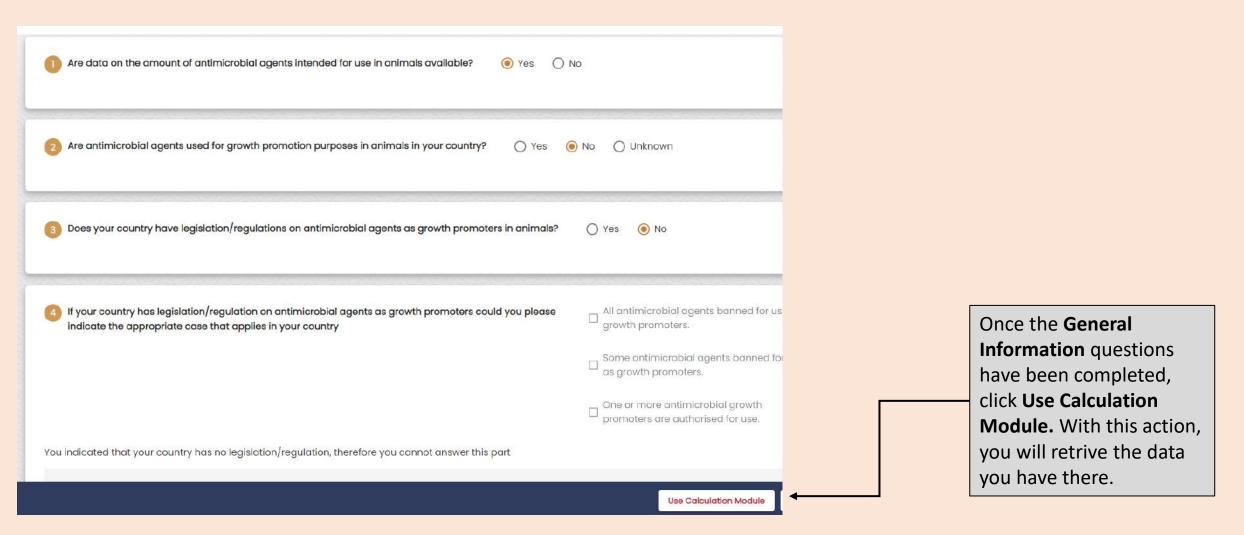
1. From the Calculation Module page, click **Generate a Reporting Option** as highlighted below.





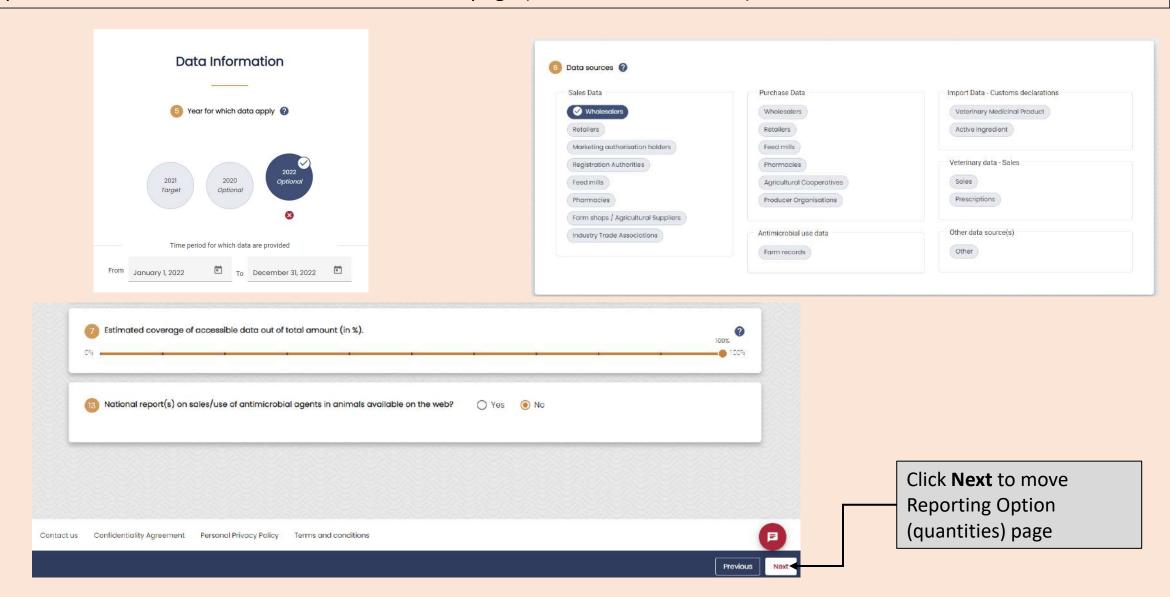


3.Complete the **General Information** page **(Question 1-4)** and complete a shorter version of the **Data Information** page **(Question 5,6,7 and 13)** 



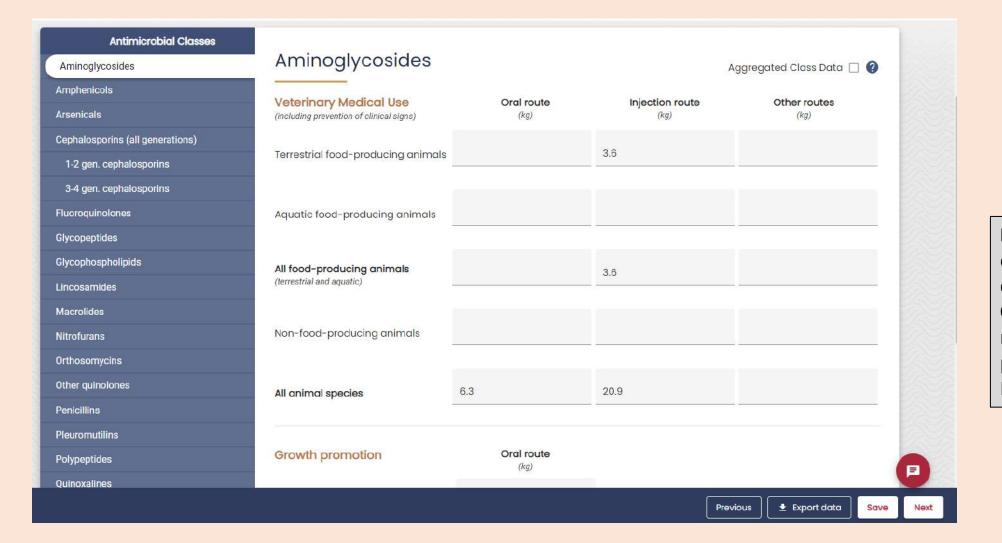


4. Complete a shorter version of the **Data Information** page (Question 5,6,7 and 13)





#### 5. Review the quantities in the Reporting Option and submit





**NB:** Quantities are not editable because they are directly linked to the **Calculation Module.** To modify the quantities, please use the Calculation Module.

# Thank you

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Organisation mondiale de la santé animale

Fondée en tant qu'OIE

Organización Mundial de Sanidad Animal





## EXERCISE FOR REPORTING SUSPECTED CASES OF SUBSTANDARD AND FALSIFIED VETERINARY PRODUCTS

Note: The case presented below is not real and created only for demonstration purposes. Names, numbers and incidents are the products of the author's imagination. Any resemblance to actual events is purely coincidental.

#### CASE 1:

On 10 January 2023, the FP-VP is aware that an inspection was conducted in an authorised seller point for veterinary products in your country two days earlier. During that inspection, there were indicators of a substandard and falsified product as there was some missing information in the labelling. The following was noted:

- The name of the product is 'INFECTSTOP EXTRA powder for use in drinking water for chickens, turkeys, ducks and pigs'. It is manufactured by 'Best Lab Ever'. The marketing authorisation holder is 'ANIMAL LOVER S.A.', based in the country Lalaland. The product is registered in your country.
- The product contains amoxicillin at the concentration of 871 mg/g.
- The product is presented in thermosealed bags. There were a total of 25 bags.
- The pack size is 200 g bags
- The label of the product is usually light yellow. However, the colour of these is dark yellow.
- There is no registration number in the label.
- The font of the Batch number (AMX/000/XYZ) and Expiry date (06/24) used in the labels is four times larger than the usual font.

Based on these findings it was decided to contact the MAH and to collect samples for laboratory testing. On 16 January 2023 the MAH confirmed that they did not make the products. On 2 February 2023 you receive the results of the HPLC analysis. The results indicated that the concentrations of amoxicillin was approximately 340 mg/mg. Other components identify in the analyses were chalk.

#### **EXERCISE:**

- 1- Complete a WOAH Immediate Notification FORM based on these components
- 2- Under section 'Any additional comment' could you indicate which time you consider that the FP-VP should start the completion of WOAH Immediate Notification report? Why?
  - a) On 10 January 2023 (at the initial suspicion)
  - b) On 16 January 2023 (after confirmation from the MAH that they did not make the product)
  - c) On 2 February 2023 (after laboratory confirmation)

Note: The case presented below is not real and created only for demonstration purposes. Names, numbers and incidents are the products of the author's imagination. Any resemblance to actual events is purely coincidental.

#### CASE 2:

A regular container with 500 boxes of inactivated rabies vaccine called 'Anti-rabies plus for dogs' arrived to City Harbour (Countryland) on 29 July 2022. Each box contains 10 bottles (glass) of 1ml of vaccine. The temperature of that day was 35 C, and the container was not refrigerated. The origin of shipment is unknown.

On 15 August 2022, the FP-VP receives the following information from the border inspection and control.

- The Marketing Authorisation Holder (MAH) as in the label is UNFAKE-LAB
- Registration Number: 0020/AB/C999
- The Batch number is 123ZZ
- The vaccine contains inactivated rabies virus, G52 strain ≥1 IU/ml as active ingredient.
- The vaccine contains aluminium (as hydroxide) as <u>adjuvant/excipient</u> at the concentration of 1.7 mg/ml.
- Each dose is a bottle (glass) containing 1 ml suspension. The product is to be injected by subcutaneous or intramuscular route.
- The product is indicated for the active immunisation of cattle, dogs, horses, cats and sheep, to reduce mortality and clinical signs due to rabies infection.
- The expiry date as in the labelling of all boxes was 03/22.
- The storage conditions as in the labelling of all boxes is between + 2°C and + 8°C, protected from light

The product is registered in Countryland and, after contacting the MAH UNFAKE-LAB, they confirmed you five days later (20 August 2022) that they did manufacture the product some time ago, and that the information in the labelling is correct. They also indicated that for there are other 100 boxes with the same batch number but these have not been identified. This veterinary medicinal product is also registered in five other countries within the region but the MAH has not received any communication.

The veterinary services of Countryland have seized the container. An alert has been issued to all stakeholders as the Veterinary Services are not sure whether there could be any products circulating in the country, or whether the products could be present in other countries of the region.

#### EXERCISE:

- 1- Complete a WOAH Immediate Notification FORM based on these components
- 3- Under section 'Any additional comment' could you indicate which time you consider that the FP-VP should start the completion of WOAH Immediate Notification report? Why?
  - a) On 15 August 2022 (at the initial suspicion)
  - b) On 20 August 2022 (after confirmation from the MAH that they did make the product.











## Regional ANIMUSE Training for WOAH Focal Points for Veterinary Products 22-24 February 2023, Bangkok, Thailand

#### **PROGRAMME**

DAY 1	Moderator: Chantanee Buranathai, WOAH SRR-SEA		
Time	Theme	Speaker	
08:00 - 09:00	Registration		
09:00 - 09:45	Official opening		
	Welcome remarks by:		
	Introduction and welcome by the WOAH Delegate of host Member	WOAH Delegate, Thailand	
	Address by the WOAH Regional Representation for Asia and the Pacific	Hirofumi Kugita, WOAH RRAP	
	AMR and Veterinary Products Department (AMR&VPD)	Morgan Jeannin, WOAH AMR&VPD	
09:45 - 10:00	Short self-introduction by participants	All facilitators and participants	
	Objectives of the seminar	Ronello Abila, WOAH SRR-SEA	
10:00 – 10:15	WOAH Strategy on AMR	Nahoko leda, WOAH RRAP	
10:15 – 10:30	Importance of monitoring quantities and usage patterns of antimicrobial agents in animals at a national level	Idrissa Savadogo, WOAH AMR&VPD	
10:30 - 10:45	History of the WOAH Data Collection	Tikiri Priyantha, WOAH SRR-SEA	
10:45 – 11:00	Session for Q&A	All	
11:00 – 11:30	COFFEE BREAK AND GROUP PHOTOGRAPH		
11:30 - 11:50	Introducing ANIMUSE and main functionalities	Mduduzi Magongo, WOAH AMR&VPD	
		[recorded]	
11:50 – 12:10	ANIMUSE – AMU Questionnaire: Online and offline submission	Morgan Jeannin, WOAH AMR&VPD	
12:10 - 12:30	ANIMUSE – AMU Questionnaire and common errors when submitting	Delfy Góchez, WOAH AMR&VPD [recorded]	
12:30 - 13:00	Session for Q&A	All	
13:00 – 14:00	LUNCH		
14:00 - 14:15	Member's Experience in testing ANIMUSE	Yi-Ming Huang, Chinese Taipei	
14:15 – 16:00	Working session 1 with feedback:	All	
	ANIMUSE – AMU Questionnaire	Facilitators	
	1. Answering the AMU Questionnaire: online and offline		
	2. Responding to WOAH queries		
	Bonus: Injection of Active Ingredients		
16:00 – 16:30	COFFEE BREAK		
16:30 – 16:50	ANIMUSE: Miscellaneous	Mduduzi Magongo, WOAH AMR&VPD [recorded]	
16:50 - 17:20	Working session 2 with feedback:	All	
	Exploring ANIMUSE	Facilitators	
	1. History tab		
	2. Chat		
	Training resources		
17:20 – 18:00	Session for Q&A	All	
19:00	WOAH Hosted Dinner		











DAY 2			
Time	Theme	Speaker	
08:30 – 08:45	Results of the 6 <sup>th</sup> WOAH Annual Report on Antimicrobial Agents Intended for Use in Animals  – Focus on Asia and the Pacific	Nahoko leda, WOAH RRAP	
08:45 – 09:00	Using WOAH's denominator (animal biomass) in analysis of quantitative antimicrobial use data	Morgan Jeannin, WOAH AMR&VPD	
09:00 - 09:20	Role of the pharmaceutical industry to support the collection on AMU data on antimicrobials	Rick Clayton, HealthforAnimals [recorded]	
09:20 - 09:40	Session for Q&A	All	
09:40 - 10:10	COFFEE BREAK		
10:10 - 10:30	Calculation of the numerator: kilograms of active ingredients	Delfy Góchez, WOAH AMR&VPD [recorded]	
10:30 - 10:45	ANIMUSE Calculation Tool and AMU National Report in Japan	Mari Matusda, Japan	
10:45 – 12:30	Working session 3 with feedback:  ANIMUSE – Calculation Module  1. Online and offline of the module  2. History of products  3. Submitting data to WOAH through the module	All Facilitators	
12:30 - 13:30	LUNCH		
13:30 - 13:45	Member's experience in designing objectives for national monitoring on AMU in animals	Rohaya Mohd Ali, Malaysia Bengthay Tep, Cambodia	
13:45 – 15:00	Working group session 4: designing system on antimicrobials intended for use in and their roles objectives for an AMU monitoring animals and identifying key stakeholders	All, Facilitators:	
15:00 - 15:30	Feedback from the working group session 4: designing objectives for an AMU intended for use in animals and identifying key stakeholders and their roles	Rapporteurs	
15:30 - 16:00	COFFEE BREAK		
16:00 – 16:25	Member's experience in data visualisation	Anne Chevance, ANSES-France	
		Ni Made Ria Isriyanthi, Indonesia	
16:25 – 16:40	ANIMUSE and data visualisation	Morgan Jeannin, WOAH AMR&VPD	
16:40 – 17:40	Working session 5 with feedback:  ANIMUSE – Data visualisation  1. Public portal  2. Member portal	All Facilitators:	
17:40-18:00	Introduction to WOAH's global project: Reporting system of Substandard and Falsified Veterinary Products  *Note: This is an additional information session, apart from ANIMUSE workshop. It is highly recommended that all Focal Points for Veterinary Products attend this session to be aware of	Andrés García Campos, WOAH AMR&VPD	
	the global project. The session will be followed by mini workshop on Day 3, targeting those who are interested in participating as a pilot.		
	End of day 2		











DAY 3			
Time	Theme	Speaker	
08:30 - 10:30	ANIMUSE: Support session for data submission	All	
		Facilitators	
10:30 - 10:45	Feedback session - ANIMUSE	All	
10:45 - 11:15	COFFEE BREAK		
11:15 – 11:30	Future perspectives: WOAH inventory for AMU field level activities	Idrissa Savadogo, WOAH AMR&VPD	
11:30 – 11:45	Overview of Fleming Fund Regional Grants	Manisha Bista & Darunee Tuntasuvan, Mott	
	- How the Fleming Fund Regional Grants can contribute to the WOAH data collection	<u>McDonald</u>	
11:45 - 12:20	AMU activities with veterinarians and farmers	Anne Chevance, ANSES-France	
		Riasat Wasee Ullah, Pakistan	
12:20-12:30	Overall Q&A	All	
12:30 - 13:30	LUNCH		
Conclusions and closing			
13:30 – 14:00	Evaluation, Closing ceremony and attendance certificate awarding	WOAH SRR-SEA	
	END of ANIMUSE WORKSHOP		
14:00 – 15:30	Briefing & feedbacking exercise for Reporting System for Substandard & Falsified Veterinary Products	Andrés García Campos, WOAH AMR&VPD	
	COFEE BREAK included in the session		
	DEPARTURE		











## Regional ANIMUSE Training for WOAH Focal Points for Veterinary Products Bangkok, Thailand, 22-24 February 2023

#### **Provisional List of Participants**

**TRAINEES** 

**AUSTRALIA** 

Dr Samantha Ellis

Senior Veterinary Officer/Department of Agriculture,

Fisheries and Forestry

**BANGLADESH** 

Dr. Md. Nazmul Hoque

Deputy Director, Animal Health

Department of Livestock Services (DLS)

**BHUTAN** 

Ms Karma Pelden Zangmo

National Centre for Animal Health

**BRUNEI** 

Dr Raihan Zulkifli

Veterinary Officer, Department of Agriculture and

Agrifood

**CAMBODIA** 

Dr Tep Bengthay

Deputy Director, Department of Animal Health and

Veterinary Public Health, General Directorate of

Animal Health and Production

**CHINA** 

Dr Qi Zhao

Assistant researcher

China Institute of Veterinary Drug Control

**CHINESE TAIPEI** 

Dr Ying-Kai Chang

**Section Chief** 

Bureau of Animal and Plant Health Inspection and

Quarantine, Council of Agriculture, Executive Yuan

FIJI

Dr Keresi Lomata

Veterinarian

Biosecurity Authority of Fiji

**INDIA** 

Dr Sushil Kumar Singh

Livestock Officer, Ministry of Fisheries, Animal

Husbandry and Dairying, Government of India

**INDONESIA** 

Dr Ni Made Ria Isriyanthi

Cooordinator of Veterinary Drug Control, Directorate

of Animal Health, Ministry of Agriculture

**JAPAN** 

Mr Takahiro Shirakawa

Subsection Chief/MAFF

KOREA R.O.

Dr Hyun Mi Kang

Senior Researcher, Animal and Plant Quarantine

Agency

**LAOS** 

Mr Intha Phouangsouvanh

Head of Division of animal and Fish Products

Management











#### **MALAYSIA**

Dr Alifah Ismail

Department of Veterinary Services Malaysia

#### **MALDIVES**

Mr Mohamed Lahfaan Moosa Veterinary Assistant / Ministry of Fisheries, Marine

#### **MONGOLIA**

Resources and Agriculture

Dr Onolbaatar Byambaa
The head of inspection and assurance department,
GAVS

#### **MYANMAR**

Dr Swe Lynn Htet
Assistant Director/Livestock Breeding and Veterinary
Department

#### **NEPAL**

Mr Nabin Upadhyaya Ghimire Veterinary Officer , VSDRI

#### **NEW CALEDONIA**

Dr Catherine Castric SIVAP DAVAR

#### **PAKISTAN**

Dr Riasat Wasee Ullah Assistant Animal Husbandry Commissioner

#### **PHILIPPINES**

Dr Alicia Layson
Senior Agriculturist/Bureau of Animal Industry

#### **SINGAPORE**

Dr Juline, Wan Ying Chua Veterinarian/National Parks Board

#### SRI LANKA

Dr Vijith Dharma Sri Bandara Hetti Pathirannehelage Registrar-Veterinary Drugs

#### **THAILAND**

Dr Sasi Jaroenpoj Veterinarian, expert level

#### **TIMOR-LESTE**

Ms Cristina da Costa Soares Veterinaria Tecnhiciang

#### **VANUATU**

Dr Ian Peebles
Biosecurity Vanuatu

#### **VIETNAM**

Dr Hue Thi Le

Deputy Chief of Veterinary Drug Division, Department
of Animal Health











#### **SPEAKERS**

Dr Yi-Ming Huang

Bureau of Animal and Plant Health Inspection and Quarantine, Council of Agriculture, Executive Yuan

Dr Mari Matsuda

Chief Research Officer

**National Veterinary Assay Laboratory** 

Ministry of Agriculture, Forestry and Fisheries

Japan

Dr Rohaya Mohd Ali

**Senior Director** 

Pengarah Kanan, Bahagian Kesihatan Awam Veterinar,

Jabatan Perkhidmatan Veterinar (DVS), Malaysia

Ms Anne Chevance

Antimicrobial Use Project Manager

French Agency for Veterinary Medicinal Products

Dr Rick Clayton (virtual attendance)

HealthforAnimals

Dr Manisha Bista (virtual attendance)

Mott MaDonald

Dr Darunee Tuntasuvan (virtual attendance)

Mott MaDonald

#### **SELF-FUNDED OBSERVERS**

Mr Paulo Gabriel Vong da Silva

Veterinary Technician, menzies, school of health

research, Timor-Leste

Mr Muhammad Faheem

Program Officer/Fleming Fund Country Grant Pakistan

Dr Liys Desmayanti (virtual attendance)

Senior Veterinary Officer, Indonesia

Dr Ana Kadir

Veterinary Officer, Department of Agriculture and

Agrifood, Brunei

Mr Fakhrul Aizat Sufri

Assistant Livestock Husbandry Officer, Department of

Agriculture and Agrifood, Brunei

#### **HOST COUNTRY**

Ms Passawee Pakpong

Veterinarian of Department of Livestock Development

Dr Premwadee Yod-ei

Veterinary (Professional level)/ Division of Animal

Feed and Veterinary Products Control, Department of

Livestock Development

Dr JULAPORN SRINHA

Senior Professional Veterinary Officer

Dr Nathaporn Chaiyanuwong

Veterinary Senior Professional Level / Animal Feed and

Veterinary Products Control, Department of Livestock

Development











#### **OBSERVERS - FAO Regional Office for Asia and Pacific**

Dr Dolphe Mader

Regional Antimicrobial Use Specialist

Dr David Southerland

Regional AMR One-Health Coordinator

#### **ORGANISER**

#### **WOAH HQ**

Dr Delfy Gochez (virtual attendance)

Data Management Officer – AMU

Dr Morgan Jeannin

Data Information Management Officer

Dr Idrissa Savadogo (virtual attendance)

**Data Information Management Officer** 

Dr Andrés García Campos

Progamme Manager, with focus on the quality of

veterinary products

#### **WOAH RRAP**

Dr Hirofumi Kugita

**Regional Representative** 

Dr Nahoko leda

**AMR Regional Project Officer** 

Dr Elva Borja

Consultant - PVS & GFTADS

#### **WOAH RR-SEA**

Dr Ronello Abila

**Sub-Regional Representative** 

Dr Chantanee Buranathai

One Health Coordinator

Dr Tikiri Wijayathilaka

Technical Officer - Antimicrobial Resistance

Mr Therajade Klangnurak

Administrative Assistant

# WOAH's Strategy on AMR and Prudent Use of Antimicrobials

Nahoko IEDA AMR Regional Project Officer 22nd Feb 2023, Bangkok



- Resolution 26
- "Combating AMR and Promoting the Prudent Use of Antimicrobial Agents in Animals"
  - The OIE develops a procedure and standards for data quality for collecting data annually from the OIE Member Countries on the use of antimicrobial agents in food-producing animals with the aim of creating an OIE global database...
- Resolution 36
- "Combating AMR through a One Health Approach: Actions and OIE Strategy"
  - The OIE develops a procedure and standards for data quality for collecting data annually from the OIE Member Countries on the use of antimicrobial agents in food-producing animals with the aim of creating an OIE global database...



- 25 -

#### RESOLUTION No. 26

Combating Antimicrobial Resistance and Promoting the Prudent Use of Antimicrobial Agents in Animals

#### CONSIDERING

- That antimicrobial agents are essential tools for protecting animal health and welfare and also contribute to meeting the increasing global demand for safe meet, milk, fish and eggs, and other products of animal origin.
- That antimicrobial resistance (AMR) is a significant global animal and human health threat
  that is influenced by the use of antimicrobial agents in some conditions.
- 3. That during the 77th General Seasion 2000, the World Assembly of Delegates (the Assembly) adopted Resolution No. 25 on Veterinary Products, which considered previous Resolutions on harmonisation of registration requirements for veterinary drugs, their responsible and prudent use and monitoring of resistance.
- 4. The recommendations of the OIE Global Conference on the responsible and prudent use of antimicrobial agents in animals, held in March 2013 in Paris, France, including recommendation No.7 to collect harmonised quantitative data on the use of antimicrobial agents in animals with the view to establishing a global database.
- The recent update and development of OIE standards and guidelines related to antimicrobial resistance, which include references to the relevant standards developed by Codex Alimentarius,
- The tripartite agreement between FAO, OIE and WHO to address as a priority antimicrobial resistance and the important contribution of the OIE to the development and achievement of the WHO global action plan or antimicrobial resistance,
- The network of OIE National Pocal Points for Veterinary Products and its role in supporting the global implementation of the OIE standards regarding veterinary products,
- The importance of the PVS pathway in supporting compliance of national veterinary services with OIE standards including legislation, as a prerequisite to ensuring good governance covering production, registration, distribution and use of antimicrobial agents at the national
- The importance of appropriate Veterinary Education and Veterinary Statutory Bodies in the promotion of veterinary oversight to ensure responsible use of antimicrobial agents in animals.

#### THE ASSEMBLY

#### RECOMMENDS THAT

 The OIE continue to develop and update standards and guidelines related to antimicrobial resistance and the prudent use of antimicrobial agents including updating regularly the OIE List of Antimicrobial Agents of Veterinary Importance.

83 GS/FR - PARIS, May 2018

RESOLUTION No. 30

#### Combating Antimicrobial Resistance through a One Health Approach: Actions and OIE Strategy

#### CONSIDERING

- That antimicrobial resistance (AMR) is both an animal and human health threat of growing concern which has been significantly considered by the OIB through the development and adoption of relevant and important standards and guidelines.
- 2. That during the 77th General Session (May 2009), the World Assembly of Delegates (the Assembly) adopted Resolution No. 25 on Veterinary Medicinal Products, which also considered previous Resolutions on the harmonising of registration requirements for veterinary drugs, their responsible and prudent use and the monitoring of resistance including recommended actions to be implemented.
- 3. The recommendations of the OHS Global Conference on the responsible and prudent use of antimicrobial agents in animals, held in March 2013 in Puris, France, including Recommendation No. 7 to collect harmonized quantitative data on the use of antimicrobial agents in animals with the view to establishing a global database, which was subsequently formally endorsed by the Assembly at the S3rd General Session OMav 2015 through the adoption of Resolution No. 26.
- 4. The contribution of the OIE to the development of the World Health Organization's (WHO) Global Action Plan on Antimirebial Resistance, under the framework of the Tripartite agreement between the Food and Agriculture Organization of the United Nations (PAO), the WHO and the OIE, which was adopted by the World Health Assembly of the WHO in May 2015.
- 5. The recommendation to Member Countries, to follow the guidance of the WHO Global Action Plan on Antimicrobial Resistance, in particular by developing national action plans, in respect of the use of antimicrobial agents in animals and ensuring close collaboration with public health efficials, adopted through Resolution No. 26 of the SErd General Session on Combuting Antimicrobial Resistance and Promoting the Prudent Use of Antimicrobial Agents in Animals,
- 6. The importance of the capacities of the national Veterinary Services to comply with the relevant standards and the particular benefit of the OIE PVS Pathway in supporting the Member Countries to update their legislation, which is a prerequisite to ensure good governance covering registration, production, distribution, prescription and use as well as control and surveillance of antimicrobial agents at the national level.
- The role of the network of the OIE National Focal Points for Veterinary Products in supporting the global implementation of the OIE standards regarding veterinary products.
- The importance of appropriate veterinary and veterinary para-professional education in the promotion of veterinary oversight to ensure responsible use of antimicrobial agents in unimals,
- 9. The action of OIE to raise the awareness of the health risk posed by antimicrobial resistance by developing communication materials and organism sub-resistance by developing communication materia



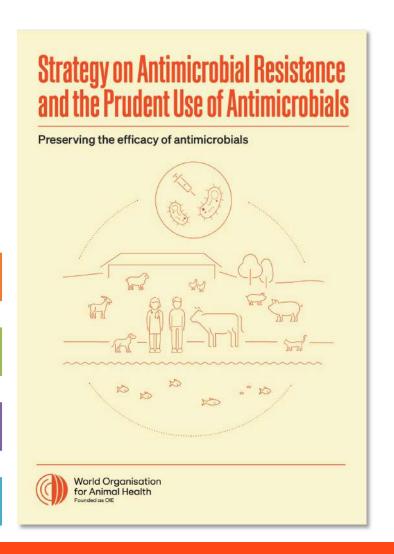
## **WOAH Strategy on AMR and the Prudent Use of Antimicrobials**



- Launched in November 2016
- Aligned with WHO Global Action Plan on AMR in 2015 and the Tripartite Partnership

#### **Objectives**

- 1 Improve awareness and understanding
  - 2 Strengthen knowledge through surveillance and research
  - 3 Support good governance and capacity building
- 4 Encourage implementation of international standards



## Improve awareness and understanding



## **5 ONLY Rules**











World Antimicrobial Awareness Week (WAAW)

#### By Global Quadripartite

Week fixed at 18-24 November every year

Campaign slogan "Antimicrobials: Handle with Care"

Cross-sectoral global theme

➤ 2021: Spread Awareness, Stop Resistance

> 2022: Preventing antimicrobial resistance together

> 2023: to be announced mid-year





ANTIMICROBIALS

Bangladesh



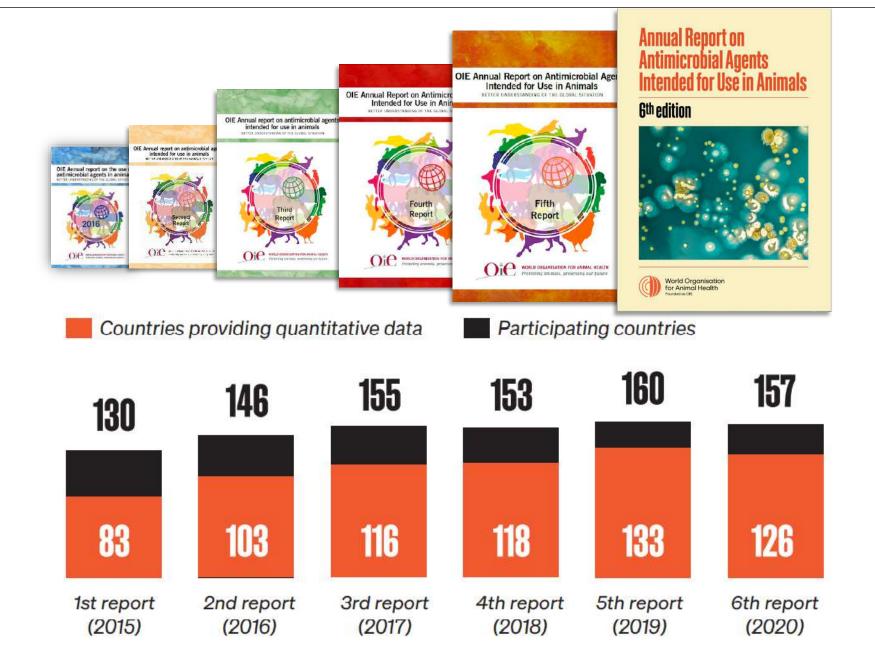
Fiji

## Strengthen knowledge through surveillance and research





## Global database on antimicrobial agents intended for use in animals (AMU)





# In-country workshops on monitoring of the quantities and usage patterns of AMU

2018: Lao PDR, Philippines, Cambodia, Myanmar

2019: Bangladesh, Bhutan, Mongolia, Nepal, Sri Lanka, Viet Nam,

2020: Indonesia, Malaysia, Pakistan

2021: India (virtual)





## Support good governance and capacity building





## Training series for Focal Points

WOAH's Focal Points for Veterinary Products (appointed by WOAH Delegates in our counterpart ministry) are the officers in charge of AMR issues and AMU

Biannual training seminars aiming to promote WOAH's activities

• 1st Cycle: Siem Reap, 2011

• 2<sup>nd</sup> Cycle: Bangkok, 2012

• 3<sup>rd</sup> Cycle: Tokyo, 2014

• 4th Cycle: Tokyo, 2016

• 5th Cycle: Bangkok, 2018

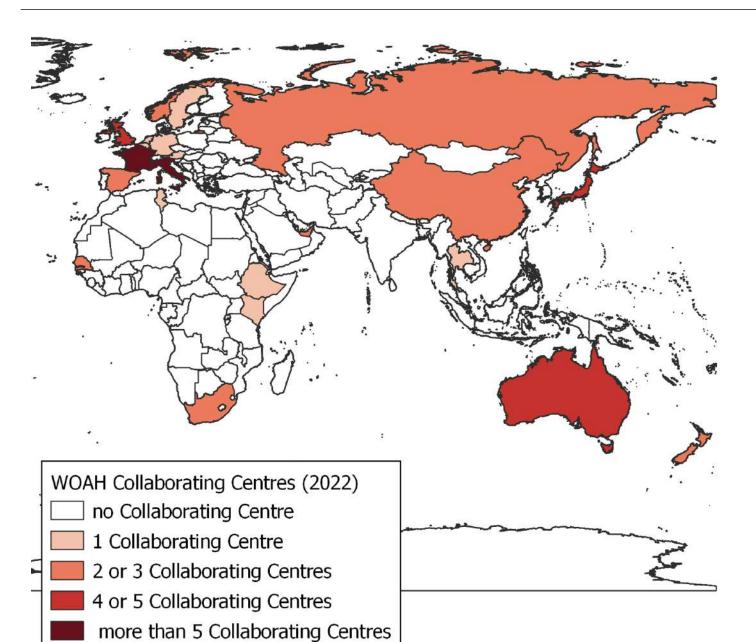
• 6th Cycle: Kuala Lumpur, 2020

• 7th Cycle: Virtual, 2022





## **WOAH Collaborating Centers & Laboratory Network**



## CC for Animal Disease & Veterinary Products Assessment (JAPAN)

- National Institute for Animal Health
- National Veterinary Assay Laboratory

#### **CC** for Food Safety

- School of Veterinary Medicine, Rakuno Gakuen University (JAPAN)
- Research Center for Food Safety (JAPAN)
- National Centre for Food Safety (SINGAPORE)



Hands-on training for AMR technicians in Asia

## Encourage implementation of international standards







# Sanitary and Phyto Sanitary (SPS) Agreement

Animal Health
"WOAH Codes &
Manuals"

Food Safety
"Codex Alimentarius"

Plant Health

"International Plant Protection Convention"











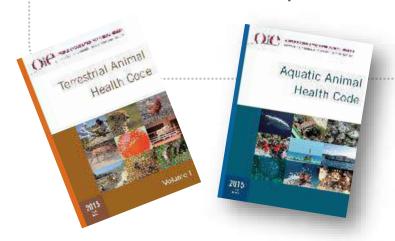


### **The WOAH Standards**

☐ Standards to improve health and animal welfare, and veterinary public health☐ Adopted by WOAH Member Countries during General Session each May by consensus

**CODES** 

Health standards for trade of animals and animal products



#### **MANUALS**

Biological standards for diagnostic tests and vaccines



Available on the WOAH website

#### Terrestrial Animal Health Code



## Terrestrial Animal Health Code (2022)

**Contents** 

Adopting & updating

Adhering & Implementing

#### **VOLUME I**

General provisions

Chapter 6.7.	Introduction to the recommendations for controlling antimicrobial resistance
Chapter 6.8.	Harmonisation of national antimicrobial resistance surveillance and monitoring programmes
Chapter 6.9.	Monitoring of the quantities and usage patterns of antimicrobial agents used in food- producing animals
Chapter 6.10.	Responsible and prudent use of antimicrobial agents in veterinary medicine
Chapter 6.11.	Risk analysis for antimicrobial resistance arising from the use of antimicrobial agents in animals

# Thank you!

Regional Representation for Asia and the Pacific Food Science Building 5F - The University of Tokyo 1-1-1 Yayoi, Bunkyo-ku Tokyo, 113-8657 JAPAN

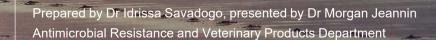
rr.asia-pacific@woah.org rr-asia.woah.org Facebook
Twitter
Instagram
LinkedIn
YouTube
Flickr







Importance of monitoring quantities and usage patterns of antimicrobial agents in animals at a national level



Regional ANIMUSE Training for WOAH Focal Points for Veterinary Products 22-24 February 2023, Bangkok, Thailand



# WOAH International Standards on Antimicrobial Resistance (AMR)

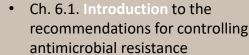
## **Terrestrial Animal Health Code**

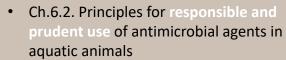


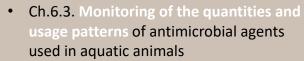


- Ch.6.7. Introduction to the recommendations for controlling antimicrobial resistance
- Ch.6.8. Harmonisation of national AMR surveillance and monitoring programmes
- Ch.6.9. Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals
- Ch.6.10. Responsible and prudent use of antimicrobial agents in veterinary medicine
- Ch.6.11. Risk analysis for AMR arising from the use of antimicrobial agents in animals

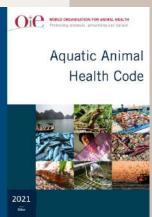
# **Aquatic Animal Health Code**







- Ch.6.4. Development and harmonisation of national AMR surveillance and monitoring programmes for aquatic animals
- Ch.6.5. Risk analysis for AMR arising from the use of antimicrobial agents in aquatic animals



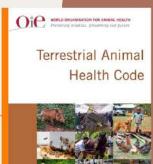
https://www.woah.org/en/what we-do/standards/codes-and-manuals/terrestrial-code-online-access/

https://www.woah.org/en/what-we-do/standards/codes-and-manuals/aquaticode-online-access/



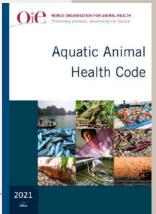
# WOAH International Standards on Antimicrobial Resistance (AMR)

# **Terrestrial Animal Health Code**



 Ch.6.9. Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals

# **Aquatic Animal Health Code**



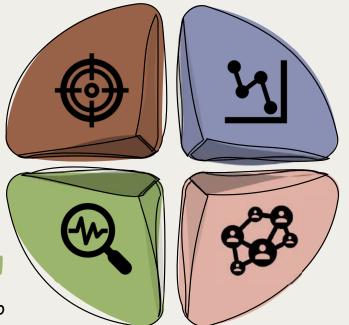
 Ch.6.3. Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals

https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial code-online-access/Nid=169&L=1&htmfile=chapitre antibio monitoring.htm https://www.woah.org/en/what-we-do/standards/codes-and-manuals/aquatic-code-online-access/?id=169&L=1&htmfile=chapitge antibio quantities usage patterns.htm



#### INTERPRETATION

Helping in the interpretation of AMR surveillance data and assisting in responding to problems of antimicrobial resistance in a precise and targeted way



#### EVOLUTION

Giving an indication of trends in the use of antimicrobial agents in animals over time and potential associations with AMR in animals

#### EVALUATION

Assisting in risk management to evaluate the effectiveness of efforts and mitigation strategies.

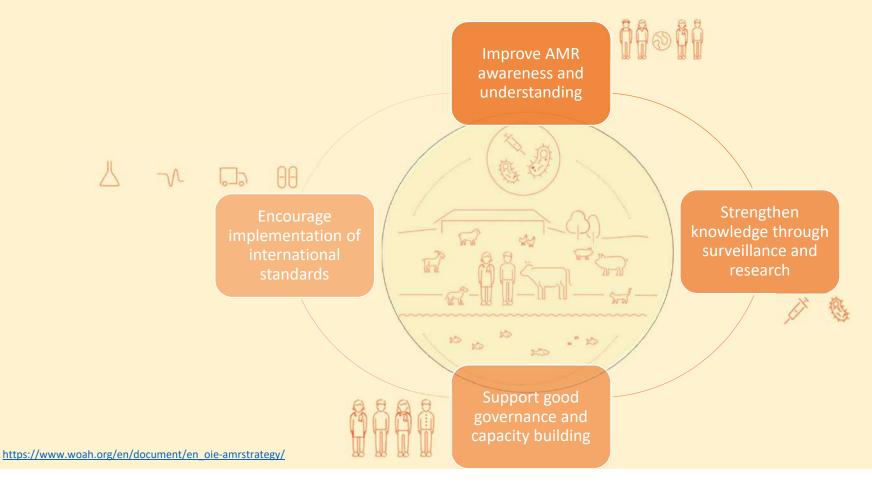
#### COMMUNICATION

Ensuring transparency and communicating on the risks (if data published)



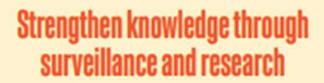
#### WOAH Strategy on AMR and the Prudent Use of Antimicrobials

The WOAH Strategy supports the objectives established in the Global Action Plan on AMR, developed by WHO with strong contribution from FAO and WOAH. It reflects the mandate of the WOAH, through four main objectives:





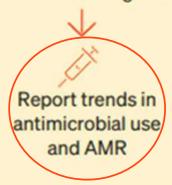
#### WOAH Strategy on AMR and the Prudent Use of Antimicrobials

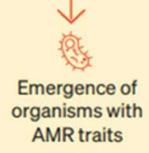


**AMR National Action Plans** 



Monitoring and surveillance systems







Strengthen knowledge through surveillance and research

- Support Members in developing and implementing monitoring and surveillance systems
- Build and maintain a database for collecting data on the use of antimicrobial agents in food-producing and companion animals, with associated analysis and annual reporting
- Enhance the development, use and functionality of WAHIS to allow analysis of data on antimicrobial use
- Guide and support research into alternatives to antibiotics to encourage the development and uptake of new tools, products and methodologies
- Identify and pursue opportunities for public-private partnerships in AMR research and risk management



# WOAH Global database on antimicrobial agents intended for use in animals

# The database is designed to:

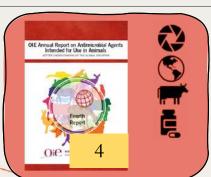
Monitor the type and use of antimicrobial products

Measure trends over time Trace circulation and use patterns globally Evaluate the quality and authenticity of antimicrobial products in use



# WOAH's Report on Antimicrobial Agents Intended for Use in Animals















Result of the Round



Regional Information



Animal Biomass



Antimicrobial Quantities Focused on One Year



Trends on Time

https://www.woah.org/en/what-we-do/global-initiatives/antimicrobial-resistance/#ui-id-3



## AMU Data Collection Sections

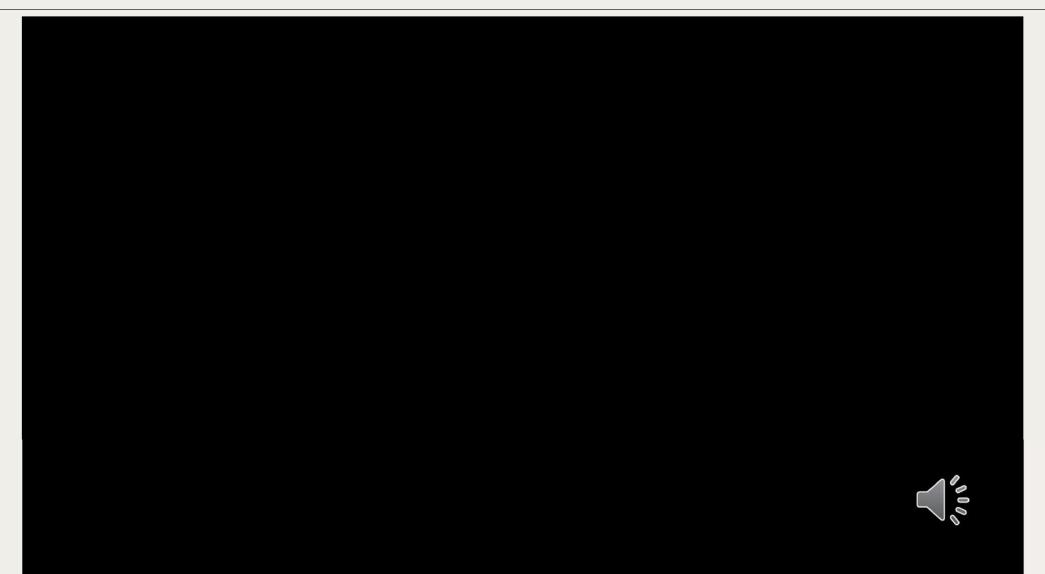
are not available

Qualitative data

Answering the questionnaire and choosing a Reporting Option it is now easier with ANIMUSE



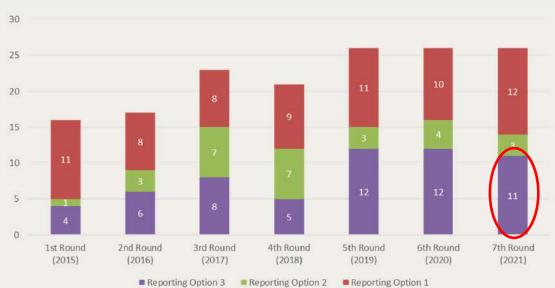
# Proportion of Members Submitting Quantitative Data on AMU in Asia





# Type of data provided – Asia







#### Next steps

- More participation from Members during this 8<sup>th</sup> Round of AMU Data Collection letters have been sent in September 2022.
- More information on:
  - Type of use
  - Animal groups
  - Route of administration



This can be easily achieved with ANIMUSE's Calculation Module





#### Long-term vision

- Provide information by animal species
- Refined animal population data with WAHIS
- Explore AMU data collection at field level

# Thank you



For any question, contact us at <a href="mailto:antimicrobialuse@woah.org">antimicrobialuse@woah.org</a>

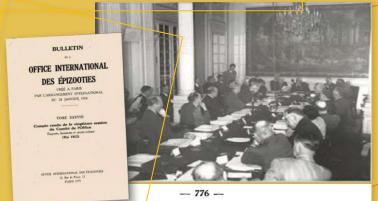






## First approaches to AMR and AMU

#### 1952 – 20th OIE Session



2º Le praticien ne doit pas utiliser les antibiotiques au gré. de sa fantaisie, mais en suivant les règles qui ont été fixées

L'atilisation des antibiotiques contre des germes insensibles à leur action ou particulièrement résistants, l'emploi de doses trop faibles ou pendant un temps trop bref entraînent des dépenses inutiles, peuvent faire apparaître des germes résistants, retardent d'autant la mise en œuvre d'un traitement efficace et conduisent à des échecs qui nuisent à une méthode qui, lorsqu'elle a été judicieusement et correctement appliquée, a permis de sauver nombre de vies humaines et animales.

2013 – 1<sup>st</sup> Global Conference on Antimicrobial Resistance (AMR)



WOAH Members agreed to collect harmonised AMU data in animals with the view to submit them to the WOAH and to establish a global database

Resolution 26 "Combating AMR and Promoting the Prudent Use of Antimicrobial Agents in Animals"

The OIE develops a procedure and standards for data quality for collecting data annually from OIE Member Countries on the use of antimicrobial agents in food-producing animals with the aim of creating an OIE global database...



Resolution 36 "Combating AMR through a One Health Approach: Actions and OIE Strategy"

The OIE actions to be compiled and consolidated within the OIE Strategy on antimicrobial resistance include:

The establishment and the management of a database for the collection of data on the use of antimicrobial agents in animals as well as the development of interpretation indicators



# 2012

Survey on the implementation of Chapter 6.9 of the Terrestrial Animal Health Code - Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals

Some of the objectives were:

- To determine what actions are needed and to help the OIE to develop its strategy regarding AMU
- To prepare the 1st OIE Global Conference on AMR



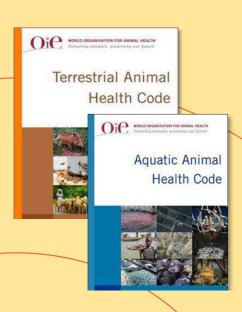
Results were presented at the 2013 - 1st Global Conference on AMR



# 2014

# **AMU Template**

Created by the experts of the WOAH (OIE) ad hoc Group on AMR – based on Chapters 6.9 and 6.3 of the Terrestrial and Aquatic Codes, respectively.





# 2014

# National Focal Points for Veterinary Products (FPVP)

Documents were discussed with the WOAH (OIE) National FPVP in the Americas; Europe; and Asia, Far East and Oceania regions; Africa was asked by email.





85% Participation

(152 Members)

2012 - Survey on the

implementation of Chapter

6.9 of the Terrestrial

Animal Health Code

Some of the objectives were: To determine what actions are needed and to help the OIE to develop its strategy

regarding AMU

To prepare the 1st OIE Global Conference on AMR

# WOAH AMU Template and Accompanying Documents

2013 - 1<sup>st</sup> Global Conference on **AMR** 



#### 2014 – OIE **AMU Template**

Created by the experts of the OIE ad hoc Group on AMR – based on Chapters 6.9 and 6.3 of the Terrestrial and Aquatic Codes, respectively.



#### 2014 — National Focal Points for Veterinary Products (FPVP)

Documents were discussed with the OIE National FPVP in the Americas; Europe; and Asia, Far East and Oceania regions; Africa was asked by email.















#### OIE Annual Report on Antimicrobial Agents Intended for Use in Animals





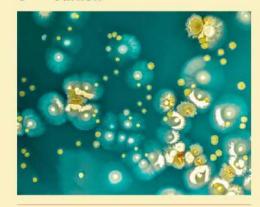


Report OTO WORLD DEGANISATION FOR ANIMAL HEALTH Protecting animals, preserving our future

OIE Annual Report on Antimicrobial Agents Intended for Use in Animals BETTER UNDERSTANDING OF THE GLOBAL SITUATION

# Rapport annuel sur les agents antimicrobiens destinés à être utilisés chez les animaux

#### Gème édition







#### OIE Annual report on antimicrobial agents intended for use in animals

BETTER UNDERSTANDING OF THE GLOBAL SITUATION

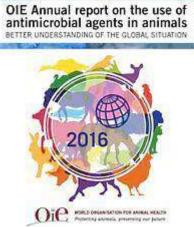


OIE Annual report on antimicrobial agents intended for use in animals

BETTER UNDERSTANDING OF THE GLOBAL SITUATION









#### **AMU Questionnaire Based on**

# Terrestrial Animal Health Code

 Chapter 6.9. Monitoring of the quantities and usage patterns of antimicrobial agents used in foodproducing animals

First adopted in 2003

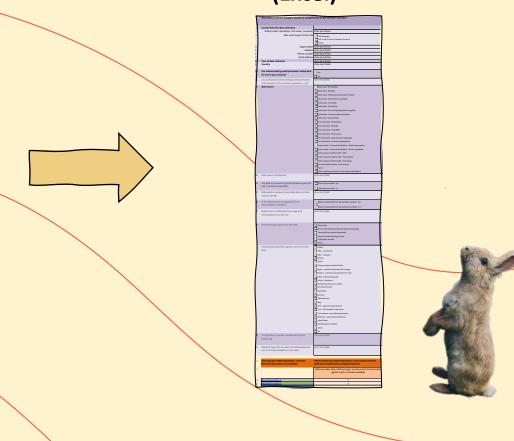
Aquatic Animal Health Code

 Chapter 6.3. Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals

First adopted in 2012

# 2015

First version of the AMU Questionnaire (Excel)





# Global database on antimicrobial agents intended for use in animals

#### Type of Reporting

#### **Qualitative Data**

Baseline data designed to allow all countries to respond

#### **Quantitative Data**

Reporting Options represent increased level of data detail

#### Option 1

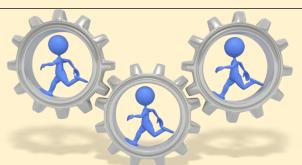
- Antimicrobial agents
- · Type of use\*

#### Option 2

- Antimicrobial agents
- · Type of use\*
- Group of animals\*\*

#### Option 3

- Antimicrobial agents
- Type of use\*
- Group of animals\*\*
- Routes of administration
- \* Type of use: veterinary medical use or growth promotion
- \*\* Groups of animals: 'terrestrial food-producing animals', 'aquatic food-producing animals' or 'Companion animals'

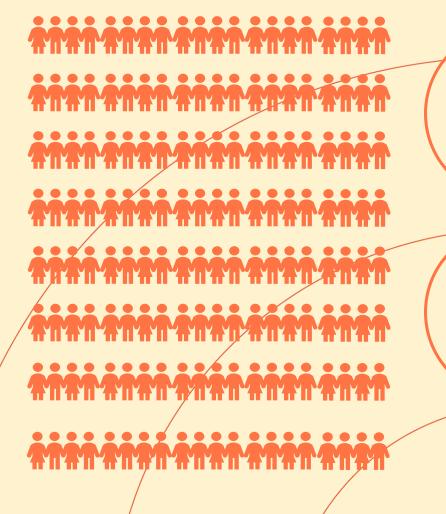


Peer-reviewed methodologies for data collection and analysis



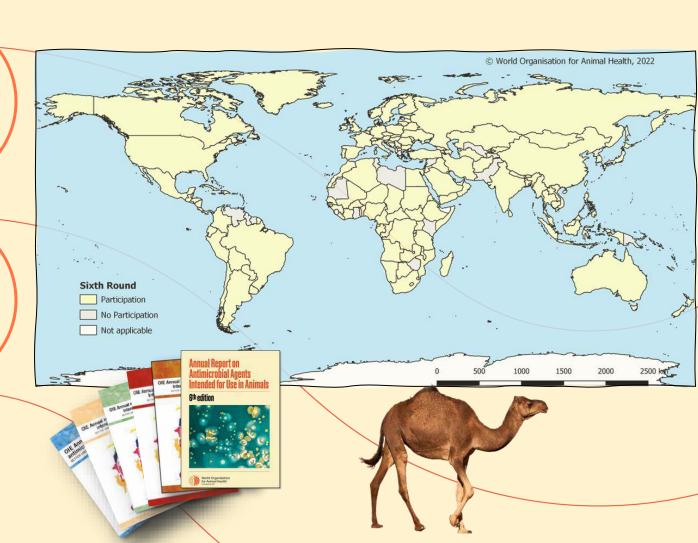


# **Participation**



**85**%

160





Recommendation n°4 of the 2<sup>nd</sup> OIE Global Conference on Antimicrobial Resistance – October 2018



To further develop the OIE data collection on Antimicrobial Agents Intended for Use in Animals, converting the current spreadsheet format to a database system, able to accommodate data submissions by animal species, and its connection to the World Animal Health Information System (WAHIS) and also allowing addition of data from field studies



2<sup>nd</sup> OIE Global Conference on Antimicrobial Resistance and Prudent Use of Antimicrobial Agents

Putting Standards into Practice

larrakesh (Morocco), 29-31 October 2018

#### DECOMMEND ATIONS

#### CONSIDERING THAT

- Antimicrobial resistance (AMR) is a serious global threat to human health, animal health and welfare, plant health, load security, and also impacts to the environment throughout the world and cannot be successfully tackled without multi-sectoral ecoperation;
- 2. The Tripartite [Food and Agriculture Organization of the United Nations (FAO), World Organization for Animal Health (OE), World Health Organization (WHO)) are collaborating with the United Nations Environment Programme (UN Environment) to ensure the development and implementation of global strategies and measures designed to control the development and spread of AMR, and contribute to the fulfilment of the United Nations Sustainable Development Academic Contributions (Contribution).
- The Tripartite is developing frameworks on AMR Stewardship and the Monitoring and Evaluation
  of the implementation of National Action Plans and has recently been strengthered through the
  signing of a Memorandum of Understanding (MoU) with a strong locus on AMR including the
  development of a detailed workplan for the corning years in collaboration with UN Environment;
- The OIE establishes global standards and guidelines and provides assistance and leadership to Member Countries to strengthen Veterinary Services and capacities to support their implementation at automat level.
- The OIE is implementing its Strategy on Animicrobial Resistance and the Prudent Use of Animicrobials, improving awareness and capacity through monitoring and training, in line with the Global Action Plan on AMR developed by the WHO in collaboration with FAO and OIE;
- Following the Political Declaration of the High Level Meeting of the United Nations General Assembly on Artimicrobial resistance in 2016, the UN Interagency Coordination Group (IACG) on AMR with the support of the Tripartite secretarial is preparing a report to the UN Secretary General by May 2019.

#### AND CONSIDERING

The commitment expressed by Ministers attending the conference, who confirmed their support to the Global strategies and initiatives developed under the leadership of the Tripartial OEI\_FAO\_WHY.O, as well as their political will to allocate the adequate resources for the implementation of those strategies at national level.

THE PARTICIPANTS OF THE DIE GLOBAL CONFERENCE ON ANTIMICROBIAL RESISTANCE AND PRUDENT USE OF ANTIMICROBIAL AGENTS

RECOMMEND TO THE TRIPARTITE (FAC, OIE, WHO)

Final versio



#### INTERACTIONS

Each round,

**+30** teleconferences & videoconferences

650 emails exchanged

#### **PROGRESS**

Since 1st round,

+ 20% Participation

+120 % Reporting Option 3

#### **UNDERSTANDING**

Each round,

**80%** of Members amend their dossiers after interacting with WOAH AMU Team

#### TRAININGS

Since 5th round,

**615** participants were trained through in-person or virtual trainings



# **Identified countries' needs**



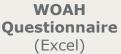
# Among all needs, these were present in many Members

- ✓ IT Tools to collect and calculate AMU data
- ✓ Access to historical data
- ✓ Trends on time
- ✓ Analysis of AMU data



# AMU Data collection: A New Phase









Annex to assist in **Guidance** to complete the WOAH calculations (PDF) Template (PDF)



#### ANIMUSE

# A Database platform designed for you



To calculate antimicrobial quantities with the Calculation module



Allows online access to complete the antimicrobial use (AMU) questionnaire and upload data collected offline.



Access historical data and generate professional outputs for data

#### **Excel & email based**

These documents are sent every year to:

All WOAH Delegates

All WOAH Focal Points for Veterinary **Products** 

Exchanges by email



# Thank you

# Introducing ANIMUSE and its main functionalities

Mduduzi Magongo Business Project Management Support 22-24 February 2023 Bangkok, Thailand



World Organisation for Animal Health Organisation mondiale de la santé animale Organización Mundial de Sanidad Animal Fundada como OIE



# ANIMUSE: Animal Antimicrobial Use Global Database



- ✓ Link: amu.woah.org
- ✓ Rebranding of system







# ANIMUSE Timeline – Key activities

#### 8<sup>th</sup> Round Opening

Invintation letters for the 8th Round of data collection were sent to countries. Members were also invitated to create their ANIMUSE accounts and

passwords

#### Training – Africa (EN)

In person ANIMUSE training for English Speaking Africa was done in South Africa 2-4 November 2022.

#### Training - Asia

In person ANIMUSE training for Asia in Bangkok, 22 - 24 February 2023.

**NB**: Training for Europe and the Americas will be scheduled in the following months













(22/02)



In person ANIMUSE training for French Speaking Africa was done in Tunisia, 30 - November to 2 December 2022.

#### Training - Africa (FR)

In person ANIMUSE training for Middle East is scheduled for 2-4 May 2023

Training – Middle

East

#### **ANIMUSE** Launch

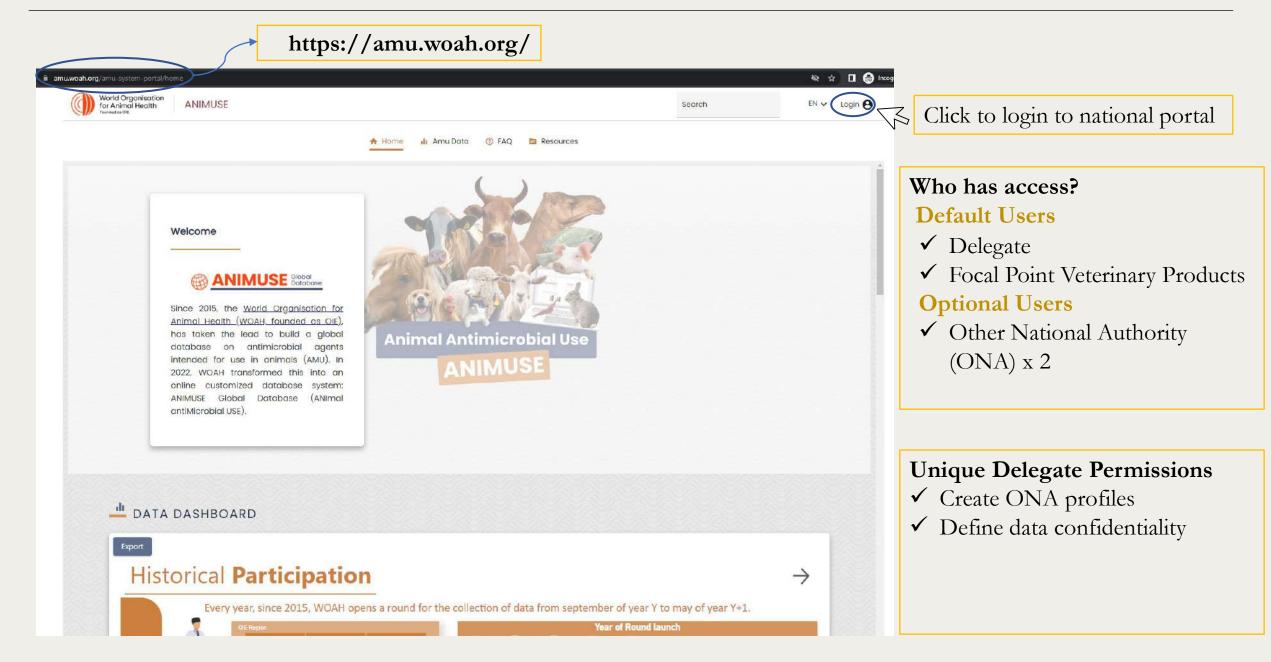
More than 200 participants, at least 65 members represented. Launch video link.

#### Login Success rate **(64%)**

As of 15/02/2023, the successful login rate to ANIMUSE for Asia is 63% and 64% globally.



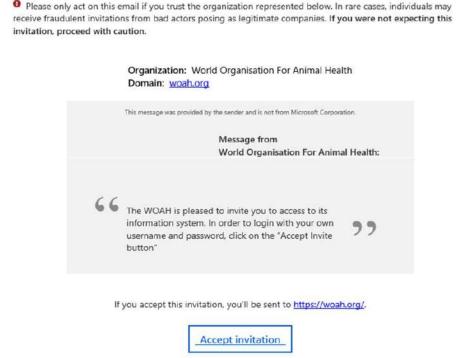
## ANIMUSE – Access and Permissions





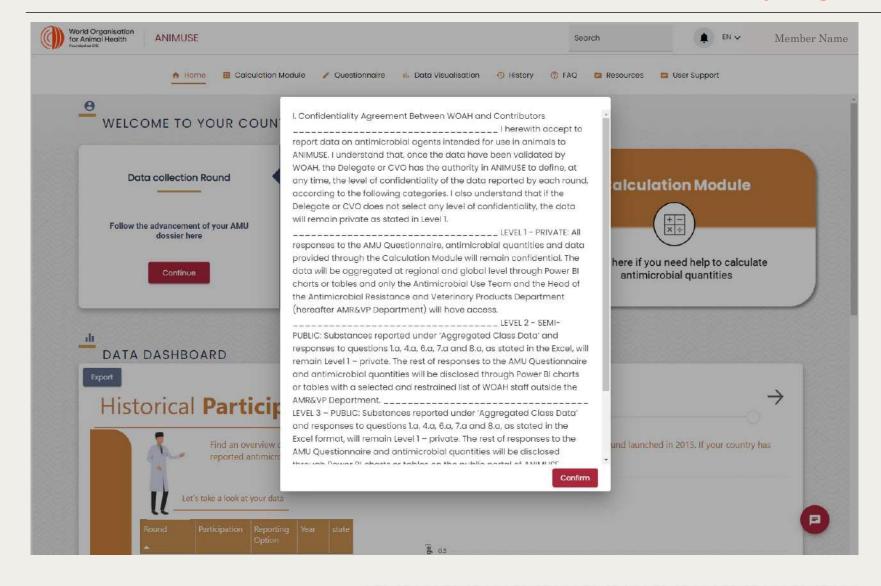
# ANIMUSE – 1<sup>st</sup> Time Login Procedure







# ANIMUSE National Portal – Confidentiality Agreement



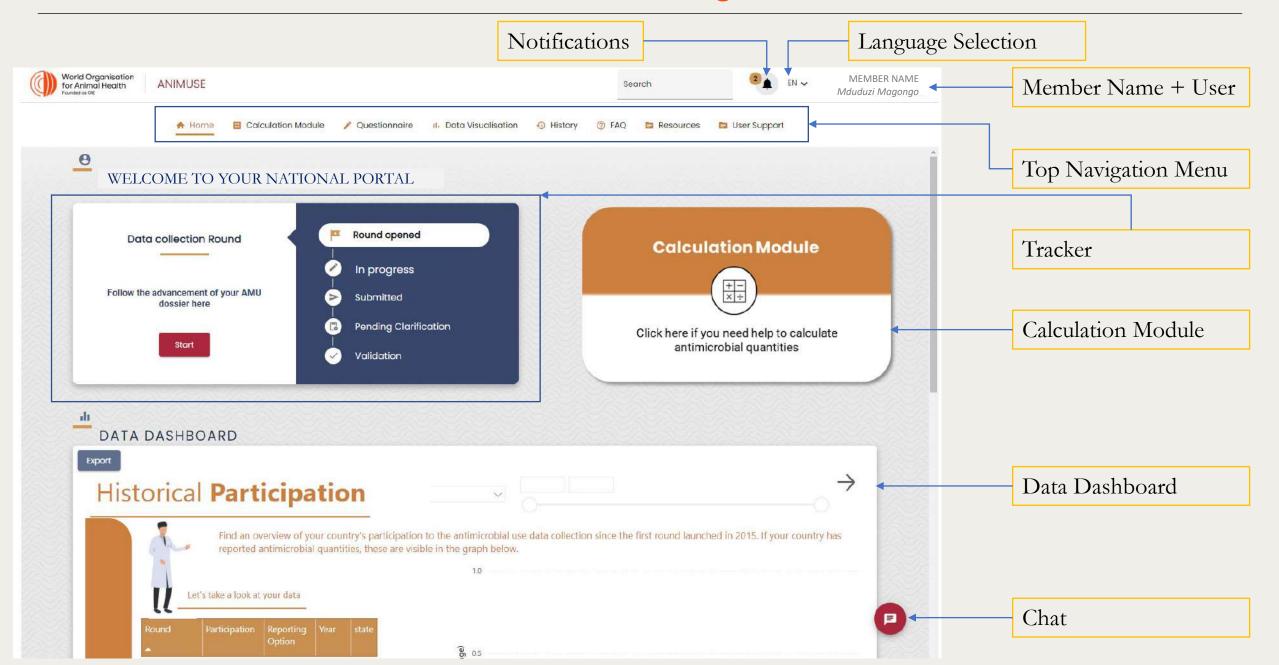
Level 1. Private

Level 2. Semi-public

Level 3. Public



# ANIMUSE National Portal – Home Page



# ANIMUSE National Portal – Home Page

#### ANIMUSE Introduction Videos





Completing the AMU Questionnaire



Consolidating data with the Calculation module



Understanding your data with the data visualisation components



Contact us

Confidentiality Agreement

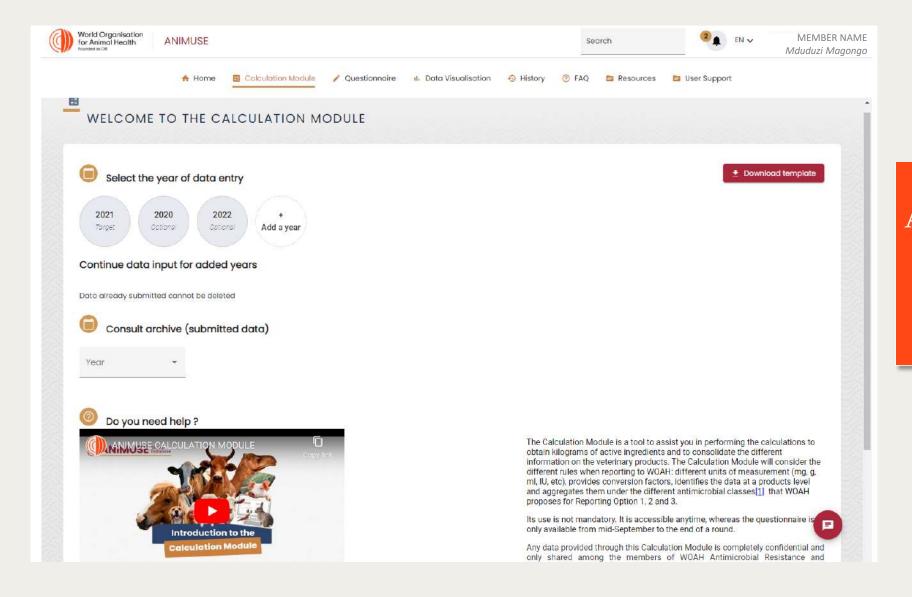
Personal Privacy Policy

Terms and conditions

Footer Menu



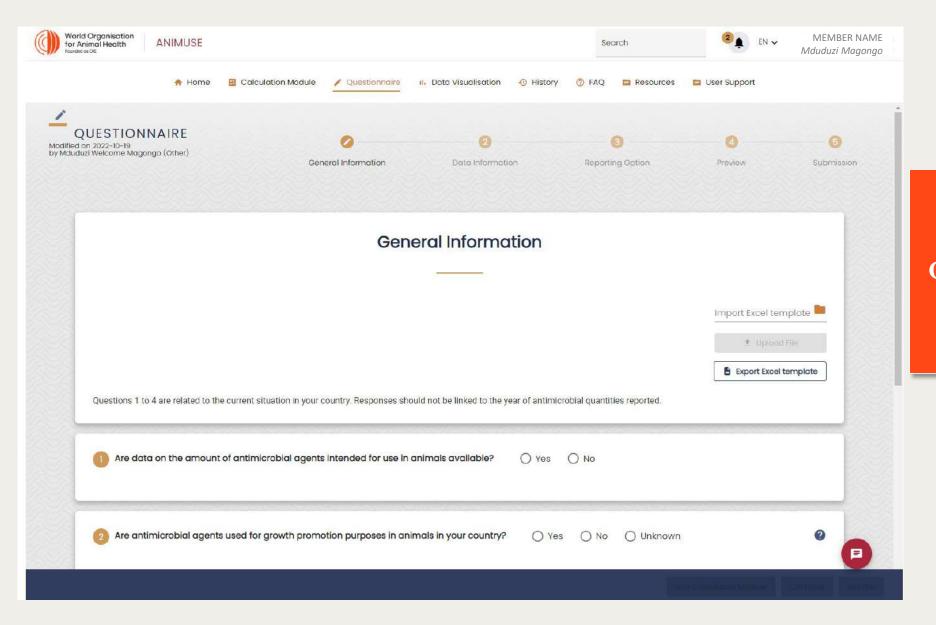
# ANIMUSE – Calculation Module



Assist you in performing the calculations to obtain kilograms of active ingredients



# ANIMUSE – Questionnaire



Complete the AMU
Questionnaire online or by
injection.

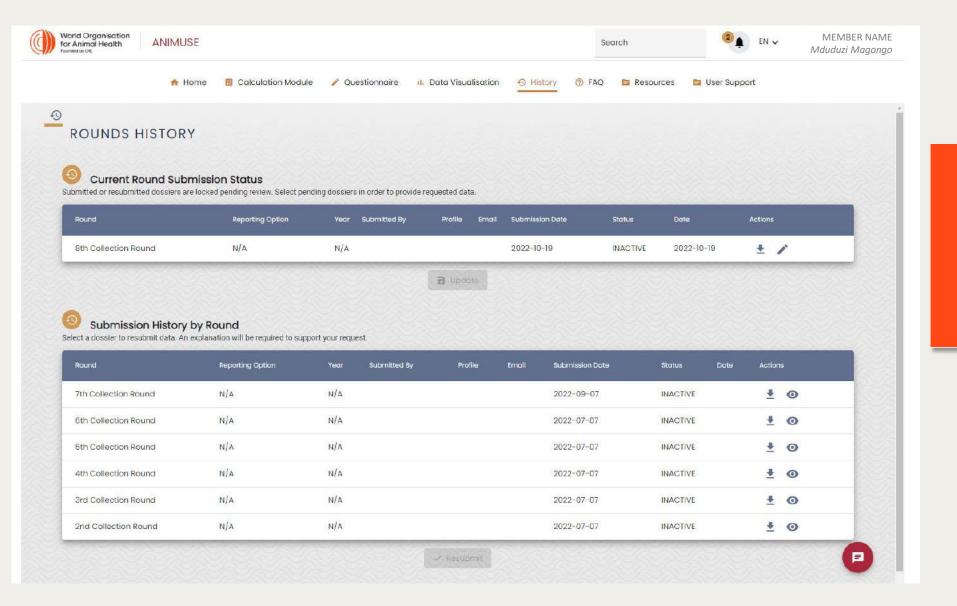


# ANIMUSE – Data Visualization



Visualise your data through interactive dashboards

# ANIMUSE – History



Access all your historical data

# Thank you

12, rue de Prony, 75017 Paris, France T. +33 (0)1 44 15 19 49 F. +33 (0)1 42 67 09 87

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Twitter
Instagram
LinkedIn
YouTube

Flickr

World Organisation for Animal Health

Organisation mondiale de la santé animale Fondée en tant qu'OIE Organización Mundial de Sanidad Animal Fundado como OIE





# AN USE Global Database

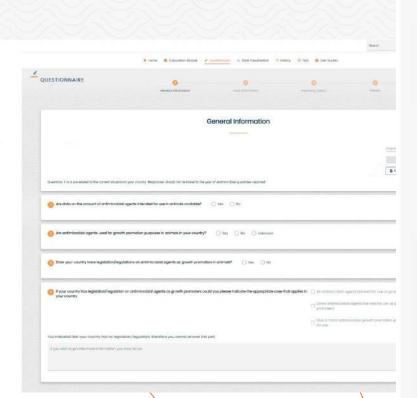


# **ANIMUSE: A new look for the same questionnaire**

### A **new look** for the Excel Questionnaire

#### More user friendly





# Type of Reporting

#### **Qualitative Data**

Baseline data designed to allow all countries to respond

#### **Quantitative Data**

Reporting Options represent increased level of data detail

# Option 1

- Antimicrobial agents
- · Type of use\*

# Option 2

- Antimicrobial agents
- · Type of use\*
- Group of animals\*\*

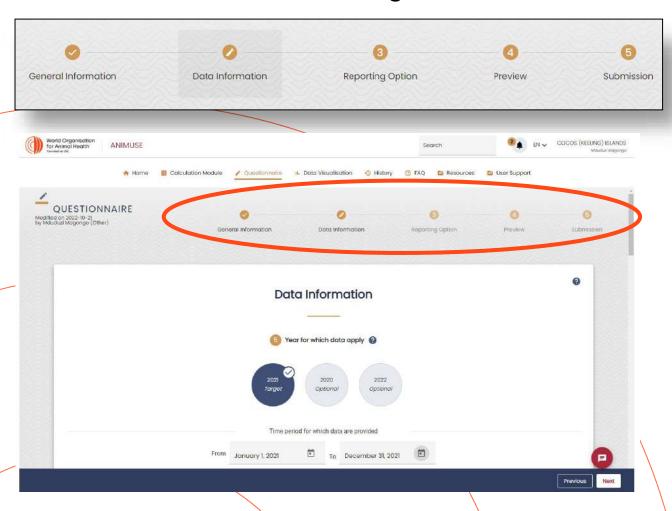
# **Option 3**

- Antimicrobial agents
- Type of use\*
- Group of animals\*\*
- Routes of administration
- \* Type of use: veterinary medical use or growth promotion
- \*\* Groups of animals: 'terrestrial food-producing animals', 'aquatic food-producing animals' or 'Companion animals'



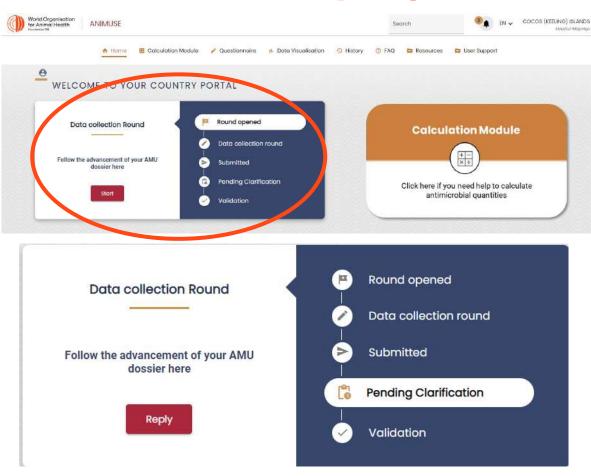
# AMU Questionnaire: Follow your progress every step of the way

# **Questionnaire navigation bar**



The Questionnaire completion

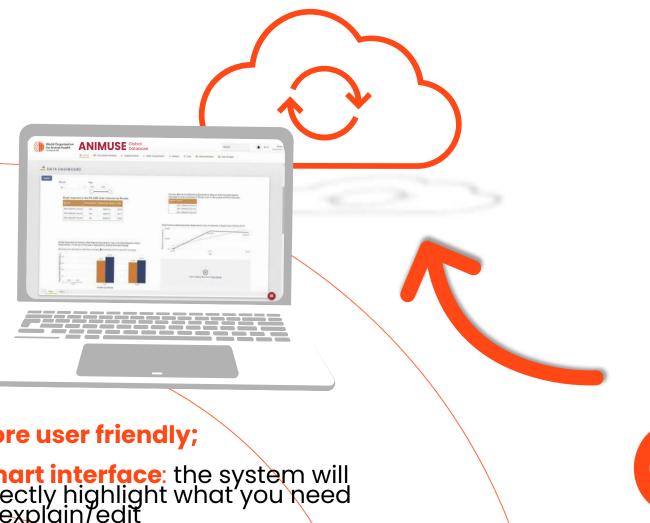
# **Submission progress**



**Submission status menu** 



# **ANIMUSE: Work online or offline**

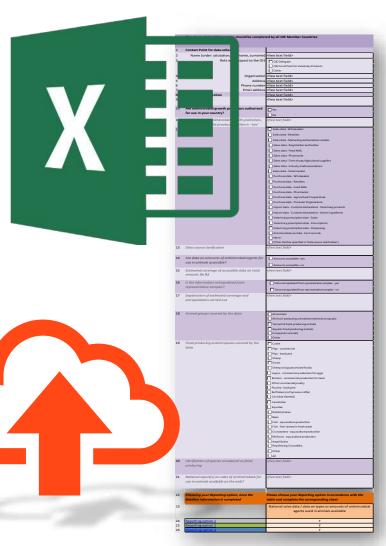


+ More user friendly;

+ Smart interface: the system will directly highlight what you need to explain/edit

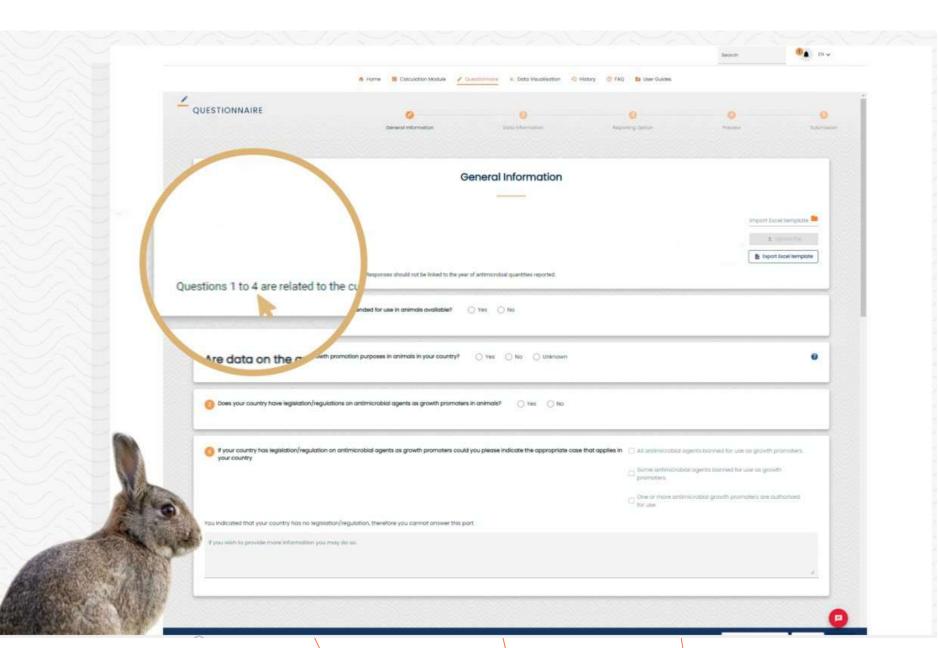
**ONLINE** 







# AMU Questionnaire: General Information





Designed to allow ALL participants to answer

Even if antimicrobial quantities are not collected at a national level



Depending on your responses, the system may ask you for more information or clarification.



# **AMU Questionnaire: Data Information**



**Help button** provides context/definitions

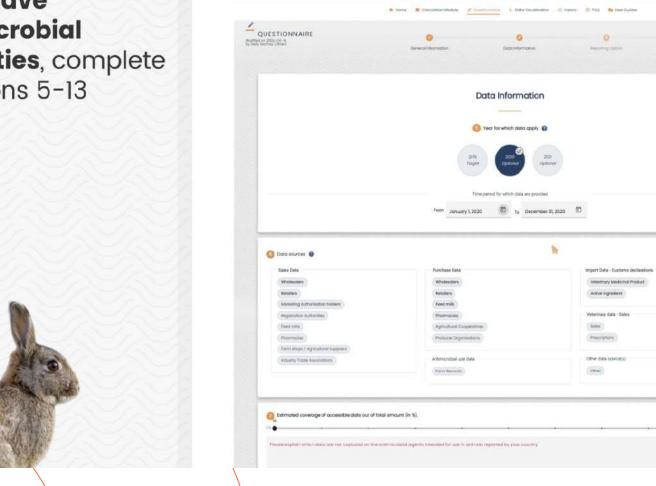
If you have antimicrobial quantities, complete questions 5-13



**Chat button** to contact the Antimicrobial Use Team

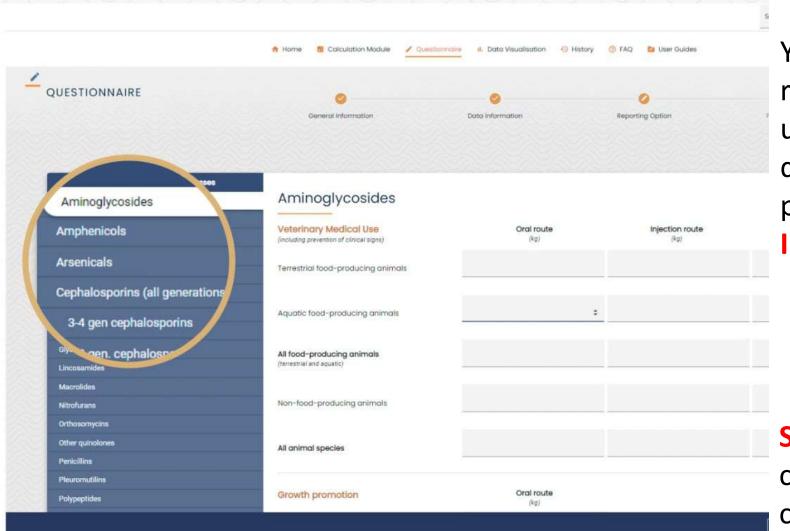


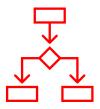
Mandatory questions will highlight in red if skipped





# **AMU Questionnaire: Reporting Option**





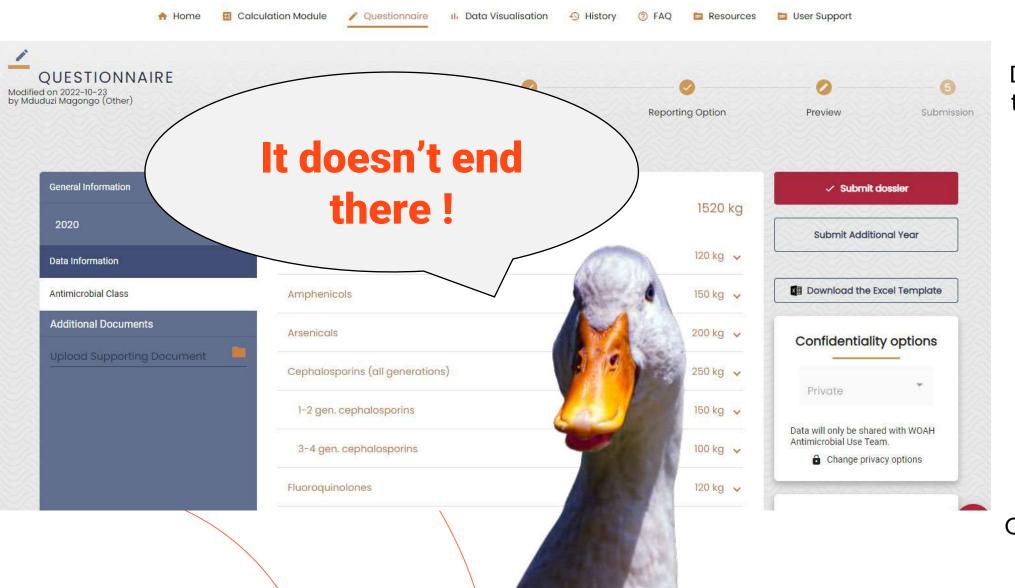
You have the possibility to report antimicrobial quantities using reporting option 1,2 or 3 depending on the answers provided in the Data Information section.



**Save** your questionnaire and complete it at the most convenient time



# **Preview: To review all your answers**





Download the Excel template filled with your answers



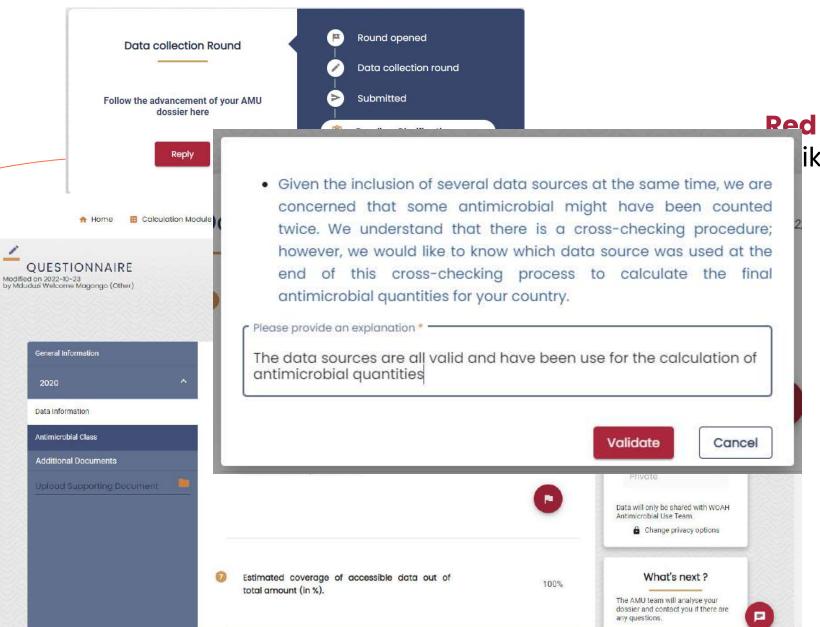
Upload additional documents if needed



Check your answers and submit to the AMU Team



# **AMU Team analysis : Provide clarifications**



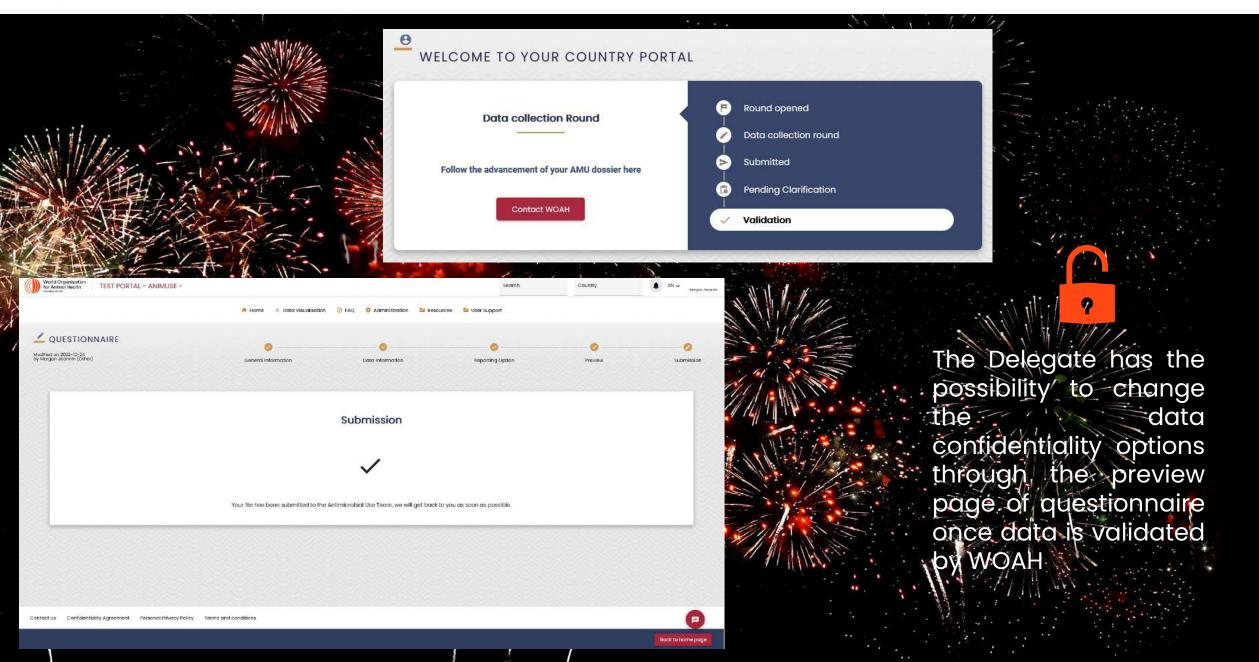


Red flags when the AMU Team would ike to clarify a question with you



Click on the flag to provide an explanation and validate your response or directly modify your answer to the question

# Dossier validated





# Thank you



ANIMUSE training

22-24 February 2023

Bangkok, Thailand



# ANIMUSE – AMU Questionnaire and

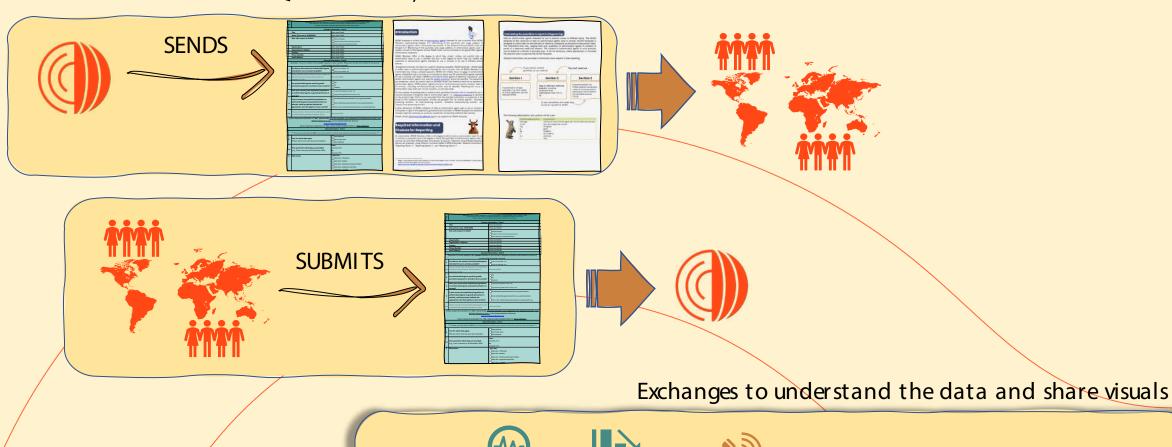
# Common Errors





# WOAH's AMU data collection procedure

# Questionnaire, Guidance and Annex

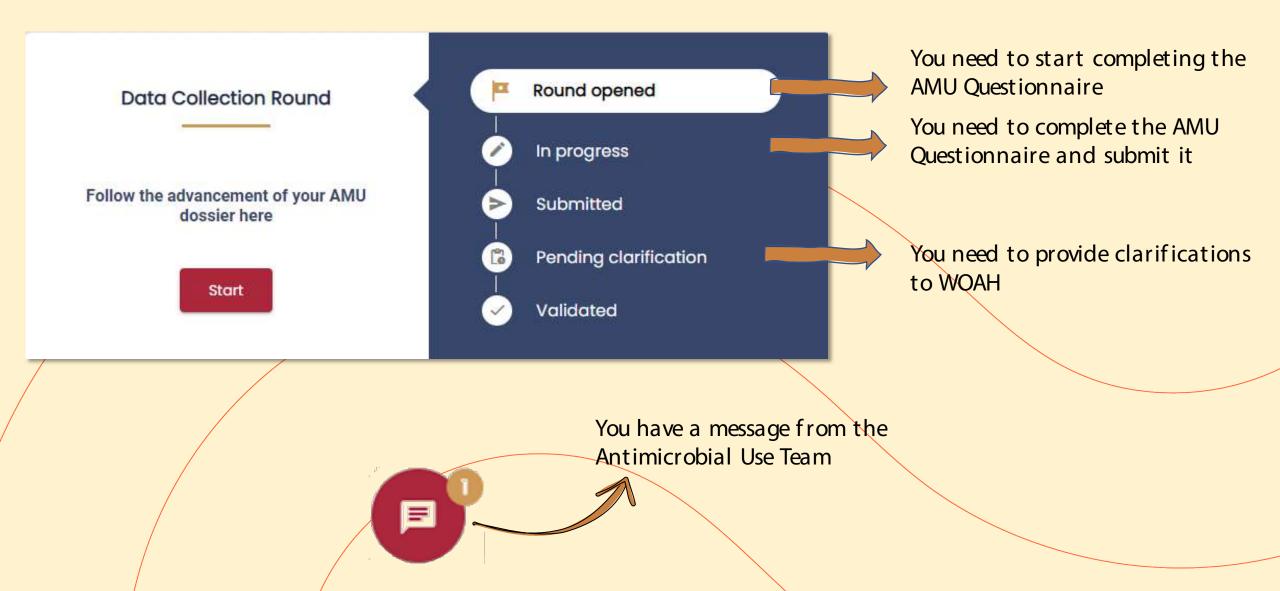


- All fields answered
- Coherence of answers
- Data over time
- Good calculations





# When are you expected to take action in ANIMUSE?





# What Can I do If my Country Is Not Able to Provide Antimicrobial Quantities?



Are data on the amount of antimicrobial agents intended for use in animals available?



Please indicate why the data are not available at this time in your country, if your answer is no.

When you click 'no', you must provide us with all the relevant information that impedes you from reporting antimicrobial quantities. WOAH is trying to analyse this information to find suitable solutions.

The Calculation Tool (now the Calculation Module in ANIMUSE) was a response to issues related with calculations and lack of IT systems that assist in the data collection procedure.

Remember, WOAH's AMU Data Collection has been designed since its creation to allow the participation of EVERYONE



# What Type of Data Should I Submit?



If quantitative data are partially available at national level, choose 'Yes'. If quantitative data are available for imports, sales, purchase, prescription, production or use at farm level, choose 'Yes'.

WOAH's AMU Data Collection accepts any type of data sources. All data sources accepted are listed in Question 6,



# Use of Growth Promoters

# What is growth promotion?

Growth Promotion means the administration of antimicrobial agents to animals only to increase the rate of weight gain or the efficiency of feed utilisation.



# What is NOT growth promotion?

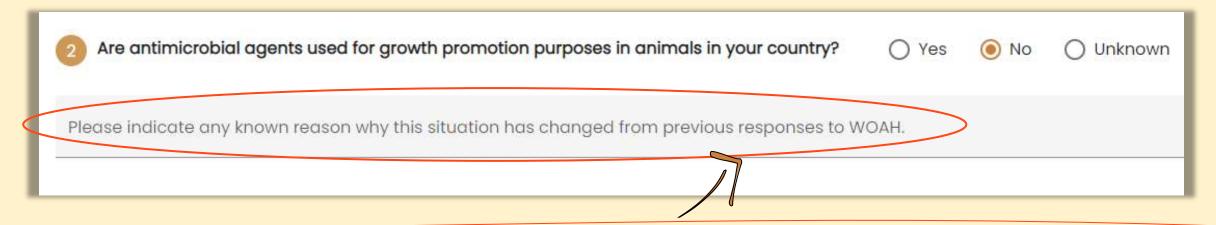
- To treat diseases
- To control diseases
- To <u>prevent</u> diseases



Prevention means to administer an antimicrobial agent to an individual or a group of animals at risk of acquiring a specific infection or in a specific situation where infectious disease is likely to occur if the drug is not administered.



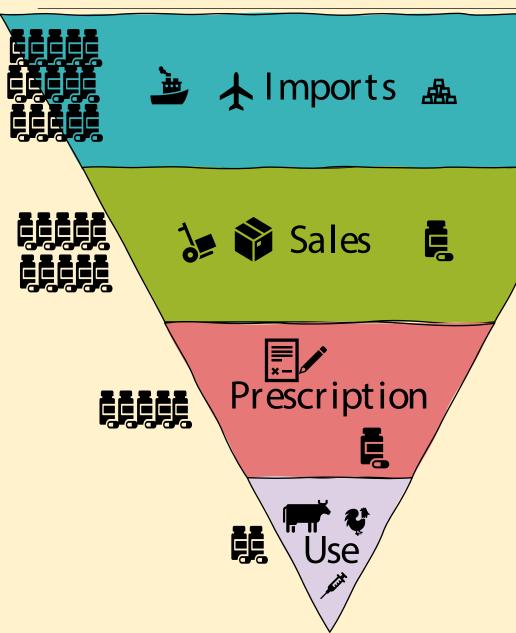
# **Use of Growth Promoters**



If what you are answering is different from previous rounds, you should provide an explanation. You can also check previous responses in the History tab by clicking on the 'eye'

Round	Reporting Option	Year	Submitted By	Profile	Email	Submission Date	Status	Date	Actions		
7th Collection Round	Baseline data	N/A	Lilou Menesses	Other National Authority		2022-03-11	VALIDATED		<u>*</u>	0	
6th Collection Round	Baseline data	N/A	Delfy Góchez	Focal point		2021-03-10	VALIDATED		<u>*</u>	0	
5th Collection Round	Option 3	2017	Delfy Góchez	Focal point		2020-04-15	VALIDATED		<u>*</u>	0	





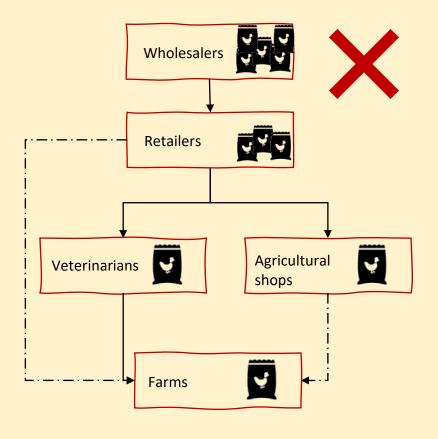
These are the main data sources reported at a global level. In Asia, the main data source comes from imports.

It is possible to estimate total usage by collecting sales data, prescribing data, manufacturing data, import and export data or any combination of these.

However, please put attention to any duplication when crosschecking data. Also, you might want to inform us which was the final data source that you used when performing the calculations.

# Risk of Duplication or Over-Estimation of Data Sources

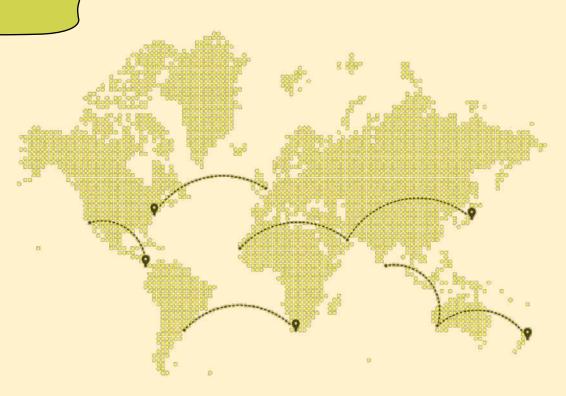
Map the distribution of veterinary products. This will help you to evaluate if there are duplications in the data collection process.



# How to Avoid Duplication or Over-Estimation of Data Sources?

Map the distribution of veterinary products. This will help you to evaluate if there are duplications in the data collection process.

If you are notifying imports or production, consider the exports



# How to Avoid Duplication or Over-Estimation of Data Sources?

Map the distribution of veterinary products. This will help you to evaluate if there are duplications in the data collection process.

If you are notifying imports or production, consider the exports

You can use different data sources for different animal species (depending on the most suitable data source for that species).



**IMPORTS** from poultry products





SALES

from companion

animal products







**USE** from aquatic animals



# Use Visuals to Identify Potential Errors

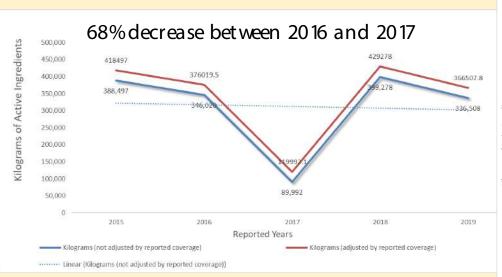


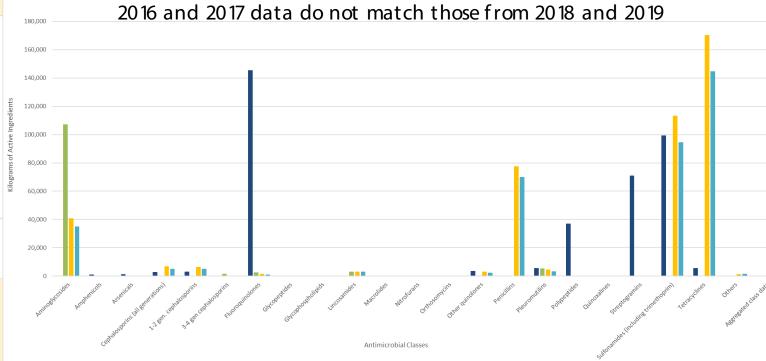
You can create your own visuals, but if needed, you can use the ones already created in ANIMUSE



In a chart, be attentive to the following things:

- Antimicrobial classes most used during the years
- Numbers of antimicrobial classes reported
- Percentage of change (%) from one year to another or in a period of time (more than á25% may indicate an error).
- Abrupt changes in the analysis of historical data





III Data Visualisation

Coming soon

**Antimicrobial Quantities** 



# Use Visuals to Identify Potential Errors



% of change can be calculated as:

Total of current year - Total of previous year

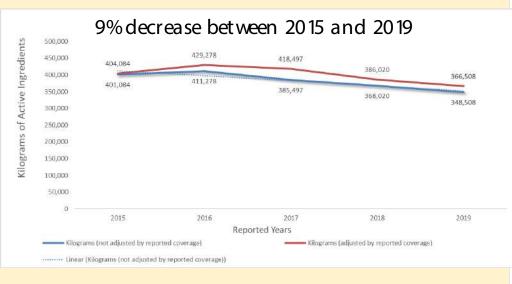
Total of previous year

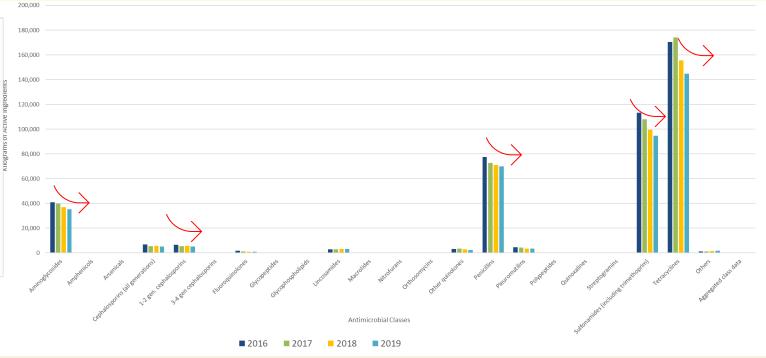
You can create your own visuals, but if needed, you can use the ones already created in ANIMUSE

in ANIMUSE

In a chart, be attentive to the following things:

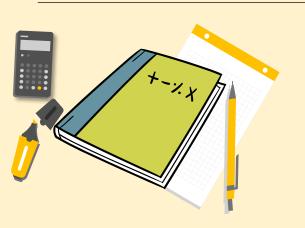
- Antimicrobial **classes most us**ed during the years
- Numbers of antimicrobial classes reported
- Percentage of change (%) from one year to another or in a period of time (more than á25% may indicate an error).
- Abrupt changes in the analysis of historical data





14

# **Avoiding Errors in the Calculations**



1 Check WOAH's recommendations for the calculations

Make sure you are using conversion factors when appropriate

Do not report WEIGHT of imported boxes, but KILOGRAM of CALCULATED active ingredients



You, as a National Authority, should have access to DISSAGREGATED data by molecules or veterinary products. Make sure you are able to validate the data notified by different stakeholders



# Introducing other ANIMUSE functionalities

Mduduzi Magongo Business Project Management 22-24 February 2023 Bangkok, Thailand



World
Organisation
for Animal
Health
Founded as OIF

Organisation mondiale de la santé animale Fondée en tant qu'OIE Organización Mundial de Sanidad Animal Fundada como OIE



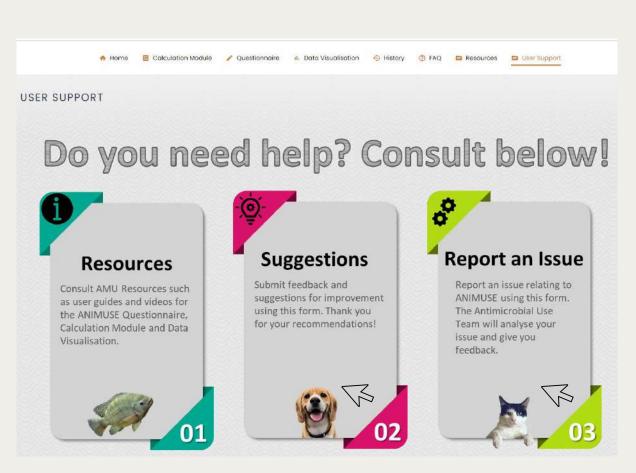
# ANIMUSE – Security Factsheet



Several security layers



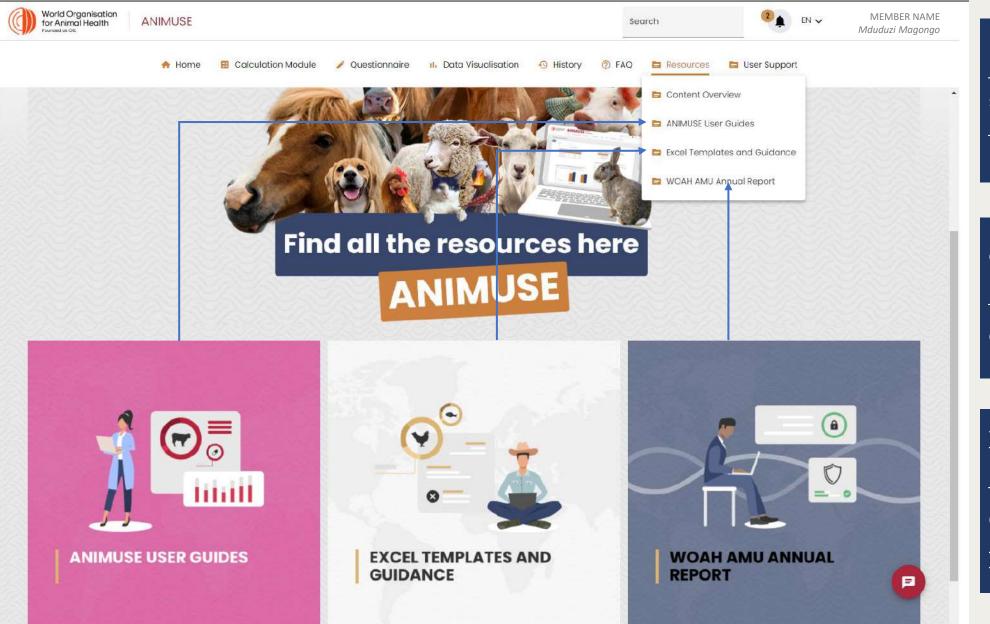
# ANIMUSE – User Support (Helpdesk)



	trial by filling in the form below. The Antimicrobial Use Team will analyse your wide with this form is processed by WOAH, as a data controller, and allow us to find more information regarding the processing and your rights on our Privacy
Policy here <u>https://www.wcoh</u> u	any benderinate-bollisat
Required	
1. First Name *	
Enter your answer	
2. Last Name *	
Enter your answer	
3. Email *	
Enter your answer	
4. Country *	
Sefect your answer	·
Select your answer  5. Role with respect to WO	AH*
Sefect your answer	
5-Role with respect to WO.  WOAH Delegate	serinary Products
5. Role with respect to WO,  work Delegate  work Focal Point for Ver	serinary Products
Select your answer  5. Role with respect to WO.  WOAH Selegate  WOAH Focal Roles for Ver  Other National Authority	serinary Products
Select your answer  5. Role with respect to WO.  WOAH Selegate  WOAH Focal Four for Ve Other National Authority  6. Category of the issue *	serinary Products
Select your answer  5. Role with respect to WO.  WOAH Selegate  WOAH Social Roles for Ver  Other National Authority  6. Category of the Issue *	serinary Products
Select your answer  5. Role with respect to WO.  WOAH Selegate  WOAH Focal Roles for Ve  Other National Authority  6. Category of the issue *  Select your answer  7. Subject *	Revivary Products



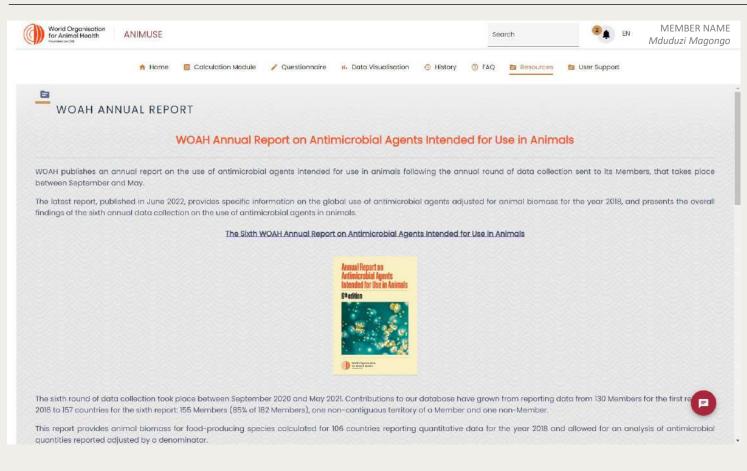
# ANIMUSE – Resources



Access the current and previous AMU Annual Reports

Questionnaire
Active Ingredients
Calculation Tool

Login Instructions
AMU Questionnaire
Calculation Module
Data Visualization







#### **Login Instructions**

Use this guide for a step-by-step guidance on how to login to ANIMUSE for the first time. Please note that you will need to be invited by the World Organisation for Animal Health to access ANIMUSE or to be created by the national Delegate.

**Download Instructions** 



#### Calculation Module

Use this guide to assist you in case you have difficulties in performing the calculations to obtain kilograms of active ingredients and to consolidate the different information on the veterinary products

Download User Guide

#### **AMU Questionnaire**

Use this guide to help you complete the World Organisation for Animal Health AMU Questionnaire. A new look for the same questionnaire as the Excel template but more **user** friendly and a smart interface.

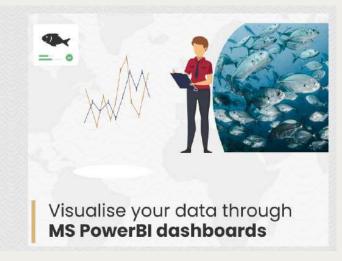
Download User Guide



#### **Data Visualisation**

Use this guide to assist you visualize your data through dashboards. Graphs are based on the data collected the previous years and are managed by the AMU Team. Their presentation and appearance can change over time, and they are created using Power BI (Microsoft)

Download User Guide





## ANIMUSE – Excel Templates and Guidance

#### Questionnaire Template

If you wish to use the Excel version of the questionnaire, you can download the Excel Template of the questionnaire on the right and work offline. Please use the guidance document to assist you in completing the Excel Template.



#### **Active Ingredients Template**

Download and use this template to complete and inject the WOAH Active Ingredients with data aggregated at active ingredient level.



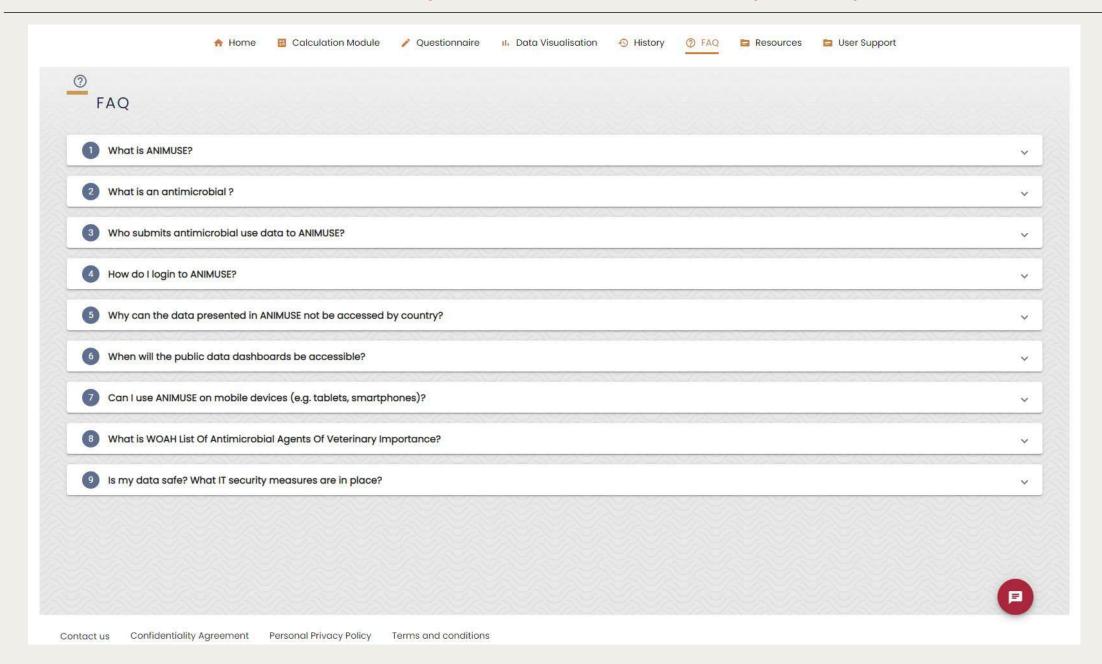
#### Calculation Tool Template

Download and use this a tool to assist you in case you have difficulties in performing the calculations to obtain kilograms of active ingredients and to consolidate the different information on the veterinary products.

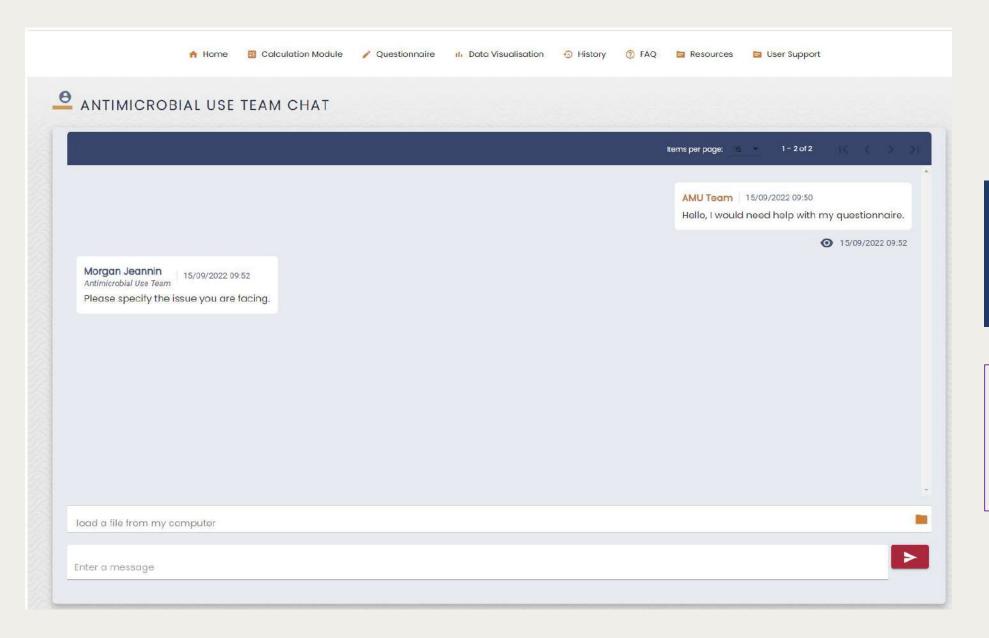




## ANIMUSE – Frequently Asked Questions (FAQs)



## ANIMUSE – Chat

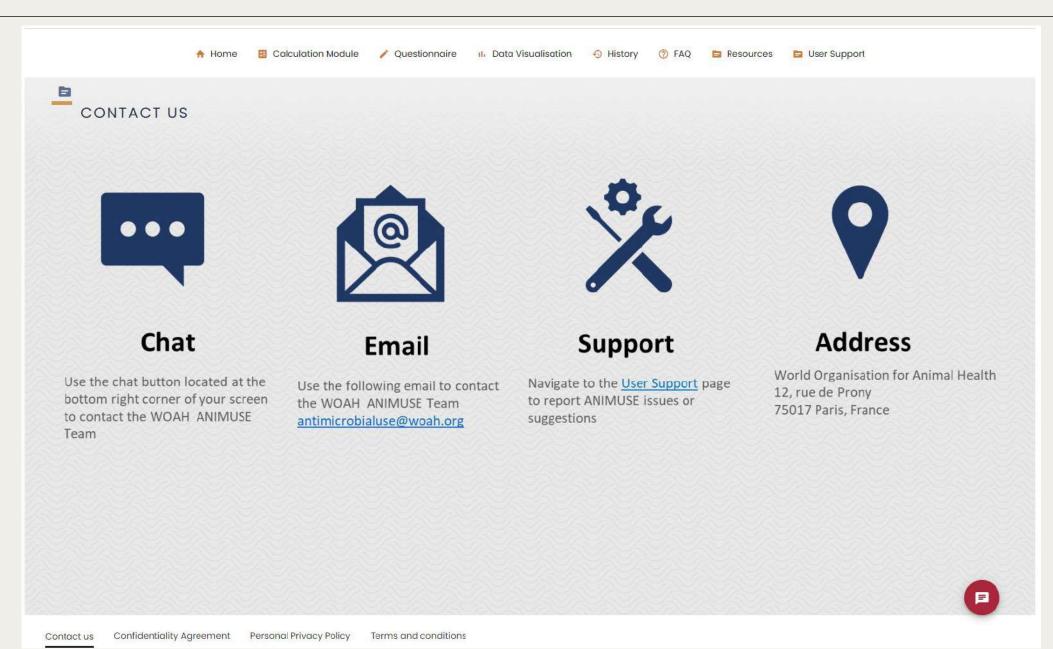




Upload files (Max. 10MBs and send messages to the AMU Team

**NB:** All messages in the chat are accessible to all users for that WOAH Member

## **ANIMUSE** – Other contacts



## Thank you

12, rue de Prony, 75017 Paris, France T. +33 (0)1 44 15 19 49 F. +33 (0)1 42 67 09 87

woah@woah.int www.woah.org Facebook
Twitter
Instagram
LinkedIn
YouTube

Flickr

World Organisation for Animal Health

Organisation mondiale de la santé animale Fondée en tant qu'OIE Organización Mundial de Sanidad Animal Fundado como OIE



# Update from 6<sup>th</sup> AMU Report From Asia-Pacific Perspective

Nahoko IEDA AMR Regional Project Officer 23rd Feb 2023, Bangkok





#### **Agenda**

- Participation to AMU data collection
- AMU quantity per animal biomass
- Common species in Asia-Pacific
- AMU trends in Asia-Pacific
- Antimicrobial Growth Promoters

## Annual Report on Antimicrobial Agents Intended for Use in Animals

#### 6th edition







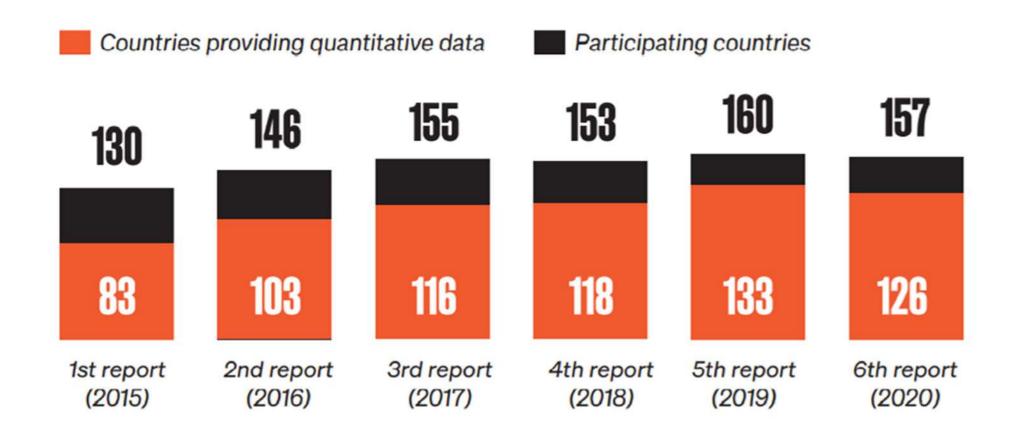
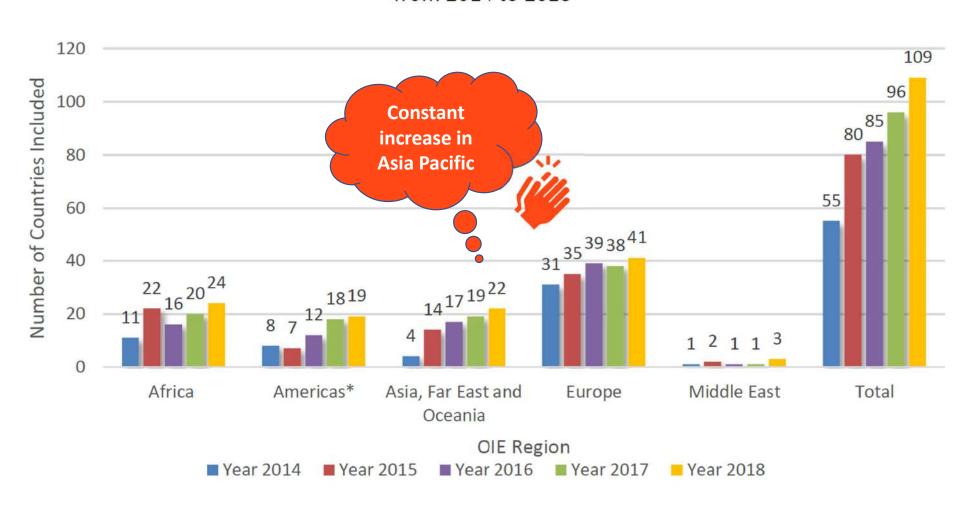


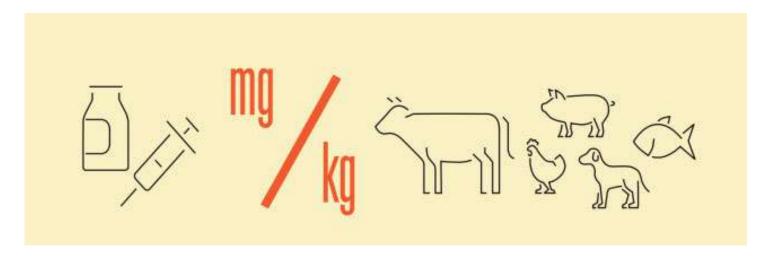
Figure 15. Number of Members included in the antimicrobial quantities analysis by OIE region, from 2014 to 2018





#### **Quantity per Animal Biomass**

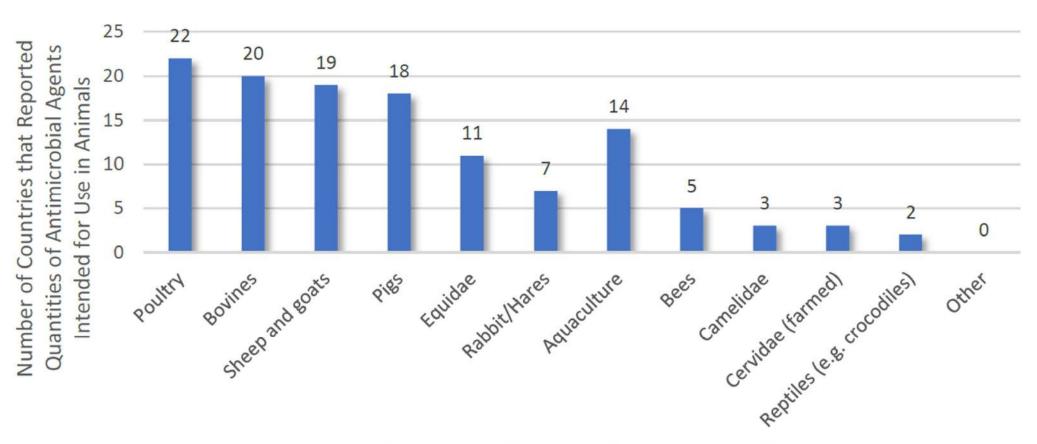
To **compare** the quantitative AMU data among the regions and over-time, (...) previous *ad-hoc* group on AMR agreed to analyze the antimicrobial quantities using the **estimated animal biomass as a dominator**.



Animal biomass is calculated based on the census data reported to **WOAH WAHIS** interface (reported by VS via Delegates) and validated by WOAH staff. **FAOSTAT** data was also used only to complement it and when necessary.



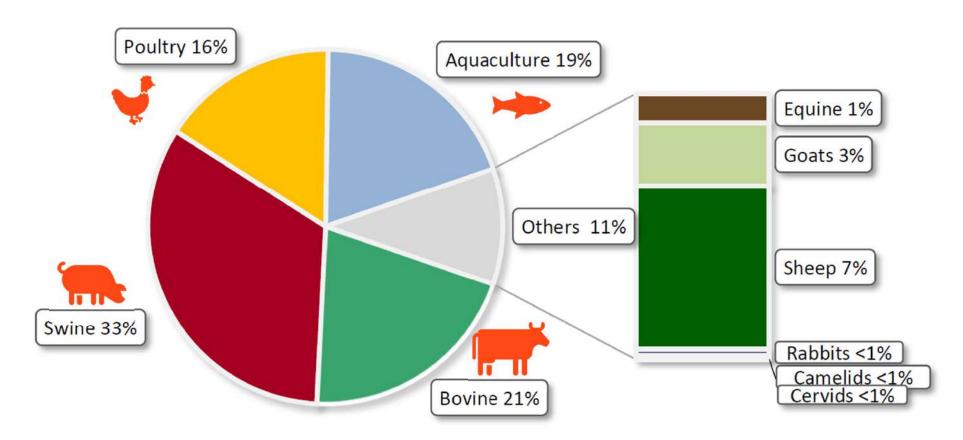
Figure A20. Food-Producing Animal Species Included in Quantitative Data Reported by 22 Members: in Asia, Far East and Oceania in 2018



Food-Producing Animal Species Covered

#### What Animal Species are Common in Asia & Pacific?

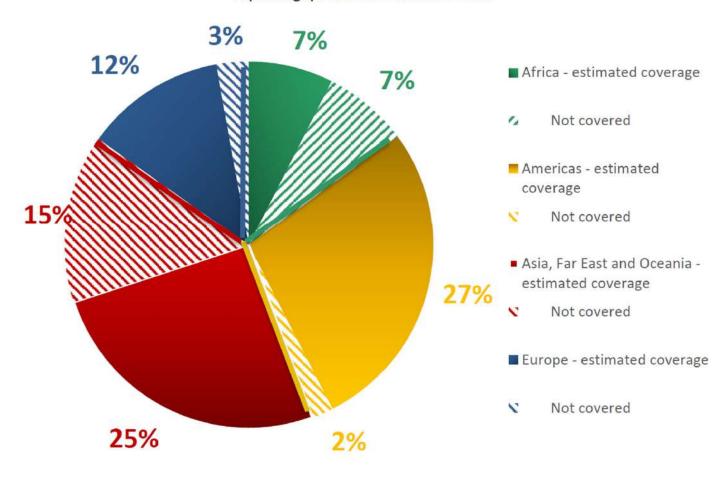
Figure A22. Species Composition of Animal Biomass for the 21 Members in Asia, Far East and Oceania Included in 2018 Quantitative Data Analysis





#### Coverage of reported AMU data within the estimated biomass

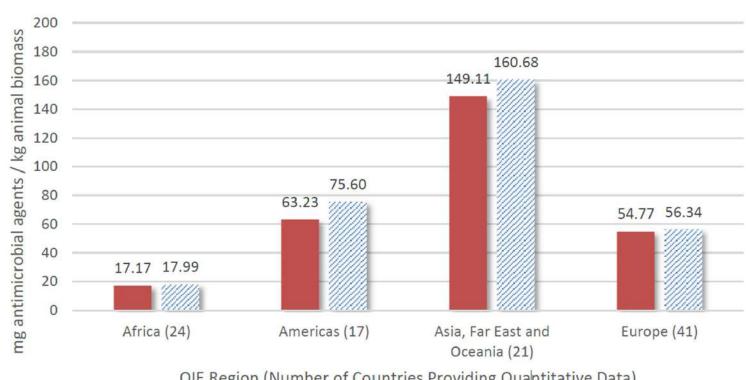
Figure 32. Regional percentages of estimated biomass covered by Countries reporting quantitative data for 2018\*



The Middle East was not included in the visual, but the region's coverage is included at the global level.

#### **AMU** quantity per animal biomass

Figure 37. Quantities of antimicrobial agents intended for use in animals adjusted by animal biomass, 2018 regional comparison (mg/kg)



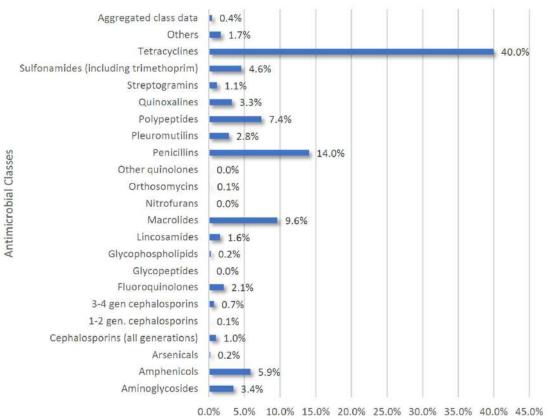
OIE Region (Number of Countries Providing Quantitative Data)

■ Regional (not adjusted by reported coverage) Regional (adjusted by reported coverage)



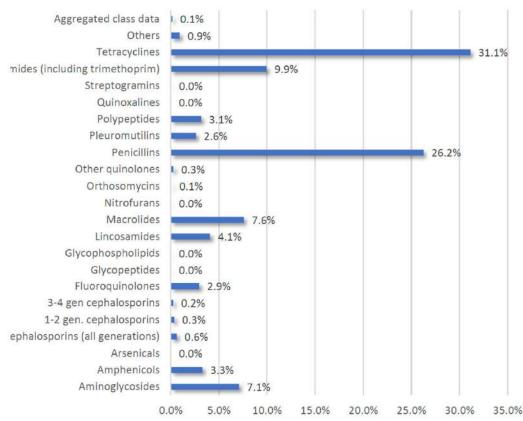
#### Which Class of Antimicrobials are Frequently Used?

**Figure A19.** Proportion of Antimicrobial Classes Reported for Use in Animals by 22 Members in Asia, Far East and Oceania in 2018





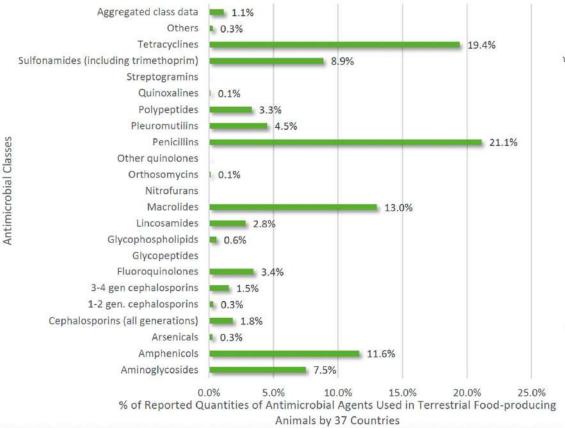
by 41 European Members in 2018



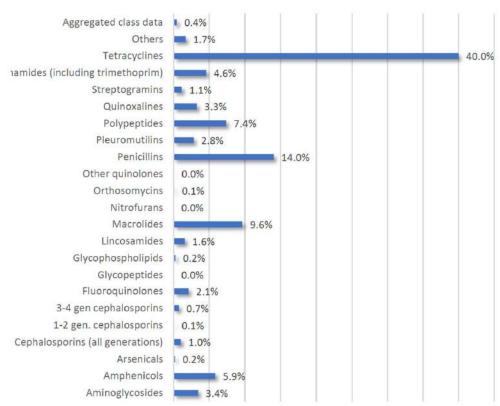
% of Reported Quantities of Antimicrobial Agents Used in Animals by 41 Countries

#### Which Class of Antimicrobials are Frequently Used?

**Figure 22.** Proportion of antimicrobial classes by terrestrial food-producing animals as reported by 37 Countries in 2018



**Figure A19.** Proportion of Antimicrobial Classes Reported for Use in Animals by 22 Members in Asia, Far East and Oceania in 2018

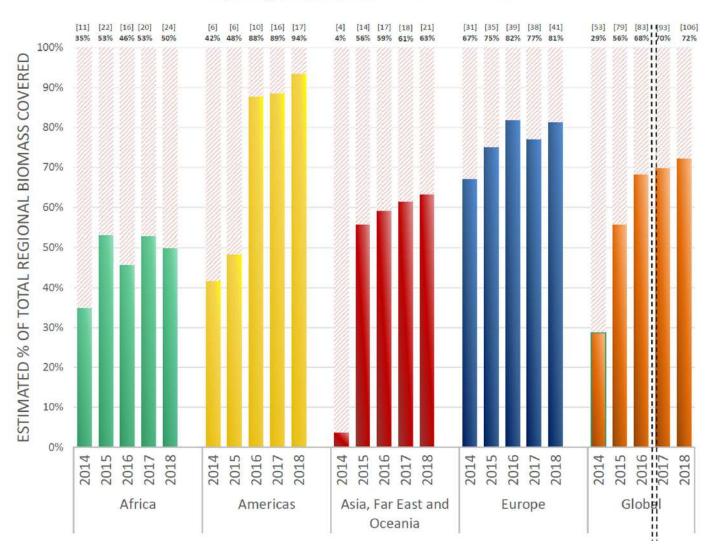


0.0% 5.0% 10.0% 15.0% 20.0% 25.0% 30.0% 35.0% 40.0% 45.0%

% of Reported Quantities of Antimicrobial Agents Used in Animals by 22 Countries



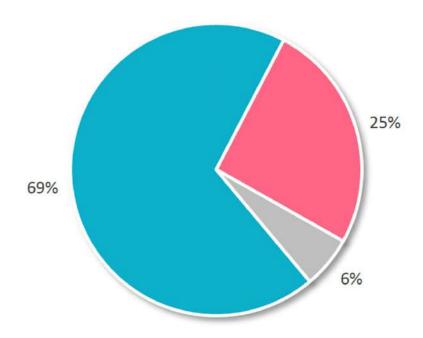
**Figure 31.** Estimated percentage of total regional and global biomass covered by Countries reporting quantitative data from 2014 to 2018



#### **Use of Antimicrobials as Growth Promoter**



Figure 10. Use of antimicrobial growth promoters in 157 Countries in 2020



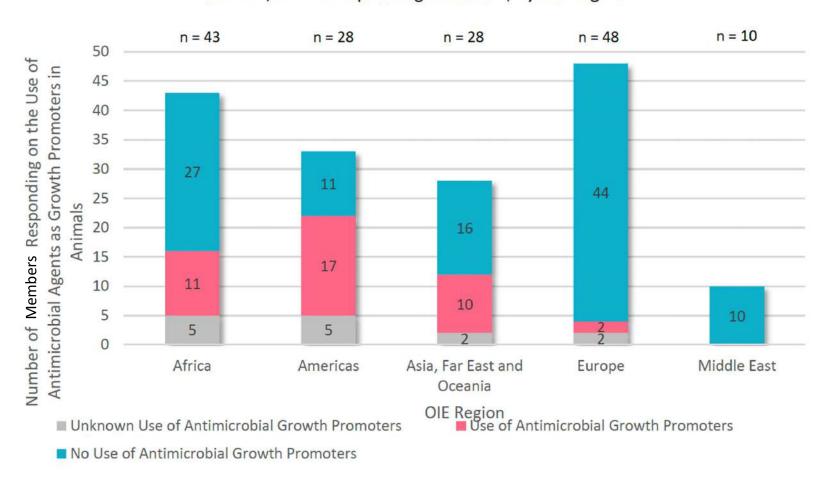
- No Use of Antimicrobial Growth Promoters
- Use of Antimicrobial Growth Promoters
- Unknown Use of Antimicrobial Growth Promoters



#### **Use of Antimicrobials as Growth Promoter**



**Figure 11.** Number of Members using antimicrobial agents for growth promotion in animals in 2020, of 157 responding Countries, by OIE region

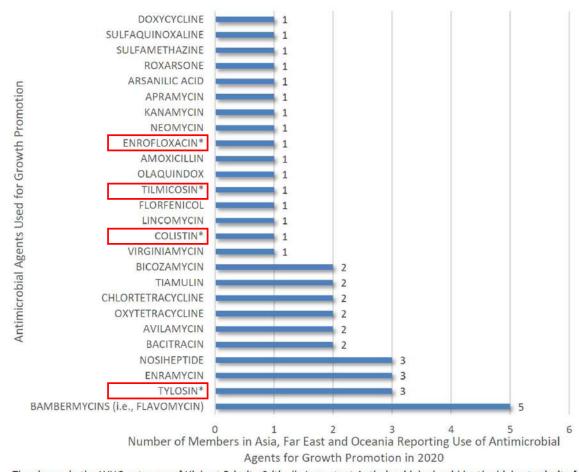




#### Use of Antimicrobials as Growth Promoter in Asia

**Figure A16.** Antimicrobial Growth Promotors Used in Animals in Asia, Far East and Oceania in 2020 as reported by Seven Members

- 7 Members out of 28 who reported the use of AGPs listed the agents utilized regarding 2020
- High frequency in the use of Bambermycins
- Indicated in red: The classes in the WHO category of Highest Priority Critically Important Antimicrobials (in human medicine) should be the highest priority for Countries when phasing out the use of antimicrobial agents as growth promoters.



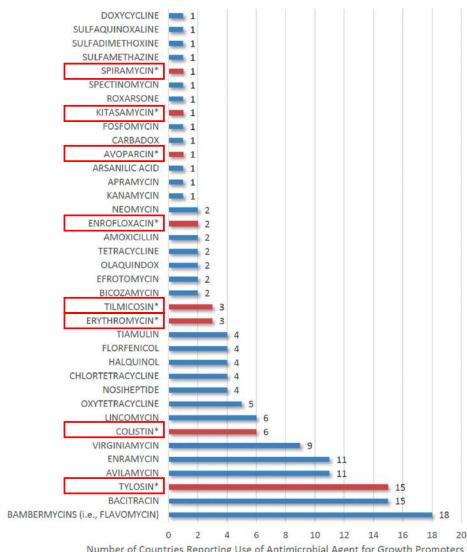
<sup>\*</sup> The classes in the WHO category of Highest Priority Critically Important Antimicrobials should be the highest priority for Countries when phasing out the use of antimicrobial agents as growth promoters.



#### **Use of Antimicrobials as Growth Promoter**

- Responses from 27 countries regarding 2020
- High frequency in the use of Bambermycins, Bacitracin, Tylosin, etc.
- Indicated in red: The classes in the WHO category of Highest Priority Critically Important Antimicrobials (in human medicine) should be the highest priority for Countries when phasing out the use of antimicrobial agents as growth promoters.

Figure 14. Antimicrobial agents used for growth promotion in animals in 27 Countries in 2020



Antimicrobial Agents Used for Growth Promotion

Number of Countries Reporting Use of Antimicrobial Agent for Growth Promoters in 2020



## **Key findings: Progress in Animal Health Sector**

The use of antimicrobials critical to human health is declining in animals

-62%
Polypeptides

-43% \\_

An antimicrobial is classified as highest priority and critically important when it is the sole therapy or one of few alternatives to treat serious human diseases. These antimicrobials are vital for human health. We must preserve their efficacy by using them in a sustainable way.

The use of antimicrobials for growth promotion is no longer a practice in 69% of participating countries

In 2020,



countries do not use antimicrobials for growth promotion



countries use antimicrobials for growth promotion

Growth promotion means using antimicrobials in healthy animals to boost productivity. This practice should be phased out in the absence of a risk analysis.



It's also important to preserve the antimicrobials efficiency from the perspective of veterinary medicine (animal health & welfare) and for protecting farmers livelihoods.

## Thank you!

Regional Representation for Asia and the Pacific Food Science Building 5F - The University of Tokyo 1-1-1 Yayoi, Bunkyo-ku Tokyo, 113-8657 JAPAN

rr.asia-pacific@woah.org rr-asia.woah.org

**Facebook** Twitter Instagram LinkedIn YouTube Flickr

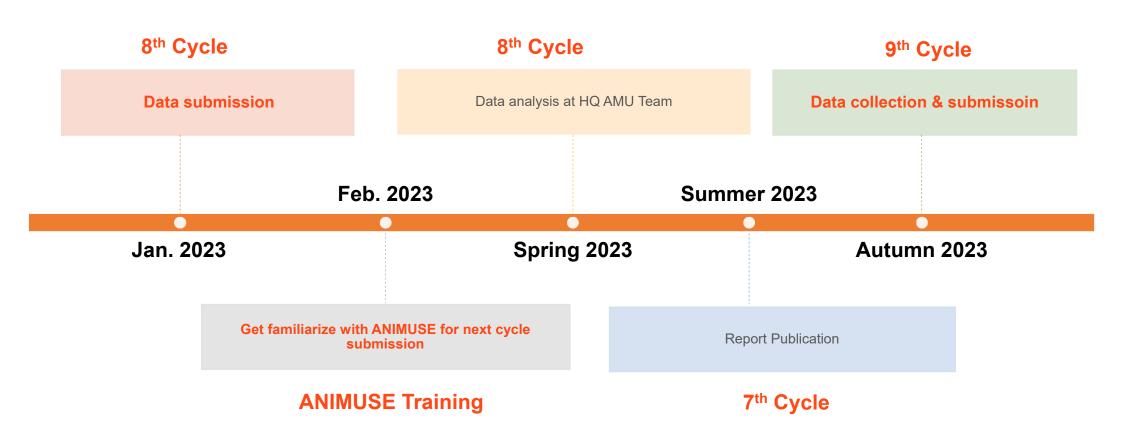








#### Timeline for next report / data collection





## **Proposal**

#### Title

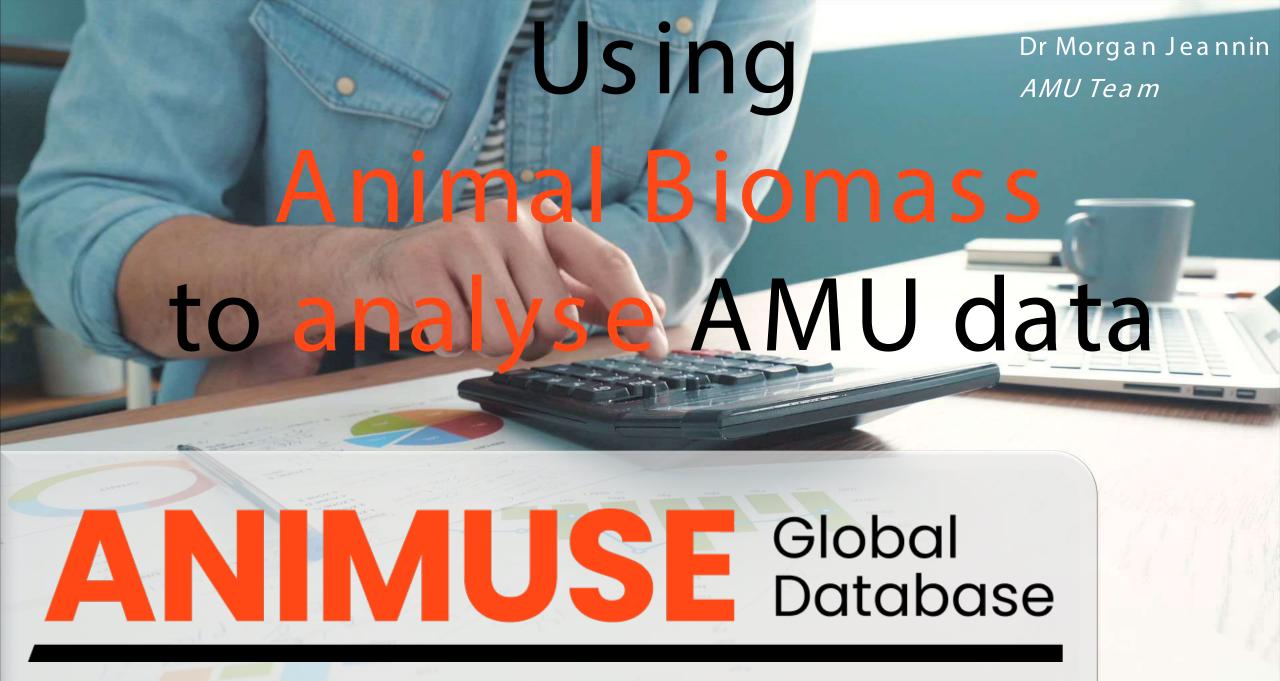
- Sample
- Sample

#### Title

- Sample
- Sample

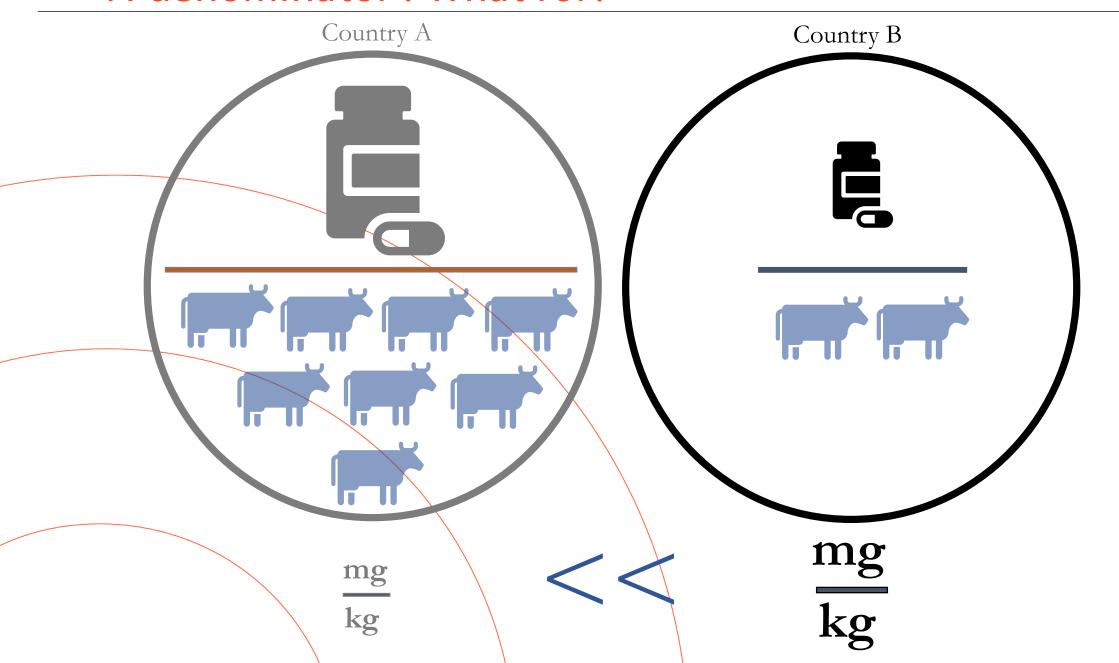
#### Title

- Sample
- Sample





## A denominator: What for?





## WOAH Animal Biomass denominator

Quantities of antimicrobial agents (mg)

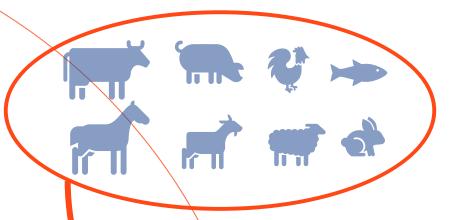
Animal biomass

(kg)

mg/kg



as **reported** by the **country** to the WOAH AMU data collection for the target year



Total weight of all foodproducing animals in the target year

 $\downarrow$  = 1

ANIMAL' BIOMASS Calculated Animal Biomass by AMU Team for a country for the target year





Methodology developed by WOAH ad hoc Group on AMR that acknowledged each country will have variability of their animals' population numbers, cycle factors and average weights.



Based on Terrestrial Animal Health Code Chapter 6.9 & Aquatic Animal Health Code Chapter 6.3 – « When comparing AMU data over time, changes in size and composition of animal populations should also be taken into account.»



Adjusting the quantitity of AM by the biomass improves the possibilities of,

I following AMU over time, taking into account the changes in animal population



- □ Comparing AMU between different regions, with different species of food-producing animals and different farming systems.
- → proxy to measure the population exposed to AMU during the year of data collection



### Which data are available?

















#### Data needed

The number of animal present in the country for each age category of each species and their mean body weight.

#### WAHIS

#### Data available globally

 WAHIS census data → number of live animals per species at one time of the year (+/- age categories)



 FAO data → Production data: Number of animals slaughtered, for each species, in a whole year + mass of animal slaughtered & census data



#### Participation from the Countries

We need help from Members with validation of national animal population numbers and average species weights.



## Methodology: How is calculated?

## General principles

- Animals with a life duration of <u>less than one year</u> → Use yearly **production** data
- Animals with a life duration of more than one year  $\rightarrow$  Use census data, combined with estimates of average weights by sub-region/country.
- **Privilege census data** when possible → Production data might not reflect backyard slaughter practices

## General Methodology

- Animal biomass is calculated using country-level animal population data by species, data-derived estimates of their average weights by sub-region and country, and average reproductive rates of short-lived species (cycle factors).
- → kilograms animal biomass used as a *denominator* in analysis of antimicrobial use data (mg/kg)

Find out more with the peerreviewed methodologies for data collection and analysis





Different AMU surveillance programs → Different weight calculation methodologies



- o Canada, ESVAC (EU), Thailand: weight at time of treatment
- USA, Japan: a verage weight by production category

## From production data → carcass weight



$$carcass\ weight\ (kg) = \frac{weight\ of\ species\ slaughtered\ (kg)}{number\ of\ species\ slaughtered\ (heads)}$$

• From carcass weight -> live weight at time of slaughter



live weight at slaughter 
$$(kg) = \frac{carcass\ weight\ (kg)}{conversion\ coefficient\ (k)}$$



#### Refinement of Animal Biomass Calculation













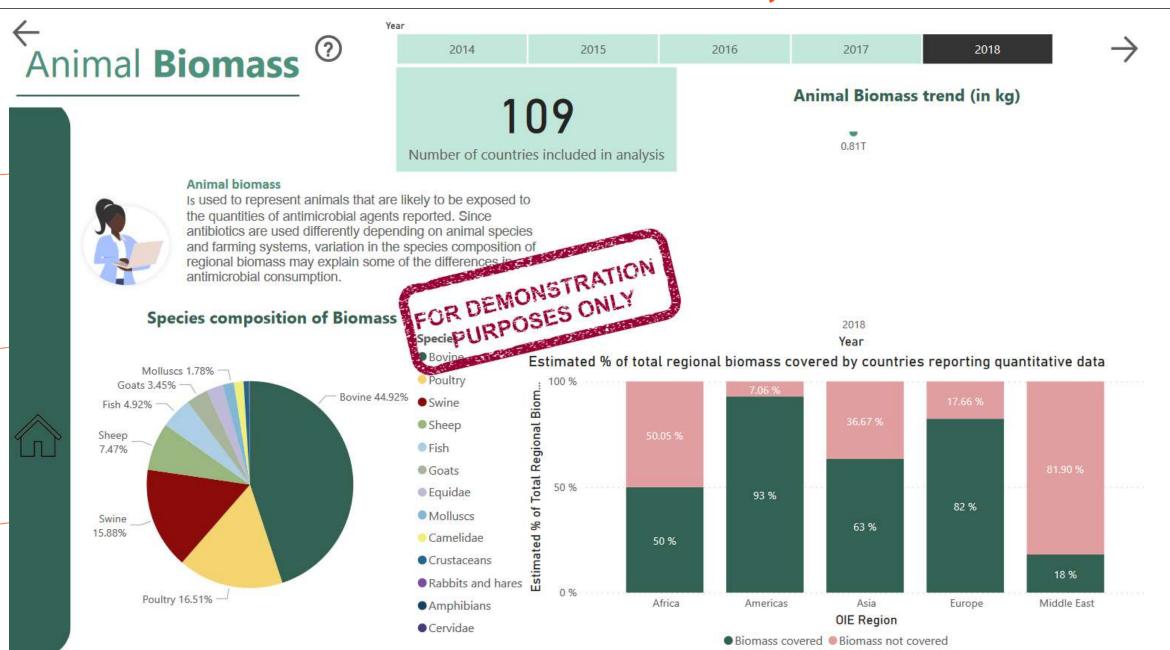


- To refine the calculations of the Animal Biomass: considering region/country particularities
- Continued collaboration of the countries to research and verify:
  - ✓ Animal population figures
  - ✓ Average animal weights
  - ✓ Carcass conversion coefficients
  - ✓ Distribution of age groups in a species
  - ✓ Cycle factors
- Evolution of WAHIS system: Importance of countries'
   commitment in reporting a nimal population figures
  - Animal categories + sub-categories by age groups
  - Increased country-level understanding: Cycle factors, Mean live weight at slaughter...



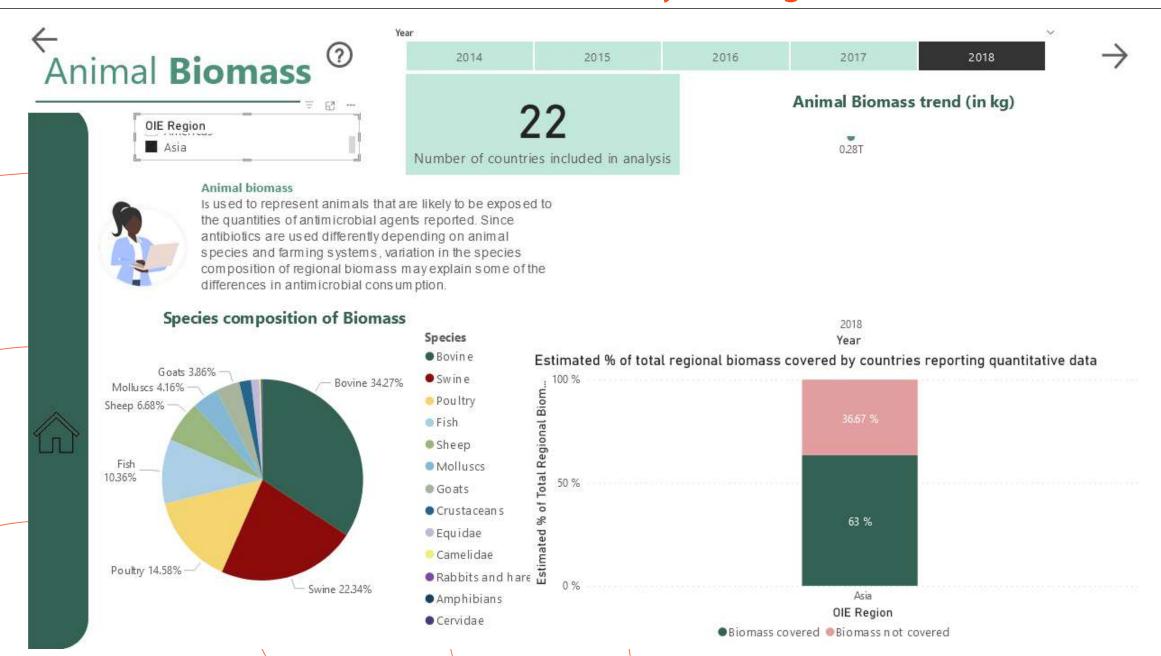


## Discover the Animal Biomass: Globally





# Discover the Animal Biomass: For your region





# Discover the Animal Biomass: Relevant to you (Private Portal)



**Animal biomass** 



2014 2015

15.2bn

2016

15.4bn

2017

2018

15.8bn

## $\rightarrow$

14.9bn

#### **Animal Biomass trend**

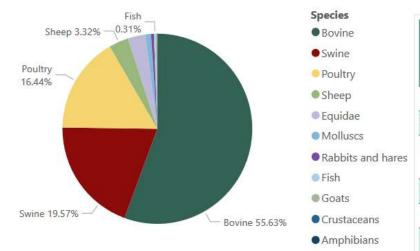
15.5bn



Is used to represent animals that are likely to be exposed to the quantities of antimicrobial agents reported. Since antibiotics are used differently depending on animal species and farming systems, variation in the species composition of regional biomass may explain some of the difference in antimicrobial consumption.

This denominator is calculated by WOAH using publicly available databases (e.g. WAHIS, FAOSTAT etc). More information on the animal biomass methodology can be found in the annual report or in published articles.

#### **Species composition of Biomass**



2014	2015	2016	2017	2018
		Year		

Species	Retained population for calculation (Nbr Heads)	Data source	Biomass (Tonnes)	Relative proportion
Bovine	96251355	WAHIS	42718M	55.63%
Swine	56588327	WAHIS	15028M	19.57%
Poultry	4229736000	FAOST AT	12620M	16.44%
Sheep	37759485	WAHIS	2551M	3.32%
Equidae	4690881	WAHIS	2302M	3.00%
Molluscs		WAHIS	746M	0.97%
All Specific Biomass	4434189442	WAHIS	76783M	100.00%



# Discover the mg/kg: Relevant to you (Private Portal)

# mg/kg Analysis



mg/kg (non adjusted by reported coverage)
 mg/kg (adjusted by reported coverage)

79.54

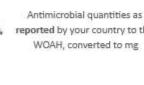


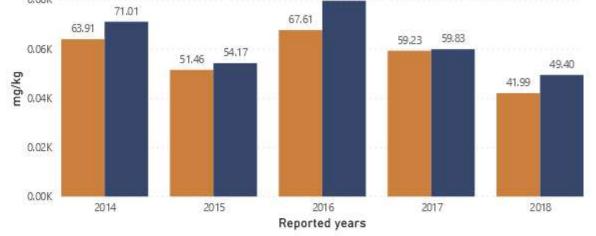
#### mg/kg

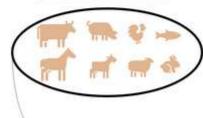
The analysis of quantities of antimicrobial agents intended for use in animals as reported by countries is presented as part of a calculation that is determined by adjusting the quantity of antimicrobial agents reported (mg) by the animal biomass (kg) which provides an indicator that can be compared between countries, regions and over time



reported by your country to the WOAH, converted to mg







Animal Biomass: Total weight of food-producing animals in

the target year, calculated by WOAH from animal population public databases

#### Global ranking of antimicrobial usage by mg/kg

Year	Position*	Number of Countries**	state
2014	23	61	VALIDATED
2016	36	97	VALIDATED
2015	37	95	VALIDATED
2017	43	116	VALIDATED
2018	48	128	VALIDATED

<sup>\*</sup>Position: The ranking of your country in relation to other countries, with 1 being the highest value for mg/kg. \*\*Number of countries: the total number of countries that provided data for that year

# Thank you

# **ANIMUSE** training

# 22-24 February 2023 Bangkok, Thailand

12, rue de Prony, 75017 Paris, France T. +33 (0)1 44 15 19 49 F. +33 (0)1 42 67 09 87

woah@woah.int www.woah.org Facebook Twitter

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<u>Instagram</u>

LinkedIn

YouTube

Flickr



Organisation mondiale de la santé animale

Organización Mundial de Sanidad Animal

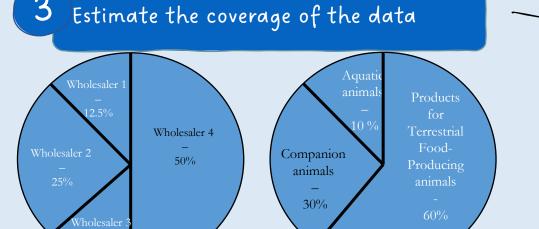






# How to start?

- 1 Map a distribution system of the veterinary products at national level
- 2 If you request that different stakeholders calculate the data, make sure they receive a training and that you can have access to all their calculations





Different considerations for estimating the coverage:

- The number of stakeholders that contributed and their relative contribution to the total
- Animal species covered by the products
- Types of products covered (oral products are usually predominant)

**Table 2:** Conversion of International Units (IUs) of certain antimicrobial agents into mg and relevant active entities, based on the ESVAC conversion factors<sup>1</sup>

	Antimicrobial agent in the veterinary medicine	Antimicrobial active entity for reporting to WOAH	International Units per mg	Conversion factor to mg for multiplication
	Apramycin	Apramycin	552	0.00181
	Bacitracin	Bacitracin	74	0.013514
	Benzylpenicillin (penicillin G) <sup>2</sup>	Benzylpenicillin	1670	0.0006
	Chlortetracycline	Chlortetracycline	1000	0.001
	Colistin methane sulfonate sodium (colistimethate sodium INN)	Colistin	12700	0.000079
	Colistin sulfate	Colistin	20500	0.000049
	Dihydrostreptomycin	Dihydrostreptomy cin	777	0.00129
	Erythromycin	Erythromycin	920	0.001087
	Gentamicin	Gentamicin	620	0.001613
1	Kanamycin	Kanamycin	796	0.001256
	Neomycin	Neomycin	762	0.00131
	Neomycin B (Framycetin)	Neomycin B (Framycetin)	706	0.00142
	Oxytetracycline	Oxytetracycline	880	0.00114
	Paromomycin	Paromomycin	750	0.00133
	Polymyxin B	Polymyxin B	8403	0.000119
	Rifamycin	Rifamycin	887	0.001127
-//	Spiramycin	Spiramycin	3200	0.000313
100	Streptomycin	Streptomycin	760	0.00132
1	Tetracycline	Tetracycline	982	0.00102
1	Tobramycin	Tobramycin	875	0.001143
1	Tylosin	Tylosin	1000	0.001

**Table 3:** Conversion of content stated in mg, g or kg of derivates/compounds of antimicrobial agents in the veterinary product into corresponding mg, g or kg antimicrobial active entity for reporting to WOAH, based on the ESVAC conversion factors<sup>3</sup>



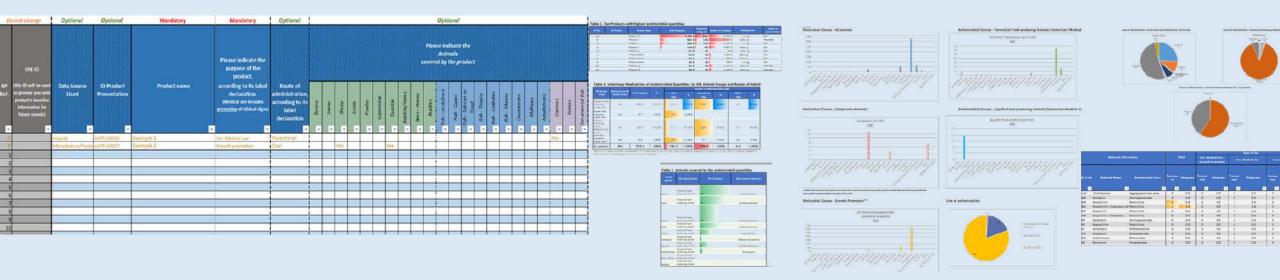
Derivate or compound	Active entity	Conversion factor for multiplication
Benethamine benzylpenicillin <sup>4</sup>	Benzylpenicillin	0.61
Benzathine benzylpenicillin <sup>5</sup>	Benzylpenicillin	0.68
Cefapirin benzathine <sup>6</sup>	Cefapirin	0.78
Cefalexin benzathine <sup>7</sup>	Cefalexin	0.74
Cloxacillin benzathine8	Cloxacillin	0.78
Oxacillin benzathine <sup>9</sup>	Oxacillin	0.77
Penethamate hydriodide 10	Benzylpenicillin	0.60
Procaine benzylpenicillin <sup>11</sup>	Benzylpenicillin	0.57



# ANIMUSE: Calculation Module

# Context

- Not mandatory.
- Based on the Calculation Tool Excel.
- This Module, as the Calculation Tool, collects data at a veterinary product level to help with the calculation of kilograms of active ingredients.
- Any information provided in the Module is confidential, regardless of the confidentiality status of the dossier.





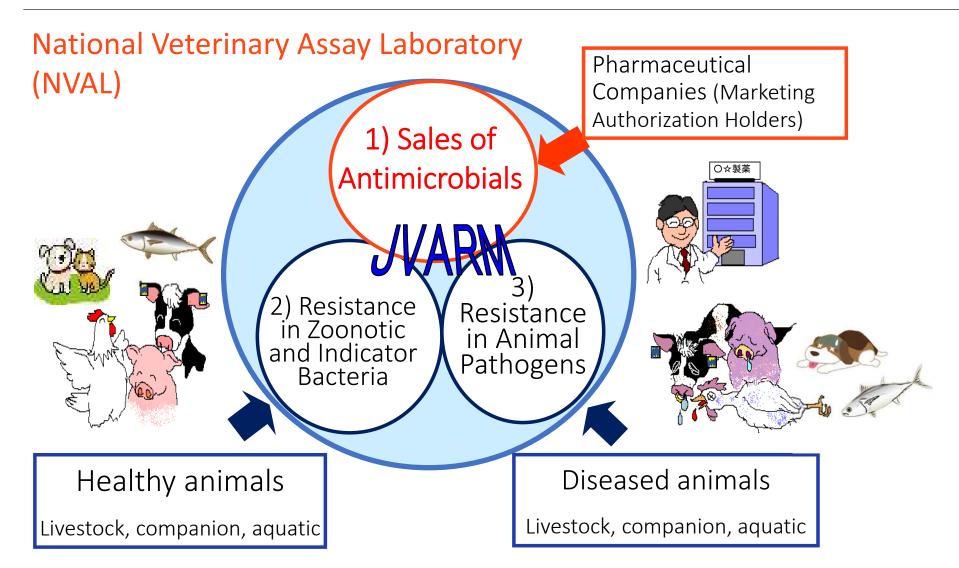
# ANIMUSE Calculation Tool and AMU National Report in Japan

Mari Matsuda National Veterinary Assay, MAFF, JAPAN 23 Feb. 2023, Regional ANIMUSE Training for WOAH Focal Points for Veterinary Products, Bangkok, Thailand





# JVARM: Japanese Veterinary Antimicrobial Resistance Monitoring





# JVARM: Japanese Veterinary Antimicrobial Resistance Monitoring

#### Under the Pharmaceutical and Medical Device Act

# Pharmaceutical companies (Marketing Authorization Holder)

**Format** 





Report

# **NVAL**

Summing up, Analysis, Evaluation

Report on the NVAL website

- Sales amount
- The name of antimicrobials
- Annual weight in kilograms of the active ingredients
  - The route of administration
- Estimated percentages of sales for each animal species



# JVARM HP (https://www.maff.go.jp/nval/yakuzai/yakuzai\_p3.html)

#### 1) JVARMのデータ/ data from JVARM

\*各データについては以下のアイコンをクリックして下さい。







# JVARM HP (https://www.maff.go.jp/nval/yakuzai/yakuzai\_p3.html)

#### 1) JVARMのデータ/ data from JVARM

\*各データについては以下のアイコンを



#### 動物用医薬品等販売高年報

Annual Report of Sales Amount and Sales Volume of Veterinary drugs, Quasi-drugs, Medical Devices and Regenerative Medicine Products

飼育動物診療施設に販売された人用抗菌剤量調査の結果 こちら

動物用医薬品等取締規則に基づき報告された取扱数量等を、集計し掲載しています。





# NVAL HP (https://www.maff.go.jp/nval/yakuzai/yakuzai\_p3.html)

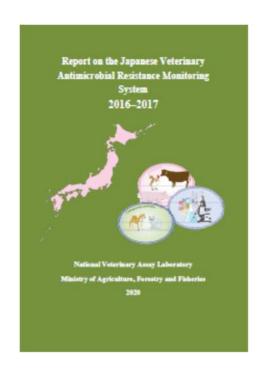
#### 1) JVARMのデータ/ data from JVARM

#### 各種抗生物質・合成抗菌剤・駆虫剤・抗原虫剤の販売高と販売量

Sales Amounts and Sales Volumes (Active Substance) of Antibiotics, Synthetic Antibacterials, Anthelmintics and Antiprotozoals

Sales Amounts and Sales Volumes (Active Substance) of Antibiodics, Synthetic Antibacterials, Antireliminus and Antiprotozoals																							
R3(2021)										Esti		.動物別推定割 es of Sales for Ea	J合 ach Animals Specie	es									
系統名 Class		区分 Active substance		投与経路 Route of administration	販売高金額 (千円) Sales amount (¥1,000)	原末換算量 (Kg) Amount of pure active substance (Kg)	肉用牛 Beef Cattle	乳用牛 Dairy Cow	馬 Horse	豚 Pig	肉用鶏 Broiler	採卵鶏 Layer	犬•猫 Dog/Cat	水産用 (淡水) Fish (Freshwater)	水産用 (海水) Fish (Seawater)	観賞魚 Ornamental Fish	その他 Others						
抗生物質 Antibiotics	アミノグリコシド系 Aminoglycosides	硫酸アプラマイシン	Apramycin sulfate	経口 Oral	77,872	1,565.	0	0		0						L							
				成分·計 Total	77,872	1,565.2																	
		硫酸カナマイシン	Kanamycin sulfate	経口 Oral	71,241	4,309.2	0.0%	0.0%	0.0%	50.0%	50.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.09						
				注射 Injection	195,341	3,218.4	16.7%	43.3%	0.5%	15.9%	18.7%	3.9%	1.0%	0.0%	0.0%	0.0%	0.09						
				注入·挿入 Infusion	55,991	131.3	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.09						
				その他 Others	3,845	32.0	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.09						
				成分・計 Total	326,418	7,691.0			-														
		硫酸ゲンタマイシン	Gentamicin sulfate	経口 Oral	50,112	13.6	50.0%	50.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.09						
				注射 Injection	12,962	3.1	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.09						
				経皮 Cutaneous	210,017	8.0	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	0.0	0.0						
				その他 Others	110,687	6.2	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.09						
				成分・計 Total	383,778	30.9																	
		硫酸ジヒドロストレプトマイシン	Dihydrostreptomycin sul	te 注射 Injection	91,946	2,761.3	31.7%	31.7%	13.4%	20.0%	1.9%	0.0%	1.2%	0.0%	0.0%	0.0%	0.09						
				注入·挿入 Infusion	90,284	407.2	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.09						
				成分·計 Total	182,230	3,168.6						1											
		硫酸ストレプトマイシン	Streptomycin sulfate	経口 Oral	162,612	17,268.0	0.3%	0.3%	0.0%	65.9%	33.6%	0.0%	0.0%	0.0%	0.0%	0.0%	0.09						
				成分・計 Total	162,612	17,268.0																	
		硫酸フラジオマイシン	Fradiomycin sulfate	経口 Oral	14,280	73.5	40.0%	60.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.09						
				注入·挿入 Infusion	11,647	36.6	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.09						
				経皮 Cutaneous	133,177	10.8	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	0.0%	0.09						
1				成分·計 Total	159,104	120.9																	
			系統名·計 Class Tota		1,292,014	29,845																	

# **JVARM Report**



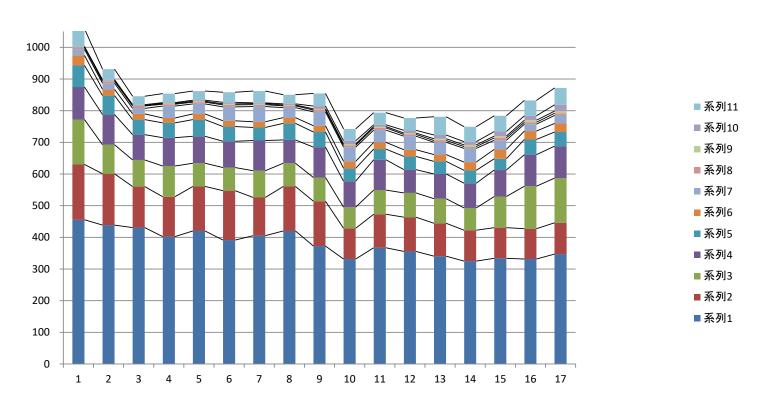
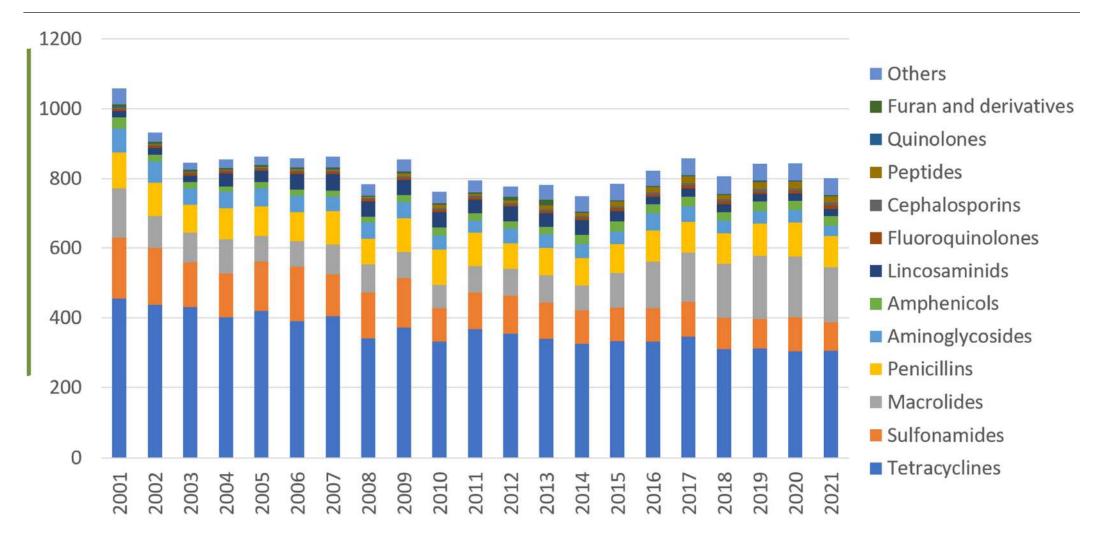
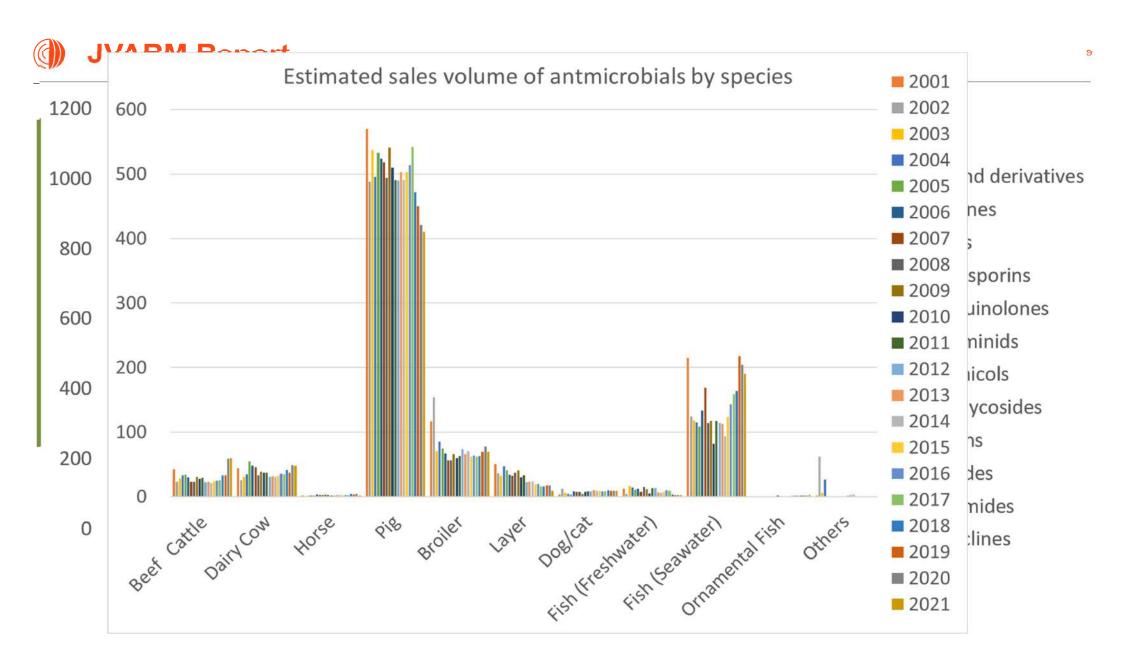


Fig. 3.2 Volumes of veterinary antimicrobials (in tons of active ingredient) sold by pharmaceutical companies in Japan between 2001 and 2017



# **JVARM Report**







# Nippon AMR One Health Report (NAOR)

Nippon AMR One Health Report (NAOR) 2020

January 8, 2021
The AMR One Health Surveillance Committee

- National Action Plan on Antimicrobial Resistance 2016-
- NAOR 2017- annually report
- AMR
  - Human
  - Animal (livestock animal, companion animal, aquatic, wild animal)
  - Foods
  - Environment

#### AMU

- Livestock
- Aquatic
- Companion animal
- Human
- Agriculture

**Animal Total** 



# Nippon AMR One Health Report (NAOR)

### Amount of veterinary antimicrobials in active gradient by class (t)

Class	2013	2014	2015	2016	2017	2018	2019	2020
Penicillins	78.2	78.0	83.7	90.0	88.1	89.0	92.4	97.0
Cephalosporins (total)	5.6	5.5	5.9	6.5	6.6	7.1	8.0	7.7
(1st generation cephalosporins)	4.7	4.6	5.0	5.4	5.5	5.7	6.6	6.4
(2nd generation cephalosporins)	0.2	0.2	0.1	0.2	0.2	0.2	0.1	0.2
(3rd generation cephalosporins)	0.7	0.7	0.8	0.9	1.0	1.2	1.3	1.2
Aminoglycosides	39.5	40.6	35.5	47.9	44.8	35.6	35.2	36.9
Macrolides	77.7	70.4	98.4	134.1	140.8	154.7	180.7	173.7
Lincosamides	39.0	43.3	28.7	21.9	25.3	22.8	21.3	21.5
Tetracyclines	340.5	324.8	333.9	331.5	347.1	311.2	313.0	304.4
Peptides	11.8	10.0	14.5	14.0	20.0	12.3	19.6	19.1
Other antibacterials	26.0	28.8	32.4	32.0	36.2	37.5	36.0	36.3
Sulfonamides	103.9	97.6	96.7	95.8	99.1	88.8	84.7	98.5
Quinolones	1.0	1.9	1.7	1.7	1.8	1.5	2.6	2.3
Fluoroquinolones	5.5	5.6	7.3	6.1	6.8	6.6	7.5	7.1
Thiamphenicol and derivateives	21.5	26.1	29.7	26.5	27.1	24.8	27.4	25.6
Furan and derivatives	14.5	1.8	1.2	1.6	1.4	1.3	1.4	1.2
Other synthetic antibacterials	15.0	14.0	13.3	12.1	13.1	12.0	11.7	11.7
Total	779.7	748.4	783.0	821.7	858.1	805.2	841.4	842.9

NAOR 2022(https://www.mhlw.go.jp/content/10900000/001045158.pdf)



# Nippon AMR One Health Report (NAOR)





# **AMU Monitoring in Japan -Summary-**

- Under the law, collect data from MAH
  - WOAH Reporting Option 3
  - From 2001

## National Report

- NVAL HP
- JVARM Report
- One Health Report

#### Future Tasks

- Estimation based on Biomass Data → WOAH Biomass
- On farm level data collection



# **WOAH AMU Technical Reference Group (TRG)**

## Purpose

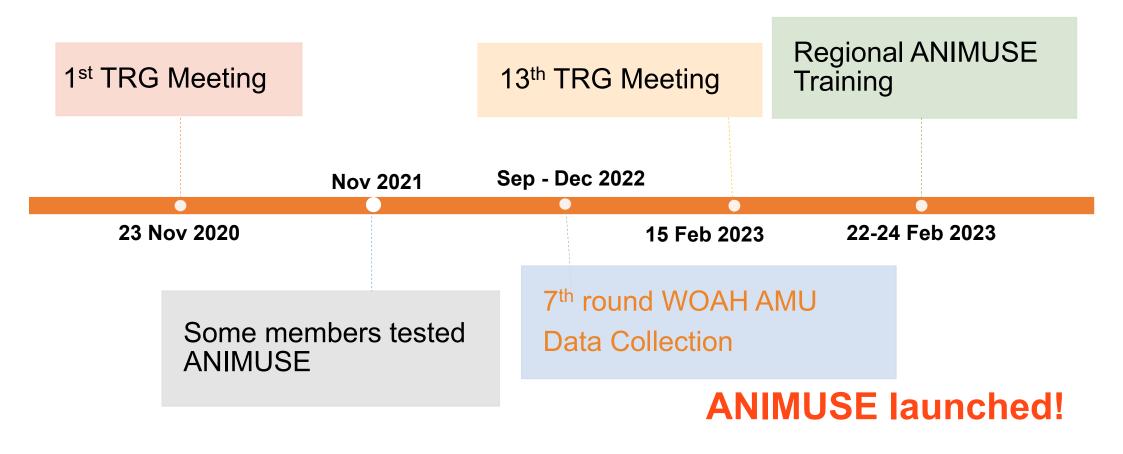
To support the WOAH Antimicrobial Use database by;
 Contributing to an efficient transition from the collection of AMU data via Excel template into a database system, providing advice, inputs and sharing previous related experiences

#### Members

- WHO
- FAO
- EMA
- Country representative (four countries)
- WOAH AMU team
- From Nov. 2020 (1st Meeting)



# **WOAH AMU Technical Reference Group (TRG)**

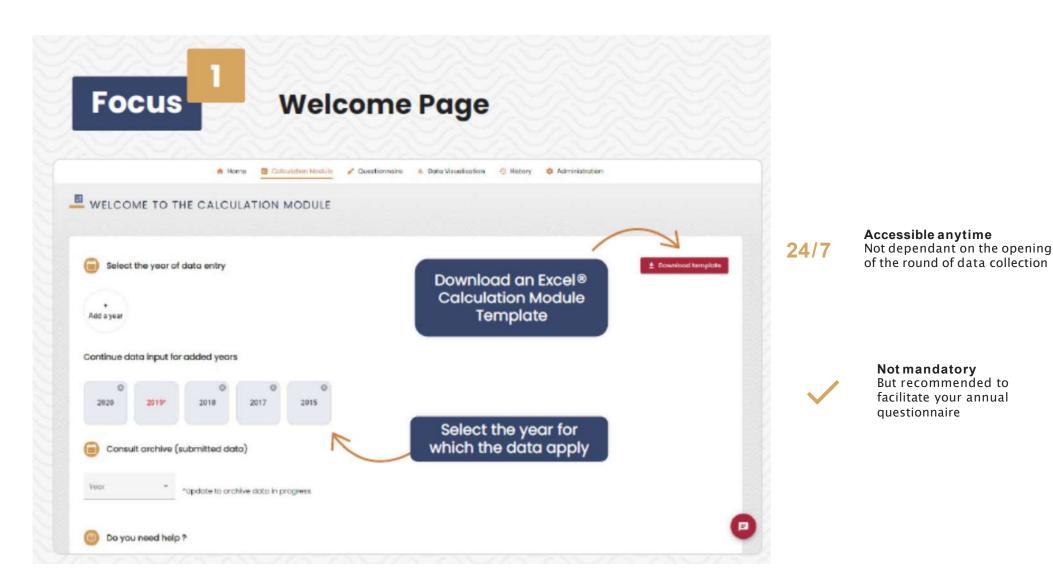




#### What is Calculation Module?

- The calculation module is an optional module to facilitate data collection at nation level
- It's a tool to help you to directly indicate the number of antimicrobials used so that the application calculates the amount it represents in each class.
- Consolidating the data from different stakeholders and assist with the calculation of antimicrobial quantities
- You have the ability to upload data based on a template available, but not only. It's also possible to use existing tool.
- The calculation module is the highlight of ANIMUSE!







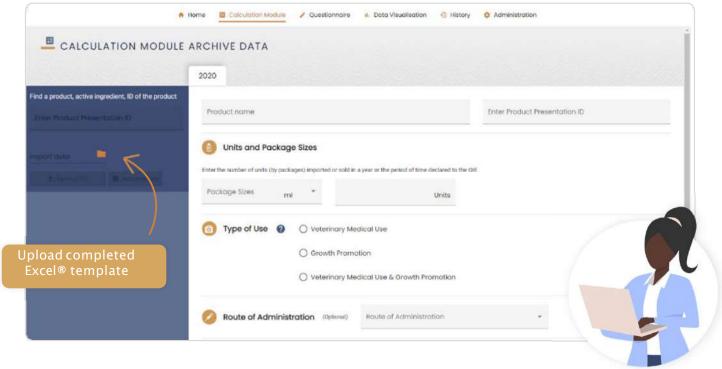
# Calculation module template

Do	not change	I <i>Optional</i>	Optional	Mandatory	Mandatory	I I <i>Optional</i>	Optional							<u> </u>														
	WOAH ID				Please indicate the purpose of the product,	pose of the product,										Plea.	Anir	nals										
N° Ref.	(this ID will be used to provide you with product's baseline information for future rounds)	Data Source Used	ID Product Presentation	Product name	(Medical use includes	according to its label declaration. (Medical use includes administration,	Swine	Sheep	Goats	Pouttry	Camelidae	Equidae	Rabbits	Bees - Honey	Reptiles	Fish - Undefined	Fish - Carp	Fish - Salmon or Trout	Fish - Tilapia	Fish - Catfish	Fish - Marine	Crustaceans - Prawn/shrimp	Molluscs	Amphibians	Canines	Felines	Ornamental fish	
O		Imports	ASFR-20156	Example 1		Injection	l L	:																		Yes		
O		Manufacture/Produ ction	ASFR-20157	Example 2		I I <i>Oral</i>	l L	į	Yes				Yes			į												
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2		) 				I I	l I									-											$\Box$	_
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# **Adding your Veterinary Products**

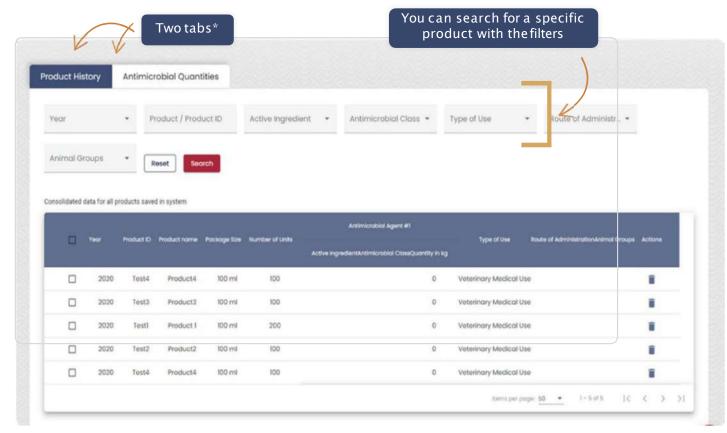


Create the veterinary products

You can import your data and it's available anytime.

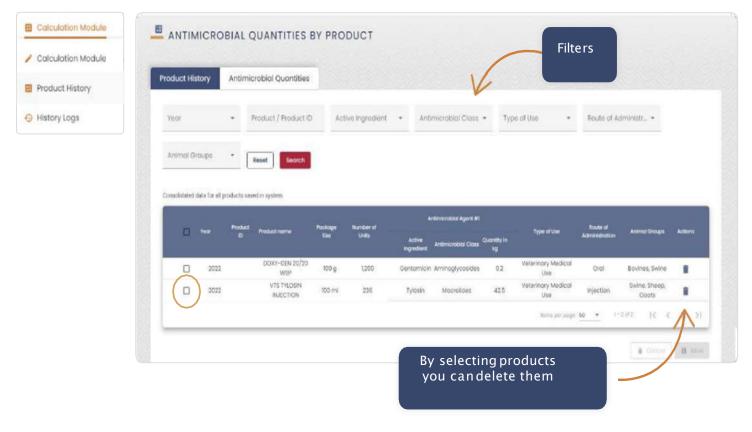


# Focus Product History



The Product history allows you to visualize different entries for the same product





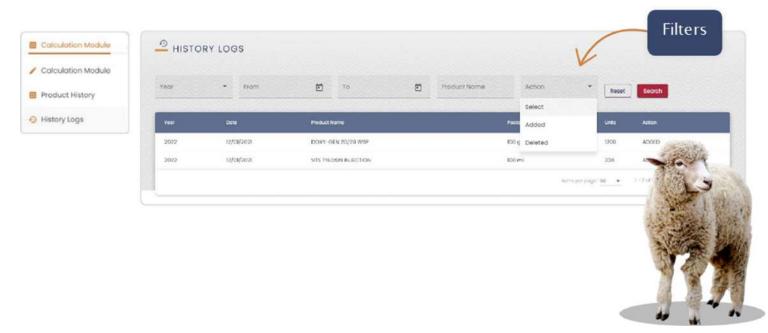
You can search for a specific product with the filters

The Consolidated Data allows you to **visualise** the **consolidated** data for the same product with same package size.





On this page you can know if another profile from your country has also used the Calculation Module.

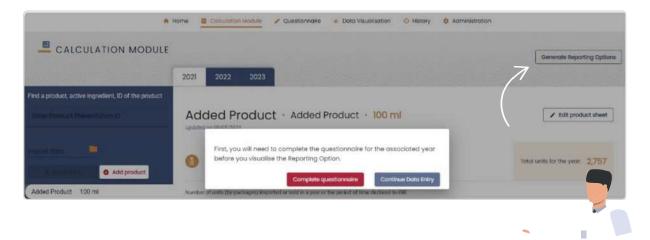


You can search for a specific product with the filters





# **Generating a Reporting Option**



Once you click on "Generate Reporting Options" you can choose to complete the questionnaire with your data or to continue to add other product entry.

Once the data are ready, you can generate a Reporting
Option to submit to WOAH

# Thank you!

Regional Representation for Asia and the Pacific Food Science Building 5F - The University of Tokyo 1-1-1 Yayoi, Bunkyo-ku Tokyo, 113-8657 JAPAN

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# National monitoring on AMU Representation of the results

Anne Chevance, Anses-ANMV (France) anne.chevance@anses.fr

Bangkok, 02/2023





# Agenda

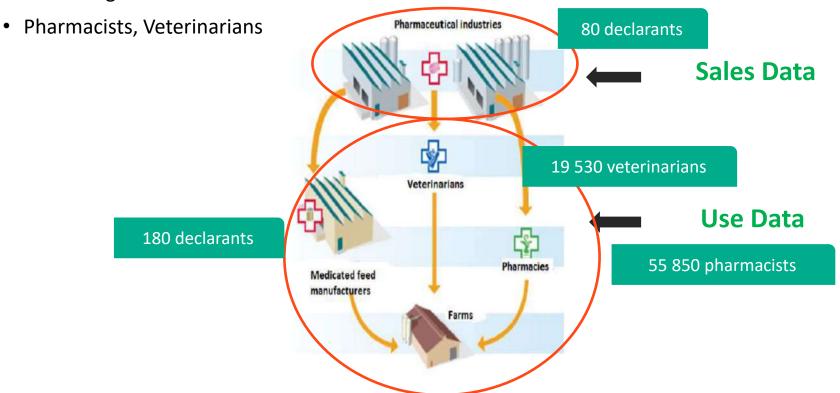
- 1. How to deal with large amounts of complex data?
- 2. The data visualisation
  - a. To check data quality
  - b. Data analysis
  - c. Evaluate progress
- 3. The limits of the analysis & communication



# What data are we collecting in France?

- Mandatory declaration of sales and delivery of antimicrobials
- Who should declare?

Marketing Autorisation Holders -Feed mills manufacturers





# Dealing with a large amount of data

➤ Monitor antimicrobial usage -> collect data from declarants, link the data with other information (composition, pharmaceutical form, class of antimicrobial...)

➤ Data are collected for different years

for different species

- How to deal with huge tables ?
- How to check the validity of the data?
- How to interpret the data in the best way ?





# How to deal with large amounts of complex data?

- > Difficult to detect trends or points needing attention with spreadsheets
- ➤ Using charts or graphs to create meaningful visuals (even with limited budgets and IT ressources)
- > French experience :
  - Use of different functionnalities of Excel
  - Use of free softwares : R, QGIS
  - Implementation of specific tools with Business Intelligence (funding of the Ministry of Agriculture)



# Agenda

- 1. How to deal with large amounts of complex data?
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### Data visualisation to validate sales data

Historical check by sales presentation

Package	ID VMP	Veterinary Medicinal Product	Sales 2021	Sales 2020	Absolute Difference in sales
Boîte de 1 flacon de 250 mL	298886	PRODUCT 3	0	28984	-28984
Boîte de 1 flacon de 250 mL	298886	PRODUCT 3	0	28984	-28984
Boîte de 3 plaquettes thermoformées de 10 comprimés	267086	PRODUCT 5	27398	30489	-3091
Boîte de 3 plaquettes thermoformées de 10 comprimés	267086	PRODUCT 5	27398	30489	-3091
Boîte de 1 plaquette thermoformée de 20 comprimés	252806	PRODUCT 5	139830	133843	5987
Boîte de 1 plaquette thermoformée de 20 comprimés	252806	PRODUCT 5	139830	133843	5987
Boîte de 1 flacon de lyophilisat et de 1 flacon de solvant de 5 mL et 1 bouchon compte-goutte	252446	PRODUCT 9	281740	256460	25280
Boîte de 1 tube de 5 g	252326	PRODUCT 9	416962	391882	25080
Pot de 1 kg	248606	PRODUCT 4	2829	2991	-162
Pot de 1 kg	248606	PRODUCT 4	2829	2991	-162
Pot de 500 g	248606	PRODUCT 4	4635	5341	-706
Pot de 500 g	248606	PRODUCT 4	4635	5341	-706
Boîte de 1 flacon de lyophilisat, 1 flacon de solvant de 5 mL et 1 bouchon compte-gouttes	248366	PRODUCT 4	262440	224489	37951
Boîte de 1 flacon de lyophilisat, 1 flacon de solvant de 5 mL et 1 bouchon compte-gouttes	248366	PRODUCT 4	262440	224489	37951



#### Data visualisation to validate sales data

- Historical check by sales presentation
- Easy with the Excel conditional format (configurable limits)
- In case of significant difference, contact the declarants

Package	ID VMP	Veterinary Medicinal Product	Sales 2021	Sales 2020	Absolute Difference in sales
Boîte de 1 flacon de 250 mL	298886	PRODUCT 3	0	28984	-28984
Boîte de 1 flacon de 250 mL	298886	PRODUCT 3	0	28984	-28984
Boîte de 3 plaquettes thermoformées de 10 comprimés	267086	PRODUCT 5	27398	30489	-3091
Boîte de 3 plaquettes thermoformées de 10 comprimés	267086	PRODUCT 5	27398	30489	-3091
Boîte de 1 plaquette thermoformée de 20 comprimés	252806	PRODUCT 5	139830	133843	5987
Boîte de 1 plaquette thermoformée de 20 comprimés	252806	PRODUCT 5	139830	133843	5987
Boîte de 1 flacon de lyophilisat et de 1 flacon de solvant de 5 mL et 1 bouchon compte-goutte	252446	PRODUCT 9	281740	256460	25280
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Pot de 500 g	248606	PRODUCT 4	4635	5341	-706
Pot de 500 g	248606	PRODUCT 4	4635	5341	-706
Boîte de 1 flacon de lyophilisat, 1 flacon de solvant de 5 mL et 1 bouchon compte-gouttes	248366	PRODUCT 4	262440	224489	37951
Boite de 1 flacon de lyophilisat, 1 flacon de solvant de 5 mL et 1 bouchon compte-gouttes	248366	PRODUCT 4	262440	224489	37951



# Agenda

- 1. How to deal with large amounts of complex data?
- 2. The data visualisation for
  - a. Data visualisation to support data quality
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# Data analysis / Report

- Avoid dashboards or graphs with all the detailed factors, present the results with simple or double entry table
- ➤ Preference to graphs / dashboards are quickly not easily readable (but sometimes necessary...)



# Data analysis / Report

- > Quantities of antibiotics and other indicators
- Whatever the indicator, results can be presented
  - for different years,
  - for different classes,
  - for different pharmaceutical forms,
  - for different species...

#### The aim: make the data meaningful and the report easy to read

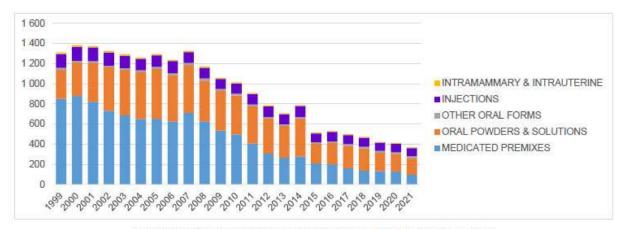


Figure 1: Change in tonnage by pharmaceutical form since 1999

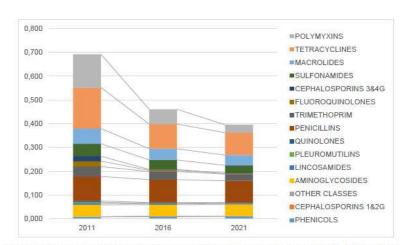
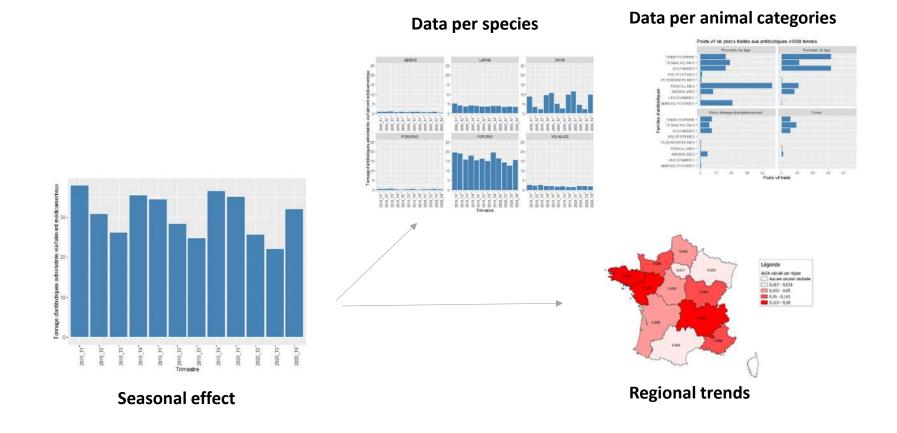


Figure 3: Change in ALEA indicators by antimicrobial class between 2011, 2016 and 2021



# Data analysis / Report

For use data, possible to go further





# Agenda

- 1. How to deal with large amounts of complex data?
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# Data visualisation to evaluate the efficacy of management

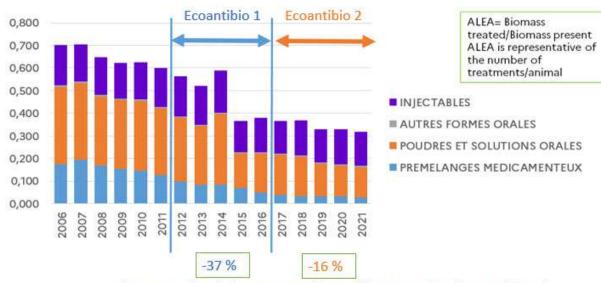
#### measures

Goal of the 1st plan Ecoantibio:

Decrease by 25% of the use of
antimicrobials in animals in 5 years

Goal of the 2nd plan Ecoantibio:
To maintain over time trends
towards declining exposure of
animals to antibiotics

#### Exposure to antimicrobials (ALEA)



The target of reducing exposure by 25 % in 5 years has been achieved



# Data visualisation to evaluate the efficacy of management

#### measures

Additional targets
Law 2014-1170 of 13 October 2014
on the future of agriculture, food
and forestry:
Decrease of the use of
Fluoroquinolones and 3<sup>rd</sup> 4<sup>th</sup>
generation cephalosporins of 25 %
in 3 years based on 2013 data

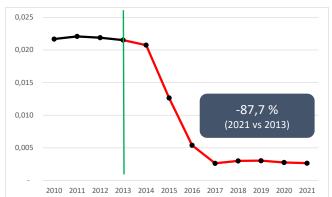
**Ecoantibio2**: Decrease by 50 % of the use of Colistin in animals in 5 years

Third & fourth generation cephalosporins

0,025
0,02
0,015
0,01
-93,8 %
(2021 vs 2013)

2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021

#### Fluoroquinolones









# Agenda

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# Different steps in the data analysis

Example, France 1999-2001 (1)

#### Data



#### Results



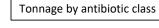
#### Consequences

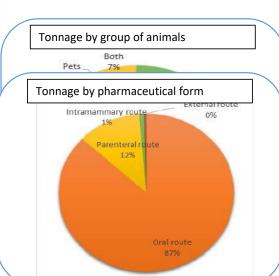
#### Data from the MAH

Number of units sold for each presentation (01/01/N-31/12/N)

#### Data on VMPs

Qualitative & quantitative composition
Pharmaceutical form





Lack of involvement of the animal sectors in the rational use of antibiotics

First decreases observed for Premixes



# Different steps in the data analysis

Example, France 2002-2007 (2)

#### Data



#### Results



# Consequences

#### Data from the MAH

Number of units sold for each presentation 01/01/N-31/12/N)

#### Data on VMPs

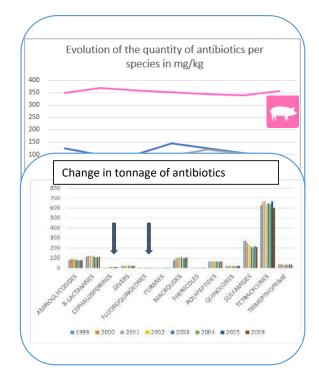
Qualitative & quantitative composition

Pharmaceutical form

#### **Animal Population Data**

Slaughtered and census data

& Assessement of the repartition by species



Difficulties to involve the stakeholders in an effective commitment to reduce usage of antibiotics, and especially to reduce usage of Fluoroquinolones and Cephalosporins 34G



# Different steps in the data analysis

Example, France 2008-2022 (3)

Data



#### Results



#### Consequences

Data from the MAH

Number of units sold for each presentation 01/01/N-31/12/N)

% of sales by species

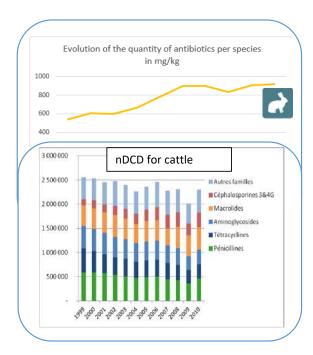
Data on VMPs

Qualitative & quantitative composition Pharmaceutical form

**Daily dose, duration of treatment** 

**Animal Population Data** 

Slaughtered and census data



Partnership with the Rabbits sector to set up surveys

Initiatives from the pig sector to limit the use of C34G ( ≥ of the exposition by 95 % between 2010 and 2016)

Good practice guides
Interprofessionnal charters
EcoAntibio 1 & EcoAntibio 2



- Data visualisation is useful
  - to follow temporal, regional trends...
  - to define target goal and evaluate the efficacy of managements measures
- The more detailed the analysis is, the more meaningful the results are
- The public opinion will focus on a limited number of messages: what key results to highlight in the reports?
  - > Sensitive subject : real impact of communication
- Highlight different results depending on the angle from which we observe the data
  - Keep in mind the limits of our data management, of our data analysis

# Thank you!





Égalité Fraternité

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# **Proposal**

#### Title

- Sample
- Sample

#### Title

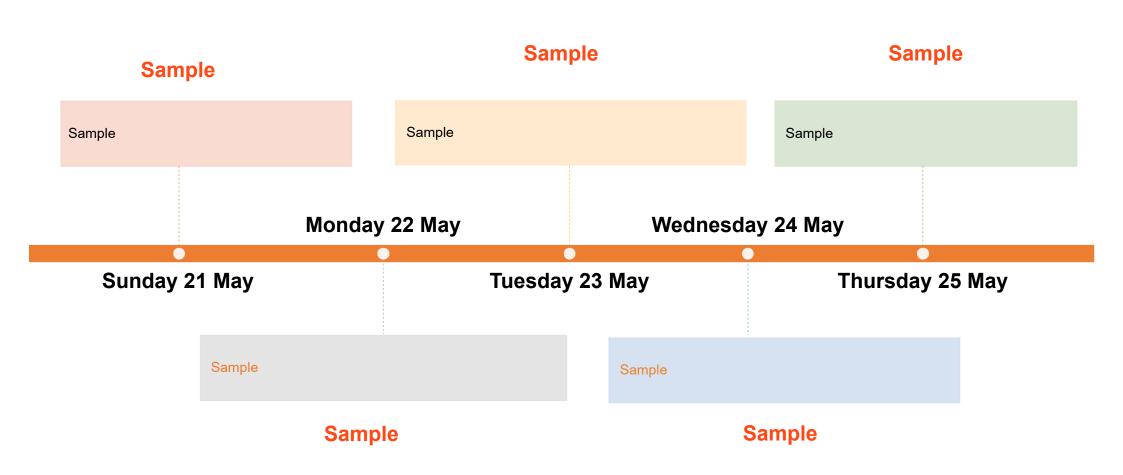
- Sample
- Sample

#### Title

- Sample
- Sample



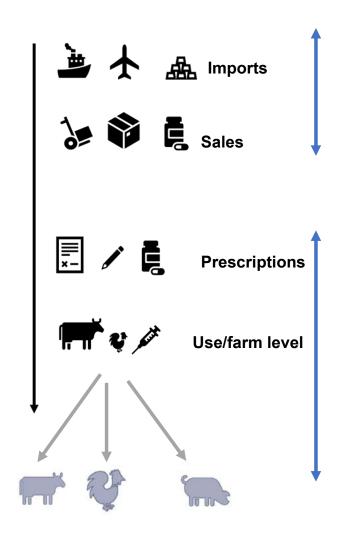
# Timeline (click to change)







# Field level AMU data collection: Understanding



# Imports and sales data

Collected at country level since 2015 – Currently 7th round.

Provides an estimation of AMU at a national level — Essential to evaluate national use of antimicrobials and for international reporting

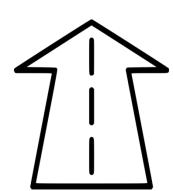


Complementary

**Field level data** represents the monitoring of antimicrobials that are directly administered to food-producing animals for any purpose, via any route of administration.

Usually at a very local level

- Understand the reasons of AMU
- Species
- · Routes of administration, real used dose,
- · The off-label use
- Unauthorized use of veterinary product





# Field level AMU data collection: Understanding

		Import and sales level (= <b>WOAH Global AMU</b> <b>data collection</b> since 2015)	Field level data collection (standalone projects ongoing at sub- national level)
Lilia	Scale	National level	Local /Sampling
	Objective	Global comparison between countries and regions	Reasons for AMU, antimicrobials usage patterns
<b>O</b>	Targeted species	Data concern all animals in the country	Usually, projects concern one production category of one species at a time
<b>Y</b>	Data providers	National authority, importers, wholesalers etc.	Field veterinarians, farmers etc.



# Field level AMU data collection: Background

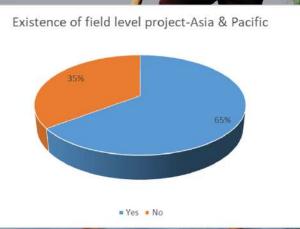


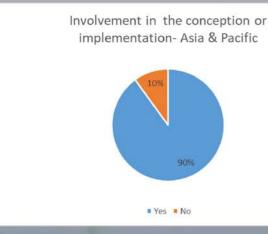
\* Recommendation n°4 of the **2nd OIE Global Conference on Antimicrobial Resistance** – October 2018, To further develop the OIE data collection on Antimicrobial Agents Intended for Use in Animals, converting the current spreadsheet format to a database system, able to accommodate data submissions by animal species, and its connection to the World Animal Health Information System (WAHIS) **and also allowing addition of data from field** 

Identifying Countries planning or conducting AMU monitoring at field level

studies.

Make sure WOAH Focal Points for Veterinary Products have access to the results of those fields studies







## **Inventory: Objectives**



Ensure that National authorities have access to the projects information of AMU field level studies conducted in their countries



Complement imports and sales data and empower National authorities for informed decision making



Better understanding methodologies of in-countries projects for providing better support in collecting data



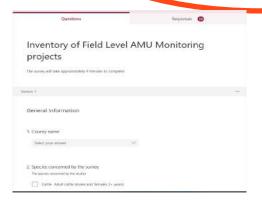
Have a better understanding of the situation of field level monitoring projects globally



# What's the Inventory

#### Microsoft form:

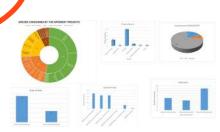
- collect projects information
- Accessible on ANIMUSE
- To be filled by countries and relevant stakeholders



**Inventory:** Database

#### **Data visualization:**

- graphs accessible on ANIMUSE





## What does it contain



Literature review of projects conducted and published by universities, researchers etc.

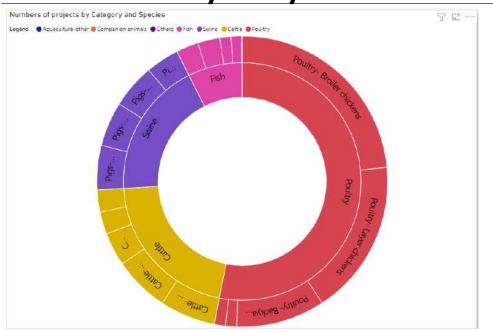


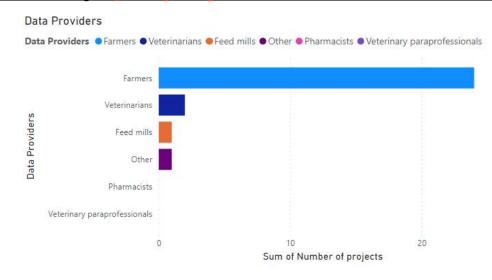
Project information collected with other organisations and stakeholders



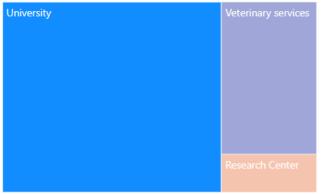
Possibility to add projects information from FPVP

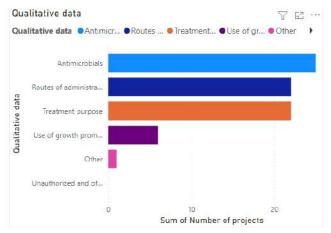
# Preliminary analyses from the Inventory (18 projects from Asia&Pacific)

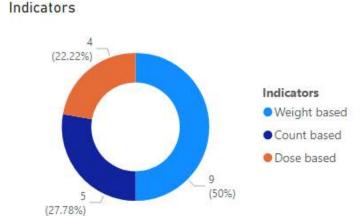




#### **Projects Bearers**









# **Next plan**



Test it with countries and make the necessary adaptations: ANIMUSE training



Gather as much data as possible: literature review, ANIMUSE training, liaisons with researchers and relevant stakeholders



Defining clear inclusion criteria for projects to be added in the inventory



Display on ANIMUSE: Inventory form and Graphs will be available on ANIMUSE



# How can I add an existing project in the inventory?

Any study whether they are qualitative or quantitative can be added

#### 1. Open the Microsoft form



#### 3. Submit to WOAH AMU-Team

Compa	ison between data provide	ers		
Results	presented to data provider	rs .		
Other				
Bac	k	Submit		

#### 2. Fill it with project information

* Required	
nequired	
General Information	
1. County name *	
TURKS AND CAICAOS ISLANDS	~
10.110 (11.10 (10.10) (10.10)	
2. Species concerned by the survey	/*
Species concerned by the survey     The species concerned by the studies	·-
The species concerned by the studies	
The species concerned by the studies  Cattle- Adult cattle (males and fem.)	
The species concerned by the studies	
The species concerned by the studies  Cattle- Adult cattle (males and fem.)	
The species concerned by the studies  Cattle- Adult cattle (males and fem:  Cattle- Adult dairy cattle	nales 2+ years)

#### **Accessible here:**

https://forms.office.com/Pages/ResponsePage.aspx?id=Y\_X68 W2wNUyHOTTMwoDcrzxHXQr6wJxOpd8\_stY4PbNUM0VDN0FZ SkZaSDBLOUpUNDBPMko0MUNVQi4u

# Thank you

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World Organisation for Animal Health

Organisation mondiale de la santé animale Organización Mundial de Sanidad Animal



# AMU activities with veterinarians and farmers in France

Anne Chevance, Anses-ANMV (France) anne.chevance@anses.fr

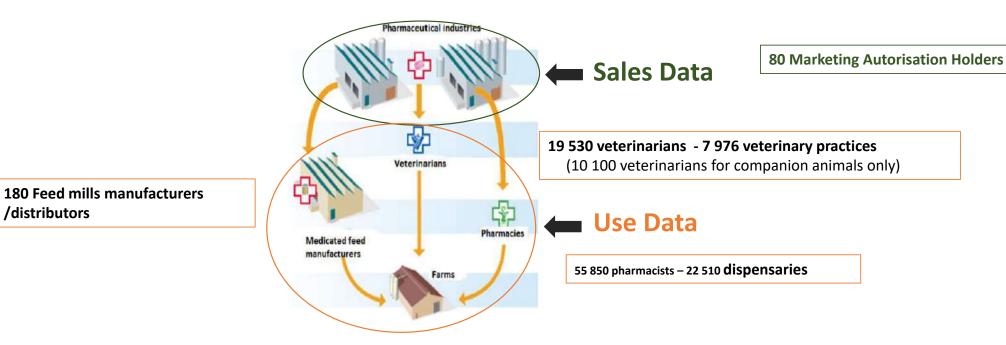
Bangkok, 02/2023





/distributors

# Antimicrobial monitoring systems in France



#### Huge system to be built!

- Numerous actors / declarants
- Numerous sofwares used by Veterinarians
- Big volume of data and various flows of exchange



# Different possible data sources for AMU

#### Consumption data can be collected at different levels.

Data sources close to the use of antimicrobials will provide the most reliable estimates of Antimicrobial consumption and will be more likely to provide precise data on the animal, dose, duration of treatment, indications ...

			Animal	
		All species together	Detail by species	Detail by animal categories
Exemples of data sources	Comments			
Imports	Volumes match import cycles rather than consumption patterns	Yes	No	No
Marketing authorisation holders	May not be able to examine data at regional, local, facility or prescriber level	Yes	No	No
Wholesalers	Distribution and supply data are likely to be closer to actual consumption than purchase data	Yes	Yes	No
Feed mills manufacturer	For medicated feed	Yes	Yes	yes
Farm level	May have detailed information, diagnosis, dose, duration, number of animals treated	Yes	Yes	Yes
Prescription	May have detailed information, diagnosis, dose, duration, co-prescribed medicines	Yes	Yes	Yes

In blue: systems in place or under development in France



# Sales by Marketing Authorisation Holders: a first step

AMU estimation at national level

Useful to raise Awareness



# **Example: the veal calf sector**

• In 2011, a first AMU estimation in the national report on the antibiotics sales

- MAH estimated the percent of sales for cattle & all oral treatments were

allocated to calves

		<u></u>
Sales in mg/kg	19,55	350,32
Tonnage sold	183,46	75,62
	Cattle	Calves

X 18

- In 2013-2014, a field survey confirmed significant antibiotics use in veal calf sector.
- In 2015, an awareness campaign was launched: an interprofessional charter for good health control and proper use of treatments drugs in the production of veal calves.

# Monitoring at farm level – Veal Calves



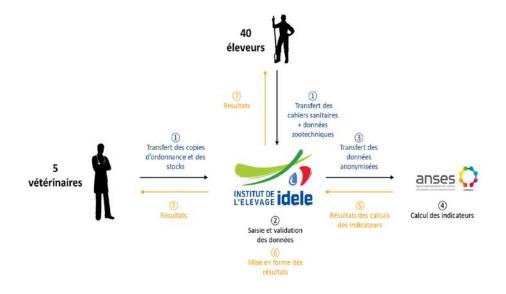
A permanent observatory on the use of antimicrobials in veal calf farms was set up by ANSES-ANMV and the French Livestock Institute (IDELE)

The data collection was launched in 2016 and deployed with a panel of volunteer breeders.

The data are analysed with a software tool specifically developed at ANSES-ANMV

to enable farmers, together with livestock technicians and veterinarians, to assess their antimicrobial use practices







#### **Network of 40 farms**

- Collection of usage data at the farm level and of farmer's pharmacy before and after each batch of animals
- In parallel collection of veterinarian prescriptions
  - The step of validation: A necessity!

Some differences between farmers registrations and veterinary records

- ✓ All the treatments reported by the farmers are kept
- ✓ Durations are sometimes amended
- ✓ Prescribed VMP which are missing from the farmers registrations are added

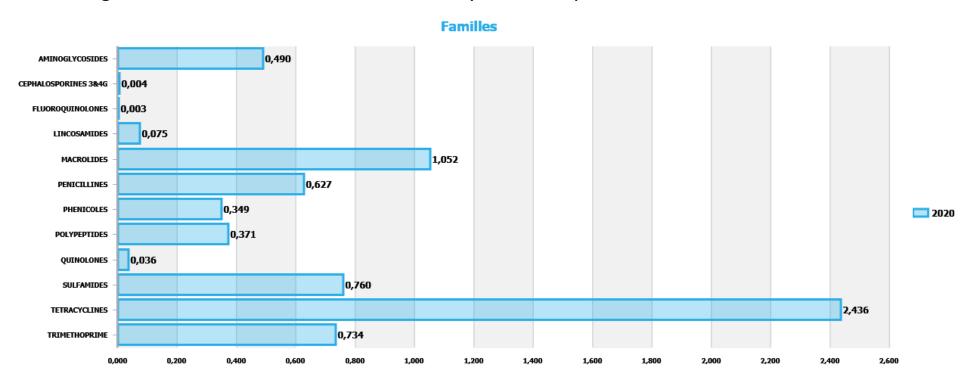








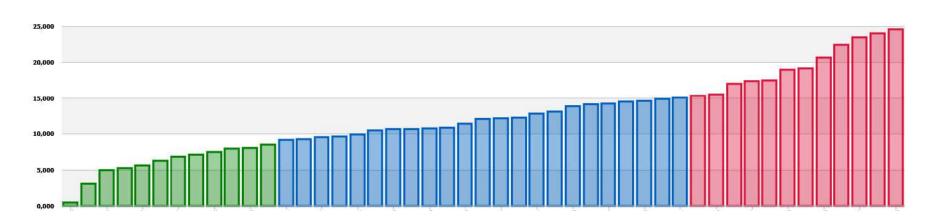
- Number of treatments per veal calf
- 88% oral treatments + 12% injectables
- Among the antimicrobial classes used, tetracyclines are predominant.



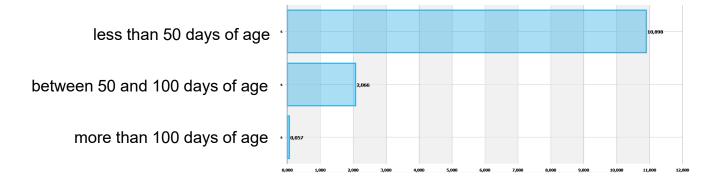


### Number of treatment <u>days</u> per veal calf : here <u>only tetracyclines</u> treatments





A bar in the histogram represents one veal calf batch Benchmarking





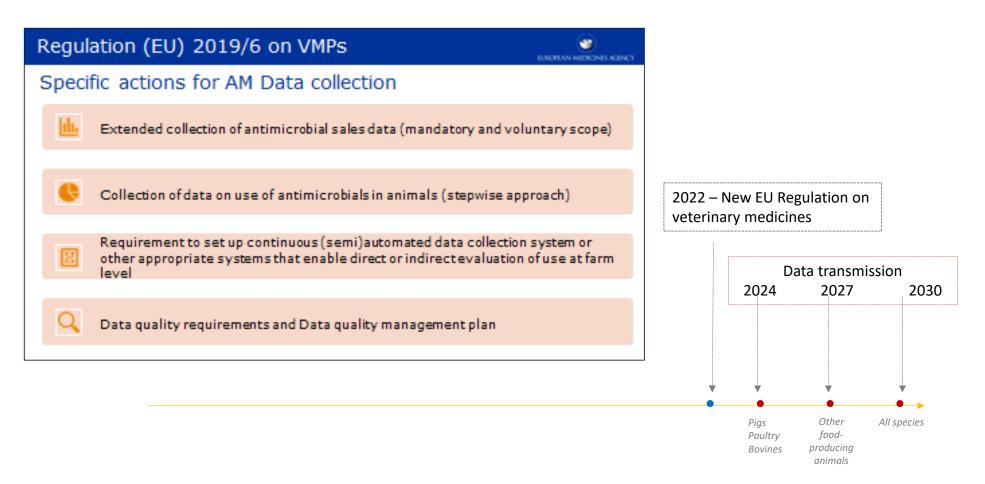
#### Different indicators are calculated, but:

- Number of treatments per animal
- Number of treatment days per animal
- Close to the use of antimicrobials
- Easy to calculate
- Meaningful for the breeders



#### Improvement of antimicrobial monitoring systems

New European Regulation: collection system on Use data per species/animal categories





#### Use data

### Calypso: a French projet



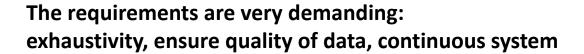
An information system including other data transmission and consultation tools, in a broader view of the veterinarians activities in the veterinary public health framework.

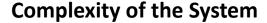
#### Priority business process on data collection on use of antimicrobials

- Discussed since 2014
- Prepared since 2017
- Managed by the French Veterinary Council (official mandate from the French Ministry of Agriculture)
- Based on deliveries and prescription data collection
- From softwares/practice management systems in use
- All species considered
- Individual reporting (self-evaluation, follow-up improvement)



### Calypso: a French projet





Various cases to consider to establish specifications (for example)

- Veterinarians prescribe and deliver / Veterinarians prescribe and Pharmacists or Feed mills manufacturers deliver
- Making the link between prescription and delivery
- Fractionning of the delivery
- Need to cover veterinary medicines but also use off label of Human medicines
- Manage duplicate declarations, lack of declarations....

#### **Opportunities**

Involvement of all stakeholders
Will enable self evaluation of veterinarians



#### Monitoring of antimicrobial consumption is a key activity

- Important information to promote prudent use of antimicrobials
- More precise data are useful to target interventions
- Enable to evaluate the efficacy of management measures by species
- Essential element of integrated surveillance (AMU & AMR)



# Thank you!

Regional Representation for Asia and the Pacific Food Science Building 5F - The University of Tokyo 1-1-1 Yayoi, Bunkyo-ku Tokyo, 113-8657 JAPAN

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Liberté Égalité Fraternité











### AMU Activities with Vets and Farmers-Pakistan's Perspective

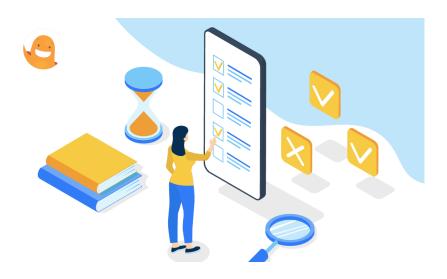
Riasat Wasee Ullah 24th Feb 2023

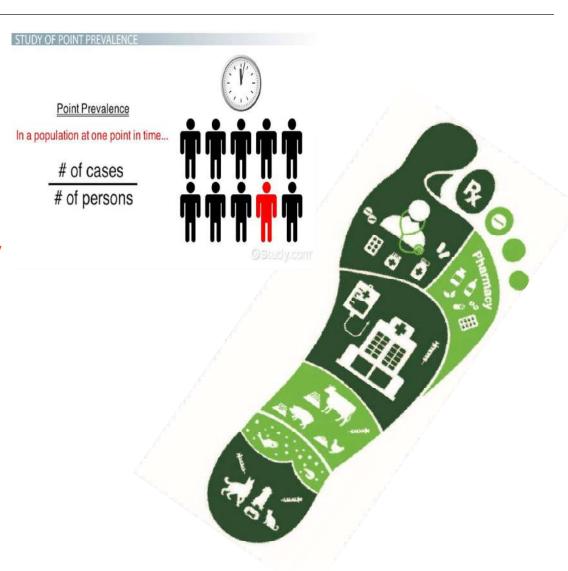
Assistant Animal Husbandry Commissionner /WOAH-FP for DN & VP Ministry of National Food Security and Research, Pakistan





- Footprint Analysis
- KAP Surveys on AMU
- PPS Studies in Poultry and Dairy

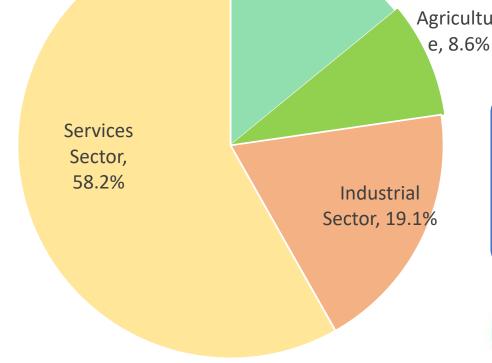


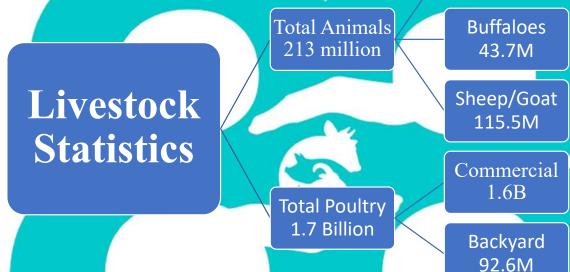




#### **Contribution in GDP**









#### **AMU/C Data Collection**

#### Human Health Sector

- ❖Pharmaceutical sales obtained from IQVIA at the level of manufacturers and distributors, comprising 85% of the pharmaceutical market.
  - ATC J01 class (antimicrobials for systemic use).
- Antibiotic import for vertical programs by international agencies
- A survey by IQVIA for public sector procurement of antibiotics provided data for the remaining 15%.

Consumption was analyzed according to the Anatomical Therapeutic Chemical/ Defined Daily Dose (ATC/DDD) methodology.



#### **AMU/C Data Collection**

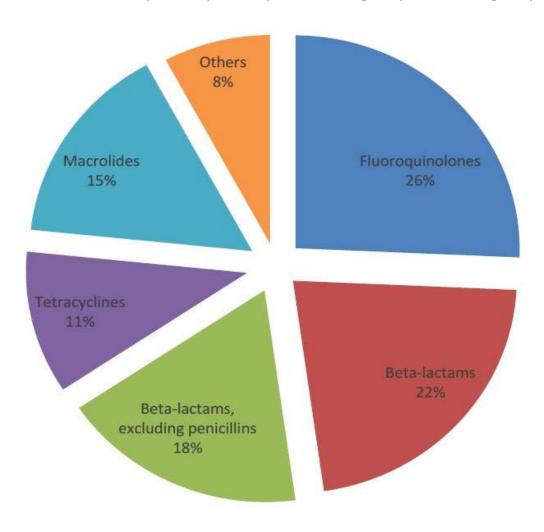
#### Animal Health Sector

- ❖The data source from the Pakistan Export Import Database (EXIM).
- ❖5 sources were used to identify, verify, and extract all antibiotic products meant for use in animals
  - ❖The list of manufacturers that are known to produce antibiotics used in animals
  - ❖The WHO/WOAH list of Medically Important Antibiotics with 125 active ingredients.
  - The DRAP (Drug Regulatory Authority of Pakistan) list of all manufacturers (both human and animal sectors) licensed in responding year.
  - ❖An online Drug Information System (DIS) containing licensed human medicines in Pakistan as well as manufacturers
  - ❖ Product catalogues on manufacturers' websites, or other online sources including social media (Facebook; LinkedIn) information that is publicly available.



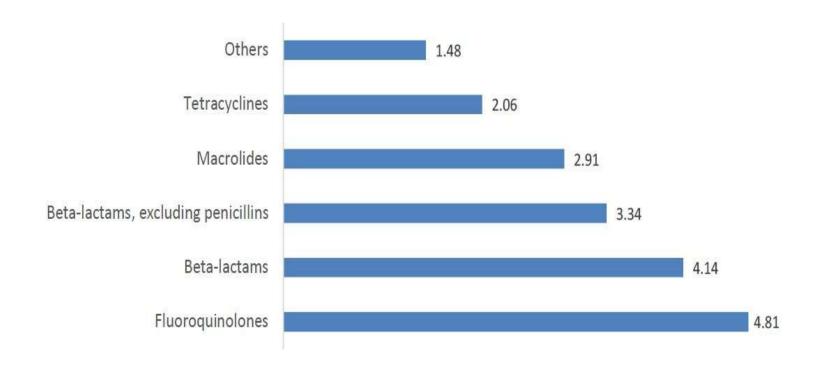
#### **Results-Human Health Sector**

Antibiotic consumption by therapeutic sub-group/ATC sub-groups





#### **Results-Human Health Sector**

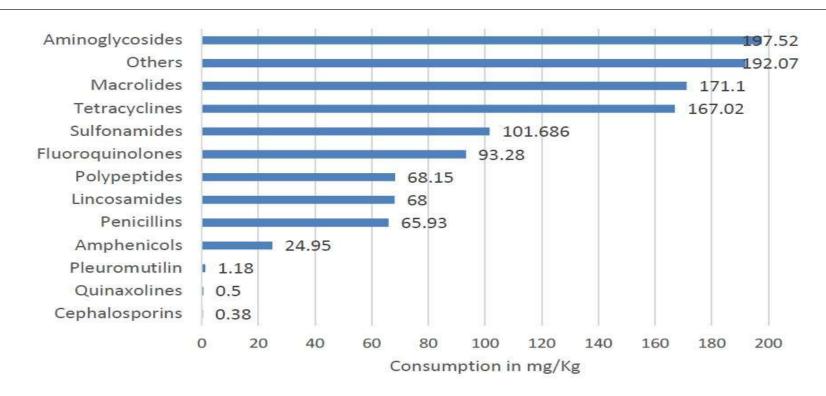


DID: The total consumption of systemic antibiotics in humans was 18.60 DID.

Kg of API: The total estimated antibiotic consumption was 1,651,908.96 kg (1,652 MT).



#### **Results-Animal Health Sector**

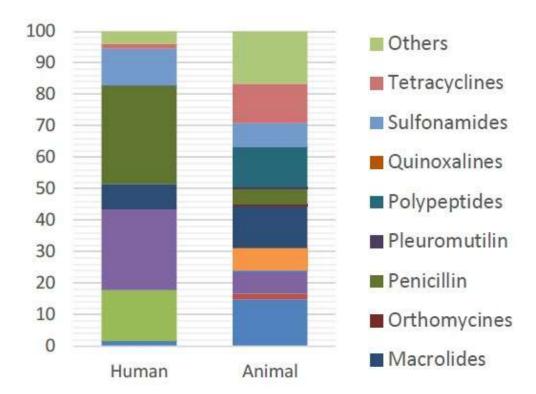


- The estimated total consumption of medicines and medicated feed in the veterinary sector was 1,481.78 kg.
- Total consumption comprised of 1,253.52 kg as APIs and 228.46 kg of medicated feed.
- Total consumption in mg/PCU, or biomass, was estimated at 22.94 mg/Kg



#### **Antibiotic Footprint**

The estimated combined antibiotic consumption across sectors for 2019 in Pakistan was 3,072 MT<sub>6</sub>

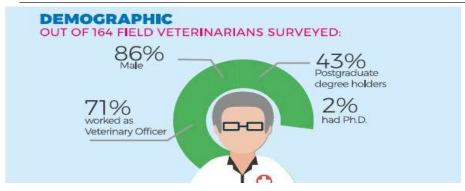


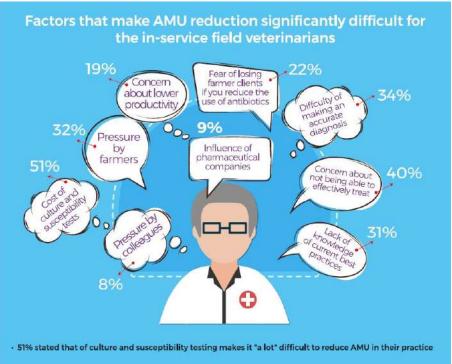
Relative consumption by antimicrobial group in humans and animals (%, MT)

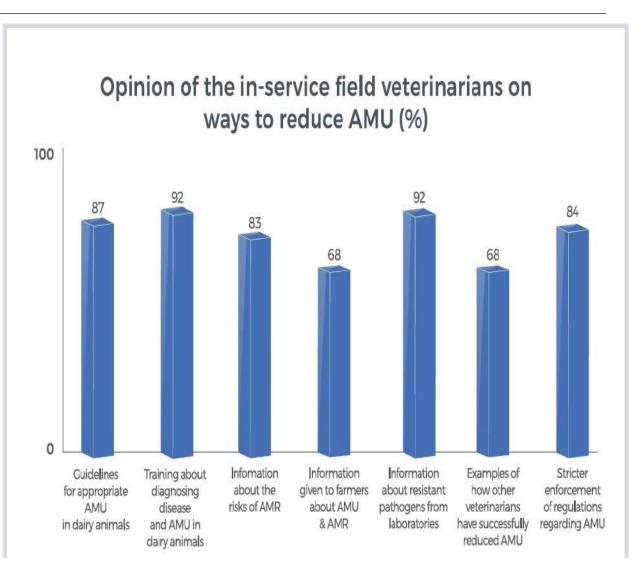




#### **KAP Survey of In-service Field Veterinarians**

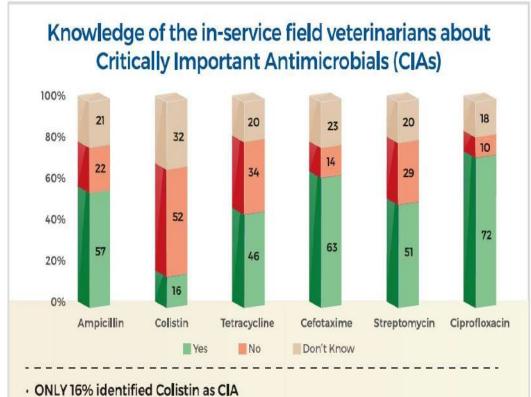


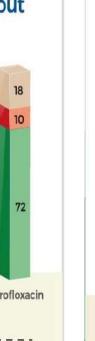


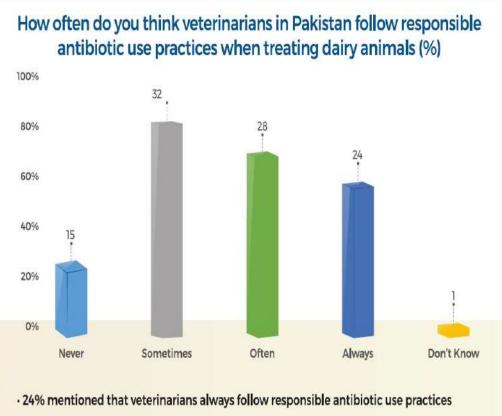




· 73% were able to identify Ciprofloxacin as CIA

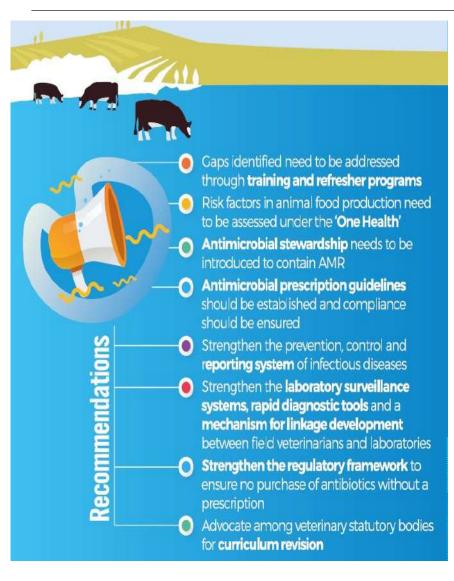




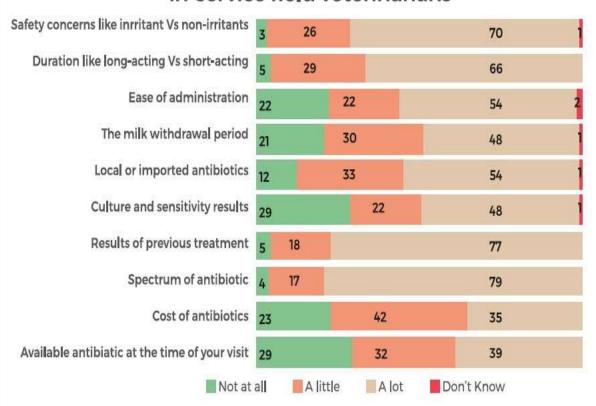




#### KAP surveys



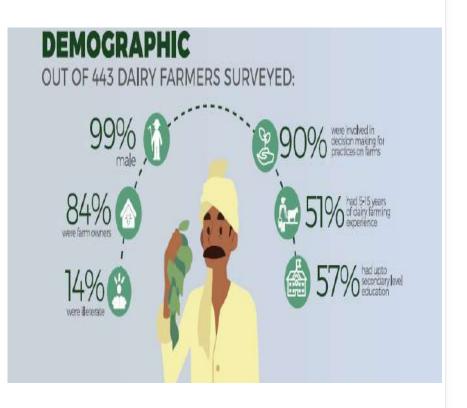
### Factors that affect the AMU choice of the in-service field veterinarians



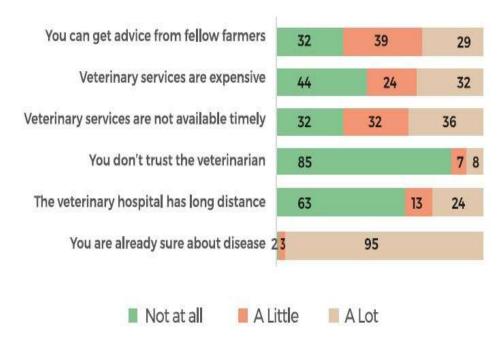
- For 79% of veterinarians spectrum of antibiotics affected their AMU choice "alot"
- For 77% of veterinarians, results of previous treatment with the same antibiotic affected their AMU choices "a lot"



#### **KAP** surveys of farmers



### Factors affecting dairy farmers decision of antibiotic purchase without veterinary consultation (n=326) %

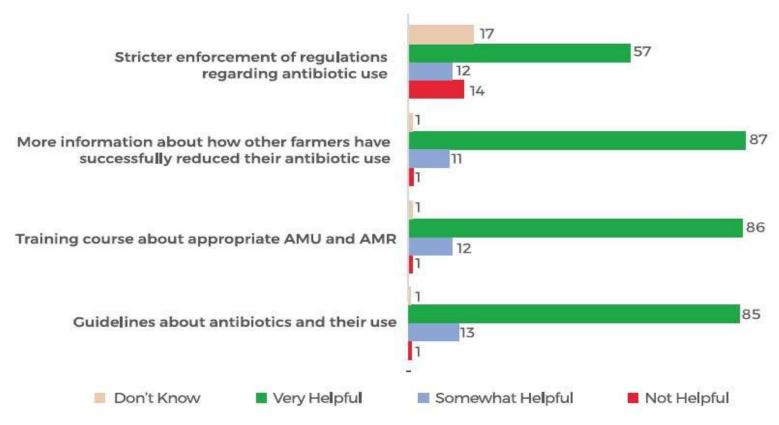


- 95% of farmers did not consult veterinarians in the purchasing of antibiotics as they were confident in their own judgment
- · 36% mentioned that veterinary services are not timely available.



#### **KAP** surveys of farmers

#### Dairy farmer's opinion on ways to reduce AMU



- · 87% considered success stories of other farmers reducing the antibiotic use on their farm, very helpful
- 86% considered awareness on judicious use of antibiotics on farm to be very helpful

#### **AMU in Poultry-PPS**

Geographical locations chicken farms in Puniat Khyber Pakhtunkhwa. ~



1< Open Access Article Quantification and Trends of Antimicrobial Use in Commercial Broiler Chicken Production in Pakistan by 🕷 Muhammad Umair 1 🖾 🕒, 👰 Muhammad Faroog Tahir 2 🖂, 🚷 Riasat Wasee Ullah 3 🖂, Q Jabir Ali 1 2 0 Naila Siddique 4 2 Q Q Ayesha Rasheed 5 2 Muhammad Akram 3 4 🚇 Muhammad Usman Zaheer 2 🖾 🔟 and 🚇 Mashkoor Mohsin 1,7 🖾 🗓 1 Institute of Microbiology, University of Agriculture, Faisalabad 38000, Pakistan <sup>2</sup> The Fleming Fund Country Grant Pakistan, Health Security Partners, Washington, DC 20037, USA <sup>3</sup> Livestock Wing, Ministry of National Food Security and Research, Islamabad 44000, Pakistan 4 National Reference Laboratory for Poultry Diseases, Animal Sciences Institute, National Agriculture Research Center, Islamabad 44000, Pakistan <sup>5</sup> The Fleming Fund Country Grant Pakistan, DAI, Islamabad 44000, Pakistan \* Author to whom correspondence should be addressed. Antibiotics 2021, 10(5), 598; https://doi.org/10.3390/antibiotics10050598

ed ITER xycycline (196.81 mg/PCU) omycin (136.74 mg/PCU) noxicillin (115.04 mg/PCU) (mg/PCU) use in summer Tilmiscosin Chlortetracycline

Order Article Reprints

#### Veterinary consumption of highest priority critically important antimicrobials and various growth promoters based on import data in Pakistan

Muhammad Umair, Samuel Orubu, Muhammad Hamid Zaman, Veronika J. Wirtz . Mashkoor Mohsin

Published: September 14, 2022 • https://doi.org/10.1371/journal.pone.0273821

Article Authors Metrics Comments Media Coverage Peer Review

The results indicated during the study per kg. Results demonst farms (462.5 mg/PCL

winter flocks compared to summer.

#### Abstract Abstract

1. Introduction

2. Methodology

4. Discussion

3. Results

#### Background

Antimicrobial resistance (AMR) is a global public health emergency driven by the indiscriminate use of antimicrobial agents in humans and animals. Antimicrobial consumption surveillance guides its containment efforts. In this study, we estimated, for the first time, veterinary consumption of Critically Important Antimicrobials with Highest Priority (CIA-HtP) for Pakistan.

ncreased by 117% in winter flocks gher (459,7%) in winter than in n is a life-saving drug for people.

#### (mg/PCU) use in a winter

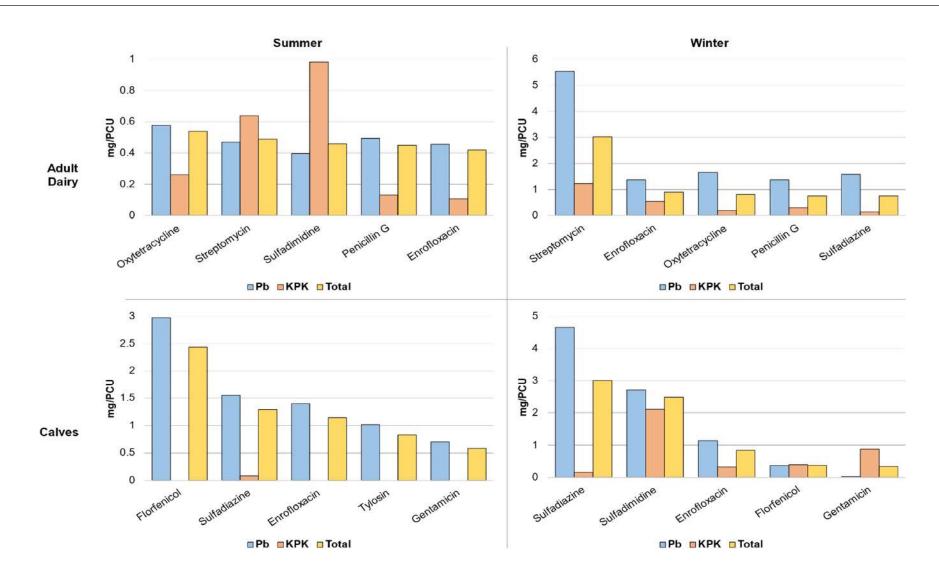


n belong to critically important antimicrobial

classes (CIA) for human medicine as classified by the World Health Organization (WHO).



#### **AMU in Dairy-PPS**





#### **Farmers Awareness**

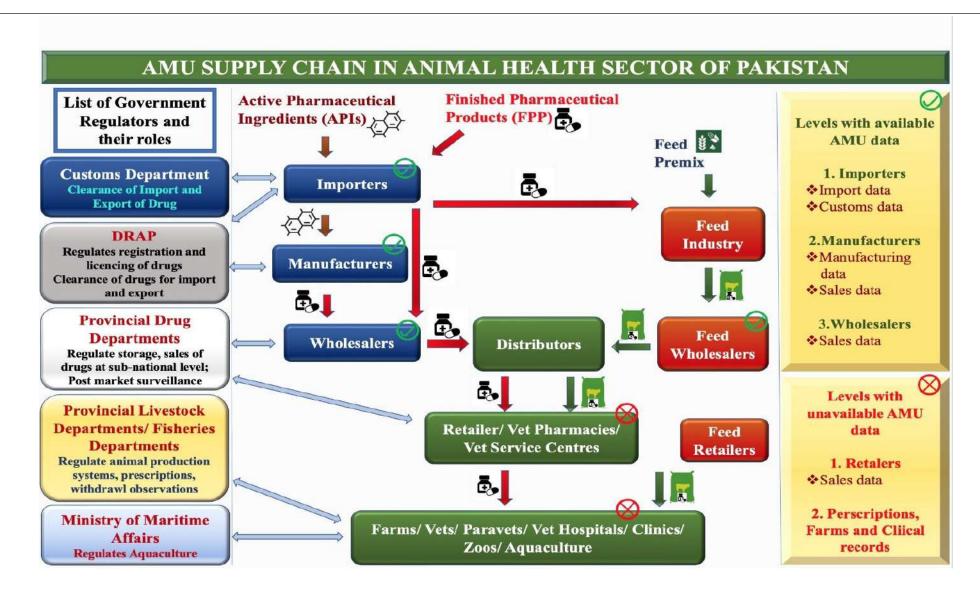








#### **Data Sources**



## Thank you!













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### Introduction to WOAH's global project:

# Reporting system of Substandard & Falsified Veterinary Products

Andrés García Campos

23/02/2023

Programme Manager



Organisation mondiale de la santé animale Fondée en tont av/OIE Organización Mundial de Sanidad Animal





# Agenda

**Background & Context** 

**WOAH's Project on SFVPs** 

Actions and take-home messages



### Background & Context

Caution with interpretation!!

3 % illegal



Healthforanimals 2017

### 52 % SFVPs





Vidhamaly et al., 2022 - BMJ Global Health









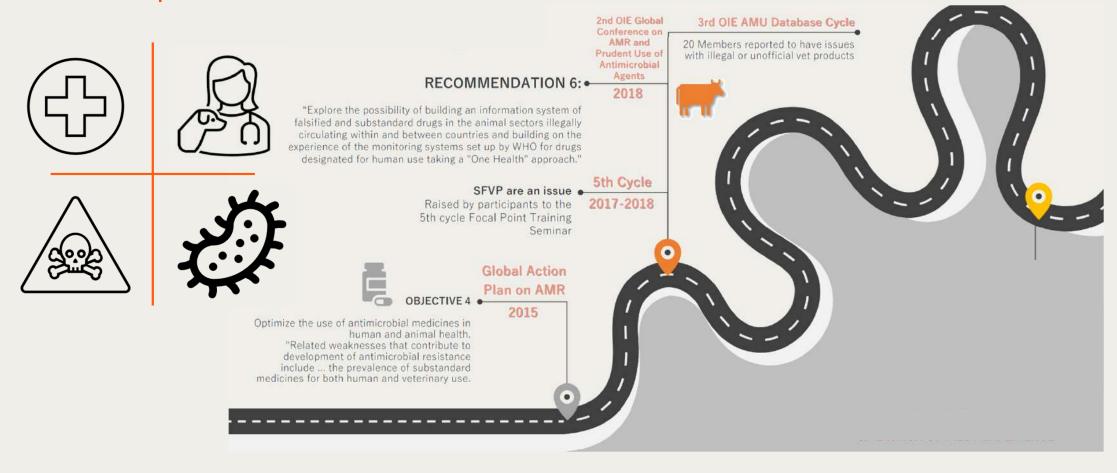
Original

**Falsified** 

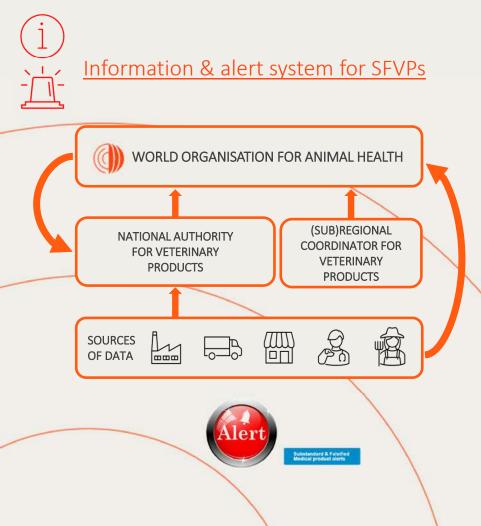


### Background & Context

#### Consequences



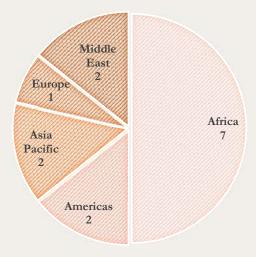


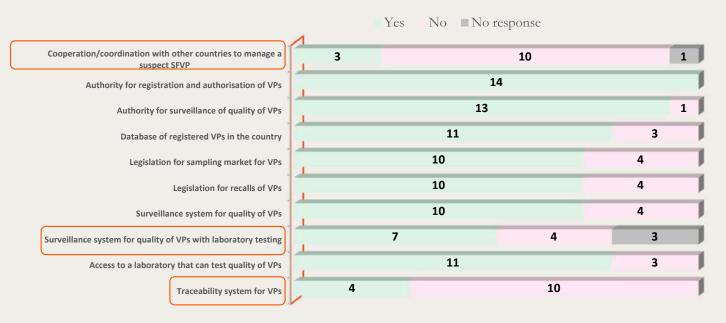


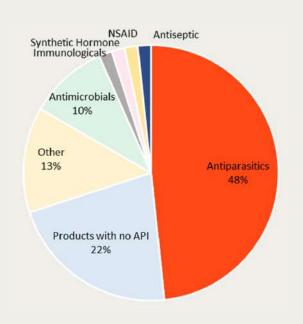
#### Pilot Phase 1

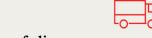
**Goal**: To pilot an information and alert system for SF veterinary products with WOAH Members, to allow the collection of:

- Information on the in-country situation related to VP quality
- WOAH Members' feedback on the data collection tools for their refinement towards an on-line tool









Unauthorised





Site of discovery

Distributors 31

Authorised sellers 11

sellers 9

control 3

3

Reasons of suspicious

Recall from MAHs / NCA 8

Routine inspection & Surveillance 35



Detection by external source

1
Т

Number Number products Classification incidents Suspect Confirmed Substandard 22 20 17 **Falsified** 10 0 12 Unregistered 0 0 0 Unknown 10 0 **TOTAL** 38 30 29





### WOAH asks for your collaboration!!









### Benefits















### What do you need to do?



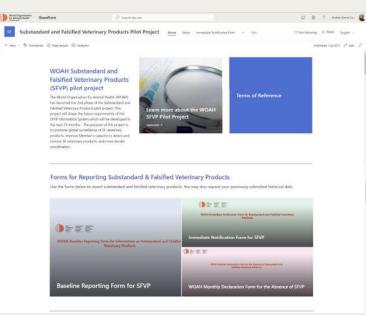
Substandard and Falsified

Veterinary Products Pilot

Project - Home
(sharepoint.com)





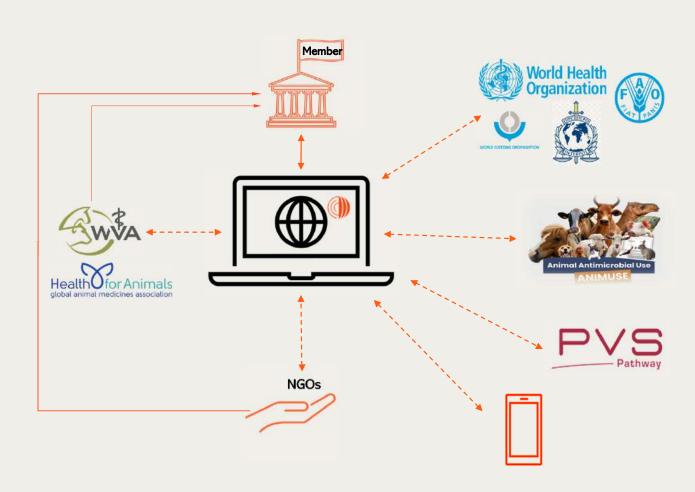


WOAH Baseline Reporting Form (Blue Form)

WOAH Immediate Notification Form (Green Form)

WOAH Monthly Declaration Form (Pink Form)



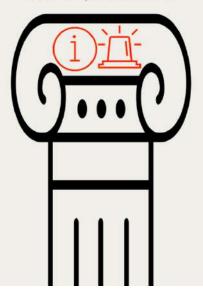






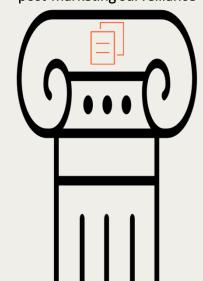


Development an information & alert system for SFVP



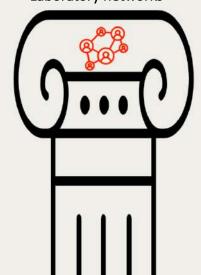


Development of Guidelines on post-marketing surveillance





Development Regional Laboratory networks

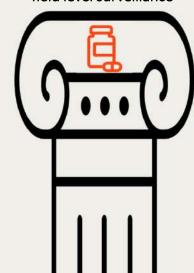








Guidelines & tools for field level surveillance





#### Actions and take-home messages

- The success of the project depends on creating a Platform for YOU
- WOAH would like to understand our Members' needs to create a platform fit-for-purpose
- Participation is very simple
  - WOAH Baseline Reporting Form once a year
  - WOAH Immediate Notification Form as early as possible, even if information is incomplete
  - WOAH Monthly Declaration Form **ONLY** if no incidents were found the month before
- Consent sharing data, totally or partially, is strongly encouraged but not mandatory. WOAH will always act according to every Member's wish
- Contact <u>sfvp@woah.org</u> by email on SharePoint for any questions issues



#### Interested in participating?

- Project experience Day 3: Let us know if you would like to be part of this experience
  - In person Approach to me and let me know by tomorrow before closing ceremony
  - <u>sfvp@woah.org</u> or <u>a.garcia@woah.org</u>
- Particularly of interest for
  - Members already enrolled
  - Rest of Focal Points who wish to participate
- SharePoint navigations and exercise of reporting → Bring your laptop, check inbox before the session
- Feedback form to be completed (5-10 min)
- Should you like to be part of this project for 2023, please let us know stvp@woah.org



### Actions and take-home messages





# Thank you Merci Gracias

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