出國報告
（類別：其他：研討會）

參加第 1 屆動物劣藥及偽藥（SFVP）工作坊及世界動物衛生組織 SFVP 監測及監控之試點型系統會議

服務機關：農業部動植物防疫檢疫署
姓名職稱：黃怡銘技正、陳昱憲技士
派赴國家：泰國曼谷
報告日期：113 年 9 月 4 日
出國期間：113 年 6 月 11 日至 6 月 15 日

目次

一、緣起及目的

根據《陸生動物衛生法典》第 3.4.11.5 條款及 2018 年第二次世界動物衛生組織（World Organisation for Animal Health, WOAH）全球抗微生物藥物抗藥性及其謹慎使用大會之第六項建議，WOAH 正在建立動物劣藥與偽藥監測及監控系統 (Veterinary Monitoring and Surveillance System for Substandard And FalsifiEd VMP, VSAFE)。其目的是收集來自其網絡之動物劣藥及偽藥（Substandard and Falsified Veterinary Products, SFVP）之通報，並隨後通知並支援會員國，識別並將之從市面上之流通掃除。

於 2022 年，WOAH 在 14 個自願之會員國中啟動了一項試點項目，代表所有地理區域，該項目於 2023 年擴增至 42 個自願國，以更好地了解會員國之需求並制定該系統所需之規範。目前缺乏可靠之數據，因此需要驗證之證據以改善目前之知識。SFVP 問題屬國際性，因此需協調全球性之因應方式。此外，檢測 SFVP 可能會很困難，需要技術支持。在這種情況下，我們亟需要有全球性之系統。透過該系統收集之資訊，可用於改善取得優質動物用藥產品之途徑。因此，區域研討會旨在達到以下目標：(1) 提高各國對 SFVP 之影響及危害之認識。(2) 了解各國檢測 SFVP 之機制，並將各國納入 WOAH 監測系統 VSAFE。(3) 辨識主要缺口和工作領域，以支援各國按防疫一體方法（One Health Approach）執行預防、檢測及應對。

二、行程及會議議程

- 2024 年 6 月 11 日（二）：臺北往曼谷。
- 2024 年 6 月 12 日（三）：

時間	主題	主持人/主講人
09：00 ~ 9：15	開幕式及引言	Dr. Javier Yugueros Marcos（WOAH AMR及動物用藥產品部 主管）
09：45 ~ 10：15	WOAH 工作坊目標	Dr. Tikiri Priyantha（WOAH東南亞區代表）
10：15 ~ 10：45	WOAH 對動物劣藥及偽藥之任務及願景	Dr. Javier Yugueros Marcos
10：45 ~ 11：15	茶敘、團體照	
11：15 ~ 12：15	以防疫一體的方法應對人與動物用之劣藥及偽藥	Dr. Paul Newton（牛津大學醫藥品質研究組）
12：15 ~ 12：30	WOAH 合作中心對動物劣藥、偽藥管理經驗分享-日本	Dr. Yuka Kobayashi（日本國家動物用藥檢驗所）
12：30 ~ 13：00	會員國對動物劣藥、偽藥管理經驗分享： 1. 馬來西亞 2. 泰國	1. Dr. Alifah Binti Ismail（馬來西亞獸醫服務部） 2. Ms. Witthayarat Dangyai（泰國食品藥物管理署）；Dr. Chusak Ardsoongnearn（泰國畜牧發展局）
13：00 ~ 14：30	午餐	
14：30 ~ 16：30	動物劣藥及偽藥產品事件之情境案例1演練	引導員：WOAH的AMR及動物用藥產品部門之 Andrés García Campos計畫經理

時間	主題	主持人/主講人
		所有與會者
16：30 ~ 17：00	茶敘	
17：00 ~ 17：30	海關執法措施	Mr. Billy KH YEUNG （世界海關組織亞太地區情報聯絡辦事處）
18：30	晚宴	

■ 2024 年 6 月 13 日（四）：

時間	主題	主持人/主講人
9：00 ~ 9：20	劣藥及偽藥之「預防、檢測和應對」—全球倡議及區域活動	澳洲衛生與老年護理部醫藥用品管理局 (Department of Health and Aged Care, Therapeutic Goods Administration, Australia) 的 Paul Huleatt 博士
9：20 ~ 9：40	WHO針對劣藥及偽藥產品之全球監控和監測系統 (Global Surveillance and Monitoring System, GSMS)	WHO總部劣藥及偽藥產品事件小組之Anita Sands女士
9：40 ~ 10：00	於畜牧場端收集動物劣藥及偽藥產品數據（FAO RAP 佛萊明基金AMR專案計畫）	聯合國糧食及農業組織亞太地區辦事處（FAO RAP）抗微生物藥物抗藥性（AMR）專案計畫協調員 Jutamart Jattuchai
10：00 ~ 10：20	介紹 WOAH 針對動物劣藥及偽藥之監控系統 (VSAFE)	WOAH的AMR及動物用藥產品部門之Andrés García Campos計畫經理
10：20 ~ 10：50	茶敘	
10：50 ~ 11：30	兩個會員國進行VSAFE使用經驗分享 試點型動物劣藥、偽藥監測及監控系統 (VSAFE)之緬甸使用經驗分享 農業化合物及動物用藥法規制度之紐西蘭經驗分享	 緬甸畜牧繁育及獸醫局之副局長 Dr. Swe Lynn Htet 紐西蘭初級產業部食品安全處之 Warren Hughes博士
11：30 ~ 13：00	WOAH動物劣藥及偽藥（SFVP）即時通報表 ---- 按情境案例1練習填報	WOAH的AMR及動物用藥產品部門之Andrés García Campos計畫經

時間	主題	主持人/主講人
		理
13：00 ~ 14：30	午餐	
14：30 ~ 15：30	動物劣藥及偽藥產品事件之情境案例2演練	引導員：Andrés García Campos 全體參與者
15：30 ~ 16：00	茶敘	
16：00 ~ 17：00	動物劣藥及偽藥產品事件之情境案例2演練(續)	引導員：Andrés García Campos 全體參與者
17：00 ~ 17：30	PANGEA行動 — 應對動物劣藥、偽藥之一種方法	國際刑警組織（Interpol）統籌員（Coordinator）Chi Wang Lam

■ 2024 年 6 月 14 日（五）：

時間	主題	主持人/主講人
9：00 ~ 9：20	獸醫師對動物劣藥、偽藥觀點	Mr. Nackanun Chitaroon （泰國動物健康產品協會）
9：20 ~ 9：40	動物健康產業對動物劣藥、偽藥觀點	Dr. Carel du Marchie Sarvaas （HealthforAnimals）
9：40 ~ 10：15	RAGNA— 強化國際合作，確定具體行動，並在人用藥及動物用藥之間交流經驗	瑞典藥物局的Katarina Lönnquist
10：15 ~ 10：45	茶敘	
10：45 ~ 11：15	為什麼跨部門合作很重要？佛萊明基金（The Fleming Fund）在其方案策略中應對AMR及SFVP之第二階段	佛萊明基金的全球管理代理者 Mott Macdonald 公司的 Robert Rosenthal先生
11：15~ 11：30	WOAH亞太地區動物用藥產品之品質管理調查結果	WOAH的AMR及動物用藥產品部門之Andrés García Campos計畫經理
11：30 ~ 12：00	開放討論-亞太地區（人醫及獸醫）合作及動物劣藥及偽藥管理	Andrés García Campos 全體參與者
12：00 ~ 12：40	1 分鐘分享-工作坊之總結、回饋或心得	全體參與者
12：40 ~ 13：00	閉幕結語	全體參與者
13：00 ~ 14：30	午餐	

■ 2024 年 6 月 15 日（六）：曼谷返回臺北。

三、過程及會議內容

（一）開幕式及引言

本次會議由 WOAH 之 AMR 及動物用藥產品部（WOAH Headquarters AMR & VP Department）負責人 Dr. Javier Y. Marcos 進行開場。

- 會議主要討論目標為動物劣藥及偽藥：劣等品質，泛指不符品質標準、不符產品規格或兩者均不符合狀況下，已核准之動物用藥產品（Veterinaty Product）；偽藥，則指未經核准或以詐欺方式偽裝為原廠藥之產品（Substandard and falsified veterinary products, SFVP），這類產品通常可透過不同方式流通，如街頭市場、不受監管之網站、藥局、診所或醫院，並對動物及人類防疫將產生負面影響，包括抗微生物藥物抗藥性（Antimicrobial resistance, AMR）之生成。
- 為支援各會員國解決 SFVP 所帶來問題，世界動物衛生組織（WOAH）正在致力於開發全球資訊和警報系統，目的為透過網路接收 SFVP 相關通知，並隨後透過警報通知所有會員國，協助各會員國辨識並將這類產品自市面上掃除。
- WOAH 在 2022 年自全球所有區域中找出 14 名會員國自願進行 SFVP 預警系統初步試點，並根據各參與國所回饋之經驗及建議進行改進，本

階段目標則是將自願參與試點國家擴大至 40 國，以便更解使用者需求並制定系統所需規格。

- 開場後，由各國家代表進行簡短自我介紹，本次會議參與國家包含泰國（主辦國）、日本、韓國、越南、菲律賓、馬來西亞、印尼、緬甸、寮國、柬埔寨、印度、孟加拉、斯里蘭卡、尼泊爾、巴基斯坦及我國。

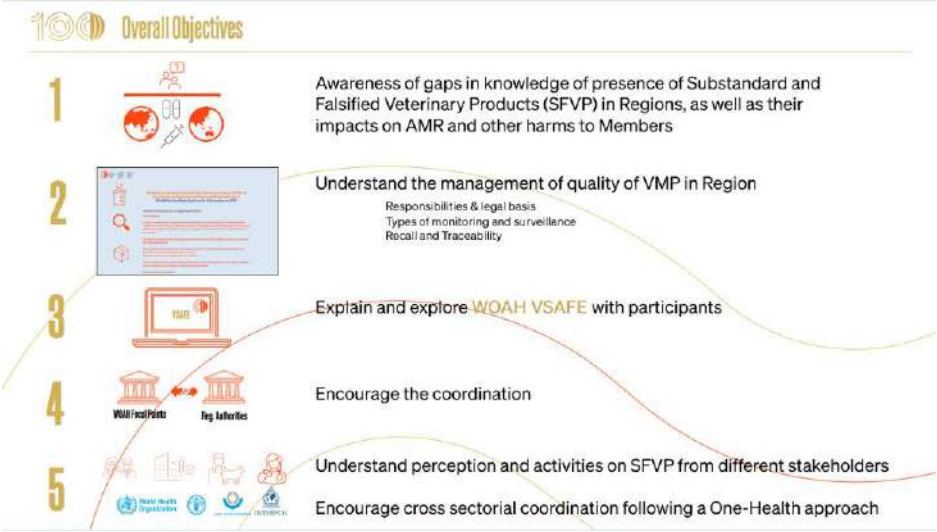
（二）WOAH 工作坊目標

本章節由 WOAH AMR 及動物用藥產品部（WOAH Headquarters AMR & VP Department）暨亞太地區代表處（Regional Representation for Asia and Pacific）及東南亞地區次代表處（Subregional Representation for Southeast Asia）之 Dr. Tikiri Priyantha 進行簡報「第一屆世界動物衛生組織試點動物劣藥及偽藥之監測及監控系統（WOAH-VSAFE）(1st Workshop on Substandard and Falsified Veterinary Products (SFVP) WOAH pilot Veterinary Monitoring and Surveillance System for SFVP (WOAH - VSAFE))」。

本次會議目標為促使參加所有會員國家：

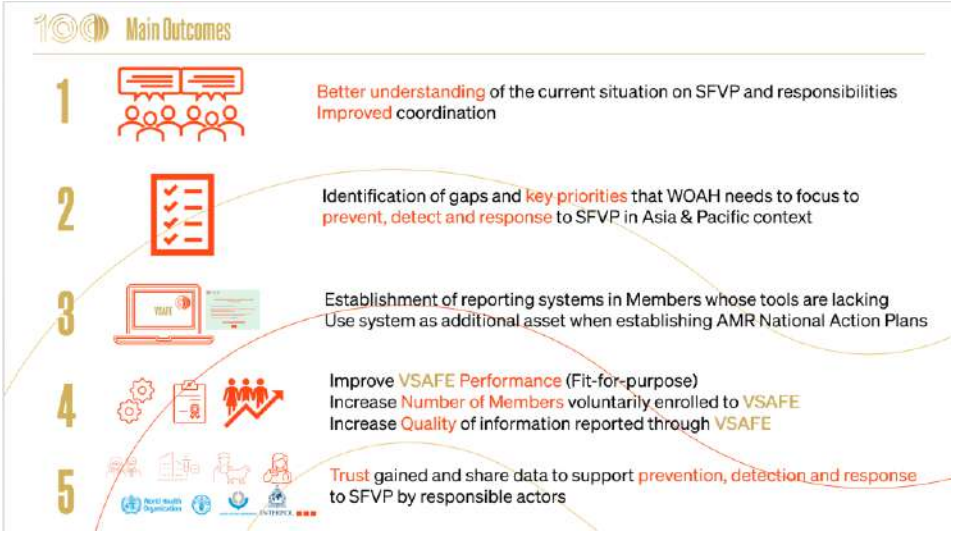
- 強化各地區對 SFVP 之認知及警覺、了解 SFVP 對 AMR 之影響與對其他會員之損害。
- 了解各地區動物用藥品之品質管理，如權責範圍與依據法規、監測和監控的類型/方式、產品召回與追溯政策。

- 向所有參與者說明並探討 WOAH VSAFE 系統。
- 鼓勵各國家主管機關間與 WOAH 聯絡窗口協調或協作。
- 了解不同利害關係人對 SFVP 之看法與所採取行動，並鼓勵以「防疫一體」之方法進行跨部門協調。



並且以下列成果為目標：

- 充分了解目前對 SFVP 狀況並且進行改善及協調。
- 確認目前亞太地區之缺口及關鍵優先事項，以防範、偵測及應對 SFVP。
- 為缺乏工具的會員國建立通報系統，並以該通報系統提供資訊作為國家制定 AMR 行動計畫之資料來源。
- 提升 VSAFE 系統之效能（適用性）、增加願意使用 VSAFE 系統之會員國數量，並提升通報至 VASFE 系統之資料品質。
- 權責單位以互信立場分享及建立數據，以支持對 SFVP 之防範、偵測和應對。



（三）WOAH 對動物劣藥及偽藥之任務及願景

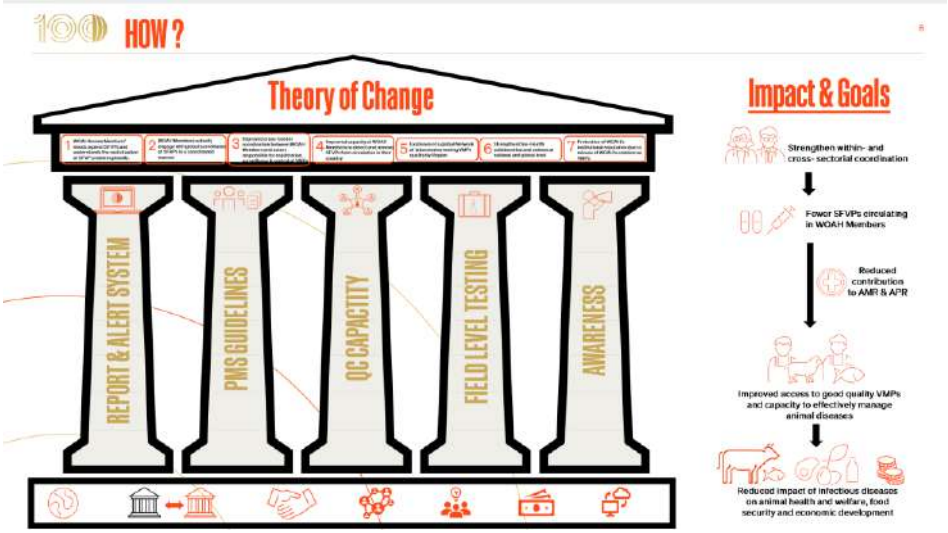
本章節由 WOAH AMR 及動物用藥產品部（WOAH Headquarters AMR & VP Department）負責人 Dr. Javier Y. Marcos 進行簡報「為何要避免使用動物劣藥及偽藥?（Why to avoid using SFVP ?）」。

- 講者引用亞歷山大·弗萊明於 1945 年 12 月 11 日諾貝爾演講所提及「未來可能會有一天，任何人都能在商店裡買到青黴素（penicillin）。這樣的情況下，無這方面知識的人可能會因為隨便使用藥物而服用不足的劑量，這樣會讓微生物暴露在不夠致命的藥量中，結果就是微生物變得具

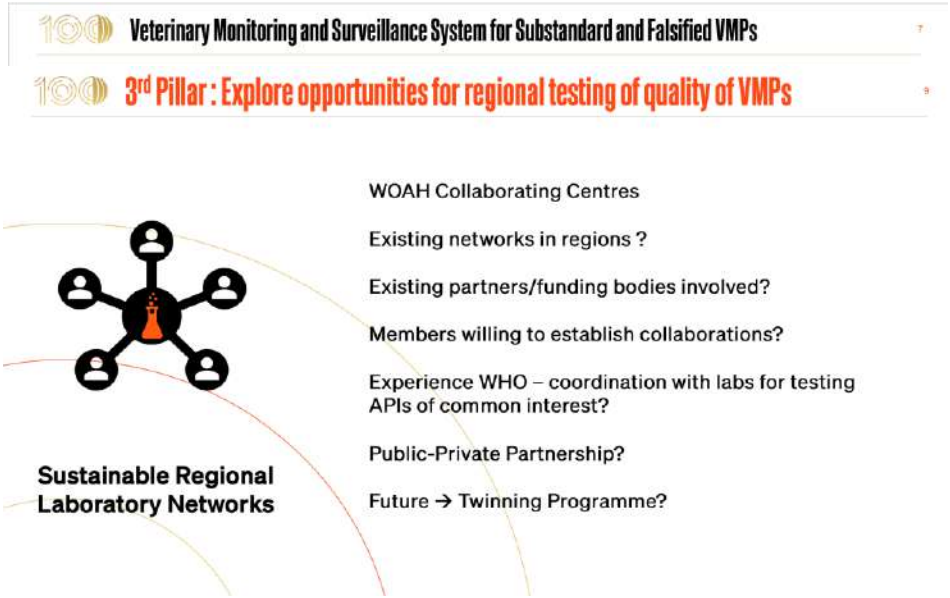
有抗藥性。」，以此為開場，AMR 導致諸多層面問題，包括藥物安全性與有效性、動物防疫管理、食品安全、經濟、民眾對獸醫體系失去信任、動物用藥產業之聲譽……。

- SFVP 特性：
  - 不論動物種別，無論陸生、水生或非產食動物之用藥均有可能出現。
  - 無地域性。
  - 無論一般藥品或疫苗均可能發生。
- 因此針對動物劣藥及偽藥，國際上已透過各種條文、決議與建議，作為指引或行動依據，如：
  - 陸生動物衛生法典（Terrestrial Animal Health Code）3.4.11.5 條規範動物用藥產品的零售、使用和可追溯性，要求國家建立監測系統，以保證動物用藥產品之品質及防範偽造產品。
  - 陸生動物衛生法典（Terrestrial Animal Health Code）6.10.3.10 條規範含有抗微生物藥物或動物用藥產品之運銷和管理，要求主管機關確保所有含有抗微生物藥物之動物用產品不是非法、劣質、偽造或未經核准的處方，並且防止這類產品進入運銷系統。
  - WOAH 於 2015 年 5 月 26 日通過之 26 號決議，為打擊動物偽藥產品，應強化國際間合作，包括與世界海關組織（World Customs Organisation）和國際刑警組織（Interpol）等國際組織合作。
  - WOAH 於 2018 年舉行的全球抗微生物藥物抗藥性會議（OIE Global Conference on Antimicrobial Resistance）所提出之第六項建議，借鑒世界衛生組織（WHO）為人用藥物設立之監測系統經驗，採用「防疫一體」之方法建立一個針對動物劣藥及偽藥之資訊系統。
- WOAH 為因應動物劣藥及偽藥，提出以下七個理論基礎作為解決方案：
  - 了解各會員國對抗 SFVP 需求，並了解全球真實情況。
  - 各會員國積極參與全球監測 SFVP，以協調一致方式進行。
  - 加強各會員國跨境合作，改善各國內檢測級掃除 SFVP 能力。
  - 提高各會員國之技術能力，以檢測和掃除其國內所流通之 SFVP。
  - 各地區建立全球實驗室網絡，以檢測動物用藥產品之品質。

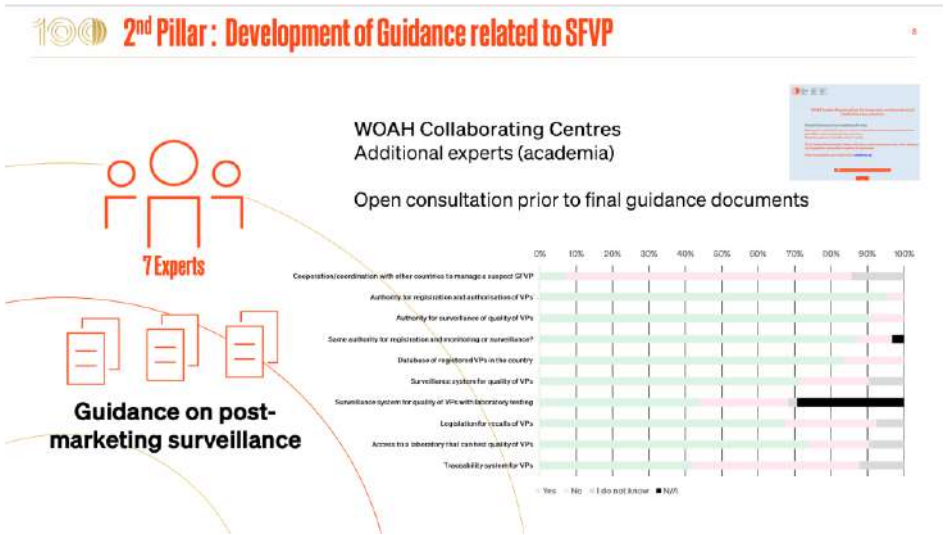
- 加強國家和全球層面之防疫一體合作和行動。
- 防止動物用藥產品因誤用 WOAH 標誌所造成之影響，以維護 WOAH 相關機構聲譽。



- 為了實現上述理論基礎，分別展開以下五項行動來因應 SFVP：
  - 建立回報及警示系統：即本次會議所推廣之系統，其參考 ICH 對人用藥品監控系統所設計，透過各會員國主管機關自各種管道回報動物劣藥及偽藥資訊至 VASFE 系統，秉持包容、不批判及不羞辱等精神，與會員國間進行資訊分享。透過該系統，會員國可查詢、分析自行通報之數據資料、查詢區域間已通報事件、並可有條件公開自身提供之警報及產出年報。



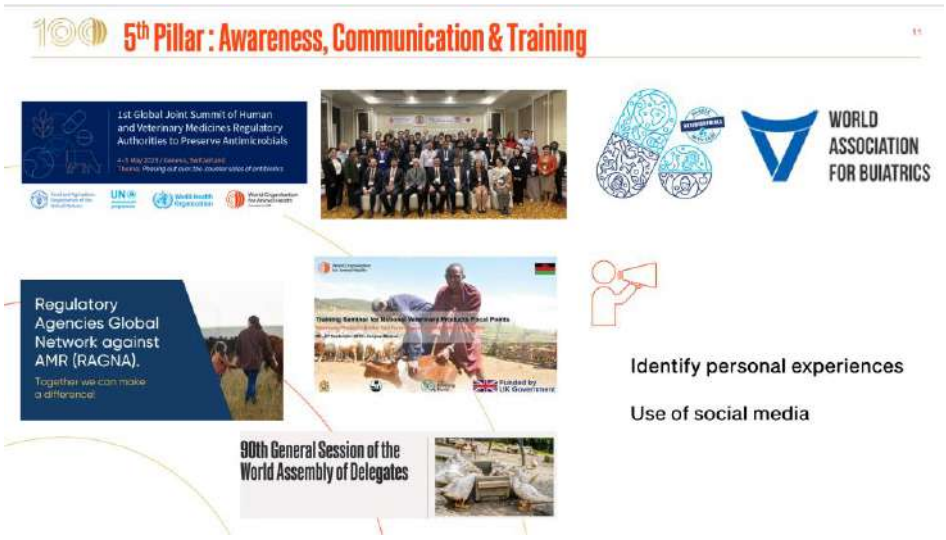
- PMS 指引及問卷：即制定對抗 SFVP 相關之指導原則，透過 WOAH 協作中心邀請 7 位專家對各會員國所填報動物用藥產品上市後監測提供諮詢及指導。



- 尋求區域間動物用藥產品品質監測之機會：透過 WOAH 區域協作中心盤點該區域現有實驗室、現有合作夥伴及資金來源、故會員國參與意願及規劃未來合作計畫等方式構築區域間實驗室網絡。

- 現場使用情況監測：強化對現場所使用之動物用藥產品品質監測及調查，仍以 WOAH 協作中心對調查區域現有設備進行評估及提出使用建議，並徵詢有意願之會員進行監測系統試點活動。

- 提升意識及認知：透過各種活動，如第 1 屆人用藥和動物用藥品監管機構全球聯合峰會、全球監管機構抗微生物藥物抗藥性網絡(RAGNA)等，對 WAOH 會員國提出示警、溝通與訓練，以提升對本議題之關注與認知，同時亦透過社交媒體傳播相關資訊。



- 本單元著重於強調了 VSAFE 系統作為因應 SFVP 之重要性，該系統目標為分享和分析區域內的相關訊息，以提高各國主管機關之監管效率。

VSAFE 系統提供給所有會員國免費使用。本系統於協作初期，歡迎各會員國上傳通報動物劣藥及偽藥資訊，不限於一般藥品，其他動物用藥產品如激素、疫苗、消毒劑或診斷劑均為可通報品項。

（四）以防疫一體的方法應對人與動物之劣藥及偽藥

本章節由英國牛津大學，熱帶醫學和全球健康中心，熱帶健康網絡及傳染病數據觀察站之醫藥品質研究小組（Medicine Quality Research Group (MQRG), MORU Tropical Health Network & Infectious Diseases Data Observatory, Centre for Tropical Medicine & Global Health, Nuffield Department of Medicine, University of Oxford, UK） Dr. Paul Newton 進行簡報「以防疫一體的方法應對人與動物劣藥及偽藥產品（Substandard and falsified veterinary and human medicines – a One Health approach）」。

- 首先，講者 Dr. Paul Newton 介紹所在英國牛津大學醫藥品品質研究小組（MQRG），係由來自英國、美國、寮國、越南及西班牙等 10 個國家之研究者所組成，成員涵蓋藥劑師、醫師、數據科學家及資訊學家外，另有博士生等 16 位組成之專業小組，其工作範疇為：
  - 調查劣藥及偽藥產品之流行病學；
  - 調查使用劣藥及偽醫產品對病患之影響與對 AMR 之影響；
  - 評估各種技術運用於藥品上市後監測篩檢劣藥及偽藥之優缺點及可行性；

- 利用新型分析儀器、工具進行偽藥及其成份來源之分析。

- 進而達成以下目標：
  - 與政策制定者合作，提供全球藥品品質；
  - 幫助容易被忽略的族群，如中低收入國家建立研究團體
  - 培育更多研究團隊。

- WHO 所定義的劣質及偽造醫藥品定義：
  - 劣藥（Substandard）：分為兩種情況，第一種為降解（Degraded），為 WHO 定義之劣藥，指藥品出廠仍屬合格產品，但因銷售端保存不當，導致藥品成分降解；第二種為未達規格標準（Out of specification），指藥品於工廠階段即因各種因素生產出不合格產品。

    真實案例：類固醇注射劑因黴菌汙染導致美國多州爆發黴菌性腦膜炎，受害使用者約 400 人等…；或新冠疫情期間，觀察到許多因為保存條件不當，造成降解的劣質新冠疫苗。
  - 未登記或無許可證之藥物產品（Unregistred/ Unlicensed）：指未經當地主管機關評估或核准之藥品，可能在未經允許之情況下銷售、使用，並可能違反當地或國家法律和法規。
  - 偽藥（Falsified）：故意或以欺騙方式偽造其身份、成分或來源之醫療產品。

    真實案例：迦納共和國查獲之偽造之抗瘧疾藥品「Coartem」，名稱以錯誤的德文拼寫，實際成分無原廠藥品之主成分 artemether 及 lumefantrine，反而含該藥品所含成分 pyrimethamine 7 mg，經由藥品成分鑑定顯示，其內花粉來自東亞，進一步與真品比對發現具有源自印度的落羽松成分；此外，除了各種偽藥外，亦有偽造之疫苗持續被各國發現等，如新冠疫情流行期間發現許多偽造的新冠疫苗。

- 此外，更需注意的是，新藥需經過臨床試驗後評估其安全性與有效性，故須確保在試驗所使用藥物的品質，但在某些案例中，發現用於臨床試驗藥品為劣藥或偽藥，進而影響試驗數據，因此需更加嚴格審視用於臨床試驗之藥物品質。

- 劣藥與偽藥產品不限於藥物、疫苗，診斷試劑及醫療器材，皆對使用者

造成直接威脅，特別是抗感染藥物，這類產品還可能增加抗藥性出現及疾病傳播之風險。在防範這類問題最大的挑戰是缺乏獲得可靠之訊息，故無法推測造成影響之程度及廣度。然而，透過一些醫藥品質科學文獻調查工具，則可跨越地理及時間限制，將調查之數據加以繪圖視覺化，而幫助科學家、醫療專業人員和政府人員填補一些空白之關鍵訊息。

- Medicine Quality Monitoring Globe（http://www.iddo.org/mqmglobe/），目前具有英文及法文版本，可根據藥品、報告類型、收集類型、藥品來源和品質分類來篩選研究，提供在不同時間、地點已所發現劣質或偽造之醫療產品情況，並整理為報告摘要，對象藥品涵蓋傳染病（抗瘧藥、抗病毒藥物、抗生素、抗結核藥物）、非傳染性疾病（抗糖尿病藥物和心血管疾病管理）、動物用藥品、醫療設備和疫苗等領域等數據。目前透過本工具，團隊已在抗瘧藥調查上取得成果，未來規劃進一步擴展至其他醫療產品。

- 因人類及動物（包含經濟動物及伴侶動物）在複雜的生態關係中共存，使用動物劣藥及偽藥，將損害到動物防疫與農業生產、農業及家畜貿易網絡、人類及動物營養，以及食品安全。除此之外，亦會增加 AMR 風險。因此，動物用藥品質之數據，對政府制定政策及所實施之措施至關重要，可惜目前這類數據及研究皆有限。依照目前統計，314 篇報告資

料對 2335 件動物用藥品之品質報告，約有 6.5%為不合格樣品。大部分數據來自韓國和中國的上市後監測，僅少數來自低收入和中等收入國家的流行病學調查。超過一半之調因未有周延之抽樣計畫，導致數據代表性不足。93.7%的樣本直接由外包裝判定劣藥或偽藥。由於數據不足，根據以上結果難以準確推估中低收入國家之動物用藥品品質情形。根據過往資料，以流行病學方式調查動物用藥品品質所見問題如下：

- 樣本數量小；
- 許多國家無公開可用之科學數據；
- 僅少數為隨機調查；
- 共識不足；
- 報告對數據過度解讀；
- 報告品質待改善且更新資料過於緩慢。

- 動物劣藥及偽藥所帶來衝擊，可分為三面向：
  - 經濟面向：造成經濟損失、資源浪費與增加使用者自付支出；
  - 防疫面相：動物疾病流行率增加、抗生素抗藥性增加、對動物醫療失去信心、增加動物發病率及死亡率；
  - 社會經濟面向：生產力下降、收入減少、社會流動性下降與貧困加劇。

Fig. 2: Impact of substandard and falsified medical products

- 目前可用於供應鏈端檢測問題的醫療產品方法及工具，講者介紹多種攜

帶式設備，如 Minilab、拉曼光譜儀（Raman spectroscopy）或試紙型分析設備（Paper Analytical Devices）等…。但使用這類產品仍有許多問題需要克服，如原理理解及人員訓練、證據力薄弱、單一設備無法檢測所有藥品品質檢測項目以及所有類型藥品等，更進一步需要思考能否將設備及其結果與國家參考實驗室進行鏈結等…。

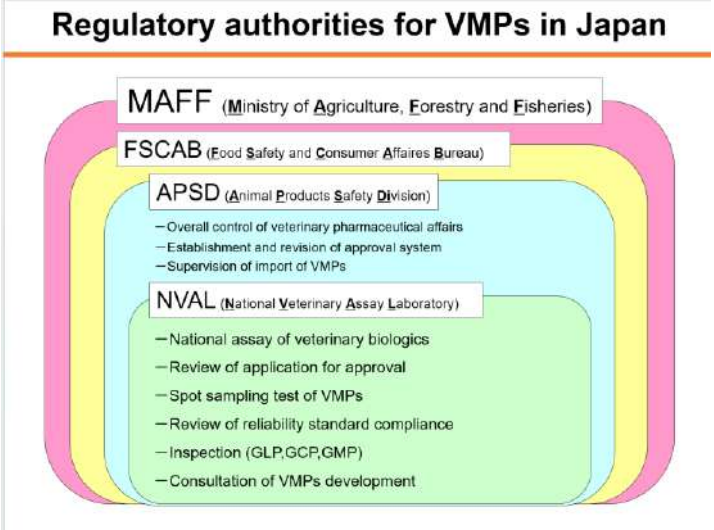
- 調查偽藥方式，可透過來源與貿易路線兩方面著手進行：
  - 分析藥物來源：
    - 基因組分析法：利用生物組成和環境 DNA 可能可提供藥片與膠囊和賦形劑的環境與來源、製造時間或是樣品內所含 DNA（如細菌、真菌、植物和人類 DNA）。
    - 化學法：使用同位素質譜法分析藥片中賦形劑或水源或是植物類型；或對藥片包裝中的氣相進行分析，取得生產過程資訊。
  - 貿易路線：透過繪製國際貿易路線和地理節點，增加檢查和監管的有效地點。
- 對於面臨劣質藥品及偽造藥品議題，講者建議可朝以下方向進行改善：
  - 強烈建議全球人用藥及動物用藥品主管機關以及相關組織共同參與並共同對抗；
  - 提升更多國家和國際政治上之意願與公眾參與；
  - 強化國家內與國家間共享資訊，以更多、更好及更及時資訊，如藥物品質研究、相關政策施行之數據與知識。
  - 支持更多具目的性研究，例如：研究劣藥及偽藥之熱點地區及其變化，分析不同社區的信任度及健康行為，評估對經濟和抗微生物藥物抗藥性之影響，優化篩查設備及通報系統。

（五）WOAH 合作中心對動物劣藥、偽藥管理經驗分享-日本

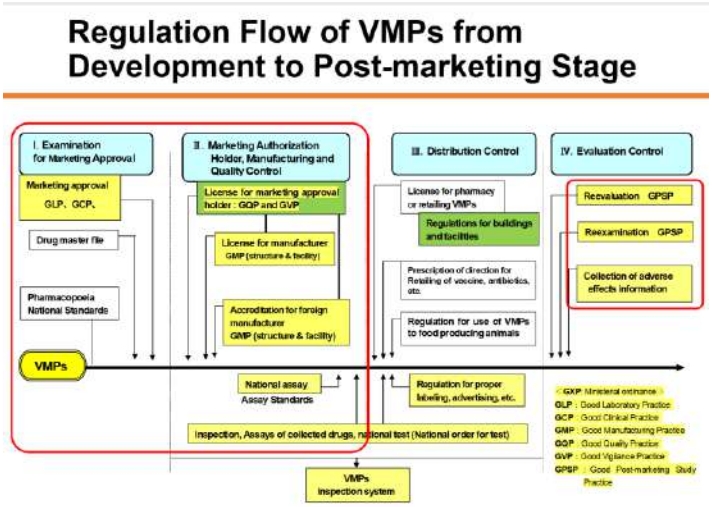
本章節由農林水產省（Ministry of Agriculture, Forestry and Fisheries, MAFF）所屬食品安全與消費者事務局（Food Safety and Consumer Affaires Bureau, FSCAB）之動物產品安全部（Animal Products Safety Division, APSD）國家動物醫藥品檢查所（National Veterinary Assay Laboratory, NVAL）Dr. YuKa

進行簡報「日本動物用藥產品品質管理（Management of the quality of Veterinary Medicinal Products (VMPs) in Japan）」，由於日方講者所隸屬單位，非該國專司檢驗動物用偽劣藥之機構，故無法對相關內容進行分享，故主題以日本國家動物用藥品檢驗所工作內容及如何維持日本動物用藥產品品質進行報告。

- 日本動物醫藥品檢查所屬於該國技術單位，主要負責業務如：
  - 動物用生物藥品國家檢驗；
  - 審請案件審查；
  - 動物用藥品抽驗檢測；
  - 標準符合性審查；
  - GLP/GCP/GMP 檢查；
  - 動物用藥品開發諮詢。



- 日本動物用藥產品包含疫苗、抗生素、其他藥品以及醫療器材，根據講者所提供流程圖，該國動物用藥品管理可分為四階段如下，各階段皆有所需遵守規範：
  - 上市許可審查，提交資料需符合優良藥品實驗研究規範（GLP）及藥品優良臨床試驗作業指引（GCP）。
  - 上市時，許可證持有者需符合優良品質規範（GQP）及優良監視規範（GVP）；生產工廠需符合優良藥品製造規範（GCP）。
  - 藥品運銷時，需符合販賣業需具備許可證、販賣場所建築設施規範、藥品處方指示及產食動物用藥規範。
  - 再評估管理，需符合優良上市後研究規範（GPSP）之再評估、再檢查，並收集藥物不良反應資訊。
  - 另外尚需遵守該國國家檢驗標準、抽驗制度以及標籤廣告相關規範。



※VMPs: vaccines, antimicrobials, and other veterinary medicines and diagnostic kits

- 有關日本動物用藥品之國家檢驗，動物用生物藥品需根據規定進行國家檢驗，未通過 NVAL 檢驗之疫苗不得銷售、儲存或展示。對於動物用生物藥品，需檢查每批產品之製程紀錄。。此外，對於法定傳染病或狂犬病之生物藥品，需要實際執行樣品測試以確認其效力，當動物用藥品通過所有檢驗後，方可確認其品質、安全及效力，並允許上市流通。
- 動物用生物藥品之國家檢驗流程，由製造商申請批次檢驗，經由藥品檢查員抽樣並將申請與樣本送至 NVAL 後，經該所檢驗及判定結果後將報告透過地方政府通知申請業者。倘檢驗未通過，則該批藥品需在藥品檢查員監督下進行銷毀。統計 2022 年數據，NVAL 進行 315 次國家檢驗，僅 1 件產品未通過檢測。
- 有關該國動物用藥品上市後監測，目的為檢驗製造和運銷過程之藥品，去除有害藥品以維護其品質。抽樣方式採不通知且隨機抽樣方式，由藥品檢查員進行現場檢查，收集樣品並送至 NVAL。該所以國家檢驗並評估結果。倘結果不合格，則產品必須回收和處置。統計 2023 年數據，NVAL 進行了 56 次測試，僅 2 件產品未通過檢測。
- 倘該國動物用藥品之品質、效力或安全性依照最新標準有所疑義，則需進行再評估並蒐集副作用：

- 許可證持有者需於核准後 2 年或 6 年進行評估，整理結果並申請再檢查其效力和安全性。
- 倘藥品於診所、農場或家使用並發生副作用時，許可證持有者持應確認副作用並向 MAFF 報告。並調查副作用內容，並決定處理措施，如召回、原因調查和改進措施。NVAL 將審查和調查報告內容，決定應對副作用的措施。

- 有關日本動物用藥品副作用資訊，該國主管機關已建置公開之資料庫「副作用情報データベース」（https://www.vm.nval.go.jp/ sideeffect ），供大眾瀏覽其資訊，資料來源則由農林水產省及許可證持有者共同蒐集及協作。

（六）會員國對動物劣藥、偽藥管理經驗分享-馬來西亞

本章節由馬來西亞動物用藥品主管機關-馬來西亞獸醫服務部（Department of Veterinary Services, DVS Malaysia）Dr. Alifah Binti Ismail 進行簡報「馬來西亞動物用藥品質管理系統及因應動物劣藥及偽藥措施（THE SYSTEM FOR THE MANAGEMENT OF THE QUALITY OF VMPS AND TACKLE SFVP IN MALAYSIA）」。

- 馬來西亞管理動物用藥相關產品分別由兩個部門所屬三機關根據不同種類產品分別管理：
  - 農業及工業部（Ministry of Agriculture and Industry）之農藥委員會（Pesticide Board, Department of Agriculture），依據該國農藥法（Pesticide Act 1954）及其規定管理該國農藥法內附表一所列產品；
  - 農業及工業部之獸醫服務部（Department of Veterinary Services, DVS），依據該國動物法（Animal Act 1953）、動物飼料法（Animal Feed Act 2009）管理動物疫苗、動物用生物藥品以及動物飼料與添加物。
  - 衛生部（Ministry of Health, MOH）之國家藥品監管局（National Pharmaceutical Regulatory Agency, NPRA），依據該國毒藥法及其規定（Poison Act 1952 and its regulation）、藥品銷售法（Sale of Drugs and its regulation 1952）及其規定與危險藥物法（Dangerous Drug Act 1952）管理該國毒品法規內附表一所列藥品、非處方用藥以及控制內外寄生蟲用藥。
- 講者所屬獸醫服務部由以下四個單位組成，各司不同業務：
  - 政風單位；
  - 獸醫健康部門（Veterinary Health）-獸醫公共衛生組（Veterinary Public Health Division）並細分為：
    - 畜牧業污染控制與管理部門（Livestock Industry Pollution Control and Management Section）；
    - 動物用藥產品管理部門（Veterinary Product Management Section），含動物用藥產品登記單位（Veterinary Product Registration Unit）及動物用藥產品控制單位（Veterinary Product Control Unit）；

- 動物來源之食品安全部門（Food Safety of Product from Animal Origin）；
- 獸醫發展部門（Veterinary Development）；
- 各地方單位（DVS State）。

- 該國動物用藥產品之管理，主要由動物用藥產品登記單位及動物用藥產品管控單位進行管理：
  - 動物用藥產品登記單位執掌為：
    - 協調和管理動物用疫苗擁有權許可申請。
    - 協調和管理動物用生物製品（疫苗、抗微生物藥物、激素和診斷試劑）的登記。
    - 協調和管理疫苗製造廠認證申請。
    - 擔任 TCVP 和 NVPCC 會議的秘書處。
    - 協調疫苗文件審閱者的培訓。
    - 提供與動物用藥產品登記相關的指南和手冊。
  - 動物用藥產品控制單位執掌為：
    - 計劃和協調藥品監測計劃，並編制動物用藥產品監測手冊。
    - 監控現場使用的動物用藥產品，並在監測期間報告濫用和未登記的動物用藥產品。
    - 與外部相關機構協調行動，對藥品監測指數採取行動。
    - 提供與動物用藥管理和使用相關的指南。
    - 協調與業界和外部機構的技術會議，討論動物用藥產品相關問題。
    - 協調修訂《1953 年動物法》以加強動物用藥產品的法律執行。

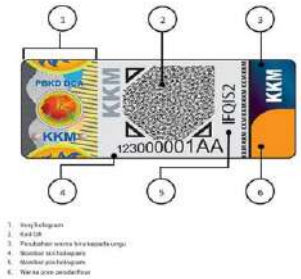
- ◆ 協調與跨機構利益相關者（如抗微生物藥物抗藥性技術工作組 - AMR TWG 4，OIE，FAO）及其他相關機構的動物用藥品相關會議。
- ◆ 協調 DVS 各州官員之培訓，執行藥品監測計劃。

- 馬來西亞之動物用藥品監測計畫，主要工作為資訊之收集與調查，以確保使用動物用藥品之安全性並能謹慎使用，監測方向及項目為：
  - ■ 動物醫療場所之動物用藥品記錄保存；
  - ■ 動物用藥品之儲存情況；
  - ■ 動物用抗生素藥物之使用情況；
  - ■ 動物用藥品之處置方式。

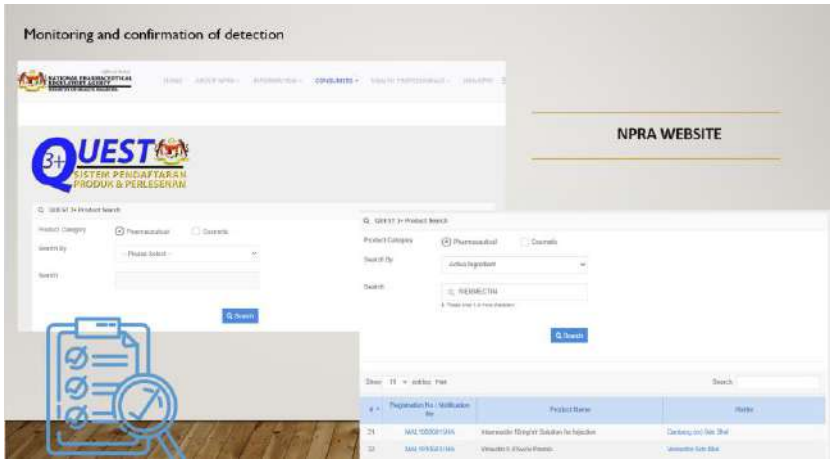
  對於不合格動物用藥品之偵查，則透過例行性動物用藥監測、網路販賣動物用藥品及檢舉案件為資訊來源並開啟調查。
- 馬來西亞動物用藥品主管機關已建立相關資訊系統可查詢動物用藥品資訊，可透過官方網站、官方 APP 確認公開之動物用藥品資訊。

  - ■ 藥品標籤-國家藥品監管局所建立之標籤（具二維條碼），可透過該條碼查詢藥品相關資訊。

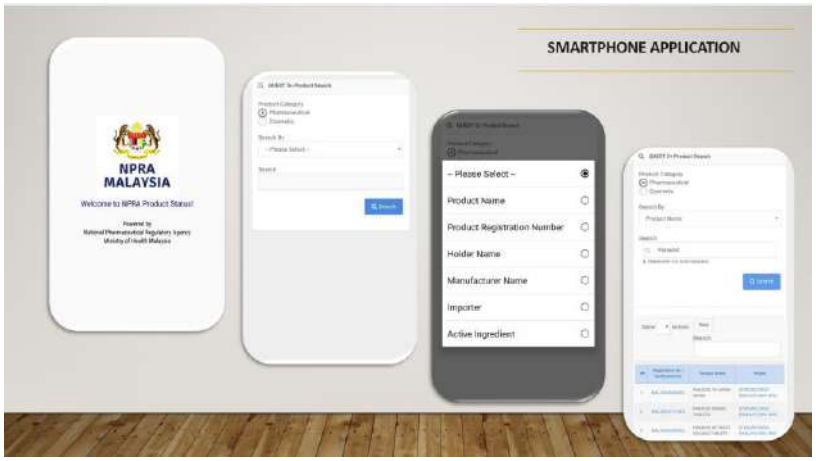
Hologram : Farmatag for KKM (NPRA) indicaton for NPRA Registered Product



  - ■ 國家藥品監管局網站-可查詢已核准藥品資訊。



- 行動裝置 APP-功能同該國國家藥品監管局網站資訊。



- 馬國對不合格之動物用藥品處理過程：
  - DVS 監測發現不合規之動物用藥品，如藥物濫用、未登記或禁用藥品後，透過衛生部通報系統（https://moh.spab.gov.my）通報；
  - 藥品執法部門接收通報後，按驗證投訴的真實性、調查問題的根源、執法採取相應行動、起訴違規者並結案；
  - 最終處理結果回由藥品執法部門回報至 DVS。
  - 調查結果有違法之處罰方式：
    - 企業如果犯有相同的違法行為，初犯可被罰款最高至 50,000 馬幣，再犯最高罰款可達 100,000 馬幣。

- 個人如果被判有罪，初犯可能被罰款最高 25,000 馬幣，或監禁不超過 3 年，或兩者兼施；再犯最高罰款可達 50,000 馬幣，或監禁不超過 5 年，或兩者兼施。
- 所查獲物品將被銷毀。

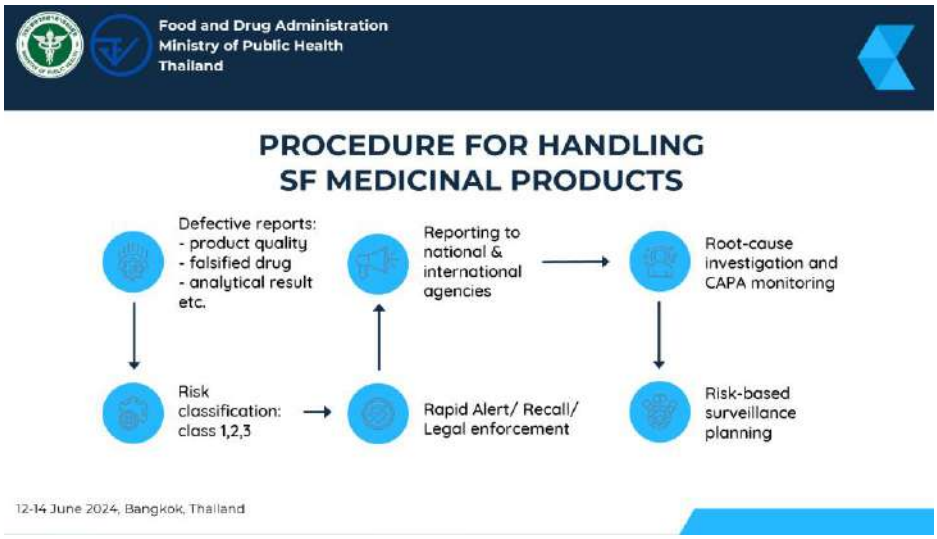
（七）會員國對動物劣藥、偽藥管理經驗分享-泰國

本章節由泰國公共衛生部食品藥物管理局（Food and Drug Administration, Ministry of Public Health, Thialand） MS. Wittahyarat Dangyai 及農業與合作部畜牧發展部畜產品品質管理局（Agriculture and Cooperatives, Department of Livestock Development, Bureau of Quality Control of Livestock Products）Dr. Chusak Ardsoongnearn 分別進行簡報「劣藥及偽藥產品處裡方針（SF MEDICINAL PRODUCT HANDLING）」及「畜產品品質管理局之抗生素品質管理（Quality Control of Antimicrobials at BQCLP）」說明泰國對於動物用藥品之行政及實驗室管理。

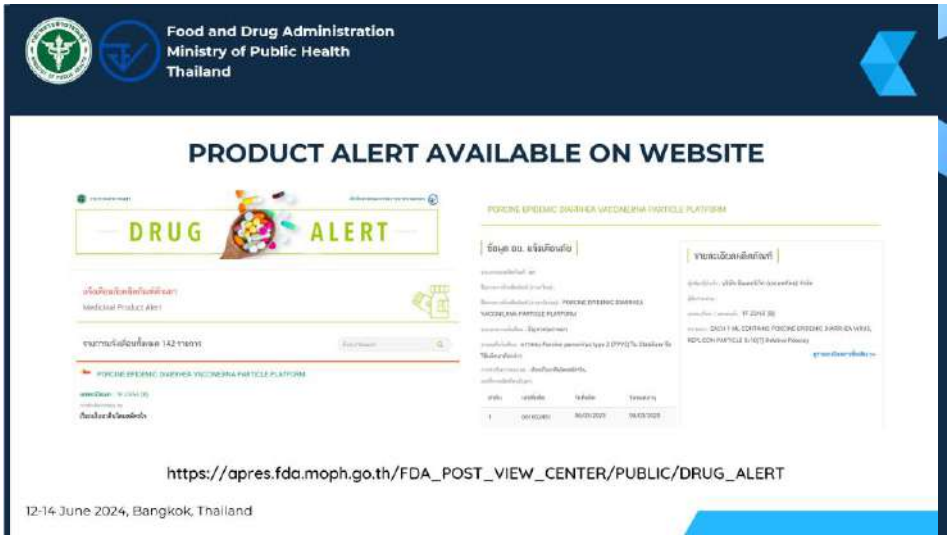
- 泰國管理動物用藥品之法源依據為藥品法（Drug Act B.E. 2510），據其第 72 條規定，任何人不得製造、進口或銷售：
  - 偽藥；
  - 劣藥；
  - 變質的藥品；
  - 未登記藥品；
  - 處方遭註銷或撤回超過 6 個月以上藥品以及

- 經主管機關命令註銷之藥品。

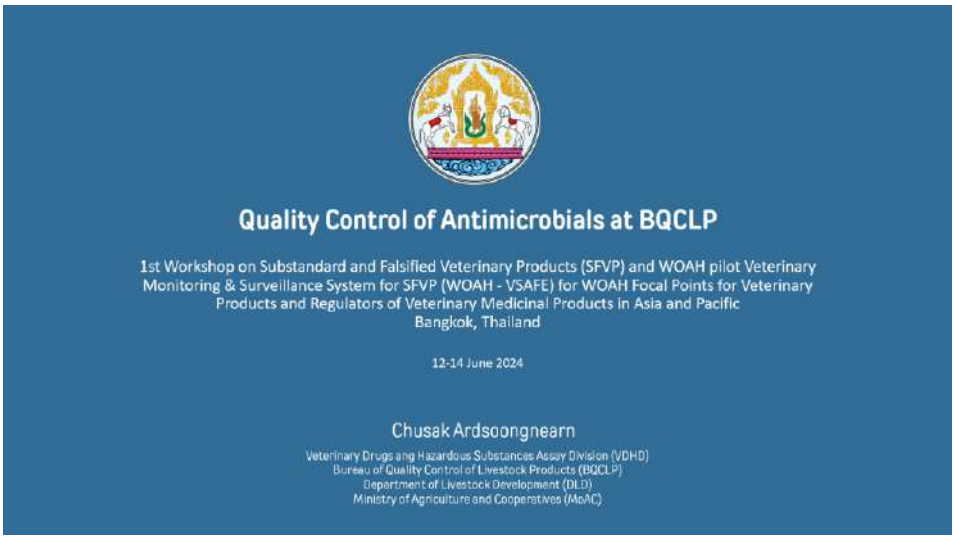
- 根據藥品法第 73 條，該國之偽藥定義為：
  - 完全或部分模仿真品之藥品或物質；
  - 仿冒其他藥品名稱進行標示或偽造有效期限者；
  - 以不實生產商或產地進行標示者；
  - 以不實處方進行標示者或
  - 所含有效成分高於或低於標示成分 20%以上藥品。
- 泰國屬於 PIC/S GMP 會員國，故針對 SFVP 需儘速發布警報並召回以符合該規範，其標的物涵蓋人用藥品及動物用藥品，包括活性成分或供試驗研究藥品，但不含醫療器材及評估中藥物。
- 該國對於 SFVP 行政處理程序如下：
  - 調查並發布不良藥品報告（Defective report），該報告針對產品品質、分析結果或是否為偽造藥品進行記錄；
  - 根據報告進行風險分類（1、2、3 類）；
  - 發布警報、召回產品並採取法律行動；
  - 向外部機關發佈報告，如國內其他政府機關、世界衛生組織、PIC/S 成員及東協後市場警報系統（ASEAN Post-Marketing Alert System）；
  - 原因調查並執行預防矯正（CAPA）措施並且
  - 根據分險制定相關監測計畫。



- 不良藥品報告（Defective report），該表單登載不良產品資訊含品牌名稱/商品名、產品許可證號碼、對象動物、分類（偽藥等判定及說明）、有效成分、劑型、有效成分含量、批號、生產及有效日期、包裝形式及大小、製造/輸入業者資訊、不良品詳情及召回原因、銷售端及輸出資訊、監督管理機關採取行動、建議行動、發佈機構資訊（泰國公共衛生部食品藥品管理局）、聯絡人及聯絡資訊、報告簽屬人簽名等…。本類藥品報告可於泰國 FDA 官方網站進行查詢：Http://apres.fda.moph.go.th/FDA_POST_VIEW_CENTER/PUBLIC/DRUG_ALERT。



- 泰國動物用藥品抗生素品質管理，由農業與合作部所屬畜牧發展部畜產品品質管理局之動物用藥品和危險物質檢測組（Veterinary Drugs and Hazardous Substances Assay Division, VDHD）進行實驗室端品質管理，其地位類似我國農業部獸醫研究所動物用藥品檢定中心，主要任務為：
  - 根據藥典進行動物用藥品主成分分析及鑑別；
  - 檢測動物用藥品及牧場動物用飲水中是否具禁用物質成分；
  - 進行消毒劑效果試驗（AOAC 方法）；
  - 分析畜產品中危險物質含量（如消毒劑成分）；
  - 評估含藥物飼料添加物之藥品含量、均勻度及殘留；
  - 分析技術研究與發展。



- 有關泰國動物用藥品市售抽驗監測，亦由 VDHD 執行，根據「亞洲藥品安定性研究指南（Asian Guideline on Drug Product Stability Study）」，泰國屬於 IVB 區域（高溫和高濕）。因此該國對動物用藥品之儲存方式相對關注，並以市售藥品抽驗進行監控。整體流程為透過該國畜牧發展部國內 77 個省份之地方辦公室至所轄各地動物用藥品販賣場所及牧場進行抽樣，送至前述實驗室進行分析，並由同局之動物飼料和動物用藥產品控管理部組（Division of Animal Feed and Veterinary Products Control, AFVC）將檢測報告轉送泰國 FDA 並執行後續行政處理。
- VDHD 作為泰國動物用藥品國家分析實驗室，該國政府編列大量預算充實該單位分析儀器設備以提升檢測量能，如液相層析儀與液相層析儀串聯質譜儀（HPLC-DAD-FD-ELSD, UHPLC-DAD-FD, HPTLC, LC-MS/MS 及 LC-MS 離子阱）、氣象層析儀與氣相層析儀串聯質譜儀（GC-FID, GC-MS/MS）、紫外光分光光度計及拉曼光譜顯微鏡等…，並根據其儀器設備推動 ISO/IEC 17025:2017 實驗室認證，該實驗室自 2011 年至今已取得 14 項認證，其項目及取得認證時間如下：
  - Enrofloxacin 分析（2011）；
  - 以 LC-MS 離子阱分析牧場飲水中乙型受體素成分（salbutamol, clenbuterol 及 ractopamine）（2011）；
  - 動物用藥品（無菌製劑）酸鹼度分析（2013）；

- Tylosin 分析（2011）；
- 消毒劑效果試驗（稀釋法）（2011）；
- Ivermectin 分析（2017）；
- 以 UHPLC-DAD 分析牧場飲水中 Nitrofurans, nitroimidazoles 及 chloramphenicol 成分（2017）；
- 以 UHPLC-DAD 分析畜產品中危險物質成分 glutaraldehyde, formaldehyde 及 glyoxal 成分（2017）；
- 以電位差滴定儀分析畜產品中危險物質成分碘複合物中 available iodine 成分（2017）；
- 以電位差滴定儀分析畜產品中危險物質成分次氯酸鹽中 available chlorine 成分（2017）；
- 以電位差滴定儀分析畜產品中危險物質成分四級銨鹽成分(2017)；
- 以 LC-MS /MS 分析牧場飲水中乙型受體素成分（salbutamol, clenbuterol 及 ractopamine）（2019）；
- 以 LC-MS /MS 分析牧場飲水中 Nitrofurans, nitroimidazoles 及 chloramphenicol 成分（2019）；以 LC-MS /MS 分析含藥物飼料添加物中 salinomycin 成分之均勻度及殘留性（2023）。

（八）動物劣藥及偽藥產品事件之情境案例 1 演練

由 WOAH 的 AMR 及動物用藥產品部門之 Andrés García Campos 計畫經理主持與引導與會人員分組討論與報告「劣藥與偽藥產品事件之情境演練案例 1」。

WOAH 特別做「免責聲明」，強調所展示之案例非真實，僅為演練目的而創作。名字、數字及事件均為作者想像之產物。何與實際事件相似之處純屬巧合。

考量劣藥及偽藥產品事件之現場實務狀況會隨著時間之推移，調查所取得之線索係一點一滴揭露出來，而無法於第一時間即知曉所資訊。因此，情境演練將據此分五個時間點，一步一步透露出線索。請與會人員根據每個時間點所揭露之線索，思考下表項目，進行小組討論並記錄討論結果。請注意，沒有錯誤之答案，也沒有唯一之標準答案，解決方案可能有很多種。

您可以確定的事實是什麼？	您缺少哪些訊息？	您辨識出哪些風險？	您採取了什麼行動？

事件於第 1 個時間點揭露之線索

上圖為我們目前掌握之線索訊息。各組就下列問題進行討論並記錄討論結果。

您可以確定的事實是什麼？	您缺少哪些訊息？	您辨識出哪些風險？	您採取了什麼行動？
● 這個國家具有藥物安全監視系統。 ● 2 件通報乳房炎乳牛治療失敗 ● 乳牛、病原、藥物名稱、臨床性乳房炎	● 缺少受案內乳牛之資訊 ● 治療劑量 ● 產品資訊，例如製造商名稱、批號 ● 投藥天數 ● 抗微生物藥物敏感性試驗（AST） ● 產品購買資訊	● 該產品無效 ● 經濟損失 ● 受污染之牛奶產品	● 產品採樣及檢測 ● 調查

事件於第 2 個時間點揭露之線索

上圖為我們目前掌握之線索訊息。各組就下列問題進行討論並記錄討論結果。

您可以確定的事實是什麼？	您缺少哪些訊息？	您辨識出哪些風險？	您採取了什麼行動？
● 乳房內抗生素注射器是在網路上購買 ● 產品缺乏儲存條件及注意事項 ● 產品過期	● 產品儲存條件及注意事項訊息	● 藥物過期	● 進行實驗室檢測 ● 提高民眾認知 ● 與媒體合作，向公眾提供準確之訊息

事件於第 3 個時間點揭露之線索

上圖為我們目前掌握之線索訊息。各組就下列問題進行討論並記錄討論結果。

您可以確定的事實是什麼？	您缺少哪些訊息？	您辨識出哪些風險？	您採取了什麼行動？
● 另一國家的 WOAH 動物用藥聯繫窗口通報他們的海關發現了這個問題。而在這個國家進口藥品卻未被海關發現。 ● 細菌培養及敏感性試驗結果顯示獸醫師開立了正確之產品，MASTOP 應該有效。 ● 商家按照規定方式包裝、存儲和銷售某種藥品。然而，有一位農民發現這個產品藥物非常黏稠，這使得它難以投藥。 ● 農民的行為：使用了可疑的產品（可疑點：產品被重新包裝、黏稠度）	● 需要知道產品來源：產品是如何到達零售商？需要做產品溯源。可能需要持證商及海關之協助	● 供應鏈中存在不符合規格之產品	● 追蹤並追溯受影響之產品

事件於第 4 個時間點揭露之線索

第1時間線索 第2時間線索 第3時間線索 第4時間線索 第5時間線索

您將注射器送到國家品質管控實驗室進行檢測4天後，您收到了檢測報告結果如下：

	注射器 (參考)	HappyFarming 注射器	CooolCows 注射器
物理與化學			
密度	3.45	4.69	5.2
顏色	乳白	白-黃	白-黃
有效成份			
Cefalexin(mg/syringe)	200	91	130
Kanamycin(I.U./syringe)	100,000	64,226	77,920

您向持證商聯繫後，他們確認**他們確實生產了**該產品，但分析結果與他們的原始紀錄不一致。

上圖為我們目前掌握之線索訊息。各組就下列問題進行討論並記錄討論結果。

您可以確定的事實是什麼？	您缺少哪些訊息？	您辨識出哪些風險？	您採取了什麼行動？
● 持證商確認了製造商，但分析結果與他們的原始紀錄不同 ● 涉及的兩種產品均為劣藥	● 何時購買？ ● 儲存條件？	● 產品的實際品質 ● 供應鏈中可能存在的問題	● 進一步檢測製造商的產品，以進一步釐清產品之品質

事件於第 5 個時間點揭露之線索

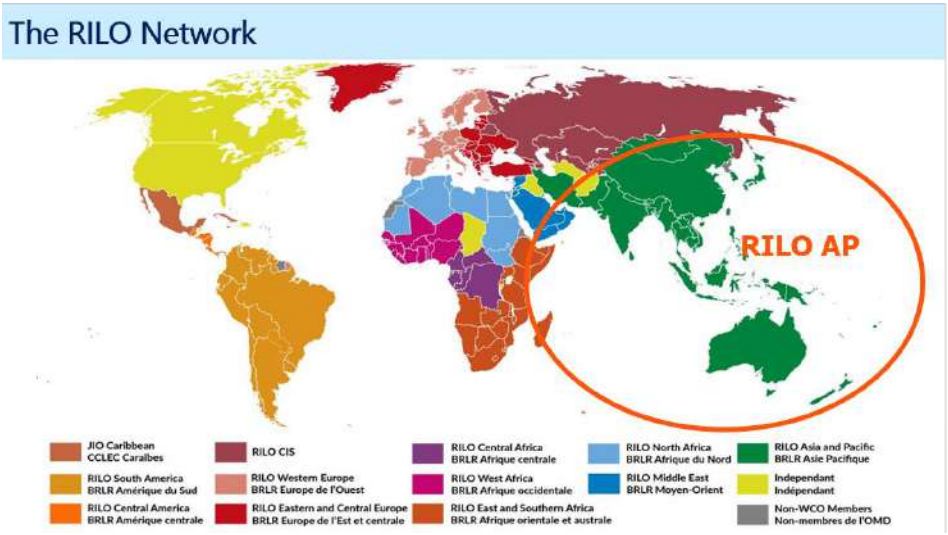
上圖為我們目前掌握之線索訊息。各組就下列問題進行討論並記錄討論結果。

您可以確定的事實是什麼？	您缺少哪些訊息？	您辨識出哪些風險？	您採取了什麼行動？
● Ani Mal 商店持有過期產品	● Ani Mal 是否為合法銷售動物用藥品之商店？ ● 需要產品過期後之交易證據	● 市場上流通之藥物產品為合格產品。	● 啟動執法程序 ● 發布新聞稿

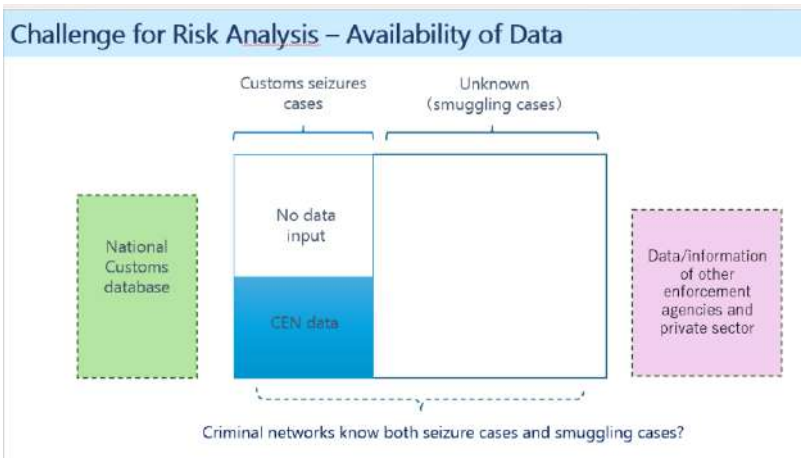
（九）海關執法措施

本章節由世界海關組織（World Customs Organization, WCO） 亞太地區情報聯絡辦公室（Regional Intelligence Liaison Office of Asia and the Pacific, RILO A/P）Mr. Billy KH YEUNG 情報分析師進行簡報「海關執法措施（Customs Enforcement Initiatives）」，說明世界海關組織對於 SFVP 可共同協助部分。

- A/P 為世界海關組織之區域機構，負責支援 WCO 會員國之海關管理，其任務包含促進情報交換與互助、為區域或全球情報衍生之執法行動提供運作支援、蒐集及分析各種來源之資訊並解析其內產品情報與維持與促進其他執法機構或組織之區域合作。於亞太區域參與 RILO A/P 之會員國共計 35 個，包含阿富汗、澳洲、孟加拉國、不丹、汶萊、柬埔寨、中國、斐濟、香港（中國）、印度、印尼、伊朗、日本、韓國、老撾人民民主共和國、澳門（中國）、馬來西亞、馬爾地夫、蒙古、緬甸、尼泊爾、新西蘭、巴基斯坦、帕勞、巴布亞新幾內亞、菲律賓、薩摩亞、新加坡、所羅門群島、斯里蘭卡、泰國、東帝汶、湯加、瓦努阿圖和越南。本機構之總部可於會員國間變動，自 1987 年起自香港、日本、中國、韓國等，2024 年起總部再次設立於日本。
- RILO 於全球各地設立區域辦公室，除 RILO A/P 外，尚有包括加勒比海、南美洲、中美洲、西歐、東歐和中歐、西非、中非、東南非、北非、中東、獨立區域和非世界海關組織（WCO）會員國，各區域辦公室支援該區域內情報交換及執法行動，並且與全球各辦公室相互協作。

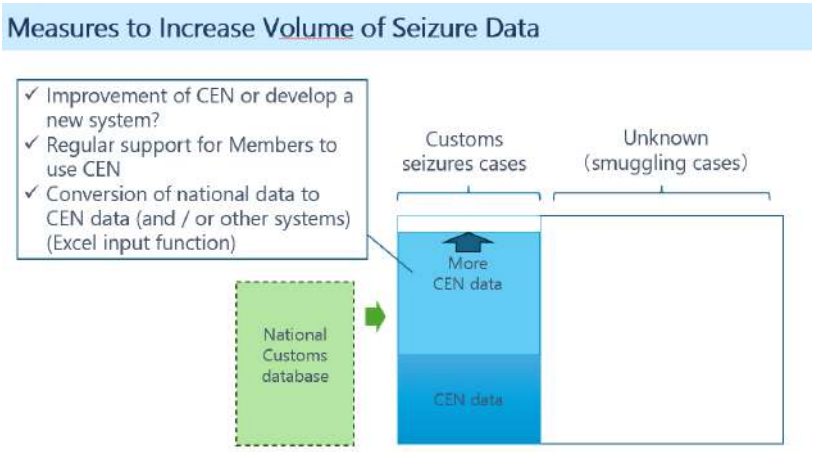


- RILO 根據情資發佈警報訊息（alert information），以鼓勵會員國的海關管理部門立即採取行動，並定期發佈分析報告（analysis reports）呈現地區走私趨勢及資訊，以支援會員國海關管理部門的邊境執法。
- 據 WCO 之海關執法網路（Customs Enforcement Network, CEN）統計資料，2022 年非法貿易數據中查獲違反 4300 萬件非涉智慧財產權商品、1.9 億件共計 192 公噸之非法藥品，比例上以郵件居多，多於船運及車輛上查獲，而亞太區則是最大宗的出貨地點。但根據統計，上開數量僅為所有走私案件之 20%，顯示尚有許多非法貨物未被海關查獲。
- CEN 進行風險分析主要挑戰為數據可用性，無論海關查獲案件數據不完整，或缺乏走私案件數相關數據都對風險分析造成阻礙，為了彌補這方面不足，應該更有效地利用各國海關數據庫及其他執法機構或私人單

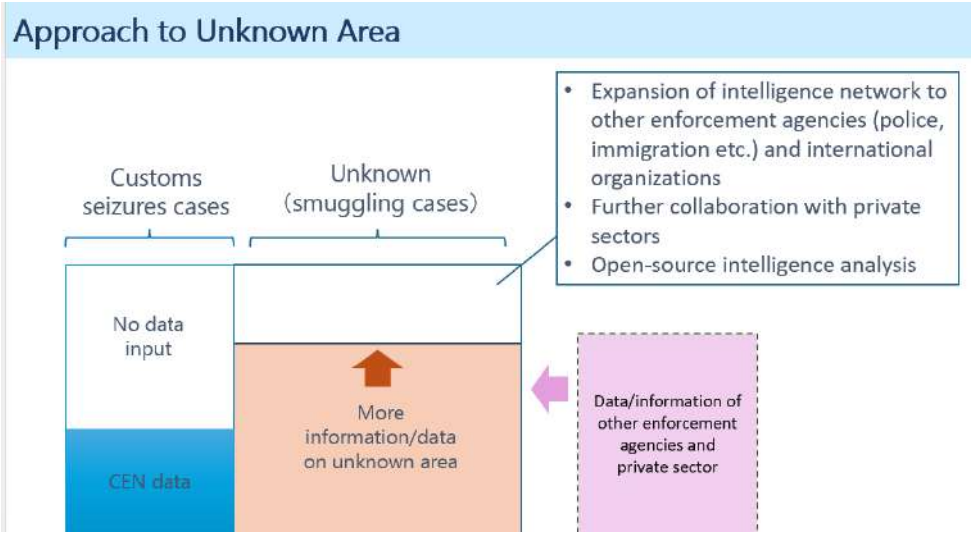


位資訊，以提高風險管理和執法效率。

- 透過各種改進方式，如改進 CEN 系統或開發新系統、透過 CEN 系統為各會員國提供定期情資來源或將各國數據轉換為 CEN 可用數據之格式等方式，以便掌握走私案件之全貌，從而提升執法效率及風險管理能力，並可反應在海關提升之查獲數量。



- 面對風險分析所接觸未知領域，可能因為現有 CEN 系統內資料蒐集侷限性或未被查獲或未報告之走私案件，為降低這類未知領域資料缺口，應擴展情資來源網絡，含其他執法機構（如警政、移民等）並和國際組織、私人企業進一步合作，以取得更全面情報進行分析。



- 海關面對劣質或偽造動物用藥產品可能應對方式，需確認：

- 產品是否符合相關法規，如有無許可證或其他政府機構之核准；
- 產品是否符合智慧財產權法規或海關法規。

- 因此，作為防範 SFVP 的協力單位，WCO 呼籲各國主管機關採取下列行動以對抗動物劣藥及偽藥。
  - 各單位重建聯繫或建立新聯繫；
  - 相互分享資訊；
  - 避免資源運用重疊；
  - 重新確認各法律要求；
  - 提高大眾對動物劣藥及偽藥關注意識。

（十）劣藥及偽藥之「預防、檢測和應對」— 全球倡議及區域活動

由澳洲衛生與老年護理部醫藥用品管理局 (Department of Health and Aged Care, Therapeutic Goods Administration, Australia) 的 Paul Huleatt 博士進行簡報。

世界衛生組織 (WHO) 會員國之劣藥、偽藥產品制度

根據 WHA 第 65.19 號決議，「WHO 會員國制度之目標係保護公共健康，促進獲得價格合理、安全、有效和高品質之醫療產品，並透過會員國和 WHO 秘書處之間有效合作，促進劣藥及偽藥產品之預防與控制的相關活動。」

WHO 指導委員會之指導委員係由 6 個洲際區域（非洲、美洲、東地中海、歐洲、東南亞及西太平洋）代表，每個區域有 2 名指導委員會成員，共 1 名主席國，11 名副主席國。關於主席國及副主席國任期，每隔兩次定期會議結束時到期。主席國在各區域間按英文字母順序輪換。現任主席國為盧旺達，副主席國分別為埃塞俄比亞、美國、巴西、伊朗伊斯蘭共和國、阿曼、以色列、塞爾維亞、印度、印尼、澳洲、韓國。WHO 讓所有會員國透過不同方式聚集、討論面臨之挑戰，並採取行動對抗這些劣藥、偽藥產品。全體會議和指導委員會會議在瑞士日內瓦舉行。

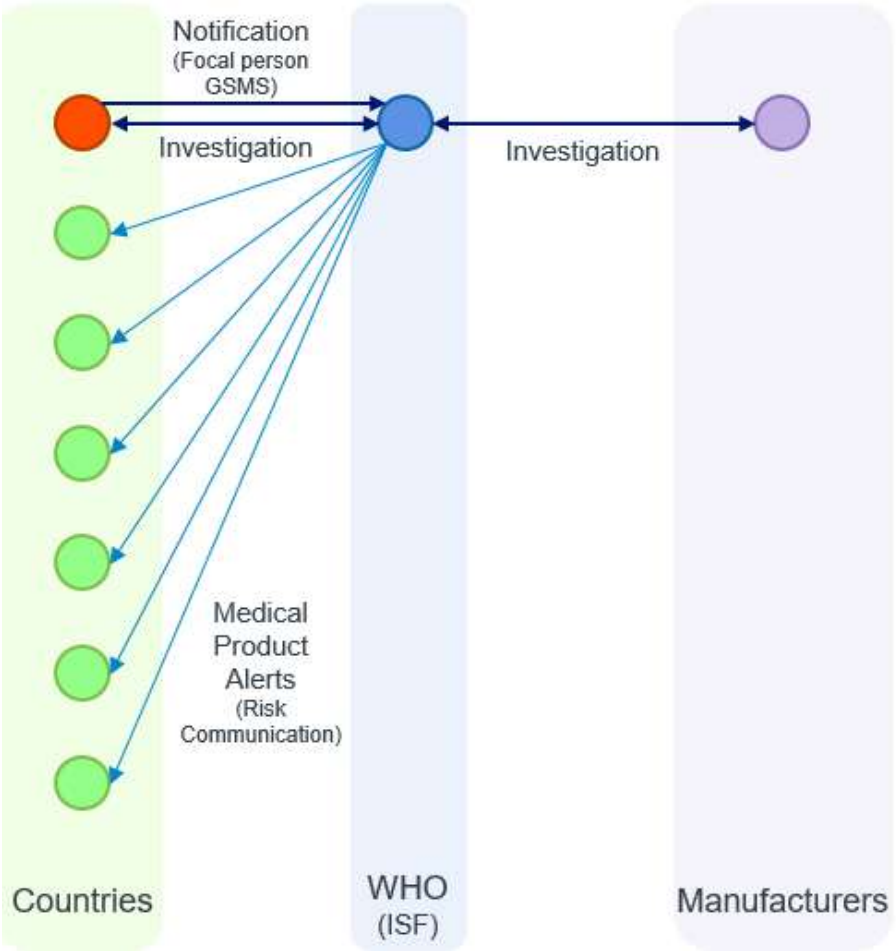
劣藥、偽藥檢測與實驗室檢驗

關於檢測劣藥、偽藥之事件觸發因子可能是直接或間接的，一旦觸發因子促使檢測發動後，我們檢測可考慮使用計畫性檢測（例行或有針對性：較大型的工

作，執行時間軸較長，無立即之時間壓力）或應對性檢測（集中檢驗量能、時間緊迫）。間接觸發因子可能是在某國家發現了劣藥、偽藥產品，並且其他國家也有來自相同製造商的產品，該國家可能想要開始檢查這些產品。這可能是一個較大型的工作，執行時間軸較長，沒有立即之時間壓力。直接觸發因子則非常明顯，例如，有些藥物引起了不良反應報告，人們生病了，你懷疑是某種藥物引起，需要進行檢測。在這種情況下，時間非常緊迫，應採取集中量能檢測。在觸發因子出現後，應採取分層的方法進行檢測。

劣藥及偽藥產品之檢測和應對 — 國家級應對措施

在檢測和應對過程中，我們可以畫一個小圖來展示從國家到 WHO 的最有效處理方式。綠點代表各國，藍點是 WHO，紅點代表發現劣藥、偽藥產品之國家，該國的聯絡窗口（Focal person）會使用全球監控及監測系統 (Global Surveillance and Monitoring System, GSMS) 通報 WHO，並觸發調查。這將包括製造商和該國，WHO 可透過調查了解受影響之產品及相關國家，並進行風險溝通，可能會發布醫療產品警報。



如何發現劣藥、偽藥產品（紅點）？使用分級方式進行檢測，並根據需要提升所使用之技術，利用 WHO 既有系統是關鍵。此外，確保會員國 GSMS 聯絡人接受培訓、建立國內管道以通報藥物品質瑕疵、建立國內管道以進行風險溝通及應對之管道亦重要。挑戰之一為所安排之品質管控實驗室應符合要求之標準，例如檢測所需時間、樣本數量和可接受之成本。這些服務可以由第三方或其他 WHO 會員國之品質控制實驗室提供服務。

洲際區域實驗室檢測之考量因素

若使用第三方實驗室，可能涉及多個國家及 WHO 聯繫。考量一個情境，倘若一個產品被懷疑為不合格，確定需要更大規模的分析，但這些分析在該國無法進行，則需要啟動洲際區域國家級品質管控實驗室檢測協議並送樣。然而，可能出現未預期的複雜情況，包括所需的檢測可能暫時無法進行（例如，無菌檢測設

備故障）、樣本累積導致處理時間延長、樣本可能被實驗室降級處理、無法達到約定時限、樣本可能因過期風險而浪費、劣藥產品可能被用了、分析結果可能不足以決定後續行動。

檢測前的決策

- 是否進行檢測？採取理性的方式
- 對於人類醫療產品，這可能是一個複雜的決定
- 觸發檢測之因素是什麼？已知之訊息為何？缺少之訊息為何？
- 檢測後，將提供哪些關鍵之附加訊息？
- 誰來做「檢測或不檢測」之決策？需要一個跨領域專家團隊，例如臨床醫師、藥劑師、化學家、毒理學家、實驗室分析師和實驗室管理者等
- 檢測後之行動可能是什麼？並且是否準備好採取行動？需要考慮和準備多種應急方案

劣藥及偽藥產品 — 檢測前的決策階段

關鍵問題為是否需要進行檢測，我們需要採取合理方式來考慮這一點。這可能是一個非常複雜的決定。對於人類醫療產品而言，產品檢測觸發因子是什麼？已知訊息與缺失訊息是什麼？您是否有足夠的訊息來確定何時需要檢測？

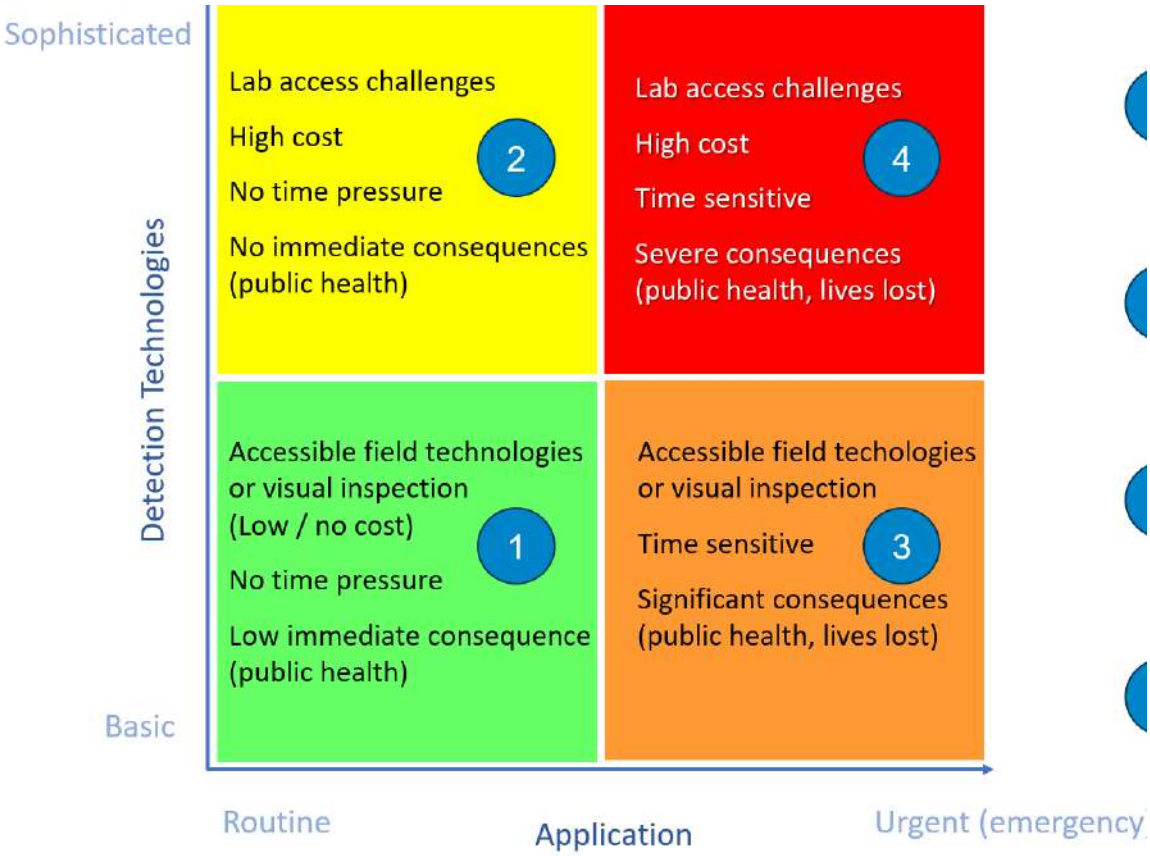
另一個關鍵問題是分析將提供哪些關鍵訊息？這些訊息將幫助您確定後續行動。對於人類產品，為了做出這一決定，您需要召集一個跨領域專家團隊。這不是由領導經理決定，也不是分析師能夠單獨決定，您通常需要臨床醫師、藥劑師、化學家、毒理學家、實驗室分析師及實驗室管理者等。因此，您需要所有這些人的參與來做出決策。此外，檢測後行動可能是什麼，並且是否準備好採取行動？若結果符合有效藥物成分（API）規範，您會做什麼？如果結果未達標準，該怎麼辦？如果所有結果都達標，您會做什麼？

劣藥及偽藥產品 — 檢測後之行動

在檢測後，與相關利益相關者之溝通亦為關鍵。您將要做什麼？為什麼要這樣做？適時採取法規及刑事行動（例如，銷毀隔離產品、啟動產品召回等）。適

時透過 GSMS 向 WHO 報告該事件（可參考有關世界衛生組織（WHO）之疑似偽藥檢驗之指導原則附件 5。）

最後，以下圖矩陣方式，討論樣品檢測情境，以思考可能遭遇不同情境之方法。縱軸上至下為檢測技術難度由高階至基礎，從基礎之目視檢查或儀器等簡單技術，一直到高階之先進儀器，例如 LC-MS/MS，用於複雜之分析。橫軸左至右上為檢測技術之應用由例行性至緊急性。



我們希望大多數情況下是在綠色區塊（1 號情境）中，能夠使用平價且容易取得之分析方法進行例行姓檢測，沒有時間壓力，無立即之公共衛生關注。基礎例行性檢測案例，包括例行市場監測，可使用便宜之薄層色譜（TLC）篩查糖漿藥物中是否含有二甘醇（DEG）污染。

2 號情境為進行較長時間之分析，沒有時間壓力，但可能存在較高實驗室成本或實驗室技術挑戰。高階例行檢測案例：發現一種無菌注射抗生素產品含有可見顆粒。有替代產品可用。可透過第三方協議進行多項檢測，執行活性藥物成分（API）分析，沒有時間壓力，但成本昂貴。

3 號情境為急需進行檢驗時，情況開始變得有些緊張。希望能依靠一些基本技術，但時間緊迫，後果嚴重（涉及公共衛生及人員死亡）。基礎緊急檢測案例：當發生中毒事件，需要快速篩查確定是否存在乙二醇污染，可以在現場快速使用 TLC 技術。

4 號情境最為困難，您需要使用高階之實驗室設備、技術及成本，具有公共衛生風險，可能有人員死亡，時間緊迫，您需要快速得到答案。高階緊急檢測案例：注射抗生素產品涉及多次嚴重不良事件（如死亡）。需要快速進行實驗室檢測，涉及風險溝通與臨床調查。

（十一）WHO 針對劣藥及偽藥產品之全球監控和監測系統 (Global Surveillance and Monitoring System, GSMS)

由 WHO 總部劣藥及偽藥產品事件小組之 Anita Sands 女士簡報「WHO 針對劣藥及偽藥產品之全球監控和監測系統 (GSMS)」。

WHO 在處理人類醫療產品方面有很多經驗，WHO 希望這些經驗對獸醫領域的工作有所幫助，尤其係在防止、檢測及因應劣藥與偽藥產品方面。WHO 希望與獸醫能在這方面合作，因為 WHO 認為兩者有很多相似之處。本簡報說明「WHO 全球劣藥及偽藥產品監控及監測系統」、「如何向 WHO 通報」、「WHO 如何利用這些訊息發布全球醫療產品警報」。

什麼是劣藥及偽藥產品？

什麼是劣藥及偽藥產品？此定義非常關鍵！此為全球協作行動之必要條件。WHO 花了很長時間才就劣藥及偽藥產品之定義達成共識。WHO 關注點主要係公共衛生，而非知識產權。依據世界衛生大會第七十屆會議通過之工作定義文件，定義如下：

- **劣藥 (Substandard medical products)**：核准之醫療產品未能達到其品質標準或規格，或兩者皆未達標，亦稱為「未達規格標準 (out of specification)」。

- **偽藥 (Falsified medical products)**：故意或以欺騙方式偽造其身份、成分或來源之醫療產品。
- **未登記或無許可證之藥物 (Unregistered/unlicensed medical products)**：未經國家或區域法規監管機關評估及/或核准之醫療產品，並在該市場上進行銷售、運銷或使用。

WHO 有另一個專門負責強化監管之團隊，他們使用一個名為全球基準之工具，幫助法規監管機關了解制度中之缺口，以及需要哪些新文件、新程序、新政策來處理未登記與無許可證之產品。

什麼是 WHO 全球監測和監控系統 (Global Surveillance & Monitoring System, GSMS)？

WHO 因應會員國之要求，建立了 GSMS，以應對劣藥與偽藥產品。GSMS 目標包括評估劣藥與偽藥產品造成之規模與危害；了解為什麼這些劣藥或偽藥產品會出現；促進會員國之間的協調與合作；對防疫與治理制度造成變革；強化監管能力，以防止、檢測與因應劣藥及偽藥產品。

關於了解為什麼這些劣藥或偽藥產品會出現，當一個母親無法在正常藥局或合法之銷售店獲得她孩子需要之藥物時，她可能會去任何她知道的非正規市場或認識之賣藥人，快速購買藥物。這也可能是成本問題所致，有時在其他地方可以更便宜獲得這些藥物。劣藥與偽藥產品可能係季節性出現。例如，在 COVID-19 疫情期間，人們迫切需要疫苗時，突然間就能找到疫苗。因為有人會去回收箱收集小瓶，重新填充並再次出售。所以，當取得藥物之管道缺乏時，即會創造出現劣藥或偽藥之機會。

如何實現 GSMS 目標？將 GSMS 作為劣藥與偽藥產品訊息與情報中心之樞紐；鼓勵並改善國家監管機關通報劣藥與偽藥產品；當 WHO 收到這些報告時，有助於 WHO 內部啟動支援機制，為會員國提供技術支援來因應關鍵事件。一般而言，10 個事件中，有 9 個不需要 WHO 額外干預。事件進入 WHO 系統後，WHO 會審查、檢查紀錄，並將其納入資料庫。涉及重大事件時，WHO 會於適當時機發布全球醫療產品警報。

當你發現發生了某個偽藥或劣藥事件時，你可能會想，我們應該做得更多，或者認為可能是我們的監管制度某些方面做得不夠好。其實，你不應該這樣想，有時人們會因為認為監管制度失敗而不願通報事件。但事實並非如此，沒有任何系統能百分之百無懈可擊。我們都需要根據數據做出決策，包括檢查員之部署與檢查我們的法規是否真正落實。因此，WHO 希望創造一個會員國之間可以交換訊息之平台，WHO 重視保密性，理解有些資料無法共享，但整體而言，我們一起合作比單獨處理要好得多。

WHO 全球監控和監測系統不僅僅是一個資料庫，其服務項目包括監控及監測工具、聯絡窗口網絡、風險溝通、事件管理、資料庫、分析見解、培訓、規範指導及強化國家監管機關。

透過資訊共享以協調因應

下圖案例展示了全球報告系統如何協調資訊共享並引發行動。本案例係偽造 Defibrotide 產品之偽藥，它用於治療接受骨髓移植的患者。本案例展示了偽藥及劣藥產品並不限於低收入地區。WHO 在世界各地都看到了通報。本事件最初在澳大利亞被發現兩批 Defibrotide 偽藥，由拉脫維亞 (Latvia) 通報給 WHO，WHO 與拉脫維亞 (Latvia)、英國協調後，發現這些偽藥產品被供應到英國、沙烏地阿拉伯、瑞士和巴西，進而發布警報。之後又發現更多批次偽藥被供應到阿根廷、新加坡和馬來西亞。一個國家通報事件後，我們可以透過國際協作發現更多資訊，證明這些產品在多個國家流通。一旦發布警報後，WHO 開始收到更多通報事件。這種情況經常發生。

Coordinating response through information sharing

- Two batches of falsified Defibrotide initially identified in Australia. Reported to WHO by Latvia.
- WHO coordination with Latvia & UK identified the supply of the falsified products to UK, Saudi Arabia, Switzerland, Brazil.
- **Following publication** of Alert No 5/2020 - falsified batches also reported supplied to Argentina, Singapore, Malaysia

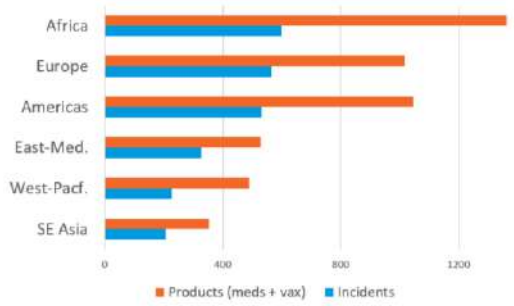
World Health Organization

6

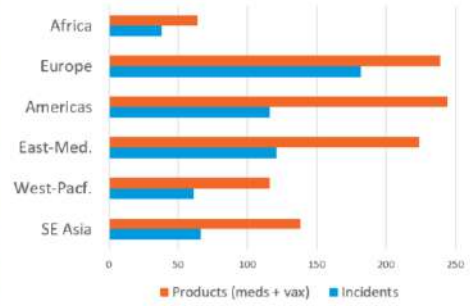
下圖展示了自 2012 年以來，WHO 收集之數據。橙色代表可疑產品，藍色代表事件。此表示一個事件可能包含多個可疑產品。你可能在一次檢查中發現多個可疑產品，WHO 將這些產品與事件做相關聯。

WHO Global Surveillance and Monitoring System

Total incident* and suspect product records Sept 2012 to Feb 2024**



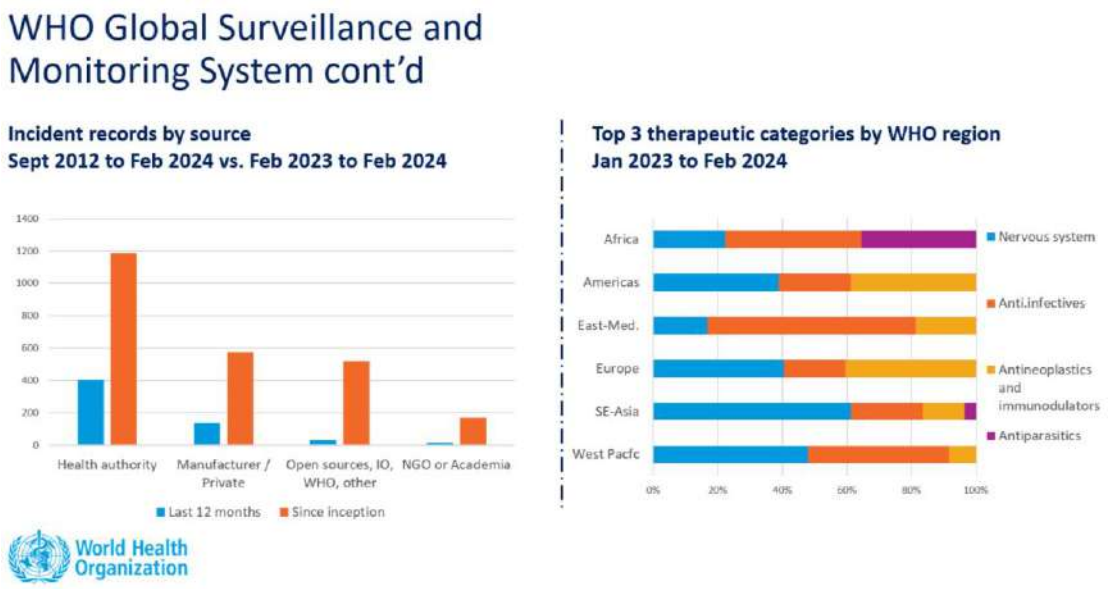
Total incident and suspect product records Feb 2023 to Feb 2024



World Health Organization

*Where an incident is notification of potential substandard or falsified medical products at one time and in one place.
** Where different lot numbers are considered different suspect products.

WHO 亦統計通報者之身分，除了國家聯絡窗口之外，尚有其他通報者係不能查看 GSMS 聯絡窗口名單或培訓資料，主要係業者通報，因為他們擔心偽藥產品，並能夠更快地檢測到它們。製造商通常是 WHO 之重要通報者（如下圖左），他們可以檢測到偽藥產品，並擁有情報網絡來收集資訊。WHO 還透過公開平台收集資訊，例如 Facebook、Twitter 及新聞。WHO 亦關注學術界研究，將其納入 GSMS。



WHO 亦查看通報之產品類別（如上圖右）。例如高價之 Defibrotide、非洲地區通報之抗寄生蟲藥物，東地中海地區之抗感染藥物。WHO 分析這些趨勢，以了解哪些產品在通報中佔據重要位置。

如何建立 GSMS 通報管道？

1. 由國家主管機關指派之聯絡窗口。
2. 透過 WHO 國家和地區辦事處，向總部之 ISF 團隊提名（並副知 rapidalert@who.int）。
3. 聯絡窗口必須完成劣藥及偽藥產品之電子課程。
4. 聯絡窗口取得 WHO 入口網站之登錄權限。

5. 聯絡窗口創建登錄資訊後，即可開始通報劣藥、偽藥產品事件。(ISF 團隊可以為聯絡窗口提供培訓)。

為什麼要發布警報？

WHO 全球醫療警報係對偵測到之劣藥及偽藥產品做出因應。

WHO 發布警報之條件包括：

- 對公共衛生的立即和重大威脅；或
- 嚴重的不良事件或患者傷害；並且
- 產品在一個以上國家存在風險。

WHO 醫療產品警報的影響

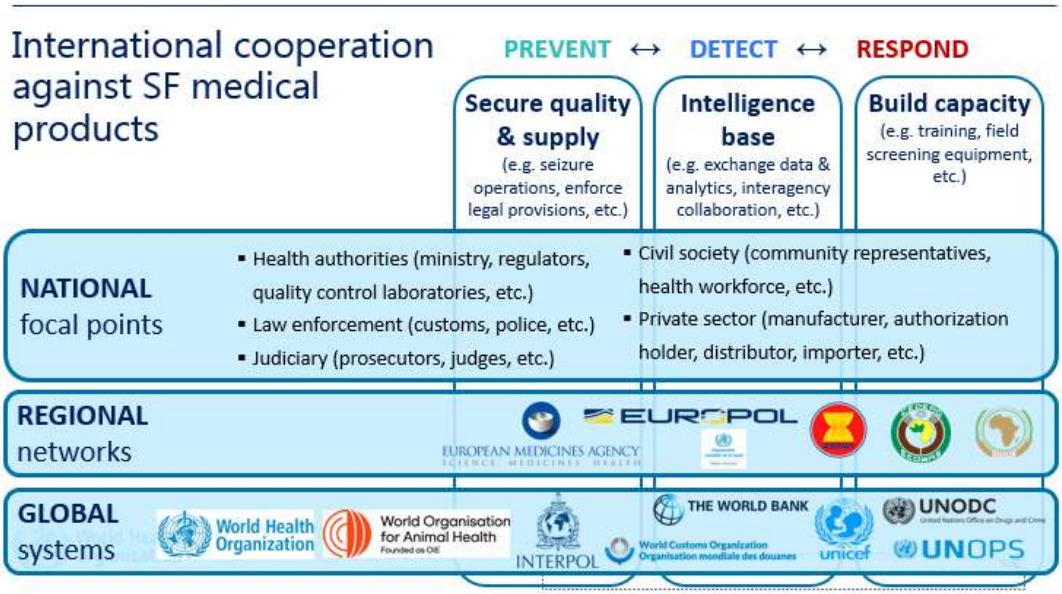
這些警報會透過電子郵件發送給國家聯絡窗口及合作夥伴，而且所有警報均會發布於網站上。以下為去年之警報

- 警報 No 1/2023（烏茲別克）：於寮國及柬埔寨檢測到產品。
- 警報 No 5/2023（伊拉克）：在印度檢測到其他污染批次。
- 警報 No 8/2023（馬爾地夫和巴基斯坦）：在貝里斯、斐濟和寮國檢測到產品。

國際合作對抗劣藥及偽藥產品

WHO 與世界海關組織、國際刑警組織及聯合國毒品和犯罪問題辦公室合作，並建立了洲際區域網絡與國家級協作。預防、檢測及因應為 WHO 之主要策略。預防措施方面，係要確保品質及藥品供應（例如查封行動，依法執行等）。檢測為情報之基礎（例如數據交換和分析，機構間合作等），需提高檢測之敏感度 (sensitivity) 和特異性 (specificity)，以利通報並加速資訊反饋系統。因應措施方面，需要進行技術能力建設（例如培訓，現場篩查設備等）。劣藥與偽藥因應措施首先保護公眾健康、確認並實施矯正行動，以避免重複發生（行政監管與司法

行動）。國家聯絡窗口包括衛生機關（部會、法規主管機關、品質管控實驗室等）、執法機關（海關、警察等）、司法機關（檢察官、法官等）、民間社會（社區代表、醫療工作者等）、私部門（製造商、藥物許可證持有者、運銷商、進口商等）。



（十二）於畜牧場端收集動物劣藥及偽藥產品數據（FAO RAP 佛萊明基金 AMR 專案計畫）

由聯合國糧食及農業組織亞太地區辦事處（FAO RAP）抗微生物藥物抗藥性（AMR）專案計畫協調員 Jutamart Jattuchai 簡報「於畜牧場端收集動物劣藥及偽藥產品數據」。

透過防疫一體之方法，讓撒哈拉以南之非洲、南亞和東南亞的食品及農業部門參與生成式數據（具 AMR 專一性及敏感性），並基於證據做出決定，採取行動，以對抗 AMR。

有關畜牧場端動物劣藥及偽藥產品調查及數據收集，可以做什麼？

FAO 計畫從小地方著手開始，建立一個農民田間學校（Famer Field School, FFS），以試點型的方式進行畜牧場端數據收集。所謂農民田間學校（FFS）係指一個「沒有圍牆的學校」，即在畜牧場環境中進行，這些環境最多可容納 15 至 25 名有共同興趣的農民，這些農民對於最佳生產方式具有共同興趣，並以觀察

和實驗之方式學習。FFS 係由經過三週培訓之引導員進行指導，引導員係從農民培訓而來。以成人為中心之學習並共同創造解決方案，重點為引導而非教學。他們將自己識別出他們所遇到的生產問題，並希望找到最佳解決方案，在輔導和引導之下創建這些解決方案。

FFS 參與者每週或每兩週在主辦畜牧場舉行會議，通常跨越生產週期。這些農業學校的方法在佛萊明基金專案取得了成功，20 個 FFS（約 500 名家禽農民）在非洲實施，採用更多良好之生產做法，並減少了抗微生物藥物之使用。於非洲之肉雞農民田間學校，成功推動良好作業方式（生物安全及生產）、負責任地使用抗微生物藥物、改善生產及盈利能力、改變農民行為、產出數據。

用於評估 FFS 之動物用藥產品工具軟體係由 FAO 肯亞的 Mark Caudell 博士開發，這些工具軟體的目的係收集動物生產中使用之所有產品數據，包括抗微生物藥物，如抗生素、抗病毒藥物、抗寄生蟲藥、維生素、消毒劑、傳統藥物及疫苗，並將其與使用模式之數據一起記錄，包括藥物類型及其相關資訊（劑量、有效成分、成本）、實際劑量（給予量及使用時間多久）、給藥原因（治療或預防）、藥物是否開處方及由誰開處方。這將使我們能夠使用這些模式了解抗微生物藥物之使用情況，學校評估也將包括在內。

使用動物用藥產品工具軟體

在 FFS 開始之前，數據收集員將在畜牧場收集有關生物安全、家庭、畜牧場背景之數據。為了收集可靠之數據，該工具軟體應與提供給農民（FFS 參與者）之收集材料一起使用，最好在初次拜訪畜牧場或社區之宣傳會議期間進行，這些材料包括 (1)容器或袋子，用於收集所有用完之產品及其相關之收據或處方；(2)記錄用藥數據（藥物類型、劑量、治療天數、疾病）之紀錄表。

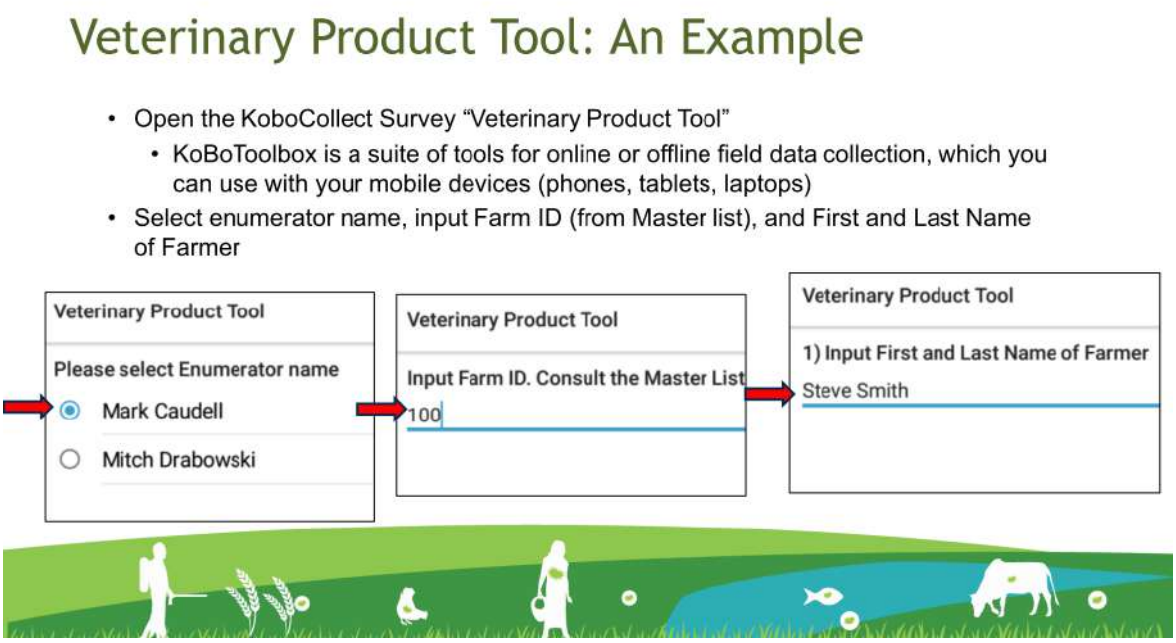
完成一個生產週期後，數據收集員將返回畜牧場，使用動物用藥產品工具軟體收集數據。於畜牧場端，數據收集員或引導員將要求農民帶來任何紀錄或收據、未完成之動物用藥產品及裝有已用完之動物用藥產品的桶或袋子。

動物用藥產品工具軟體：實作範例

1. 打開 KoboCollect 調查「動物用藥產品工具軟體」，KoBoToolbox 是一套

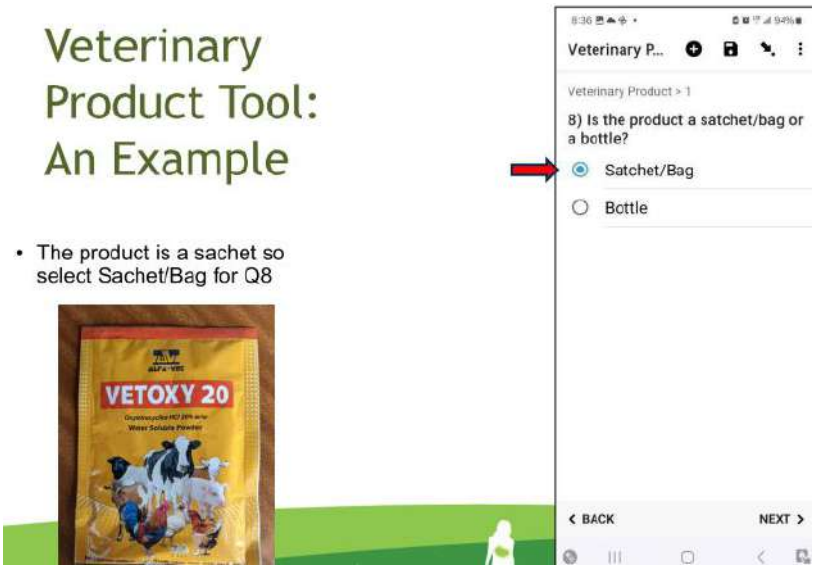
線上或離線之現場數據收集工具軟體，您可以在行動設備（手機、平板電腦、筆記本電腦）上使用。

2. 選擇數據收集員之姓名，輸入畜牧場 ID（從主列表）及農民姓名（操作如下圖）。

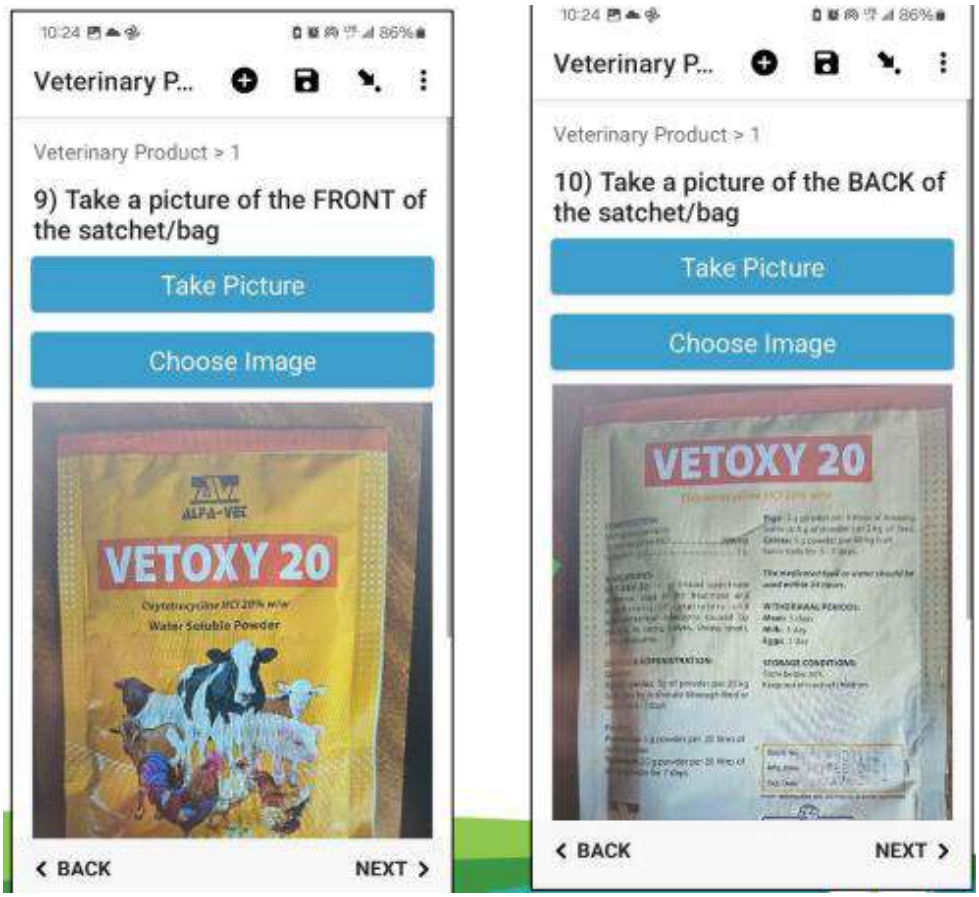


3. 首先確認手機相機是否可正常運作，若可，請選擇「Yes」，並拍攝動物用藥產品照片。若相機無法正常運作，請選擇「No」，並請手動輸入產品名稱和公司名稱。
4. 在這個範例，我們假設您的相機可正常運作。您從桶中取出的第一個產品是 Vetoxy 20。查看產品包裝得知，有效成分為 Oxytetracycline，這是一種抗生素，故選擇「Antimicrobial」。「Veterinary Product >1」表示這是您正在收集資料的第一個產品（操作如下圖）。

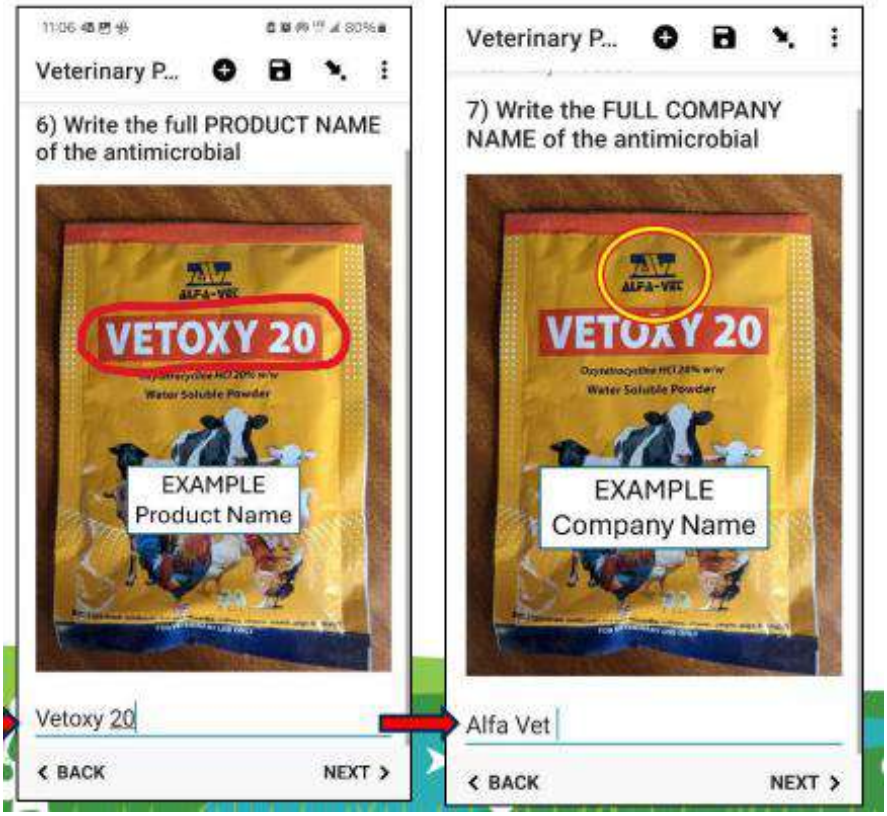
5. 下一步將是輸入包裝類型，由於這個產品是袋裝的，故在問題 8 選擇「Satchet/Bag」（操作如下圖）。



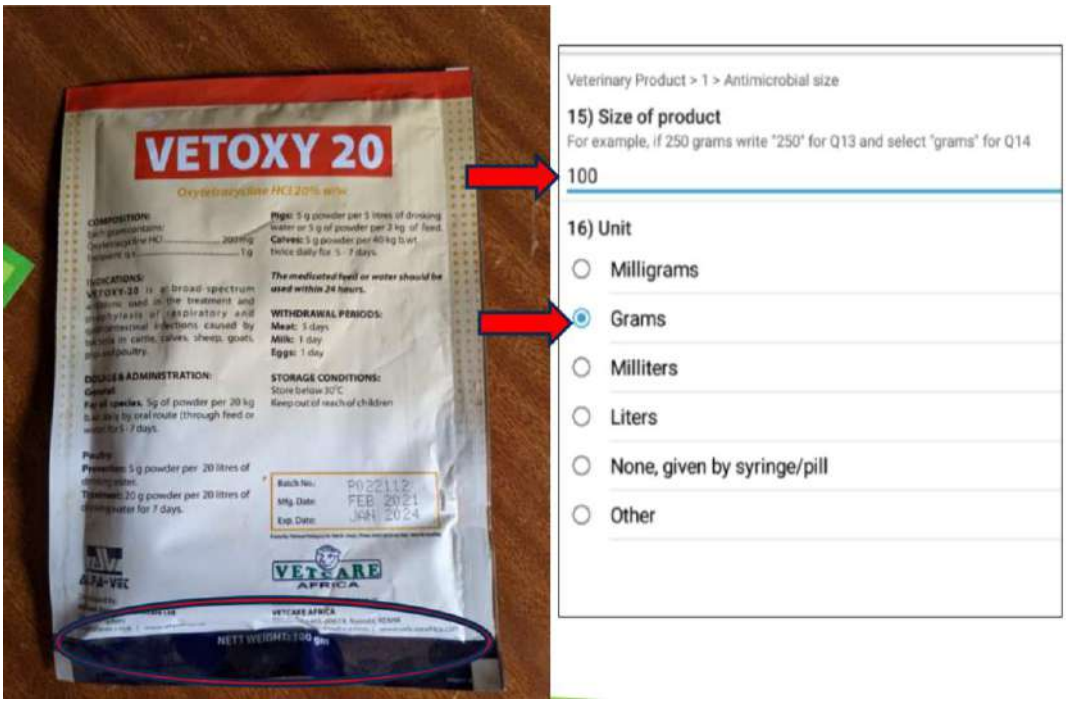
6. 使用相機拍攝包裝之正面和背面，確保照片應清晰可讀，並且所有資訊都應包含在照片中。拍照後，選擇「OKAY」，然後選擇「NEXT」（操作如下圖）。



7. 若手機相機無法正常運作，或農民給您的是一個紙本紀錄。您就需要手動輸入產品名稱和公司名稱。軟體介面會向您顯示一個範例圖片。在此範例中，產品名稱是 Vetoxy 20，公司的名稱是 Alfa Vet。務必將產品名稱和公司名稱填寫正確，這非常重要（操作如下圖）。

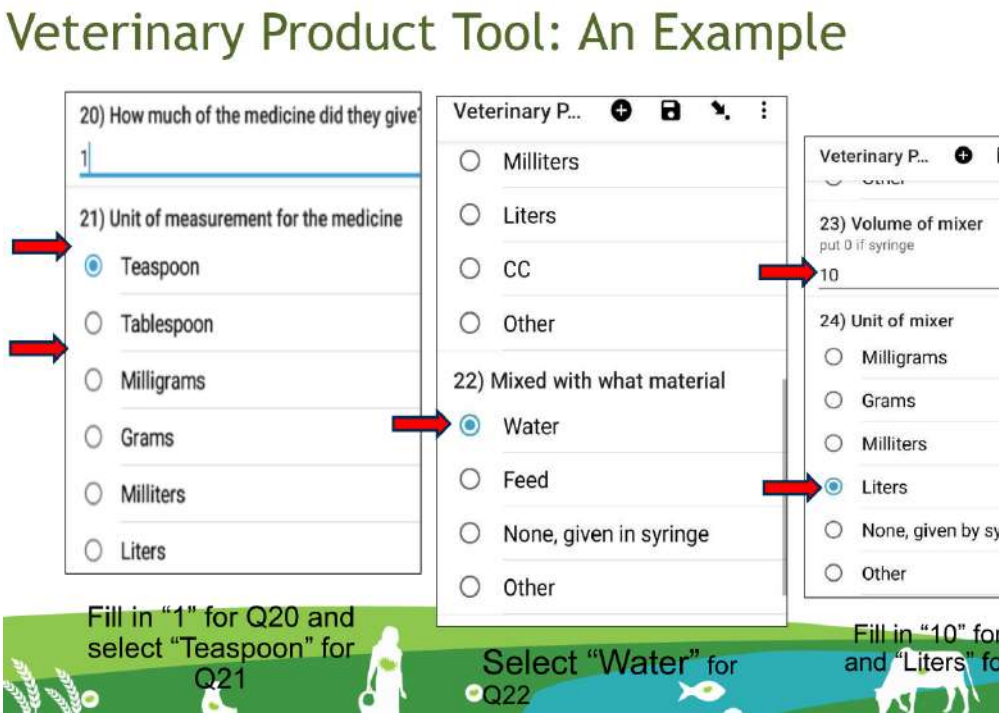


8. 填寫產品包裝大小之規格。在包裝背面，我們可以看到是 100 克，所以第 15 題就填寫「100」，第 16 題就選擇「Grams」作為單位（如下圖）。

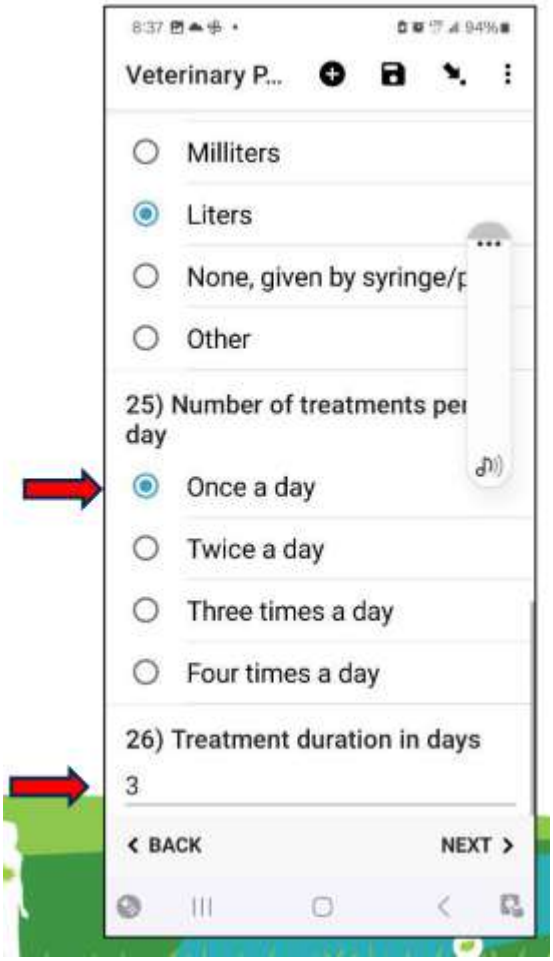


9. 詢問農民該抗生素是否有處方？即農民是否與動物醫療專業人員談過，而該專業人員告訴他們應購買什麼抗生素；或給他們紙本處方。在這個範例，這位農民說他有處方，所以第 17 題選擇「Yes」。這位農民說，是民營獸醫師開立的處方，所以第 18 題選擇「Private vet」。關於抗微生物藥物之成本，這位農民說他花了 250 先令（當地貨幣）購買了抗生素。所以第 19 題填寫「250」(如下圖)。

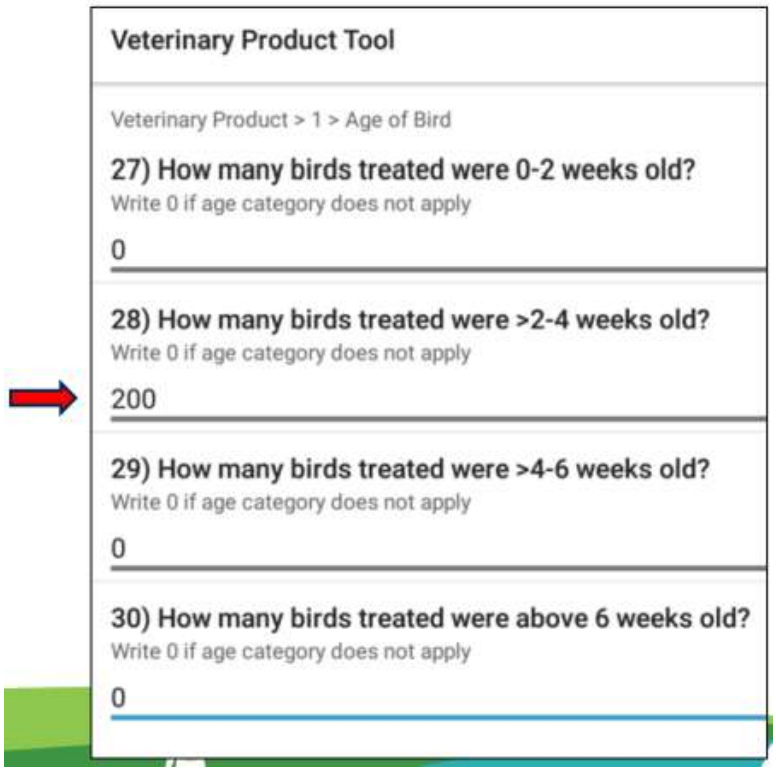
10. 詢問農民實際劑量率 (actual dose rate) 之資訊，包括投藥數量、持續投藥時間、投藥給多少數量之家禽、家禽之年齡。以下圖示為例，農民表示，他使用 1 茶匙之藥物混合於 10 公升的水中，則第 20 題「給藥數量」填寫「1」，第 21 題「藥物量測單位」選「Teaspoon」，第 22 題「混合材料」選「Water」，第 23 題混合物之容量填寫「10」，第 24 題「混合物之單位」填寫「Liters」。



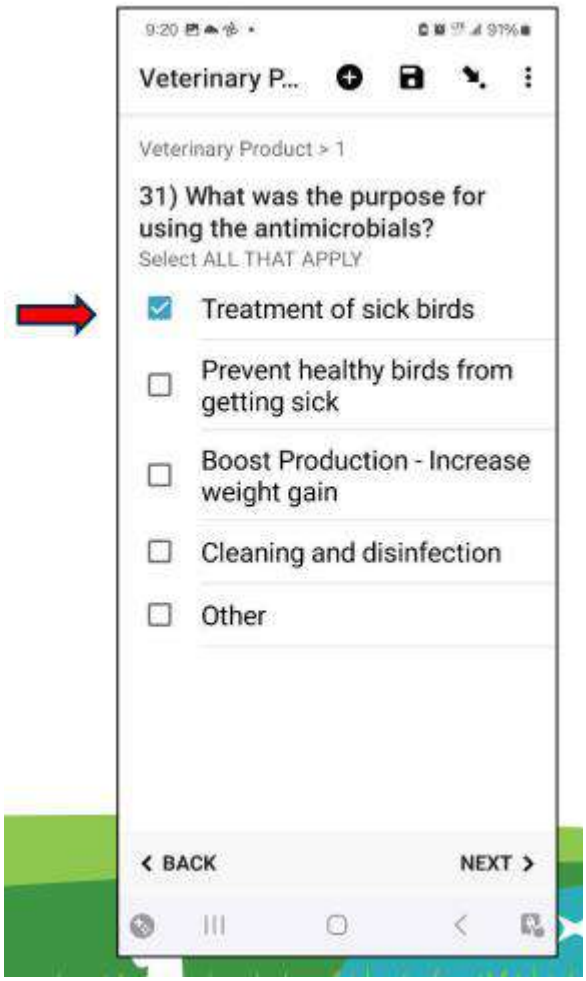
11. 詢問農民投藥頻率及持續投藥時間。以下圖示為例，農民表示他每天一次，持續三天，則第 25 題選擇「Once a day」，第 26 題「投藥天數」填寫「3」。



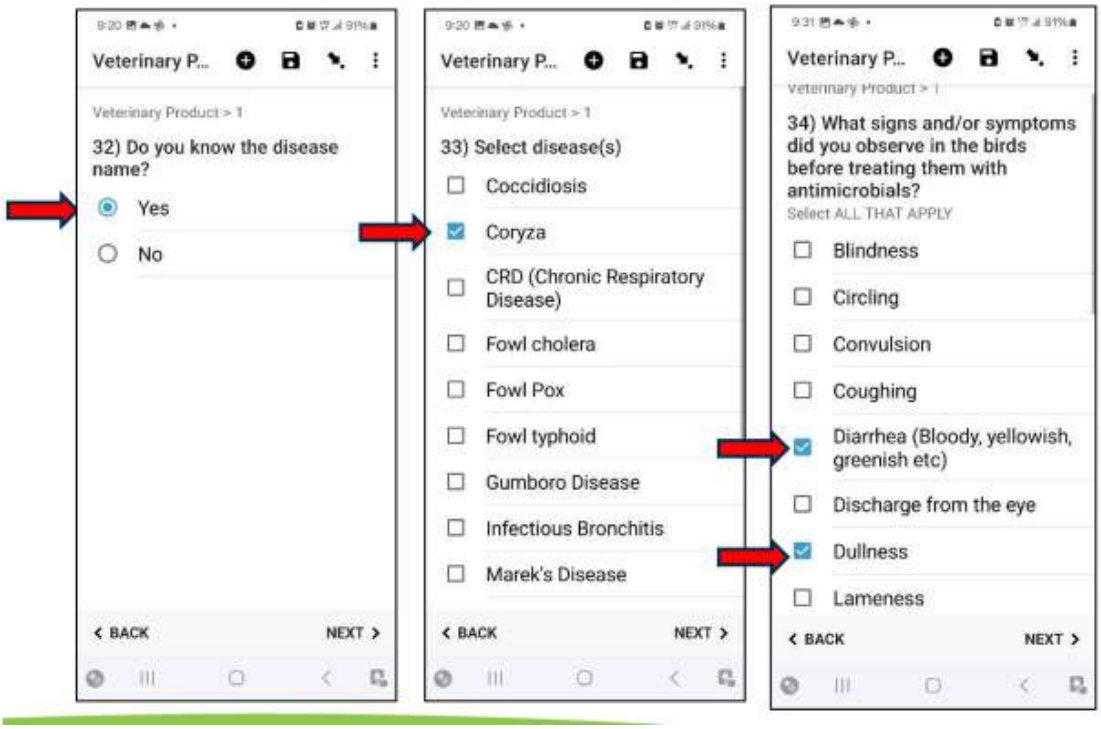
12. 農民表示他投藥治療了 200 隻 3 週齡之家禽，故在第 28 題輸入「200」，其餘狀況不符，故輸入「0」(如下圖所示)。



13. 農民表示，他使用抗生素來治療疾病，則第 31 題「使用抗微生物藥物之目的」，則勾選「Treatment of sick birds」。



14. 我們還會詢問農民是否確實知道疾病名稱，若農民知道病名，則我們可以輸入這些資料，並記錄觀察到之症狀及症狀程度。以下圖示案例，農民表示，他知道這種疾病之病名，所以第 32 題選擇「Yes」。農民表示，該病名為傳染性鼻炎 (Infectious Coryza)，則第 33 題選擇「Coryza」。農民表示，症狀為下痢與遲鈍，故第 34 題選擇「Diarrhea」及「Dullness」。



15. 以上涵蓋了 FAO 計畫收集之所有資料。當我們填寫完第 1 個動物用藥產品後，系統軟體會詢問您資料是否已填畢或要再填寫第 2 個動物用藥產品？

總結

柬埔寨、寮國和菲律賓於畜牧場端之動物劣藥、偽藥產品資料收集將作為肉雞農民田間學校 (Broiler Farmer Field Schools, BFFS) 之部分工作，並以數位化之方式管理資料。數據收集員會經過培訓，由政府或學術機構之主教練進行培訓。FAO 於此試辦階段，樣本量將較小，規劃在每個國家進行 1~2 個農民田間學校 (FFS) 試辦調查，每個試辦調查最多可容納 25 名農民，而在未來具有擴大規模之可能性。該資料收集需要眼觀調查與取得紀錄資料，此項軟體紀錄工作雖無法驗證該藥物是否合格，但有助於偽藥、劣藥相關資訊之收集。這項新開發軟體工具需要依據當地國需求，因地制宜做調整。畜牧場端收集之劣藥、偽藥資料，由政府主管機關至 VSAFE 通報致 WOAH，可將 VSAFE 通報工作整合納入至畜牧場端動物劣藥、偽藥長期監測及監控計畫中。

（十二）介紹 WOAH 針對動物劣藥及偽藥之監控系統 (VSAFE)

由 WOAH 的 AMR 及動物用藥產品部門之 Andrés García Campos 計畫經理簡報「介紹 WOAH 針對動物劣藥及偽藥之監控系統 (VSAFE)」。

VSAFE 於 2022 年開始第一階段試辦，當時有 14 個會員國參加，2023 年第二階段試辦，參加之會員國增加至 42 個，目前有 57 個會員國參加，而且參與 VSAFE 之會員國數量仍持續增加中。WOAH 核心價值觀為包容，對於參與劣藥與偽藥通報之國家不批評、不羞辱，WOAH 之核心價值觀為信任，所有利益相關者之間的信任是這一切運作的核心。

VSAFE 起源 – WOAH 法典、決議及會員國建議

依據陸生動物衛生法典第 3.4.11.5 條款，關於「動物用藥之零售、使用及可追溯性」方面提及「獸醫法規應提供行動依據，以解決……，一個針對國內上市之動物用藥產品的品質監測系統，包括偽藥監控系統」。

依據 2015 年 5 月 26 日「打擊 AMR 並促進於動物謹慎使用抗微生物藥物」通過之第 26 號決議，第 10 點：「OIE 應加強與國際組織（如世界海關組織和國際刑警組織）及利益相關者之合作，以打擊假冒藥品，旨在確保可取得品質合格之抗微生物藥物」。

按「OIE 全球 AMR 會議之將標準付諸行動措施」第 6 點建議：「考慮建立一個資訊系統，專門用來追蹤動物劣藥及偽藥，這些藥品可能會在國內或跨國之間非法流通。OIE 擬借鑒 WHO 人用藥品監測系統方面之經驗，並採用防疫一體之方式來進行」。

依據陸生動物衛生法典第 6.10.3.10 條款，關於動物用抗微生物藥物之運銷及管理方面提及，主管機關應確保所有動物用抗微生物藥物產品沒有違法、沒有品質不合格、沒有偽造之藥品或未經核准之製劑，並防止這些違法藥品進入市場流通。

定義及分類標準

WOAH 參考 WHO 名詞定義及分類標準，調整如下：

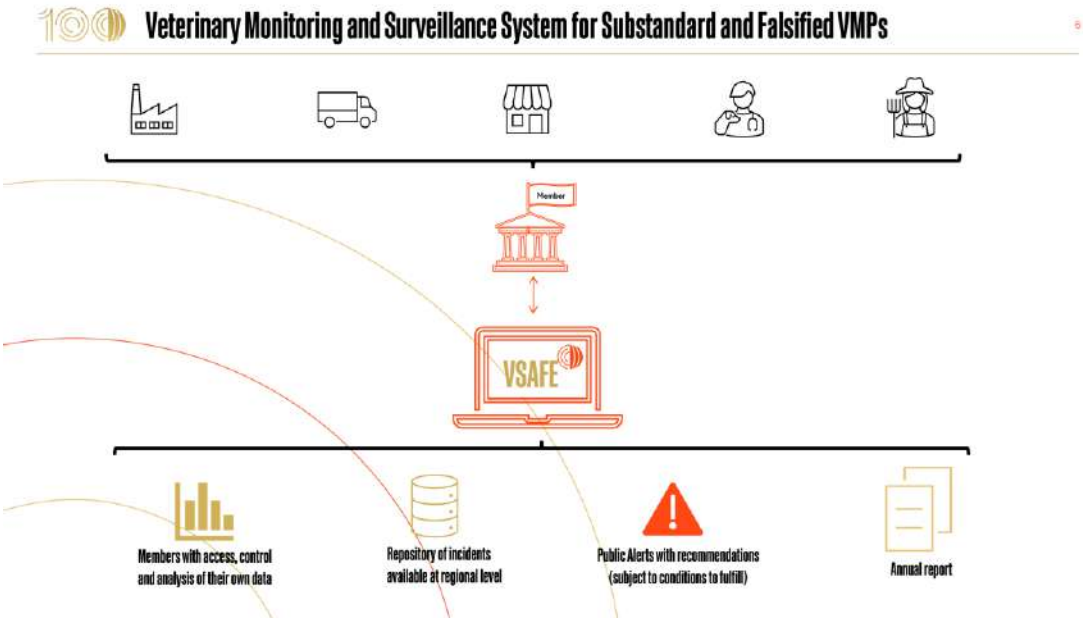
		劣藥 (Substandard)	**偽藥 (Falsified)**	**未登記或無許可證 (Unregistered/Unlicensed)**
定義 (資料來源：WHO IFS Team)		被核准之動物用藥產品未能符合其品質標準或其規格，或兩者皆未符合。	未經核准之動物用藥產品以故意或欺騙方式偽造其產品身份	在某個市場上銷售、運銷或使用之動物用藥產品沒有經過該國家或該地區之主管機關進行評估及/或核准，因而違反該國家或該地區之相關法律。
事件標準	**疑似**	這個動物用藥產品外觀看起來好像有在其發現之國家做登記。 **AND** 這個動物用藥產品沒有通過現場篩檢及/或沒有通過當地實驗室檢測。	這個動物用藥產品未通過現場篩檢，及/或當地實驗室檢測。	這個動物用藥產品外觀看起來好像沒有在其發現之國家做登記。
	已確認	獸醫主管機關已確認這個動物用藥產品在該發現國已有登記。 **AND** 這個產品標示之製造商或持證商（MAH）已確認他們**確實製造了**這個產品。 **AND** 這個產品標示之製造商或持證商（MAH）已確認，實驗室檢測結果與其紀錄不符。	標示的製造商或持證商（MAH）已確認他們**並未製造**這個產品。	獸醫主管機關已確認這個動物用藥產品在發現國家未登記。 **AND** 這個產品標示之製造商或持證商（MAH）已確認他們確實製造了這個產品。

- MAH (manufacturing authorization holder) = 持證商。
- IFS Team (Incident Substandard and Falsified Medical Products Team) = 劣藥及偽藥產品事件小組。

動物劣藥與偽藥監測及監控系統 (Veterinary Monitoring and Surveillance System for Substandard And FalsifiEd VMP, VSAFE)

動物劣藥及偽藥產品發現與通報者可能為持證商、運銷商、合法販賣業者、獸醫師或畜禽水產養殖業者。WOAH 之願景係將通報資訊傳達給上述利害關係者及國家主管機關。WOAH 目標係提供風險溝通與警報，於需要之時機，WOAH 專家團隊將根據制定之標準做出決定，但並不是所有情況都需要發出高級別警報，這需要根據具體情況進行評估。VSAFE 功能如下：

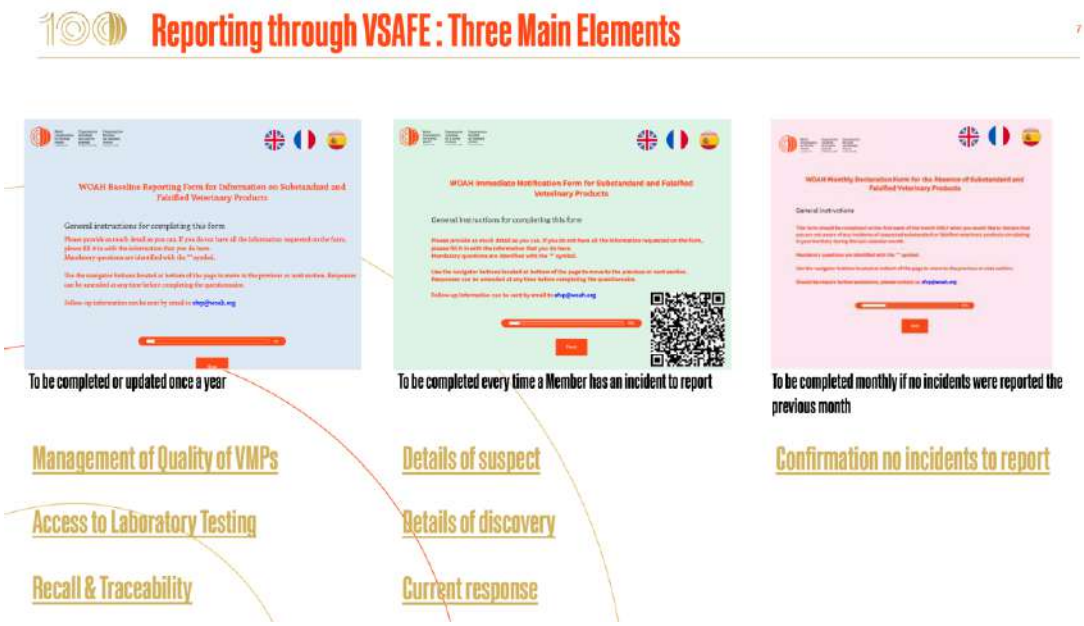
1. 數據管理及分析：WOAH 會員國可以透過 VSAFE 讀取、管控及分析自己國家之數據。
2. 事件資料庫：洲際區域事件資料庫。
3. 公共警報與建議：依據事件狀況，給予建議。
4. 年度報告：每年產出報告與總結。



VSAFE 三大表單

第一份為藍色之基礎資料報表（WOAH Baseline Reporting Form for Information on Substandard and Falsified Veterinary Prouducts）。填報資訊包括該會員國針對動物用藥產品之品質管理、是否有實驗室檢測、是否有動物用藥產品

召回與可追溯性制度。WOAH 目前要求會員國針對基礎報表，每年更新一次，以確保資料係最新的。



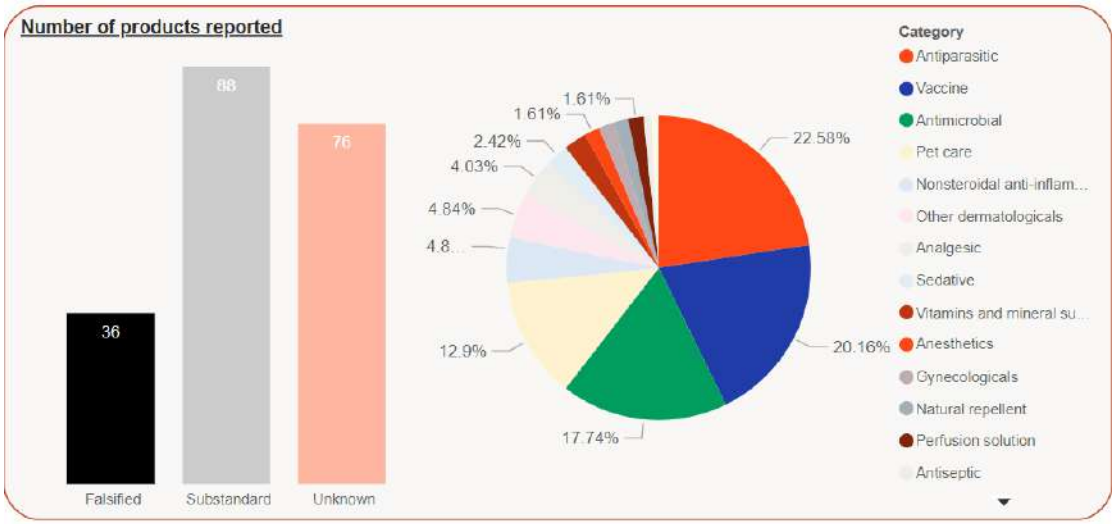
第二份為綠色之即時通報表單（WOAH Immediate Notification Form for Substandard and Falsified Veterinary Prouducts）。這個表單係當您有懷疑或想要通報劣藥或偽藥產品事件時，要填報之表單，包括嫌疑產品之詳細資訊、調查結果之詳細資訊及當前之因對措施。

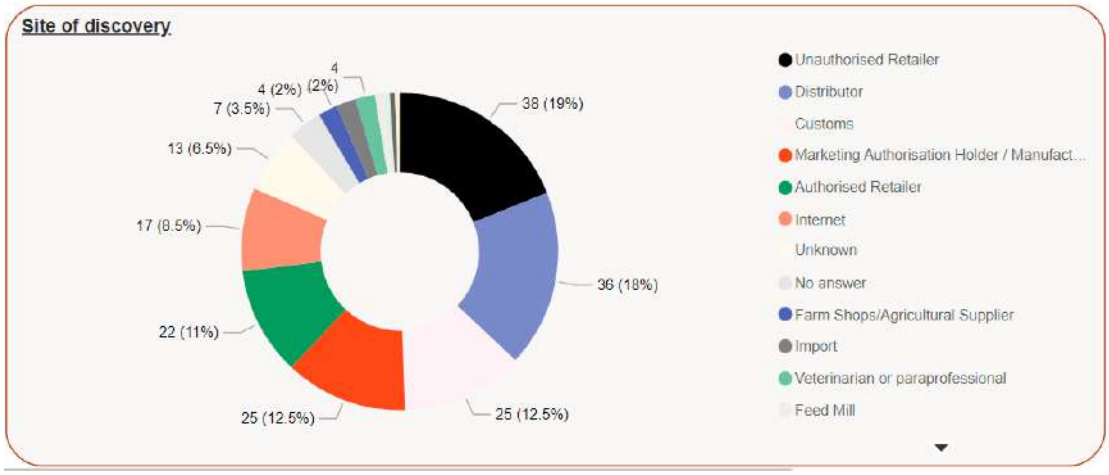
第三份為粉紅色之無事件聲明月報表（WOAH Monthly Declaration Form for the Absence of Substandard and Falsified Veterinary Prouducts）。若前一個月沒有發生任何動物劣藥、偽藥產品事件需通報，則每個月初完成此表單。這主要係為了確認會員國仍持續參與使用 VSAFE 平台，並且 WOAH 能夠了解會員國之需求。

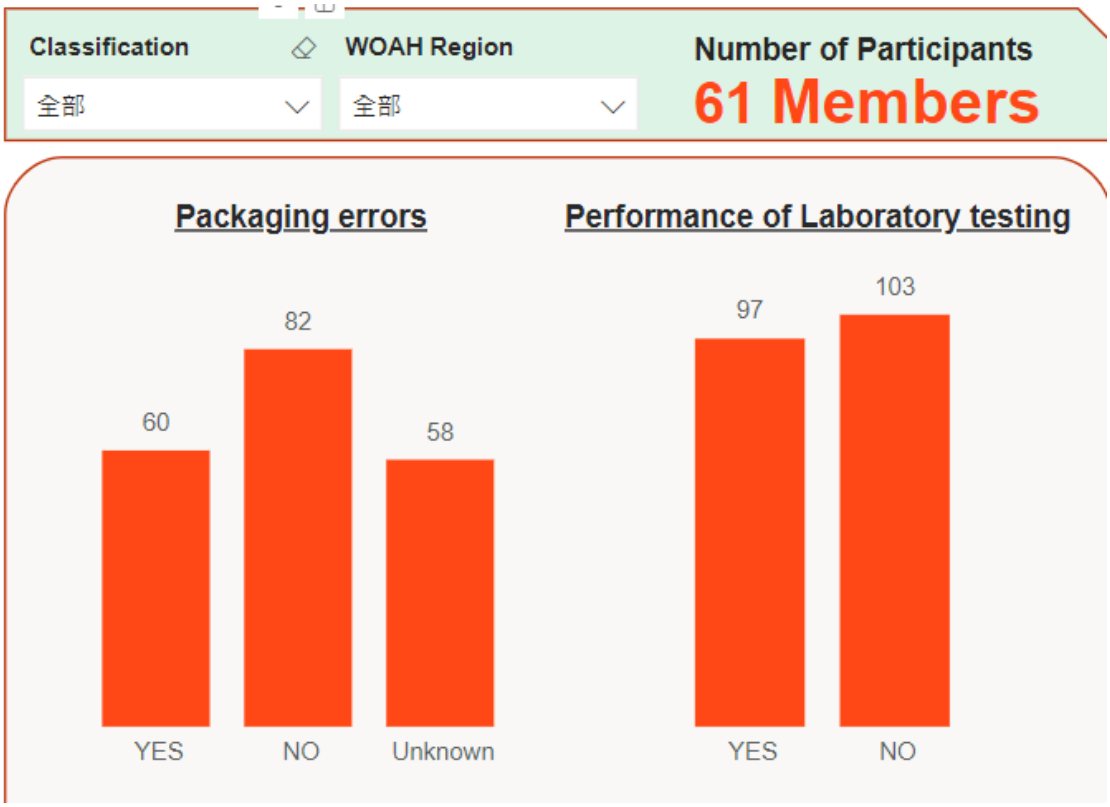
VSAFE 視覺化儀表板

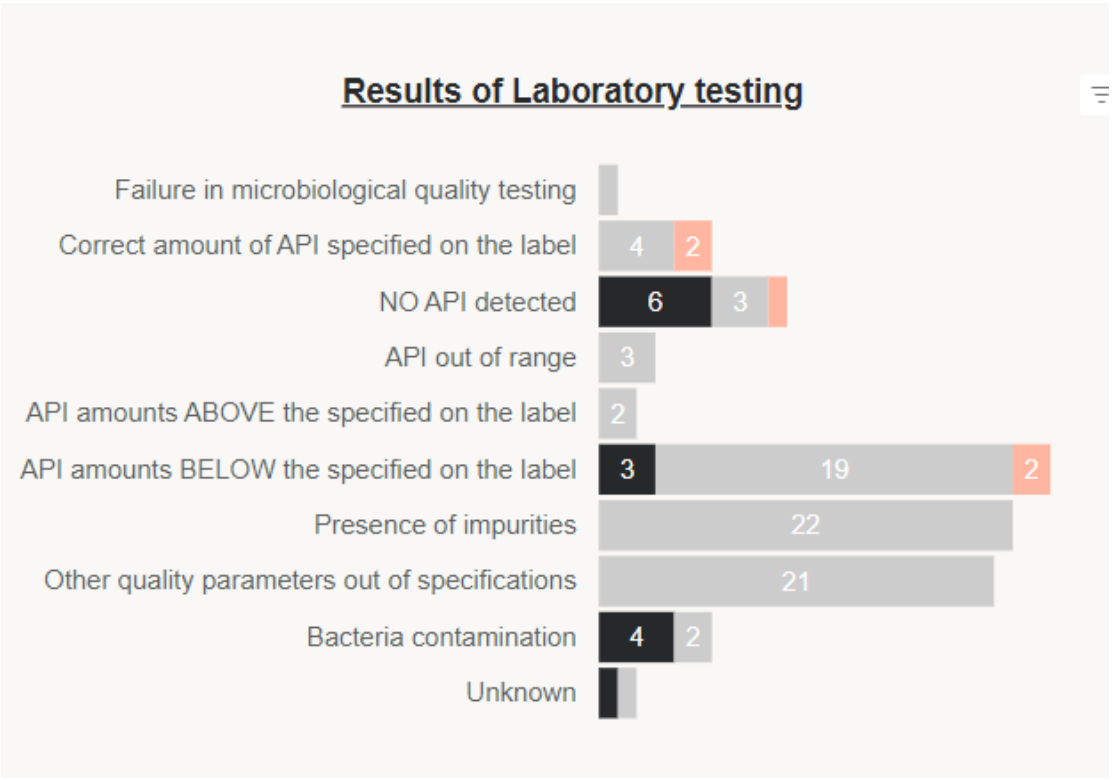
VSAFE 將依據會員國提供之資料，使用 Power BI 軟體製作視覺化儀表板(以下為示意圖)，該視覺化儀表板不會有機密資訊，而係提供簡易資訊讓各會員國看到全球通報情況。儀表板數據包括通報之產品數量（偽藥：N 個、劣藥 N 個、未知：N 個）；通報之產品分類（包括抗寄生蟲藥、疫苗、抗微生物藥物、寵物

護理、NSAID、其他皮膚病藥、止痛藥、鎮靜藥、維生素及礦物質補充品等）；發現地點分類數量統計及佔比（包括未經核准之零售商、經銷商、海關、持證商、經核准之零售商、網路、未知、空白沒有回答、畜牧場商店或農業供應商、進口、獸醫師或獸醫助理、飼料廠）；參加之會員國數量；實驗室檢測結果分類統計。這些數據可以幫助會員國制定監測策略。假設您在 VSAFE 看到在您的區域內有通報疫苗劣藥進口，您可以加強海關之監測，要注意的是，劣藥及偽藥沒有國界，所以我們不僅要關注區域內之情況，尚需關注全球之情況。請使用 VSAFE 平台來幫自己國家做分析。






Classification
全部
WOAH Region
全部
Number of Participants
61 Members
Packaging errors
60
82
58
YES
NO
Unknown
Performance of Laboratory testing
97
103
YES
NO


Results of Laboratory testing
Failure in microbiological quality testing
Correct amount of API specified on the label
4
2
NO API detected
6
3
API out of range
3
API amounts ABOVE the specified on the label
2
API amounts BELOW the specified on the label
3
19
2
Presence of impurities
22
Other quality parameters out of specifications
21
Bacteria contamination
4
2
Unknown

WOAH 之目標係從目前只有參與國之 SharePoint 平台，轉移到更廣泛的系統，這將在未來幾年內完成，讓其他重要利害關係者得以有權限查看相關資料，並了解劣藥與偽藥之處置過程。最終目標為參與之單位包括獸醫師協會、WHO、FAO、國際刑警組織（Interpol）、非政府組織、私部門單位。WOAH 目標不是取代國家主管機關之職責，而是當有需要時，提供支援，並確保報告之品質與和可信度。

VSAFE 資訊技術工具開發

根據與 WHO 及 WOAH 會員國之經驗，WOAH 花了將近兩年時間創建 VSAFE。VSAFE 目前處於試辦階段，WOAH 目前有超過 90 項功能需求及 29 項技術需求，但最重要的是，會員國之意見反饋至關重要。若 WOAH 沒有會員國之反饋，WOAH 將創建一個不符合目的之 VSAFE 平台，造成 WOAH 與會員國之金錢與時間浪費。

VSAFE 開發之功能包括，但不限於：

- 資訊安全：無數據洩漏。
- 替會員國及外部利害關係者提供不同級別之 VSAFE 訪問權限。
- 搜尋已通報之可疑動物用藥產品。
- 針對同一事件之即時通報，自動保存通報與更新。
- 自動通報及事件後續追蹤。
- 若有取得通報案件之圖像，則可上傳圖像。

針對為何 WOAH 會員國應加入 VSAFE？ 優點及權限如下：

VSAFE 功能	會員國	WOAH 夥伴及直接利害關係者	其他身份
有權限查閱自己的資料	✓	✓	✓
公眾警報	✓	✓	✓
年度報告	✓	✓	✓

自行通報	✓	✓	✓
最終驗證之主要聯絡人	✓	✓	✗
可搜尋全部之動物用藥產品通報	✓	✗	✗

WOAH 知道有些國家已經有自己的動物劣藥及偽藥產品監測系統，若會員國已有自己的系統，則可分享任何報告或表單，以減少您的行政工作量。若會員國沒有自己的動物劣藥及偽藥產品監測系統，則 VSAFE 可以作為會員國建置自己國家資訊系統之參考模型。

（十三）試點型動物劣藥、偽藥監測及監控系統 (VSAFE)之緬甸使用經驗分享

由緬甸畜牧繁育及獸醫局之副局長 Dr. Swe Lynn Htet 簡報「試用型 VSAFE 之緬甸使用經驗分享」。

VSAFE 之背景說明

於 2023 年 2 月 22 日至 24 日於泰國曼谷舉行的 WOAH 區域性 ANIMUSE 系統使用培訓期間，WOAH 首次介紹了 VSAFE 系統。緬甸 2023 年 2 月自願參加 WOAH 全球劣藥及偽藥產品資訊及警報系統之第二階段試點計畫。

參加國需辦理之 VSAFE 工作項目

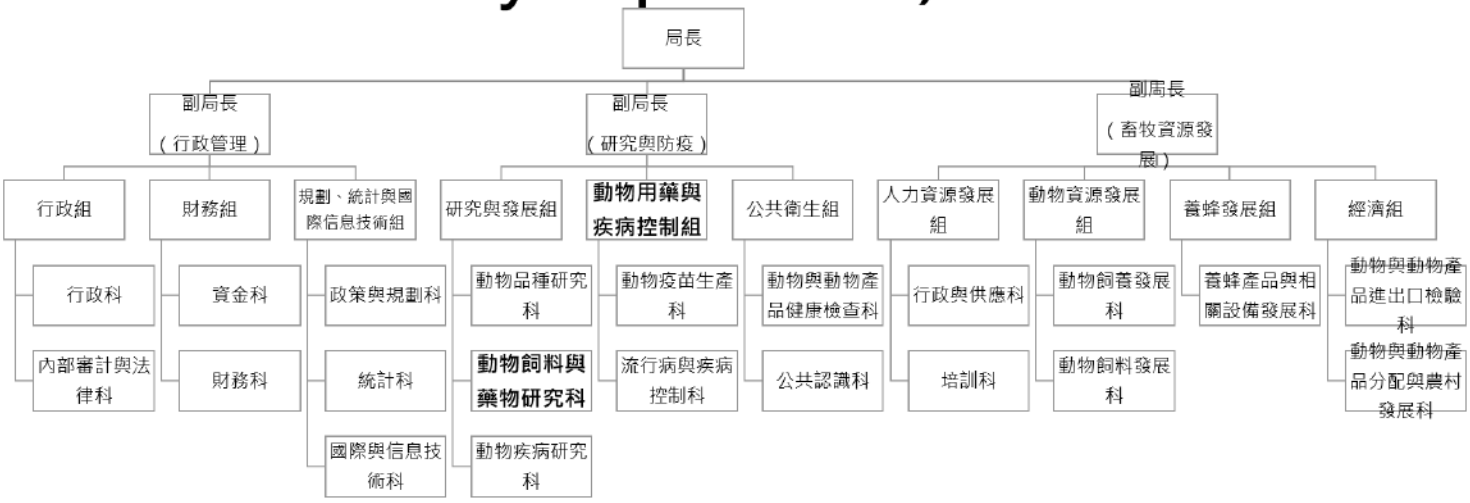
- 每年填報一次 WOAH 之 SFVP 基礎資料報表，填報所需時間約莫 5~10 分鐘，參加國應在 1 月 15 日至 4 月 1 日期間提交。
- 當參加國發現疑似或確定之 SFVP 事件時，則立即提交一份 SFVP 即時通報表，填報所需時間約莫 10~15 分鐘。倘若當下無法取得通報表單所有資訊時，最少應填報以下內容：

  1. 產品名稱及包裝上標示之登記字號。

2. 包裝上標示之製造商。
3. 包裝上標示之批號。
4. 發現之日期及地點。

- SFVP 即時通報表具有開放性之文字框，可供參加國填寫每個事件之其餘相關訊息（例如數量、懷疑為 SFVP 之原因、實驗室檢測執行情形、不良反應檢測等），以便在資源或時間不足之情況下進行通報。
- WOAH 團隊在收到 SFVP 事件通報後，會提供具有「事件編號 (reference number)」之電子郵件。參加國可使用該事件編號，更新同一事件之後續資訊及追蹤辦理情形。
- 修訂 WOAH 之 SFVP 即時通報表，以確保產品所有規格及類別選項均充分呈現並設計符合目的。
- 若參加國已經有一個國家級 SFVP 監測系統，該國可提供其目前所使用之任何模板表單給 WOAH。WOAH 目標是建立一個最終系統，允許各會員國將該國表單資訊直接填至 WOAH 之 VSAFE 系統中，進而減少通報者之行政負擔。
- 若某月份無任何 SFVP 事件，參加國必須填報某月無 SFVP 事件之聲明表，僅需 1 分鐘時間，即可完成填報。此表單必須在每個月結束後之 7 天內提交。
- 參加國至少每年提供一次數據收集工具之反饋，並指出其他應考慮的問題，以供 WOAH 進行 VSAFE 資訊系統改進、完善。

緬甸畜牧繁殖及獸醫局 (Livestock Breeding and Veterinary Department) 組織圖



WOAH VSAFE 試點第二階段之緬甸經驗分享

1. 總體而言，目前使用 VSAFE 平台，使用情況良好。
2. SFVP 通報表之設計（藍色、綠色、粉紅色表單）易於遵循且具使用者友善。由於緬甸於使用 VSAFE 階段內，沒有疑似或確定之 SFVP 於市面上流通，故緬甸係提交無 SFVP 事件（粉紅色表單）之月報聲明。
3. 緬甸刻正密切與其他相關部門和組織合作與協調，以減少並遏制 SFVP 之非法買賣。

（十四）農業化合物及動物用藥法規制度之紐西蘭經驗分享

由紐西蘭初級產業部食品安全處之 Warren Hughes 博士簡報「紐西蘭農業化合物及動物用藥品法規制度」。

農業化合物及動物用藥品組

農業化合物及動物用藥品組（Agricultural Compounds and Veterinary Medicines Team, ACVM Team）隸屬於紐西蘭初級產業部（Ministry for Primary Industries, MPI）食品安全處，為 ACVM 法之主管機關，主要工作項目為：

1. 負責農業化合物之登記，包括動物用藥品、農業（園藝）化學品、脊椎動物毒素（管制害蟲之產品）。
2. 獨立之科學評估及對產品管理所有技術方面之審查，包括製造、進口、銷售與使用。
3. 政策級標準制定，包括向國際論壇（VICH、OECD 和 WOAH）提供意見。
4. 根據 2014 年食品法，評估及制訂食品中藥物最大殘留容許量（MRLs）。

何謂農業化合物？

係指任何物質或物質之混合物.....，其目的為：

1. 管理或撲滅害蟲。
2. 維持、促進或調節生產力及繁殖。
3. 滿足營養需求。
4. 標記、操作、捕捉或使動物失去活動能力。
5. 診斷、治療及預防疾病。
6. 任何用於生鮮初級農產品收割後處理之物質。
7. 任何在動物或其產品上使用的物質，以直接管理動物或其產品。

農業化合物及動物用藥品法及其相關法規（**The ACVM Act and Regulations**）

ACVM 法之目的為：

1. 預防或管理與使用農業化合物相關之風險，包括：
   (1) 公共衛生風險。
   (2) 初級產品貿易風險。
   (3) 動物福利風險。
   (4) 農業安全風險。

2. 確保使用農業化合物不會導致國內食品違反殘留標準。
3. 確保提供消費者足夠關於農業化合物之訊息。

透過產品登記以進行風險管理

動物用藥產品登記分為管制性與非管制性，如下表。

非管制性動物用藥品	管制性動物用藥品
風險管控係需要透過積極之監管，但若飼主遵循所有標籤指示，則可管理使用風險，包括食品中藥物殘留風險。	風險管控係需要積極之監管，並且需要獸醫師進行診斷、治療及監測，並依據產品標籤指示使用。
僅限涉及動物福利時，使用者得依據專家建議，標籤外使用。	產品之所有使用均由獸醫師主導，所有風險亦由獸醫師進行管理。
可以「非處方」銷售產品。	僅限有獸醫師處方之情況下銷售產品

產品登記所需資料

所有需要登記之產品都必須經過風險評估及審核過程，評估內容包括：

1. 配方化學和製造（良好製造規範, GMP）。
2. 效力。
3. 對象動物或植物之安全性。
4. 殘留（若適用）。
5. 所需產品或特定風險之數據（抗微生物藥物抗藥性, AMR）

產品登記後之法規

1. 廠商必須透過以下方式維持其產品登記：
   (1) 透過核准變更之方式，使所有產品資訊及標籤維持在最新資料。
   (2) 通報所有現場使用藥物之不良反應事件報告（Adverse Event Reportings, AERs），並通報來自海外之重大 AERs。

(3) 提供所有可能影響產品登記或風險概況之新資訊。

2. 「農業化合物及動物用藥品法」核准紐西蘭主管機關（ACVM），得於產品登記後，執行以下措施：

(1) 藥物產品召回。

(2) 暫停產品登記。

(3) 發布禁令通知。

(4) 評估藥物不良反應事件。

(5) 重新評估已登記之藥物產品。

3. 紐西蘭主管機關（ACVM）依法得：

(1) 要求廠商所有產品必須符合法規，包括產品之廣告宣傳內容。

(2) 評估產品及/或藥物有效成分於國內及國際發生之問題。

(3) 農業化合物及動物用藥品組（ACVM）與初級產業部（MPI）其他單位，進行跨部門合作，包括食品中藥物殘留監測計畫、動物產品、藥物產品核准上市。

藥物不良反應事件（Adverse Events）

藥物不良反應事件係指在動物或植物中任何不利且非預期之觀察，包括：

1. 使用藥物或治療後之副作用。
2. 動物或農作物之安全問題。
3. 食品中之藥物殘留問題。
4. 藥物效能不足。
5. 該藥物與其他產品之相互作用。

已登記藥物產品之重新評估

紐西蘭主管機關，可於下列情況下，執行已登記藥物產品之重新評估：

1. 初級產業部（MPI）登記產品後之監測有所發現，包括藥物不良反應事件、GMP 稽核與食品中藥物殘留監測。
2. 新出現之國內風險，包括於檢測藥物殘留或使用藥物產品之其他問題。

3. 新出現之國際風險，國外化合物禁令、藥物使用限制改變了貿易風險。

登記產品重新評估結果之後續處置

1. 維持現狀。
2. 修正產品資訊，例如標籤說明或警告、停藥期。
3. 修正產品登記管理，例如產品登記之新要件、狀態變更；放寬限制或增加限制。
4. 撤銷產品登記。

紐西蘭主管機關之違規查核監測級通報工具

1. 持證商（MAH）之通報表，將其違規產品通報給主管機關。
2. 民眾線上通報表，通報可能違規之產品或違法行為。
3. 藥物不良反應事件通報。
4. 場所之稽核與檢查。
5. 一般而言，不會對藥物產品執行例行性檢測，除非發現某些產品不符合規定或為假冒產品，並且調查顯示需要進一步檢測。

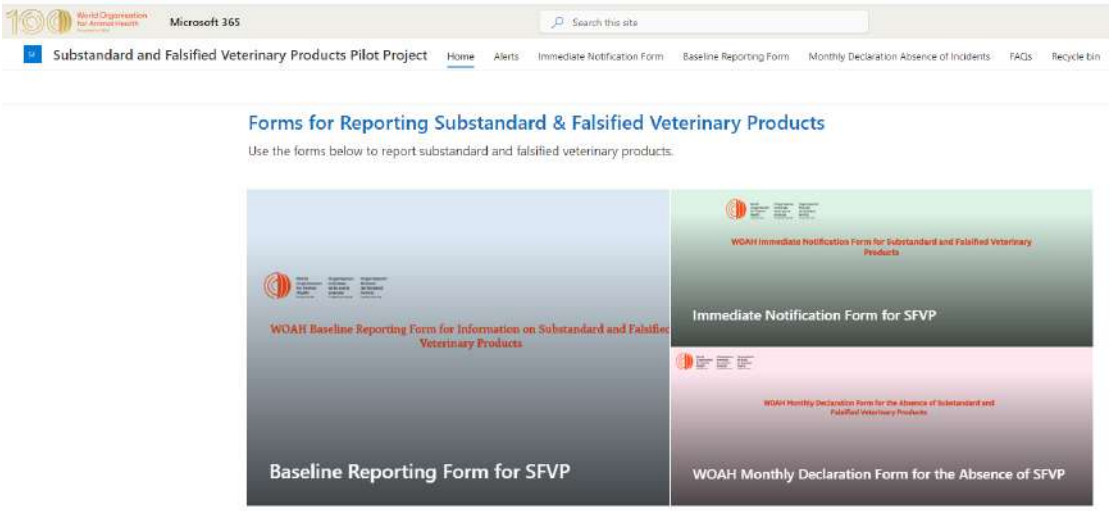
紐西蘭使用 VSAFE 試點系統（VSAFE Pilot System）之經驗分享與意見回饋

1. 紐西蘭截至報告當日，很少收到市面上劣藥與偽藥產品通報。自 VSAFE 啟動以來，無任何通報。注意：紐西蘭政府不做例行性額外檢測。
2. 因此，紐西蘭尚無需通報劣藥或偽藥產品。
3. 由於紐西蘭未曾使用 VSAFE 即時通報表，因此無法對此表單之使用發表評論。
4. VSAFE 每個月之無 SFVP 事件聲明表很容易完成填報。
5. 當發布警報時，若能在開頭用項目符號點及做摘要，將有助於我們快速分類和評估風險。

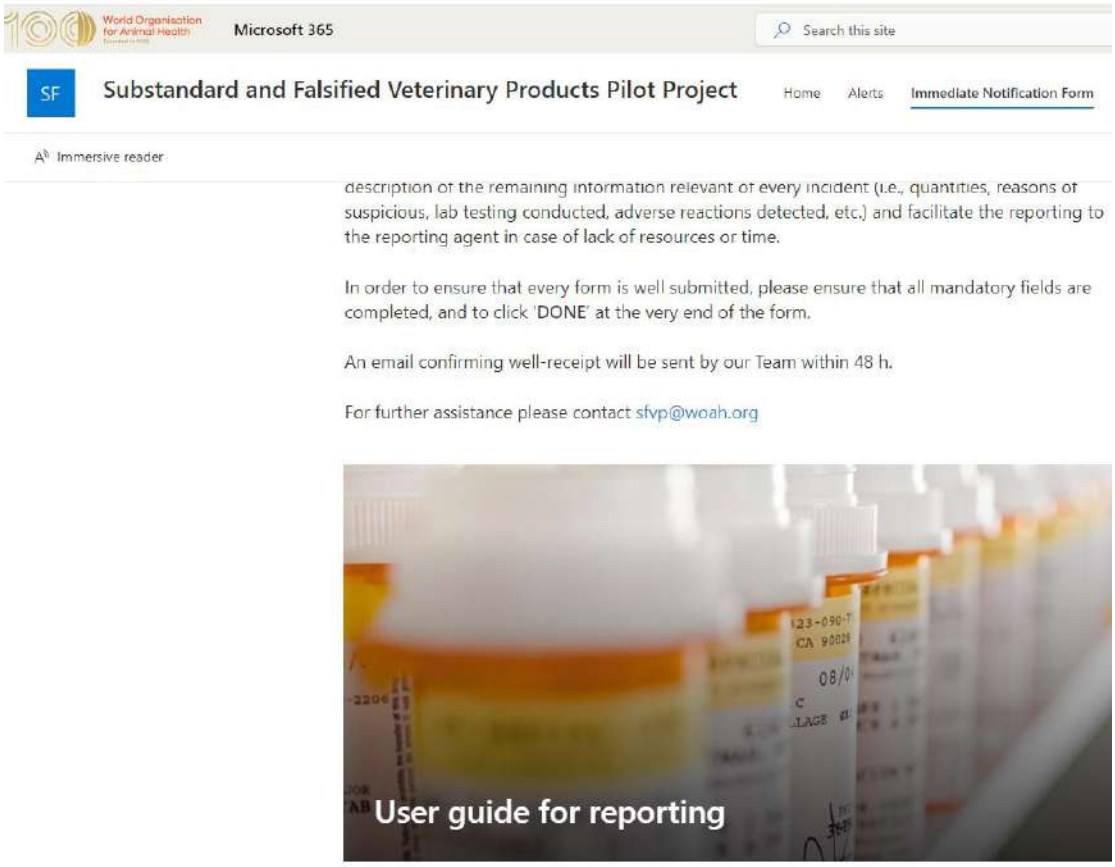
（十五）WOAH 動物劣藥及偽藥（SFVP）即時通報表 ---- 按情境案例 1 練習填報

由 WOAH 的 AMR 及動物用藥產品部門之 Andrés García Campos 計畫經理簡報「WOAH 動物劣藥及偽藥即時通報表（WOAH Immediate Notification Form for SFVP）」。

會員國自願參加 WOAH 之 VSAFE 試點計畫，WOAH 即會給予會員國權限，申請 VSAFE 網站之帳號與密碼。登入後，挑選綠色表單，即為 SFVP 即時通報表（如下圖）。



下方有使用者通報指引（User guide for reporting）供參考（如下圖）。倘若有相關疑義，可洽詢 info@woah.org。



WOAH 了解在實務上，針對 SFVP 事件，政府機關通常於第一時間可能無法掌握所有資訊，但在填報 WOAH 之 SFVP 即時通報表，至少應提供下列資訊：「產品名稱」、「製造商」、「批號」、「發現日期及地點」。表單欄位以星號*標註者為必填項目。其餘欄位資訊，則儘可能提供。SFVP 即時通報表分為五個部分，如下：

1. **一般資訊**：是否有任何理由導致該 SFVP 事件無法與他人分享？
2. **嫌疑產品之詳情**：
   (1) 品牌名稱。
   (2) 有效成分名稱及力價 (strength)。
   (3) 藥物劑型及投藥途徑。

(4) 持證商或（MAH）或製造商。

(5) 產品識別資訊：

- 登記字號。
- 批號。
- 有效期限。
- 製造日期。

(6) 對象動物（包括標籤內及標籤外使用）。

(7) 是否有照片可提供？

3. **發現詳情**：

(1) 發現日期。

(2) 通報給主管機關之日期。

(3) 藥物之單位類型及數量。

(4) 發現原因。

(5) 發現地點。

(6) 資料來源。

4. **初步評估**：

(1) 產品是否登記？

(2) 包裝或標籤是否有錯誤？

(3) 是否進行了實驗室檢測？

5. **現階段之因應措施**：

(1) 是否召回產品？

(2) 是否發布警報？

(3) 是否有不良反應事件？

SFVP 即時通報表第 10 題為詢問 WOAH 會員國是否同意與他人分享資料，此題為必填欄位。表單內容如下：

***10. 是否有任何理由導致此通報之訊息無法與 WOAH 及他人分享？**

☐ Yes

☐ No

備註：若 WOAH 會員國選擇「No」，則表示您同意該訊息可以與其他國際組織（例如世界海關組織、國際刑警組織）以及 WOAH 參與國分享，並且在揭露通報會員國名稱之情況下進行資訊分享。若 WOAH 會員國選擇「Yes」，則接續回答第 11 題。

11. 請說明若訊息不能完全分享給他人，則可以分享給誰及如何分享：

☐ 可以與其他國際組織（例如世界海關組織、國際刑警組織）以及參加 WOAH VSAFE 之國家在洲際區域層級分享，且不揭露通報會員國之名稱，但揭露受影響之洲際區域。

☐ 不能與其他國際組織（例如世界海關組織、國際刑警組織）分享，但可僅與參加 WOAH VSAFE 之國家分享，且不揭露通報會員國之名稱，但揭露受影響之洲際區域。

☐ 不能與其他國際組織（例如世界海關組織、國際刑警組織）分享，但可僅與參加 WOAH VSAFE 之國家分享，且不揭露通報會員國之名稱。

☐ 其他（請具體說明）：_____

備註：在以上所有情況下，參加 WOAH VSAFE 之國家同意該訊息可用於編寫 WOAH 之年度公開報告，描述 SFVP 於洲際區域及全球範圍內之存在，並匿名處理（即不揭露通報 SFVP 之國家）。

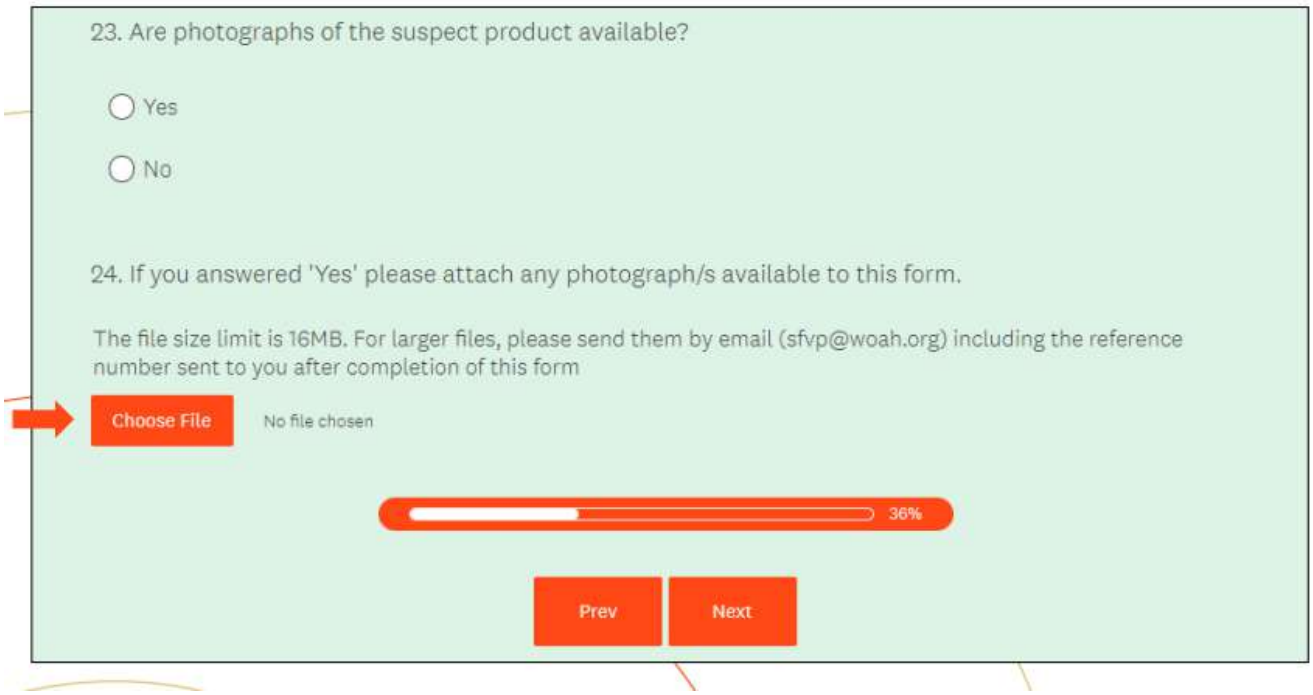
23. 是否有嫌疑產品之照片？

☐ Yes

☐ No

24. 若您勾選「Yes」，則請將任何可用之照片上傳至此表單。

備註：照片檔案大小限制為 16 MB。針對較大之照片檔案，請透過電子郵件發送至 (sfvp@woah.org)，並請於該電子郵件註明本 SFVP 之事件編號（reference number），該事件編號會在您完成本表單送件後，透過電子郵件寄送給您。



填寫 SFVP 即時通報表，在理想情況下係具備下列項目：

1. 於拍攝照片中，放置尺寸大小之參考物件。
2. 至少應填寫以下資訊：
   (1) 品牌名稱 (Brand Name)。
   (2) 有效成分之名稱及力價 (Name & Strength of API)。
   (3) 持證商或製造商之名稱（Name of MAH/manufaturer）。
   (4) 產品識別資訊（Product identification）：
   - 登記字號（Registration Number）。
   - 批號（Batch Number）。
   - 有限期限（Expiry date）。
   - 製造日期（Date of manufacturing）。
3. 產品檢測之結果與其標籤或包裝不一致。

SFVP 即時通報表之包括多選、單選、文字輸入及下拉式選單，如下所示。

多選題

30. 若已做實驗室檢測，則結果為何？

☐ 有效藥物成份（Active Pharmaceutical Ingredient, API）數量與標籤之標示一致。

☑ API 數量超過標籤之標示（過量）。

☐ API 數量低於標籤之標示（不足）。

☐ 檢測到標籤上未標明之其他 API。

☐ 未檢測到 API。

☑ 存在與規格不符之雜質

☐ 細菌污染。

☐ 其他（請具體說明）：_____

單選題

27. 是否已聯繫製造商或持證商（marketing authorization holder, MAH) 確認他們是否生產了該動物用藥產品？(即使該製造商位於您國家以外之地方)

☐ 是，他們確認「沒有」生產該產品。

☑ 是，他們確認生產了該產品。

☐ 是，但尚未收到回應。

☐ 否，尚未聯繫。

☐ 不詳（Unknown）。

文字輸入

31. 發現日期（如果知道，則請填寫）（例如：DD/MM/YYYY）請遵守格式

_____

32. 向獸醫主管機關通報之日期(如果知道,則請填寫)(例如:DD/MM/YYYY)

_____

下拉式選單

37. 發現嫌疑動物用藥產品之地點（即在供應鏈中之哪個環節發現或購買了嫌疑之動物用藥產品）（盡可能避免以空白回應）

> 海關

> 運銷商（Distributor）

> 畜牧場商店或農業供應商

> 飼料廠

> 進口商

> 網路

> 持證商或製造商

> 藥局

> 零售店（經核准銷售動物用藥品之店）

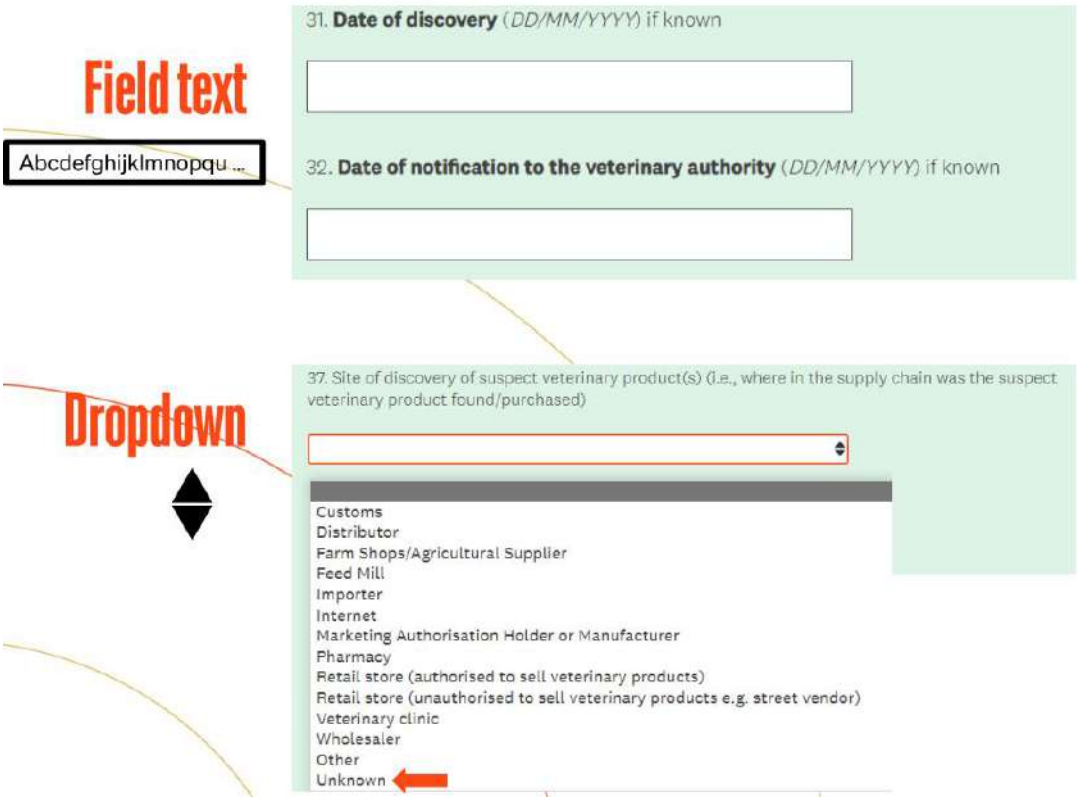
> 零售店（未經核准銷售動物用藥品之店，例如路邊攤）

> 獸醫診所

> 批發商

> 其他

> 未知



VSAFE 參與國提交 SFVP 即時通報表後，將會在 48 小時內收到附有「事件編號」之確認信，如下：

寄件者：sfvp@woah.org

收件者：drgentil@zzz.org

抄送：woahregional@woah.org

主題：WOAH 動物劣藥及偽藥產品即時通表之收到確認 – 事件編號 IN012345ZZZ-01

附件：IN012345ZZZ-01.pdf（114 KB）

Dr. Gentil 您好

非常感謝您提交 WOAH 動物劣藥及偽藥產品即時通報表。我們的團隊已確認收到您的通報。請查收您的紀錄副本。

您的事件編號是 **IN012345ZZZ-01**。請在聯繫我們團隊時使用此事件編號，以便我們更新該事件通報表之訊息。若有相關問題需要進一步釐清，則我們的團隊將與您聯繫。

如果您需要進一步協助，請隨時聯繫我們：sfvp@woah.org。

Kind Regards,

WOAH – SFVP Team

12, rue de Prony, 75017 Paris, France
T. +33 (0)1 44 15 19 85

https://www.woah.org/en/home/

World Organisation for Animal Health
Founded in 1924

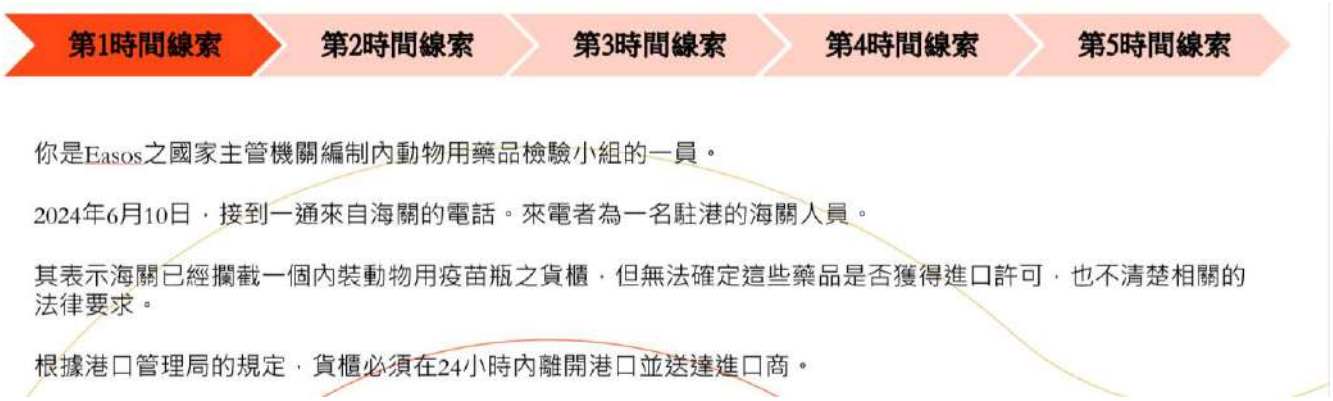
請使用情境案例 1 來做下列工作：

1. 登記加入 VSAFE，並熟悉操作介面。
2. 請根據 WOAH 動物劣藥及偽藥即時通報表之提問，儘可能提供相關資訊。
3. 使用反饋及建議表單，強調以下事項：
   (1) 對 VSAFE 優化之任何反饋及建議。
   (2) 對即時通報表優化之任何反饋及建議。

*（十六）*動物劣藥及偽藥產品事件之情境案例 2 演練

本章節由 WOAH AMR 及動物用藥產品部計畫經理 Dr. Andrés García Campos 主持並引導與會人員分組討論與報告「劣藥與偽藥產品事件之情境演練案例 2」。如同 6 月 12 日所分組進行之情境案件 1 之演練模式再進行不同樣態之情境由各小組進行討論，所參討論成員由日本代表、馬來西亞代表、澳洲代表及我國代表共 8 人進行分組討論，並由我國代表該小組分享討論結果。

- 本分組討論規則同前次情境案例演練，每段線索釋出後，小組就所獲得資訊，討論可確認事實、遺漏之資訊、可鑑別風險以及可採取之行動。每階段討論時間 5 分鐘。
- 第 1 時間線索，其揭露資訊及討論結果如下：



Update 1 | Update 2 | Update 3 | Update 4 | Update 5

可確認事實	所遺漏之資訊	可鑑別之風險	所該採取行動
查獲一個內裝有疫苗之貨櫃	1. 是否有疫苗進口或轉運的文件？ 2. 進口商的資料以及疫苗的詳細信息，如名稱、品牌、適應症、製造商等。還有海關信息， 3. 疫苗運送之起訖地點與國家	1. 疫苗的儲存條件是否適當，溫度控制如何？ 2. 疫苗之詳細信息為？是細菌疫苗、病毒疫苗或基因產品？是否為活疫苗或滅毒、死毒疫苗？	1. 在事實釐清前，扣留該疫苗。 2. 該疫苗是否需要檢疫

- 第 2 時間線索，其揭露資訊及討論結果如下：

第1時間線索 | 第2時間線索 | 第3時間線索 | 第4時間線索 | 第5時間線索

你所在機關受邀於次日上午進行緊急檢查。因為該貨櫃必須於當日下午16:00前離開現場。

在打開貨物後，發現這批貨物內含50箱名為「CLEARRABIES」之犬用狂犬病死毒疫苗。
每箱內含10瓶（即10 dose），每dose含死毒之G52株狂犬病病毒，其力價為≥1 I.U./dose。
進一步檢查，見部分箱子顏色有所差異。

產品標籤資訊如下:

名稱: CLEARRABIES
註冊號碼: 1108-VC
批號: 69007-ADF
製造日期: 2022年12月
有效期限: 2025年12月
製造商: Vaccbest S.A.
上市許可持有人 (MAH): PHARMVACDOG LIMITED
儲存特別注意事項: 儲存並運輸於冷藏環境（2°C至8°C）

貨物文件僅有送達地址：「Easos，Bravos市，Arya's工業區，253號地號」。無進口商或出口商名稱。

Update 1 | Update 2 | Update 3 | Update 4 | Update 5

可確認事實	所遺漏之資訊	可鑑別之風險	所該採取行動
1. 無進口商或出口商相關相關信息； 2. 部分箱子顏色不同； 3. 運輸貯存方式不正確，疫苗需要儲存在2-8°C的環境中，但大部分貨物只能提供室溫條件。	1. 運輸條件； 2. 進口商及出口商之相關訊息。	1. 不當之運輸、儲存條件可能會影響疫苗品質； 2. 箱子顏色不同可能代表著這些疫苗非原廠產品； 3. 若疫苗為偽造，品質可能會有問題。	1. 扣留該疫苗； 2. 聯繫上市許可持有人確認疫苗是否由他們生產。

- 第 3 時間線索經討論後，其時間線索及討論結果如下:

第1時間線索 | 第2時間線索 | **第3時間線索** | 第4時間線索 | 第5時間線索

當駕車回機關途中，偶然經過Arya's工業區的253號地號。發現該地點為一座中型倉庫，周圍設有良好的圍欄，但外觀無任何標識。

根據國家登記的動物用藥品資料庫，確認到產品「CLEARRABIES」之上市許可持有人（MAH）為PHARMVACDOG LIMITED公司。

經洽詢PHARMVACDOG LIMITED負責人後，確認貨櫃非屬該公司所申請輸入。

由於疫苗已被主管機關扣押，等待進一步的調查。而貨櫃已經被清關並離開港口。

另該國目前正致力於推動狂犬病控制計劃。

Update 1 | Update 2 | **Update 3** | Update 4 | Update 5

可確認事實	所遺漏之資訊	可鑑別之風險	所該採取行動
1. 送貨地點為無任何標示之倉庫； 2. 許可持有者未進口這些疫苗。	倉庫中的儲存條件未知，	即使該疫苗由許可持有者合法生產，但若以非法方式進口，仍可能影響該國狂犬病防疫及生物安全。	調查該疫苗的上市許可持有人，確認疫苗是否由其生產

- 第 4 時間線索經討論後，其時間線索及討論結果如下:

第1時間線索 | 第2時間線索 | 第3時間線索 | **第4時間線索** | 第5時間線索

2024年6月12日，機關決定對Arya's工業區253號之倉庫展開檢查。
從外觀看，倉庫似乎是空的，在工業區保全人員允許下，進入了該倉庫。

倉庫缺乏通風設施、窗戶或冷藏裝置。

除此之外，更發現了其他動物用藥品，如：
- 1,000箱之「CLEARRABIES」，與前述查獲之貨品相同，但儲存於室溫中。
- 30瓶（1升）TICKATIK外用液劑，用於控制牛隻蜱蟲感染。

與「CLEARRABIES」實際製造商Vaccbest S.A.溝通後，確認所分享的產品照片中的產品是偽造的。

另於倉庫中，發現一份租約，根據其資訊顯示該倉庫出租人為「Tyrion Lannister」。

Update 1 | Update 2 | Update 3 | **Update 4** | Update 5

可確認事實	所遺漏之資訊	可鑑別之風險	所該採取行動
1. 倉庫缺乏適當的儲存條件； 2. 已確認「CLEARRABIES」為偽造疫苗； 3. 倉庫由Tyrion Lannister租用； 4. 倉庫還儲存另一種名為『TICKATIK』之動物用藥品。	1. 進口人身份仍未知。 2. 無「TICKATIK」相關資訊，尚無法確認是否為偽造藥品。	1. 偽造疫苗可能缺乏品質和效力。 2. 使用偽造之狂犬病疫苗，音效力未知，可能導致該國狂犬病防疫失控。	1. 調查Tyrion Lannister所租用倉庫及其內儲存貨品情況。 2. 聯繫TICKATIK的許可持有者確認產品真偽。 3. 將這「CLEARRABIES」及『TICKATIK』送實驗室分析，確認品質。 4. 封存貨品並採取法律行動。與其他主管機關，如警察，合作進行調查。

- 第 5 時間線索經討論後，其時間線索及討論結果如下:

第1時間線索 | **第2時間線索** | **第3時間線索** | **第4時間線索** | **第5時間線索**

經確認，倉庫出租人Tyrion Lannister為SERVIAGRO S.L.公司之授權獸醫，該公司營業場所位於Arya's工業區266號地塊，距離之前查獲藥品之倉庫僅距離2街區。

由於SERVIAGRO S.L.公司非屬核准之販賣業者，故亦無任何進口通知。

此外，Dr. Lannister亦未被列為任何動物用藥品進口商之負責人。

機關隨後對SERVIAGRO S.L.進行了檢查，並在其場地後方的貯存地點中發現了25包CLEARRABIES和75瓶TICKATIK。上述產品之異常情況與在Bravos市Arya's工業區253號地塊查獲的產品相似。

當把本情況通報VSAFE報告後，WOAH SFVP團隊指出:
已有兩個其他國家報告了偽造之CLEARRABIES情形；
另有七個國家也報告了TICKATIK之偽造情況。

Update 1 | Update 2 | Update 3 | Update 4 | **Update 5**

可確認事實	所遺漏之資訊	可鑑別之風險	所該採取行動
1. SERVIAGRO S.L公司地址與倉庫不同； 2. SERVIAGRO S.L.公司為Tyrion Lannister所持有，但並經官方授權之販賣業，無權進行動物用藥品進口和販賣； 3. SERVIAGRO S.L.公司中發現與倉庫相同產品。	1. 製造商仍未知； 2. 疫苗和其他產品的流通記錄尚未掌握。	1. 偽造疫苗之品質及生物安全問題； 2. 偽造疫苗出現於多個國家，已成為全球性問題。	1. 確認Tyrion之前是否銷售過相同的產品，追踪銷售信息，並向公眾發出警告避免使用相關產品； 2. 向VSAFE通報； 3. 追踪是否有犬隻已使用偽造疫苗； 4. 調查其他偽造藥品，如TICKATIK。

（十七）PANGEA 行動 — 應對動物劣藥、偽藥之一種方法

由國際刑警組織（Interpol）統籌員（Coordinator）Chi Wang Lam 簡報「假冒商品與全球健康計畫（Illicit Goods & Global Health Programme, IGGH）公共衛生與藥物犯罪：PANGEA 行動 — 應對動物劣藥、偽藥之一種方法」。

你期望政府會做什麼？你期望政府僅僅通報偽藥、劣藥案件？還是期望政府徹底調查供應鏈，找出幕後的犯罪分子，並將他們犯繩之以法。我們需要跨部門合作才能做到這一切，僅僅是一個部門係無法做到。

我的第二個問題是，關於昨天的情境演練案例 1，提到在辦公室和倉庫的檢查。你打算做什麼？你是否有能力調查電腦？也許你們之中有一些人可以。但我相信你們許多人是公務獸醫師。如果你需要聯繫警方，請他們幫助你扣押電腦，看看電腦中存儲了什麼。從電腦中挑選出一些關鍵字，看看這台電腦上的商店做了哪些交易及過去紀錄。

國際刑警組織之全球結構

1. 比利時的布魯塞爾 — 國際刑警組織駐歐盟特別代表辦公室
2. 荷蘭的海牙 — 國際刑警組織駐歐洲刑警聯絡局
3. 奧地利的維也納 — 聯絡辦公室
4. 衣索比亞的阿迪斯阿貝巴 - 國際刑警組織駐非洲聯盟代表
5. 新加坡 — 國際刑警組織全球創新綜合體
6. 肯亞的內羅比 — 地區辦事處
7. 辛巴威的哈拉雷 — 地區辦事處
8. 喀麥隆的雅溫得 — 地區辦事處
9. 象牙海岸的阿比讓 — 地區辦事處
10. 巴巴多斯的布里奇敦 — 國際刑警組織加勒比地區聯絡辦公室
11. 阿根廷的布宜諾斯艾利斯 — 地區辦事處
12. 薩爾瓦多的聖薩爾瓦多 — 地區辦事處
13. 美國的紐約 — 國際刑警組織駐聯合國代表
14. 法國的里昂 — 總秘書處

國際刑警組織透過安全網絡連結 196 個會員國（如下圖）。

國際刑警組織在每個會員國都設有一個**國家中央局（National Central Bureau, NCB）**，這是各會員國針對國際刑警組織活動之聯絡窗口，這個國家中央局為國家警察的一部份，這個國家中央局可與其他國家中央局溝通，也可以與國際刑警組織的總部溝通。國際刑警組織的總部在法國的里昂。國家中央局透過安全全球警察通信網絡（稱為 I-24/7），將他們的國家執法機關與其他國家、總秘書處連接起來。現今許多犯罪具跨國性質，如網路犯罪、逃犯或被有組織犯罪集團推動之非法商品。當犯罪超出他們的國家管轄範圍時，則那個國家需要國際上的支援來解決犯罪問題。

如果你想進行調查，你認為這是一個涉及其他國家之案件，或者你想讓國際刑警組織支援你進行調查。首先，你必須做什麼？你不能直接打電話給我（國際刑警組織），你必須聯繫你的國家中央局。透過他們，他們會將你的請求發給我們（國際刑警組織）或其他國家中央局。現在問題來了，有多少人知道你們國家中央局的聯絡窗口？如果你想知道你的國家中央局，請隨時聯絡我知道，我可以請你的國家中央局聯繫你，以利將來若你想與警察合作，甚至與國際刑警組織合作。

國際刑警組織的核心

國家中央局（NCB）是國際刑警組織及其運作方式之核心。他們從其他 NCB 尋求所需的訊息，以幫助調查他們自己國家之犯罪或罪犯，並分享刑事數據資料和情報以協助其他國家。作為全球調查的一部分，NCB 與以下機關合作：

- 他們自己國家之執法機關
- 世界各地的其他 NCB 和分局
- 國際刑警組織總秘書處在全球的辦事處

NCB 還可以為他們自己國家的警察開發培訓計畫，以提高對國際刑警組織活動、服務和資料庫之認識。

共享犯罪數據資料

NCB 將國家犯罪數據提送至我們的全球資料庫，這些數據符合各自國家之法律規定，確保數據之準確性，並在適當時間以正確之方式放在正確的地方，從而使警方能夠識別趨勢、防止犯罪或逮捕罪犯。例如，國際刑警組織的紅色通緝犯令會提醒所有國家警方。如果你想了解更多，你可以訪問我們（國際刑警組織）的網站。

國際刑警組織連接

我們（國際刑警組織）透過技術和人員連接世界各地的警察，跨越司法管轄區、時區和語言的障礙。國際刑警組織是唯一有核准和技術基礎設施在全球範圍內共享警務訊息之組織。所有 196 個會員國均透過一個稱為 I-24/7 之安全通信系統連接在一起，並與國際刑警組織的總秘書處保持聯繫。這也使各會員國能夠實時訪問國際刑警組織之資料庫及服務。我們（國際刑警組織）還協調不同犯罪領域之警察及專家網絡，這些人透過工作小組和會議聚在一起，分享經驗和想法。

國際刑警組織賦能

國際刑警組織為警察提供應對當前挑戰所需之知識、技能和可持續工具。國際刑警組織支援調查，例如法醫鑑定、協助在全球範圍內定位逃犯，並為地面行動提供協調支援。培訓是國際刑警組織工作之重要部分，這樣會員國就能高效地使用國際刑警組織的服務，並將最佳做法納入到其日常工作中。

國際刑警組織警報

國際刑警組織為全球犯罪數據之樞紐，擁有在需要行動時提醒會員國之機制。警察需要最新之全球犯罪數據來成功進行國際調查。該組織的 19 個資料庫包含數百萬攸關於人員、被盜財產、武器等之訊息。

國際刑警組織通告分類如下：

1. 紅色通告 — 通緝犯
2. 綠色通告 — 警告及情報
3. 黃色通告 — 失蹤人員
4. 橙色通告 — 立即威脅
5. 藍色通告 — 附加資訊
6. 紫色通告 — 犯罪手法
7. 黑色通告 — 未確認身份之屍體
8. 國際刑警組織 — 聯合國安全理事會特別通告：受聯合國安全理事會制裁之實體及個人

藥物犯罪行動 — PANGEA 行動

為什麼我們做這項行動？對於警察來說，他們會專注於毒品、槍支、爆炸物走私、恐怖主義等等，所以雖然他們會關注藥物犯罪，但如何引起他們的關注，並要求他們部署資源來打擊藥品犯罪？國際刑警組織有專門之行動，有案例訊息可分享給其他國家。PANGEA 行動包含：

- 由國際刑警組織主導之全球行動（分為前期、行動期及後期）
- 針對非法藥品的網路銷售；
- 將非法藥品從流通市面中掃除；
- 提高公眾意識；
- 收集數據並傳播情報；
- 識別案件並協調國際調查；
- 提供建議；
- 增強能力建設；
- 加強合作關係。

提高公眾意識

國際刑警組織秘書長 Jürgen Stock：「我們面臨一項重大的挑戰為，太多人仍然認為假冒和盜版是無害的犯罪，但這些是由龐大且複雜的犯罪組織在背後運作的嚴重跨國犯罪。」公眾意識有助於教育及保障消費者之安全及知情權。

藥物犯罪行動之觀察結果

1. 未經核准及不受監管之網路藥局數量在增加；
2. 使用較小的包裹來運送；
3. 使用郵政信箱作為中轉站來重新轉寄產品以增加隱蔽性，此趨勢增加；
4. 濫用國際運輸公司或國家郵政服務；
5. 申報不實。

藥物犯罪行動 — PANGEA 行動之勃起功能障礙藥物 （Erectile Dysfunction, ED）

- 在過去的 PANGEA 行動報告顯示查獲大量案件。
- 2018 年查獲量佔 5 百 10 萬單位。
- 2019 及 2020 年佔總查獲量之 38%和 56%。
- 2021 年佔總查獲量之 54%。

- 透過未經核准及未受管制的網站、電子商務平台、交易市場等運銷非法之勃起功能障礙藥物，已經成為一個全球性且持續擴大之問題。

合作是破獲藥物犯罪之成功關鍵，針對非法商品，強化合作之夥伴關係，如下圖

（十九）獸醫師對動物劣藥、偽藥之觀點

本章節由泰國動物健康產品協會（Animal Health Products Association, AHPA）顧問 Dr. Nackanun Chitaroon 進行「泰國動物健康產品協會簡介」及「對動物劣藥及偽藥之觀點（SFVP Perspective）」簡報，說明泰國動物用產業市場產值，及該產會對動物劣藥及偽藥之看法。

- 泰國動物健康產品協會（www.thaiahpa.com）成立於 1983 年，由 67 家公司所組成之協會，佔有泰國動物用藥品及相關健康產業用品超過 90 %之市場占有率。該協會設有會長、副會長與秘書各一人，並設有 6 位委員以及 6 位顧問之任期兩年之委員會，該協會出版各式資料如市場資訊「AHPA Market Information」、型錄「Veterinary and Animal Health Products」以及商業指引「Good Business Practice Guideline」提供會員及大眾參考。

- AHPA 與泰國官方及民間其他協會均有合作關係，如：
  - 政府主管機關（法規及認證）：泰國食品藥物管理局（FDA，主管動物用藥品，法源依據為藥品法）、畜牧發展部（DLD，主管飼料與消毒劑，法源依據為飼料品質管理法、危險物質法）、漁業部（DOF，主管養殖漁業飼料，法源依據為飼料品質管理法）；
  - 海關（關稅）：泰國海關；
  - 商會與協會（技術支援或企業社會責任）：泰國商會（THAI Chamber of Commerce）、各專業或其他協會：
  - 協會成員。
- 泰國致力發展農牧業，其動物產品市場規模龐大，經 AHPA 統計該國動物用產品市場規模年產值約 375 億泰銖，其來源以雞、豬用產品與飼料廠隻飼料添加劑佔大宗。
  - 各動物種別及其產品產值如下表：

產品	蛋雞	肉雞	種雞、種鴨	肉鴨、蛋鴨	豬、母豬	肉牛、乳牛	犬、貓	魚、蝦	飼料廠	總計
	市場規模（百萬泰銖/年）									
維生素-礦物質預混料	360.6	978.7	135.8	189.1	1117.8			770.6		3,553
抗球蟲藥	21.5	368.9	2.7		54.2					4,773
飼料添加劑（抗生素）					1492.6			142.2		1,635
飼料添加劑（生長促					193.6					194
飼料添加劑	219.0				774.4	482.6	359.7	298.6	12075.5	14,210
疫苗	364.0	1339.5	587.0	102.2	3000.0		928.8			6,322
抗生素（水溶散）	168.3	188.1	83.4	87.2						527
抗生素（注射劑）					913.4	365.6	294.0			1,573
其他藥品（水溶散）	269.3	609.5	67.6	48.8						995
其他藥品（注射劑）					373.8	300.0				674
驅內寄生蟲劑	84.1		43.3	16.5	120.0		684.9			949
驅外寄生蟲劑	42.1		33.8		125.8	238.7	929.3			1,370
驅蟲劑						573.6	670.0			1,244
消毒劑	101.0	522.0	30.4	22.6	313.2					1,630
水質改善劑										719
殺蟲劑	101.0	313.5	25.4		13.9					454
藥用洗毛精							546.0			546
其他						260.6	194.7			455
總計	1730.8	4320.6	1009.6	466.3	8492.2	2221.1	4607.4	2570.6	12075.5	37,495
百分比	4.62%	11.52%	2.69%	1.24%	22.65%	5.92%	12.29%	6.86%	32.21%	100%

ANIMAL HEALTH MARKET 2023

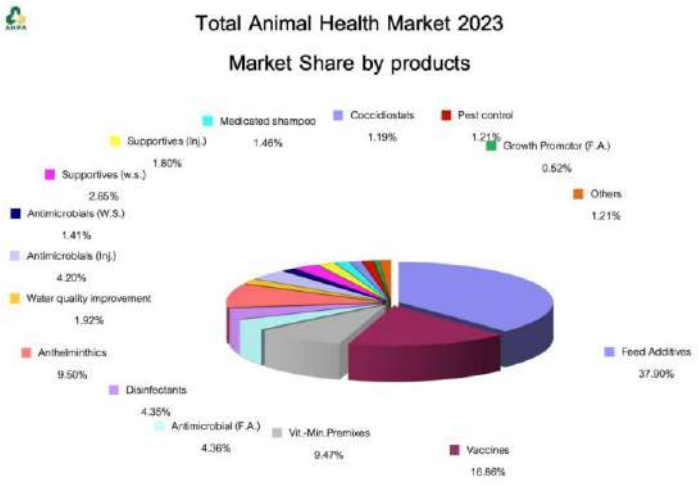
MARKET SIZE CLASSIFIED BY PRODUCT GROUP

POPULATION /PRODUCTION (Million)	LAYER	BROILER	BREEDER	MEAT D.	PIG	DAIRY	DOG	SHRIMP(Ton)	FEED MILL (M.Ton)
	51.04	1,741.49	16.91	59.0	17.20	0.68	7.80	0.28	20.73
			Duck BREEDER	LAY.DUCK	SOW ON	BEEF	CAT	FISH (Ton)	
			0.47	10.50	0.79	4.10	5.30	0.39	

Products	TOTAL	Market Size Baht/Year	Market Size Baht/Year	Market Size Baht/Year	Market Size Baht/Year	Market Size Baht/Year	Market Size Baht/Year	Market Size Baht/Year	Market Size Baht/Year	Market Size Baht/Year
1. Vit.-Min.Premixes	3,552,563,354	360,573,122	978,701,522	135,816,029	189,071,399	1,117,761,282			770,640,000	
2. Coccidiostats	447,250,871	21,512,623	368,895,189	2,663,059		54,180,000				
3. Antimicrobial (F.A.)	1,634,773,310					1,492,623,310			142,150,000	
4. Feed Additives (G.P.)	193,591,332					193,591,332				
5. Feed Additives	14,209,857,893	219,014,785				774,365,328	482,640,000	359,700,000	298,600,000	12,075,537,780
6. Vaccines	6,321,814,581	363,999,415	1,339,469,165	587,225,731	102,218,897	3,000,121,373	0	928,780,000		
7. Antimicrobials (W.S.)	526,938,390	168,281,664	188,081,219	83,357,986	87,217,520					
8. Antimicrobials (Inj.)	1,572,986,837					913,401,905	365,584,932	294,000,000		
9. Supportives (W.S.)	995,189,302	269,250,663	609,522,470	67,633,254	48,782,915					
10. Supportives (Inj.)	673,813,333					373,813,333	300,000,000			
11. Endoparasiticides	948,774,164	84,140,832		43,285,283	16,458,214	120,009,835		684,880,000		
12. Ectoparasiticides	1,369,676,913	42,070,416		33,816,627		125,749,870	238,700,000	929,340,000		
13. Endectocides	1,243,600,000						573,600,000	670,000,000		
14. Disinfectants	1,629,909,224	100,968,998	522,447,831	30,434,964	22,558,945	313,248,485			640,250,000	
15. Water quality improvement	718,956,000								718,956,000	
16. Pest control	453,651,752	100,968,998	313,468,699	25,362,470		13,851,584				
17. Medicated shampoo	546,000,000							546,000,000		
18. Others	455,268,000						260,568,000	194,700,000		
TOTAL	37,494,615,258	1,730,781,517	4,320,586,096	1,009,595,405	466,307,890	8,492,717,638	2,221,092,932	4,607,400,000	2,570,596,000	12,075,537,780
Percentage	100.00	4.62	11.52	2.69	1.24	22.65	5.92	12.29	6.86	32.21

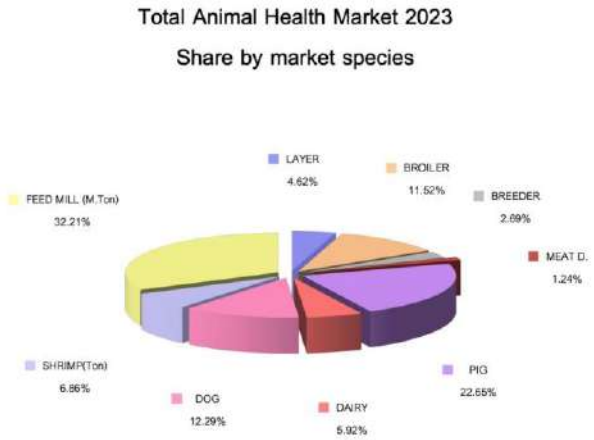
■ 按產品分類區分，其排序如下表：

產品種類	百分比
飼料添加劑	37.90%
疫苗	16.86%
維生素-礦物質預混料	9.47%
飼料添加劑（抗生素）	4.36%
消毒劑	4.35%
驅蟲劑	9.50%
水質改善劑	1.92%
抗生素（注射劑）	4.20%
抗生素（水溶散）	1.41%
其他藥品（水溶散）	2.65%
其他藥品（注射劑）	1.80%
藥用洗毛精	1.46%
抗球蟲藥	1.19%
殺蟲劑	1.21%
飼料添加劑（生長促進）	0.52%
其他	1.21%



- 按產品之對象動物種別區分，其排序如下表：

產品種類	百分比
飼料廠	32.21%
豬	22.65%
雞	18.83%
狗貓	12.29%
魚蝦	6.86%
牛	5.92%
鴨	1.24%



- 泰國動物健康產品產業對其國家針對 SFVP 建議因應方向：
  - 主管機關應加強市售動物用監控與管理，確保市場動物用藥品品質；
  - 加強向消費者教育，提升對 SFVP 認知，以促進正確之用藥選擇；
  - 加強處方箋之查驗，防止 SFVP 流通；
  - 改善動物用藥品檢驗登記之流程及縮短所需時間，確保市場產品之法性與品質；
  - 增加更多合格檢測實驗室，以確保動物用藥品之安全性與有效性。

（二十一）動物健康產業對動物劣藥、偽藥觀點

本章節由全球動物健康協會（HealthforAnimals）執行董事 Mr. Carel du Marchie Sarvaas 進行「非法動物用藥-來自動物健康產業的觀察（Illegal veterinary medicines-observations from the animal health industry）」簡報，分享動物用藥品製造業者對 SFVP 之看法。

- 全球動物健康協會（HealthforAnimals）代表全球約 115 國家之有關動物用健康產業公司組成，內含全球前十大動物健康企業（如 Zoetis、Virbac、IDEXX、ZENOAQ、Elanco、Borhringer Ingeheim、vetoquinol、MSD、Phibro 及 Ceva 等）及各地相關協會，該協會成員之產品涵蓋抗寄生蟲產品、疫苗、抗生素、診斷用產品、數位產品、基因產品和外用藥品，代表全球約 85%之動物用藥產品市場。

- 動物用藥品產業長久以來透過各國執法行動資訊、市場端測試數據以及使用者端（如獸醫師或產業）獲得本議題相關資訊：

- 全球各地皆有相關的犯罪活動，但各國所採取反制方式或執法程度有所不同；
- 以經濟層面分析，動物用藥品市場產值約 450 億美元，其產值僅佔人用藥市場之 2~3%，因此在非法或偽造的問題程度相對較小；
- 具出口食品之國家，通常具有較完備法規與執法力度，因此非法產品相對較少；
- 但產業端對於犯罪集團及其參與者資訊或非法藥品對動物、人類及環境之實際影響，則相對無這方面資訊。

- 產業端角度對於非法動物用藥產品認知與 WOAH 有些許差異如下，但所有情況都歸類於非法情形：
  - 未於當地國核准之動物用藥品；
  - 使用或供應未經核准之使用方式（如，無處方箋）；
  - 偽造藥品（如，侵犯智慧財產權、商標權、偽造標籤或成分不同等狀況）；
  - 違反製劑規範，如不同藥品製劑混用。
- 非法藥品藥品根據產業端經驗，非法動物用藥品市場之形成與擴大，通常具備以下關鍵因素：
  - 農民與獸醫可提供服務方面，通常在偏遠地區，可獲取高品質藥品之途徑有限，且畜牧業者通常缺乏對非法產品知識並以價格作為選擇指標。
  - 動物用藥品輸入業者及販賣業者方面，通常較小型業者，銷售管道有限且財務能力較差，難以支撐合法途徑之業務運作。另相對於所提供產品品質與商譽，更注重利益。
  - 政府主管機關若法規不完善或缺乏執法能力，則難以有效治理；除主管部門外，其他部門對違法動物用藥品對公共健康威脅認知

有限，導致政府部門於政策制定及資源分配上，難以對非法動物用藥品形成有效打擊。

- 為正式非法動物用藥品問題，動物用藥品產業對動物劣藥及偽藥因應措施如下：
  - 持續關注本議題，並關切 SFVP 對公共衛生、動物、環境以及企業利益所造成危害；
  - 致力維持合法供應鏈，以防止 SFVP 流通；
  - 支援 WOAH 評估 SFVP 造成之問題規模與性質，並提供協助；
  - 與主管機關合作，於司法調查 SFVP 案件時，提供必要資訊；
  - 支援各國與全球性活動，如協助 VASFE 計畫提供相關產品資訊、協調並交換資訊並採取積極調查與起訴。
- 面對全球性劣質及偽造之動物用藥品議題，產業端亦提出所觀察到現象與挑戰，將影響合法動物用藥品之市場流通，如：
  - 主管機關資源不足，人力、經費不足而各種打擊行動形成阻礙；
  - 比起人類健康，動物健康相對較不被重視；
  - 實務上，動物健康可能連帶引起食品汙染、面臨人畜共通疾病，藥品藥效不足或微生物與寄生蟲所產生抗藥性。
  - 倘當地國主管機關未能採取積極態度因應動物劣藥及偽藥，則影響合法業者引進藥品之意願。
- 目前法動物用藥面臨挑戰：
  - 合法動物用藥品需通過各國藥品查驗登記後，始得於批發商或獸醫師將產品售予動物、寵物主人或農民；亦可通過藥局、藥品販賣業、飼料廠或零售業者（例如寵物店、超市），部份情形亦能通過網路或電商平台出售。
  - 非法動物用藥品來源為未經過核准之非法製造業找，大部分透過電商平台進入市場，而該情況日益嚴重，但很鮮少有平台採取遏

止這類犯罪行為之措施，產業端希望各國主管機關能多加關切此情況。

- 根據該協會統計 Amazon 為平台業者中心相對積極處理該類情況，其他有類似案件平台尚有 Fruugo、Mercado Libre、Shopee、Facebook Marketplace、Walmart、Etsy、Wish、1688.com、AliExpress、Alibaba Group、OfferUp、Rakuten、Lazada、TikTok、Cdiscount、ManoMano、Mercari、Newegg、Shopify、Lojas Americannas 及 eBay 等。

- 因此，全球動物健康協會對於因應 SFVP 提出一系列建議行動如下：
  - 法規主管機關（Regulation & Enforcement Agencies）：
    - 制定相對應法規；
    - 更有效及嚴格執法；
    - 與警政、海關、其他主管機關、專業機構、動物用藥品業者間合作；
    - 採取法律行動並提起訴訟。
  - 電商平台及網站（E-Commerce & Internet Sitess）：
    - 提高認知；

- ◆ 停止販售非法動物用藥品；
- ◆ 強化商業網站並對使用者提出警示；
- ◆ 遵守當地國法規。

■ 經核准之藥品製藥商（Manufacturers of Authorised Medicines）：

- ◆ 提高認知；
- ◆ 蒐集資訊；
- ◆ 主動提出與當地執法機關合作；
- ◆ 評估技術以支援執法行動；
- ◆ 保護專利、商標以及聲譽。

■ 獸醫、零售商、批發商、飼料廠（Veterinarians, Retailers, Wholesalers, Feed Mills）：

- ◆ 提高認知；
- ◆ 檢舉非法產品；
- ◆ 與執法單位合作；
- ◆ 保持警惕；
- ◆ 不鼓勵非法複方產品及疫苗。

■ 農民（Farmers）：

- ◆ 認知使用 SFVP 對效果、安全、殘留與對環境之風險；
- ◆ 使用非法產品之商業風險；
- ◆ 檢舉非法產品。

■ 寵物飼主（Pet Owners）：

- ◆ 清楚認知使用非法產品對效果與安全之風險；
- ◆ 檢舉非法產品。

- 本協會針對 SFVP 議題，據其經驗及資訊提出全球研究報告「Illegal Veterinary Medicines: Impact and Effective Control」（https://healthforanimals.org/resources/publications/publications/new-report-illegal-veterinary-medicines-impact-and-effective-control/），以製藥業及農藥面臨本議題所汲取經驗及教訓為基礎，提出對非法動物用藥品之行動建議與想法供大眾參考。

最後，講者再次強調全球和各國家主管機關應加強合作，嚴格執法，並支持本次 WOA 所推動之 VSAFE 資訊共享計劃，以保障合法供應鏈的運作和公共健康安全。

（二十一）RAGNA — 強化國際合作，確定具體行動，並在人用藥及動物用藥之間交流經驗

由瑞典藥物局的 Katarina Lönnquist 簡報「RAGNA — 強化國際合作，確定具體行動，並在人用藥及動物用藥之間交流經驗」。瑞典藥物管理局（Swedish Medical Products Agency, SMPA）為藥物及其他醫療產品（包括環境方面）開發、生產和銷售之國家主管機關，對象包括人類和動物。

抗微生物藥物抗藥性（AMR）為 SMPA 首要優先工作項目

瑞典藥物局的 AMR 專家來自人類、獸醫和環境領域，每週開會一次，以確保其全球活動具協調一致性。若該局收到來自歐盟藥物局（EMA）的問題和調查，

不同領域會一起回應，保持防疫一體之視角。我們在機關內部進行資訊共享，並且與瑞典其他主管機關合作，定期會面，開展針對 AMR 之不同活動。

瑞典藥物局日常工作包括科學建議、核准新產品開發之臨床試驗、產品登記文件之評估、執行檢查、藥物安全監測（Pharmacovigilance）、國家治療建議之制定，以及因應偽藥、劣藥產品之行動，並與海關及警察合作。

對抗 AMR 之全球監管機關網絡（Regulatory Agencies Global Network against AMR, RAGNA）背景

RAGNA 係在 2023 年 5 月 5 日首次人用藥及動物用藥全球聯合峰會議期間提出。2023 年 5 月 10 日世界衛生組織的 Haileyesus Getahun 訪問瑞典藥品局。2023 年 5 月 25 日瑞典藥品局（SMPA）局長批准啟動 RAGNA。2023 年 6 月 28 日舉行第 1 屆 RAGNA 會議。RAGNA 係由歐盟理事會瑞典主席團發起之一項倡議，瑞典在前兩年主持該網絡，之後將轉交給其他國家。這一倡議由瑞典發起，但不會永久由瑞典運行。瑞典與四方組織（FAO, UNEP, WHO 及 WOAH）密切合作，創建了不同文件及活動，均為自願參加且免費。

RAGNA 目標

RAGNA 目標係加強各監管機關之間在 AMR 方面之國際合作；確定各監管機關在對抗 AMR 方面可以採取之具體行動；在人醫及獸醫監管機關之間，交流對抗 AMR 之經驗與做法。

RAGNA 之成就

RAGNA 第 1 年之成就包括邀請了超過 500 名國際代表、建立了一個數位平台來共享文件、進行了 6 次數為會議、制定了權責範圍、制作並發布 RAGNA 之行動呼籲、編製了 2024-2025 年之計畫。

RAGNA 之行動呼籲

2024 年 9 月的聯合國大會 AMR 會議係一個提出具體可行措施之機會，這些措施是在監管機關之職責範圍內。RAGNA 行動呼籲是一份文件，包含了針對 AMR 之優先監管措施，旨在對 AMR 產生重大影響、在所有國家均可行，且成本低，並符合防疫一體視角。

RAGNA 會議

RAGNA 會議每隔一個月舉行一次，每次會議持續 1.5 小時，以數位方式進行。將報告與討論融合在一起。會議錄影可供 14 天內查看。下一次 RAGNA 會議於 2024 年 6 月 19 日舉行，會議內容包括如何利用 RAGNA 行動呼籲產生影響、各國對 AMR 情況之介紹、分組討論國家間如何互相支持並分享經驗。

歡迎加入 RAGNA

您可以透過發送電子郵件，加入 RAGNA：Ragna@lakemedelsverket.se，並可造訪 RAGNA 之數位平台，以了解更多資訊。

（二十二）為什麼跨部門合作很重要？佛萊明基金（The Fleming Fund）在其方案策略中應對 AMR 及 SFVP 之第二階段

由佛萊明基金的全球管理代理者 Mott Macdonald 公司的 Robert Rosenthal 先生簡報「佛萊明基金第一階段成果及第二階段品質與協調」。

佛萊明基金是一個由「英國健康與社會照護部」發起之英國援助計畫，旨在收集及分享 AMR 數據。英國健康與社會照護部之佛萊明基金目前支持 21 個亞洲和非洲國家應對 AMR。該基金提供資金及資源給不同國家與地區，支持他們開展 AMR 監測工作，包括直接給國家與地區提供補助金、支持國際性之計畫，並提供獎學金。該計畫重點關注中低收入國家，因為這些國家最可能受到 AMR 擴散之最嚴重後果。佛萊明基金第一階段（2017-2023 年）於全球資助項目達 2 億英鎊；第二階段於全球資助項目達 1.33 億英鎊，計 26 個國家之 58 個資助項目，而於東南亞地區資助項目達 2,470 萬英鎊（資助當地國家及獎學金）。

動物劣藥及偽藥產品（SFVP）問題是我們工作之上游問題，這些 SFVP 產品在某種程度上助長了 AMR 問題，我們最終在下游看到了動物和人類防疫方面之細菌抗藥性增加。因此，我們倡導防疫一體方法（One health approach），你會發現許多國家和受資助者在跨部門合作應對 AMR 問題，包括巴布亞新幾內亞、越南、孟加拉國和尼泊爾。今天我將談論的內容是如何促進跨部門合作，因為這是應對 AMR 的主要挑戰之一。佛萊明基金項目主要集中在建立實驗室能力和 AMR 監測上，因此，我們比較關注 SFVP 及不當使用藥物對 AMR 監測系統造成之影響。

以佛萊明基金之方法建立實驗室能力和 AMR 監測

1. **實驗室能力**：資助國家及中央採購
   (1) 基礎設施
   (2) 設備及試劑
   (3) 微生物學能力
   (4) 品質管理體系（QMS）
   (5) 實驗室資訊管理系統（LIMS）
   (6) 生物安全和生物安保（Biosafety & Biosecurity）
   (7) 樣本收集及運輸
   (8) 生物庫（Biorepository）

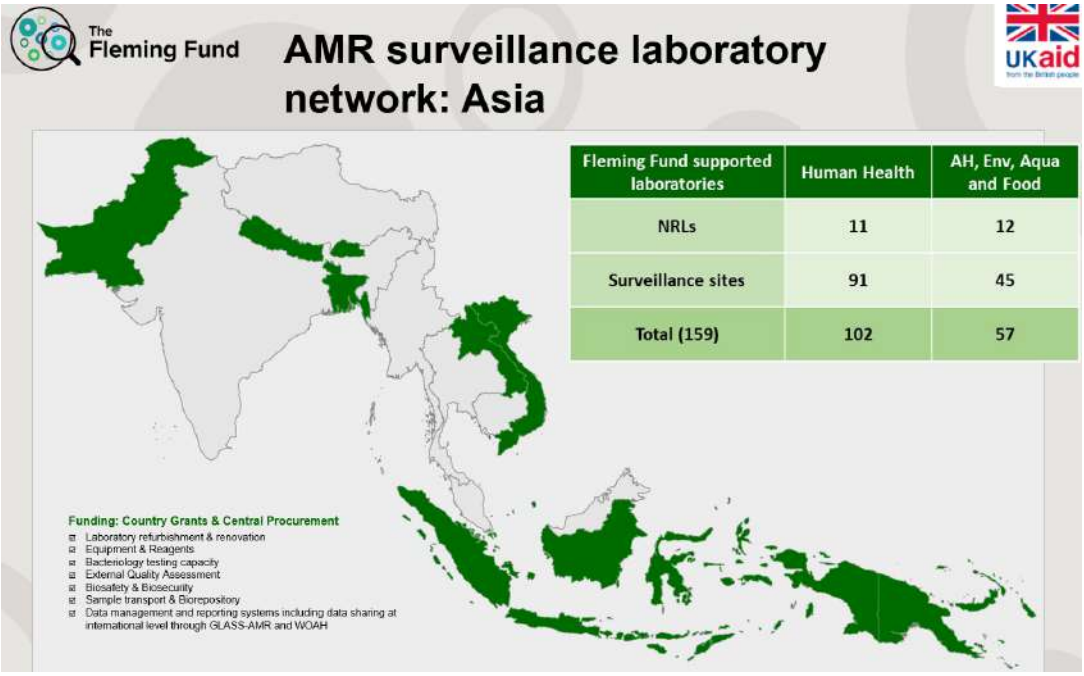
2. **人員能力**：資助獎學金計畫及開放大學課程
   (1) AMR 實驗室
   (2) AMR/ AMU/ AMC 監測
   (3) 抗微生物藥物管理
   (4) AMR 宣導
   (5) AMR 防疫經濟學
3. **地區能力**：資助地區
   (1) 地區品質保證網絡
   (2) 數據及資訊共享平台

(3) 監測數據之品質與使用

(4) AM 病原之高階檢測

佛萊明基金第一階段（2017-2023 年）

首先介紹佛萊明基金做得如何？在動物防疫領域抗微生物藥物使用量（AMU）方面取得了哪些成果？下圖綠色標記之國家是我們資助 AMR 監測發展的地方，你可以看到在南亞及東南亞有 159 個接近 200 個實驗室強化了監測 AMR 能力，包括印度、巴基斯坦、尼泊爾、孟加拉、不丹、東帝汶、印尼、越南、寮國、巴布亞紐幾內亞。而泰國及馬來西亞未列入其中，是因為這些國家太富有、太有能力，不是我們的重點。我們主要關注於低收入與中等收入國家。



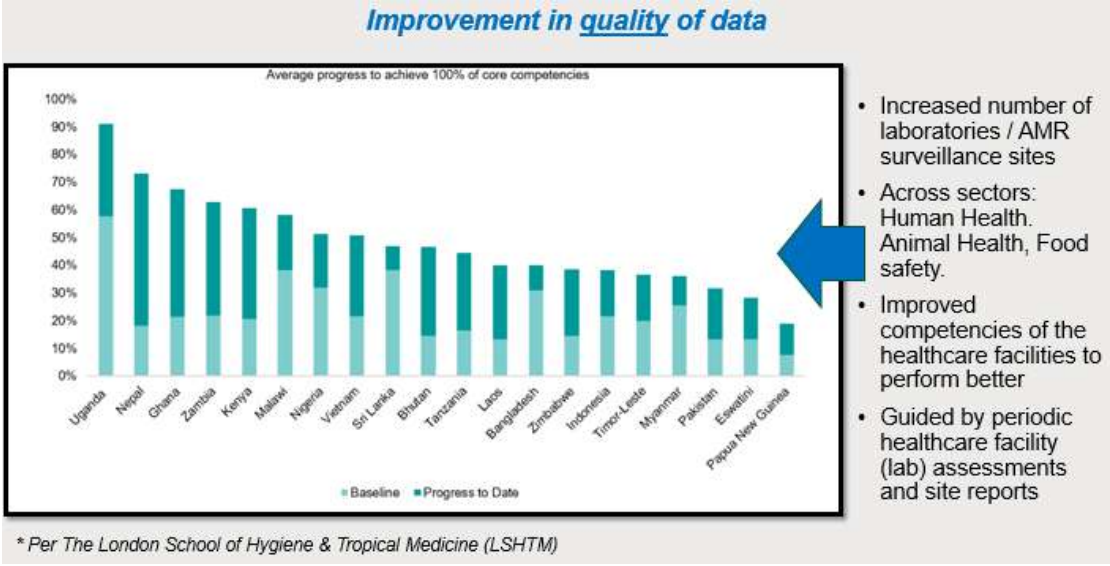
佛萊明基金第一階段亮點：幫助各國學習並發展能力，以更好應對 AMR

1. 制定或實施了超過 75 項 AMR 國家行動計畫。
2. 在東南亞之三個國家中，改善其對 WOAH 之 AMU 報告。
3. 181 名研究員在微生物學及流行病學方面提升了技術能力，並訓練了超過 3000 名醫護人員關於抗微生物藥物管理(Antimicrobial Stewardship, AMS ）原則。
4. 支持了超過 240 個實驗室。
5. 透過資助國家及地區，支持了 22,713 名培訓參與者。

6. 17 個佛萊明基金資助之國家登記加入了 WHO 全球 AMR 監測系統（WHO's Global AMR Surveillance System, GLASS），比 2017 年增加了 2 個。
7. 資助 11 個地區優化國家資料之數據及品質，建立實驗室之外部稽核（External Quality Assessment, EQA），並為非洲針對 AMR 建立了新全基因體定序技術能力。

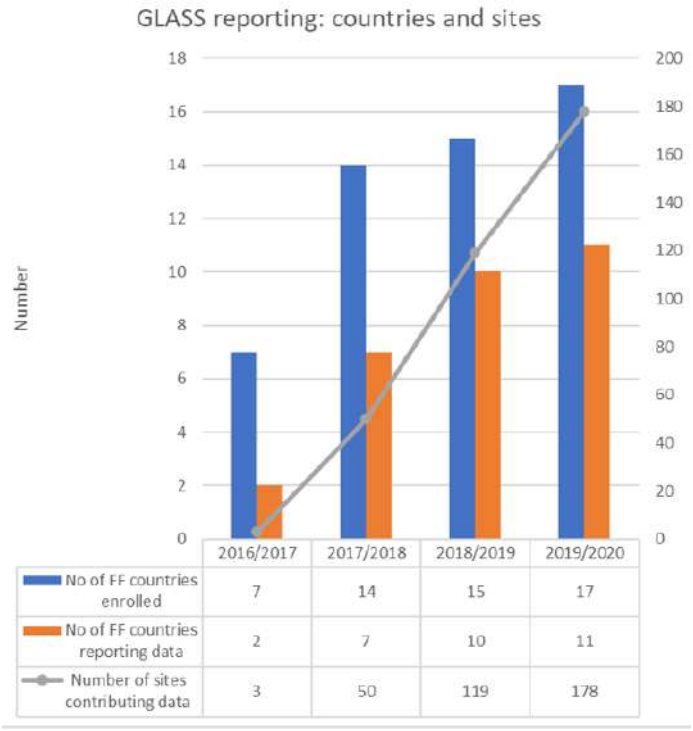
衡量佛萊明基金第一階段之成功：優化資料品質

我們改善了資料之品質的質量，項目包括增加了實驗室或 AMR 監測點之數量；跨部門（人類防疫、動物防疫、食品安全）；提高了醫療機構之能力，使其表現更好；由醫療機構（實驗室）定期評估及現場報告指導。我們使用之衡量標準（benchmark）係根據倫敦衛生與熱帶醫學院（LSHTM）之數據，如下圖淺色部分。圖中深藍綠色顯示資料品質之進步情況，統計時間是從 2017 年到 2022 年 4 月這段期間。下圖顯示，我們幾乎所有的國家實驗室能力都有顯著進步。那些進步較小的區域，則是因為我們在各種原因下，無法順利啟動或完成補助計畫所導致。



同時，資料數量已經大幅增加。加入 GLASS 之佛萊明基金國家數量，從 2016 年的 7 個國家增至 2020 年底的 17 個國家。據我所知，這個數字現在是 19 個。

幾乎所有這些國家都在向 GLASS 提交數據，起初只有 2 個國家提交數據，現在大約有 16 個國家從不同地點向 GLASS 提交數據。下圖藍色為加入 GLASS 之佛萊明基金國家數量，橙色為提交數據之佛萊明基金國家數量，灰色為提交數據之地點數量。



衡量佛萊明基金第一階段之成功：提升技術能力

透過國家資助在動物和人類防疫領域 31,411 人次參與培訓。在佛萊明基金資助國家中，31,422 人次參與培訓及超過 10,834 人員接受指導。在佛萊明基金資助地區中，4,473 人次參與培訓（截至 2021 年第三季度），181 名獎學金獲得者。培訓主題包括全基因體定序、AMR 數據共享、用於政策制定之 AMR 數據、高階微生物學培訓、AMR 數據分析、溝通、監測流程之設計與使用、AMU 或 AMC 調查工具、AMR 數據收集、樣本運輸、採樣、基礎微生物學培訓、品質管理、生物安全與生物安保（Biosafety and Biosecurity）、AMR 數據管理、臨床人員（醫師、護士、藥師）之 AMR 培訓或教育。

動物 AMU 亮點：支持 WOAH 之 ANIMUSE 問卷報告

國家	佛萊明基金協助 WOAH 之亞洲報告	AMU 資料選項*
寮國	開發了國家 AMU 監測系統，並提高了資料之品質及數量	2
越南	建立了國家 AMU 資料收集系統，並提供了資料分析之培訓	1
巴基斯坦	為當地政府提供畜牧場端 AMU 調查之培訓及技術支援	**3**
東帝汶	建立了國家 AMU 監測系統，並提高了資料之品質及數量	**3**
巴布亞紐幾內亞	開發了國家 AMU 資料收集系統	1
孟加拉	提高了 AMU 資料之品質及數量，提供了點盛行率調查（Point Prevalence Survey, PPS）及資料分析培訓	1
不丹	提高了資料之品質及數量，提供了 AMU 調查及資料分析培訓	1
印尼	提高了資料之品質及數量，提供了 AMU 調查與資料分析	1
尼泊爾	提高了 AMU 資料之品質及數量，進行了 AMU 調查、資料收集、資料分析	**3**

*備註：

1 號選項：AMU 資料包括「動物醫療用或促進生長用」AMU 數據。

2 號選項：AMU 資料包括「動物醫療用或促進生長用」AMU 數據、「陸生產食動物、水生產時動物或非產食動物」AMU 數據。

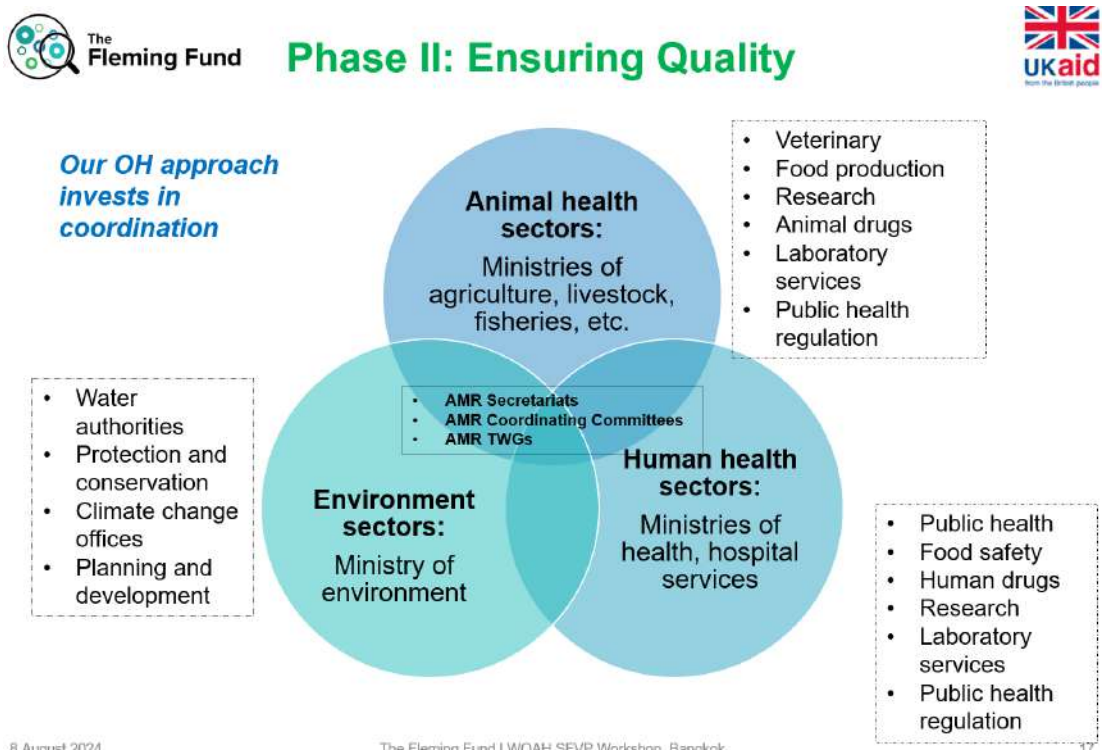
3 號選項：AMU 資料包括「動物醫療用或促進生長用」AMU 數據、「陸生產食動物、水生產時動物或非產食動物」AMU 數據、「投藥途徑」AMU 數據。

- 總體而言，提高了提交給 WOAH 的資料品質及數量（不丹、孟加拉國、印尼、尼泊爾、東帝汶、巴基斯坦與寮國）
- 全球支持 WOAH 之「動物用藥產品品質」計畫
- **尼泊爾**：從家禽場收集了兩輪 AMU 資料；開發了收集及管理來自醫院與畜牧場端之 AMU/AMC 數據之軟體。
- **孟加拉國**：於人類醫療站（Human Health sites, HH sites）、家禽及水產養殖場進行了防疫一體之點盛行率調查（Point Prevalence Survey, PPS）。

- **印尼**：擴大了 AMU 監測範圍，並進行了資料分析及解讀。
- **巴基斯坦**：開發了跨部門 AMR/AMU 指標儀表板之軟體；於動物防疫領域（家禽、牛）執行首次 AMU 監測；進行了畜牧場 AMU、動物飼養與處方的知識、態度與實踐（Knowledge, Attitudes and Practice, KAP）調查；提高了獸醫學生與專業獸醫師之 AMR 意識。
- **東帝汶**：建立動物防疫領域之國家 AMU 監測；標準治療指引；基本藥物名單和抗生素指引。
- **越南**：協助建立電子系統。私部門直接提供進口藥物、抗微生物藥物銷售量與動物防疫領域之 AMU 資料。
- **寮國**：2022 年在動物防疫領域進行了國家 AMU 監測，包括：1）評估動物防疫部門之 AMU 資料收集、2）就評估結果進行會議、3）實施監測。

佛萊明基金第二階段（2023-2025 年）：如何提升品質及促進協調？

AMR 這個問題相當棘手，因涉及許多部門（動物衛生部門、人類衛生部門、環境部門）。我們需要找出如何讓政府、相關機構、部門在各個層面進行合作之方法。解決問題唯一之方法是讓人們彼此交談。因此，我們的工作重點是資助跨部門之交流機會。



在佛萊明基金第二階段（確保品質）有 4 項成果領域，其中 3 項重點為品質。

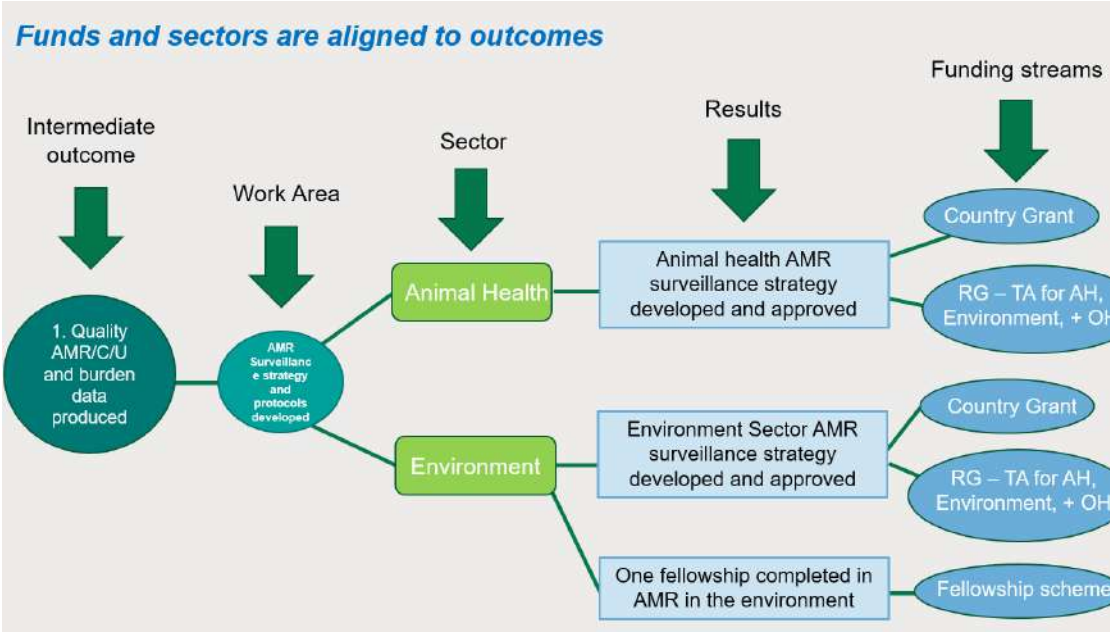
	成果領域	與動物防疫 AMU 相關之範例
1	產出之 AMR/AMU/AMC 資料品質	支持開發或修訂 AMU 監測策略、計畫及流程、畜牧場端 AMU 監測（定性或定量）
2	資料分析之品質	實驗室資訊管理系統（LIMS），資料管理軟體
3	資料傳輸以供分析之品質	資料分析及報告（國內/國際），開發或升級獸醫師處方指引
4	可永續性	支持建立功能性 AMU 技術工作組；在政府機關中支持 AMU 研究員；成本核算，經濟價值，政策制定之證據

國家級之投資策略：確保不同部門和計畫之間的一致性及協調

這些策略透過與各部門進行高度協商，確保策略一致性，並在不同領域進行與計畫朝向同一個目標結果來努力。

佛萊明基金第二階段（確保品質）：資金及部門行動均一致朝向目標結果

下圖展示了如何協同工作，為了實現最左邊的結果（即產出高品質之 AMR 與 AMU 資料），佛萊明基金有各種不同的資金來源，我們在每個部門的不同點上協同工作，確保所有行動者都朝著相同的結果努力。



佛萊明基金第二階段（確保品質）：推廣工具以促進標準化及衡量進展

我們建議受資助者遵循 WOAH 關於 AMU 資料收集與報告之指引（例如：2020 年《OIE 標準、指引與抗微生物藥物之抗藥性及其使用的決議》）。有兩個標準用於 AMR 監測：(1) 在人類防疫領域，將倫敦衛生與熱帶醫學院（LSHTM）核心標準用於技術能力審查及 GLASS 報告。(2) 在動物防疫領域，將梅西大學（Massey）之家禽流程用於畜牧場之 AMR 監測。上述這些標準及流程已成為衡量每個國家進展之有用指南。

佛萊明基金開發之監測站點和監測系統規劃及監測工具已提供給受資助者使用，除了 SFVP 監測外，還包括醫院、土壤、飼養場及動物用藥產品公司等方面之監測。這些都是未來幾年需要投資之監測系統的一部分，以實現其完全運作。

提高對跨部門治理之支持：優先考慮需要跨部門協作之項目

1. 國家行動計畫（National Action Plan, NAP）：我們嘗試做的關鍵項目為支持 NAP 之制定與修訂，這些行動計畫是指導跨部門合作之關鍵文件，因此我們投入了大量資金來制定這些計畫。

2. 佛萊明獎學金計畫：旨在支持前線工作或政策崗位上的人員，無論是動物防疫領域或人類防疫領域。是否有佛萊明基金獎學金獲得者在場？有兩位，恭喜你們。佛萊明基金在第一階段每個獎學金獲得者平均投資了 8 萬英鎊，使他們在工作中表現更好，跨部門合作更順利。
3. 整合性監測：我們還資助整合性監測，主要使用聯合國機構之指南，整合性監測非常複雜，需要跨部門協作。
4. 監測治理及領導之制度化（包括技術工作組、AMR 協調委員會及秘書處）：我們專注於資助監測治理及領導之制度化，透過技術工作組、AMR 協調委員會及秘書處來實現 AMR 治理，這些國家很少有足夠的資金來支付跨部門協作工作之個人薪資，但我們可以支付這些個人及秘書處必要的薪水，提供會議空間和場地、資助計畫，所有這些都是為了讓人們坐下來，討論他們國家需要做什麼。
5. 於較大型之防疫系統，將監測系統制度化：我們資助整個系統，識別系統之缺口及需求，制定強化系統之藍圖，這不能由單一機關完成，必須協同合作。所有這些工作，許多情況下涉及數十萬英鎊，最終旨在強化真正之系統。
6. 成本運營計畫：為應對 AMR 所需之重要工具，了解需要做什麼？成本是多少？何時完成？這需要跨部門討論，所以成本運營計畫是促進跨部門交流和協作之重要工具。

衡量佛萊明基金第一階段之成功：佛萊明政策及專業研究員學習共同合作，成為 AMR 倡導者

最後談談佛萊明獎學金計畫，我們有兩種類型之研究員：政策研究員與專業研究員。在第一階段資助了近 200 名研究員，平均每人獲得 8 萬英鎊的投資，這些研究員接受長期的輔導與指導，以支持他們在 AMR 領域的發展。

在一些國家有大量專家，例如澳大利亞、美國、英國。如何將這些專家與巴布亞新幾內亞等地的個人聯繫起來？我們開發了 12 ~ 24 個月的長期獎學金計畫，確保這些人得到教練與導師的支持，成為 AMR 領域的倡導者，並在 AMR 討論中具備專業技能。

很多工作涉及從組織內部領導協調，不僅僅是機關內部協調，還包括跨機關之協調。我們的政策研究員接受專門的培訓和輔導，以領導這種跨部門協同合作。研究員的協作培訓：

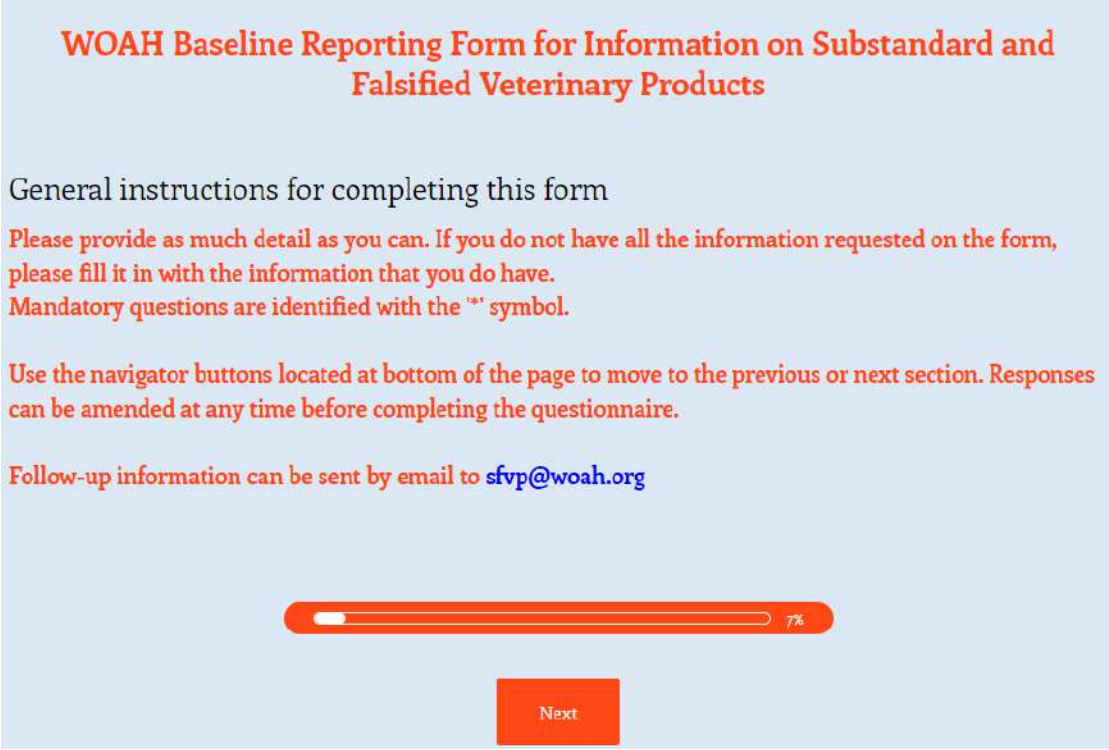
1. 透過一個國家內所有研究員之間的工作社群，即來自多個部門的研究員在獎學金期間將進行溝通交流。
2. 研究員們會開發整合性、跨部門的專案計畫。
3. 政策研究員的工作計畫中內建了跨部門協作、防疫一體以促進並圍繞衛生部門之跨領域問題。

動物防疫人員與醫院人員之間存在交流問題，那麼如何解決呢？創造專案計畫讓人們一起工作，創造空間讓他們計畫合作。獎學金計畫是一個很好之專案計畫和空間，它產生了巨大之影響。

（二十三）WOAH 亞太地區動物用藥產品之品質管理調查結果

由 WOAH 的 AMR 及動物用藥產品部門之 Andrés García Campos 計畫經理簡報「WOAH 亞太地區動物用藥產品之品質管理調查結果」。

各會員國於出席本研討會之前，均已被要求填報藍色之 WOAH 基礎資料報表（WOAH Baseline Reporting Form for Information on Substandard and Falsified Veterinary Prouducts），如下圖。



WOAH 基礎資料報表關注四個面向：

4. 過去事件之資訊
   (1) 去年是否有任何懷疑或確認之動物劣藥及偽藥產品（SFVP）事件？
   (2) 是否已向 WOAH 通報？
   (3) 是否與其他國家合作了？
5. 動物用藥產品（VMPs）品質管理
   (1) 負責產品登記之主管機構
   (2) 負責監測及監控（monitoring & surveillance）產品品量之主管機構
   (3) 是否已建立監測及/或監控系統？
   (4) 該系統是否涉及實驗室檢測？
6. 有可供使用之實驗室檢測：

   您的國家是否有實驗室可以進行動物用藥品品質檢測，或是否可以使用其他國家之實驗室進行檢測？

7. 產品召回及可追溯性

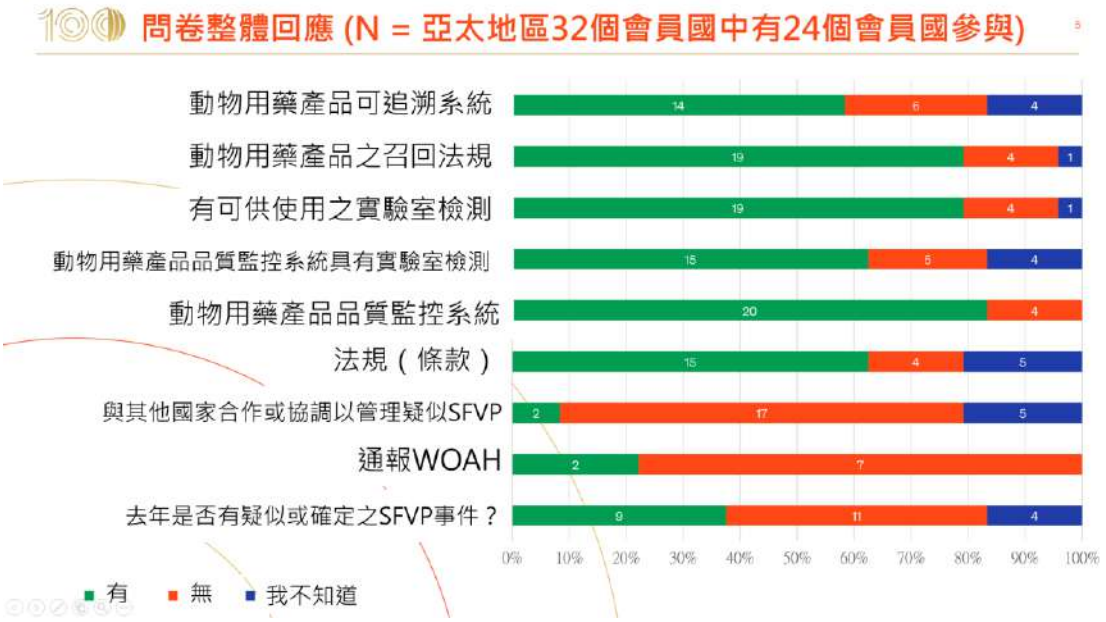
(1) 是否有產品召回之相關法規？

(2) 是否有可追溯性系統？有哪些系統？

WOAH 亞太地區有 32 個會員國，其中有 24 個會員國自願參與 VSAFE。這些會員國回應之數據將幫助 WOAH 了解該地區之優先事項以及會員國提供之建議，以便 WOAH 開始行動，並制定相關指導。而在解釋這些結果時，需要小心，雖然會員國之回應是根據該國已知之資訊，但有時 WOAH 在驗證過程中發現答案可能很模糊或不確定。因此，最終對這些結果之解釋需要很謹慎。

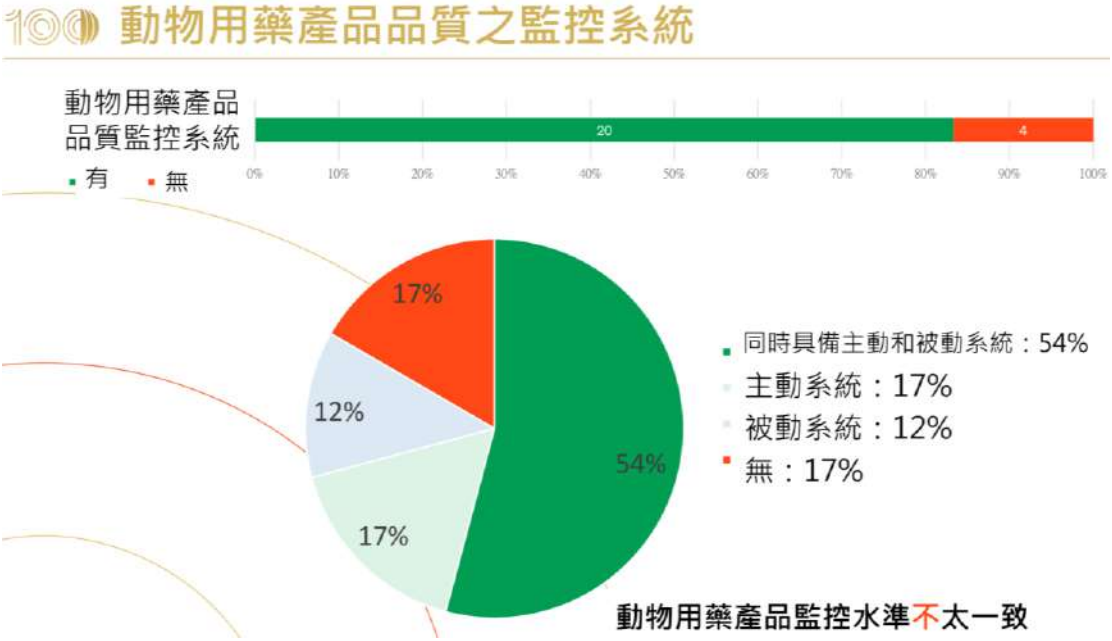
從下圖可以發現，藥物、疫苗和預混料（飼料與藥物混合）之產品登記、監測及監控之權責，在某些會員國係由農業部負責，而在某些會員國係由衛生部負責，某些情況下為兩個部門均參與，而在其他會員國中，則可能係其他部門負責，或者沒有任何部門負責。

權責項目		農業部	衛生部	兩者	其他或無
產品登記	藥物	15	8	0	1
	疫苗	16	5	2	1
	預混物	20	1	2	1
監測及監控 (monitoring & surveillance)	藥物	15	6	2	1
	疫苗	16	6	1	1
	預混物	20	1	2	1

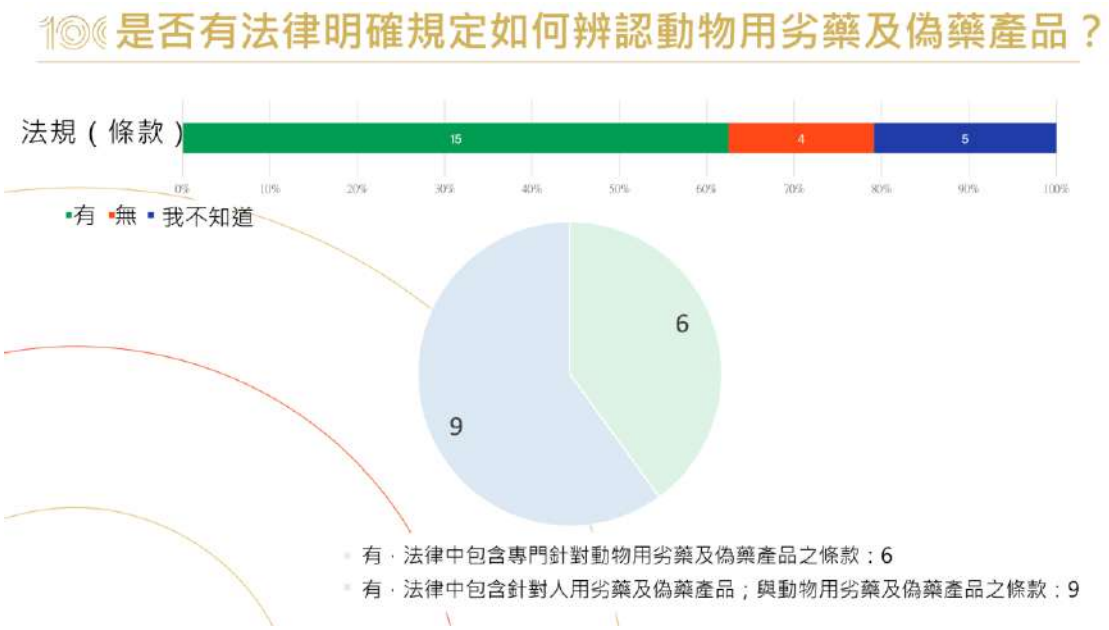


有關問卷整體回應統計結果，上圖綠色表示「有」橙色表示「無」，藍色表示「我不知道」。24 個參與之會員國中，有關國家是否有動物用藥品之召回法

規，19 個會員國表示有，4 個會員國表示無。而有關國家是否具有動物用藥品可追溯系統，14 個會員國表示有，6 個會員國表示無。其餘統計請參考上圖。



根據上圖統計顯示，於動物用藥產品品質監控系統方面，在 20 個會員國中，54%同時具備主動及被動系統之監控，因此他們會透過檢查及隨機抽樣執行主動監控，或等待來自畜牧場和寵物飼主之通報。17%之會員國只有主動系統之監控，12%之會員國只依賴被動系統之監控，而 4 個會員國沒有任何系統監控。我們需要注意的是，即使我們同時具備主動和被動系統，但實際上更偏向於被動系統，這是由於各國不同之能力或資源，或權責部門更優先處理人用藥產品而非動物用藥產品。



針對 15 個會員國中，6 個會員國有專門針對動物劣藥及偽藥產品之法律條款，9 個會員國有針對人用劣藥及偽藥產品；與動物劣藥及偽藥產品之法律條款。

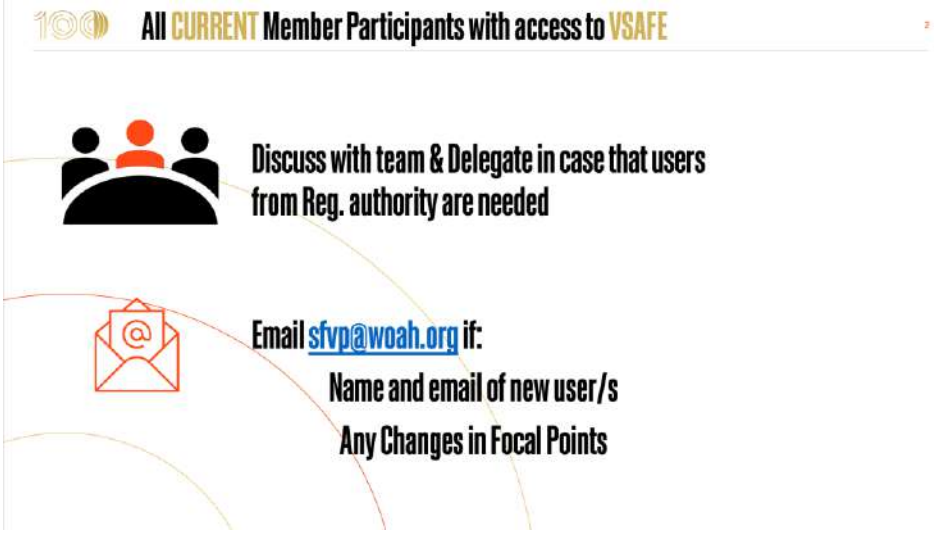
對於上述 WOAH 所做之調查，您的想法是什麼？您認為 WOAH 應該優先處理哪些事項，以便 WOAH 能夠預防、偵測並應對 SFVP？

（二十四）開放討論亞太地區（人類醫療及獸醫）合作管理動物劣藥及偽藥產品（SFVP）

本章節由 WOAH AMR 及動物用藥產品部計畫經理 Dr. Andrés García

Campos 主持，與參與會議之各國代表座談並交換意見。

- 針對本次會議推廣之通報系統 VSAFE，主辦單位希望可有更多夥伴加入使用並分享資訊，當越多國家使用，該系統可提供資訊將越豐富。
- 對於目前已使用 VSAFE 之國家，主辦方希望可再次盤點國內其他主管機關一同參與使用之可能性，倘需增加新使用者或變更 Focal point 聯絡人資訊，可向 WOAH 聯繫（sfvp@woah.org）。



- 本次會議所有參與者所申請之 VSAFE 帳號密碼，可使用至 2024 年 6 月 25 日，期間內所有功能皆可持續使用；仍建議與各機關首長討論或跨部會與不同主管機關協調評估是否參與使用該系統，若同意加入使用 VSAFE，亦可向 WOAH 聯繫申請。

（二十五）1 分鐘分享-工作坊之總結、回饋或心得

本章節由 WOAH AMR 及動物用藥產品部計畫經理 Dr. Andrés García Campos 主持，與參與會議之各國代表座談並交換意見。

- 會議進入尾聲，主辦方 WOAH 之 AMR 及動物用藥產品部（WOAH Headquarters AMR & VP Department）負責人 Dr. Javier Y. Marcos 再次強調，WOAH 在亞洲區域發起多項倡議及活動，其中 VSAFE 系統為一年多前因應監控動物劣藥及偽藥所開發，該平台為專為各會員國所設計，

因此鼓勵大家多加利用併上傳資料，若會員國都不提供資料，則該平台即失去建置意義，而使用者們也會逐漸忘記如何操作。

- 使用該系統之時間越長越可體現其價值，另亦可協助統計動物劣藥及偽藥數據，又因系統中資料來源皆為自各國動物用藥品主管機關所提供，屬可信賴資料來源，善加利用本系統則可確保協助國家監控動物劣藥及偽藥，有助於確保動物使用高品質之動物用藥品。
- 因應現今消費習慣，如何監督及控制動物用藥品於網路銷售為重大問題。倘若善加利用 VASFE 系統並上傳有關已登記或未登記之產品數據，則對於掃除市場上動物偽藥極有幫助。
- 主持人再次感謝本次會議所有與會夥伴，於三天會議期間積極參與，特別是進行分組情境案例演練，令這次會議圓滿達成目標；此外，也感謝本次會議來自各組織、機構與國家之講者，提供並分享專業知識。WOAH 期待與大家一起共同合作，確保亞太區域所流通之動物用藥品之品質。
- 另作為本次會議之結尾，主辦方希望各與會者寫下一段 1 分鐘之心得或作為回國後向長官報告參與會議內容：

防範動物劣藥、偽藥產品已成為一全球性議題，動物劣藥及偽藥不單影響動物防疫，也關係到食品安全。處裡本議題所涉及之專業及工作領域廣泛，單靠動物用藥品主管機關之力很難獨立完成，需與地方政府、海關、警察、實驗室及動物用藥產品行業進行合作。若出現動物劣藥及偽藥於市場上流通，則儘可能利用 WOAH 之 VASFE 系統進行通報外，亦可尋求國際間合作。

（二十六）閉幕結語

第 1 屆動物劣藥及偽藥工作坊及世界動物衛生組織 SFVP 監測及監控之試點型系統會議正式結束，主辦單位期盼有更多會員國加入使用 VSAFE

系統行列，並且積極使用並上傳國內所發現之動物劣藥及偽藥產品，共同防堵日益嚴重之問題，使動物可使用高品質之動物用藥品，進而維護食品安全並控制細菌抗藥性問題。

四、心得與建議

一、我國法規對於動物劣藥與偽藥產品之定義與 WOAH 定義有些許差異，故我國參與 VSAFE 系統所通報之動物劣藥及偽藥產品，需注意應依據 WOAH 定義。WOAH 參考 WHO 規定，制定動物「劣藥」、「偽藥」、「未登記或無許可證」產品定義及分類標準，使 WOAH 會員國於國際通報之標準具一致性。WOAH 主要依據三項標準進行分類判定。第一、這個動物用藥產品在當地國是否有做產品登記？第二、持證商（Marketing Authorization Holder, MAH）或製造商已確認該產品是否是由他們製造？第三、這個動物用藥產品是否通過實驗室品質標準或規格檢測？

二、值得我們注意的是，僅有動物劣藥及偽藥產品為 VSAFE 通報之標的，而「未登記或無許可證藥物」產品不是 VSAFE 通報之標的。此與我們法規認知之重點查緝藥物，有些許差異，我國法規針對「未登記或無許可證」之未經核准擅自輸入者，判定為刑責最重之「動物禁藥」，但此非 WOAH 關注品項，WOAH 關注於不合格藥品（包括偽造原廠牌之藥品）。因為我國法規所認定之未經核准擅自輸入之藥品，可能是其他國家合法登記且經檢驗合格之藥品。

三、我們起初認為必須掌握所有線索，才能至 VSAFE 通報劣藥或偽藥產品事件，然而透過本次會議，我們瞭解到 WOAH 考量於現場實務上，我們無法於第一時間掌握所有線索，因此，倘若有懷疑，即可向 WOAH 通報劣藥或偽藥產品，之後隨著時間之推移，掌握之線索越來越多，則依據第一時間通報之事件編號（reference number），補充更新後續之調查結果及處辦情形即可。事件編號是由 VSAFE 於會員國第一時間通報時，即會以 email 提供給通報窗口。但通報資料至少要包含以下：1. 廠牌名稱。2. 有效成分名稱及其力

價。3. 持證商或製造商之名稱。4.產品識別資訊：(1) 登記字號。(2) 批號。(3) 有限期限。(4) 製造日期。

四、我國於本研討會議期間，SFVP 即時通報表情境演練時，詢問 WOAH 相關疑義，倘若於同一時間同一地點，發現 3 種劣藥或偽藥產品時，則我們於第一時間填寫的 SFVP 即時通報表，是要填寫在同一張表格，或是填寫三張不同表格。WOAH 回應，要填寫 3 張 SFVP 即時通報表，這 3 種不同的劣藥或偽藥產品將視為 3 個事件，這 3 個事件會分別有自己的事件編號（reference number）。

五、我國未來送交至 VSAFE 系統之劣藥及偽藥資料，倘若有數據分析或系統操作介面之優化需求，則可於 VSAFE 介面填寫「Submit feedback and suggestions」表單；或寫 email 發送至 sfvp@woah.org，提出改良 VSAFE 之使用需求。

六、SFVP 即時通報表可以幫助我們確認已掌握之事實是什麼？缺少哪些資訊？該事件我們辨識出哪些風險？我們還需要採取哪些行動以補足缺漏之資訊？我們還需要採取哪些行動以因應辨識出之風險？對於完全沒有經驗的新手，即時通報表單可以一步一步帶領我們，將整個 SFVP 事件的拼圖，一塊一塊拼湊起來。一旦有這種制度化、系統化之流程，對於業務承辦人員流動後，新手亦可很快地進入狀況。

七、我國未來在參與 VSAFE 通報偽藥及劣藥時，可依個案決定能限定分享之資訊及分享之對象。倘若通報國之訊息不能完全分享給他人，則可以分享給誰及如何分享？有幾個選項可供通報國聲明需保密之資訊，選項包括「可以與其他國際組織《例如世界海關組織、國際刑警組織》以及參加 WOAH VSAFE 之國家在洲際區域層級之分享，且不揭露通報國之名稱，但揭露受影響之洲際區域」等。

八、WOAH 於會場上提供之兩個情境演練，可考量於我國各地方動物防疫機關動物用藥業務聯繫會議時，供與會人員分組討論、演練與報告，亦可於該會議告知關於 WOAH VSAFE 相關訊息，供地方人員對於劣藥與偽藥之管理專業知識與國際接軌。

九、動物劣藥、偽藥會造成治療失敗、農民對動物醫藥體系失去信任、促進 AMR 及造成食品供應之短缺，可見動物劣藥及偽藥之通報、查緝與掃除對一個國

家之重要性，連帶影響至動物防疫、食品供應之穩定性等。因此，有必要適時審視我國每年投入於違法藥物查緝經費及人力等資源是否需調整。

五、附圖

WOAH 動物劣藥、偽藥資訊系統工作坊與會成員合照

動物偽藥、劣藥調查情境案例演練之分組報告：
我國與會代表陳昱憲技士負責報告該組討論結果

會後與日本代表（左 2、右 3）、馬來西亞代表（左 3、右 2）合影

六、附件

（一）附件 1：「WHO 對於檢測「疑似」偽藥之指導原則」。

（二）附件 2：本研討會之講者簡報。

（三）附件 3：RAGNA（Regulatory Agencies Global Network Against AMR）簡介

Annex 5

WHO guidance on testing of "suspect" falsified medicines

1. Introduction

1.1 "Suspect" medicines

"Suspect" medicines can be divided into three main categories of products as follows:[1]

(a) substandard medicines

Also called "out of specification", these are authorized medicines that fail to meet either their quality standards or their specifications, or both.[2]

(b) unregistered/unlicensed medicines

Medicines that have not undergone evaluation and/or approval by the national regulatory authority (NRA) for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.

These medicines may or may not have obtained the relevant authorization from the NRA of their geographical origin.

(c) falsified medicines

Medicines that deliberately/fraudulently misrepresent their identity, composition or source.
Any consideration related to intellectual property rights does not fall within this definition.
Such deliberate/fraudulent misrepresentation refers to any substitution, adulteration, reproduction of an authorized medicine or the manufacture of a medicine that is not an authorized product.

This document deals specifically with products that are suspected to belong to the third category, i.e. "falsified" medical products.

1.2 Responsibility of regulatory authorities

NRAs should establish rules and instruments that control the production, distribution and commercialization of medical products in order to ensure their quality through rigorous regulatory oversight, including postmarketing surveillance, in line with national legislation and regulations on pharmaceutical products. Rigorous regulatory oversight of medical products throughout their

[1] Based on World Health Assembly (WHA) A70/23 and WHA70(21) for "medical products".

[2] When the authorized manufacturer deliberately fails to meet these quality standards or specifications due to misrepresentation of identity, composition or source, then the product should be considered "falsified".

life cycle is necessary to recognize and remove unauthorized and/or falsified products and to protect the supply chain against infiltration of such products.

Falsified medical products can originate from inside or outside the legal supply chain. It is important that NRAs secure the supply chain and raise awareness among health workers and patients of risks associated with medicines from illegal sources.

A legal definition of falsified medicines and specific legal provisions to penalize acts related to falsification of medicines will empower NRAs to take actions against this problem. In implementing and enforcing legal provisions on falsified medicines, NRAs should collaborate with customs, police, legislature, industry experts, judiciary, prosecutors and enforcement agencies at the national and international level as appropriate.

1.3 The role of the World Health Organization

The World Health Organization (WHO), through its Expert Committee on Specifications for Pharmaceutical Preparations, sets technical standards on quality assurance of pharmaceutical products, including guidance on registration, good manufacturing practices (GMP), good distribution practices (GDP) and quality control (QC) testing of medicines, and on other topics that are relevant to the regulatory oversight of medicines.

A survey conducted among regulatory authorities of WHO Member States (*1*) indicated the need for specific technical guidance on laboratory testing of suspect falsified products. The present document was developed in response to the survey findings and complements the Committee's guidelines on sampling and market surveillance (*2*).

The Member State Mechanism on substandard and falsified medical products, created in 2012, makes recommendations to support regulatory authorities to prevent, detect and respond to activities and behaviours that result in falsified medical products (*3*). This document is intended to complement the Member State Mechanism's recommendations in accordance with the sixty-seventh World Health Assembly resolution WHA67.20 on Regulatory system strengthening for medical products (*4*).

2. Scope

This document provides technical guidance on laboratory testing of samples of suspect deliberately falsified medical products detected on the markets of WHO Member States and related aspects of sampling and reporting. This guidance should be read in conjunction with the guidelines on sampling and market surveillance (*2*).

3. Glossary

The definitions given below apply specifically to the terms used in this document. They may have different meanings in other contexts.

authorized product. A product in compliance with national and regional regulations and legislation. National or regional regulatory authorities can, according to national or regional regulations and legislation, permit the marketing or distribution of medical products with or without registration and/or licence.

chain of custody. A chronological and continuous record of the seizure and custody of the suspect product and the subsequent transfer of a sample of the suspect product to the laboratory as well as the handling of the sample within the laboratory.

falsified product. For the purposes of this document, a product that has been deliberately and/or fraudulently misrepresented as to its identity, composition or source, and which therefore requires testing beyond the routine quality control testing. Such deliberate/fraudulent misrepresentation refers to any substitution, adulteration, reproduction of an authorized product or the manufacture of a product that is not an authorized product.

> "Identity" shall refer to the name, labelling or packaging or to documents that support the authenticity of an authorized product. "Composition" shall refer to any ingredient or component of the product in accordance with applicable specifications authorized/recognized by the NRA. "Source" shall refer to the identification, including name and address, of the marketing authorization holder, manufacturer, importer, exporter, distributor or retailer, as applicable.[3]

forensic. Related to analysis for law enforcement purposes.

marketing authorization (product licence, registration certificate). A legal document issued by the competent medicines regulatory authority that authorizes the marketing or free distribution of a pharmaceutical product in the respective country after evaluation for safety, efficacy and quality. In terms of quality it establishes inter alia the detailed composition and formulation of the pharmaceutical product and the quality requirements for the product and its ingredients. It also includes details of packaging, labelling, storage conditions, shelf life and approved conditions of use.

[3] Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products. Report by the Director-General; 2017 (A70/23; http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_23-en.pdf, accessed 27 February 2018).

medical product[4] refers to medicines, vaccines and in vitro diagnostics (and in the future may include medical devices).

quality control. Embraces all measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that raw materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other pharmaceutical characteristics.

quality management. A wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.

screening technologies. The qualitative and/or semiquantitative technologies that can rapidly acquire the information or analytical data for preliminary identification of suspect medical products in the field.

standard operating procedure. An authorized written procedure giving instructions for performing standardized operations both general and specific.

4. Detection of suspect falsified products

4.1 Entry points for detection

Regulatory authorities are responsible, in collaboration with relevant national and international stakeholders, for establishing mechanisms to detect falsified products circulating in their territories and for removing them from the market. [5]

Suspect falsified products can be detected using a range of approaches, including routine inspections performed by national or regional authorities and enforcement agencies, targeted risk-based surveys (*1*), investigation of complaints, follow-up of reports on any suspicious observations in the supply chain (for example, inconsistent documentation or unexpected stock levels), discrepancy during verification and investigation of unexpected adverse events reported to have occurred with a specific product. It is important to evaluate any information on suspect falsified products reported by customs, medicines inspectorates and other authorities, procurement agencies, wholesalers and importers, pharmacies, health-care institutions, patients and other stakeholders.

[4] Working Group of the Member State Mechanism (http://apps.who.int/gb/sf/pdf_files/A_SSFFC_WG2_2-en.pdf).

[5] See also reference (*3*), Paragraph II.1. Quality monitoring and control.

4.2 Detection methods[6]

Falsified medical products may be identified by their packaging characteristics and/or by identity verification, physical and chemical testing. This may require confirmation, where appropriate, by the stated manufacturer, that the product was not manufactured by them (for example, written confirmation that packaging and other elements do not correspond to the genuine manufacturer's records).

When available, the packaging and patient information leaflets of suspect falsified medicines should always be examined visually and compared with samples or photographic images of genuine registered products if available.[7] Product protection features may also be utilized to screen and/or authenticate suspect packaging components. Attention should be paid to any irregularities or inconsistencies, such as spelling mistakes, unusual batch numbers, unusual printing of batch number and shelf life, verification of serialization data when appropriate, unexpected or modified manufacturing or expiry dates, signs of repacking, for example, to circumvent inspection activities, or instructions in a language that does not match the area of their distribution. Microscopy and other analytical techniques (including but not limited to optical techniques) may be utilized for package examination. The purpose of these technologies is to rapidly provide evidence that the sample comes from a falsified product.

An extensive list of analytical techniques that can be used to screen the market for falsified products is provided in Appendix 1. More detailed descriptions of available technologies can be found in published literature and online guidance (*5*, *6*, *7*).

The result of a screening test is only indicative (preliminary or presumptive adverse analytical result) and other analytical techniques must be applied to confirm unequivocally that a falsified medical product has been detected.

Some of the methods shown in Appendix 1 rely on a comparison with suitable reference materials or data available in a library or a reference database. Sharing of reference values and screening results through access-controlled information technology interfaces can provide strong support for the application of rapid screening technologies.

---

[6] Further guidance on screening technologies is provided by the Working Group of the WHO Member State Mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products (*3*) through its prioritized activities 2014–2015, specifically Activity C, aiming to establish and convene a working group comprising Member States' experts to assess and report on: (a) existing "track and trace" technologies in use by Member States; and (b) existing field detection devices in use or available to Member States.

[7] The manufacturer or marketing authorization holder should inform the relevant NRA of any changes to the artwork or packaging of its registered products. Details of analysis/observation of authentication features displayed on the product packaging, or embedded within the product itself, should also be included in the registration dossier. This will help the NRA to assess the authenticity of a given suspect product when conducting visual inspections.

4.3 Selection of analytical techniques

Appendix 1 provides an overview of the analytical techniques available at the time these guidelines were developed. The choice of analytical technology to be applied should be based on the information required. The regulatory authority should obtain advice about available analytical techniques including, for example, from the manufacturer and the analytical testing laboratory, before deciding which analytical technique to use, taking into account:

- the expected benefits of each technology (scientifically based), given its applicability and performance characteristics;
- opportunities for efficient use within existing postmarketing surveillance activities, such as inspections for compliance with licensing requirements, GMP or GDP;
- the availability of adequately trained local operators and cost of training;
- the expected cost of equipment, including its periodic calibration and qualification;
- recurring costs and availability of consumables, reference materials, libraries and maintenance;
- any other factors that may influence the use of analytical techniques in the national context.

5. Sampling and documentation

5.1 Sampling

Sampling of suspect falsified products is typically performed by inspectors or enforcement officers (such as police or customs officers) or other competent personnel, for example, laboratory personnel. Suspect medical products can also be detected during the complaint process. Care should be taken to ensure that the sample taken or seized is representative of the suspect medical product. A sufficient number of dosage units should be taken to enable thorough analytical testing. Guidance and advice should be sought from a suitably qualified analytical testing laboratory (*1*). However, if the requisite amount is not available all units should be collected.

5.2 Documentation of information on suspect falsified medical products

An information collection form, which is to be completed by the inspector or enforcement officer, should be comprehensive and include, but not be limited to:

- the point of detection in the supply chain (manufacturer, wholesaler, pharmacy, hospital or patient);
- the quantity of suspect product found;
- a visual description of its packaging;
- product name as marketed (if any);
- name of active substance (if known);
- the dosage units;
- the batch number;
- photographs;
- any signs of irregularities;
- the supply history of the product including the name, address of parties involved, date of transfer, etc.;
- a description of the circumstances leading to its detection (for example, adverse effects and any other relevant information).

This document should accompany the sample from the time it is taken until it is delivered to the testing laboratory. An example of an information collection form is presented in Appendix 2.

5.3 Chain of custody considerations[8]

From the time of collection or seizure of the suspect falsified medical product until its ultimate fate is decided, a rigorous chain of custody should be maintained to ensure that the integrity of the sample and its accompanying documentation is preserved. Secure packing, labelling, appropriate transport and storage conditions for the sample must be provided and documented. In addition, adequate security arrangements must be in place to prevent any theft, tampering, substitution or unauthorized disclosure of information.

The chain of custody of a sample consists of two parts. The first starts at the location where the suspect falsified medical product was seized or purchased by the inspector, or when a suspect falsified medical product has been detected by a manufacturer or any other stakeholder and includes all stages of the process of delivering the sample to the analytical testing laboratory. The second part relates to the laboratory, where all transfers of the sample must be recorded so that the analytical report generated by the laboratory can be unequivocally linked to the source of the sample.

[8] See also reference (*3*), Paragraph IV.1.1.30.

The inspectors or enforcement officers should document details of the suspect falsified product including (but not limited to):

- location of detection (name or title and address);
- at what point in the supply chain detection occurred (manufacturer, wholesaler, pharmacy, hospital, patient, etc.);
- pharmaceutical product type, pharmaceutical dosage form (tablet, capsule, injection, etc.);
- quantity and/or volume;
- date and time of seizure or purchase;
- names and signatures of the inspector or enforcement officer and the owner of the suspect falsified medicine at the location;
- the amount collected;
- description of packaging;
- location to which the sample is sent;
- other relevant information (international nonproprietary name (INN), brand name, batch number, shelf life, dosage, strength, etc.).

The inspector or enforcement officer is responsible for securing the sample appropriately and arranging transport to the testing laboratory. Whenever possible, samples that cannot be transported immediately are to be stored according to the storage conditions defined by the manufacturer, in a secure place. Otherwise, whenever possible, samples are to be stored in a secure, cool environment.

The inspector or enforcement officer should include a copy of the appropriate documentation (see section 5.2) in each transport bag or container holding the samples, to ensure that the laboratory can verify the contents upon delivery.

Samples may be taken directly to the analytical testing laboratory by the inspector or enforcement officer or handed over to a qualified and approved courier for transportation.

If an approved courier company is used to transport the samples, this should be documented in the chain of custody of the samples and the inspector or enforcement officer should record the waybill and tracking numbers of the shipment. The recipient of the sample should be informed of the expected delivery date and the storage and transportation conditions.

Within the laboratory, samples are considered to be in custody when they are:

- in the physical possession of authorized staff;
- visible to authorized staff after being in his/her physical possession;

- stored in a secure location.

The laboratory chain of custody should be reflected in all the documentation generated by the laboratory, which may include logbooks, worksheets, photographs and analytical reports where the custody of the samples during analysis and storage is recorded with the signature of the staff member concerned and the date and time of the action(s). The laboratory chain of custody shall be a continuous record of authorized staff with custody of the samples at all stages of the process from receipt to disposal. At each stage, the authorized staff involved must sign and date the entry for the action performed (for details see WHO *Guidance on good data and record management practices* (*8*)).

It is essential to ensure traceability throughout the process – from the seizure or purchase of the suspect falsified medical product to the conclusion of the investigation.

6. Regulatory actions upon detection of suspect falsified medical products

6.1 Risk assessment

When a suspect falsified medical product has been found, the relevant NRA is to be informed (for details see section 8).The NRA should then perform a risk assessment to determine what further action is required to protect public health.[9] This assessment should be done in communication and collaboration with the marketing authorization, licence or registration holder, and if applicable with the manufacturer of the genuine product, and an analytical testing laboratory with experience in testing suspect falsified medical products. WHO and other regulatory authorities should also be informed as appropriate.

Further action may include confirmatory laboratory testing of the suspect samples.

6.2 Questions to be answered by analytical testing

If laboratory analysis is to be conducted, NRAs should send the samples to a laboratory with adequate capacity to perform the testing as described in this document. If no such laboratory is available in the country concerned, the NRA should identify a competent and suitably equipped laboratory in its region or elsewhere that can advise on designing a testing plan and/or perform some or all of the testing. The manufacturer of the genuine product may also be requested to

[9] See reference (*3*), Section III. Assessment of alerts, reports and notifications received.

provide information or methods (including reference substances and a sample of the genuine product), which may be used for the testing of suspect samples and/or may be requested to analyse the samples.

Upon receipt of a suspect falsified medical product, the regulatory authority, enforcement agencies and other relevant stakeholders need to clarify the purpose and aims of testing. Some examples of questions that laboratories may be requested to answer (with the assistance of the regulatory authority, enforcement agencies and other relevant stakeholders) are listed below.

- Does the sampled product fall under the national legislation for pharmaceutical products?
- Does the sample meet specifications defined as part of the stated product's marketing authorization?
- What specific substances should the testing be designed to detect? (Examples include specific unexpected active ingredients or groups of active ingredients, specific impurities and any substances that are consistent with reported adverse effects.)
- What additional parameters should be tested to assess the health impact of the ingredients? (Examples include content, dissolution or disintegration properties and sterility.)
- Is there a forensic relationship between different falsified products? If yes, in what aspects?
- Are there any market authorization specifications and methods of analysis available for the suspect samples? *Note*: Check if there is a product monograph in *The International Pharmacopoeia*, or any national or regional pharmacopoeia.

  What are the expected excipients (if any) in the suspect samples? *Note*: As it is often not possible to answer that question, the testing should be arranged in such a way that there is no (negative) interference of the excipients in the identification and quantification of the substance that is expected to be contained in the sample.

6.3 Communication

Care should be taken by the NRA to convey clear and appropriate messages when communicating information about suspect or confirmed falsified medical products to the stakeholders. Dissemination of information should be well planned, to reach all relevant stakeholders while ensuring confidentiality as appropriate. NRAs should keep a record of the date, recipients and content of information disseminated. WHO and other regulatory authorities should also be informed as appropriate.

Patients who might be affected by falsified medical products should be advised to consult their health professional. Health professionals and procurement agencies, wholesalers and importers should be instructed on the action(s) to be taken to enable a continued supply and treatment while ensuring patient safety. In all communications the manufacturer whose name is printed on the packaging of the products should be described as the "*Stated* manufacturer", making it clear that the falsified medical product may not have originated from the stated manufacturer. Miscommunication can amount to falsely accusing the legitimate manufacturer of falsifying a product, which would be grounds for legal action by that manufacturer.

7. Confirmatory analytical testing

NRAs should refer samples to a laboratory with adequate capacity to perform the testing as described in this document. The manufacturer of the genuine product may also be requested to provide information or methods (including reference substances and a sample of the genuine product) that may be used for the testing of suspect samples or may provide technical support. Any information and/or materials provided by the marketing authorization holder to a government laboratory in support of an investigation of a suspect falsified medical product must be handled as confidential. Where necessary, material transfer agreements or confidentiality agreements are to be invoked.

7.1 Laboratory capacity

Best practices for QC laboratories and the minimum requirements for equipment are described in WHO guidance (*6*). That guidance focuses on QC laboratories using compendial or manufacturers' methods, as described in dossiers submitted for marketing authorization, to ensure compliance with the requirements of compendial monographs or manufacturer's specifications. However, these methods are designed to detect problems that may arise during the approved manufacturing process and subsequent storage and distribution and may not necessarily be appropriate to detect all possible issues that could arise with medical products that have been deliberately falsified. Methods used to authenticate suspect medical products must be suitable for their intended use.

Laboratories, normally national medicines testing laboratories, that test suspect falsified medical products should preferably be ISO/IEC 17025 accredited by a recognized accreditation body (affiliated, for example, to the International Laboratory Accreditation Cooperation, etc.) to perform the appropriate analytical procedures that are listed in their scope of accreditation. Alternatively, a WHO-prequalified laboratory with the capability to test suspect falsified medical products, an appropriate array of analytical techniques and

sufficient expertise, may be chosen. Furthermore, the laboratories should be able to perform, interpret and document the testing according to rigorous procedures to ensure that the results can withstand legal scrutiny.

Beyond the requirements of good practices, described in general WHO guidance (*6*) and ISO/IEC 17025, some additional skills and capacity, as outlined below, are required for the analytical testing of suspect falsified medical products.

7.1.1 Expertise

- **Critical thinking.** Laboratory staff should have the ability to critically appraise all that is known about each case of a suspect falsified product and not simply rely on pre-existing standard testing procedures. This skill can be strengthened through discussions with peers on specific cases and by learning from senior experts in the field.
- **Experience.** Laboratories should have access to staff with experience in designing and implementing science-based, tailor-made testing plans for suspect falsified medical products. Where this is not the case, they should cooperate with other institutions and/or refer the testing request to an institution where the required experience is available.
- **Knowledge.** Laboratory staff should have up-to-date scientific expertise enabling them to fully understand the scientific methods used in testing falsified medical products, to apply them correctly and to interpret the results adequately.

7.1.2 Equipment

Laboratories should ensure that technical equipment for testing of suspect falsified medical products about which they have adequate knowledge and experience is appropriately qualified and maintained in good condition. Investments should be planned so as to enable the basic functioning of the laboratory for all its intended purposes and to maximize the benefits of any additional specialized equipment purchased. The cost of the equipment should be considered together with that of accessory products such as consumables, reagents, standards, databases and libraries, as well as the costs of and access to installation, maintenance and training. Sharing of equipment in accordance with regional cooperation agreements can be considered to minimize the costs while maximizing the benefits.

Laboratories also need secure and adequate storage facilities for the suspect falsified samples, when not being tested, to ensure the chain of custody.

7.2 Standard operating procedure

Laboratories should develop, implement and maintain a standard operating procedure (SOP) for testing of suspect falsified medical products. Such an SOP cannot define each step in the testing, since this will be determined on a case-by-case basis. Rather, it should ensure that the laboratory follows good practice and internal quality management systems in planning, implementing and documenting its actions with regard to each request for testing. *WHO guidelines for sampling of pharmaceutical products and related materials* (*7*) and *Good practices for pharmaceutical quality control laboratories* (*6*) should be followed, as applicable.

Measures should be taken to minimize bias. Sampling should be separate from testing. Staff performing each analysis on the testing plan should be blinded to the results of the other analyses as far as possible.

The laboratory should ensure full traceability of samples and results as described in relevant WHO guidelines (*1*, *6*, *7*), and should follow rigorous procedures to preserve the integrity of samples and documentation, with a chain of custody that will stand up to scrutiny in case of legal action.

An example of an SOP for testing of suspect falsified products is provided in Appendix 3.

7.3 Testing plan and test procedures

All the available information about the samples should be provided to the laboratory in the form of a request for analysis that clearly indicates what is expected from experimental testing. The inspector or enforcement officer who collected the sample should inform the laboratory as comprehensively as possible and necessary for efficient running of the testing.

A suitable analytical testing programme should be prepared to detect the suspect substances. An initial study should then be undertaken, keeping in mind the number of sampling units available, to determine the substances to expect in the sample and parameters to be tested, and to design a science-based testing plan identifying the most efficient combination of methods to provide the required answers.

A wide range of methods may be considered for inclusion in the testing plan, which includes simple visual checks as well as the technologies listed in Appendix 1, and other forensic analyses that may assist in determining likely sources of suspect falsified medical products. Each technique should be appraised to determine its most appropriate use in order to achieve the best possible performance in the given context.

More detail on combining technologies to identify falsified medical products can be found in the literature (e.g. (*5*)). Various examples of flowcharts describing how to proceed with testing are reproduced in Appendix 4 for

illustrative purposes (with the kind permission of the authors, the European Network of Official Medicines Control Laboratories).

7.4 Interpretation and reporting of results

General good practices in interpreting laboratory testing results are described in WHO guidance (*6*). Specific points to document for testing of suspect falsified medical products include:

- reasons for selecting the particular methods used in the testing plan;
- measures taken to avoid bias in analysis and reporting;
- traceability of the measurements, with links to all physical material and to the original sample on which the test was done;
- limitations of the selected methods as used in the testing plan, together with an estimate of the measurement of uncertainty of a quantitative result, if performed, and the conclusions.

8. Reporting and regulatory action on confirmed falsified medical products

A legal framework for reporting of falsified products should be in place at national level (*9*).

The confirmed testing results should be reported to the regulatory authority of the country where the falsified product was found. It is the responsibility of the NRA, under the given circumstances, to decide how the findings should be translated into appropriate action in accordance with national legislation and in cooperation with enforcement agencies and other stakeholders.[10] The marketing authorization holder should be kept informed of the results of testing. Other regulatory authorities should be informed as appropriate. A report should be submitted to the WHO Global Surveillance and Monitoring system for Substandard and Falsified Medical Products (*10*).

9. Archiving of samples and reports

The testing laboratory should store the samples appropriately and archive the related documentation in separate secure locations for future reference as required by legislation, documenting that the integrity of samples and results have been preserved.[11]

[10] http://www.who.int/medicines/regulation/ssffc/surveillance/en/.

[11] See also reference (*3*), Paragraph IV.1.1. 30.

References

1. Combating unsafe medical products: outcomes of a survey on testing of suspect medicines. WHO Drug Info. 2014;28:317–23 (http://www.who.int/medicines/publications/druginformation/issues/DrugInformation2014_Vol28-3/en/, accessed 13 October 2016).
2. Guidelines on the conduct of survey of quality of medicines. In: WHO Expert Committee on Specifications on Pharmaceutical Preparations: fiftieth report. Geneva: World Health Organization; 2016: Annex 7 (WHO Technical Report Series, No. 996).
3. Report of the third meeting of the Member State Mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products, Geneva, 29–31 October 2014. Annex. In: Sixty-Eighth World Health Assembly. Provisional agenda item 17.3 (Document A68/33. Substandard/spurious/falsely-labelled/ falsified/counterfeit medical products. Report by the Director-General) (http://www.who.int/gb/ssffc/, accessed 13 October 2016).
4. Resolution WHA67.20. Regulatory system strengthening for medical products. In: Sixty-seventh World Health Assembly, Geneva, 16–24 May 2011. Resolutions and decisions, annexes. Geneva: World Health Organization; 2014:41–5 (http://apps.who.int/gb/ebwha/pdf_files/WHA67-REC1/A67_2014_REC1-en.pdf , accessed 13 October 2016).
5. Institute of Research Against Counterfeit medicines (IRACM). [Compilation of analytical assays, covert or coded features, techniques, traceability and tracking technologies to detect counterfeit medicines.] (http://www.iracm.com/en/table/, accessed 27 February 2018).
6. WHO Good practices for pharmaceutical quality control laboratories. In: WHO Expert Committee on Specifications on Pharmaceutical Preparations: forty-fourth report. Geneva: World Health Organization; 2010: Annex 1 (WHO Technical Report Series, No. 957; http://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodpracticesPharmaceuticalQualityControlLaboratoriesTRS957Annex1.pdf, accessed 27 February 2018).
7. WHO guidelines for sampling of pharmaceutical products and related materials. In: WHO Expert Committee on Specifications on Pharmaceutical Preparations: thirty-ninth report. Geneva: World Health Organization; 2005: Annex 4 (WHO Technical Report Series, No. 929).
8. WHO Guidance on good data and record management practices, In: WHO Expert Committee on Specifications on Pharmaceutical Preparations: fiftieth report. Geneva: World Health Organization; 2016: Annex 5 (WHO Technical Report Series, No. 996).
9. Guidance on developing a national plan for preventing, detecting and responding to actions, activities and behaviours that result in substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products, Member State Mechanism on substandard/spurious/falsely-labelled/falsified/ counterfeit medical products, Report by the Director-General. Geneva: World Health Organization; 2017 (WHA 70.23, Appendix 1; http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_23-en.pdf).
10. WHO project for the surveillance and monitoring of SSFFC medical products. WHO Drug Info. 2013;27:97–100 (http://www.who.int/medicines/publications/druginformation/issues/DI_27-2_SSFFC.pdf?ua=1, accessed 13 October 2016).

Appendix 1

Examples of analytical techniques that may be used for package identification, screening and testing of suspect falsified medical products

The list in Table 1 provides examples of analytical techniques that may be considered. These include compendial methods as well as specific advanced techniques. Each technique should be appraised to determine its most appropriate use in order to achieve the best possible performance in the given context. Laboratories may decide to outsource some of the analyses necessitating specific advanced techniques to other suitably qualified laboratories.

Note: The list should not be considered to be complete or exhaustive. It is intended to provide illustrative examples of commonly available technologies. Moreover, not all techniques are required for a laboratory that undertakes such testing.

Table 1
Illustrative examples of commonly available techniques

Main use	Technique	Full name	Remark
Identification	ATR/FTIR spectroscopy	Attenuated total reflectance/Fourier transform infrared spectroscopy	–
Identification	Melting point	–	–
Identification	XRPD	X-ray powder diffractometry	–
Identity	RI	Refractive index	–
Identification assay	Spectrophotometry (colorimetry)	–	–
Identification assay impurities	TLC	Thin-layer chromatography	–
Assay identification impurities	GC/FID	Gas chromatography with flame ionization detection	–

Table 1 *continued*

Main use	Technique	Full name	Remark
Forensics identification assay impurities	GC/MS	Gas chromatography with mass spectrometric detection	–
Assay identification impurities	LC/UV	Liquid chromatography with ultraviolet detection	–
Residual solvents impurities	HS-GC/FID	Headspace gas chromatography with flame ionization detection	–
Forensics residual solvents impurities	HS-GC/MS	Headspace gas chromatography with mass spectrometric detection	–
Inorganic impurities	ICP/OES	Inductively coupled plasma with optical emission spectroscopy	–
Inorganic impurities	ICP/MS	Inductively coupled plasma with mass spectrometric detection	–
Elemental and chemical analysis	XRF	X-ray fluorescence	–
Finished pharmaceutical product testing	Dissolution testing	–	Indication on bioavailability of the active pharmaceutical ingredient (API)
Finished pharmaceutical product testing	Disintegration testing	–	Indication of bioavailability of API
Specific testing	Sterility	–	–
Specific testing	BET	Bacterial endotoxins test	–

Table 1 *continued*

Main use	Technique	Full name	Remark
Specific testing	Osmolarity and osmolality	–	Characterization of injections and infusions
Finished pharmaceutical product testing forensics	Light microscopy	–	Particle characterization (size distribution, size, particulate impurities)
Identification	Raman spectroscopy	–	Characterization of material
Forensics	Photo scan/overlay	–	Documentation, comparison (e.g. packaging, leaflets)
Forensic	FTIR/Raman imaging spectroscopy	–	Characterization of material composition (distribution, particulate impurities)
Forensics	TEM	Transmission electron microscopy	Characterization of material morphology (tablet, particles)
Forensics	SEM-EDX	Scanning electron microscopy with energy dispersive X-ray spectroscopy	Characterization of material (surface, distribution in mixtures, particulate impurities)
Forensics; identification of impurities	LC-HRMS	Liquid chromatography with high resolution mass spectrometric detection	Characterization of unknowns down to trace levels
Forensics; identification assay impurities	LC/MS	Liquid chromatography with mass spectrometric detection	–

Table 1 *continued*

Main use	Technique	Full name	Remark
Forensics; impurities	TDS-GC/MS	Thermodesorption gas chromatography with mass spectrometric detection	Qualitative analysis of volatiles and semi-volatiles in solid samples (direct analysis/ without sample preparation)
Forensics	LC/ELSD	Liquid chromatography with evaporative light scattering detection	–
Forensics; identification assay impurities	NMR, qNMR	Nuclear magnetic resonance, quantitative nuclear magnetic resonance	Characterization of unknown compounds and mixtures – qualitative and quantitative

Appendix 2

Example of an information collection form

RECEIPT OF SUSPECT FALSIFIED PRODUCT		
Date on which the suspect product was received:		
Suspect product received by:		
Signature of the inspector/ enforcement officer and that of the owner of the product collected or seized		
Suspect product:		
Supply history of the product		
Source of the suspect product:		
Contact details of source of suspect product:	Name and surname:	
	Physical address:	
	Email:	
	Telephone number(s):	
	Other:	

INFORMATION ON SUSPECT FALSIFIED PRODUCT			
1. Suspect product name(s):			
2. Type of product (select the most appropriate box):			
Innovator product	☐	Generic product	☐
Vaccine	☐	Blood product	☐
Other biological product	☐		
Diagnostic	☐	Herbal medicine	☐
Traditional medicine	☐	Other, please specify	☐
Additional comments (if applicable):			

3. API(s) present in the product and declared strengths:	
4. Description of the dosage form:	
5. Description of product packaging (primary and secondary):	

Table *continued*

INFORMATION ON SUSPECT FALSIFIED PRODUCT		
6. Does the packaging contain any holographic security features or short message service (SMS) verifiable coding?		
	Yes ☐	No ☐
Provide description (if applicable):		
7. Is there a patient information leaflet available with the product?	Yes ☐	No ☐
8. Batch number/lot number (if available):		
9. Date of manufacture (if available):		
10. Expiry date (if available):		
11. Does this product fall under the national legislation for pharmaceutical products?		
	Yes ☐	No ☐
12. Market authorization holder (if applicable):		
13. Manufacturer(s) details as given on the suspect product packaging:		
14. Quantity of suspect product received:		

Table *continued*

INFORMATION ON SUSPECT FALSIFIED PRODUCT		
15. Does the suspect product meet specifications defined as part of the stated product's marketing authorization?	Yes ☐	No ☐
Provide full data content by scanning the code (if applicable):		
Additional information:		
16. Any other information applicable:		

TESTING REQUIREMENTS			
1. Has the product been subjected to any preliminary testing?			
Yes	☐	No	☐
If "Yes" provide a summary of results			
2. What specific substances should the testing be designed to detect?			
3. What tests or parameters should be considered to assess the product?			
4. Is this sample physically and/or chemically similar to other samples (either specified or in general)?			

5. Are the market authorization specifications available?	Yes	☐	No	☐
6. Are official testing methods available?	Yes	☐	No	☐
Description of methods available:				
7. Any specific testing requests:				

IMPACT ON PUBLIC HEALTH				
Have any adverse reactions been reported?	Yes	☐	No	☐
If "Yes" provide more information:				
Estimated number of patients adversely affected?				
Estimated number of patients at risk?				
Any other related information:				

Appendix 3

Example of the content of a standard operating procedure for testing suspect falsified tablets

1. Purpose

The standard operating procedure (SOP) describes the workflow and the required test procedures for the testing of suspect falsified tablets.

2. Scope

The SOP is only valid for the good laboratory practices/good manufacturing practices test facility of _____ .

3. Sample receipt, documentation and storage

a. Sample receipt

Upon receipt of a shipment of suspect falsified tablets for analysis, the receiving laboratory should:

- record the
  - name and signature of the person delivering the sample or courier company waybill;
  - date and time of receipt of the sample in the laboratory with signature of the staff member;
  - presence of accompanying documentation in the shipment;
- check integrity (e.g. damage, broken sealing) of shipment packaging;
- check completeness of shipment against shipping documents;
- read out and check data logger (e.g. temperature control) – if applicable;
- check and sign shipment documentation – if applicable;
- archive all documents in the corresponding project files as per the corresponding SOP xxx.xxx.xxx.

b. Sample documentation

After sample receipt and unpacking:

- document packaging that contains the suspect falsified tablets as received as photographic image(s);

- document package insert or patient information leaflet as photographic image(s);
- check contents using shipping documents and previously received information from sending party;
- document each sample: secondary packaging and primary packaging (e.g. blister) including labels as photographic image(s);
- archive all documents and photographic images in the appropriate project files as per the corresponding SOP xxx.xxx.xxx;
- store samples under appropriate storage conditions according to SOP xxx.xxx.xxx until testing, record storage location;
- prior to testing let samples equilibrate to ambient temperature.

c. Checklists and records of observations

- All the above observations should be recorded on a checklist and signed and dated upon completion by the staff member responsible for these duties.
- The time and date of storage should be verified and recorded, with the signature of the person responsible.
- The time and date of sample removal from storage for equilibration to room temperature should be recorded, with the signature of the person responsible

d. Remarks

- When using photographic images for documentation purposes, check image quality (e.g. readability of text elements, colour correctness) before proceeding.
- Ideally, sample documentation should include dimensions (e.g. primary and secondary packaging, thickness and diameter of tablets).
- The sending party should be informed of receipt of the sample – if applicable.

e. Observations

Any observations such as damaged packaging, missing or additional samples should be documented and communicated to the sending party in order to decide how to proceed.

4. Sampling and samples

- Split each sample set into three subsets.
- Subset 1 for packaging inspection and documentation and Subset 2 for analytical testing as described in the following sections.
- Keep Subset 3 as a retained sample for any further investigation.

5. Overall aspect

Inspect known product protection features (i.e. holograms, colour-shift inks, etc.)

a. Packaging

- Use Subset 1 (see section 4).
- Visually inspect the secondary and primary packaging, use authentic comparators whenever possible.
- Report observations of the external appearance of the packaging materials (including labels and printing) such as visible damage, holes, discoloration and stains, spelling mistakes and unusual typography.
- Document observations as photographic images and archive them together with corresponding notes in the project files as per the SOP xxx.xxx.xxx.
- Report results.

A reporting form should be signed and dated on completion by the staff member responsible.

b. Samples

- Use Subset 2 (see section 4).
- Visually inspect the tablets.
- Report observations of the external appearance of the tablets, such as visible fissures, holes, inclusions, discoloration or stains, presence or absence of score lines, and presence or absence of film or sugar coating.
- Document observations as photographic images and archive them together with corresponding notes in the project files as per the SOP xxx.xxx.xxx.
- Report results.

A reporting form should be signed and dated on completion by the staff member responsible.

6. Analytical testing

a. Packaging testing

- Use Subset 1 (see section 4).
- Record Fourier transform infrared spectroscopy (FTIR) or Raman spectra according to the SOP xxx.xxx.xxx in order to confirm or elucidate the identity of the primary packaging.
- Report results.
- A reporting form should be signed and dated on completion by the staff member responsible.

b. Solid medicine (tablet) testing

i. Active pharmaceutical ingredient (API)

- Use Subset 2 (see section 4).
- Homogenize at least one of the tablets of Subset 2 by mechanical grinding and use the homogenized material for the next steps.
- Confirm identity and concentration of the expected API in the suspect sample using the reference standard and corresponding compendial method. Alternatively, an in-house method can be used as long as the suspect tablet is tested against a suitable reference sample. The suitability of the in-house method for its intended use should be proven by means of validation reports and should be a stability indicative method.
- Report results.

A reporting form should be signed and dated on completion by the staff member responsible.

ii. Excipients

- Use Subset 2 (see Chapter 4).
- Record FTIR or Raman spectra of a reference sample (i.e. certified medicine reference sample) according to the SOP xxx.xxx.xxx.
- Record FTIR or Raman spectra according to the SOP xxx.xxx.xxx of the tablet, which was homogenized by mechanical grinding and compare against a reference sample in order to confirm presence and relative concentration of expected excipients.
- If differences from the data of the reference sample are observed perform in-depth analysis of experimental data (e.g. presence of unexpected substances or lack of expected substances).

- Report results.

There should be a reporting form to be signed and dated on completion by the staff member responsible.

iii. Additional tests

If tests as described in sections i. and ii. do not deliver unambiguous results additional screening tests can be performed on Subset 2. These screening tests can include:

- elemental analysis screening using inductively coupled plasma with optical emission spectroscopy (ICP-OES) or ICP/mass spectrometry (MS) as per SOP xxx.xxx.xxx;
- screening for volatiles and semi-volatiles using thermodesorption gas chromatography (TDS-GC)/MS as per SOP xxx.xxx.xxx;
- screening for volatiles and semi-volatiles via GC/MS as per SOP xxx.xxx.xxx;
- screening for non-volatile, polar compounds via high pressure liquid chromatography mass spectrometry (HPLC)/MS as per SOP xxx.xxx.xxx.

7. Dissolution and disintegration testing

- Use Subset 2.
- Perform dissolution testing in comparison to suitable reference sample.
- Report results.

There should be a reporting form to be signed and dated on completion by the staff member responsible.

8. Abbreviations

GC/MS	gas chromatography/mass spectrometry
HPLC/MS	high-pressure liquid chromatography/mass spectrometry
ICP/OES	inductively coupled plasma/optical emission spectrometry
ICP/MS	inductively coupled plasma/optical mass spectrometry
SOP	standard operating procedure

Appendix 4

Examples of flowcharts for testing of suspect falsified medicines

Explanatory note to the Appendix

This Appendix includes the examples from an "*Aide-Memoire for the Testing of Suspected Illegal and Counterfeit Medicines*" prepared by the European Official Medicines Control Laboratory **(OMCL)** Network **(*Reference*: PA/PH/OMCL (06) 81 R6, Strasbourg, July 2016) which has been reproduced with the kind permission from the Network members. Terminology may therefore differ from WHO style.**

"The original version of this document was produced in response to many presentations given at a number of Annual General Meetings of the OMCL Network (GEON).

The paper provides some practical and theoretical advice to OMCLs on the development of protocols for the confirmation or determination of counterfeit medicinal products and was adopted by the Network in 2007.

Subsequently, the testing of potentially illegal and counterfeit medicines throughout the Network has expanded and many laboratories now have established processes and expertise.

At the GEON annual meeting in June 2015, it was agreed that the "aide-memoire" document should be revised and updated to provide an overview of the overall approaches that should be taken for OMCLs analysing suspected illegal/ counterfeit medicines.

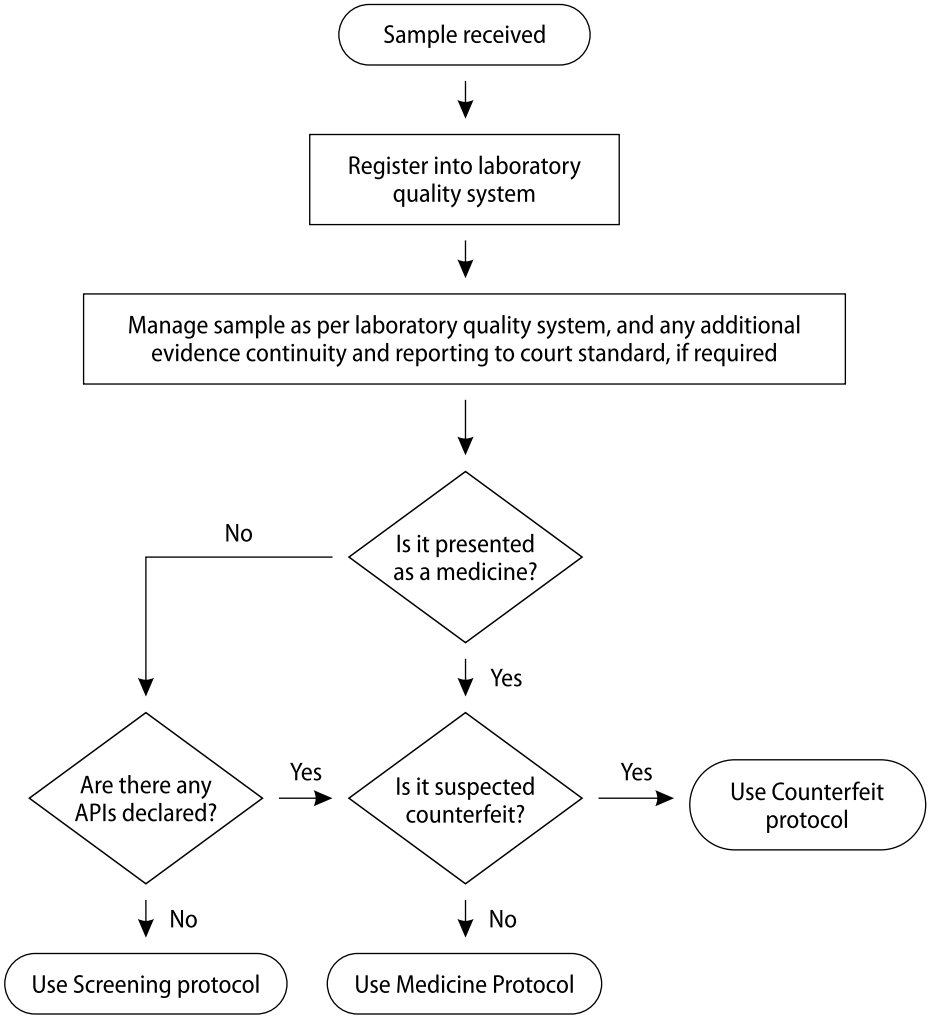
This document has been prepared to include example high-level process flows/ decision trees to assist OMCLs and promote a harmonised approach across the Network. It is recognised that OMCLs will have existing processes in place and this document does not supersede existing systems. This document is intended as an "aide memoire" only and OMCLs are not expected to be audited for compliance with the document.

The techniques listed in this document are examples only and should not be seen as exclusive or even preferred techniques. OMCLs should choose and use appropriate equipment to meet their testing needs.

The individual OMCLs' choice of specific analytical techniques and detailed testing SOPs are outside the scope of this document and should be decided locally in accordance with local legislation or policies (for example, some OMCLs may routinely quantify APIs found but others may not – either approach is acceptable), equipment availability and staff expertise/preferences.

The final decision on what techniques to use and equipment to purchase and exactly what testing to apply is left to individual OMCLs."

Example 1. Decision tree to determine testing requirements



Note:

Where no APIs are declared, often the name or marketing of the item can indicate what APIs may be present (for example, products may be marketed as weight loss or sexual potency enhancers, or have suggestive pictures/branding that implies the product's intended effect).

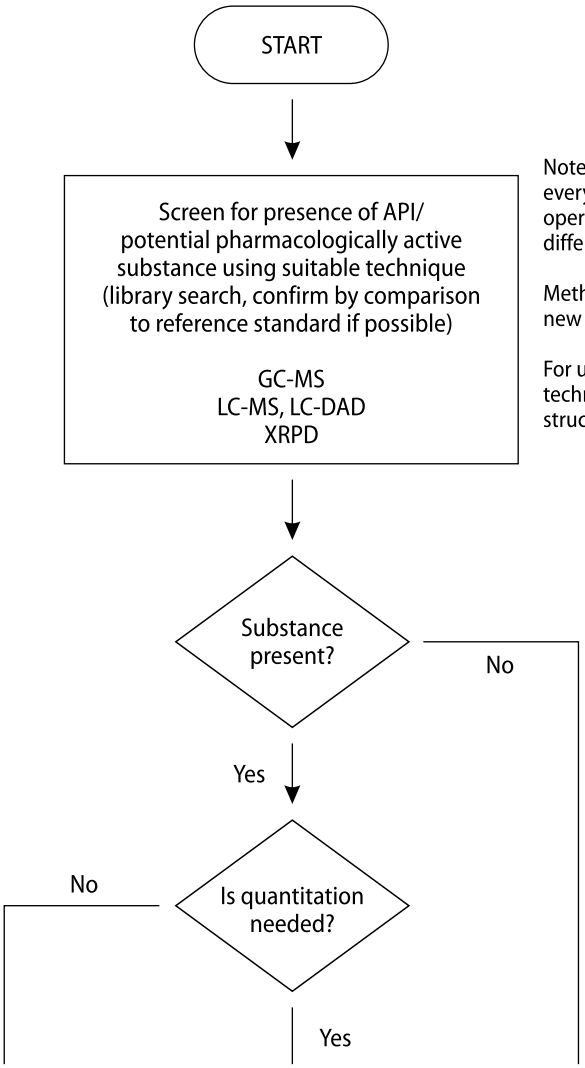
Also Internet searches using the product or producer name of the item can often provide information on APIs, use and/or indication.

Further details of the protocols that may be applied are given in the following sections.

Example 2. Screening protocol (testing for "medicines in disguise")

Samples may be presented as a food supplement, health tonic, "nutraceutical" or naturally derived or herbal product. Usually there will be either no mention of API(s) in the product or even a more positive statement such as "100% natural extracts" or similar. Alternatively samples may be presented in foreign language variants, or even unlabelled.

In these circumstances the priority of the testing is to establish whether there are any APIs/potential pharmacologically active substances present and, if there is, at what level if required.

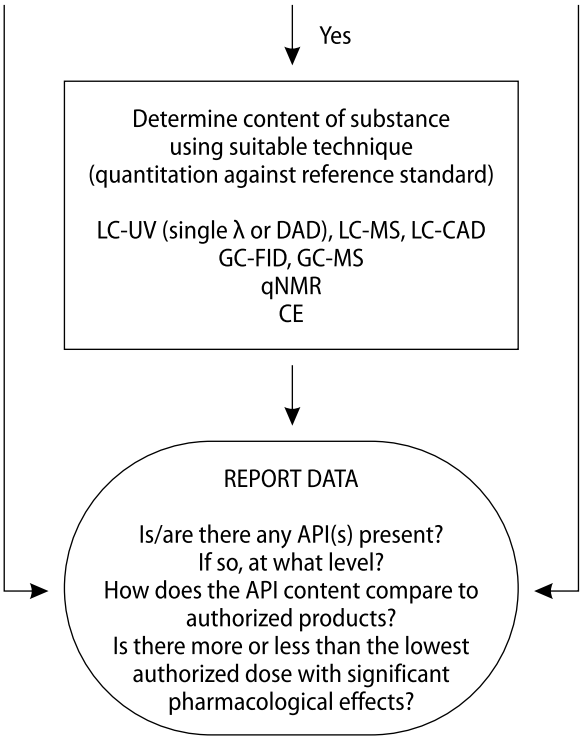


Note: screening methods may not detect every possible substance and OMCLs may operate more than one method (e.g. for different drug classes).

Methods will need to be updated to include new molecules as they are discovered.

For unknown or new molecules, advanced techniques may be needed to provide structure elucidation.

Figure *continued*



Example 3. Medicine protocol (testing of "unapproved products")

Samples may be legal, licensed medicines in other countries, but not necessarily in the country where they have been found, or they may be legal medicines sold outside of the correct, legal supply chain. They might also contain drug substances that are not licensed or legally authorized for sale or treatment. Usually the API(s) in the product will be listed on the label and the product will be packaged and presented as a medicine. In some cases, the samples may be presented in foreign language variants, so the API(s) present may be unclear.

The priority of the testing is to establish that the labelled API is present, and (if required) at what level.

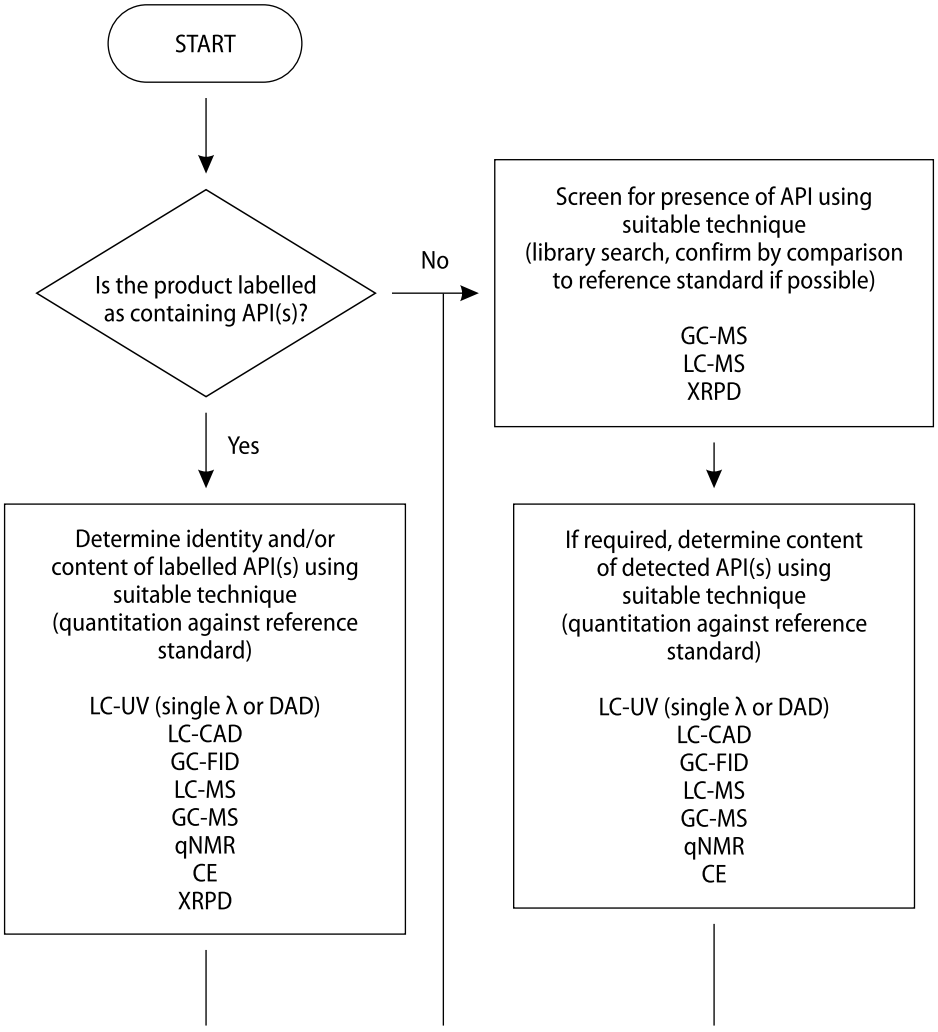
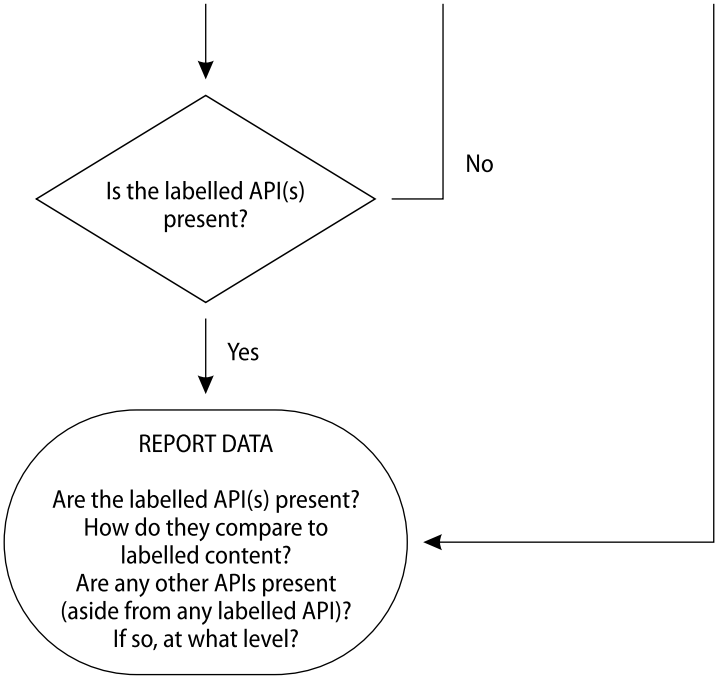
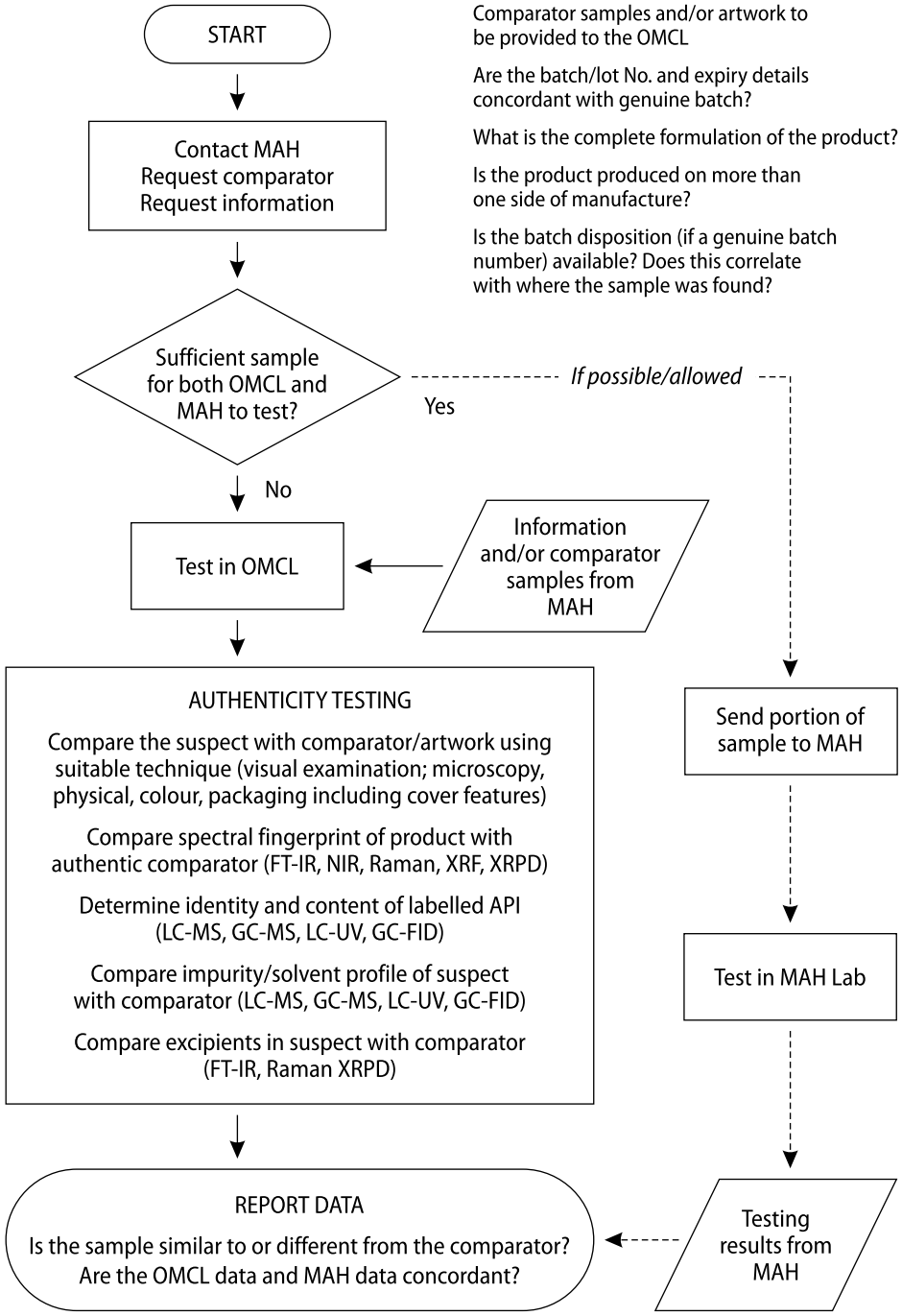


Figure *continued*



Example 4.Counterfeit protocol

For samples that are presented as licensed medicines but are suspected of being falsified, or counterfeit, it is essential that the OMCL is able to make contact with the market authorization holder of the genuine product. This may either be directly or through the competent authority, inspectorate or enforcement group. Genuine comparator batches (ideally three batches including the suspicious lot) should be obtained. If the product is manufactured at a variety of production sites samples should be obtained from each. It is not usually possible for a laboratory to determine conclusively that a sample of product is counterfeit based on testing alone. The priority of the testing can only be to say whether the suspect sample is consistent with the genuine product or not.



Note: when a suspect sample is found not to contain labelled API, the OMCL may wish to apply the screening protocol to determine what, if anything is present

1st Workshop on Substandard and Falsified Veterinary Products (SFVP)

WOAH pilot Veterinary Monitoring and Surveillance System for SFVP (WOAH - VSAFE)

Dr. Tikiri Priyantha

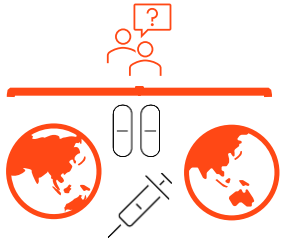
WOAH Headquarters - AMR & VP Department
WOAH Regional Representation for Asia and Pacific
WOAH Subregional Representation for Southeast Asia

12th June 2024 - Bangkok

World Organisation for Animal Health Founded in 1924
Organisation mondiale de la santé animale Fondée en 1924
Organización Mundial de Sanidad Animal Fundada en 1924

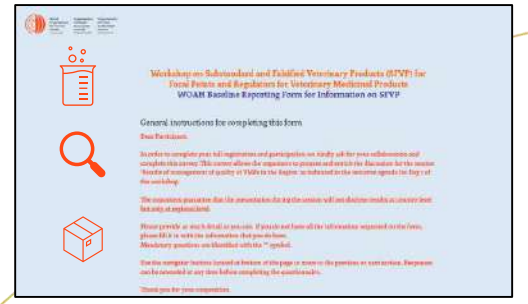
Overall Objectives

1



Awareness of gaps in knowledge of presence of Substandard and Falsified Veterinary Products (SFVP) in Regions, as well as their impacts on AMR and other harms to Members

2



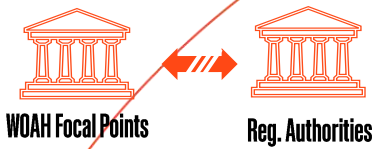
Understand the management of quality of VMP in Region

- Responsibilities & legal basis
- Types of monitoring and surveillance
- Recall and Traceability

3

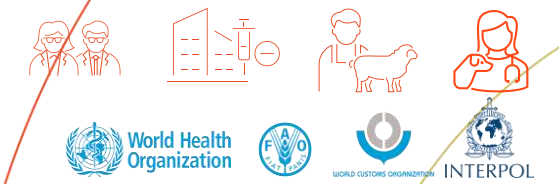
Explain and explore WOAH VSAFE with participants

4



Encourage the coordination

5



Understand perception and activities on SFVP from different stakeholders

Encourage cross sectorial coordination following a One-Health approach

Agenda

1st Workshop on Substandard and Falsified Veterinary Products (SFVP) and WOAH pilot Veterinary Monitoring and Surveillance System for SFVP (WOAH - VSAFE) for WOAH Focal Points for Veterinary Products and Regulators of Veterinary Medicinal Products in Asia and Pacific

12-14 June 2024 - Bangkok (Thailand)

FINAL PROGRAMME

DAY 1	Moderator: Dr. Andrés García Campos	
Time	**Theme**	**Speaker**
08:00 - 09:00	**Registration**	
	Official opening	
09:00 - 09:15	Welcome remarks	Dr. Javier Yugueros Marcos – Head WOAH AMR&VPD HQ
09:15 - 10:15	01 - Objectives of the seminar Short self-introduction by participants	Dr. Tikiri Priyantha – WOAH for South East Asia All facilitators and participants
10:15 – 10:45	02 - WOAH mission and vision on SFVP	Dr. Javier Yugueros Marcos – Head WOAH AMR&VPD HQ
10:45 – 11:15	*HEALTH BREAK AND GROUP PHOTOGRAPH*	
11:15 - 12:15	03 - Substandard and falsified veterinary and human medicines – a One Health approach Open discussion	Dr. Paul Newton – Medicine Quality Research Group, University of Oxford All facilitators and participants
12:15 – 12:30	04 - WOAH Collaborating Centre sharing management of SFVP – JAPAN	Dr Yuka Kobayashi – National Veterinary Assay Laboratory
12:30 – 13:00	Member experiences in the management of SFVP 05 - MALAYSIA 06 - THAILAND	Dr. Alifah Binti Ismail – Department of Veterinary Services Malaysia Ms. Witthayarat Dangyai – Thai FDA
13:00 – 14:30	LUNCH	
14:30 – 16:30	07 - Simulation exercise: incident scenario 1	WOAH as Facilitators – All participants
16:30 – 17:00	*HEALTH BREAK*	
17:00 – 17:30	08 - Customs Enforcement Initiatives	Mr. Billy KH YEUNG – RILO-WCO Asia and Pacific
18:30	WOAH Hosted Dinner	All
	End of Day 1	

DAY 2	Moderator: Dr. Tikiri Priyantha	
Time	**Theme**	**Speaker**
09:00 – 09:20	09 - Substandard and Falsified (SF) Medical Product 'Prevention, Detection and Response' global initiatives and regional activities – are there parallels for SF Veterinary Products?	Dr. Paul Brady Huleatt – Therapeutic Goods Administration
09:20 – 09:40	10 - WHO Global Surveillance and Monitoring System (GSMS)	Ms. Anita Sands – WHO Incident Substandard and Falsified Medical Products Team, WHO HQ
09:40 – 10:00	11 - FAO regional projects on Substandard and Falsified Antimicrobials at farm level	Ms. Jutamart Jattuchai – FAO RAP
10:00 – 10:20	12 - Introducing WOAH VSAFE	Dr. Andrés García Campos – WOAH AMR&VPD HQ
10:20 – 10:50	*HEALTH BREAK*	
10:50 – 11:30	Experiences from two Members enrolled in VSAFE 13 - MYANMAR 14 - NEW ZEALAND Floor open to all for discussion	Dr. Swe Lynn Htet – Livestock Breeding and Veterinary Department Dr. Warren Hughes – Agricultural Compound or Veterinary Medicine
11:30 – 13:00	15 - WOAH Immediate Notification Form Completion based on incident scenario 1	Dr. Andrés García Campos – WOAH AMR&VPD HQ
13:00 - 14:30	*LUNCH*	
14:30 – 15:30	16 - Simulation exercise: incident scenario 2	WOAH as Facilitators
15:30 – 16:00	*HEALTH BREAK*	
16:00 – 17:00	Continuation of simulation exercise 2	WOAH as Facilitators
17:00 – 17:30	17 - Operation PANGEA – a way to react towards SFVP	Mr. Chi Wang LAM – Public Health and Pharma Crime INTERPOL
	End of day 2	

DAY 3	Moderator: Dr. Andrés García Campos	
Time	**Theme**	**Speaker**
09:00 - 09:20	18 - SFVP perspective from Veterinarians	Mr. Nackarung Cutarpon – The Thai Veterinary Medical Association
09:20 – 09:40	19 - Illegal and counterfeit veterinary medicines: observations from the animal health industry	Dr. Carel du Marchie Sarvaas – HealthforAnimals
09:40 – 10:15	20 - RAGNA: Strengthen the international collaboration, identify concrete actions, and exchange experiences between human and veterinary sector	Ms. Anna Katarina Lönnquist – Swedish Medical Products Agency
10:15 – 10:45	*HEALTH BREAK*	
10:45 – 11:15	21 - Why interministerial collaboration matters? Fleming Fund's second phase in tackling AMR and SFVP into their programme strategy	Mr. Robert Rosetha – Mott MacDonald
11:15 – 11:30	22 - Results of survey for the management of quality of VMPs in WOAH Asia and Pacific Region	Dr. Tikiri Priyantha – WOAH for South East Asia
11:30 – 12:00	23 - Open discussion for collaboration (medical & vet) and in the management of SFVP in the Region	All facilitators and participants
12:00 – 12:40	24 - The workshop in one minute Feedback session of workshop	All participants Facilitator: Dr. Javier Yugueros Marcos, Head of WOAH AMR&VPD HQ
12:40 – 13:00	Conclusion remarks	Dr. Ronello Abila, WOAH SRR for South East Asia
Conclusion remarks and closing		
13:00 - 14:30	*LUNCH*	
	End of day 3	

Main Outcomes

1

Better understanding of the current situation on SFVP and responsibilities
Improved coordination

2

Identification of gaps and key priorities that WOAH needs to focus to prevent, detect and response to SFVP in Asia & Pacific context

3

Establishment of reporting systems in Members whose tools are lacking
Use system as additional asset when establishing AMR National Action Plans

4

Improve VSAFE Performance (Fit-for-purpose)
Increase Number of Members voluntarily enrolled to VSAFE
Increase Quality of information reported through VSAFE

5

Trust gained and share data to support prevention, detection and response to SFVP by responsible actors


Time for
introductions !!!

Thank you

Merci

Gracias

sfvp@woah.org

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
Founded in 1924

Organisation mondiale de la santé animale
Fondée en 1924

Organización Mundial de Sanidad Animal
Fundada en 1924

Why to avoid using SFVP?

1st Workshop on Substandard and Falsified Veterinary Products (SFVP)
and WOAH pilot Veterinary Monitoring and Surveillance System for SFVP (WOAH - VSAFE)
Asia and Pacific Region

Javier Y. Marcos
AMR & VP Department Head

13th June 2024 - Bangkok

World Organisation for Animal Health
Founded in 1924
Organisation mondiale de la santé animale
Fondée en 1924
Organización Mundial de Sanidad Animal
Fundada en 1924

To all our participants ...

World Organisation for Animal Health
Founded in 1924

Why?

ALEXANDER FLEMING

Penicillin

Nobel Lecture, December 11, 1945

I am going to tell you about the early days of penicillin, for this is the pa
of the penicillin story which earned me a Nobel Award. I have been fre
quently asked why I invented the name "Penicillin". I simply followed per-
fectly orthodox lines and coined a word which explained that the substance
penicillin was derived from a plant of the genus *Penicillium* just as many years
ago the word "Digitalin" was invented for a substance derived from the
plant *Digitalis*. To my generation of bacteriologists the inhibition of one
microbe by another was commonplace. We were all taught about these
inhibitions and indeed it is seldom that an observant clinical bacteriologist
can pass a week without seeing in the course of his ordinary work very def-
inite instances of bacterial antagonism.

It seems likely that this fact that bacterial antagonisms were so commo
and well-known hindered rather than helped the initiation of the study
antibiotics as we know it today.

Certainly the older work on antagonism had no influence on the be
ring of penicillin. It arose simply from a fortunate occurrence which
pened when I was working on a purely academic bacteriological prob
which had nothing to do with antagonism, or moulds, or antiseptic
antibiotics.

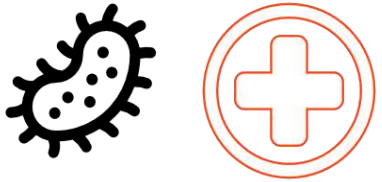
In my first publication I might have claimed that I had come to th
clusion, as a result of serious study of the literature and deep thoug
valuable antibacterial substances were made by moulds and that
to investigate the problem. That would have been untrue and I p
to tell the truth that penicillin started as a chance observation. My o
is that I did not neglect the observation and that I pursued the su
bacteriologist. My publication in 1929 was the starting-point of t
others who developed penicillin especially in the chemical field.

Penicillin was not the first antibiotic I happened to discover
described lysozyme - a powerful antibacterial ferment which
extraordinary lytic effect on some bacteria. A thick milky suspens
ria could be completely cleared in a few seconds by a fraction

The time may come when penicillin can be bought by anyone in the shops. Then there is the danger that the ignorant man may easily underdose himself and by exposing his microbes to non-lethal quantities of the drug make them resistant. Here is a hypothetical illustration. Mr. X. has a sore

Animal safety concern

Efficacy concern

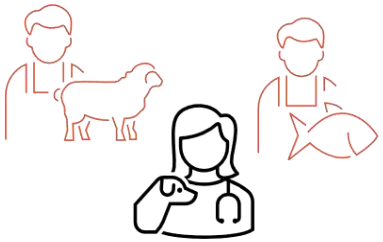


Animal health management concern

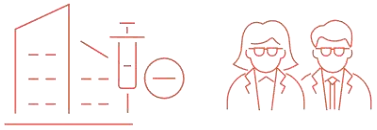
Food safety concern

Economic concern

Lose of trust concern



Reputational concern



World Organisation for Animal Health
Founded as OIE

SCOPE OF THE PROBLEM

Caution with interpretation !!

All animal species

Terrestrial, aquatic and no-food producing species at risk

No Geographical regions exempt of SFVP

Pharmaceuticals and Vaccines at risk

Responding to your needs !

Article 3.4.11.5 (xxx) :

Retailing, use and traceability of VMP

"Veterinary legislation should provide a basis for actions to address ...

a system of surveillance of the quality of veterinary medicinal products marketed in the country, including a system of surveillance for falsification"

Article 6.10.3.10 (2024):

Distribution and administration of antimicrobial agents or VMPs containing antimicrobial agents

"The Competent Authority should ensure that all antimicrobial agents and VMPs containing antimicrobial agents are ...

not illegal, substandard, falsified medicines or unapproved formulations and that these are prevented from entering distribution systems"

Resolution No. 26 Adopted on 26 May 2015

10. The OIE strengthen its collaboration with international organisations, such as the World Customs Organisation and Interpol, and stakeholders to combat counterfeit products with the aim of ensuring access to antimicrobial agents of proven quality.

6th recommendation (2018)

"Explore the possibility of building an information system of falsified and substandard drugs in the animal sector illegally circulating within and between countries and building on the experience of the monitoring systems set up by WHO for drugs designed for human use taking a 'One Health' approach"

HOW ?

Theory of Change

1. WOAH knows Members' needs against SFVPs and understands the real situation of SFVP problem globally.
2. WOAH Members actively engage with global surveillance of SFVPs in a coordinated manner
3. Improved cross-border coordination between WOAH Members and actors responsible for registration, surveillance & control of VMPs
4. Improved capacity of WOAH Members to detect and remove SFVPs from circulation in their country
5. Existence of a global Network of laboratories testing VMPs quality by Region
6. Strengthen One-Health collaboration and actions at national and global level
7. Protection of WOAH's institutional reputation due to misuse of WOAH's emblem on VMPs

REPORT & ALERT SYSTEM

PMS GUIDELINES

QC CAPACITY

FIELD LEVEL TESTING

AWARENESS

Impact & Goals

Strengthen within- and cross- sectorial coordination

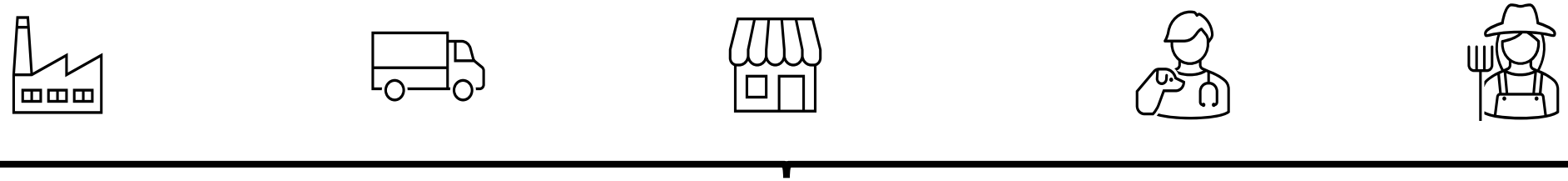
Fewer SFVPs circulating in WOAH Members

Reduced contribution to AMR & APR

Improved access to good quality VMPs and capacity to effectively manage animal diseases

Reduced impact of infectious diseases on animal health and welfare, food security and economic development

Veterinary Monitoring and Surveillance System for Substandard and Falsified VMPs

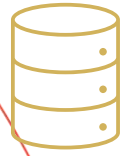


Inclusive

No judgement

No shaming

Members with access, control and analysis of their own data



Repository of incidents available at regional level

Public Alerts with recommendations (subject to conditions to fulfill)

Annual report

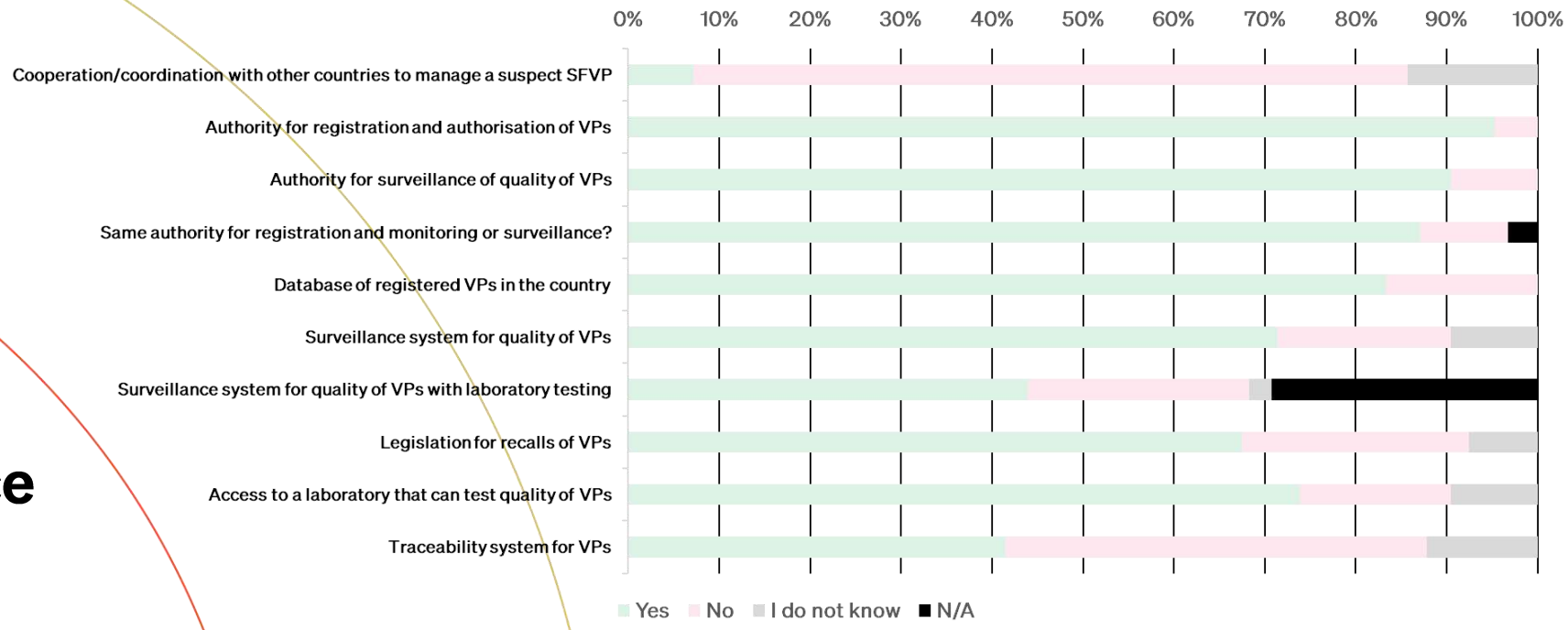
2nd Pillar : Development of Guidance related to SFVP

WOAH Collaborating Centres
Additional experts (academia)

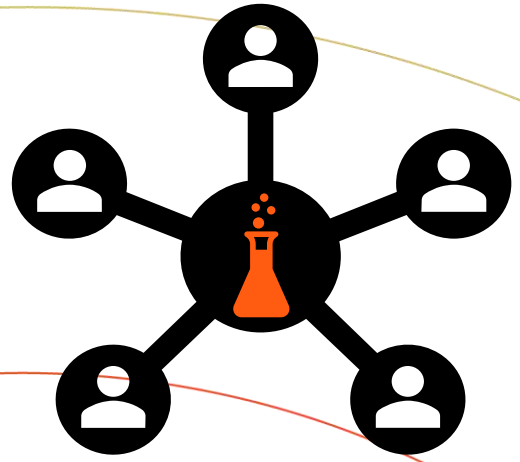
Open consultation prior to final guidance documents

7 Experts

Guidance on post-marketing surveillance



3rd Pillar : Explore opportunities for regional testing of quality of VMPs



Sustainable Regional Laboratory Networks

WOAH Collaborating Centres

Existing networks in regions ?

Existing partners/funding bodies involved?

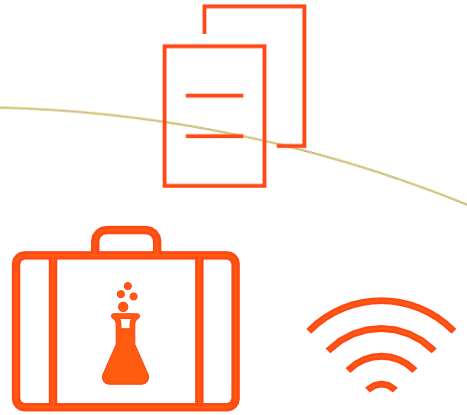
Members willing to establish collaborations?

Experience WHO – coordination with labs for testing APIs of common interest?

Public-Private Partnership?

Future → Twinning Programme?

4th Pillar : Options for strengthening surveillance of VMP quality at field level

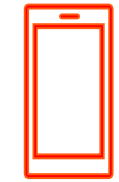


Guidelines & tools for field level surveillance

WOAH Collaborating Centres

Review of current devices available with recommendations of their use

Members willing to pilot active surveillance system



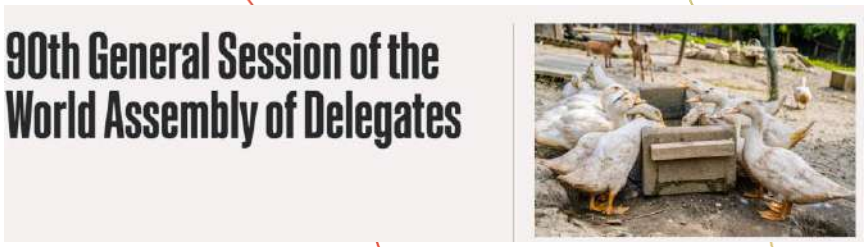
5th Pillar : Awareness, Communication & Training

HANDLE ANTIMICROBIALS WITH CARE

WORLD ASSOCIATION FOR BUIATRICS

Identify personal experiences

Use of social media



Thank you !

Merci !

Gracias !

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

sfvp@woah.org

World Organisation for Animal Health
Founded in 1924

Organisation mondiale de la santé animale
Fondée en 1924

Organización Mundial de Sanidad Animal
Fundada en 1924

Substandard and falsified veterinary and human medicines – a One Health approach

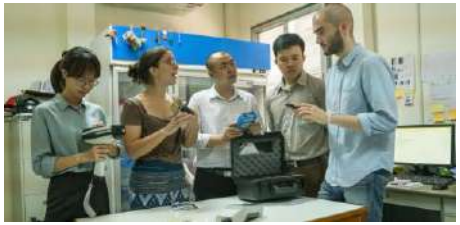
Paul Newton

Medicine Quality Research Group (MQRG), MORU Tropical Health Network & Infectious Diseases Data Observatory, Centre for Tropical Medicine & Global Health, Nuffield Department of Medicine, University of Oxford, UK

paul.newton@ndm.ox.ac.uk

Medicine Quality Research Group

CENTRE *for* TROPICAL MEDICINE *and* GLOBAL HEALTH



13 full time and 3 part time staff from 10 countries, based in UK, Lao, Vietnam, USA & Spain

8 pharmacists, 2 doctors, 3 data scientists & informaticians

3 PhD students

Key objectives

Improve our understanding of the:

a. epidemiology of substandard and falsified (SF) medical products
b. their impact on patient outcome, health systems and AMR
c. the +/- of innovative screening technologies for post-market surveillance detection of SF medical products
d. the use of novel forensic tools for estimating the sources of falsified medicines and their ingredients

To :

e. engage with policy makers to improve the quality of the global medicine supply
f. help build a research community for this neglected subject, especially in LMIC
g. help seed more research groups

A forgotten history

it in ſubſtance, it has not always ſucceeded in ſtopping the fit in the firſt inſtance of its application, but when I have been able to prevail upon my patients to perſevere in its uſe, in the ſame quantity, I have never known it fail to ſtop the fit after the ſecond intermiſſion, in which it has been taken. I ſhould imagine there is no reaſon to believe that the common Bark, which has been uſed for ſome years paſt, is not the ſame with what was formerly in uſe, or with was perhaps, originally introduced; as far as can be judged by its taſte, and its appearance, either in the lump, in powder, in decoction, or in any of the other preparations of it, it ſeems to me, at leaſt, to be preciſely the ſame as I have always ſeen it; I have, therefore, never once ſuſpected that, as a natural production, it has degenerated, much leſs have I apprehended that any artful means have been uſed by Druggiſts, to render it more ſaleable, or to increaſe their profit upon it, by which

K 4 its

Looking Back.

FROM

THE LANCET, *SATURDAY*, April 18th, 1829.

TESTS OF ADULTERATED QUININE.

THE adulteration of quinine is carried to a greater extent than is generally supposed, while the necessity of having it genuine is most important. The high price it obtains, renders it a source of successful imposition to sellers, and of corresponding disappointment to consumers; and this is most probably the cause of the various degrees of benefit with which it has been used in the same complaint. The adulterations most frequently used, are, a peculiarly fine preparation of crystals of spermaceti, starch, and the gentianæ, a preparation partaking in a great degree (when carefully made) of the appearance of quinine, but cheaper and quite useless. For the detection of the latter, I am not aware of any infallible test, excepting that of a delicate taste, difficult to be explained, and only to be acquired by constant practice. A sure test to detect the presence of spermaceti, is to heat a piece of highly-polished

Mercury (Hobart, Tas. : 1860 - 1954), Friday 3 May 1946, page 7

FAKED PENICILLIN

More than 1,000,000dol. worth of fake drugs, including penicillin, have been discovered by Allied police in Berlin. Peter Domke

QUALITY OF QUININE PREPARATIONS IN INDIAN HOSPITALS AND DISPENSARIES

By INDU BHUSAN BOSE, PH.D. (Berlin)
B. MUKERJI, M.B. (Cal.), M.D., D.SC. (Mich.)
and
R. N. CHOPRA, C.I.E., M.A., M.D., SC.D. (Cantab.), F.R.C.P. (Lond.)
BREVET-COLONEL, I.M.S.

- Pathophysiology
- Diagnostics
- Epidemiology
- Drug discovery
- Clinical trials
- Meta-analyses

Optimum therapy & national policy

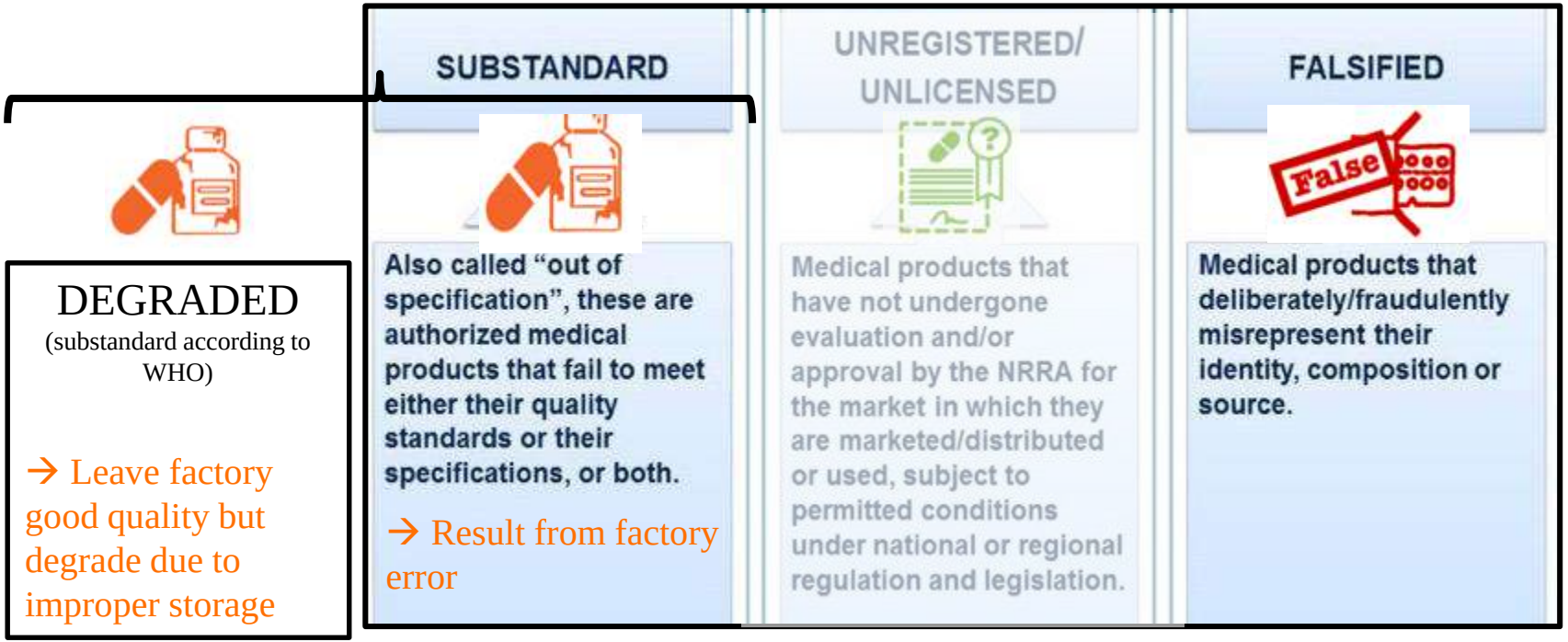
Prescribing
Adherence
Medicine Quality

Rx

Patient/ animal use

WHO definition of substandard and falsified medical products

- Focus on public health, not on protection of intellectual property rights (‘counterfeit’ no longer used by WHO)
- Three separate classification - origins and solutions differ considerably
- Not possible to reliably classify a medicine without packaging analysis
- WHO estimated in 2017 that 10.5% of medicines in LMIC are SF




Specific antimalarial
ARTESUNATE
TABLETS
Each tablet contains Artesunate 50mg
青蒿琥酯片
每片含青蒿琥酯50mg
Guilin Pharmaceutical Co.,Ltd.
桂林南药股份有限公司
12 Tabs
Specific antimalarial
ARTESUNATE
TABLETS
Each tablet contains Artesunate 50mg
青蒿琥酯片
每片含青蒿琥酯50mg
Guilin Pharmaceutical Co.,Ltd.
桂林南药股份有限公司
12 Tabs

Falsified ‘Coartem’ - Ghana

3 different packaging types. First discovered by Ghanaian MRA & USP

Wrong German spelling

No artemether or lumefantrine

Pyrimethamine 7 mg/tab

Pollen suggests eastern Asia

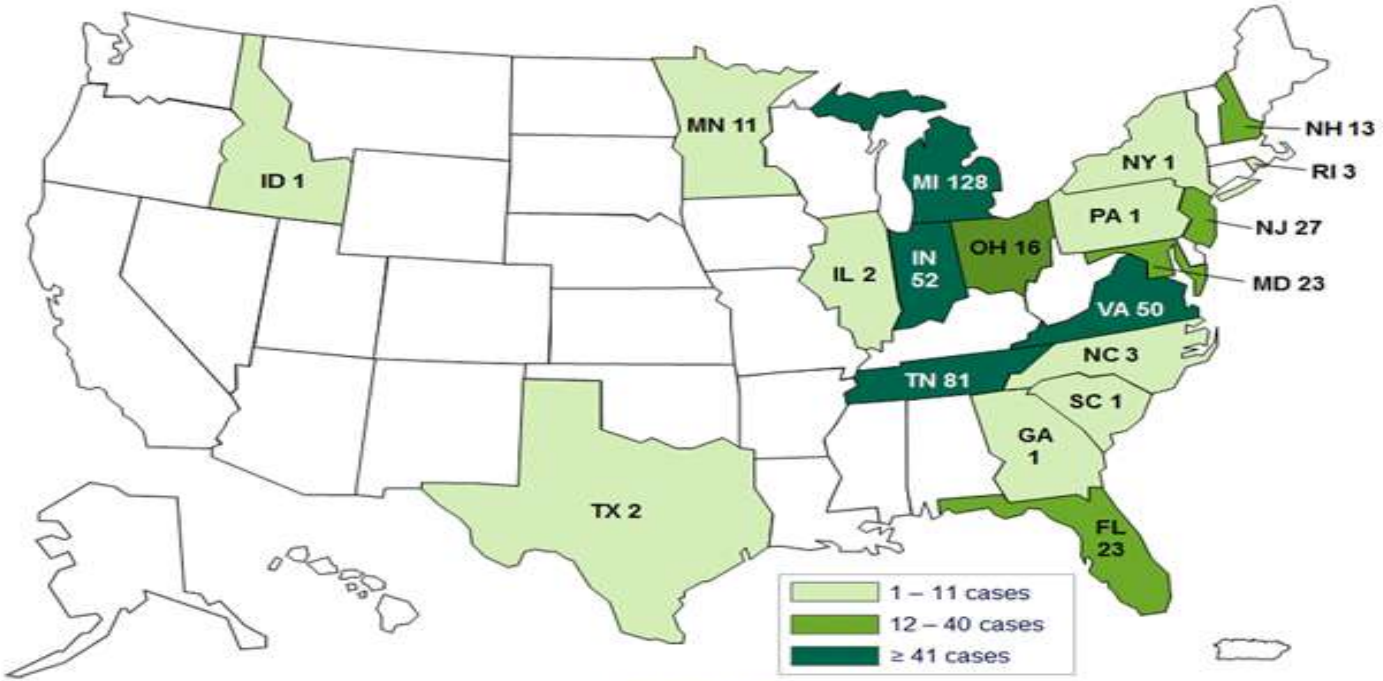
Dacrydium pierrei in genuine comparators

Multistate Fungal Meningitis Outbreak - Current Case Count

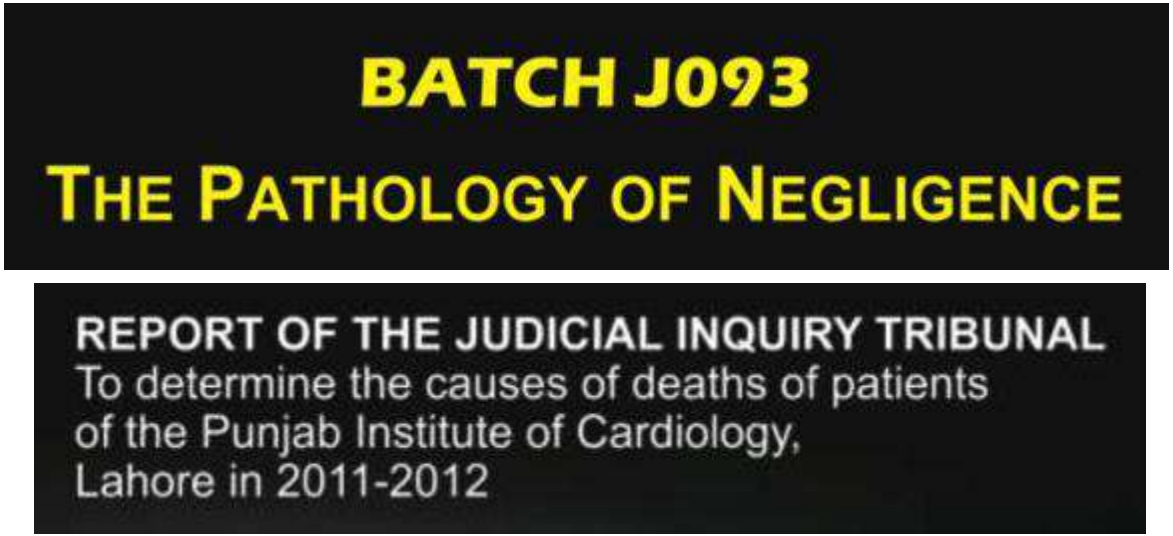
November 9, 2012 2:30 PM EST Previous Case Count Maps

NOTICE: Going forward, we will be providing case count updates on Mondays, Wednesdays, and Fridays.

Cases with Fungal Infections Linked to Steroid Injections



[View Larger Map]



125 cardiology patients died in Lahore with bone marrow failure after taking ‘isosorbide mononitrate 20mg’

However, it contained an excessive dose of the antimalarial pyrimethamine, resulting in fatal bone marrow suppression

Gross factory error (i.e. substandard)

Falsified vaccines

Charge Filed in Fake Flu Vaccine Investigation

10/28/2005 3:48:00 PM

To: National and State Desks

Contact: John Yembrick of the U.S. Department of Justice, 713-567-9388 or usatty.txs@usdoj.gov, Web: http://www.usdoj.gov/usao/txs

HOUSTON, Oct. 28 /U.S. Newswire/ -- At a press conference today, United States Attorney Chuck Rosenberg announced the unsealing of a criminal charge filed against Iyad Abu El Hawa, age 35, for his role in a scheme to defraud Medicare by administering fake flu vaccines at company sponsored health fairs. El Hawa was arrested last evening following the filling of a criminal complaint. Currently in federal custody, El Hawa is expected to appear before a United States Magistrate Judge this afternoon. At that time the United States will seek his detention without bail pending further criminal proceedings.

Counterfeit vaccines in Indonesia: managing the issue through media

N. Nurlaela Arief
Faculty of Communication Science, Universitas Padjadjaran, Kabupaten Sumedang, Indonesia and
Department of Corporate Communications, Bio Farma, Bandung, Indonesia
Siti Karlinah and Yanti Setianti
Faculty of Communication Science, Universitas Padjadjaran, Kabupaten Sumedang, Indonesia, and
Sri Susilawati
Faculty of Dentistry, Universitas Padjadjaran, Bandung, Indonesia

Open Forum Infectious Diseases
INVITED ARTICLE

Counterfeit Rabies Vaccines: The Philippine Experience

Karl Evans R. Hesson,[1,2] Anthony Aldrin C. Santiago,[3] and Sherilyne S. Naeque[4]
[1]Hospital Infection Control and Epidemiology Center, The Medical City, Ortigas Avenue, Pasig City, Philippines [2]Section of Infectious Diseases, Department of Medicine, The Medical City, Ortigas Avenue, Pasig City, Philippines [3]Department of Pharmacy, The Medical City, Ortigas Avenue, Pasig City, Philippines [4]Legal Services Department, The Medical City, Ortigas Avenue, Pasig City, Philippines

Background. In December 2018, a large, tertiary, university-affiliated hospital in the Philippines discovered that their legitimate supply chain was infiltrated with counterfeit rabies vaccines.

Methods. All vials suspected to be counterfeit were quarantined and surrendered to the Philippine Food and Drug Administration. Patients who may have received the counterfeit products were recalled, evaluated, and revaccinated accordingly. Vials of the counterfeit vaccines were sent to various laboratories for testing.

Results. Two batches of counterfeit rabies vaccines were found to have infiltrated the hospital's supply chain between December 2017 and December 2018. Of the 1711 patients who may have received counterfeit vaccines, 1397 patients were successfully contacted, and 734 were revaccinated with at least 1 dose of authentic rabies vaccine. The counterfeit vials were sterile, contained no toxic substances, and both contained active antirabies ingredient. No report of rabies infection or other adverse events were noted.

Conclusions. Our experience demonstrates the need for strong intervention and collaborative response from all stakeholders—government and regulatory bodies, the pharmaceutical industry, and individual institutions and consumers—to effectively eradicate counterfeiting and protect our patients.

Keywords. counterfeit vaccines; rabies; supply chain.

World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Ref. RHT/SAV/Alert 2.2016 — 11 February 2016

Medical Product Alert N° 2/2016

Falsified AMARIL yellow fever vaccines circulating in South East Asia

Clopidogrel for a clinical trial in USA

2007 clopidogrel labeled as ‘Plavix’ worth £1 million shipped from a EU wholesaler to a UK wholesaler and then to a pharmaceutical company in the USA, for use as a comparator in a clinical trial

The entire consignment was found to be falsified, tablets contained only 50- 80% stated clopidogrel

One of the ringleaders was sentenced to eight years imprisonment

CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials

Kenneth F Schulz,[1] Douglas G Altman,[2] David Moher,[3] for the CONSORT Group

The CONSORT statement is used worldwide to improve the reporting of randomised controlled trials. **Kenneth Schulz and colleagues** describe the latest version, CONSORT 2010, which updates the reporting guideline based on new methodological evidence and accumulating experience

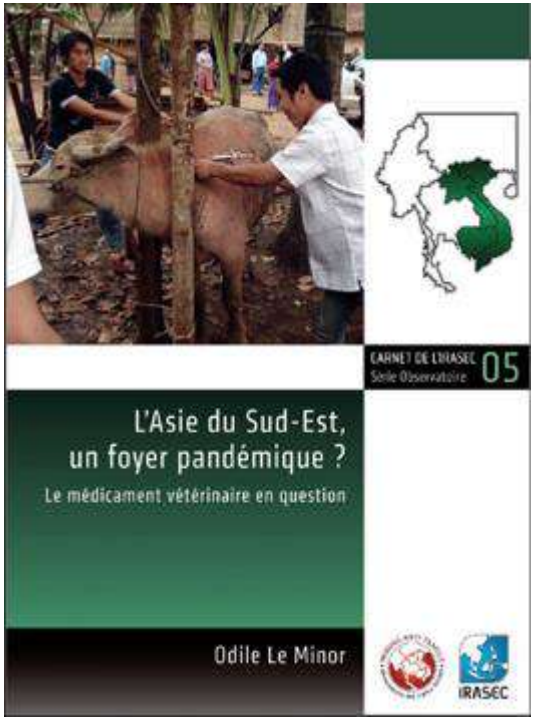
dence and additional experience has accumulated since the last revision in 2001. Consequently, we organised a CONSORT Group meeting to update the 2001 statement.[4-6] We introduce here the result of that process, CONSORT 2010.

Intent of CONSORT 2010

The CONSORT 2010 Statement is this paper including the 25 item checklist in the table and the flow diagram. It provides guidance for reporting all randomised controlled trials, but focuses on the most common design type—individually

Quality assurance of drugs used in clinical trials: proposal for adapting guidelines

Paul Newton and colleagues propose that clinical trial guidelines should include a requirement to assess and state the quality of the drugs and other medical products used



Investigating the illicit market in veterinary medicines: An exploratory online study with pet owners in the United Kingdom

Monica Pons-Hernandez[1] · Tanya Wyatt[2] · Alexandra Hall[3]

Accepted: 13 August 2022

Abstract
The illicit market in veterinary medicines is an overlooked issue despite threatening the health of non-human and human animals. It is thought to be increasing within the major markets of the global North due to the growth of e-commerce and social media sites. This paper examines the online market in illicit veterinary medicines through an exploratory study of the public's online experiences as pet owners in the UK. To this end, we collected data through literature-based research and an online survey. Drawing on Passas' criminogenic asymmetries framework, the research found that the confluence of legal, political, cultural, economic and knowledge asymmetries likely facilitate the market in illicit veterinary medicines in the UK. Our research concludes that, while previous reports suggest the illicit market is dominated by medicines to treat pets, it increasingly consists of medicines for farmed animals. This brings its own set of challenges and risks, and a pressing need for further research on the market's dynamics.

Vougat Ngom *et al. Pastoralism: Research, Policy and Practice* (2017) 7:6
DOI 10.1186/s13570-017-0081-5

Pastoralism: Research, Policy and Practice

RESEARCH Open Access

Quality of veterinary pharmaceuticals and their use by pastoralists in the Far North Region of Cameroon

Ronald Romuald B. Vougat Ngom[1*], Tédja Tomdieu[2], Roland Ziébé[2], Harquin Simplice Foyet[1], Mark Mortz[3], Lazare Vondou[2], Dwayne E. Schrunk[4], Paula M. Imerman[4], Witson K. Rumbeiha[4] and Rebecca B. Garabed[1]

Epidemiol. Infect. (2008), **136**, 1156–1163. © 2008 Cambridge University Press
doi:10.1017/S0950268807009311. Printed in the United Kingdom

Inferior rabies vaccine quality and low immunization coverage in dogs (*Canis familiaris*) in China

R. L. HU[1*], A. R. FOOKS[2], S. F. ZHANG[1], Y. LIU[1] AND F. ZHANG[1]

[1] *Laboratory of Epidemiology, Veterinary Institute, Academy of Military Medical Sciences, Changchun, China*
[2] *Rabies and Wildlife Zoonoses Group, WHO Collaborating Centre for the Characterization of Rabies and Rabies-Related Viruses, Veterinary Laboratories Agency, Weybridge, Addlestone, UK*

Kang *et al. BMC Veterinary Research* (2017) 13:136
DOI 10.1186/s12917-017-1054-z

BMC Veterinary Research

RESEARCH ARTICLE Open Access

National post-market surveillance assessment of veterinary medicines in Korea during the past decade

JeongWoo Kang, Hae-chul Park, Yang ho Jang, Md Akil Hossain, Kyunghun Jeong, Mi young Jeong, Seon-Jong Yun, Sung-won Park, Dae gyun Kim and Kwang-jick Lee*

Epidemiology – how to improve our understanding to inform policy & implementation ?

https://www.iddo.org/mq-scientific-literature-surveyor

Includes published scientific data describing quality of medical products for malarial, diabetes, HIV, bacterial infections, TB, cardiovascular disease and veterinary medicines, medical devices and vaccines.

Filters studies according to medicine, report type, collection type, medicine source and quality classification. Provides customised summaries of reports per country describing SF medical products over time and location.

Filters studies according to medicine, report type, collection type, medicine source and quality classification.

The tool also in French - voir le "Medicine Quality Scientific Literature Surveyor" en français

Screenshot

Medicine Quality Scientific Literature Surveyor

Mapping medicine quality data

FILTERS

- Medical Product Class — clear
  - Search...
  - Anti-tuberculosis
  - Antibiotics
  - Antidiabetics
  - Antimalarials
  - Antiretrovirals
  - Cardiovascular
  - Vaccines
- Categories of Medicines
  - Search...
  - ACT
  - Adrenergic and dopaminergic agents
  - Agents against protozoal
- Medicines
  - Search...
  - ACT-unspecified
  - Abacavir
  - Abacavir-Lamivudine
  - Abacavir-Lamivudine-Zidovudin
- + Quality classification
- + Collection type
- + Medicine Source

Medicine Quality Map | Report Table

Satellite | Map

Filter studies by publication year range: 1985 to 2020

1985 1990 1995 2000 2005 2010 2015 2020

We would be grateful for any additional information, corrections or comments from users and authors. Visit the MQ Surveyor web page for information on Methodology, External resources, Acknowledgements, and the User guide

https://www.iddo.org/mq-scientific-literature-surveyor

Looking for a country report?

Choose a country

Reports are available for countries with more than one report of medicine quality in the database

IDDO
INFECTIOUS DISEASES DATA OBSERVATORY

French | Start tour | Medicine quality group

WWARN

Mapping medicine quality data

FILTERS

- Medical Product Class — clear
  - Search...
  - Antidiabetics
  - Antimalarials
  - Antiretrovirals
  - Cardiovascular
  - Vaccines
  - Veterinary
- Categories of Medicines
  - Search...
  - ACT
  - Adrenergic and dopaminergic agents
  - Agents against protozoal diseases
- Medicines
  - Search...
  - Acenocoumarol
  - Acetylsalicylic acid
  - Albendazole
  - Amlodipine
- + Quality classification
- + Collection type
- + Medicine Source

Medicine Quality Map | Report Table

Satellite | Map

FEEDBACK

Filter studies by publication year range: 1985 to 2024

1985 1990 1995 2000 2005 2010 2015 2020

We would be grateful for any additional information, corrections or comments from users and authors.
Visit the MQ Surveyor web page for information on Methodology, External resources, Acknowledgements, and the User guide

Looking for a country report?

Choose a country

Reports are available for countries with more than one report of medicine quality in the database

Download the data

https://www.iddo.org/mqmglobe/

Medicine Quality Monitoring Globe

Substandard and falsified medical products, including medicines, vaccines, diagnostic tests and devices are critical global public health issues. Discover a new interactive, online tool mapping real-time medicine quality media reports on the quality of medical products across the world.

OPEN GLOBE

Substandard and falsified medical products reduce the effectiveness of treatments, causing adverse drug reactions and can accelerate antimicrobial drug resistance – threatening the lives of millions. Global investment to improve the prevention and treatment of disease is wasted if the quality of the medical products actually used by patients is poor.

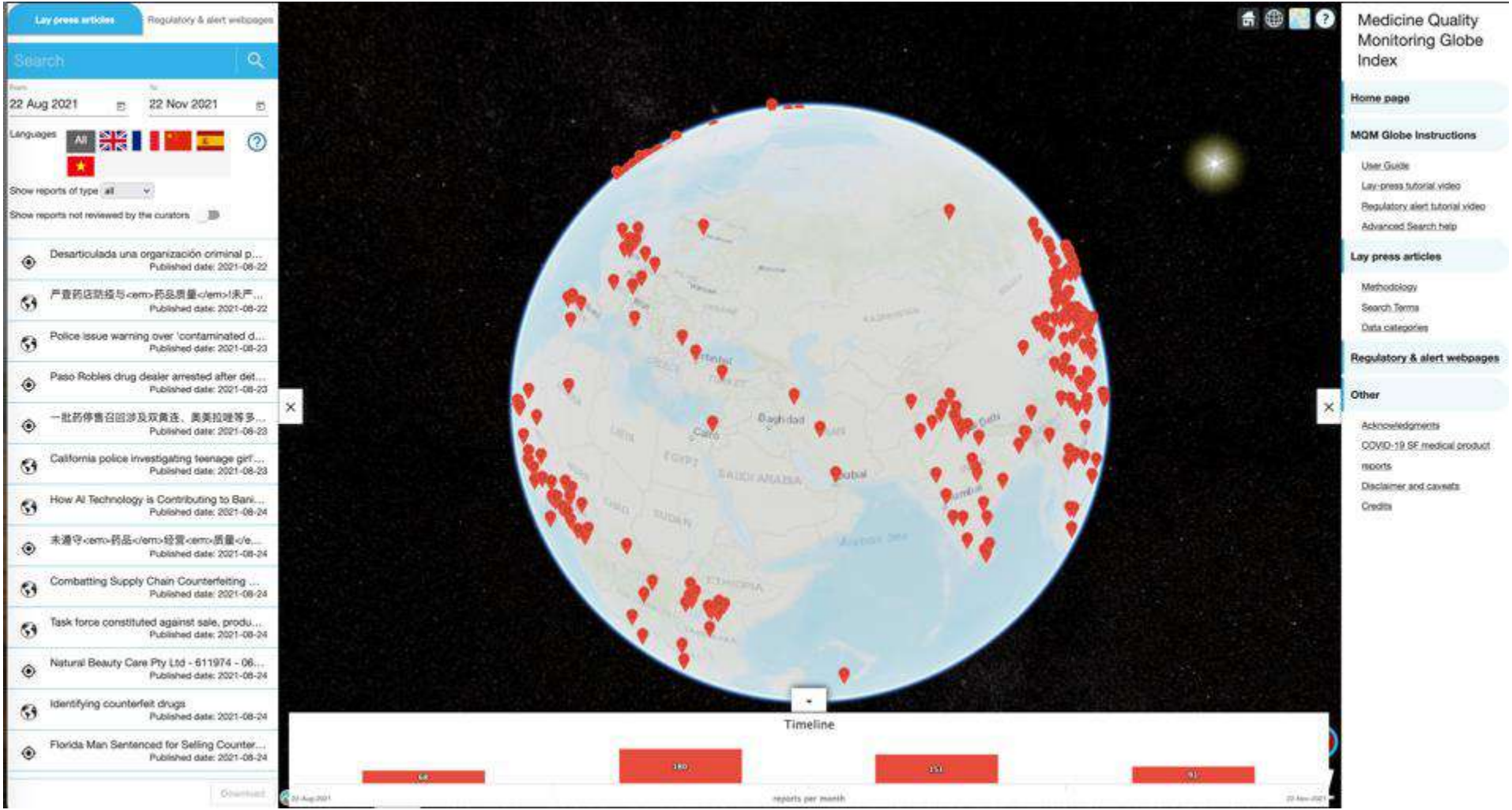
Current surveillance in most of the world is extremely limited and incidents relating to poor quality medicines are often not published in peer-reviewed scientific journals. The new Medicine Quality Monitoring (MQM) Globe helps fill evidence gaps with customised summaries of national and international newspaper reports on medicines and medical products' quality viewable on-screen in French, Spanish, Mandarin and English, and reports are available to download in three languages – English, French and Spanish. It gives early warning of new incidents, reveals the extent of the problem, how the media perceive and report cases, and may also shed light on how incidents can affect subsequent behaviours and perceptions. It has been updated to track press reports of SF medical products related to COVID-19, including key items such as masks, diagnostic tests, medicines and vaccines. There are no medicines or vaccines approved for use for COVID-19 yet. Medicines being trialled are listed here .

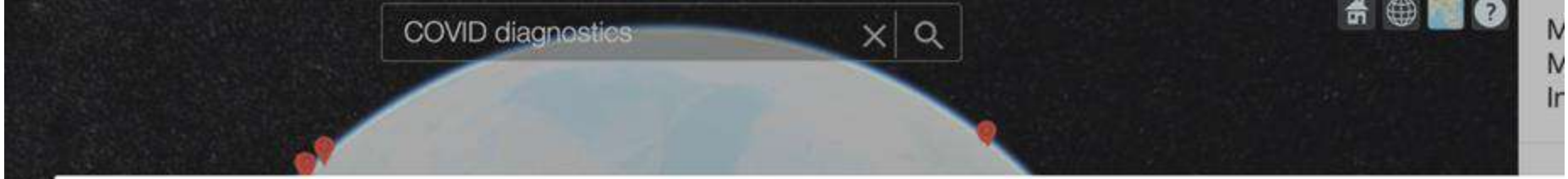
Summarizes newspaper articles, retrieved from GoogleNews (English, French, Chinese, Vietnamese & Spanish), related to SF and are curated and mapped on a Globe.

The principle target users are medicine regulatory authorities and international organisations.

As these are journalistic, rather than peer-reviewed scientific, reports, they will intrinsically be less reliable but we aim that they will give early warning of potential problems needing further investigation.

Updated for COVID-19 and now include regulatory alerts from MRA websites


Lay press articles
Regulatory & alert webpages
Search
From
22 Aug 2021
To
22 Nov 2021
Languages
All
Show reports of type all
Show reports not reviewed by the curators
Desarticulada una organización criminal p...
Published date: 2021-08-22
严查药店助纣与药品质量!求严...
Published date: 2021-08-22
Police issue warning over 'contaminated d...
Published date: 2021-08-23
Paso Robles drug dealer arrested after det...
Published date: 2021-08-23
一批药停售召回涉及双黄连、美美拉唑等多...
Published date: 2021-08-23
California police investigating teenage girl'...
Published date: 2021-08-23
How AI Technology is Contributing to Bani...
Published date: 2021-08-24
未遵守药品经营质量/e...
Published date: 2021-08-24
Combatting Supply Chain Counterfeiting ...
Published date: 2021-08-24
Task force constituted against sale, produ...
Published date: 2021-08-24
Natural Beauty Care Pty Ltd - 611974 - 06...
Published date: 2021-08-24
Identifying counterfeit drugs
Published date: 2021-08-24
Florida Man Sentenced for Selling Counter...
Published date: 2021-08-24
Download
Baghdad
Cairo
Dubai
EGYPT
SAUDI ARABIA
SUDAN
ETHIOPIA
Timeline
68
180
151
91
reports per month
Medicine Quality Monitoring Globe Index
Home page
MQM Globe Instructions
User Guide
Lay-press tutorial video
Regulatory alert tutorial video
Advanced Search help
Lay press articles
Methodology
Search Terms
Data categories
Regulatory & alert webpages
Other
Acknowledgments
COVID-19 SF medical product reports
Disclaimer and caveats
Credits



Two arrested for illegally selling Covid-19 home testing kits

2020-04-14. North West London, Croydon. Same report also mentions: Uxbridge.

A pharmacist and a surveyor have been arrested on suspicion of illegally selling coronavirus testing kits in two separate investigations by the National Crime Agency (NCA). NCA officers arrested a 46-year-old pharmacist from Croydon on Saturday under the Fraud Act 2006 after he allegedly made false and misleading claims about tests' capability. Two properties and a car linked to the suspect were searched. He was released on conditional bail.

Falsified

Private pharmacy

Medical device for screening/dia

SOURCES

ID: 527188

UK police charge man with making and selling fake coronavirus treatment kits

2020-03-21. London.

British police said on Saturday they had charged a man with making counterfeit treatment kits for coronavirus, and sending them across the world. Frank Ludlow, 59, of West Sussex, southern England, was arrested on Friday and has been charged with one count of fraud by false representation, one count of possession of articles for use in fraud, and one count of unlawfully manufacturing a medicinal product. He appeared at Brighton Magistrates Court and was remanded in custody until April 20. [...] During a search of Ludlow's home, police found 300 more treatment kits and an estimated 20 litres of chemicals used in the production of the fake kits.[testing kit] [Covid-19]

hydrogen peroxide:A01AB02

hydrogen peroxide:D08AX01

hydrogen peroxide:S02AA06

POTASSIUM:A12B

POTASSIUM:A12BA

Falsified

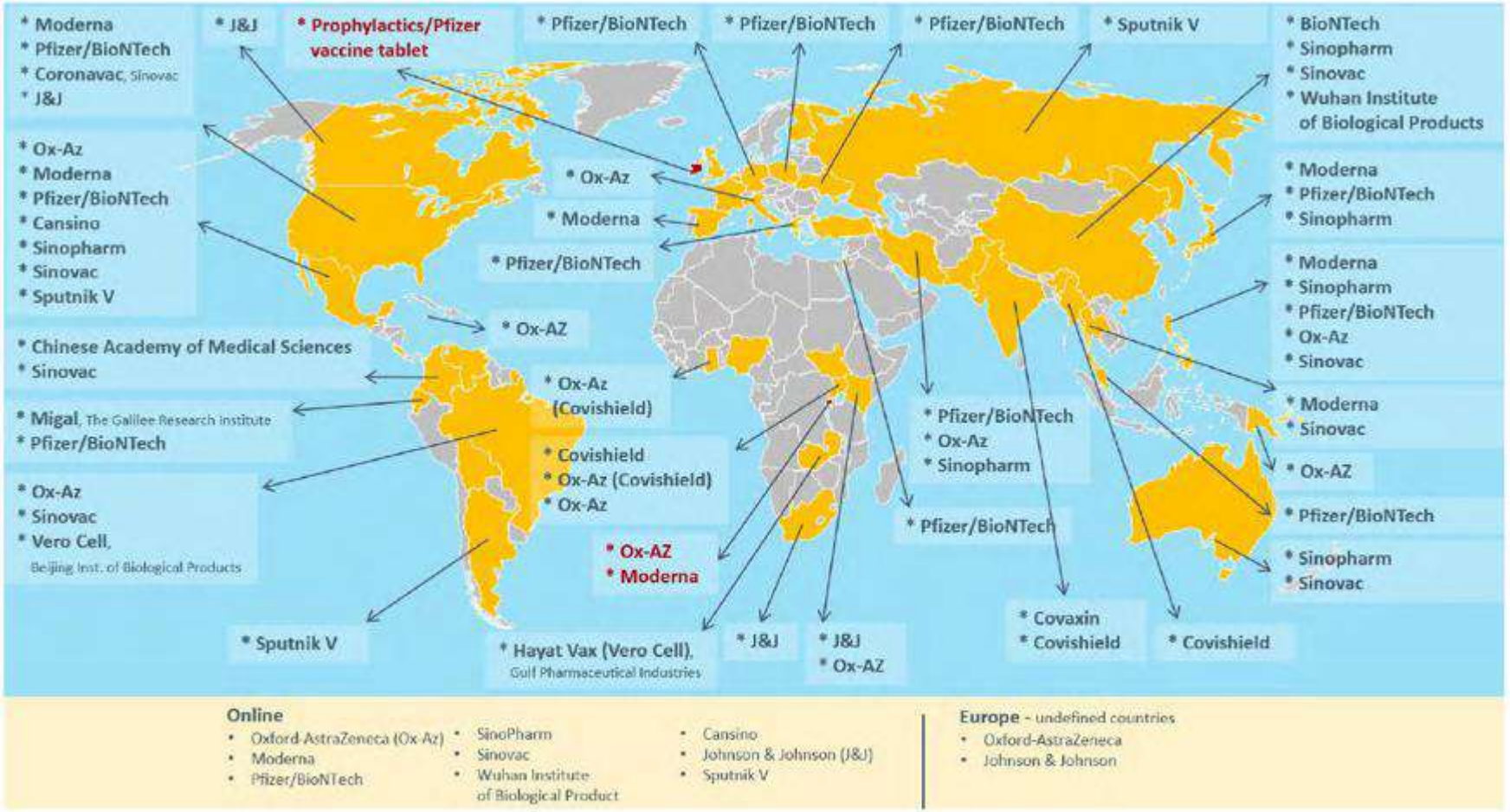


Figure 2 Countries with public reports on COVID-19 vaccine quality issues on the Medicine Quality Monitoring Globe.
Countries linked to incidents are indicated in orange. If a public report mentions a product name or a company, these details are indicated on the map, with in red the information that was added since the last issue. Ox-Az: Oxford-AstraZeneca, and J&J: Johnson & Johnson.

Veterinary Medicines

There a few data on the quality of veterinary medicines but vital to inform policy and implementation as humans coexist in complex ecological inter-relationships with vertebrates - livestock and pets

SF veterinary medical products will inevitably harm:

* animal health & agricultural production
* farming & livestock trading communities
* human and animal nutrition
* food security

Also risk antimicrobial resistance, but has received minimal investigation

* Fewer datapoints - 314 publications, with 2,335 samples and a failure frequency of 6.5%
* Majority of samples - post-marketing surveillance in Republic of Korea and China
* Only 3.5% of samples, all anti-infectives, were from 20 prevalence surveys; 53% collected in LMICs
* Prevalence survey sample size ranged from 4 to 310 samples
* 55% of surveys used convenience outlet sampling methods
* 52% of 1,246 samples failed at least one quality test

Original research

BMJ Global Health

The quality of veterinary medicines and their implications for One Health

Vayouly Vidhamaly [1,2,3] Konnie Bellingham [1,2,3] Paul N Newton [1,2,3]
Céline Caillet [1,2,3]

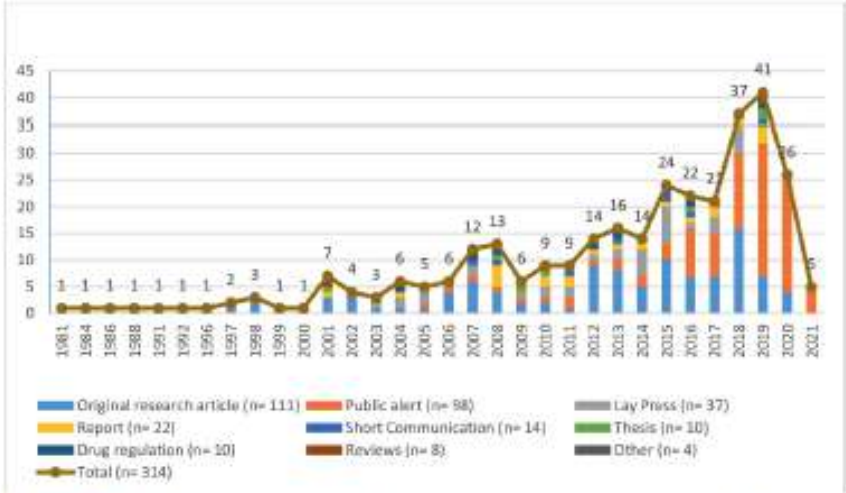


Figure 2 Number of publications per type and year of publication (note: publications published up to the 28 February 2021 only were included, hence the reduction in number of publications in 2021).

Of the failing samples:

* 93.7% were classified as Substandard or Falsified (SorF) because no packaging analysis to assess the authenticity of the samples was performed

* 3.7% = falsified
* 2.6% = substandard

These data do not mean that 53% of vet medicines in LMIC are SF – data are inadequate for accurate estimates

Table 1 Veterinary medicine failure frequency by continent/country in prevalence surveys[63]

Continent	Income level	Country	No. data points	Failure frequency % (n/N)
Asia				**72.1 (165/229)**
	LMIC	Viet Nam	47	77.3 (92/119)
	UMIC	China	7	76.1 (54/71)
	LMIC	Pakistan	1	50.0 (4/8)
	High-income setting	Hong Kong, SAR, China	4	48.4 (15/31)
Africa				**47.3 (479/1012)**
	LMIC	Cameroon	10	84.0 (63/75)
	LIC	DR Congo	1	66.7 (2/3)
	LMIC	Senegal	17	65.2 (58/89)
	LIC	Rwanda	6	65.1 (54/83)
	LIC	CAR	1	60.0 (3/5)
	LIC	Madagascar	4	57.9 (33/57)
	LIC	Benin	6	53.4 (39/73)
	LMIC	Ghana	5	52.0 (13/25)
	LMIC	Angola	1	50.0 (1/2)
	LIC	Niger	4	48.8 (21/43)
	LIC	Chad	1	46.7 (7/15)
	LMIC	Côte d'Ivoire	14	45.4 (64/141)
	LMIC	Nigeria	5	44.4 (4/9)
	LIC	Togo	14	42.9 (33/77)
	LIC	Burkina Faso	3	31.5 (17/54)
	LIC	Ethiopia	4	28.0 (14/50)
	LIC	Mali	13	26.4 (52/197)
	UMIC	Namibia	1	0.0 (0/5)
	LIC	Malawi	1	0.0 (0/3)
	LIC	Mozambique	1	0.0 (0/2)
	Unknown*	Unknown*	1	25.0 (1/4)
Internet	Not applicable	Unknown*	1	80.0 (4/5)
Total			**173**	**52.0 (648/1246)**

Problems with the epidemiological data

- Small sample sizes
- No publicly available scientific data from many countries
- Few random surveys
- Little consensus
- Overinterpretation of data
- Poor & slow reporting

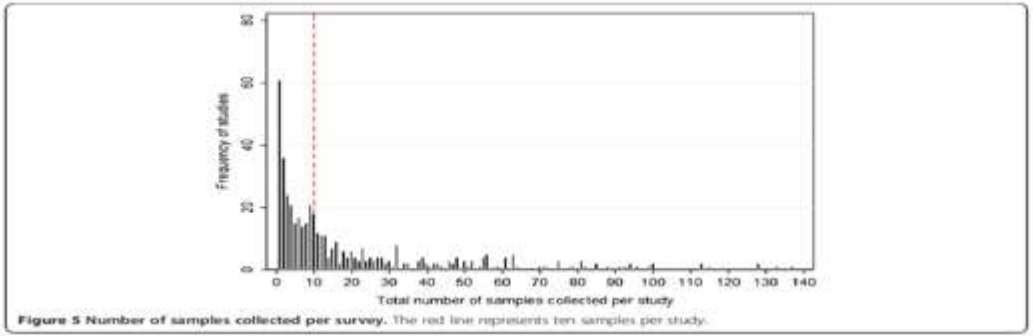


Figure 5 Number of samples collected per survey. The red line represents ten samples per study.


OPEN ACCESS Freely available online PLoS MEDICINE

Guidelines and Guidance

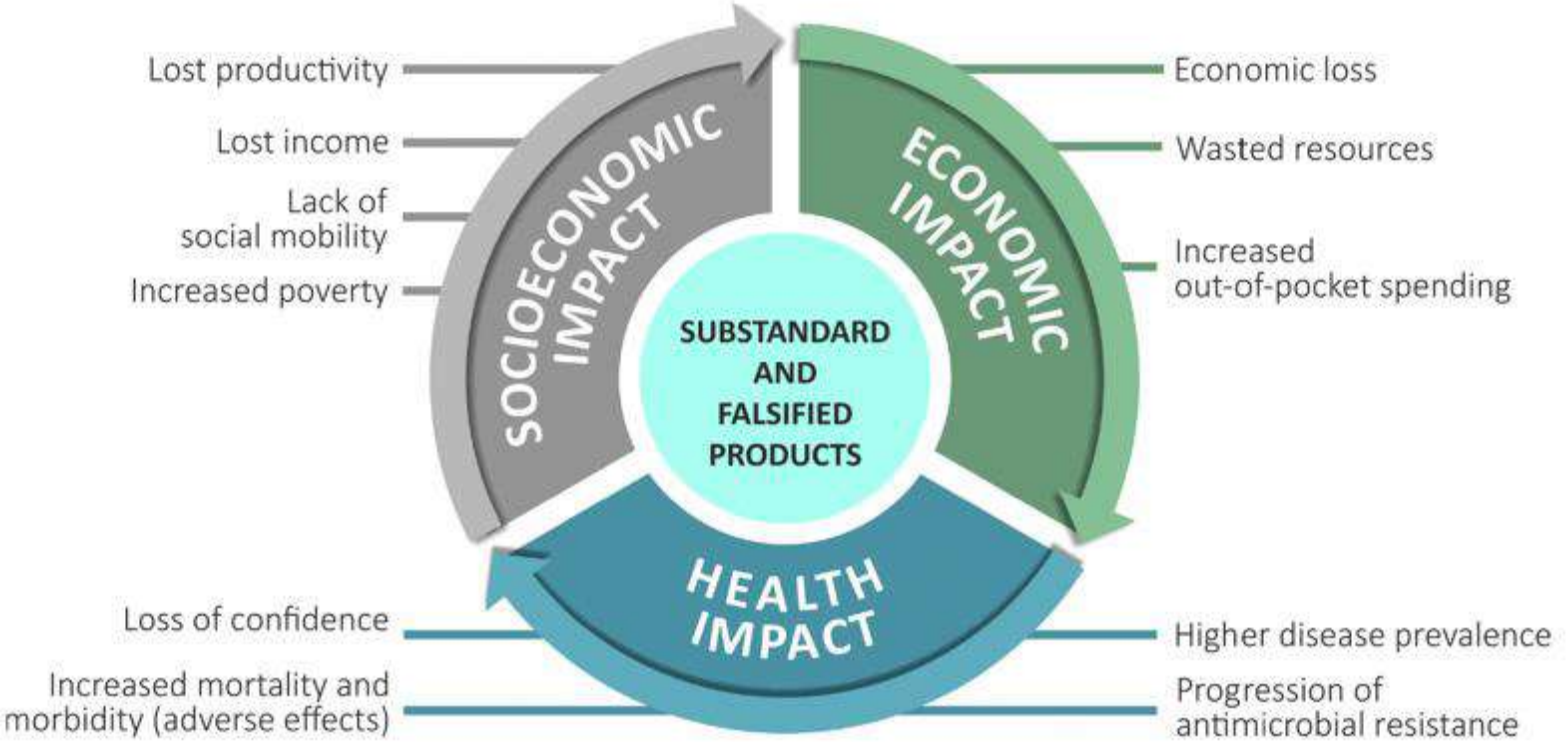
Guidelines for Field Surveys of the Quality of Medicines: A Proposal

Paul N. Newton*, Sue J. Lee, Catherine Goodman, Facundo M. Fernández, Shuntnay Yeung, Souly Phanouvong, Harparkash Kaur, Abdinasir A. Amin, Christopher J. M. Whitty, Gilbert O. Kokwaro, Niklas Lindegårdh, Patrick Lukulay, Lisa J. White, Nicholas P. J. Day, Michael D. Green, Nicholas J. White

Impact

A STUDY ON THE PUBLIC HEALTH AND SOCIOECONOMIC IMPACT of substandard and falsified medical products

Fig. 2: Impact of substandard and falsified medical products



How important are SF antimicrobials for AMR ?

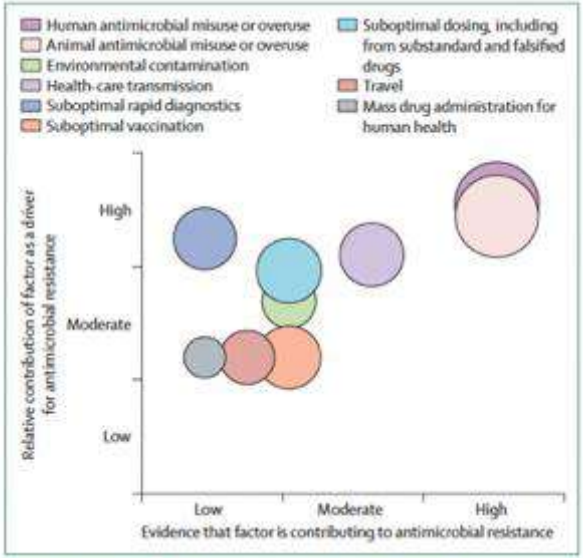


Figure 3: Role of modifiable drivers for antimicrobial resistance: a conceptual framework

An infographic to show the considered potential contribution of each factor as a driver for antimicrobial resistance. Associated relative contribution, supporting evidence, and potential population affected (diameter of bubble) was created from a two round Delphi method of contributing authors. Factors were identified from review of the national and international antimicrobial resistance literature. The Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) approach was used to identify the quality of the evidence (the study with the highest GRADE estimate was cited) supporting each driver as being contributory to the rise in antimicrobial resistance (appendix).

Antimicrobials: access and sustainable effectiveness 2

Understanding the mechanisms and drivers of antimicrobial resistance

Antimicrobial Agents and Chemotherapy

MECHANISMS OF RESISTANCE

Evolution of Rifampin Resistance in *Escherichia coli* and *Mycobacterium smegmatis* Due to Substandard Drugs

Zohar B. Weinstein,* Muhammad H. Zaman

nature communications

Perspective

https://doi.org/10.1038/s41467-023-41542-w

The uncertain role of substandard and falsified medicines in the emergence and spread of antimicrobial resistance

Received: 16 March 2023

Accepted: 7 September 2023

Published online: 03 October 2023

Check for updates

Sean Cavany, Stella Nanyonga, Cathrin Hauk, Cherry Lim, Joel Tarning, Benn Sartorius, Christiane Dolecek, Céline Caillet, Paul N. Newton & Ben S. Cooper

Approximately 10% of antimicrobials used by humans in low- and middle-income countries are estimated to be substandard or falsified. In addition to their negative impact on morbidity and mortality, they may also be important drivers of antimicrobial resistance. Despite such concerns, our understanding of this relationship remains rudimentary. Substandard and falsified medicines have the potential to either increase or decrease levels of resistance, and here we discuss a range of mechanisms that could drive these changes. Understanding these effects and their relative importance will require an improved understanding of how different drug exposures affect the emergence and spread of resistance and of how the percentage of active pharmaceutical ingredients in substandard and falsified medicines is temporally and spatially distributed.

Sub-therapeutic antimalarials in fakes – covert drug pressure for resistance. e.g.

- Artemisinin in falsified halofantrine in West Africa
- Pyrimethamine in fake artesunate & artemether-lumefantrine
- Chloroquine in falsified artesunate

SCIENTIFIC REPORTS

nature research

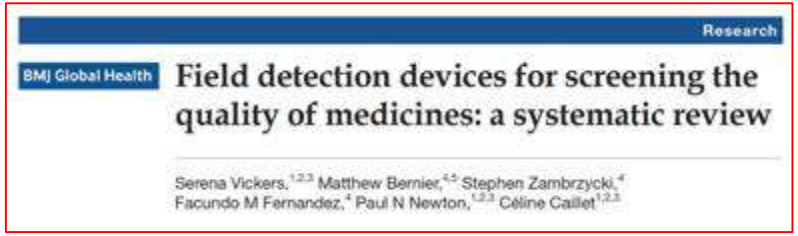
Development and selection of low-level multi-drug resistance over an extended range of sub-inhibitory ciprofloxacin concentrations in *Escherichia coli*

Carly Ching & Muhammad H. Zaman

Detection – how can SF medical products be detected in supply chains to avert public health harm ?

Medicine quality screening devices

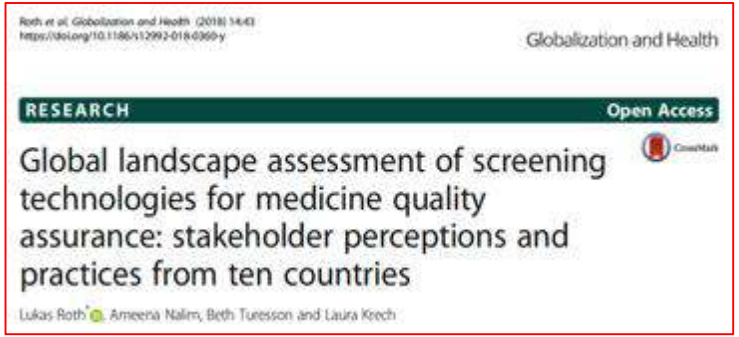
- Increasing concern about medicine quality at different levels of the distribution system
- Globally, inspectors have few tools apart from their eyes and their experience
- Over the last decade a plethora of portable devices
- Will these devices fulfill their promise to empower inspectors ?
- What is the current evidence base ?


Research

BMJ Global Health

Field detection devices for screening the quality of medicines: a systematic review

Serena Vickers,[1,2,3] Matthew Bernier,[4,5] Stephen Zambrzycki,[4] Facundo M Fernandez,[4] Paul N Newton,[1,2,3] Céline Caillet[1,2,3]


Roth et al. Globalization and Health (2018) 14:43
https://doi.org/10.1186/s12992-018-0360-y

Globalization and Health

RESEARCH

Open Access

Global landscape assessment of screening technologies for medicine quality assurance: stakeholder perceptions and practices from ten countries

Lukas Roth, Ameena Nalim, Beth Turesson and Laura Krech

Minilab

- Portable ~ 50 kg
- Visual appearance, TLC, colorimetry, disintegration tests
- ~5,000 USD
- Qualitative/Semi-quantitative; Currently 85 APIs
- Field-tested (Antimalarials and antibiotics)
    - Sensitivity/Specificity: variable

+ Good at detecting zero stated API medicines.

- Destructive, time-consuming, needs many consumables & medium lab skills with regular training. Semi-quantitative and hence limited detection of reduced % API medicines

Raman spectroscopy

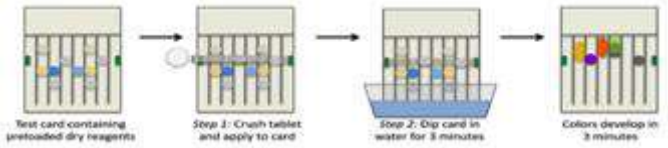
- Raman technology
- Handheld ~ 0.9 kg
- ~ 65,000 USD
- Qualitative and quantitative?
- Assays all Raman active substances in the sample – brand specific
- Lab test: fair to very good Sensitivity/Specificity

\+ Robust, user-friendly, non-destructive, can ‘see’ through some packaging, no consumables, minimal training

\- Cost, requires reference library of spectra, interference by fluorescent compounds, reduced API not detected (?), problems with co-formulated medicines if dominant signal due to one API

Paper Analytical Devices

- University of Notre Dame, USA
- 12 lines per card, colorimetry
- Up to 3 USD
- Qualitative; 60 different APIs
- Reading & analysis App being developed



\+ User friendly, inexpensive, no consumables, minimal training

\- Single-use, destructive

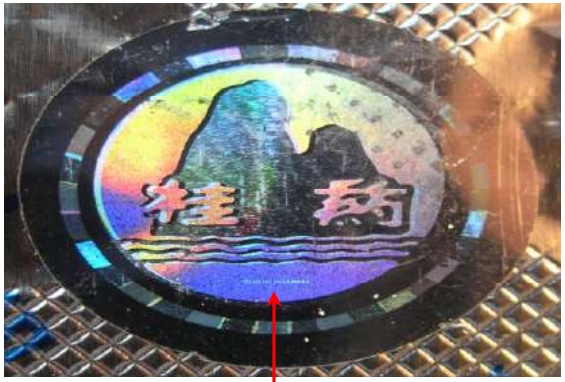
Many API cannot be tested

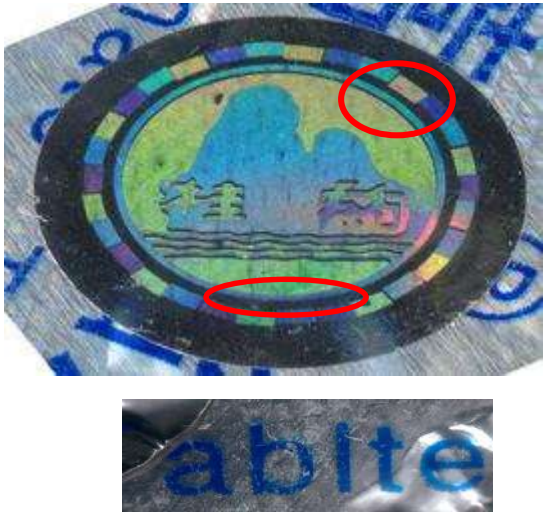
MQ Screening Devices - summary

- Just beginning to understand the complexities for real world use
- Very poor evidence base – median number of API tested per device = TWO
- Unlikely to be one device for all medicine quality issues
- Needs intensive independent evaluation of :
  - Which APIs will they work with, and in what combinations ?
  - Can they quantitate API ?
  - What to do about capsules, parenteral formulations & vaccines ?
  - Can packaging be optimized to facilitate their use ?
  - Need portable devices as surrogates for formal dissolution testing
  - What are their comparative cost effectiveness ?
  - How to construct infrastructure to implement their optimal use ?
  - Which positions in supply chains are they optimally used ?
  - How to link the devices with national reference labs ?

Where do falsified medicines & vaccines come from ?

Genuine Fake Artesunate ‘Type 4’

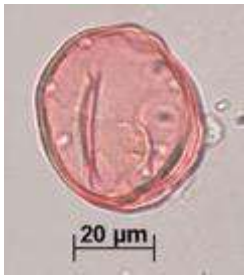




- 2000-2001 - 38 % of shop bought falsified artesunate fake
- One NGO bought 100,000 tablets in one shop
- 2002-2003 - 53% of shop bought artesunate was fake

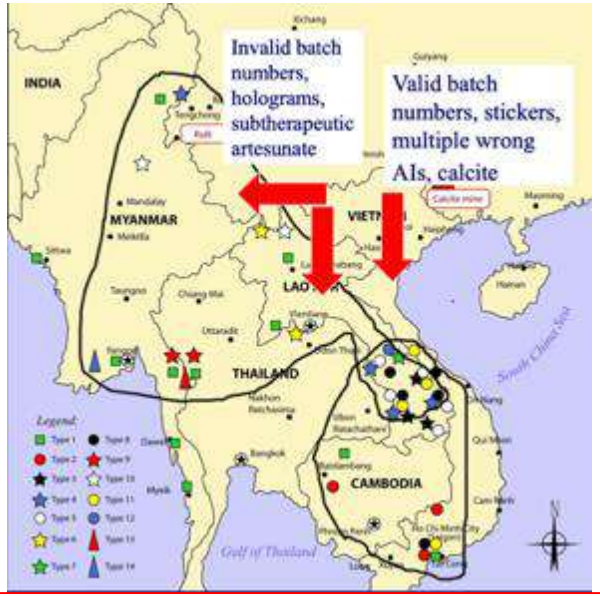
Jupiter investigation

- Epidemic of falsified oral artesunate in South-East Asia, late 90's
- Collaboration with WHO, Interpol, Guilin Pharma, Australia TGA, GNS Science, Georgia Tech, USP to investigate origin - using packaging analysis, pollen & stable isotope analysis → suggested origin in southern China
- Interpol took dossier to Ministry of Public Security in Beijing, resulting in six arrests



Pinus and *Juglans* pollen grain found in falsified tablets

Seized 240,000 packets



A Collaborative Epidemiological Investigation into the Criminal Fake Artesunate Trade in South East Asia

Paul N. Newton[1,2*], Facundo M. Fernández[3], Aline Plançon[4], Dallas C. Mildenhall[5], Michael D. Green[6], Li Ziyong[7], Eva Maria Christophel[8], Souly Phanouvong[9], Stephen Howells[10], Eric McIntosh[10], Paul Laurin[11], Nancy Blum[9], Christina Y. Hampton[3], Kevin Faure[5], Leonard Nyadong[3], C. W. Ray Soong[5], Budiono Santoso[8], Wang Zhiguang[7], John Newton[4*], Kevin Palmer[8]

Few forensic palynologists with global reference collections → environmental DNA analysis ?

FORESFA Team

Paul Newton
Céline Caillet
Kerlijn Van Assche
Cathrin Hauk
Alberto Olliaro
Stella Nanyonga Lawrence
Adipo
Andrew Payne
Heather Hamill
Federico Varese
Fanqi Zeng

Ben Cooper
Sean Cavany
Sam Harper
Sam McGregor
Benn Sartorius
Christiane Dolocek
Sebastian Fuller
Shan Jiang

Rob Ogden, Carla Perez Mon

Edinburgh
Oxford
Huddersfield
Hamid Merchant

Trento
Vienna
Simon Kelly, Aiman Abrahim, Marivil Islam

Boston
Clark Freifeld

Luana Bontempo
Alberto Roncone

New Delhi
Pavan Mamidi

Christianah Mojisola Adeyeye
Joseph Segun Akolawole

Abuja
Cape Coast

Stella Nanyonga
Kampala
Dar es Salaam
Gerry Mshana

Daniel Amoako-Sakyi
Simon Mariwah

Hanoi
Vientiane
Bangkok
Thi Ngan Do
Konnie Bellingham
Katay Kitignavong
Viengsavanh Pimxayvong

Joel Tarning
Daniel Blessborn

FAO/ IAEA Joint Centre

Origin of falsified medicines

a) Genomic approach

Biological composition and environmental DNA (eDNA) may provide information on

- environment and origin ('pharmabiome') of tablets, capsules and excipients
- time of manufacturer
- bacterial, fungi, plant, human DNA

Environmental DNA as an innovative technique to identify the origins of falsified antimalarial tablets—a pilot study of the pharmabiome

Jennifer M. Young, Craig Liddicoat, Koreent van Dijk, Patricia Tabernero, Celine Caillet, Nicholas J. White, Adrian Linacre, Jeremy J. Austin & Paul N. Newton

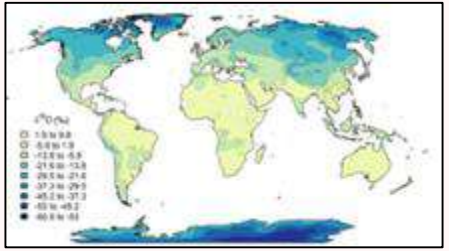
THE UNIVERSITY of EDINBURGH

b) Chemical approach

1. Isotope-ratio mass spectrometry of excipients and water in tablets can provide Information on origin (geolocation & geological environment), plant type, etc.

Forensic investigation of falsified antimalarials using isotope ratio mass spectrometry: a pilot investigation

Paul N. Newton, Lesley A. Chesson, Mayfong Mayxay, Arjen Dondorp, Patricia Tabernero, John D. Howa & Thure E. Cerling



Global map of isotope ratios ($\delta^{18}O$ ‰) in rainwater (Forensic Sci. 2012)

2. Headspace analysis of atmosphere in tablet blister → information on production process

FAO/ IAEA Joint Centre

FONDAZIONE EDMUND MACH

Trade routes of falsified medicines

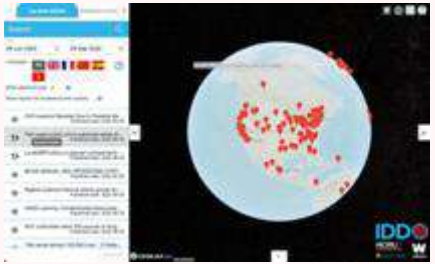
c) Social network analysis

Map trade routes and geographical nodes of international trade in SF medicines

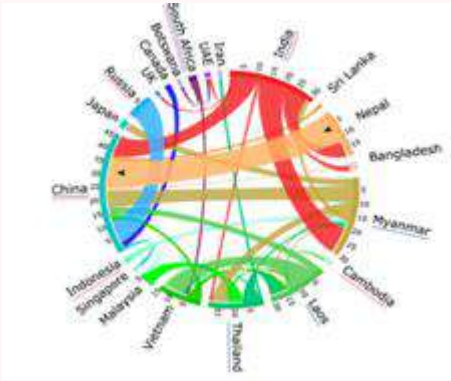
→ Identify where increased inspection and regulation may be most effective

a) Curation and data review of the Globe (lay literature on SF medicines)

b) Interviews to identify social mechanisms and relationships between traders, smugglers



The Medicine Quality Monitoring Globe[1]



Tiger illegal trade network[2]

How to engage appropriately over SF vaccines ? Difficult balancing acts

A. How to get the engagement balance correct in different communities so that people are appropriately aware but information does not drive vaccine hesitancy ?

B. How to report and publish research results without giving, unnecessarily, information that would help criminals make falsified vaccines that could evade detection techniques ?

Counterfeit vaccines in Indonesia: managing the issue through media

N. Nurlaela Arief
Faculty of Communication Science, Universitas Padjadjaran, Kabupaten Sumedang, Indonesia and Department of Corporate Communications, Bio Farma, Bandung, Indonesia
Siti Karlinah and Yanti Setianti
Faculty of Communication Science, Universitas Padjadjaran, Kabupaten Sumedang, Indonesia, and
Sri Susilawati
Faculty of Dentistry, Universitas Padjadjaran, Bandung, Indonesia

Vaccine 37 (2019) 3419–3425

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Trust collapse caused by the Changsheng vaccine crisis in China

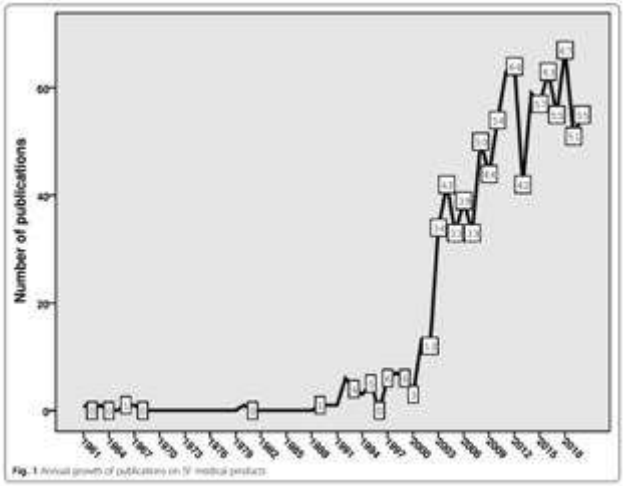
Min Zhou[a,c,d], Shujuan Qu[b,*], Lindu Zhao[c,*], Nan Kong[d], Kathryn S. Campy[e], Song Wang[a]

[a] College of Business Administration, Hunan University of Commerce, Changsha, China
[b] The Third Xiangya Hospital of Central South University, Changsha, China
[c] School of Economics and Management, Southeast University, Nanjing, China
[d] Weldon School of Biomedical Engineering, Purdue University, West Lafayette, USA
[e] Center for Public Health Initiatives, University of Pennsylvania, Philadelphia, USA

Large evidence chasms

- Epidemiology of SF medical products – where are the hot spots and why ?
- What are the trade routes of falsified medical products?
- What are the drivers ?
- What is the public health and economic impact in different communities ?
- How important/unimportant are SF antimicrobials as drivers of AMR in different communities and for which pathogen-antimicrobial pairs ?
- How common are SF vaccines and how can impact on vaccine hesitancy be minimized
- How can SF medical products be prevented ?
- What are the +/- of different medicine quality screening devices ? How can we publish but not help criminals?
- What are the optimal reporting systems to improve public health ?

Multidisciplinary – needs pharmacists, doctors, nurses, community health workers, economists, chemists, lawyers, ethicists, sociologists, policy implementation experts, forensic, data, packaging & regulatory scientists, physicists, informaticians, police, customs, policy makers, public engagement experts....



How can the situation be improved ?

1. Urgent need for support for functional national medicines regulatory authorities (NMRA) for human and veterinary medical products and related organizations globally
2. Greater national and international political will and policy & public engagement
3. Much better timely data sharing between and within countries and knowledge sharing between human and veterinary medicine quality research, policy & implemetation
4. Targeted research, such as:

   a. More research by groups in Sub-Saharan Africa and Asia

   b. Identification of hotspots of SF medical products and how they change through time and space – are hotpots for SF veterinary and human medical products coincident in time & place – do the drivers differ ?

   c. What determines, in different communities, trust in different medicines & health seeking behaviour ?

   d. Better estimates of impact on patient/animal outcome, the economy and antimicrobial resistance

   e. Which screening devices are accurate for which medicines, what are there cost-effectiveness and where are they best deployed in supply chains ?

   f. Which forensic techniques can be used to determine origin and trade routes of falsified medicines ?

   g. How to engage in different communities when there are outbreaks of SF medical products ?

   h. Optimising medicine regulatory functions for risk based post-market surveillance

MEDICINE QUALITY & PUBLIC HEALTH 2018

#MedsWeCanTrust

About the Campaign · Why Quality · Campaign in Action · Get Involved · Resources · Join the Conversation

Let's demand MEDICINES WE CAN TRUST

The Oxford Statement

MEDICINE QUALITY & PUBLIC HEALTH 2018

"Access to safe and effective medical coverage is essential to WHO goals. There is no universal health coverage, no health security without access to quality medicines."

Dr. Tedros Adhanom Ghebreyesus, Director General of WHO

27 September 2018

October 2018: Every person has the right to expect that when they use a medical product, whether medicine, vaccine or diagnostic kit, it works. But too often, that is not the case. Substandard medical products result from errors, negligence or poor practice in manufacturing, transportation and/or storage. In contrast, falsified products result from criminal fraud. Both innovative and generic products are affected.

While substandard and falsified (SF) medical products are found worldwide, they are more prevalent in countries with under-resourced national medicine regulatory authorities (NMRAs).

Representatives of governments, national and international agencies, non-governmental organisations, professional associations and academic institutions participated in the 1st International Conference on Medicine Quality & Public Health at Keble College, Oxford 23-26 September 2018.

The conference discussed the latest evidence on the epidemiology of SF medical products, their health, economic, social, legal and ethical implications, and debated interventions to ensure that all the world's population have access to affordable and quality-assured medical products.

Thank you

paul.newton@ndm.ox.ac.uk

With many thanks for the support of many Lao, Thai, FORESFA, VIE & ABACUS colleagues, MORU, IDDO, Wellcome Trust, ADB, WHO, Lao Government, French Government, NAFDAC, WWARN-IDDO, LSHTM, USP, Boston University & University of Oxford and the help of many NMRAs organizations & colleagues

Management of the quality of Veterinary Medicinal Products (VMPs) in Japan

National Veterinary Assay Laboratory,

Ministry of Agriculture, Forestry and Fisheries

MAFF

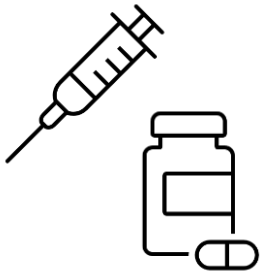
Ministry of Agriculture, Forestry and Fisheries

NVAL

National Veterinary Assay Laboratory

Topic

- ✓ Brief introduction to the NVAL
- ✓ National assay
- ✓ Sampling test
- ✓ Post-marketing Surveillance System



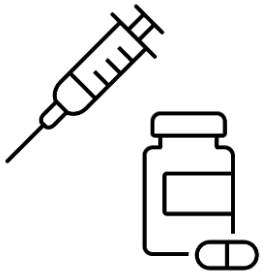
Topic

✓Brief introduction to the NVAL

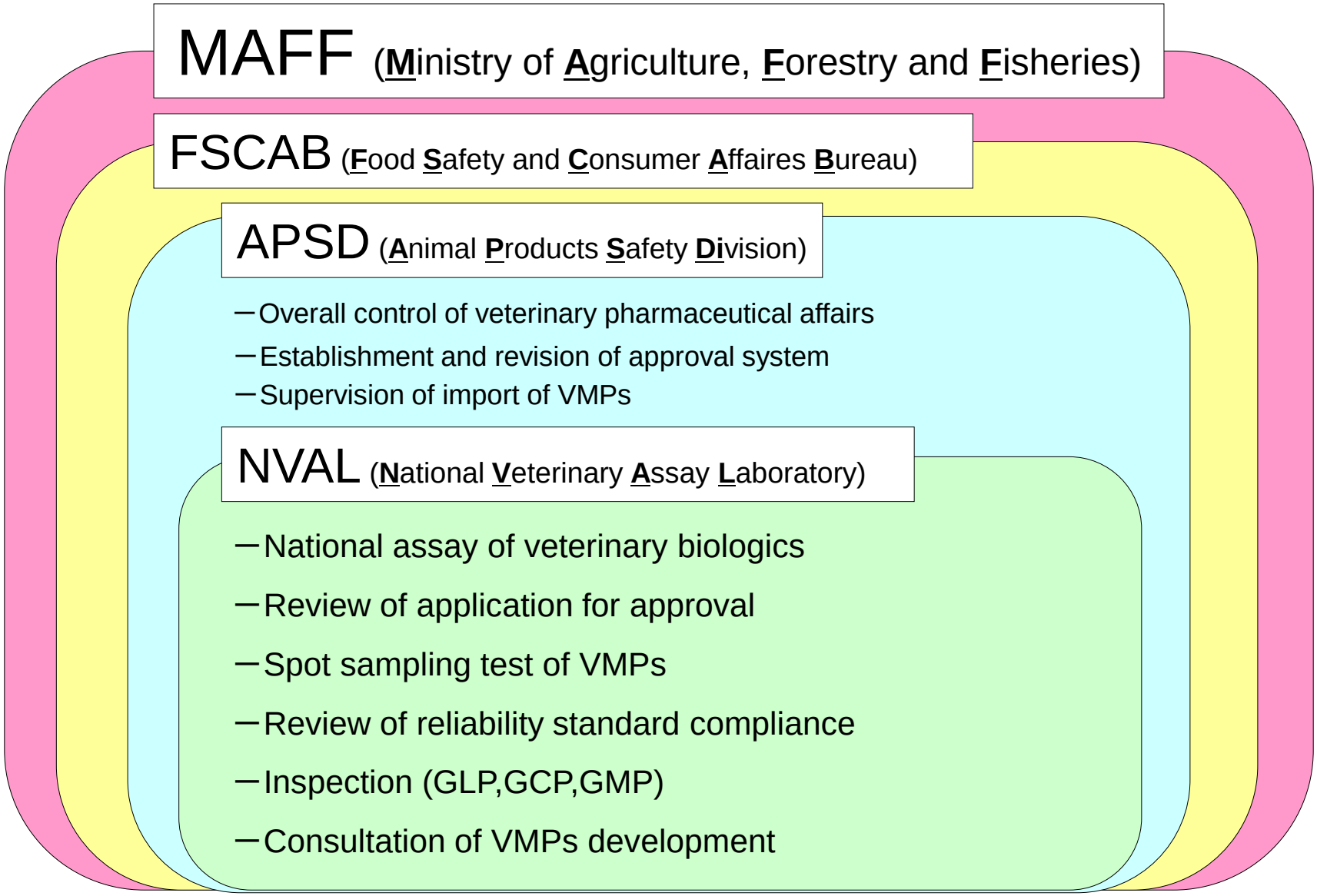
✓National assay

✓Sampling test

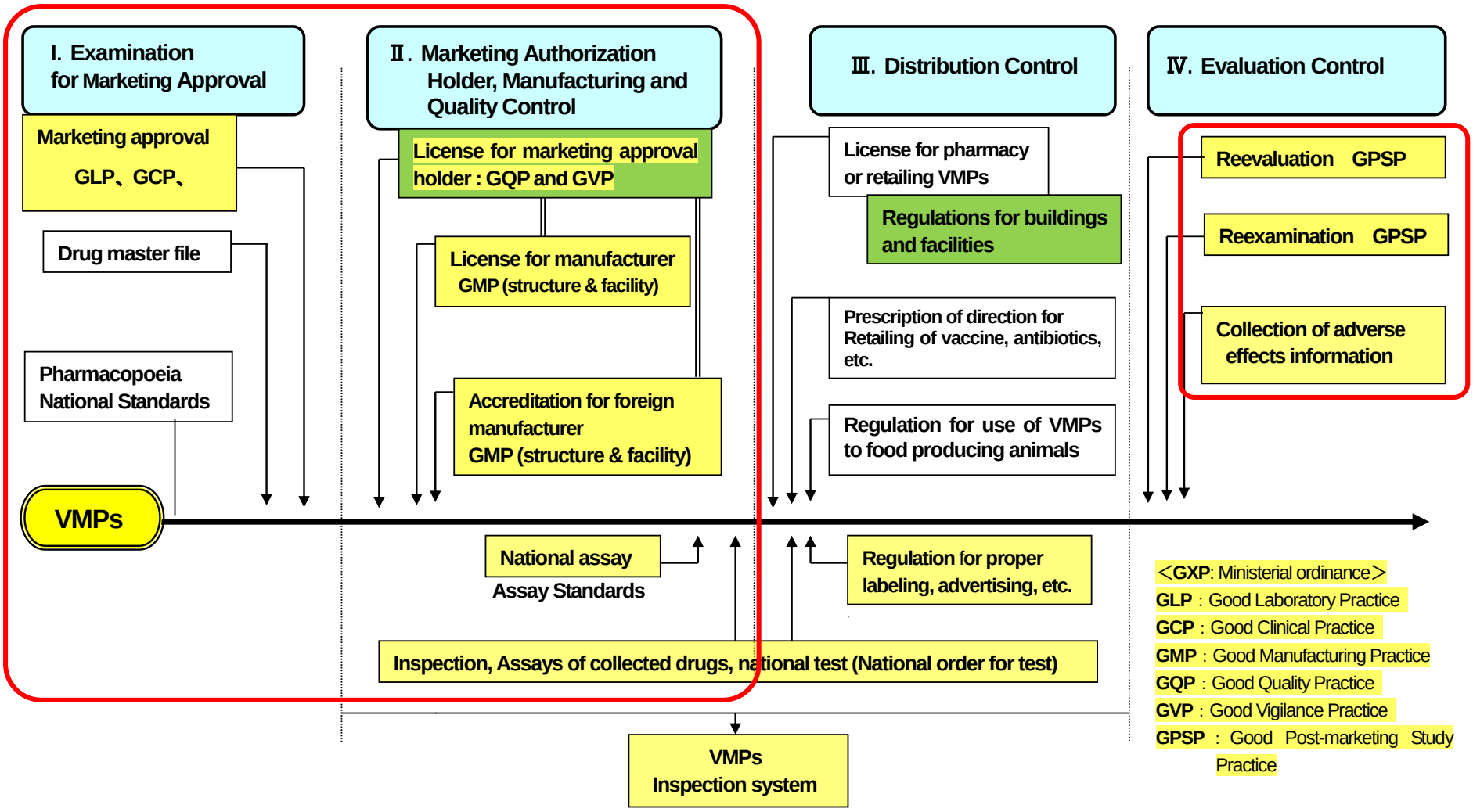
✓Post-marketing Surveillance System



Regulatory authorities for VMPs in Japan

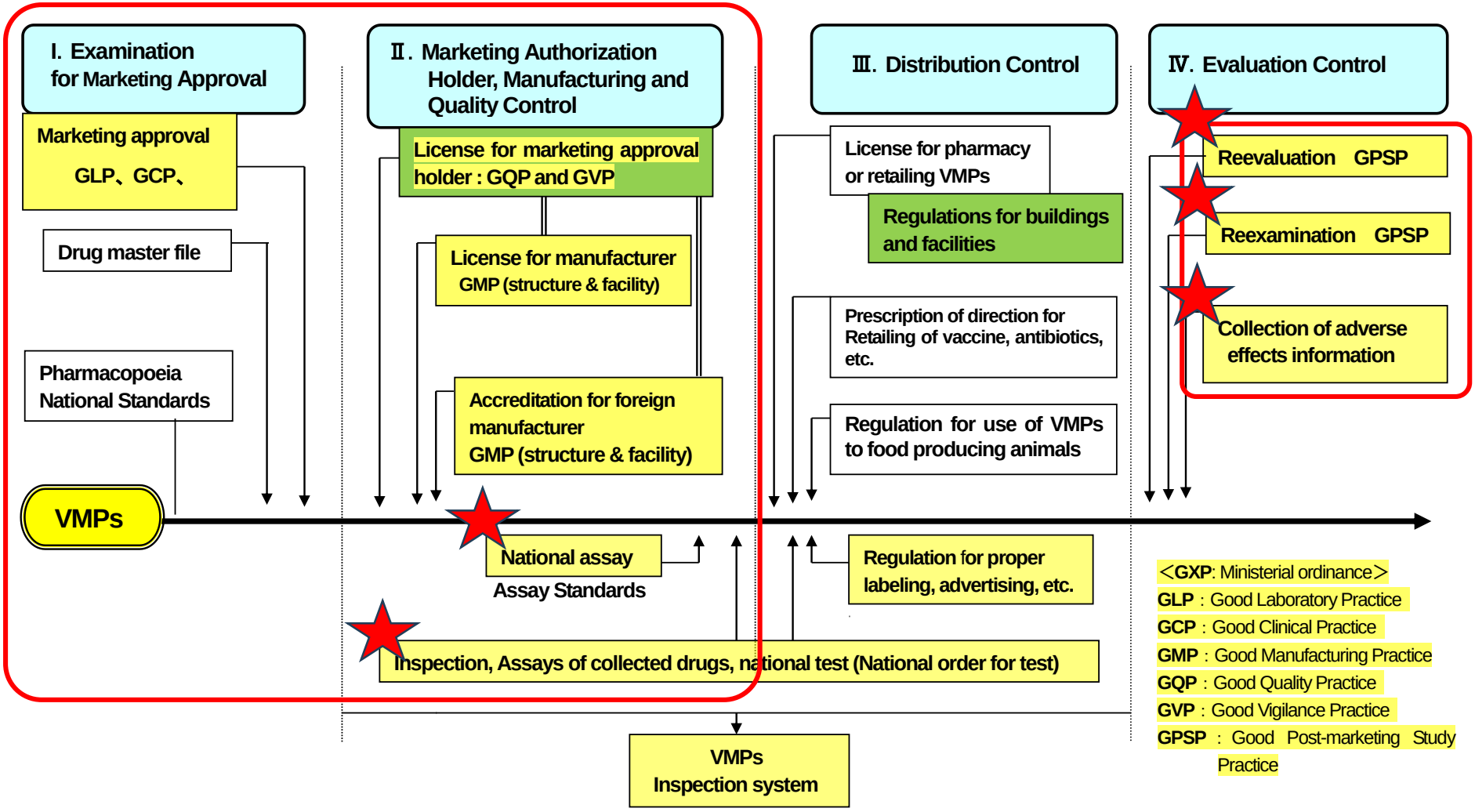


Regulation Flow of VMPs from Development to Post-marketing Stage



※VMPs：vaccines, antimicrobials, and other veterinary medicines and diagnostic kits

Regulation Flow of VMPs from Development to Post-marketing Stage



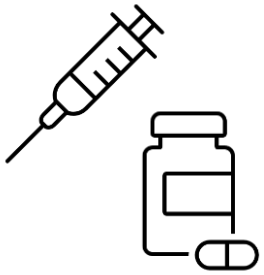
Topic

✓Brief introduction to the NVAL

✓National assay

✓Sampling test

✓Post-marketing Surveillance System



National Assay

- VMPs, especially veterinary biological products, must be subjected to national assay performed by an officer designated by the Minister.
- The drugs designated by the Minister shall not be sold, given, stored or exhibited for the purpose of sale or giving, unless they pass the tests performed by NVAL.

Veterinary biological products

✓ Checking the summary of records throughout the manufacturing process for each lot of product

✓ Checking the efficacy using test samples※

※ Veterinary biological products for livestock infectious diseases or rabies as designated by law

Pass the test

Quality, safety, and efficacy are confirmed

Process of National Assay

Veterinary biologics Manufacturer

① Application for assay (each lot)

② Sampling

Prefecture (pharmaceutical inspector)

③ Sending application and sample

The only national facility that performs tests

NVAL

receiving process
→perform national assay
→ evaluation of result

④ Notice of result

⑤ Notice of result

⑥ Distribution

Number of National Assay 315 (2022)
(Rejected drugs 1 (2022))

※The rejected drugs are discarded in the presence of a pharmaceutical inspector.

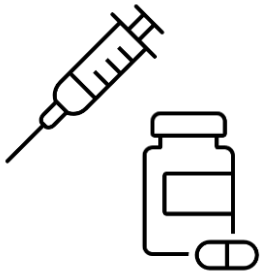
Topic

✓Brief introduction to the NVAL

✓National assay

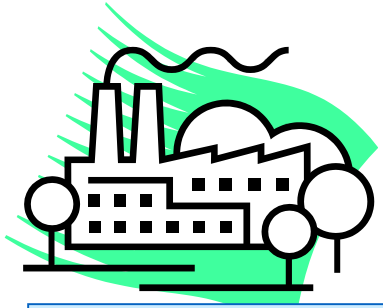
✓Sampling test

✓Post-marketing Surveillance System



Sampling Test

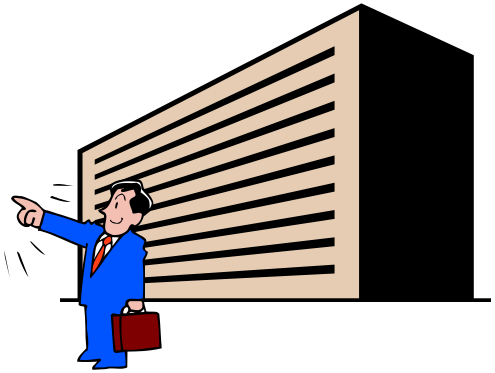
Assays are performed for VMPs which randomly collected without notice.

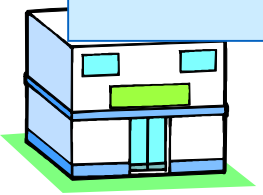


Manufacturer Distributor

①On-site inspection

Pharmaceutical inspector





②Sampling of products

NVAL
Receiving process → Test → evaluation of result

Manufacturer Distributor

③Notice of result

④if the result is unsatisfactory, product must be collected and disposed

Number of Sampling Test: 56 VMPs (2023)
(Failed the test : 2 VMPs (2023))

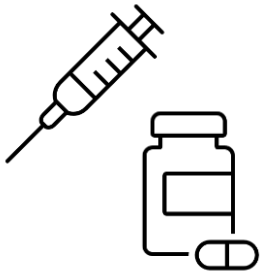
Topic

✓Brief introduction to the NVAL

✓National assay

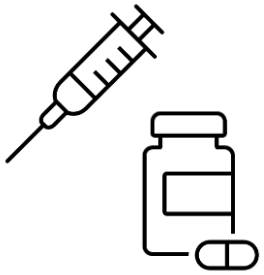
✓Sampling test

✓Post-marketing Surveillance System



Post-marketing Surveillance System

1) Reexamination
2) Reevaluation
3) Collection of information on side effects



Post-marketing Surveillance System

1) Reexamination

Newly approved VMPs

Two years
or
Six years

The marketing approval holder

Field assessment

Applying for a reexamination
of the efficacy and safety of the VMPs

Post-marketing Surveillance System

2) Reevaluation

The quality, efficacy, or safety of VMPs arise questionable in light of the recent scientific standards on veterinary medicine and pharmacology

The marketing approval holder of such VMPs must apply for re-evaluation

Post-marketing Surveillance System

3) Collection of information on side effects

Clinic, Farm, Home

Occurrence of side effects

Veterinarian, etc.

✓Confirming side effects
✓Report to MAFF

Marketing authorization holder

✓Obtaining information
✓Side Effect content investigation
✓Consideration of the need for reporting
✓Report to the Minister of Agriculture, Forestry and Fisheries
✓Dealing with the side effects(Recall, Cause investigation, Improvement measure)

MAFF

✓Review and investigation of reported contents
✓Determination of measures to address side effects
（ Emergency information, Emergency recalls, Cause investigation, Instruction to improve, Reevaluation

Database of side effects information

✓Organizing reported information
✓Disclosure of information

Access

Veterinarian

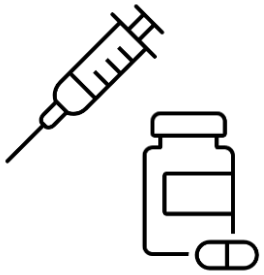
Livestock owner

Pet owner

Manufacturer

Conclusion

- ✓ Brief introduction to the NVAL
- ✓ National assay
- ✓ Sampling test
- ✓ Post-marketing Surveillance System



Thank you for your attention!

present

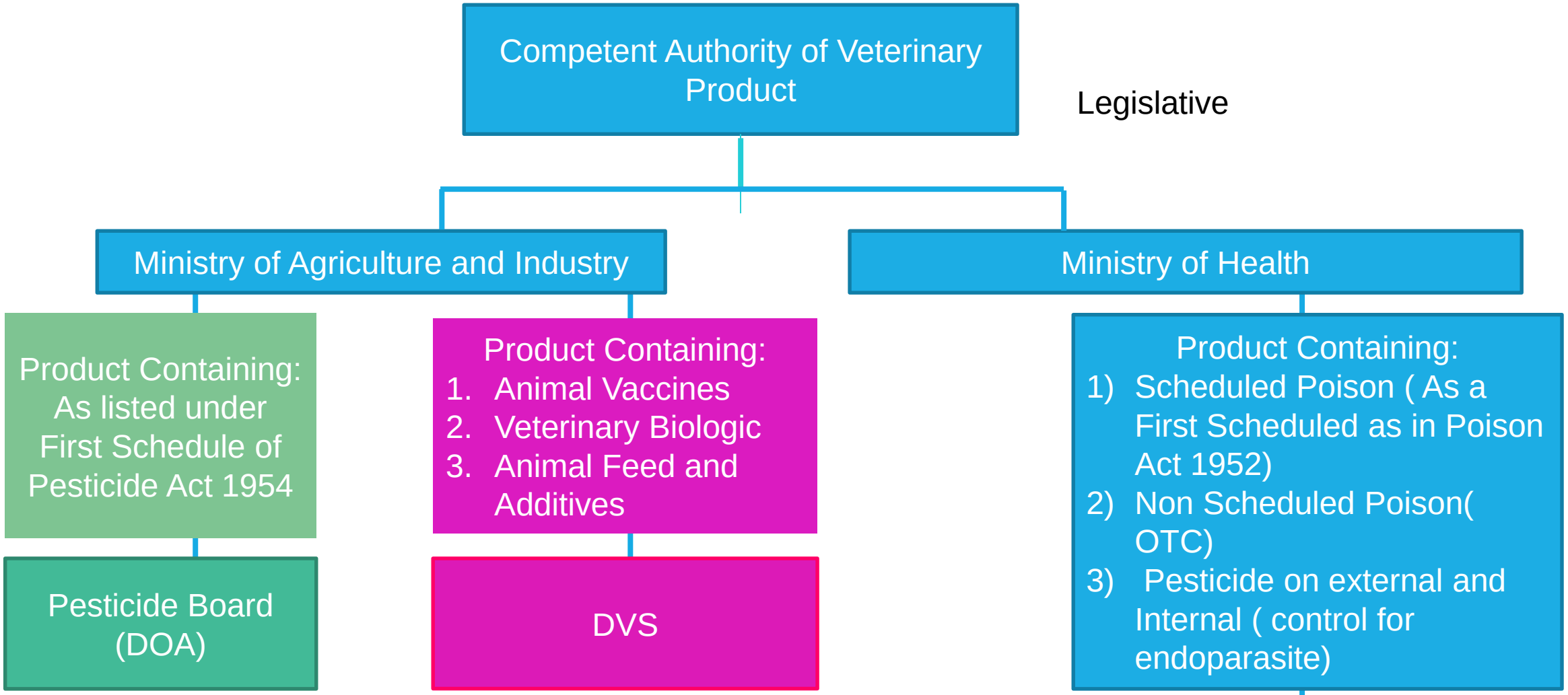
After relocation

World Organisation for Animal Health
Founded as OIE

THE SYSTEM FOR THE MANAGEMENT OF THE QUALITY OF VMPS AND TACKLE SFVP IN MALAYSIA.

DR. ALIFAH BINTI ISMAIL

THE FOCAL POINT OF VETERINARY PRODUCT (DVS MALAYSIA)



Feed additive with combination with poison schedule 1 will regulated by DCA

Pesticide combination with poison schedule 1 will regulated by DCA

Law and Regulation on Veterinary product

1. Poison Act 1952 and Its Regulation
2. Sale of Drugs and Its Regulation 1952
3. Dangerous Drug Act 1952

NPRA (Ministry of Health)

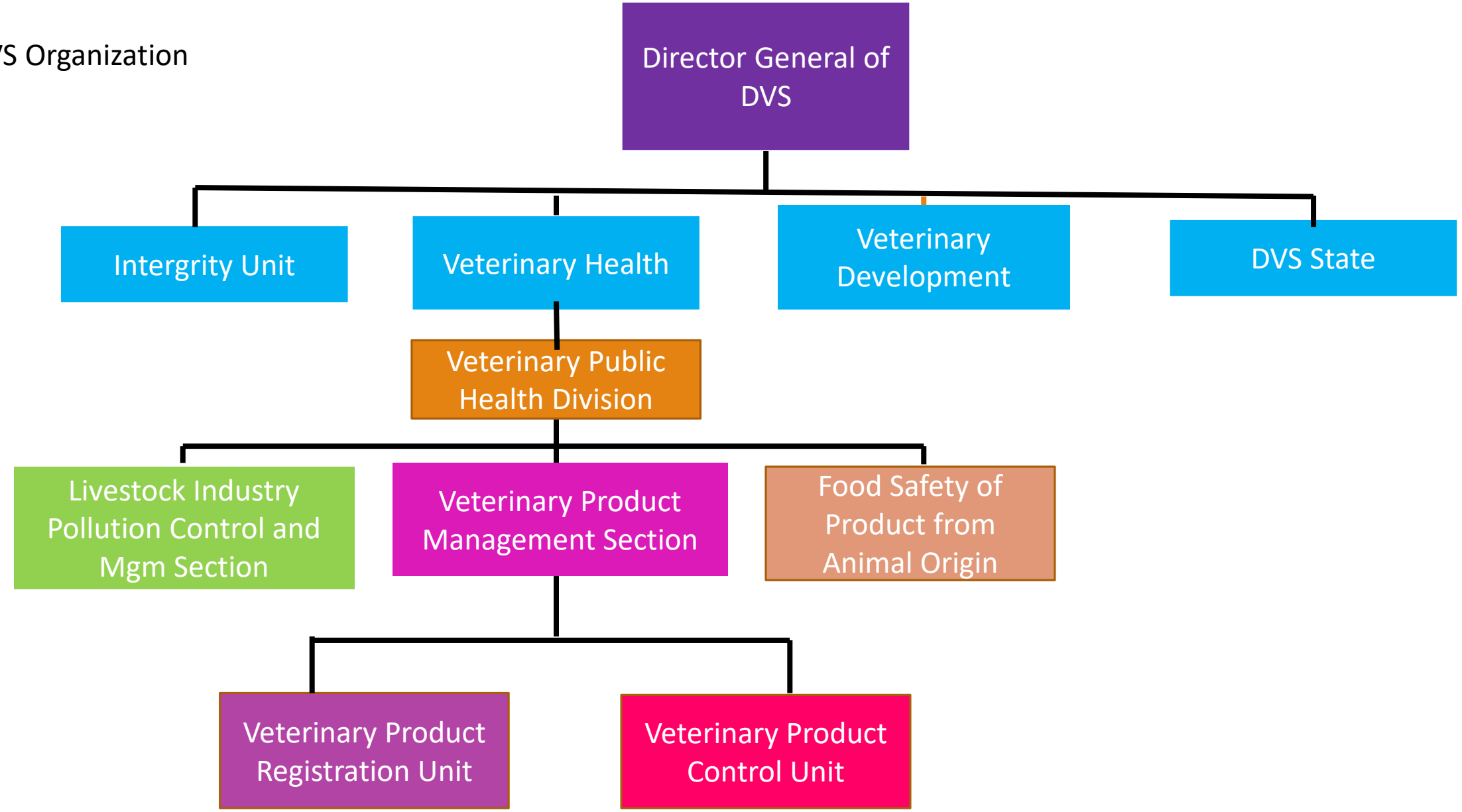
4. Pesticide Act 1954

Pesticide Board

5. Animal Act 1953
6. Animal Feed Act 2009

DVS

DVS Organization



Veterinary Product Management Section

1.Veterinary Registration Unit

1. Coordinating and managing veterinary vaccine ownership licensing application
2. Coordinate and manage the registration of veterinary biological products (vaccines, antimicrobials, hormones and diagnostic kits).
3. Coordinate and manage applications for vaccine manufacturing plant certification.
4. Secretariat of the TCVP and NVPCC Meetings
5. Coordinate training for Vaccine Dossier Reader
6. Provide guideline, manual related to registration of veterinary product

2.Veterinary Product Control Unit

1. Planning and coordinating the Pharmacosurveillance Program and preparation of the Pharmacosurveillance Manual for Veterinary Products.
2. Monitoring the use of veterinary products/medicines in the field and report of the misuse and unregistered veterinary product during the surveillance.
3. Coordinate actions with external relevant agencies to take action against pharmacosurveillance index.
4. Provide guidelines related to the management and use of veterinary medicine. Continue..

Veterinary Product Control Unit continue....

5. Coordinate technical meetings with industry and external agencies regarding veterinary product issues.
6. Coordinate the relevant Amendments to the Animals Act 1953 to strengthen the law enforcement of veterinary products.
7. Coordinate meetings related to veterinary medicine with inter-agency stakeholders (Antimicrobial Resistance Technical Working Group - AMR TWG 4, OIE, FAO) and other relevant agencies.
8. Coordinate training for officials in the DVS state to carry out the pharmacosurveillance program

Pharmacosurveilance Program

Monitoring activities on veterinary product management, involving information collection, investigation and to ensure the safety of veterinary products used.(Prudent Use)

1. Monitoring on Record Keeping of Veterinary Product in Veterinary Premises
2. Monitoring on storage of Veterinary Product
3. Monitoring on Antimicrobial Usage
4. Monitoring how the veterinary product disposal

Detection of non – conformity of Veterinary Product

1) Routine Pharmocosurveilance
2) Internet Selling Monitoring
3) Investigation on Client Complaint


KLINIK HAIWAN LAKE VIEW
AUTO ACCESSORIES
LAKSA


PET PHARMACY

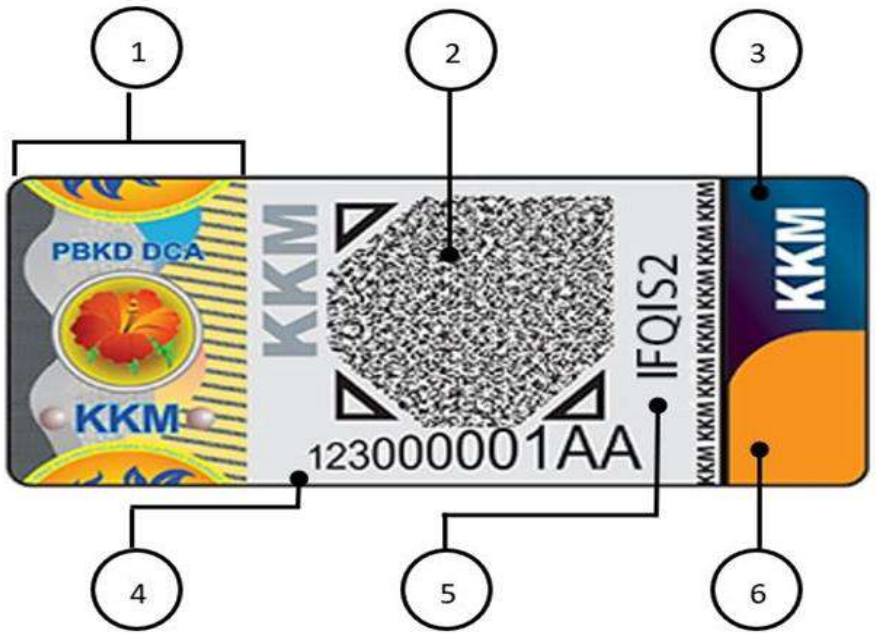

MY CATS & PETS CENTRE
JAWATAN KOSONG


ROYAL CANIN


PET DAYCARE & BOARDING
PET DAYCARE & BOARDING
NOW OPEN


KIMVET

Hologram : Farmatag for KKM (NPRA) indicaton for NPRA Registered Product



1. Imej hologram
2. Kod QR
3. Perubahan warna biru kepada ungu
4. Nombor siri hologram
5. Nombor pin hologram
6. Warna oren pendarflour

Monitoring and confirmation of detection

NATIONAL PHARMACEUTICAL REGULATORY AGENCY
MINISTRY OF HEALTH MALAYSIA

HOME | ABOUT NPRA | INFORMATION | CONSUMERS | HEALTH PROFESSIONALS | INDUSTRY

QUEST 3+ SISTEM PENDAFTARAN PRODUK & PERLESENAN

QUEST 3+ Product Search

Product Category: Pharmaceutical / Cosmetic

Search By: -- Please Select --

Search

Search

NPRA WEBSITE

QUEST 3+ Product Search

Product Category: Pharmaceutical / Cosmetic

Search By: Active Ingredient

Search: IVERMECTIN

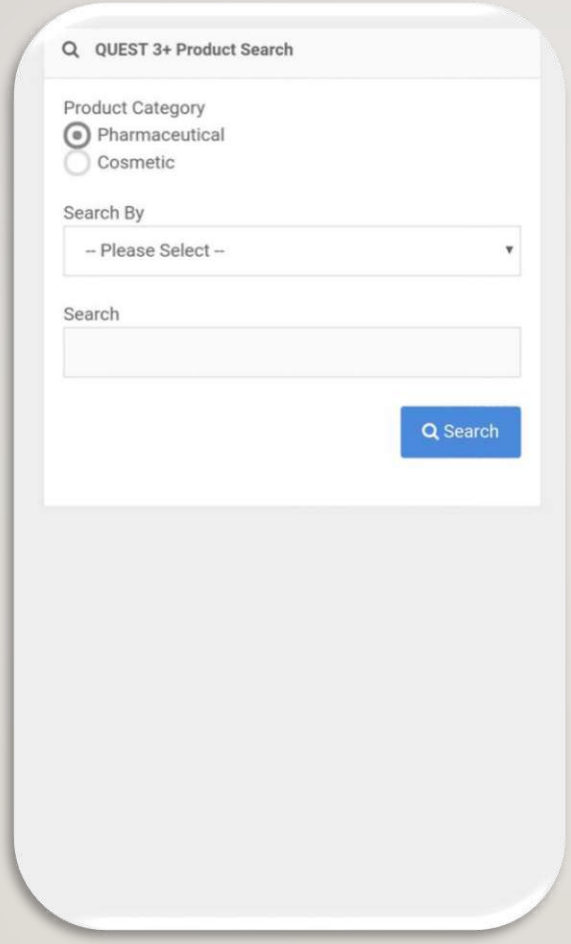
Please enter 5 or more characters

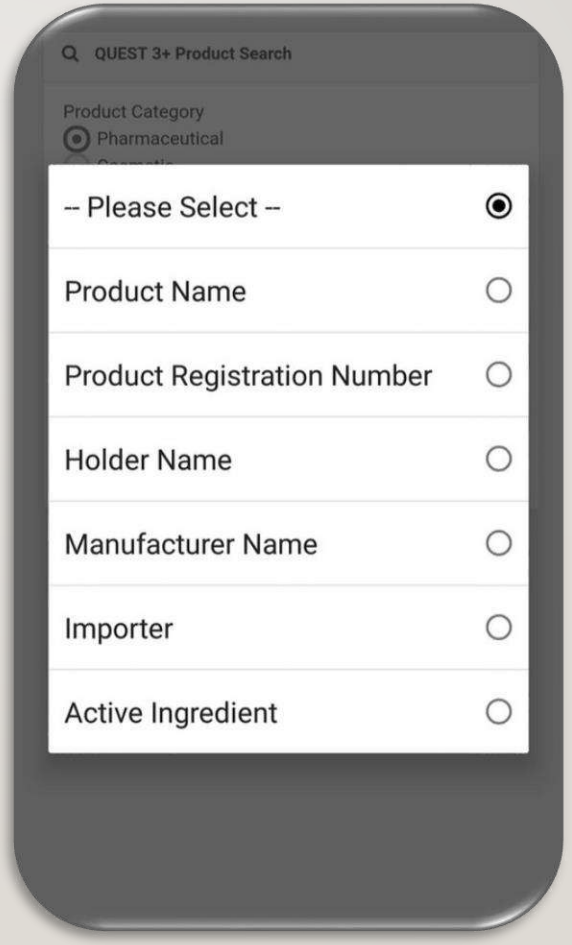
Search

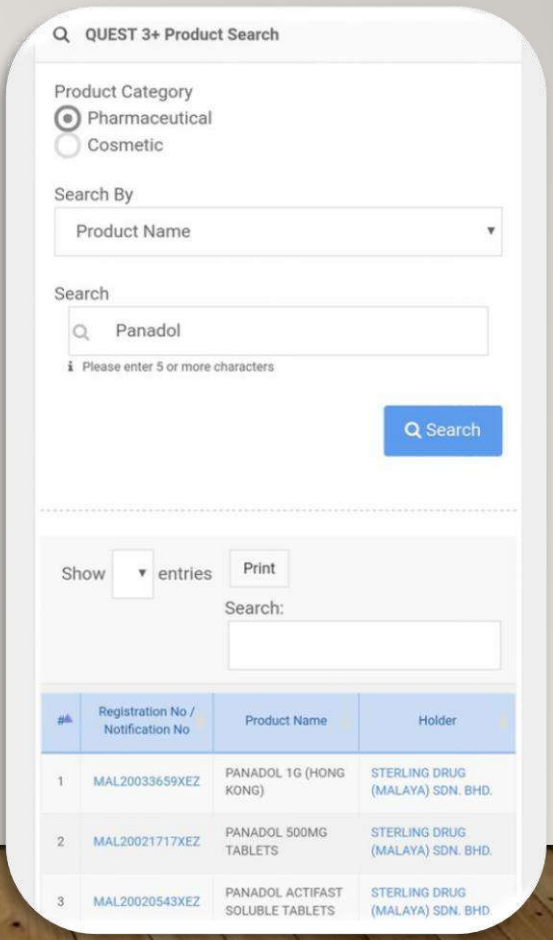
Show 10 entries Print Search:

#	Registration No / Notification No	Product Name	Holder
31	MAL19086015HA	Intermectin 10mg/ml Solution for Injection	Danberg (m) Sdn Bhd
32	MAL19106031HA	Vimectin 0.6%w/w Premix	Vemedim Sdn Bhd

SMARTPHONE APPLICATION



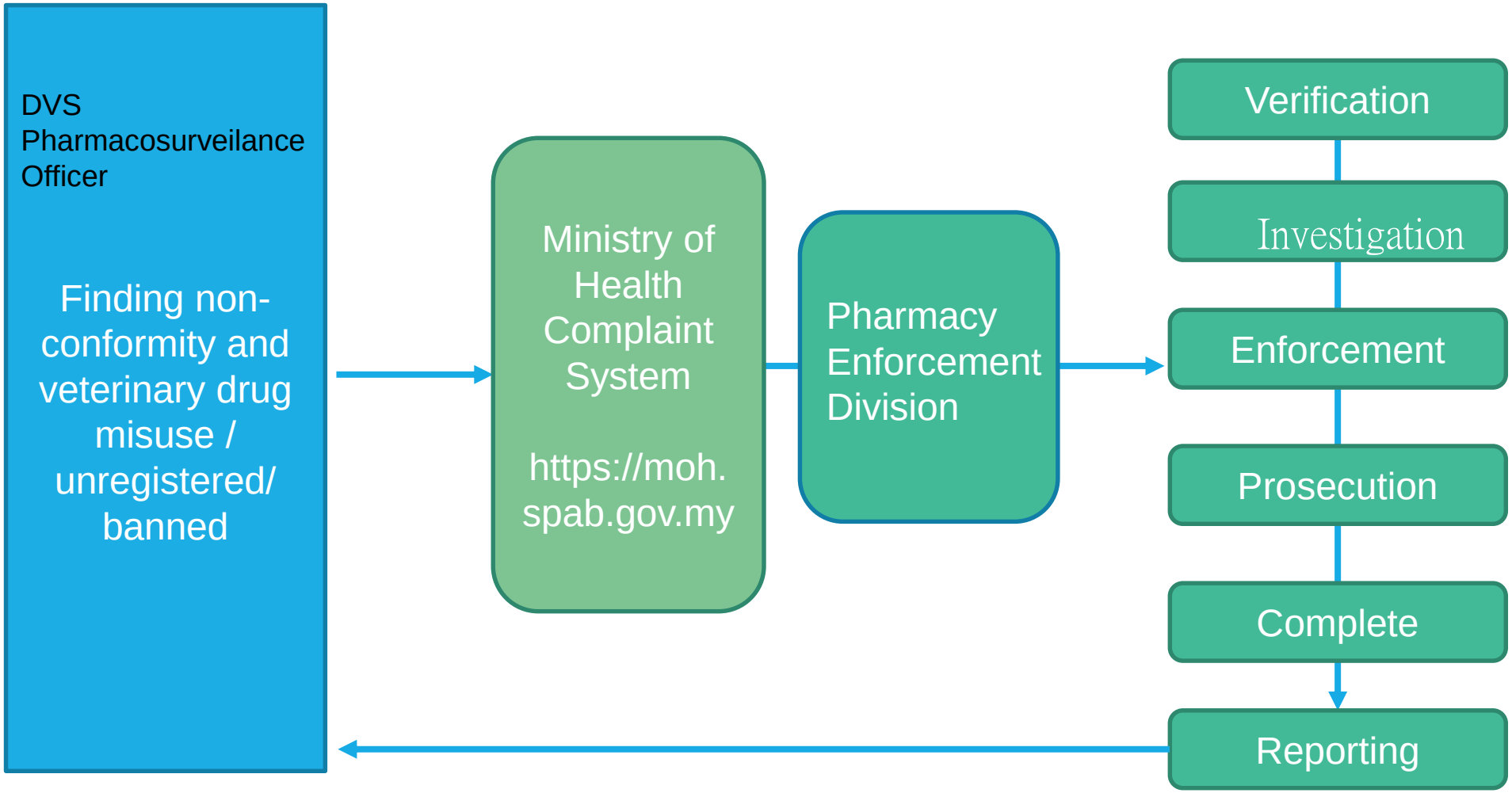




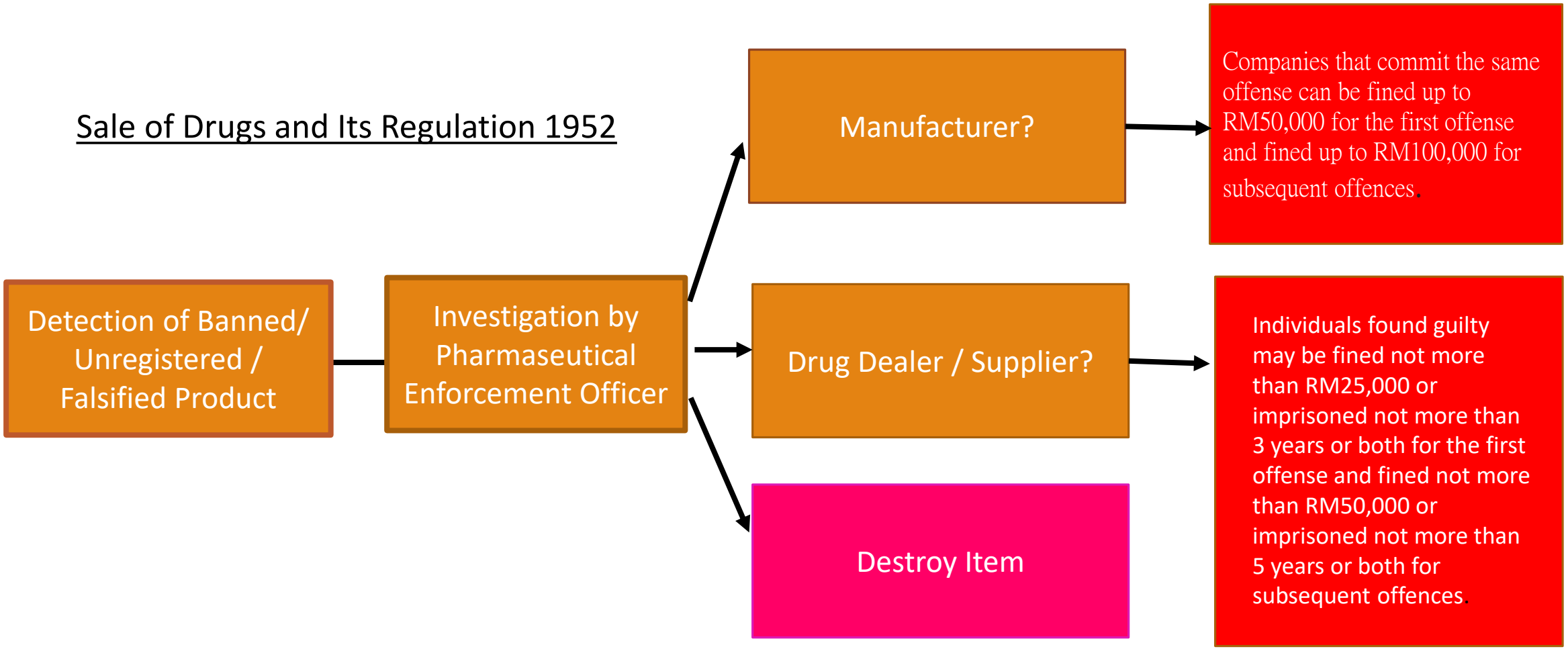
Findings

1. Unregistered Veterinary Product
2. Banned Drug
3. Expired Drug and Veterinary product usage
4. Improper storage and disposal

Reporting non-conformity



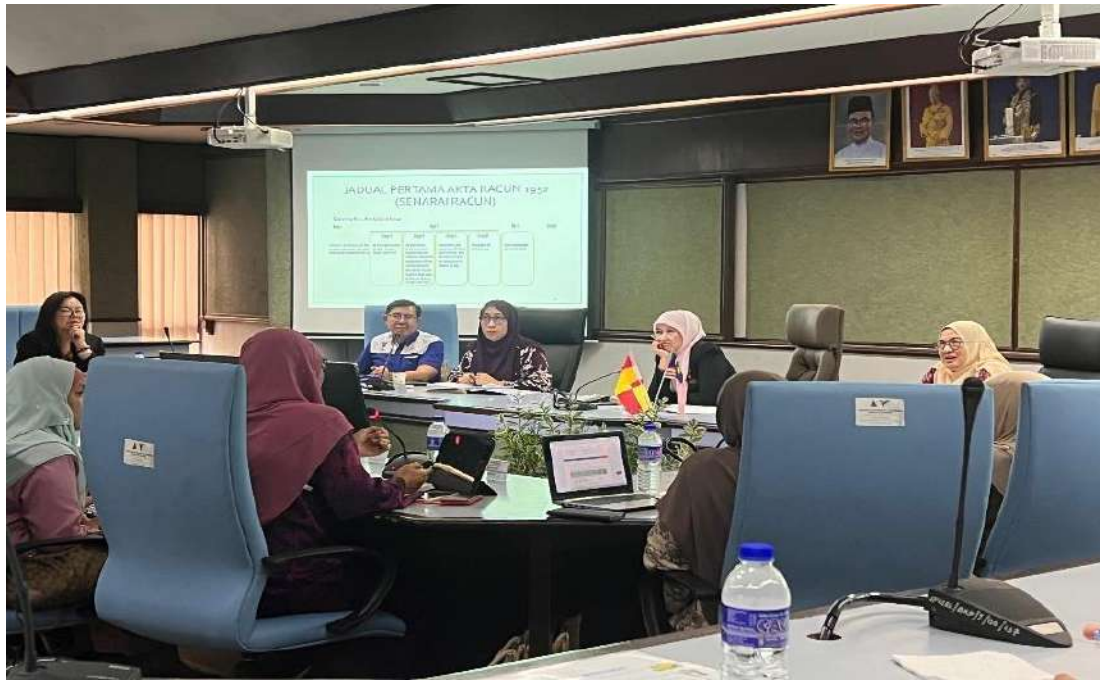
Sale of Drugs and Its Regulation 1952



Coordinating action with related Agency

COORDINATING MEETING AND DISCUSSING RELATING VETERINARY PRODUCT ISSUE INTER AGENCY

Task Force on Veterinary Product(Legislation)



Meeting Inter-Agency on Veterinary Product Issue

THANK YOU

Food and Drug Administration
Ministry of Public Health
Thailand

SF MEDICINAL PRODUCT HANDLING

MS. WITTHAYARAT DANGYAI
MR. PAIROJ OSATAPIRAT
Medicines Regulation Division

1st Workshop on Substandard and Falsified Veterinary Products (SFVP) and WOAH pilot Veterinary Monitoring and Surveillance System for SFVP (WOAH - VSAFE) for WOAH Focal Points for Veterinary Products and Regulators of Veterinary Medicinal Products in Asia and Pacific,
12-14 June 2024, Bangkok, Thailand.

LEGAL FRAMWORK

DRUG ACT B.E. 2510 (1967)

Section 72
No person shall produce, sell or import the following drugs:

01 FAKE DRUGS

02 SUB-STANDARD DRUGS

03 DETERIORATED DRUGS

04 DRUGS WHICH HAS NOT BEEN REGISTERED

05 DRUGS OF WHICH THE FORMULA REGISTRATION HAS BEEN CANCELLED OR WITHDRAWN MORE THAN 6 MONTHS

06 DRUGS OF WHICH THE FORMULA REGISTRATION HAS BEEN ORDERED CANCELLED BY THE MINISTER

SECTION 73

The following drugs or substances are fake drugs :

(1) drugs or substances which are wholly or partly an imitation of genuine drugs.

(2) drugs which show the name of another drug, or an expiry date which is false.

(3) drugs which show a name or mark of a producer, or the location of the produce the drug, which is false.

(4) drugs which falsely show that they are in accordance with a formula which has been registered.

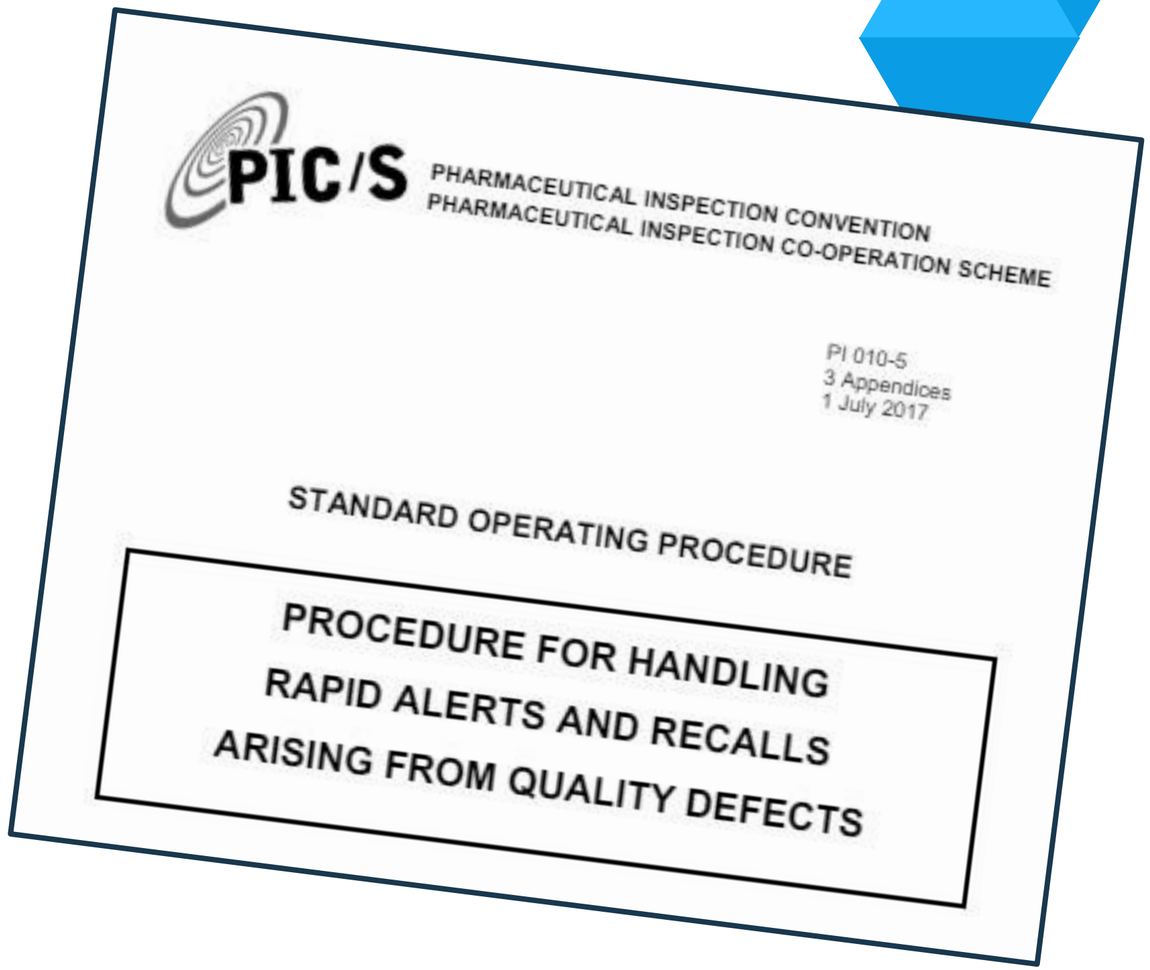
(5) drugs produced with active substances which quantity or strength lower than the minimum or higher than the maximum standards of the formula registration by more than 20%.

PIC/S COMPLIANCE

Covers Rapid Alert issuance and recall of medicinal products which have quality defects or which are falsified.

Covers both human and veterinary medicinal products, including with active pharmaceutical ingredients or investigational medicinal products.

Pharmacovigilance and Medical Devices are not included.



PROCEDURE FOR HANDLING SF MEDICINAL PRODUCTS

Food and Drug Administration
Ministry of Public Health
Thailand

CASE REVIEW

1. Received Complaint regarding illegal manufacturing of veterinary medicines
2. Site inspection collaborating with Central Investigation Bureau
3. The suspected product was identified an unregistered product

Food and Drug Administration
Ministry of Public Health
Thailand

CASE REVIEW

สำนักงานคณะกรรมการอาหารและยา FOOD AND DRUG ADMINISTRATION

แจ้งเตือนเฝ้าระวังปัญหาคุณภาพยา

RAPID ALERT NOTIFICATION OF A DEFECTIVE MEDICINAL PRODUCT

เอกสารสำคัญ – โปรดนำส่งทันที (IMPORTANT – DELIVER IMMEDIATELY)

ระดับความรุนแรงของปัญหา (Class of Defect): 1

	Reference Number: TH/V/2024/010
1. ชื่อผลิตภัณฑ์ (Brand/Trade name): En-Dex® 8000	2. ทะเบียนยาเลขที่ (Drug registration number): N/A
3. สำหรับใช้ใน (For use in): สัตว์ (Animals)	4. กรณีการปลอมแปลง พรบ. ยา มาตรา 73 (โปรดระบุ) (Falsification/Fraud - specify): Unregistered drug
5. ชื่อสามัญ (INN or generic name): Ivermectin 8,000 mcg	6. รูปแบบ (Dosage form): Tablet
7. ความแรง (Strength): รายละเอียดตามข้อ 5. As seen in no. 5	8. หมายเลขรุ่น (Batch/lot number): N/A
9. วันที่ผลิต (Date manufactured): N/A	10. วันที่ยาสิ้นอายุ (Expiry date): N/A
11. รูปแบบบรรจุภัณฑ์ (Pack size and presentation): 1 Box X 1 blister X 10 tablets	
12. ผู้ผลิต (Manufacturer): - ชื่อผู้ติดต่อ (Contact person): - โทรศัพท์ (Telephone): -	13 ผู้นำเข้าหรือสั่ง (Importer): - ชื่อผู้ติดต่อ (Contact person): - โทรศัพท์ (Telephone): -
14. รายละเอียดของปัญหาที่พบ/เหตุผลการเรียกเก็บยาคืน (Details of defect/Reason for recall): จากการตรวจสอบพบผลิตภัณฑ์ยา En-Dex® 8000 มีการนำเข้ายาสำคัญ Ivermectin 8,000 mcg ไม่ทะเบียนตำรับยา ซึ่งถือว่าเป็นผลิตภัณฑ์ "ยาที่มิได้ขึ้นทะเบียนตำรับยา" ดังแสดงในภาพถ่ายด้านล่าง The product En-Dex® 8000 labelling Ivermectin 8,000 mcg was identified an unregistered product as seen in the picture below.	

15. ข้อมูลการกระจายยาและการส่งออก (Information on distribution including exports):
โรงพยาบาล คลินิก และร้านขายยา
Hospitals, clinics and pharmacy store.
All impacted overseas markets are unknown.

16. การดำเนินการของหน่วยงาน (Action taken by Issuing Authority):
แจ้งหน่วยงานที่เกี่ยวข้องให้ทราบ
Inform other related government sectors for product monitoring and surveillance.

17. การดำเนินการในลำดับต่อไป (Proposed action):
-

18. หน่วยงานที่ออกหนังสือ (Issuing Authority):	19. ชื่อผู้ติดต่อ (Contact person):
สำนักงานคณะกรรมการอาหารและยา กระทรวงสาธารณสุข Food and Drug Administration, Ministry of Public Health, Thailand	วรสุดา ยุงทอง Ms.Worasuda Yoongthong **โทรศัพท์ (Telephone):** +66-2590-7405 **อีเมล์ (E-mail):** QA@fda.moph.go.th

20. ลงชื่อ (Signed):	21. วันที่ (Date):	22. เวลา (Time):
(Dr.Wirot Sandee-Thaksoth) Deputy Secretary - General For Secretary - General Food and Drug Administration	25 April 2024	11:03 PM

The picture of En-Dex® 8000 product labelling Ivermectin 8,000 mcg identified an unregistered product

12-14 June 2024, Bangkok, Thailand

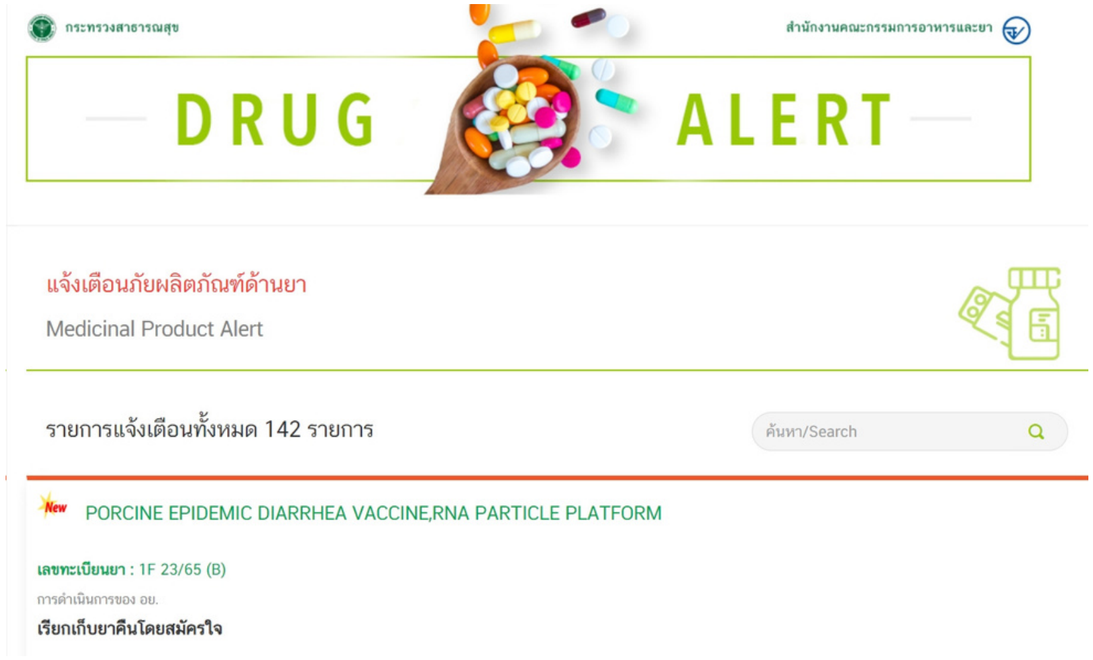
Food and Drug Administration
Ministry of Public Health
Thailand

COMMUNICATION NETWORKS

- National government sectors
- WHO
- PIC/S members
- ASEAN Post-Marketing Alert System

12-14 June 2024, Bangkok, Thailand

PRODUCT ALERT AVAILABLE ON WEBSITE



https://apres.fda.moph.go.th/FDA_POST_VIEW_CENTER/PUBLIC/DRUG_ALERT

Food and Drug Administration
Ministry of Public Health
Thailand

THANK YOU
FOR YOUR ATTENTION

12-14 June 2024, Bangkok, Thailand

Contact Us

www.fda.moph.go.th

QA@fda.moph.go.th

Quality Control of Antimicrobials at BQCLP

1st Workshop on Substandard and Falsified Veterinary Products (SFVP) and WOAH pilot Veterinary Monitoring & Surveillance System for SFVP (WOAH - VSAFE) for WOAH Focal Points for Veterinary Products and Regulators of Veterinary Medicinal Products in Asia and Pacific
Bangkok, Thailand

12-14 June 2024

Chusak Ardsoongnearn

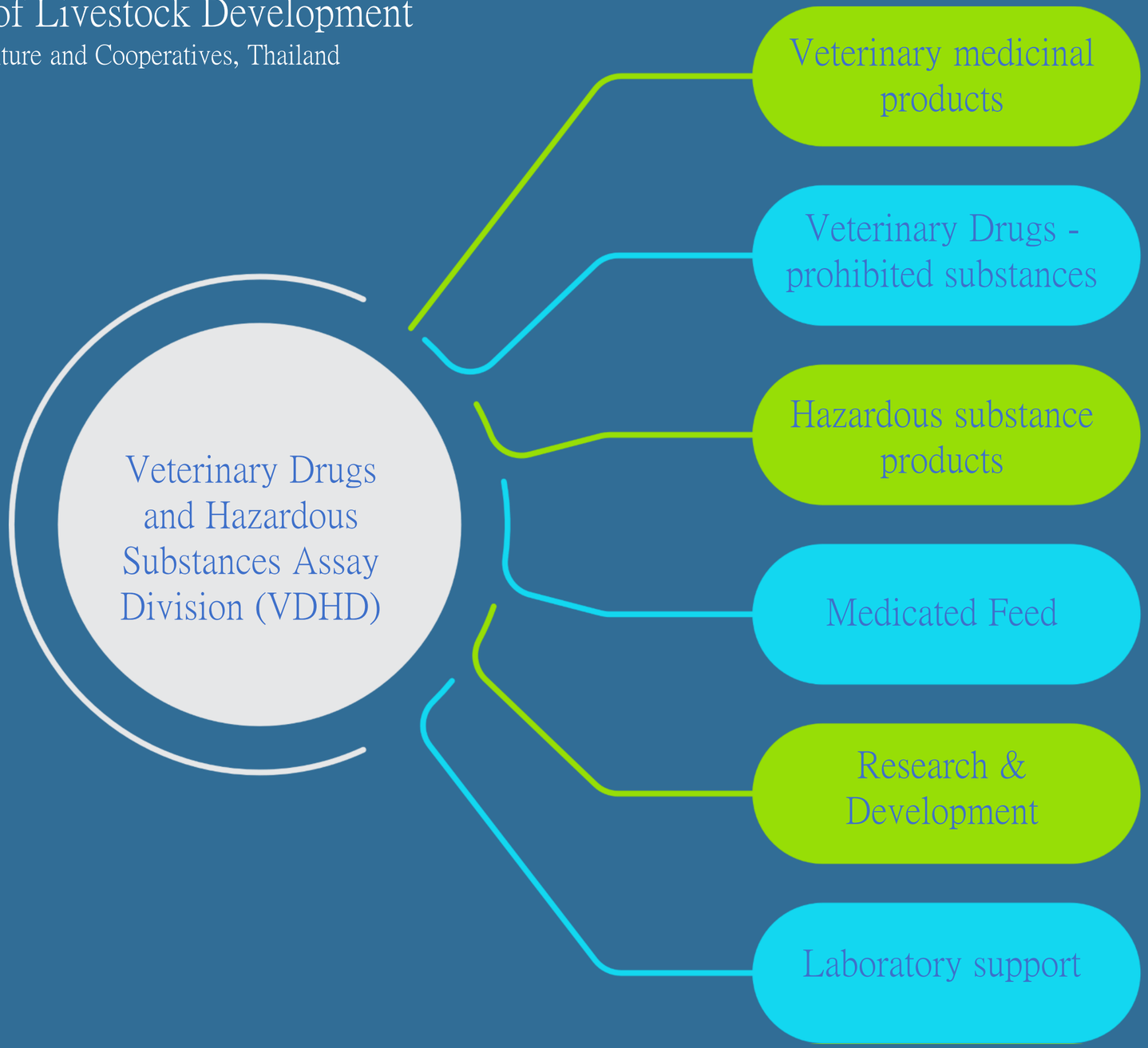
Veterinary Drugs ang Hazardous Substances Assay Division (VDHD)
Bureau of Quality Control of Livestock Products (BQCLP)
Department of Livestock Development (DLD)
Ministry of Agriculture and Cooperatives (MoAC)

Department of Livestock Development
Ministry of Agriculture and Cooperatives, Thailand

Director of BQCLP

- General Administration Section
- Laboratory Management Division
- Laboratory Quality System Division
- Laboratory Audit Division
- Feed Quality Control Laboratory Division (FQCL)
- Veterinary Public Health Laboratory Division (VPHL)
- Veterinary Drugs and Hazardous Substances Assay Division (VDHD)
- Milk and Milk Products Quality Control Division (MMPQC)

Department of Livestock Development
Ministry of Agriculture and Cooperatives, Thailand



VDHD Activities

- Testing active ingredients and identifying veterinary drugs according to British Pharmacopoeia or United States Pharmacopeia standards
- Detecting banned substances in veterinary drugs and drinking water sourced from animal farms
- Evaluating the effectiveness of disinfectants using the Official Methods of Analysis of AOAC International (2023 - latest update)
- Analyzing the percentage of hazardous substances in livestock production
- Assessing the percentage of drug content in medicated feed (homogeneity and carryover)
- Conducting research and development

Department of Livestock Development
Ministry of Agriculture and Cooperatives, Thailand

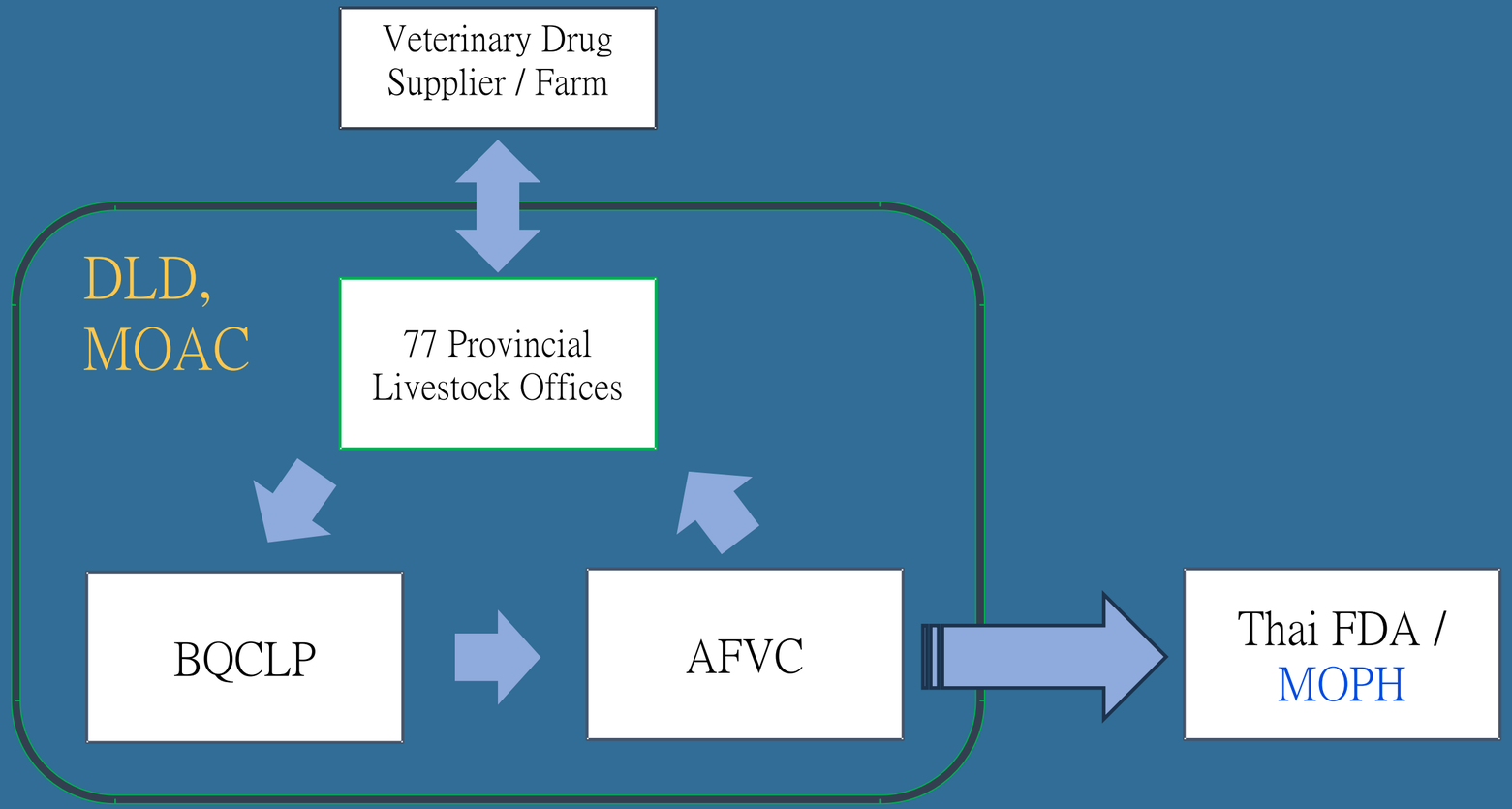
The Purpose of Post-Marketing Surveillance for Veterinary Antibiotics

- The goal is to maintain the quality of veterinary medical products, especially antibiotics, to meet defined standards after they are on the market.
- Encouraging responsible antibiotic use and reducing the risk of residues and the emergence of antimicrobial-resistant microorganisms in livestock products.

In line with the Asian Guideline on Drug Product Stability Study, Thailand falls under zone IVB (hot and very humid). If a specific batch of sensitive veterinary medical products is introduced to the market, there is a risk of significant medication deterioration due to inappropriate transportation and storage. To have a comprehensive understanding, evaluating the quality of post-market products is essential. This involves monitoring the labeled amount of active chemicals using an approved or validated methodology.

Department of Livestock Development
Ministry of Agriculture and Cooperatives, Thailand

Annual Post-Marketing Surveillance of Veterinary Medicinal Products



AFVC = Division of Animal Feed and Veterinary Products Control / WOAH Focal Points for Veterinary Medicinal Products
BQCLP = Bureau of Quality Control of Livestock Products
DLD, MOAC = Department of Livestock Development, Ministry of Agriculture and Cooperative
Thai FDA, MOPH = Food and Drug Administration, Ministry of Public Health

Analytical Instruments

Analytical instruments
- HPLC-DAD-FD-ELSD
- UHPLC-DAD-FD
- HPTLC
- LC-MS/MS
- LC-MS ion trap
- GC-FID, GC-MS/MS
- FT-IR, Raman microscope
- Automatic titrator, Karl Fischer
- UV-vis spectrophotometer
- Etc.

General laboratory instruments
- pH meter, melting point apparatus
- Analytical balance
- Density meter
- Water purifier system – DI water
- Refrigerator, reference standard refrigerator
- Evaporator (N_2, rotary)
- Glassware – volumetric
- Etc.

Department of Livestock Development
Ministry of Agriculture and Cooperatives, Thailand

Analytical instruments

HPLC-DAD-FD

HPLC-DAD-ELSD

LC-MS/MS

LC-MS ion trap

Department of Livestock Development
Ministry of Agriculture and Cooperatives, Thailand

Analytical instruments

GC-FID

HPTLC

Autotitrator / Karl Fischer

UV-vis spectrophotometer

Department of Livestock Development
Ministry of Agriculture and Cooperatives, Thailand

Certified as a laboratory in compliance with ISO/IEC 17025:2017

No.	Test	Year of Accreditation
1	Enrofloxacin assay	2011
2	Beta-agonist (salbutamol, clenbuterol and ractopamine) in potable water for farm animal by LC-MS ion trap	2011
3	pH value veterinary drugs (sterile injectable solution)	2013
4	Tylosin assay	2013
5	Efficacy of disinfectants (Use dilution)	2013
6	Ivermectin assay	2017
7	Nitrofurans, nitroimidazoles and chloramphenicol in potable water for farm animal by UHPLC-DAD	2017
8	Active ingredients (glutaraldehyde, formaldehyde and glyoxal) in livestock hazardous substances products by UHPLC-DAD	2017

VMP
HS
Trace analysis
MF

Department of Livestock Development
Ministry of Agriculture and Cooperatives, Thailand

Certified as a laboratory in compliance with ISO/IEC 17025:2017

No.	Test	Year of Accreditation
9	Active ingredients (iodine complex as available iodine) in livestock hazardous substances products by potentiometric titration	2017
10	Active ingredients (hypochlorite as available chlorine) in livestock hazardous substances products by potentiometric titration	2017
11	Active ingredients (quaternary ammonium compounds) in livestock hazardous substances products by potentiometric titration	2017
12	Beta-agonist (salbutamol, clenbuterol and ractopamine) in potable water for farm animal by LC-MS/ MS	2019
13	Nitrofurans, nitroimidazoles and chloramphenicol in potable water for farm animal by LC-MS/MS	2019
14	Determination of salinomycin in medicated feed using LC-MS/MS (homogeneity and carryover)	2023

VMP

HS

Trace analysis

MF

Thank you for your attention

Update 1 | Update 2 | Update 3 | Update 4 | Update 5

On 15 March 2024, a veterinary practitioner (Dr. Green) contacted the National Competent Authority (NCA) to report two treatment failures through the NCA's pharmacovigilance system.

Dr. Green indicated that on 05 March 2024, four (4) adult cows from the farm 'HappyFarming' (located in Kalesee province) were diagnosed with clinical mastitis caused by *Staphylococcus aureus*. The cows were treated during lactation period with **MASTOP**, an intramammary syringe containing **cefalexin** (200 mg/syringe) and **kanamycin** (100,000 I.U./syringe). After five days of initiating treatment, all treated cows did not show improvement of clinical signs.

One week later (22 March 2024), Dr. Green reported another incident of lack of expected efficacy following administration of MASTOP in lactating cows with clinical mastitis also caused by *S. aureus*. The report came from another farm called 'CooooolCows', in Puont province located at 15 km from the previous report.

According to Dr. Green, the farmers from 'HappyFarming' and 'CoooolCows' were responsible for purchasing the syringes with prescription and the subsequent administration. One of the farmers bought the syringes on-line (www.bestvetproductsever.com), whilst the other bought it in a new store with very competitive prices.

Information of MASTOP used in HappyFarming

- **Registration number :** 9677-DR
- **Batch Number :** 66766AA
- **Manufacturing date :** 12/2019
- **Shelf life :** 12/2022
- **Withdrawal periods :** Five days (milk), ten days (meat & offal)
- **Manufacturer :** Best antimicrobials, Humai, Lalaland
- **Marketing Authorisation Holder :** Cool Farming S.L., Finteju, Lalaland
- **Special precautions for storage :** None

Information of MASTOP used in CooolCows

- **Registration number :** 9677-DR
- **Batch Number :** 22989GD
- **Manufacturing date :** 02/2020
- **Shelf life :** 02/2023
- **Withdrawal periods :** Five days (milk), ten days (meat & offal)
- **Manufacturer :** Best antimicrobials, Humai, Lalaland
- **Marketing Authorisation Holder :** Cool Farming S.L., Finteju, Lalaland
- **Special precautions for storage :** None

LOCAL RADIO FM have picked up these stories, and they launched breaking news recommending citizens to stop drinking milk because of the presence of superbugs. They also urged NCA to take immediate actions and the CEO to step down.

Two days after the breaking news emission, you receive the antimicrobial susceptibility testing (AST) results from the Official laboratory. It is confirmed that **all isolates** from both farms are **susceptible/sensitive** to cefalexin and kanamycin.

The farmer who bought the products in the new store (Ani-Mal Agristore, Kalesee) indicated that syringes were offered in plastic bags (as opposed to carton package as usually presented). When administering the product, it was noted that the consistency of some of the syringes appeared thicker than usual.

After reporting both incidents to WOAH pilot-VSAFE, it was noted that substandard syringes of MASTOP had been previously reported by a Focal Point of Veterinary Products from another country, which was found by customs of their country in a package to be delivered by post.

Update 1 | Update 2 | Update 3 | Update 4 | Update 5

Four days after submitting syringes for laboratory testing to the National Quality Control Laboratory you receive the report with the following results.

	Syringe (Reference)	Syringe HappyFarming	Syringe CoolCows
Physico-chemical			
Density	3.45	4.69	5.2
Colour	Off-white	White-yellow	White-yellow
Active ingredient			
Cefalexin (mg/syringe)	200	91	130
Kanamycin (I.U./syringe)	100,000	64,226	77,920

After contacting the Marketing Authorisation Holder (MAH), they confirmed that they manufactured the product, however, the results of the analysis are not in line with their original records.

An inspector goes to the establishment of Ani-Mal Agristore. The store owner claims they did not sell the product.

Following thorough inspection of the premises, the inspector found more than 500 syringes of the MASTOP which expired dates range 01/2022 – 12/2023 available to purchase. They were stored at the back of the storeroom in a locked box.

It was noted that the website www.bestvetproductsever.com was visible on the screen of the computer, which was saved in favorites.

Case Scenario 1

1st Workshop on Substandard and Falsified Veterinary Products (SFVP) and WOAH pilot Veterinary Monitoring & Surveillance System for SFVP (WOAH - VSAFE) for WOAH Focal Points for Veterinary Products and Regulators of Veterinary Medicinal Products in Asia and Pacific

Bangkok 12-14 June 2024

Group Number : X

World Organisation for Animal Health
Founded in 1924
Organisation mondiale de la santé animale
Fondée en 1924
Organización Mundial de Sanidad Animal
Fundada en 1924

Instructions

- You will receive 5 updates
- Each update contains limited information
- Use this information to decide the enquires, investigations you pursue, and next steps
- 10-15 min for each update

What facts can you establish?	What information are you missing?	What risks did you identify?	What action did you take?

There is no wrong answer. There can be multiple solutions

Instructions

- Elect a rapporteur for completion of the tables
- Each rapporteur will present a piece of the updates
- Send presentation at sfvp@woah.org
- WOAH will wrap the session with main points of reflection

Disclaimer

The case presented 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

Update 1 | Update 2 | Update 3 | Update 4 | Update 5

What facts can you establish?	What information are you missing?	What risks did you identify?	What action did you take?

Update 1 | Update 2 | Update 3 | Update 4 | Update 5

What facts can you establish?	What information are you missing?	What risks did you identify?	What action did you take?

Update 1 | Update 2 | Update 3 | Update 4 | Update 5

What facts can you establish?	What information are you missing?	What risks did you identify?	What action did you take?

Update 1 | Update 2 | Update 3 | Update 4 | Update 5

What facts can you establish?	What information are you missing?	What risks did you identify?	What action did you take?

Update 1 | Update 2 | Update 3 | Update 4 | Update 5

What facts can you establish?	What information are you missing?	What risks did you identify?	What action did you take?

Thank you

Merci

Gracias

sfvp@woah.org

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
Founded in 1924

Organisation mondiale de la santé animale
Fondée en 1924

Organización Mundial de Sanidad Animal
Fundada en 1924

RILO
Asia / Pacific
World Customs Organization

Customs Enforcement Initiatives

Presentation from the
Regional Intelligence Liaison Office of Asia and the Pacific
World Customs Organization

June 2024, SFVP and VSAFE Workshop
Billy KH YEUNG, Intelligence Analyst, RILO A/P

Who is RILO A/P?

- Regional body of the World Customs Organization (WCO)

- RILO A/P supports border / boundary enforcement of WCO Member Customs Administrations by :
  - ✓ facilitating **intelligence exchange** and mutual assistance
  - ✓ providing operational support for regional or global intelligence-led **enforcement operations or projects**
  - ✓ **collecting and analyzing various information** source and **developing intelligence products** and
  - ✓ promoting and maintaining **regional co-operation** with other law enforcement agencies and organizations.

RILO A/P Members

Hong Kong, China
1987~1998

Japan
1999~2003

China
2004~2011

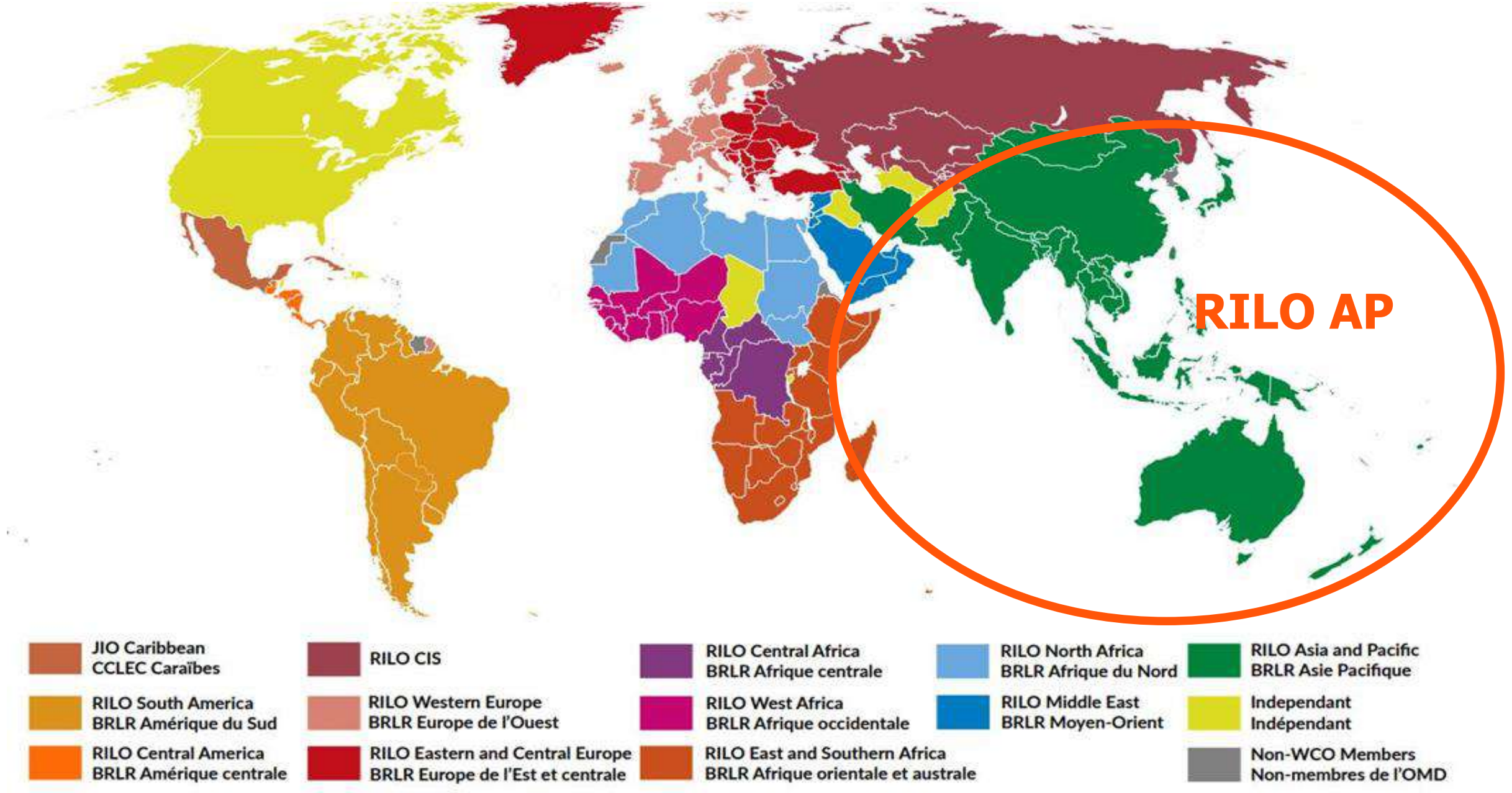
Korea
2012~2023

Japan
2024~

35 members

Afghanistan
Australia
Bangladesh
Bhutan
Brunei
Cambodia
China
Fiji
Hong Kong, China
India
Indonesia
Iran
Japan
Korea, Republic of
Lao PDR
Macao, China
Malaysia
Maldives
Mongolia
Myanmar
Nepal
New Zealand
Pakistan
Palau
Papua New Guinea
Philippines
Samoa
Singapore
Solomon Islands
Sri Lanka
Thailand
Timor-Leste
Tonga
Vanuatu
Vietnam

The RILO Network



Intelligence Products

RILO issues alert information to encourage Member Customs administrations to take immediate action, and publishes regular analysis reports showing trends of smuggling in the region and other relevant information that may support border enforcement of member Customs Administrations

RILO Asia and the Pacific — World Customs Organization

RILO A/P Alert Info. No. 2024/010

Title:	**1 MO, 2 Countries**
Issuing date :	11 April 2024
Category:	Drug
Mode of transport:	Air cargo (express mail)
Recommended action:	- Frontline officers conducting cargo examination may be aware of goods declared as "Tables" arriving from Switzerland; - Officers conducting post-import data analysis may consider studying cargo information of goods declared as "Tables" arriving from Switzerland in the past 3 months for potential extraction of useful information (e.g. consignor / consignee details) for profiling initiatives.

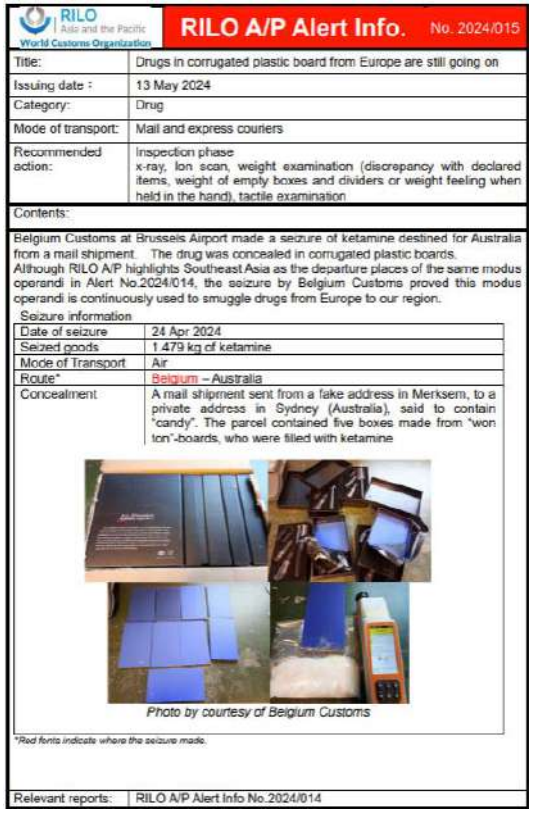
On 11 and 13 March 2024, Japan Customs and New Zealand Customs seized 2 separate shipments of MDMA respectively, both arriving from Switzerland:-

Seizure information (Case effected by Japan Customs)

Date of seizure	11 March 2024
Seized goods	MDMA (Approx. 4.8 kg)
Mode of Transport	Postal Parcel
Route*	Switzerland > Japan
Concealment	Pressed into a stone-like tabletop

*Red fonts indicate where the seizure made.

(Photos by courtesy of Japan Customs)



RILO Asia and the Pacific — World Customs Organization

RILO A/P Alert Info. No. 2024/015

Title:	Drugs in corrugated plastic board from Europe are still going on
Issuing date :	13 May 2024
Category:	Drug
Mode of transport:	Mail and express couriers
Recommended action:	Inspection phase x-ray, Ion scan, weight examination (discrepancy with declared items, weight of empty boxes and dividers or weight feeling when held in the hand), tactile examination

Contents:

Belgium Customs at Brussels Airport made a seizure of ketamine destined for Australia from a mail shipment. The drug was concealed in corrugated plastic boards.
Although RILO A/P highlights Southeast Asia as the departure places of the same modus operandi in Alert No.2024/014, the seizure by Belgium Customs proved this modus operandi is continuously used to smuggle drugs from Europe to our region.

Seizure information

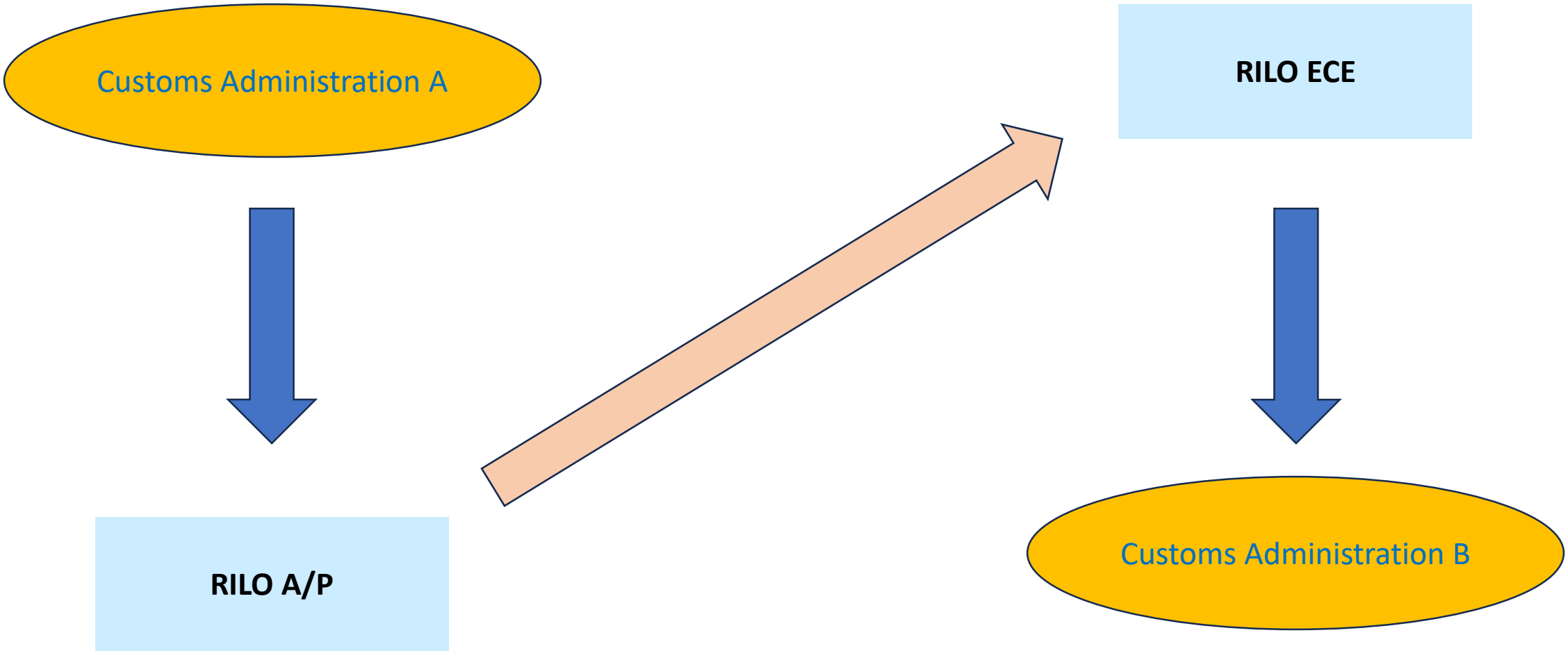
Date of seizure	24 Apr 2024
Seized goods	1 479 kg of ketamine
Mode of Transport	Air
Route*	Belgium – Australia
Concealment	A mail shipment sent from a fake address in Merksem, to a private address in Sydney (Australia), said to contain "candy". The parcel contained five boxes made from "won ton"-boards, who were filled with ketamine

Photo by courtesy of Belgium Customs

*Red fonts indicate where the seizure made.

Relevant reports:	RILO A/P Alert Info No.2024/014

Effective Communication – Fruitful Results

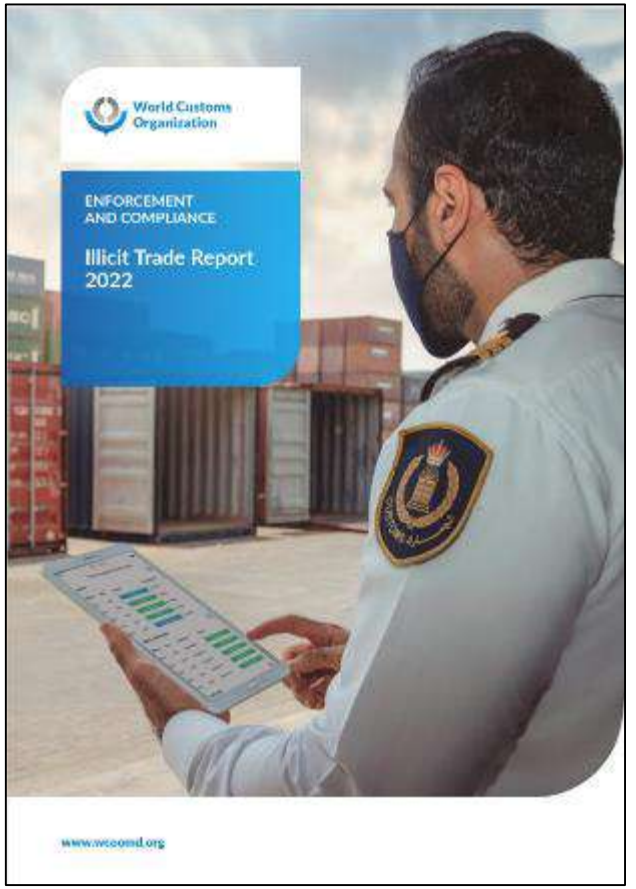


Statistical Data of WCO Member Customs Administrations on IPR

WCO Customs Member administrations reports their seizure data through the Customs Enforcement Network (CEN)

(Reported Data in Illicit Trade Report 2022)

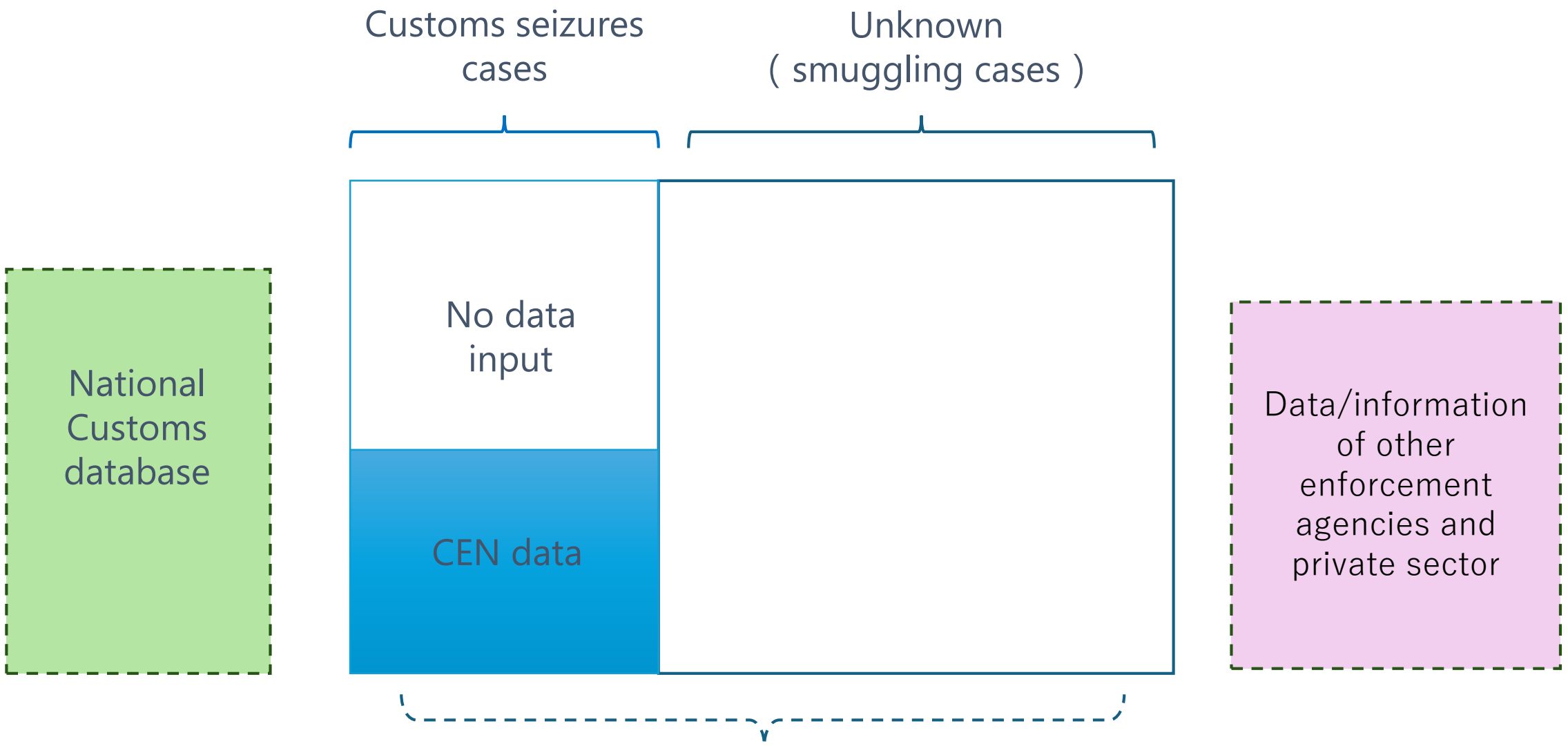
- ✓ Non-medical IPR goods: Seizure of 43 million pieces
- ✓ Illicit medicines: Seizure of 190 million pieces and 192 tons
- ✓ Mail was the most frequent conveyance means (case no.)
- ✓ Seizure volume in vessels and vehicles is notable
- ✓ Asia Pacific is the largest departure region



(Survey) What percentage of smuggling do you think the Customs authorities has found or seized in 2023?

0-10%	**2**
11-30%	**13**
31-50%	**2**
51-70%	**1**
71-90%	**0**
91-100%	**0**
Cannot answer	**13**

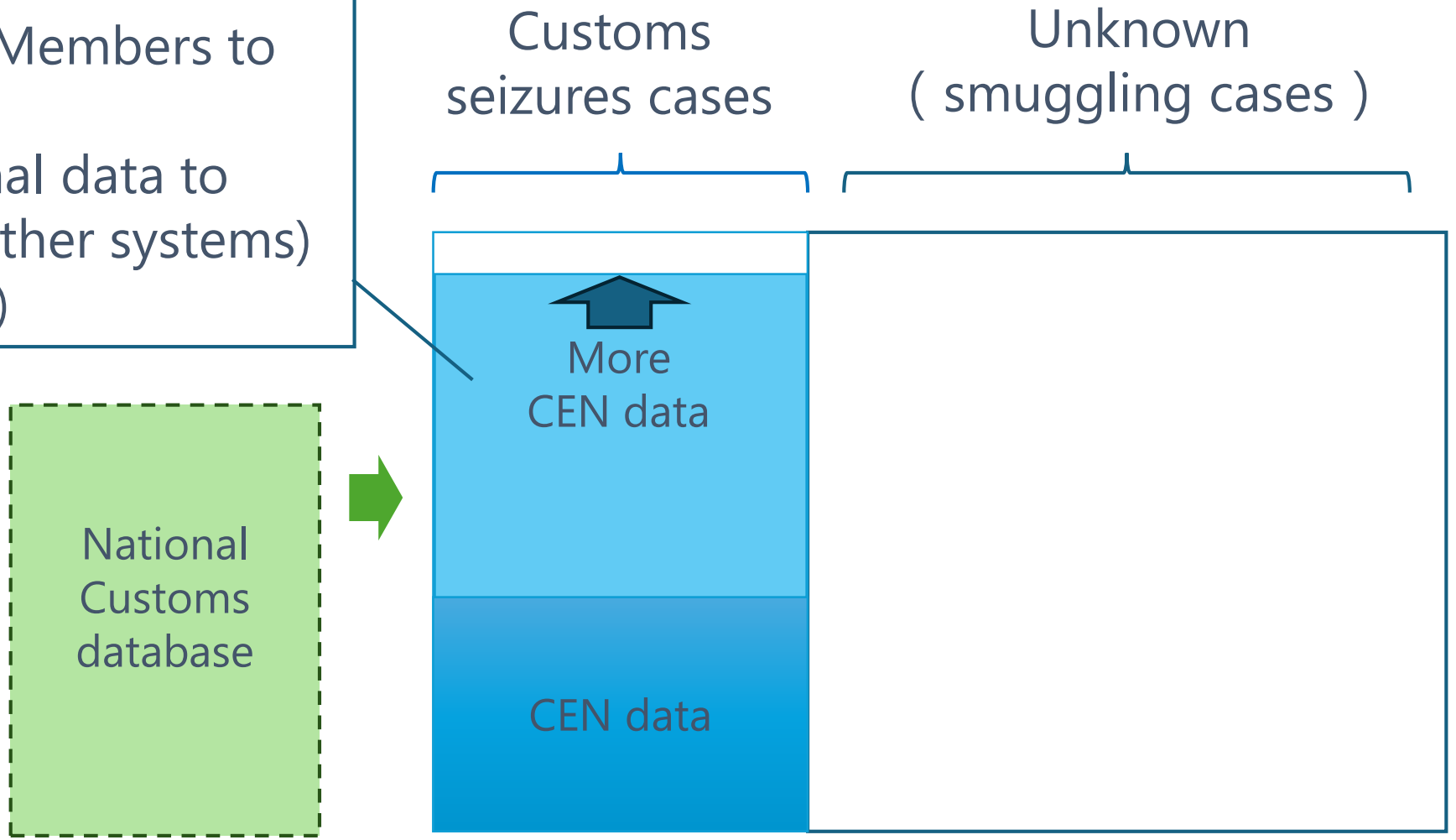
Challenge for Risk Analysis – Availability of Data



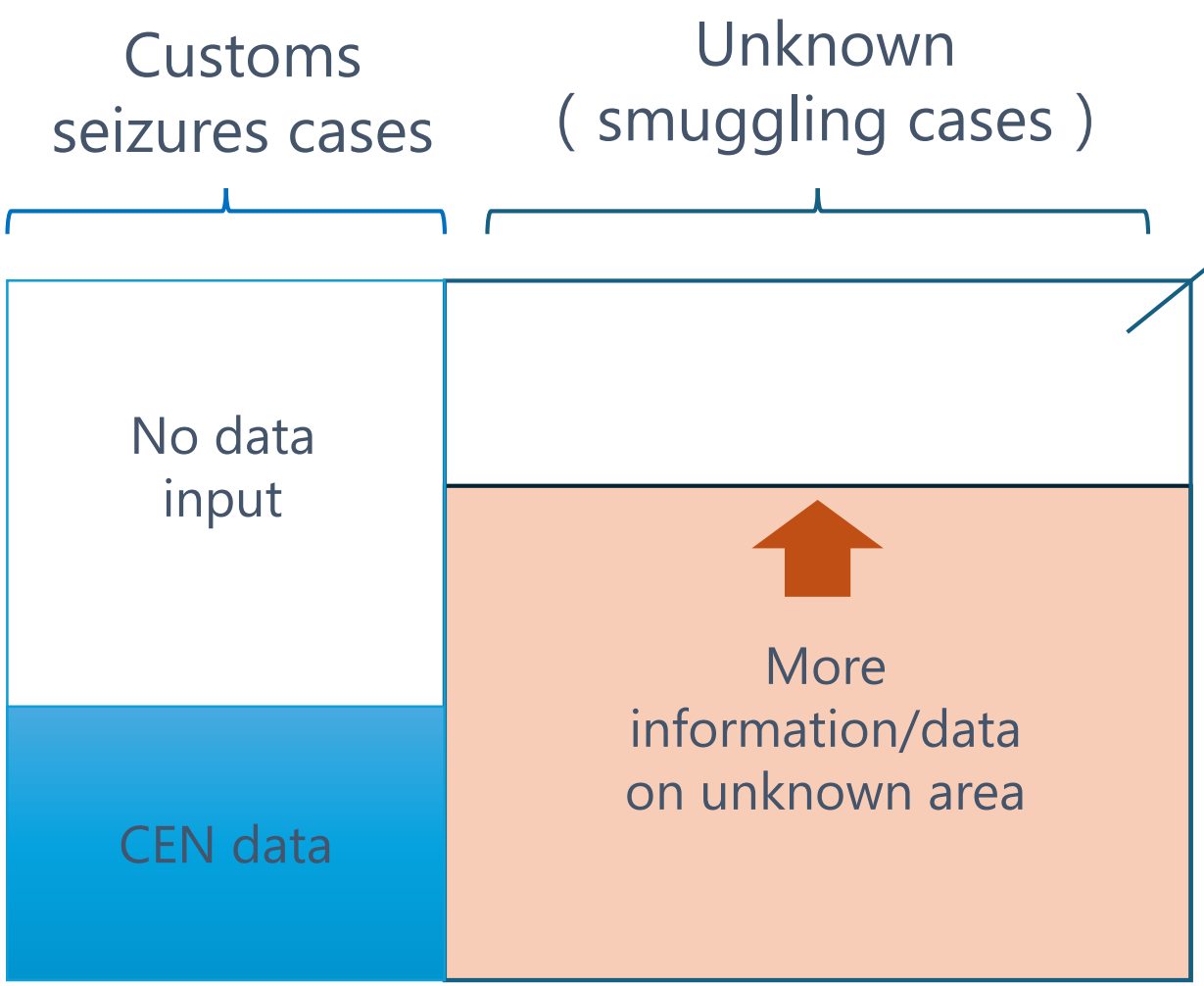
Criminal networks know both seizure cases and smuggling cases?

Measures to Increase Volume of Seizure Data

- ✓ Improvement of CEN or develop a new system?
- ✓ Regular support for Members to use CEN
- ✓ Conversion of national data to CEN data (and / or other systems) (Excel input function)



Approach to Unknown Area



- Expansion of intelligence network to other enforcement agencies (police, immigration etc.) and international organizations
- Further collaboration with private sectors
- Open-source intelligence analysis

Data/information of other enforcement agencies and private sector

Possible Approaches for Customs against SFVPs (Legal Ground)

1. Pharmaceutical Related Laws

   - Do the products meet the standards or regulations ?
   (Licence? Approval/permission by other government agencies?)

2. Intellectual Property Rights(IPR) Laws and Customs Laws

   - Counterfeit medicines? - IPR Violations ?
   (IPR infringement, Customs law violation)

Actions Proposed

1. Re-build connections, establish new ones
2. Share information
3. Avoid resource duplication
4. Re-confirm legal requirements
5. Raise awareness

RILO A/P stand ready to join hands with LEAs and the business sector to combat SFVPs.
Your request and feedback are always welcomed.

rilo@rilo-ap.org
billy.kh.yeung@rilo-ap.org

Substandard and Falsified (SF) Medical Product ‘Prevention, Detection and Response’

Global Initiatives and Regional Activities

Are there parallels for SF Veterinary Products?

Dr Paul Huleatt - Therapeutic Goods Administration - Australia

13 June 2024

1st Workshop on Substandard and Falsified Veterinary Products (SFVP) and WOAH pilot Veterinary Monitoring and Surveillance System for SFVP (WOAH - VSAFE) for WOAH Focal Points for Veterinary Products and Regulators of Veterinary Medicinal Products in Asia and Pacific

Overview

- TGA's work in the Indo-Pacific Region
- The Member State Mechanism on SF Medical Products (SFMP)
- SFMP Detection and Laboratory Testing

Background – TGA's Work in the Indo-Pacific Region

- All programs are funded by the Australian Government Department of Foreign Affairs and Trade

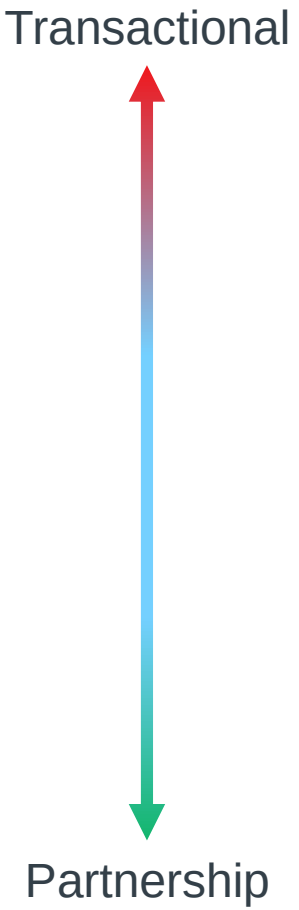
- **Pacific Medicines Testing Program (PMTP) – launched March 2018 - ongoing**
  - Provide Pacific Island Countries access to Australian laboratory testing for medicine quality assurance

- **Indo-Pacific Regulatory Strengthening Program (RSP) – October 2018 – June 2023 (7 countries); July 2023 – June 2027 (22 countries)**
  - Strengthen the capabilities of National Regulatory Authorities (NRAs) to increase the availability of better quality, safer and more effective medicines/medical devices through improved regulatory practice and collaboration
  - Two pillars: 1) Strengthen counterpart NRAs in the countries that we work with; 2) foster cooperation between stakeholders and collaboration on regulatory practice

- **The Australian Expert Technical Assistance Program – Regulatory Support and Safety Monitoring (AETAP-RSSM) –May 2021 – June 2023 18 countries**
  - Support Pacific and Southeast Asian countries' efforts to deliver safe, effective and accessible COVID-19 immunisation programs, based on a health and regulatory systems strengthening approach and in line with best practice standards.

TGA's approach to Regulatory Strengthening and Support

- **Carrying out regulatory work on behalf of another NRA**: laboratory testing
- **Information Sharing and Knowledge Transfer**
- **Adapting TGA 'best practices' and capacity building**: 'on-the-job' training in a variety of regulatory functions, e.g. Quality, non-clinical and clinical evaluations and pharmacovigilance.
- **Enabling Reliance**: bilateral, product specific reviews and supporting multilateral approaches (e.g. ASEAN JACG) for market authorisation of medicines and vaccines.



The Member State Mechanism on SF medical products

Goal (as per WHA Resolution 65.19)

"The goal of the Member State Mechanism is to protect public health and promote access to affordable, safe, efficacious, and quality medical products, and to promote through effective collaboration among Member States and the Secretariat, the prevention and control of substandard and falsified medical products and associated activities."

Governance

The Member State Mechanism has a chair supported by 11 vice chairs, representing the six regions of WHO.

The terms of office of the chairperson and vice-chairpersons start at the end of a regular session of the Mechanism and expire at the end of every second regular session. The chair rotates amongst the regions on an alphabetical basis.

Current Vice Chairs

Africa

Rwanda (chair)
Ethiopia

Americas

USA
Brazil

Eastern Mediterranean

Islamic Republic of Iran
Oman

Europe

Israel
Serbia

South-East Asia

India
Indonesia

Western Pacific

Australia
Republic of Korea

The Member State Mechanism on SF medical products (MSM)

- Plenary and Steering Committee meetings are held in Geneva, Switzerland
- Working groups for 2024-2025:

  A. Regulatory capacity building for Prevention, Detection and Response
  B. Global Focal Point Network
  C. Detection Technologies
  D. Leveraging Stakeholder Competencies
  E. Risk Communication Strategies
  F. Supply Chain of High-Risk Excipients
  G. Internet Sales
  H. Informal Markets
  I. Emerging Issues
  J. Implementation of Traceability Systems

- Technical briefing sessions

SFMP Detection and Lab Testing

Triggers for Testing

- Triggers can be:

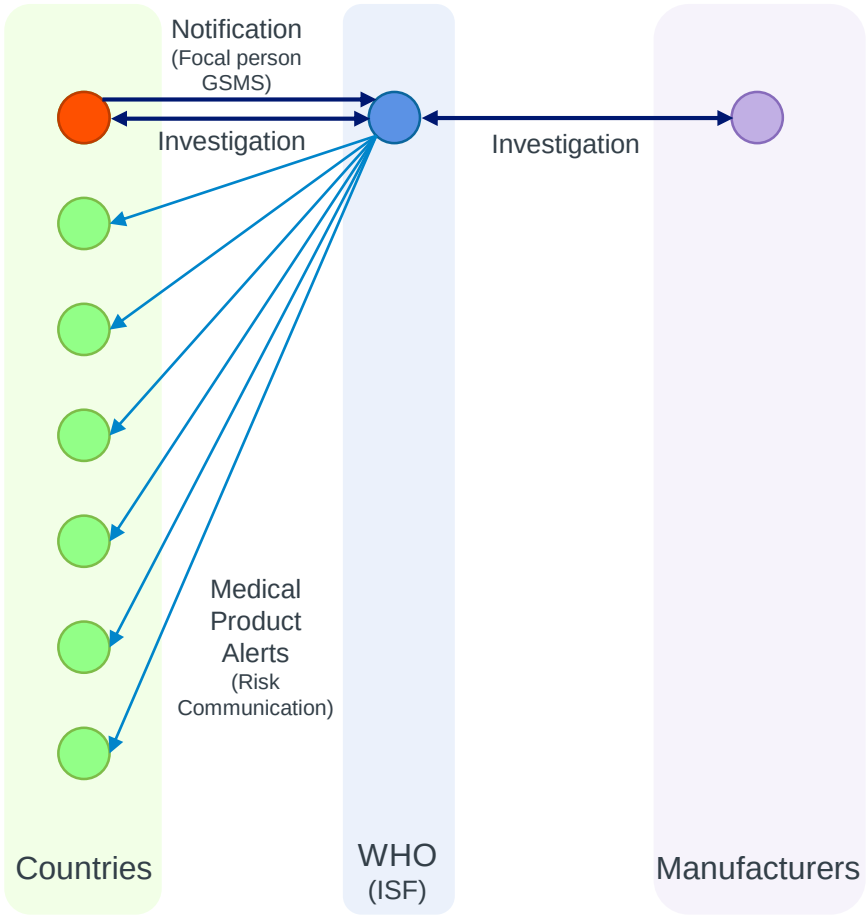
Indirect	Direct
SFMPs have been found in one country and products made by the implicated manufacturer are being supplied in another country	People are getting sick and an SFMP is suspected to be the cause

- Testing can be:

Campaign (routine or targeted)	Responsive testing
Larger undertaking, longer timeframe	Focused effort, tight timeframes

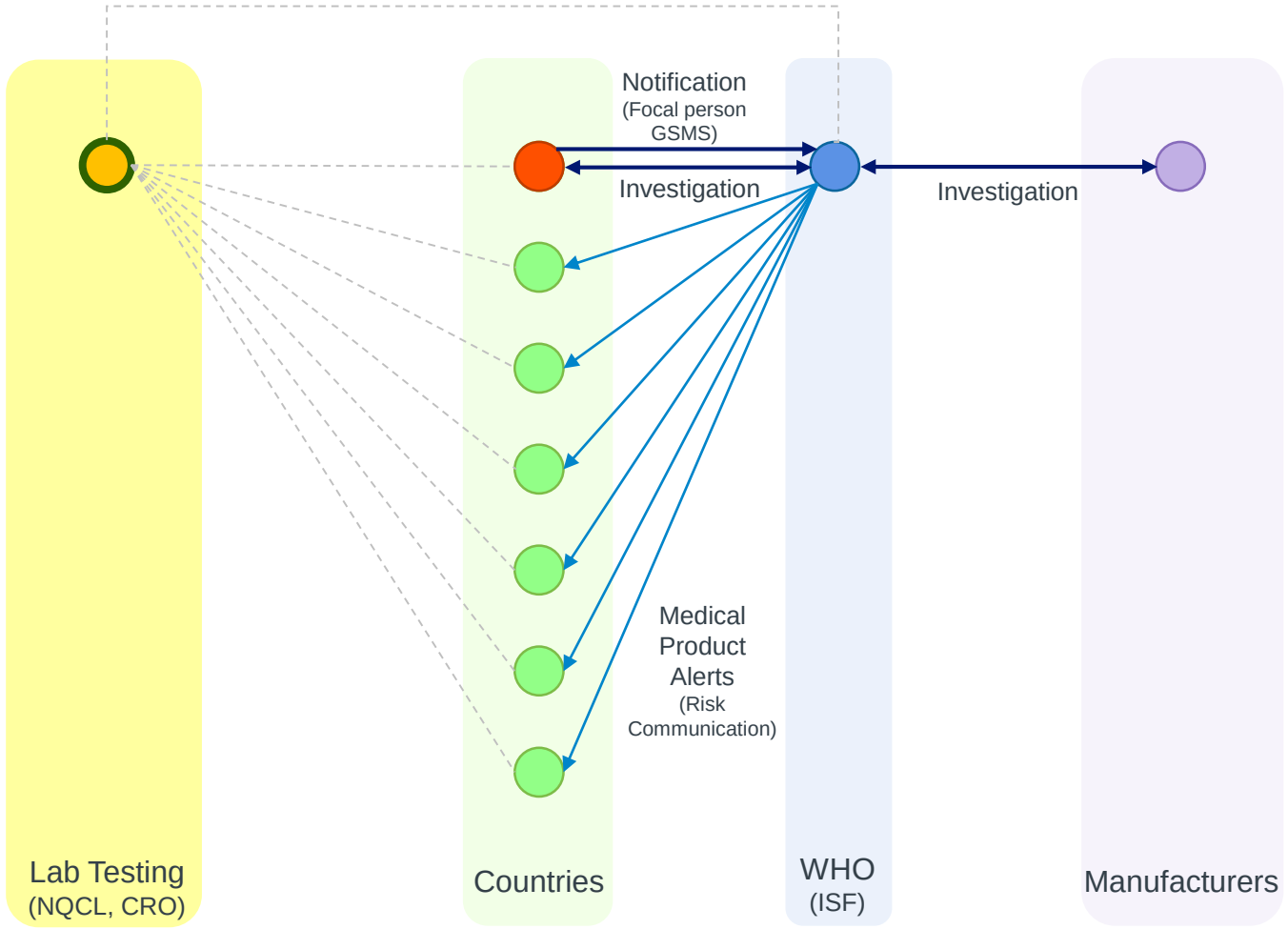
- Following a trigger, a layered approach to testing should be taken.

Detection and Response of SFMP – National Level Response



- **Use a layered approach to testing and escalate the use of technology as needed**
- Leverage established systems (WHO)
- Ensure GSMS focal points are trained
- Establish domestic channels for reporting medicine quality defects
- Establish domestic channels for risk communication and response
- NOTE: Fee for service arrangements with QC labs (3rd party or other member states) should meet required service standards, e.g. testing timeframes, number of samples, and an acceptable cost.

Considerations for Regional Laboratory Testing



- WHO engaged
- Bilateral engagement (*ad hoc*)
- Bilateral engagement (existing arrangement)
- Focus is on provision of analytical services
- Responsive arrangements that are mutually agreed and demand driven

- The provider dictates testing regimes and schedules
- The service is provided at the convenience of the provider
- Focus extends beyond the provision of analytical services
- Risk communication and response activities are duplicative and uncoordinated

A Scenario to Consider….

- A product is suspected of being substandard
- It is determined the laboratory analyses are required and these are not available in the country
- A testing agreement with a regional NQCL is invoked
- Samples are sent
- Unanticipated complications may arise…

- Required tests may be temporarily unavailable (e.g. sterility testing suite is down)
- A sample backlog results in a protracted turnaround time
- Samples may be deprioritised by the lab
- Agreed timeframes cannot be met
- Shortage or Stock out risk
- Expiry risk where ‘Good’ product could go to waste
- An SF product could be consumed…
- Analytical results may not be sufficient for determining a course of subsequent action

Laboratory Analysis – SFMP Considerations

Analysis and Results

Pre-testing Decisions

- To test or not to test?! Take a rational approach
- For human medical products this can be a complex decision
- What was the trigger? What is known and what information is missing?
- What critical, additional information will the analyses provide?
- Who needs to inform the 'test/don't test' decision? A multi-disciplinary team! e.g. Clinicians, Pharmacists, Chemists, Toxicologists, Lab Analysts and Lab Managers etc
- What might the post-testing actions be and are they ready to be taken? Multiple contingencies need to be considered and prepared for.

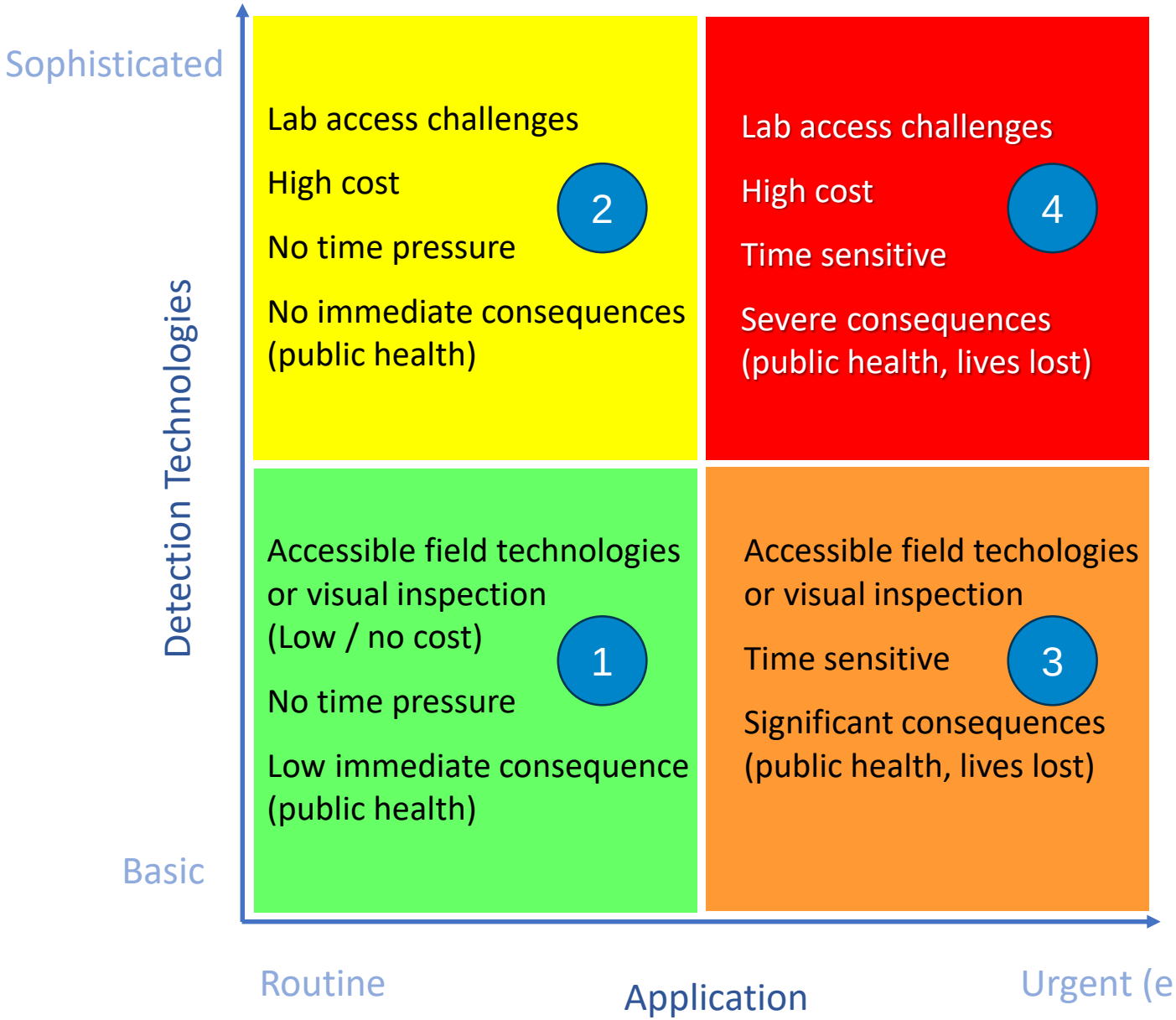
Analysis and Results

Post-testing Actions

- Communication with relevant stakeholders: what will be done and why it needs to be done.
- Take regulatory and criminal action (e.g. destroy quarantined product, initiate a recall, etc) as appropriate
- Communication with relevant stakeholders: what has been done and why.
- Report the incident to the WHO via the GSMS if appropriate to do so.

Testing Scenario Matrix

Examples



1. Thin Layer Chromatography (TLC) is used for screening syrup medications for contamination with diethylene glycol (DEG). Routine market surveillance

2. A sterile, injectable antibiotic product with a long-dated expiry has been found to contain visible particles. Alternative products are available. A third-party testing agreement with a lab in another country is used for API assay etc

3. A poisoning event has occurred. There are fatalities. DEG poisoning is suspected with syrup medications implicated. TLC is used in the field to rapidly screen for the toxin (responsive testing)

4. An injectable antibiotic product has been implicated in several serious adverse events. Third party testing has been requested, but a clinical investigation has not been completed.

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

WHO’s Global Surveillance and Monitoring System for SF medical products

Anita Sands

Incidents, Substandard and Falsified Medical Products Team

World Health Organization

Overview

1. WHO's Global Surveillance & Monitoring System for substandard and falsified medical products
2. Reporting to WHO
3. Issuing WHO Global Medical Product Alerts

World Health Organization

What are substandard and falsified medical products?

Substandard: Authorized medical products that fail to meet either their quality standards or specifications, or both. Also called “out of specification”.

Falsified: Medical products that **deliberately/fraudulently** misrepresent their identity, composition or source.

Unregistered/unlicensed: *Medical products that have not undergone evaluation and/or approval by the National or Regional Regulatory Authority (NRRA) for the market in which they are marketed / distributed or used*

Working Definitions Document approved by the Seventieth World Health Assembly

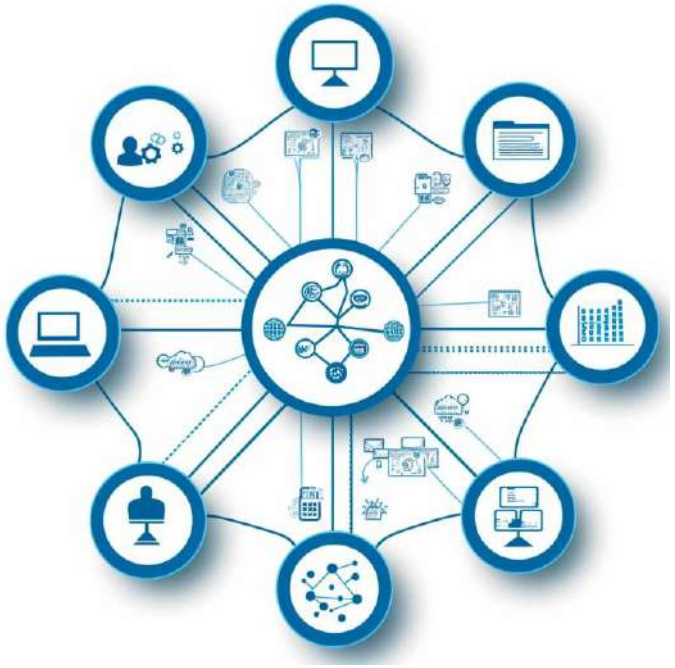
A common global understanding is necessary for coordinated action

World Health Organization

What is the WHO Global Surveillance & Monitoring System?

OBJECTIVES

- Assess the scale and harm caused by SF medical products
- Understand the driving forces of SF products
- Facilitate coordination and collaboration amongst Member States
- Influence change in health and governance systems
- Strengthen regulatory capacities to prevent, detect and respond to SF medical products



HOW IS THIS ACCOMPLISHED?

- Act as a central hub for information and intelligence on SF products
- Encourage and improve reporting of SF medical products by NRAs
- Provide technical support to Member States responding to critical incidents
- Coordinate international response to critical incidents
- Issue WHO Global Medical Product Alerts when appropriate

WHO established GSMS including the network of focal points in response to request from WHO Member State mechanism on SF medical products

World Health Organization

Services of WHO Global Surveillance and Monitoring System

Incident management

Surveillance and monitoring tools

Training

Database

Network of focal points

Normative guidance

Analytical insights

Risk communication

NRA reinforcement

World Health Organization

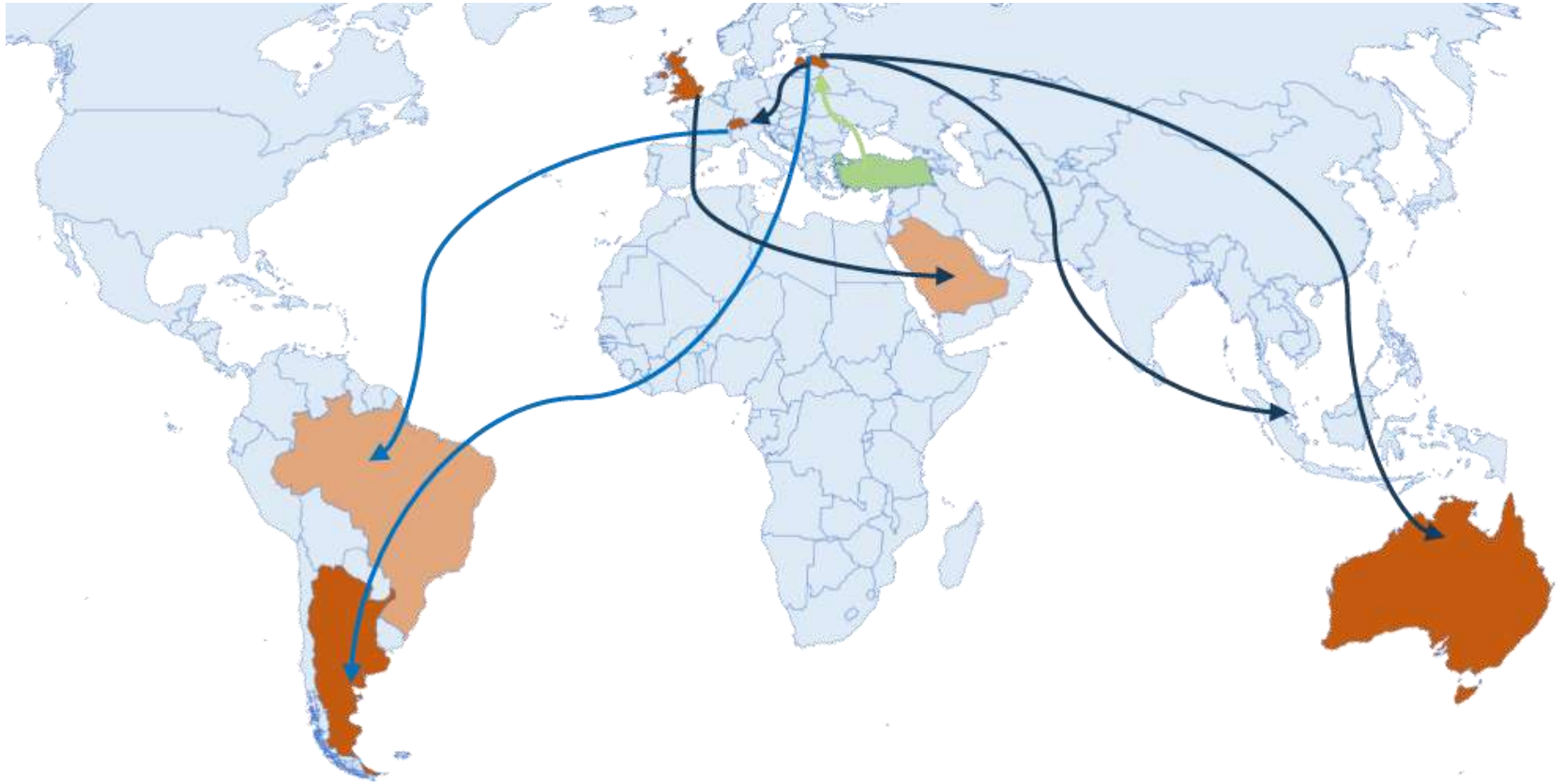
Service accessible via the GSMS reporting portal

Coordinating response through information sharing

- Two batches of falsified Defibrotide initially identified in Australia. Reported to WHO by Latvia.

- WHO coordination with Latvia & UK identified the supply of the falsified products to UK, Saudi Arabia, Switzerland, Brazil.

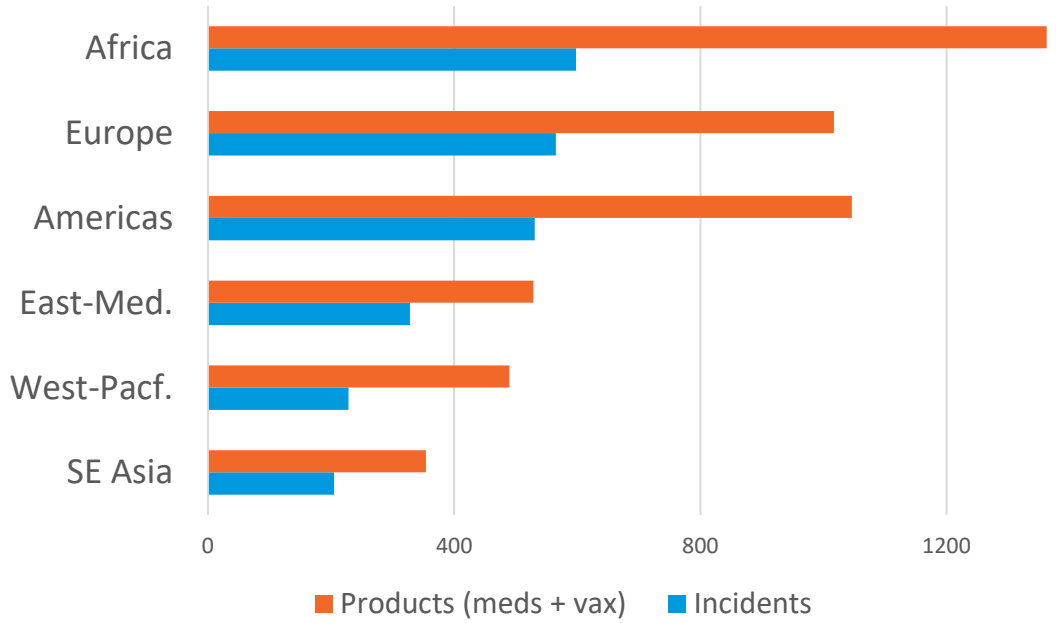
- **Following publication** of Alert No 5/2020 - falsified batches also reported supplied to Argentina, Singapore, Malaysia



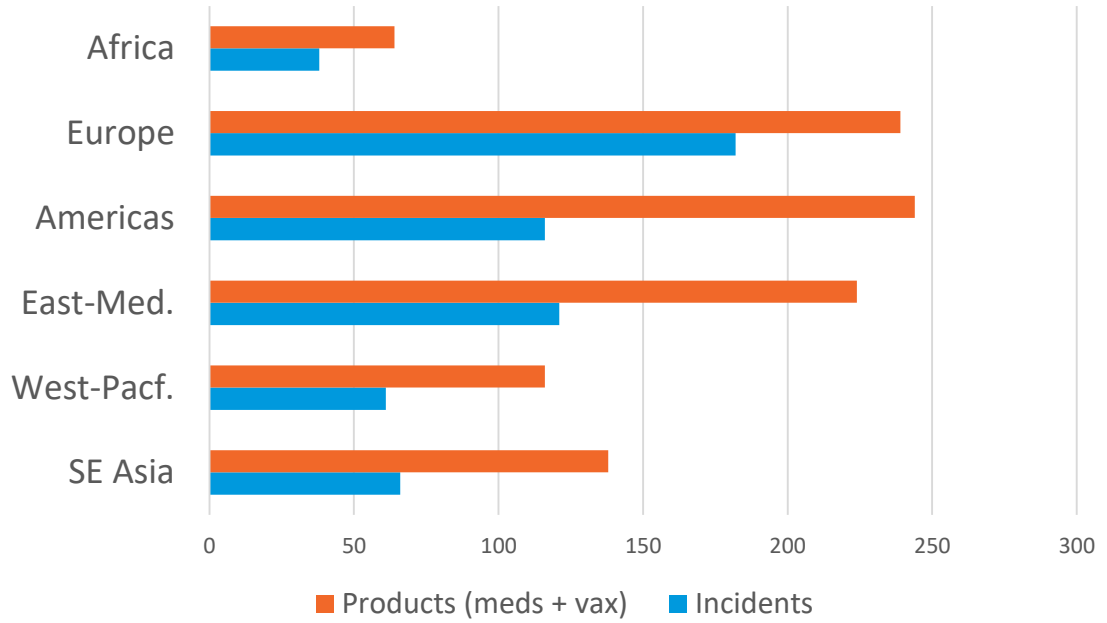
World Health Organization

WHO Global Surveillance and Monitoring System

Total incident* and suspect product records Sept 2012 to Feb 2024**



Total incident and suspect product records Feb 2023 to Feb 2024

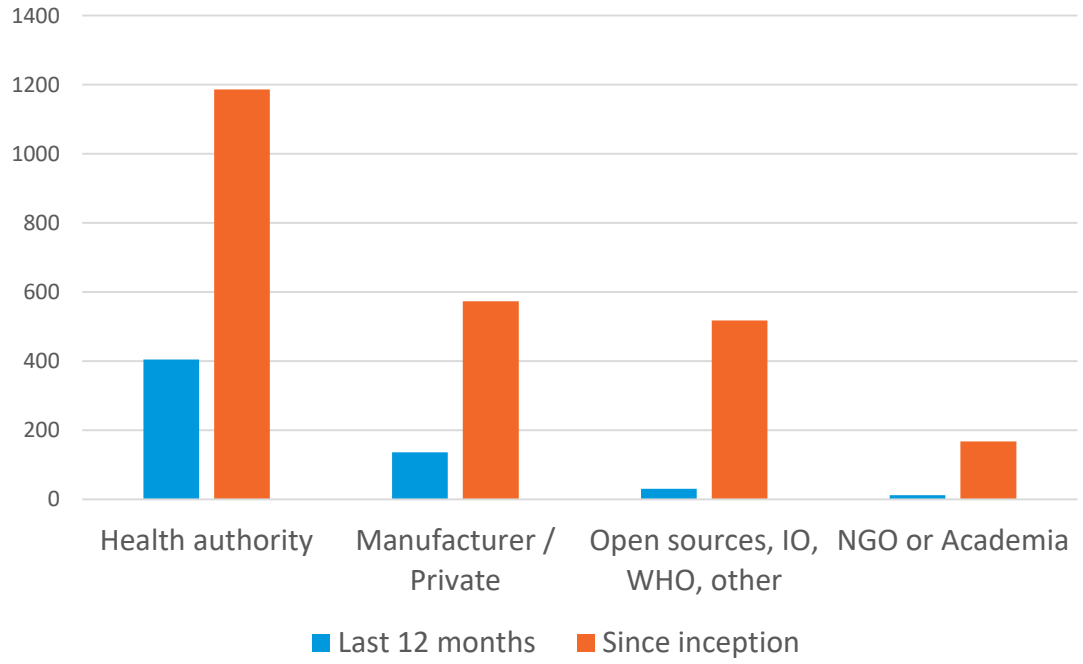


World Health Organization

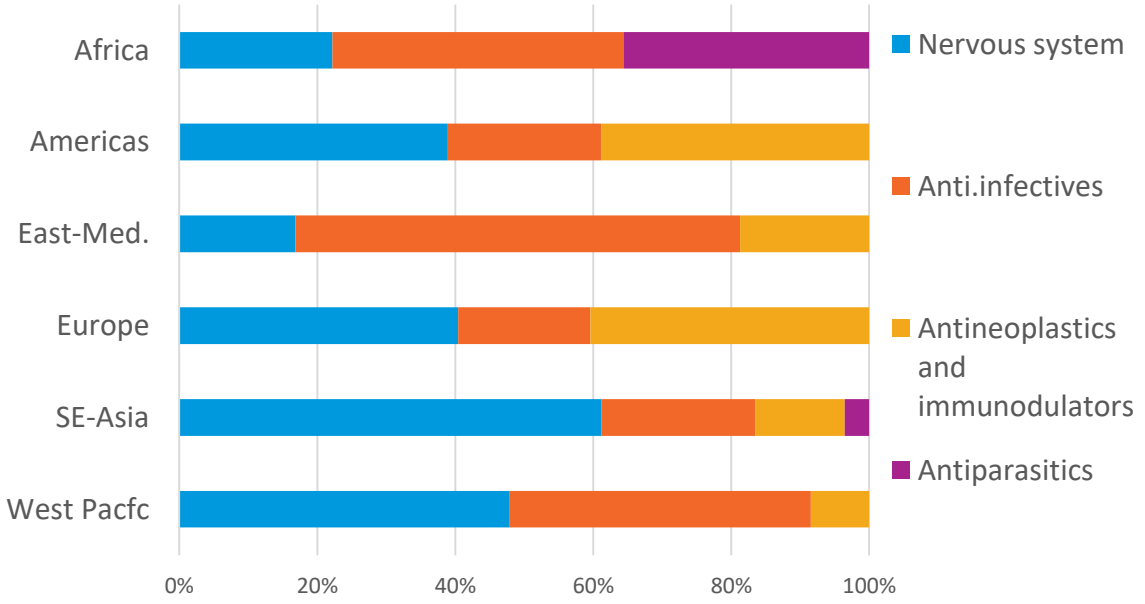
*Where an incident is notification of potential substandard or falsified medical products at one time and in one place.
** Where different lot numbers are considered different suspect products.

WHO Global Surveillance and Monitoring System cont'd

Incident records by source
Sept 2012 to Feb 2024 vs. Feb 2023 to Feb 2024



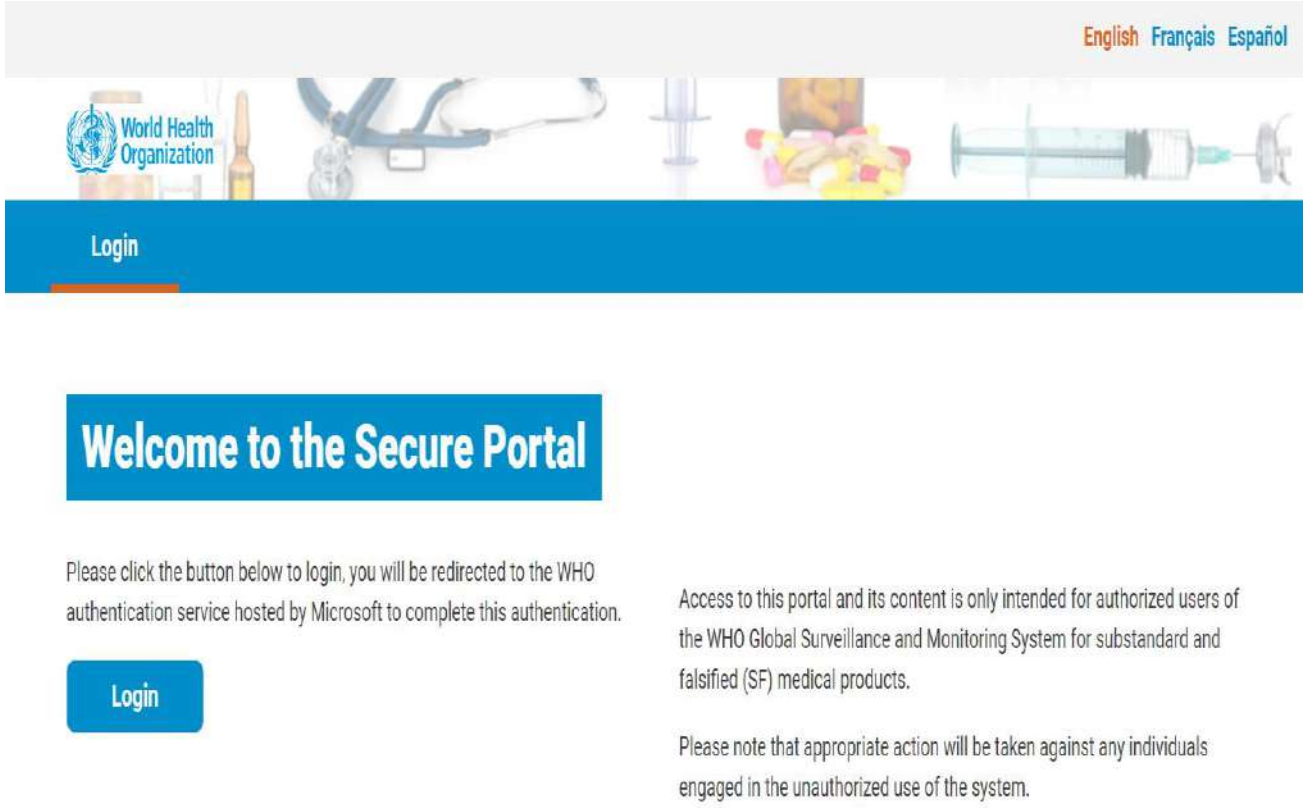
Top 3 therapeutic categories by WHO region
Jan 2023 to Feb 2024



World Health Organization

How to report to the GSMS

1. Focal Points appointed by national authorities
2. Nomination communicated to ISF team at HQ, via WHO Country and Regional Offices (cc rapidalert@who.int)
3. Focal Points must complete the eCourse on SF Medical Products
4. Focal Points provided access to WHO Online Portal
5. Focal Points create their log in details and can start reporting immediately.



ISF Team can provide training for Focal Points

World Health Organization

Why are alerts issued?

WHO Global Medical Alerts are in response to detection of an SF product

Conditions for issuing an Alert include:

- Immediate and significant threat to public health; or
- Serious adverse event or patient harm; and
- Risk that product is in more then one country.

World Health Organization

Impact of WHO Medical Product Alerts

REACH

- Alerts emailed to **national focal points** and partners
- All Alerts published online https://www.who.int/teams/regulation-prequalification/incidents-and-SF/full-list-of-who-medical-product-alerts

IMPACT

- Alert N°1/2023 (Uzbekistan): products detected in Laos & Cambodia
- Alert N°5/2023 (Iraq): additional contaminated batches detected in India
- Alert N°8/2023 (Maldives and Pakistan): products detected in Belize, Fiji, Lao People's Democratic Republic.

World Health Organization

International cooperation against SF medical products

PREVENT ↔ DETECT ↔ RESPOND

	Secure quality & supply (e.g. seizure operations, enforce legal provisions, etc.)	**Intelligence base** (e.g. exchange data & analytics, interagency collaboration, etc.)	**Build capacity** (e.g. training, field screening equipment, etc.)
NATIONAL focal points	▪ Health authorities (ministry, regulators, quality control laboratories, etc.) ▪ Law enforcement (customs, police, etc.) ▪ Judiciary (prosecutors, judges, etc.)	▪ Civil society (community representatives, health workforce, etc.) ▪ Private sector (manufacturer, authorization holder, distributor, importer, etc.)	
REGIONAL networks	EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH; EUROPOL; Organisation mondiale de la Santé Région africaine; asean; CEDEAO ECOWAS; African Union		
GLOBAL systems	World Health Organization; World Organisation for Animal Health Founded as OIE; INTERPOL; THE WORLD BANK; World Customs Organization Organisation mondiale des douanes; unicef; UNODC United Nations Office on Drugs and Crime; UNOPS		

Strategy to prevent-detect-respond to SF medical products

PREVENTION

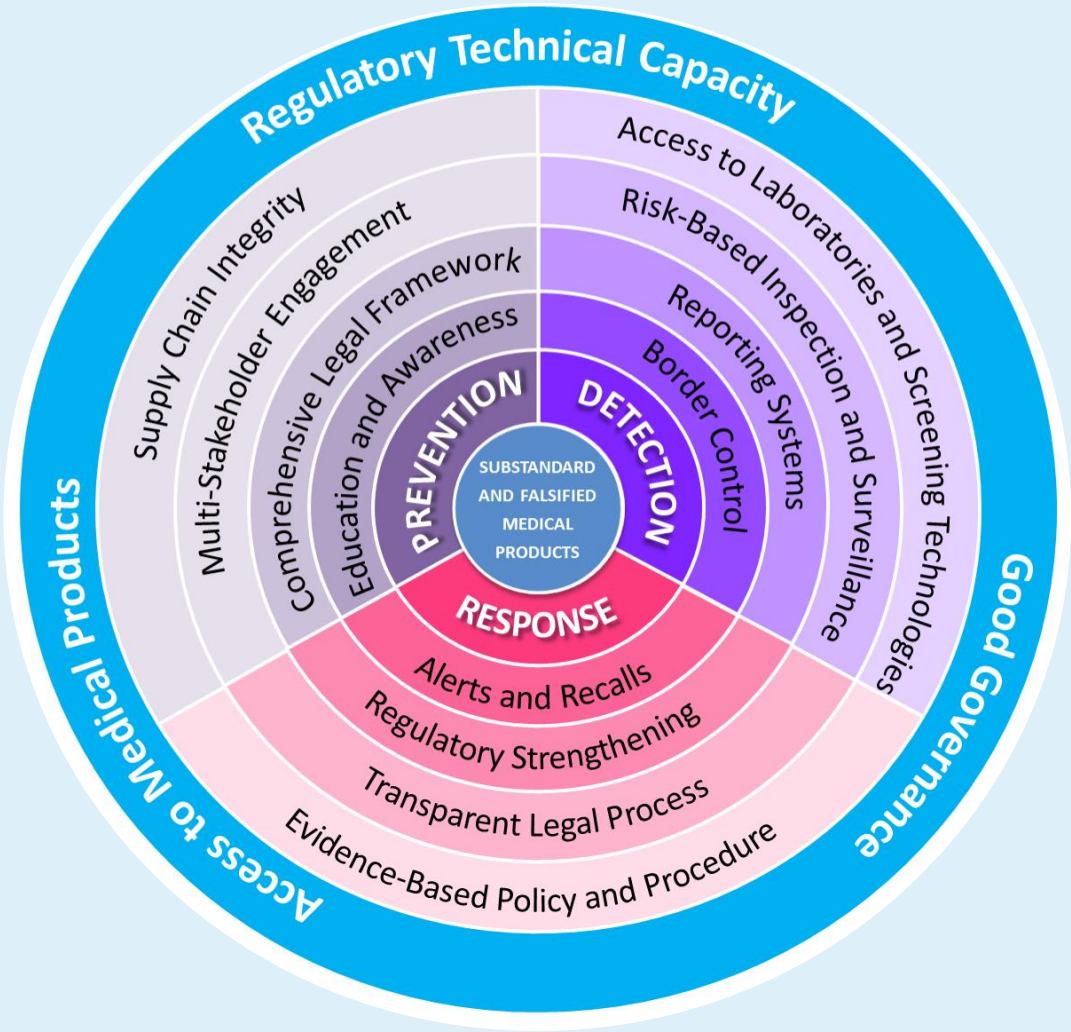
- Demand and require quality at all supply chain levels
- Ensure the safety and security of the supply chain

DETECTION

- Increase sensitivity and specificity of detection
- Facilitate reporting and accelerate information feedback systems

RESPONSE

- Protect the health of citizens in the first place
- Identify and implement corrective actions to avoid recurrence (regulatory and judicial actions)



World Health Organization

Thank you

For more information, please contact:
Anita Sands
Technical Officer, Regulation and Prequalification
sandsa@who.int

World Health Organization

Food and Agriculture Organization of the United Nations

UKaid from the British people

The Fleming Fund

Substandard and Falsified Veterinary Product Data Collection at Farm Level

(FAO RAP Fleming Fund AMR Project)

Jutamart Jattuchai
Regional AMR Project Coordinator
FAO RAP

“Engaging the food and agriculture sectors in sub-Saharan Africa and South and Southeast Asia to generate data-for-action to combat antimicrobial resistance using a One Health approach”

“Data generation (AMR specific and sensitive) for evidence-based decision making in food and agriculture sector”

1. Strengthened Laboratory & Surveillance Capacity and related data management infrastructure
2. Antimicrobial use and good practices promoted
3. Evidence based AMR economic argument developed and supported
4. Policies and Governance enhanced to minimize roles of sub-standard and falsified antimicrobials
5. Implementation of multi-sectoral One Health AMR National Action Plans (NAPs) supported

Global & FAO Action Plans

Tools/Approach

- PMP
- ATLASS
- InFarm
- Farmer Field School
- Country initiatives
- One Health approach

UKaid from the British people

The Fleming Fund

SUBSTANDARD AND FALSIFIED VETERINARY PRODUCT SURVEY/ DATA COLLECTION AT FARM LEVEL

What can be done?

Start Small

Develop an approach for on-farm pilot data collection using Famer Field School

FARMER FIELD SCHOOL (FFS)

What are Farmer Field Schools?

- A "**school without walls**", where groups of 15-25 farmers with a common interest learn "best" ways of production through **observations** and **experimentations**
- Guided by a FFS facilitator(s) who go through 3-week training (TOF)
- Focused on **adult-centered learning and co-created solutions (facilitation not teaching)**
- FFS participants meet weekly/biweekly on a host farm
- FFS usually span production cycle

"20 FFS (around 500 poultry farmers) was successfully conducted in 5 Fleming Fund project countries in Africa, resulting in more adoption of good practices and reduction in the use of antimicrobials."

FF3 BROILER FARMER FIELD SCHOOL

- Promote good practice (biosecurity and production)
- Responsible use of antimicrobials
- Improve production and profitability
- Behavior changes
- **Data generation**

BROILER FARMER FIELD SCHOOL

Africa:

- Regional Training of Master Trainer - completed
- In-country Facilitator trainings - completed
- In-country implementations – started/ on-going
- Evaluation tools – developed/ to be deployed

Asia:

- Regional Training of Master Trainers – on-going by lead Master Trainer from Africa (FVM, RUA, Cambodia)
- FFS Tools from Africa will be contextualized and used in Asia

BROILER FARMER FIELD SCHOOL TOOLS

- House/ Farm Background
- Biosecurity
- Economic
- AMU/ **Veterinary Product**

Veterinary Products Tool for FFS Evaluation

Developed by
Dr Mark Caudell, FAO Kenya

Veterinary Products Tool: Objectives

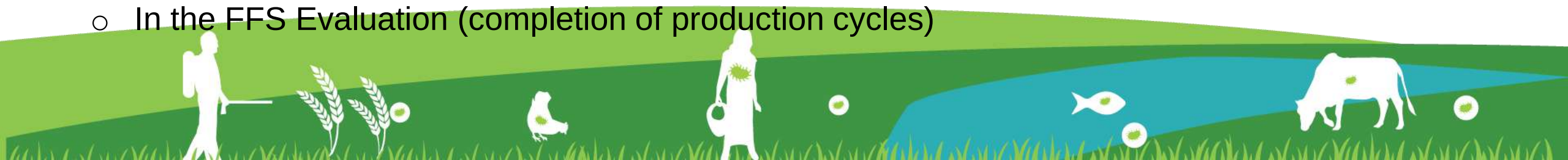
- The objective of the veterinary products tool is to collect data on **all the products used in animal production** including:
  - Antimicrobials, such as antibiotics, antivirals,
  - Antiparasitic/Acaracides
  - Vitamins
  - Disinfectants
  - Traditional Medicine
  - Vaccines

- Data is collected on **usage patterns**, including:
  - The type of drug given and associated information (dosage rate, active ingredients, cost)
  - Actual dose rate: how much and how long the drug was given
  - The reasons the drug was given (therapeutic, prophylaxis)
  - Whether drug was prescribed and by who

Allows us to determine the impact of FFS on antimicrobial usage patterns

Using the Veterinary Product Tool

- **Prior to the start of FFS**, the enumerator will **collect data on Biosecurity and Household/Farm Background** (separate surveys) at the farm.
- For the collection of reliable data, **the tool should be used in conjunction with collection materials that are given to the farmer (FFS participant)**, preferably during an initial visit to the farm/community awareness meeting, these materials to include:
  - A **bin/bag** to collect all finished products and associated receipts/prescriptions
  - A **data record sheet** to write down use data (type of drug, dosage, treatment days, disease)
- Upon completion of a cycle/defined period, **the enumerator returns to farm to collect data using the veterinary product tool**.
- In the FFS Evaluation (completion of production cycles)

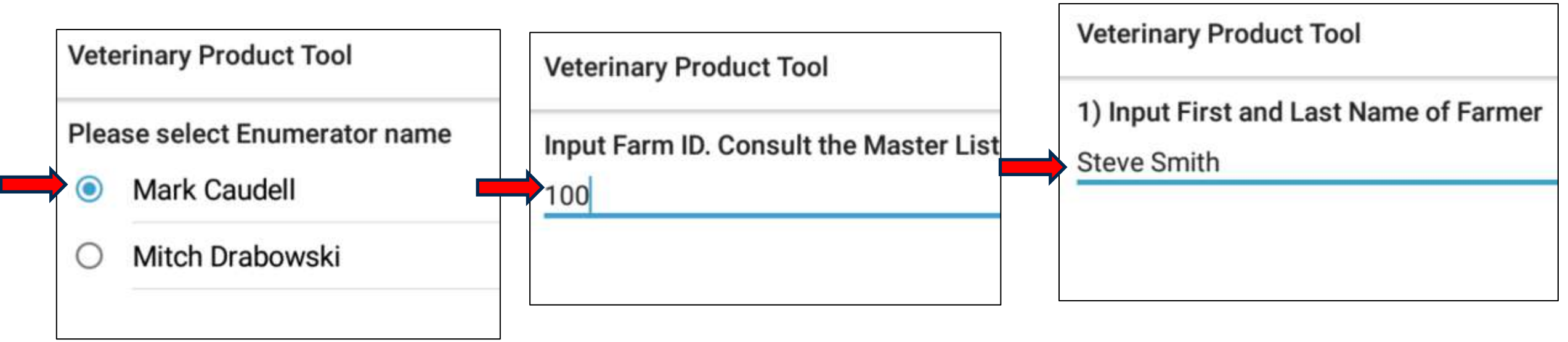


At the farm

- Enumerators/ facilitators will ask the farmer to
  - bring any **records/receipts**,
  - **unfinished veterinary products**
  - the **bucket/bag holding the finished veterinary products**

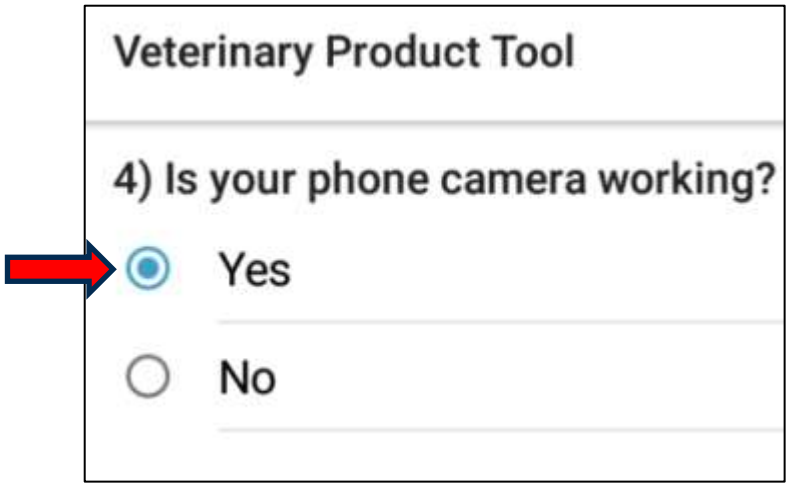
Veterinary Product Tool: An Example

- Open the KoboCollect Survey “Veterinary Product Tool”
  - KoBoToolbox is a suite of tools for online or offline field data collection, which you can use with your mobile devices (phones, tablets, laptops)
- Select enumerator name, input Farm ID (from Master list), and First and Last Name of Farmer



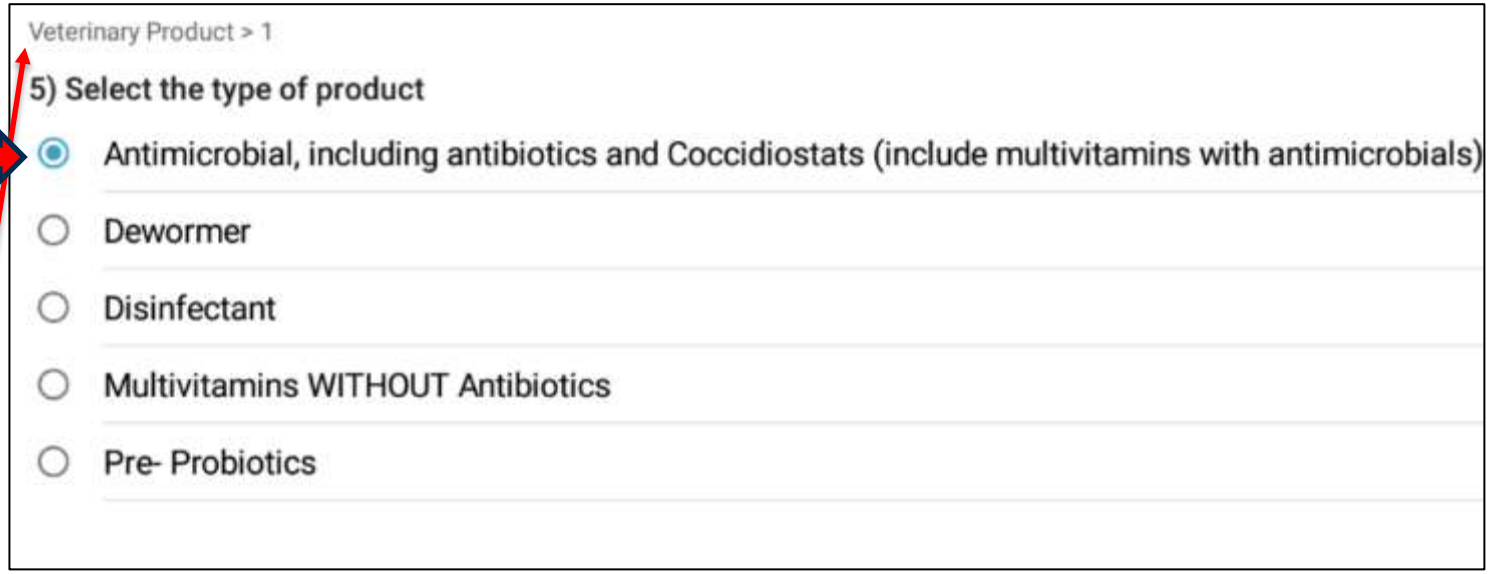
Veterinary Product Tool: An Example

- If phone camera is working, select yes and you will take pictures of the veterinary products.
- If NO, you will write in the product name and company name
- First, **we will assume your camera is working**



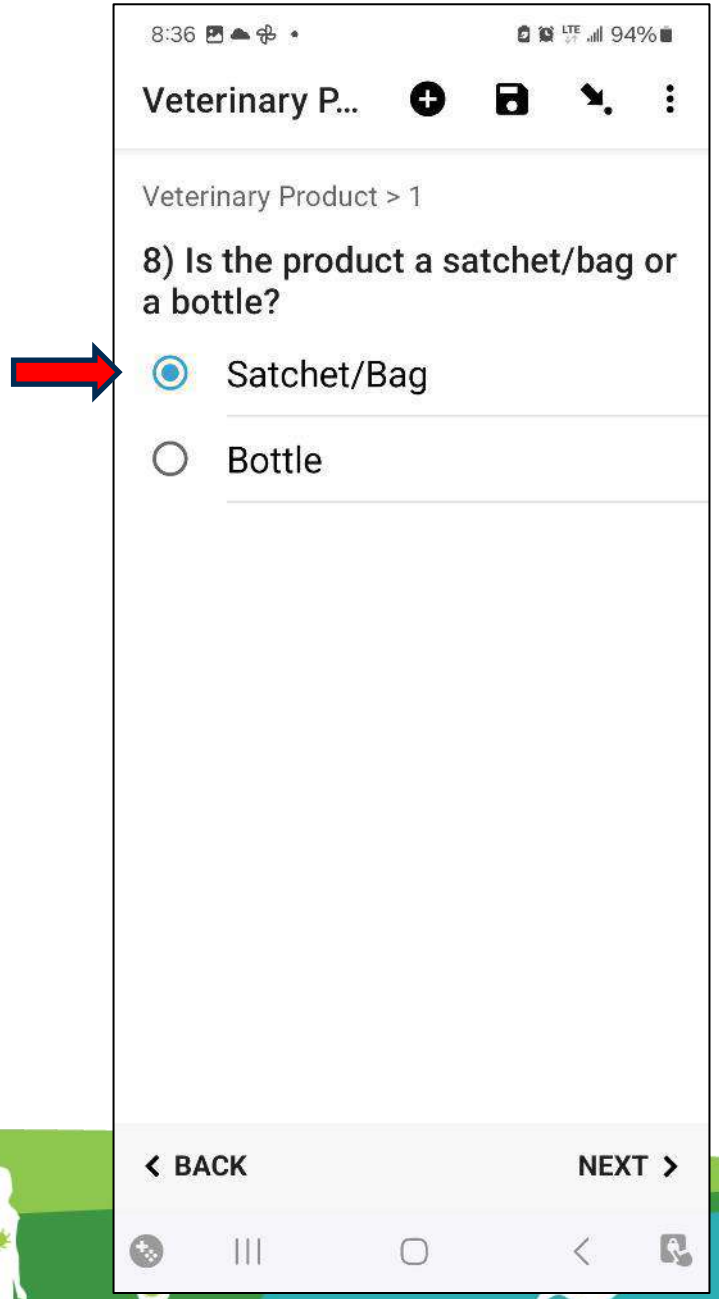
Veterinary Product Tool: An Example

- The first product you get from the bucket is Vetoxy 20, which is an antibiotic
- Confirm it is an antibiotic by looking at active ingredients, here “Oxytetracycline”
- Select Antimicrobial
- Indicates this is first product you are collecting information on



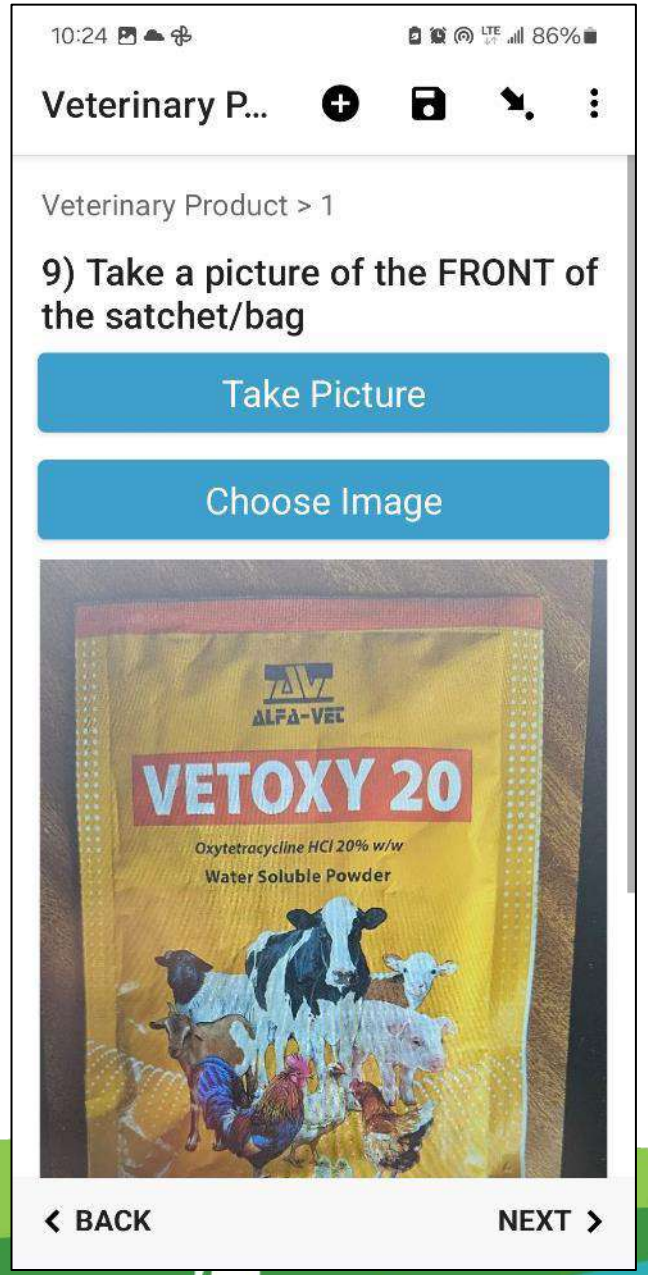
Veterinary Product Tool: An Example

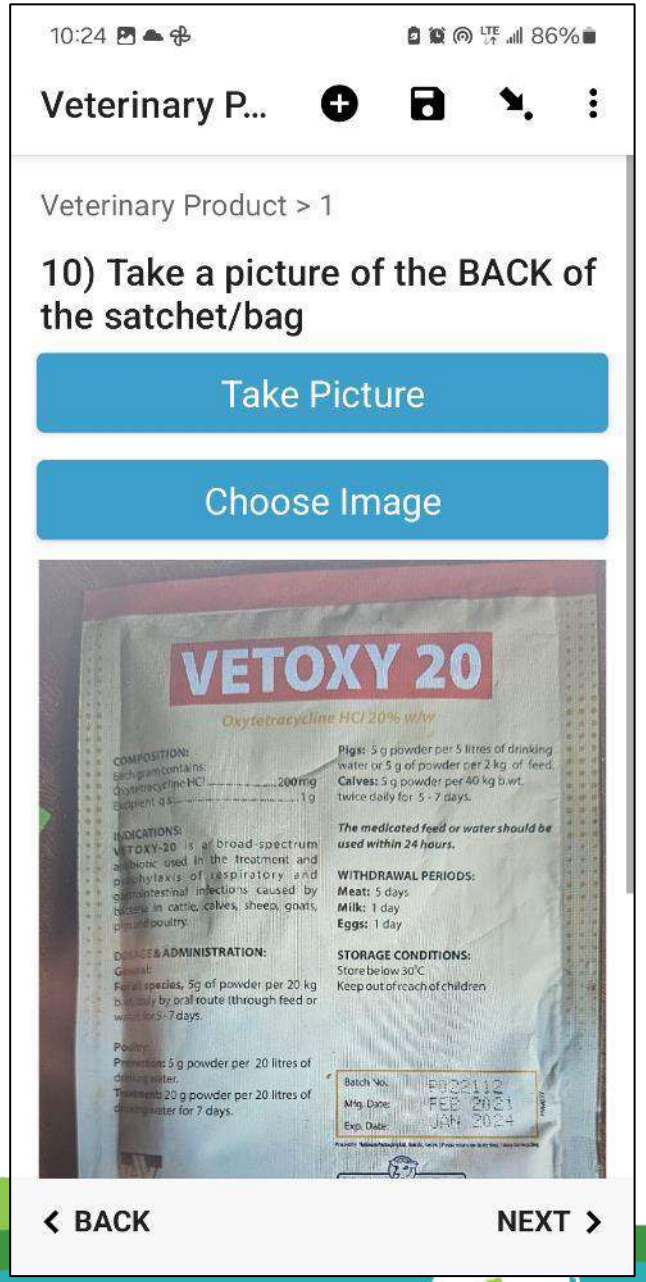
- The product is a sachet so select Sachet/Bag for Q8



Veterinary Product Tool: An Example

- Now, take picture of the **Front and Back** of the sachet
- Make sure that information is **readable** and **all information is included in the picture**
- After taking picture, select OKAY and then select NEXT





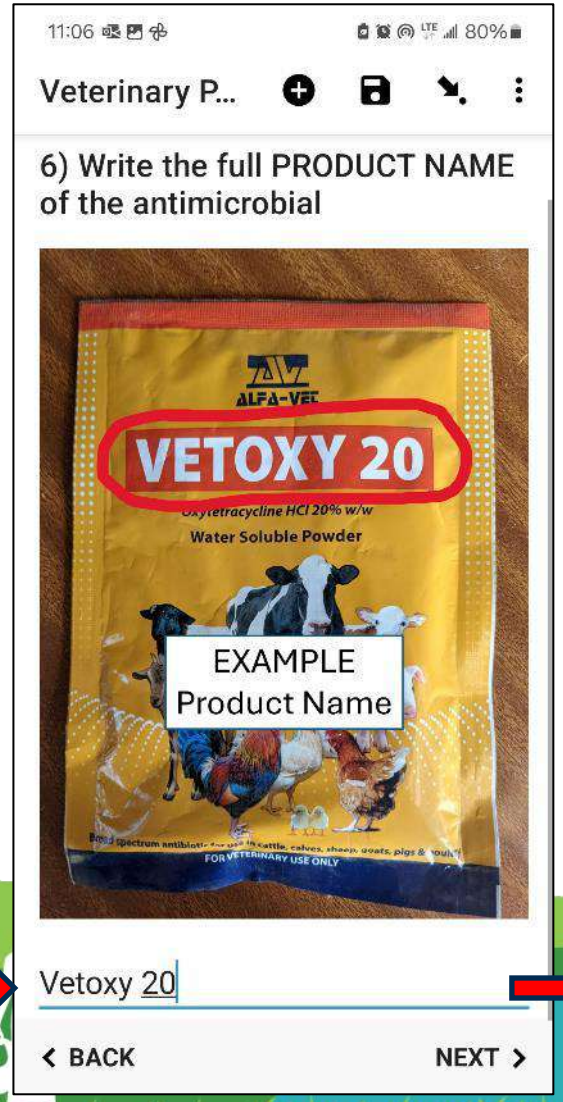
Veterinary Product Tool: An Example

If

- Phone's **CAMERA IS NOT WORKING**, OR
- The farmer has given **you a written record**

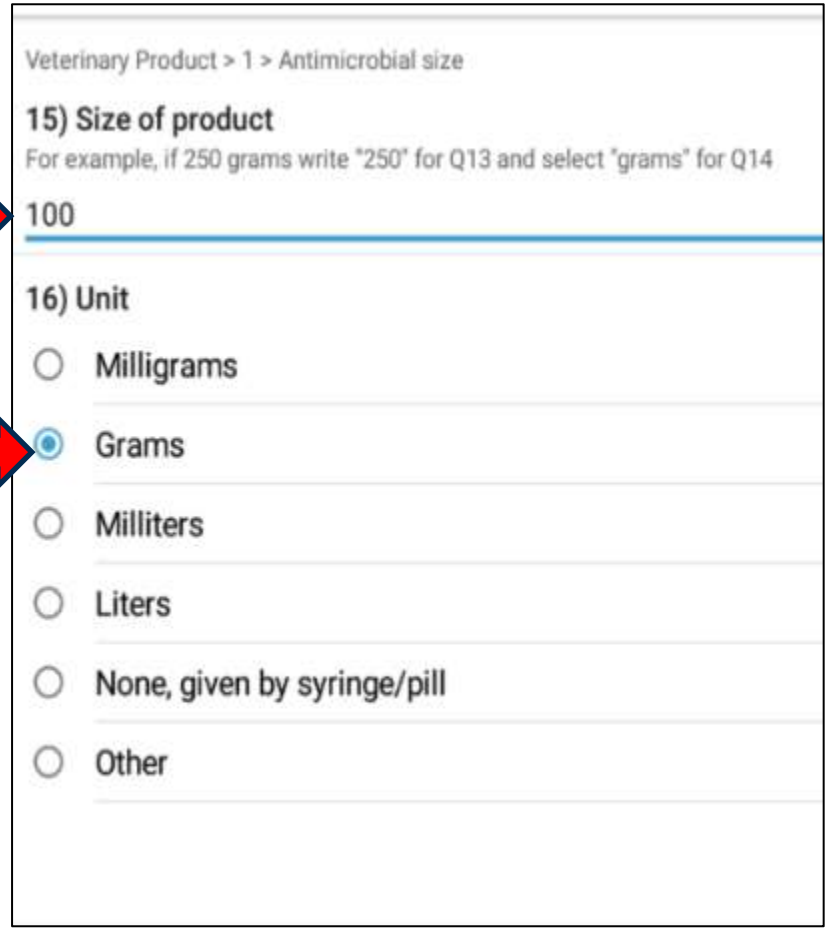
THEN

- **You will write in the product name and company name of the product**
- The survey will show you **an example picture**
- For this example, the **product name** is Vetoxy 20 and the company name is **Alfa Vet**
- It is **VERY IMPORTANT** to write **the correct product name** and **company name**



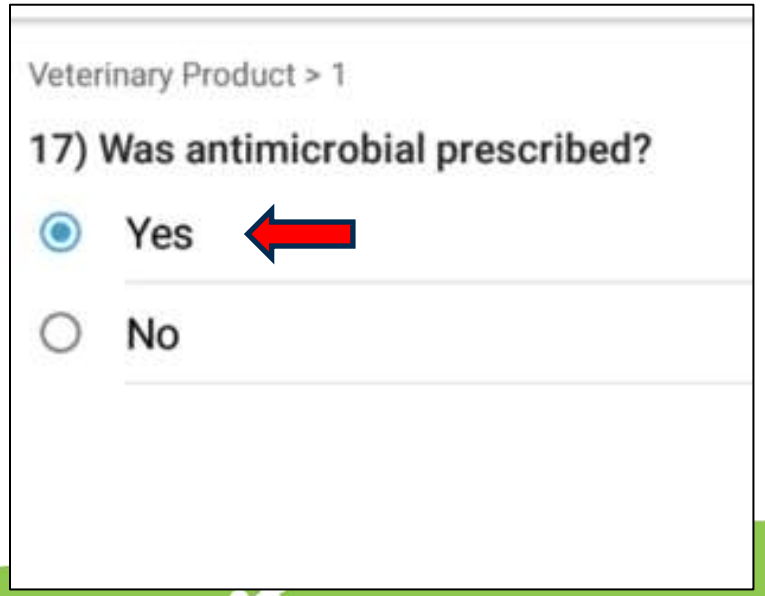
Veterinary Product Tool: An Example

- After taking pictures/writing name, fill out **size** of the product
- On the back, we can see it is **100 grams**
- Fill in “100” for size in Question 15 and “grams” for unit in Question 16.

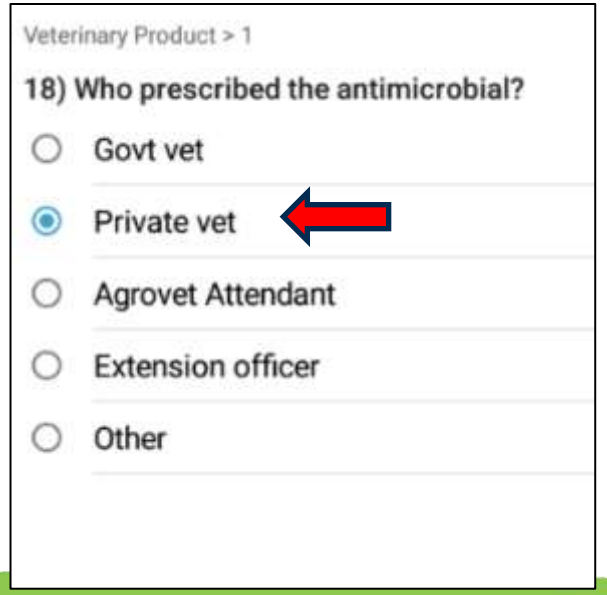


Veterinary Product Tool: An Example

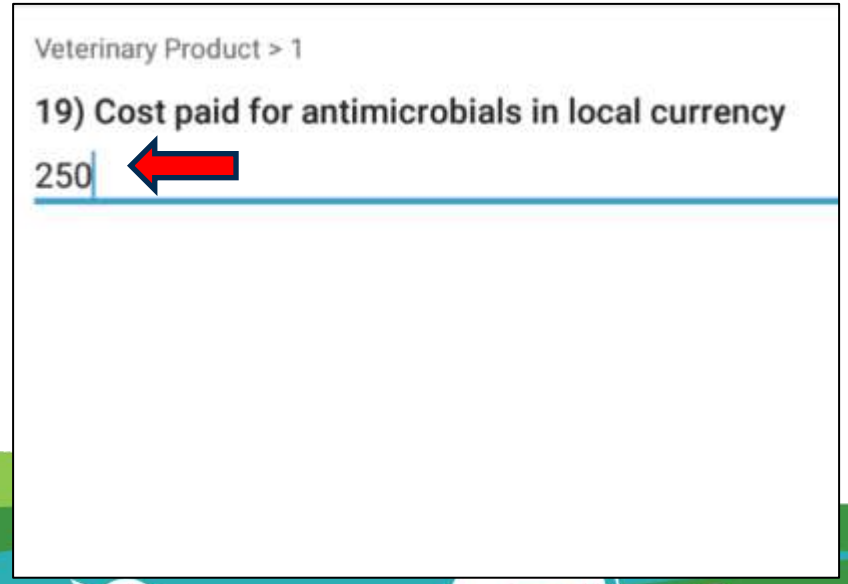
- Ask the farmer is the antibiotic was prescribed, meaning he talked with an animal health professional that told them what antibiotic to buy or gave them a paper prescription
- This farmer said **he got a prescription**



- This farmer said he got a prescription **from a private vet**

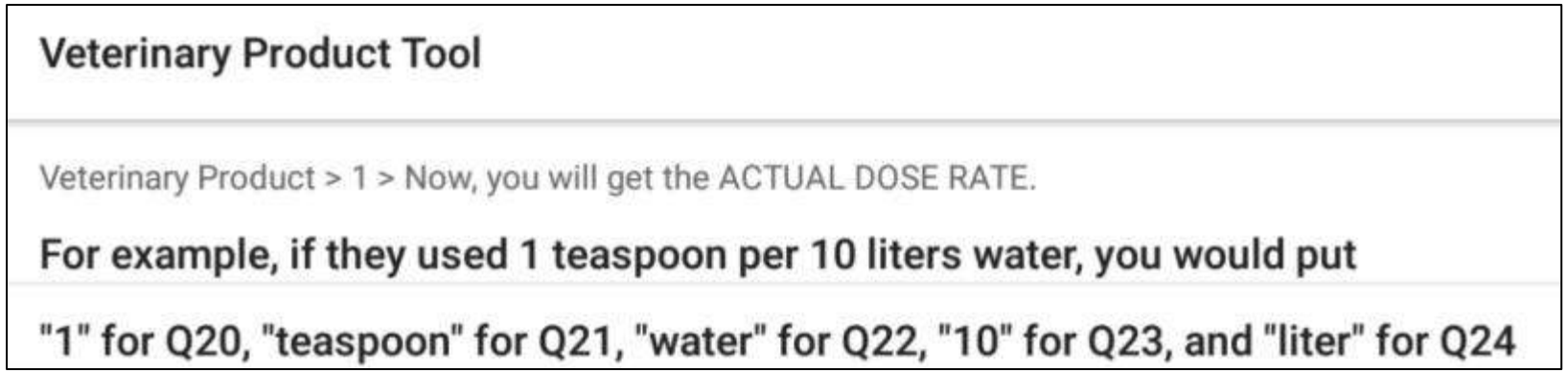


- This farmer said he paid **250 shillings (local currency)** for the antibiotic



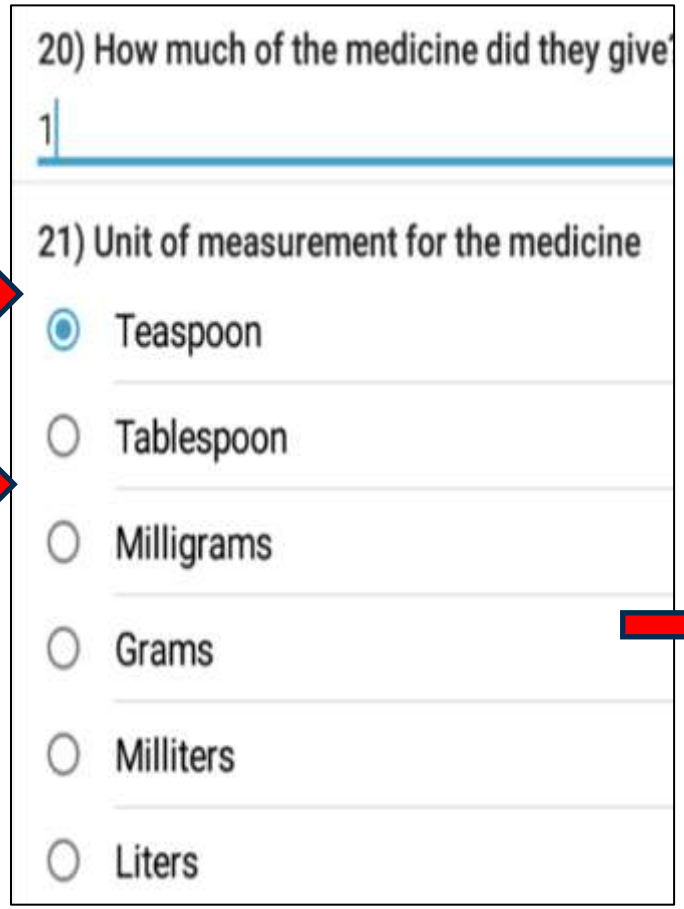
Veterinary Product Tool: An Example

- Now, you will collect information on the **actual dose rate which is how much was given, how long, and to how many birds, and bird age**
- The survey first provides an example of a farmer who says **he mixed 1 teaspoon in 10 liters of water**

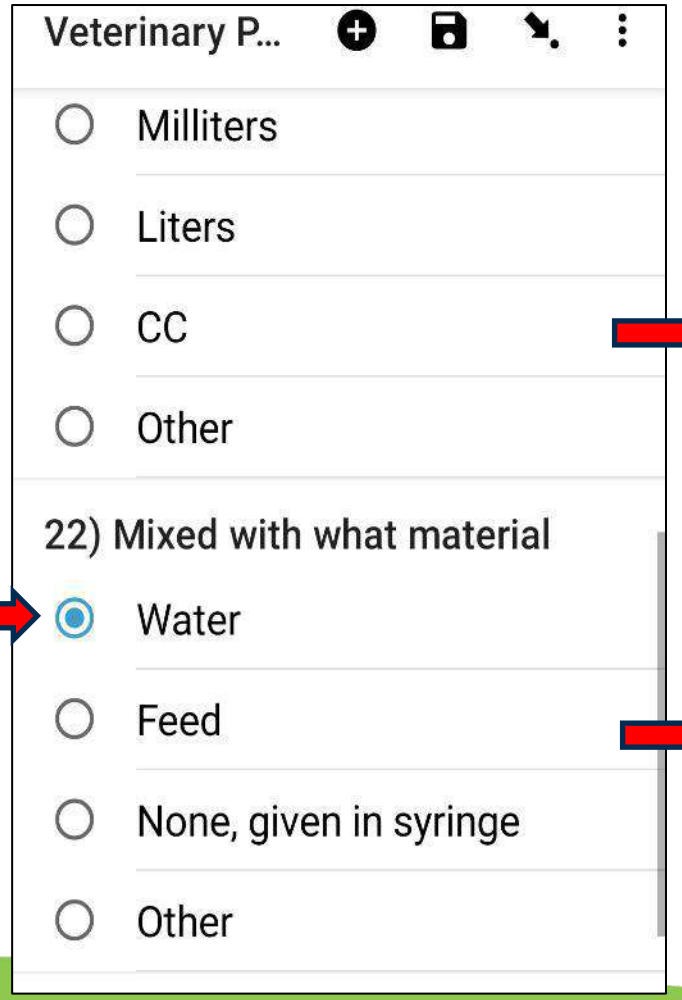


Veterinary Product Tool: An Example

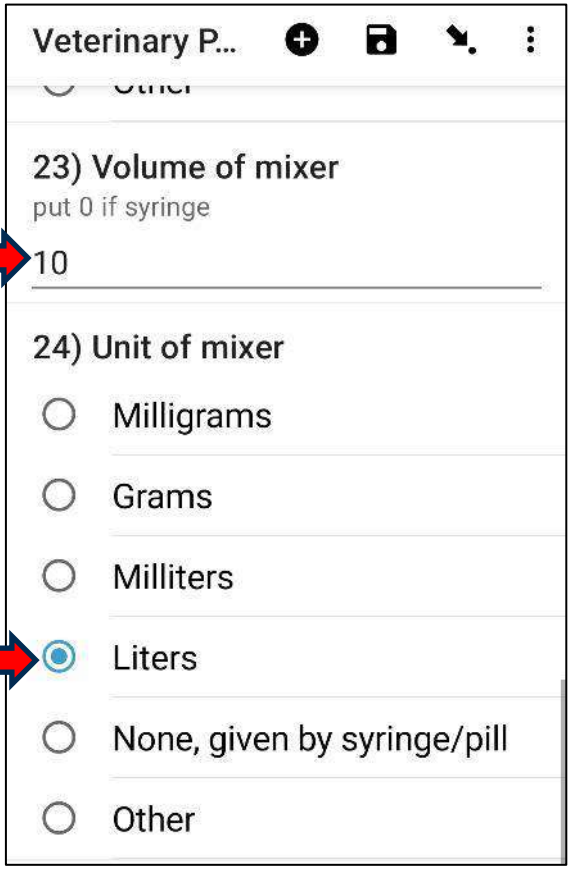
- The Farmer says **he mixed 1 teaspoon in 10 liters of water**



Fill in “1” for Q20 and select “Teaspoon” for Q21



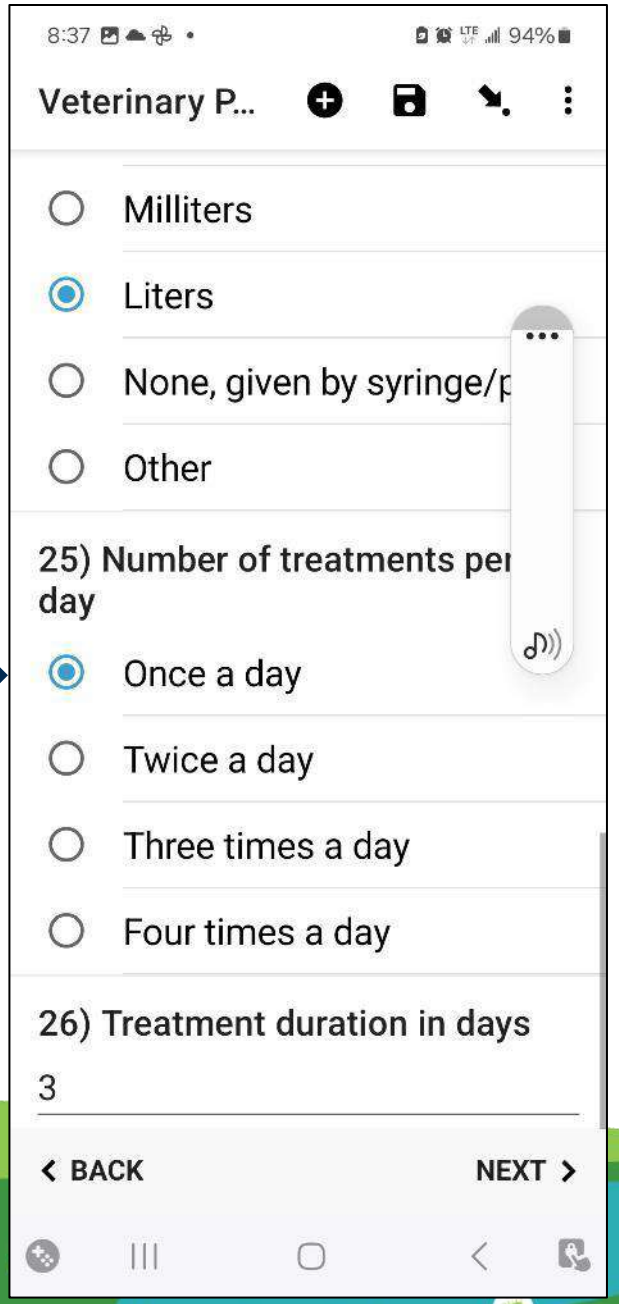
Select “Water” for Q22



Fill in “10” for Q23 and “Liters” for Q24

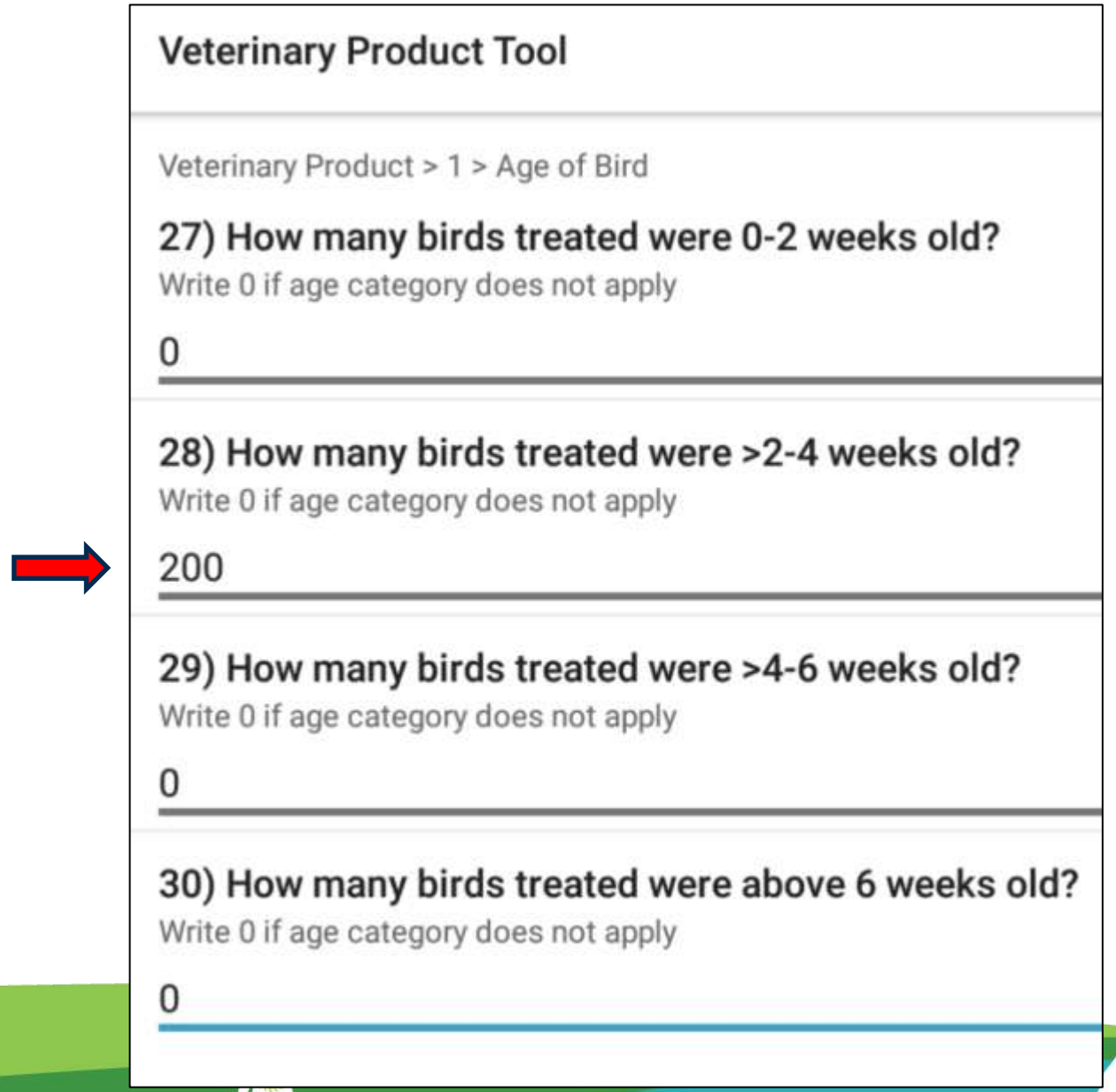
Veterinary Product Tool: An Example

- The farmer said he gave **once a day for three days**
- Fill in “Once a day” for Q25
- Fill in “3” for Q26



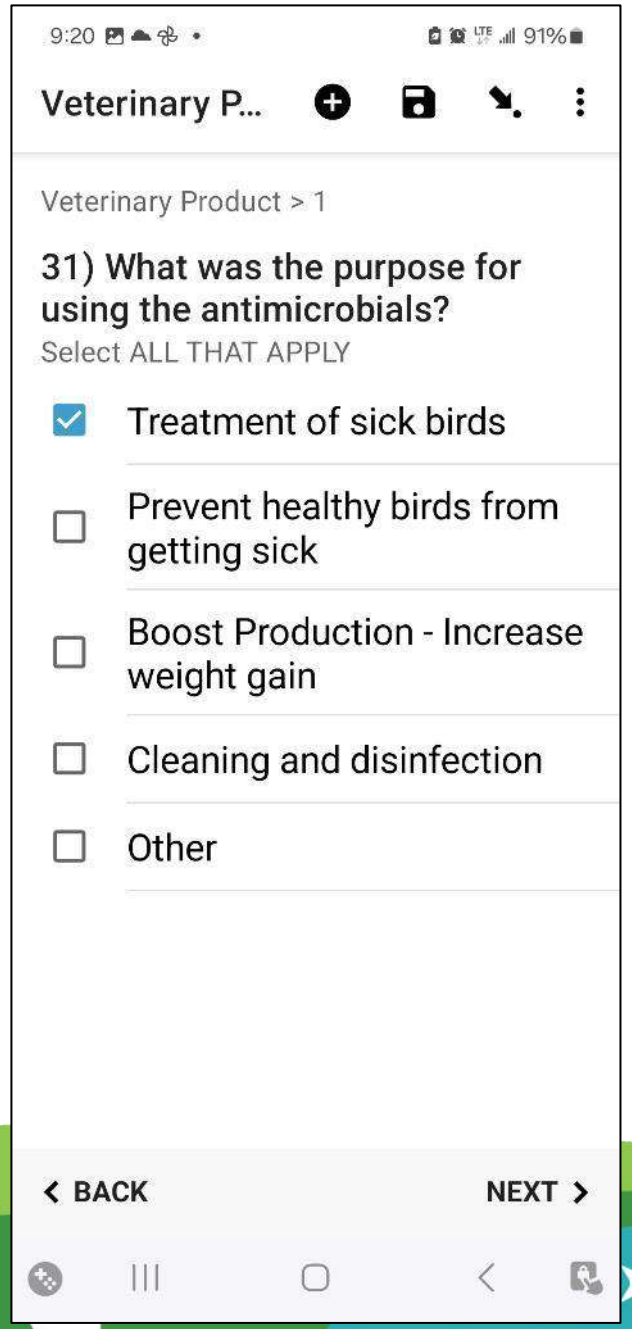
Veterinary Product Tool: An Example

- The farmer said he treated **200 birds that were 3 weeks old**
- Input 200 for Q28



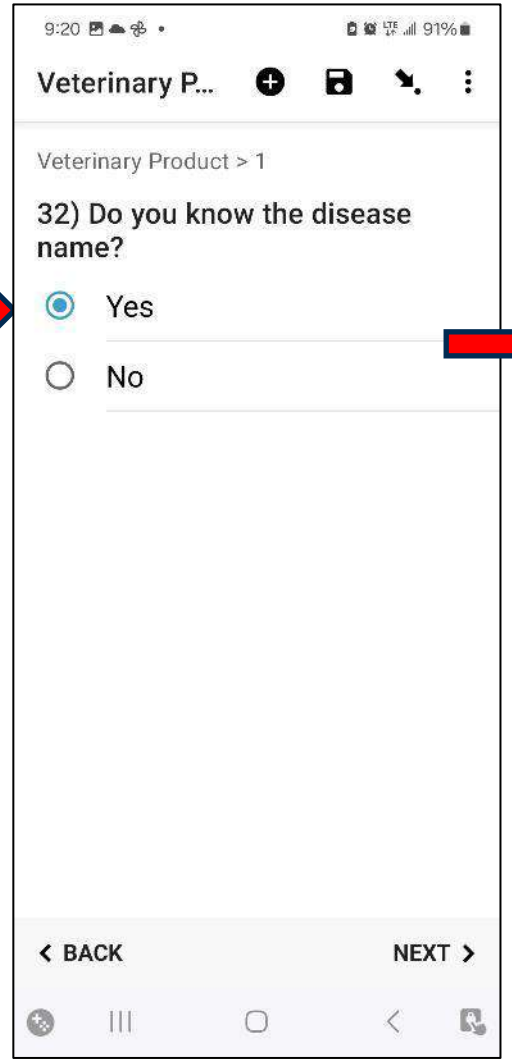
Veterinary Product Tool: An Example

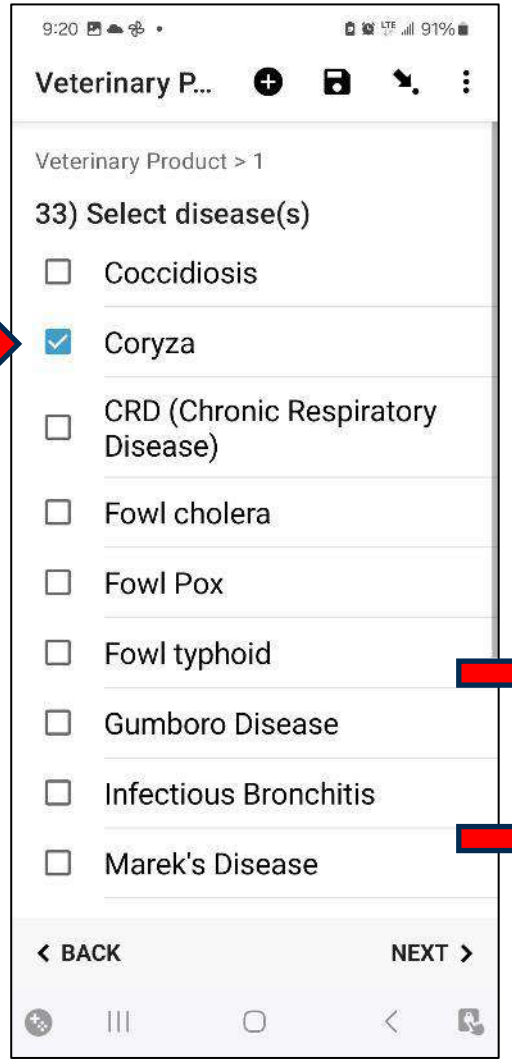
- The farmer said he used **the antibiotic for treating disease**
- Select “Treatment of sick birds” for Q31

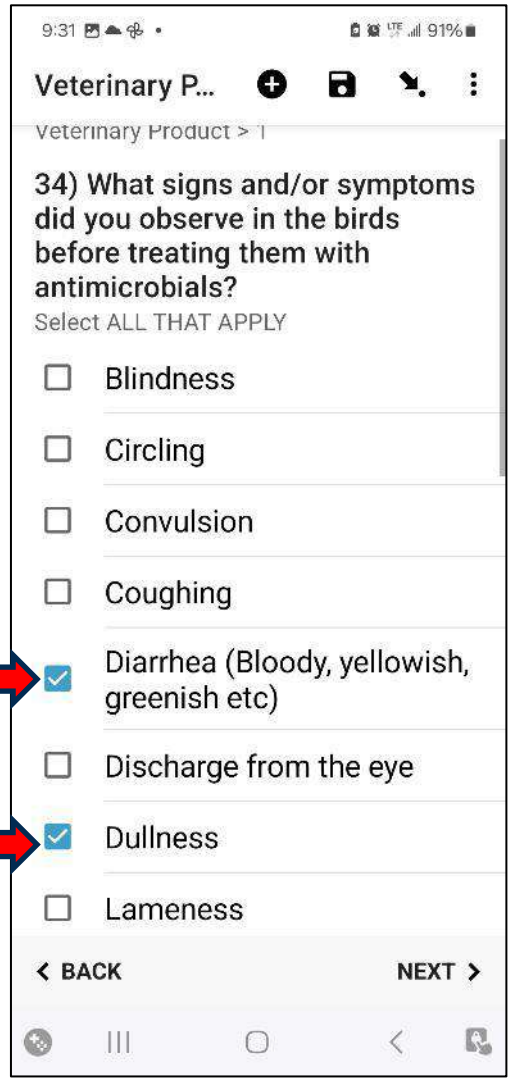


Veterinary Product Tool: An Example

- The farmer said **he knew the disease**
- Select “Yes” for Q32
- He said the disease was **“Infectious Coryza”**
- Select “Coryza” for Q33
- He said the symptoms were **Diarrhea** and **Dullness**
- Select “**Diarrhea**” and “**Dullness**” for Q34

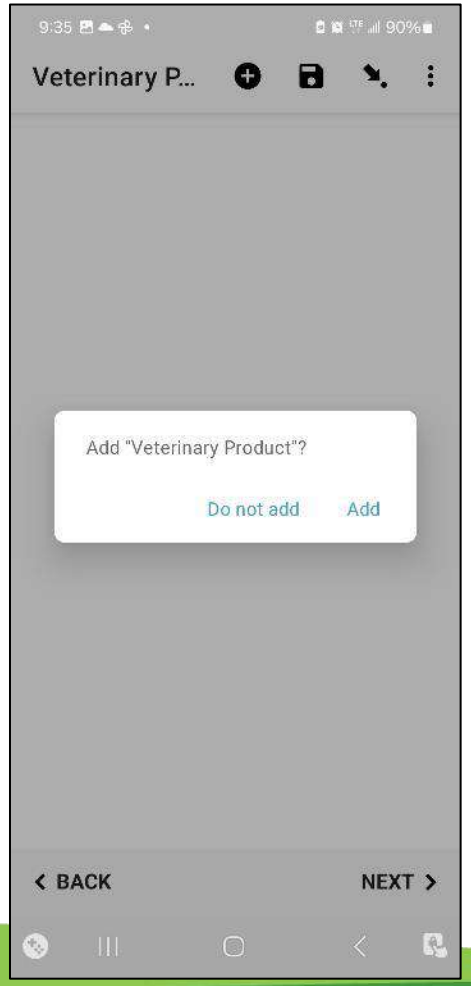






Veterinary Product Tool: An Example

- After finishing the product, the survey will ask “Do you need to add another veterinary product from bucket/unfinished products?



Summary:

- Substandard and falsified veterinary product data collection at farm level will be conducted as a part of BFFS in Cambodia, Lao PDR and Philippines
- Enumerators are trained facilitators/ master trainers (government/ academia)
- Sampling size will be small at this piloting stage (1 or 2 FFS in each country) with potential for scale-up
- Visual investigation/ records
- This is newly developed tools – regional/ country contextualization needed

Relevant & complement to VSAFE:

- Data collection on SFVP at farm level to be reported by the government officials -- relevant authority?
- Integrate into long-term SFVP monitoring and surveillance plan at farm level?
- Link to focal points for VSAFE inputs/ report?

Introducing WOAH VSAFE

1st Workshop on Substandard and Falsified Veterinary Products (SFVP)
and WOAH pilot Veterinary Monitoring and Surveillance System for SFVP (WOAH - VSAFE)
Asia and Pacific Region

Andrés García Campos
Programme Manager - AMR & VP Department

Mduduzi Welcome Magongo
Business Project Management Support at AMR & VP Department

13th June 2024 - Bangkok

World Organisation for Animal Health
Founded in 1924

Organisation mondiale de la santé animale
Fondée en 1924

Organización Mundial de Sanidad Animal
Fundada en 1924

To all our participants ...

World Organisation for Animal Health
Founded in 1924

Our journey

Global Information & Alert System for Substandard and Falsified VMP

Pilot Phase 1

2022

14 Members

Pilot Phase 2

2023

42 Members

Inclusive

No judgement

No shaming

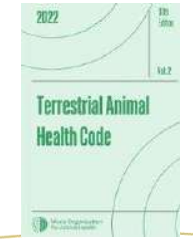
Veterinary Surveillance System for Substandard And FalsifiEd VMP

VSAFE

57 Members ... AND Increasing !!

Substandard & Falsified Veterinary Products

Rational – WOAH's Code, Resolutions & Recomemndations by Members



Article 3.4.11.5 :

Retailing, use and traceability of VMP

"Veterinary legislation should provide a basis for actions to address …

a system of surveillance of the quality of veterinary medicinal products marketed in the country, including a system of surveillance for falsification"

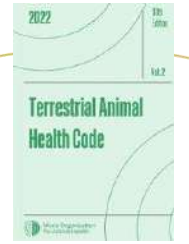
Resolution No. 26 Adopted on 26 May 2015

10. The OIE strengthen its collaboration with international organisations, such as the World Customs Organisation and Interpol, and stakeholders to combat counterfeit products with the aim of ensuring access to antimicrobial agents of proven quality.

OIE GLOBAL CONFERENCE ON ANTIMICROBIAL RESISTANCE
Putting Standards into Practice

6th recommendation

"Explore the possibility of building an information system of falsified and substandard drugs in the animal sector illegally circulating within and between countries and building on the experience of the monitoring systems set up by WHO for drugs designed for human use taking a 'One Health' approach"



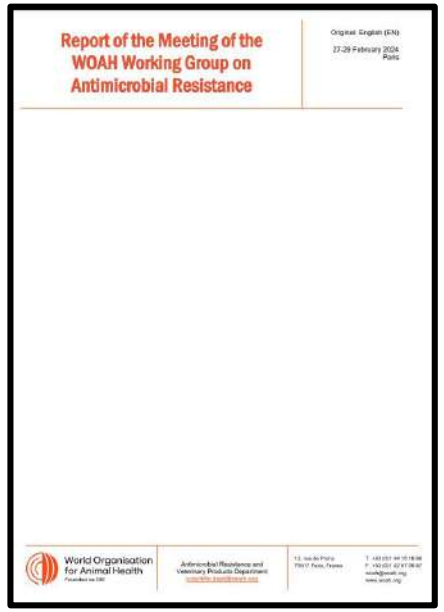
Article 6.10.3.10 :

Distribution and administration of antimicrobial agents or VMPs containing antimicrobial agents

"The Competent Authority should ensure that all antimicrobial agents and VMPs containing antimicrobial agents are …

not illegal, substandard, falsified medicines or unapproved formulations and that these are prevented from entering distribution systems"

Recommendation from WOAH Working Group on AMR – February 2024


Report of the Meeting of the WOAH Working Group on Antimicrobial Resistance

Original: English (EN)
27-29 February 2024
Paris

World Organisation for Animal Health

Propose to WOAH Council for a New Resolution for adoption at 92nd General Session

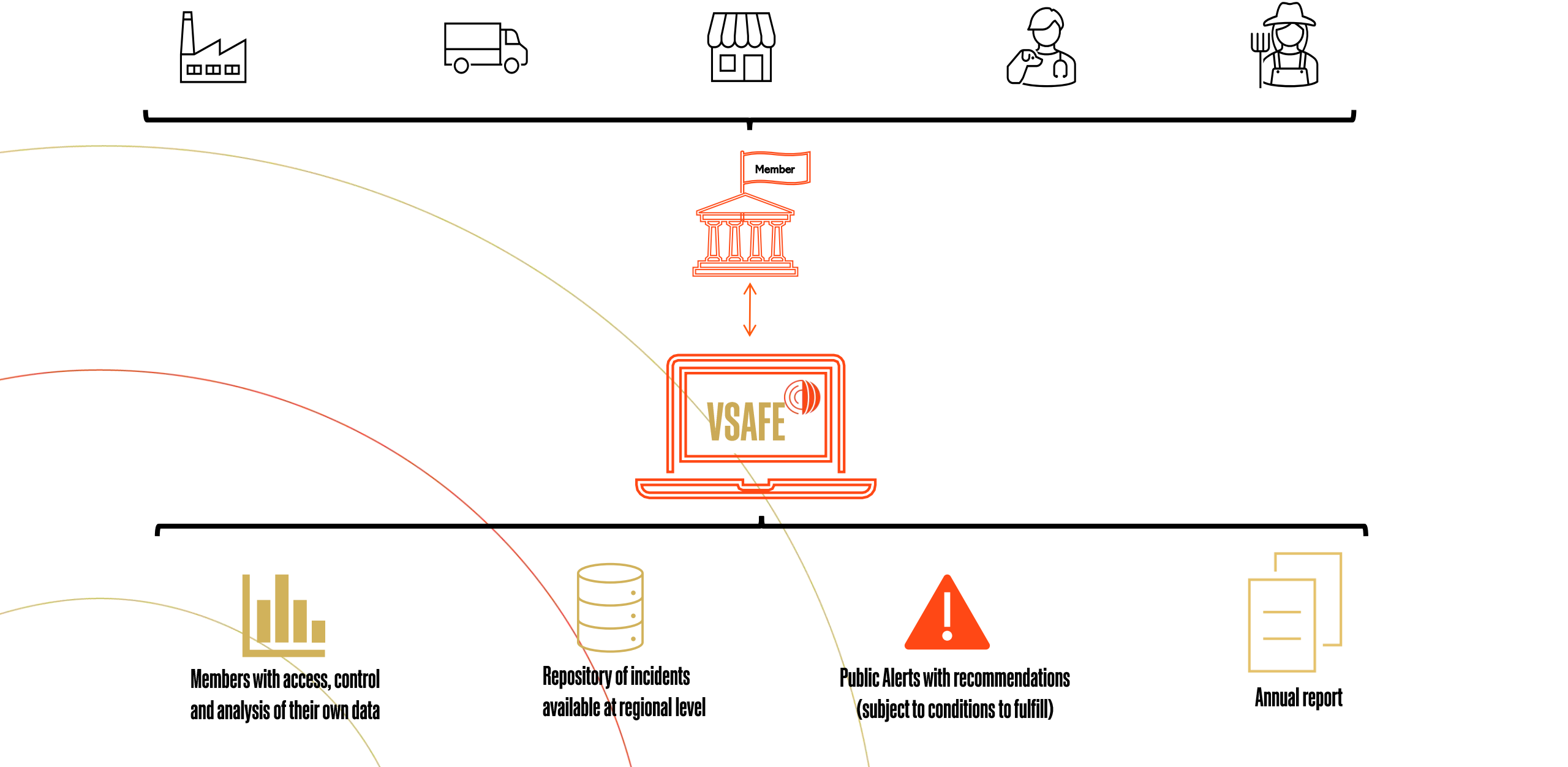
Definitions & Classification Criteria

Adapted from the WHO's definitions and criteria

		Substandard	Falsified	Unregistered / Unlicensed
Definition (Source WHO: IFS Team)		Authorised VP* that fail to meet either their quality standards or their specifications, or both	Unauthorised VP that deliberately or fraudulently misrepresent their identity	VP that has not undergone evaluation and/or approval by the national or regional regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.
Incident criteria	Suspect	The VP appears to be registered in the country where it is found AND The VP failed field screening examination, and/or local laboratory testing	The VP failed field screening examination, and/or local laboratory testing	The VP does not appear to be registered in the country where it is found
	Confirmed	The veterinary authority has confirmed that the VP is registered in the country where it was found AND The stated manufacturer or MAH** has confirmed that they did make the product AND The stated manufacturer or MAH has confirmed that the results of laboratory testing do not correspond to their records	The stated manufacturer or MAH has confirmed that they did not make the product	The veterinary authority has confirmed that the VP is not registered in the country where it was found AND The stated manufacturer or MAH has confirmed that they did make the product

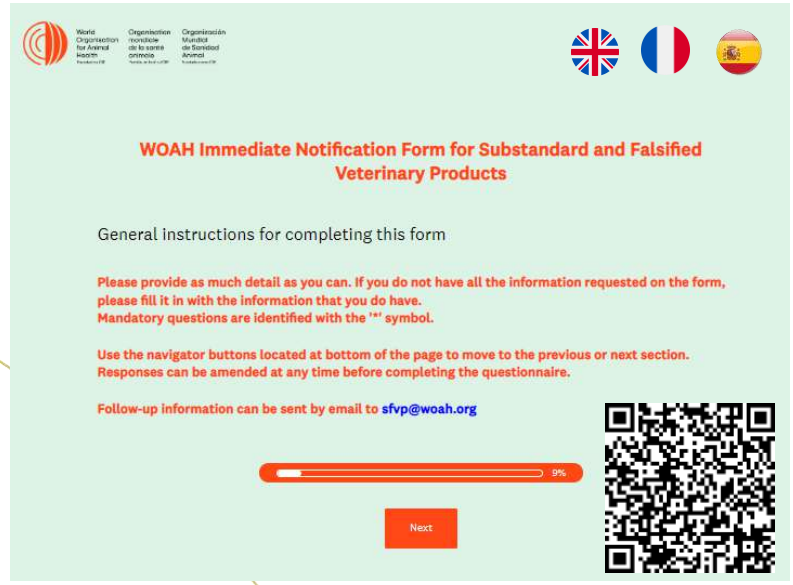
* VP = veterinary products, **MAH = manufacturing authorisation holder

Veterinary Monitoring and Surveillance System for Substandard and Falsified VMPs



Reporting through VSAFE : Three Main Elements

To be completed or updated once a year



To be completed every time a Member has an incident to report

To be completed monthly if no incidents were reported the previous month

Management of Quality of VMPs

Access to Laboratory Testing

Recall & Traceability

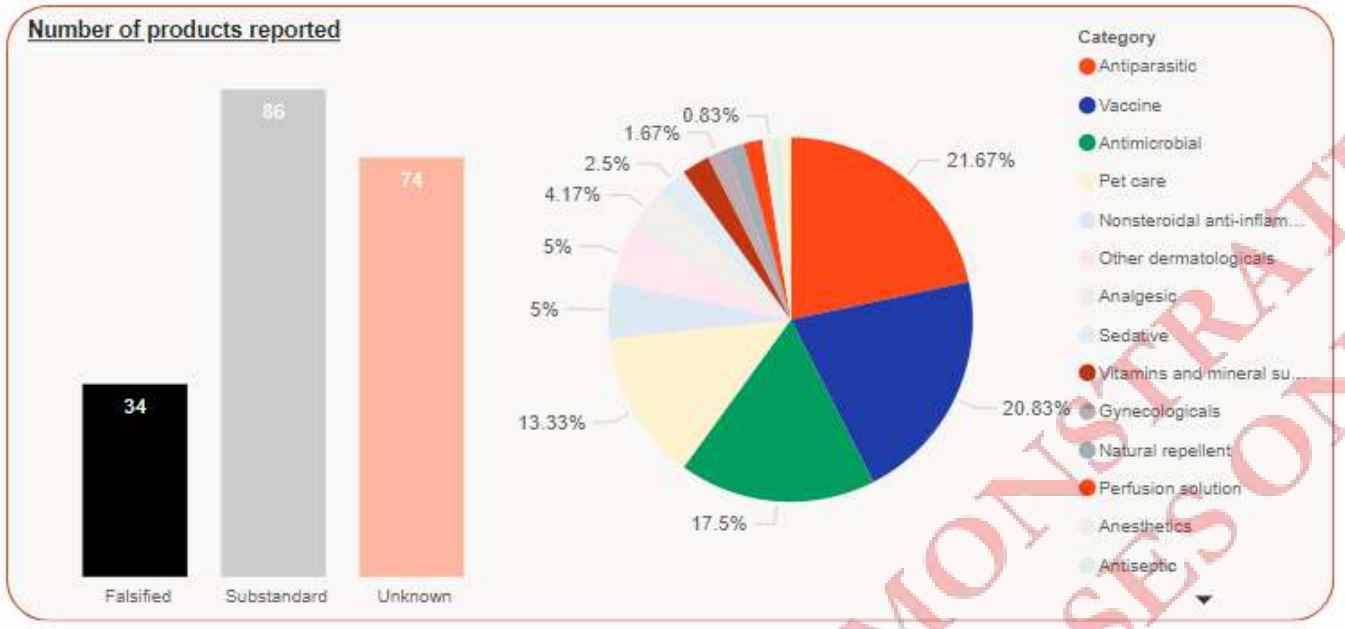
Details of suspect

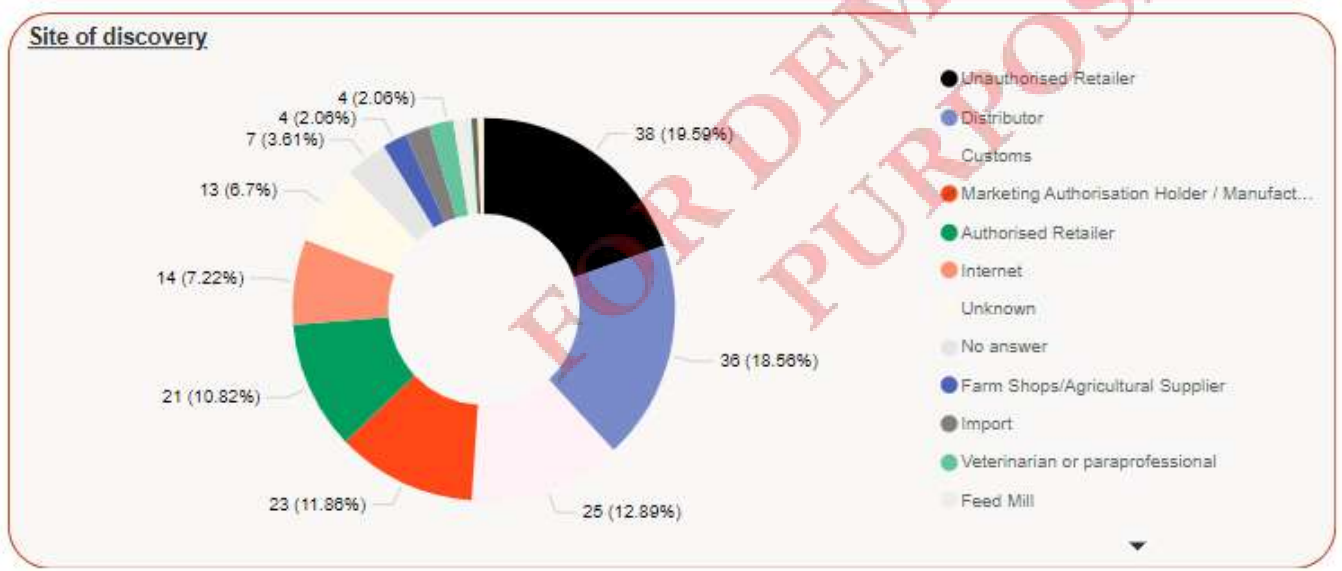
Details of discovery

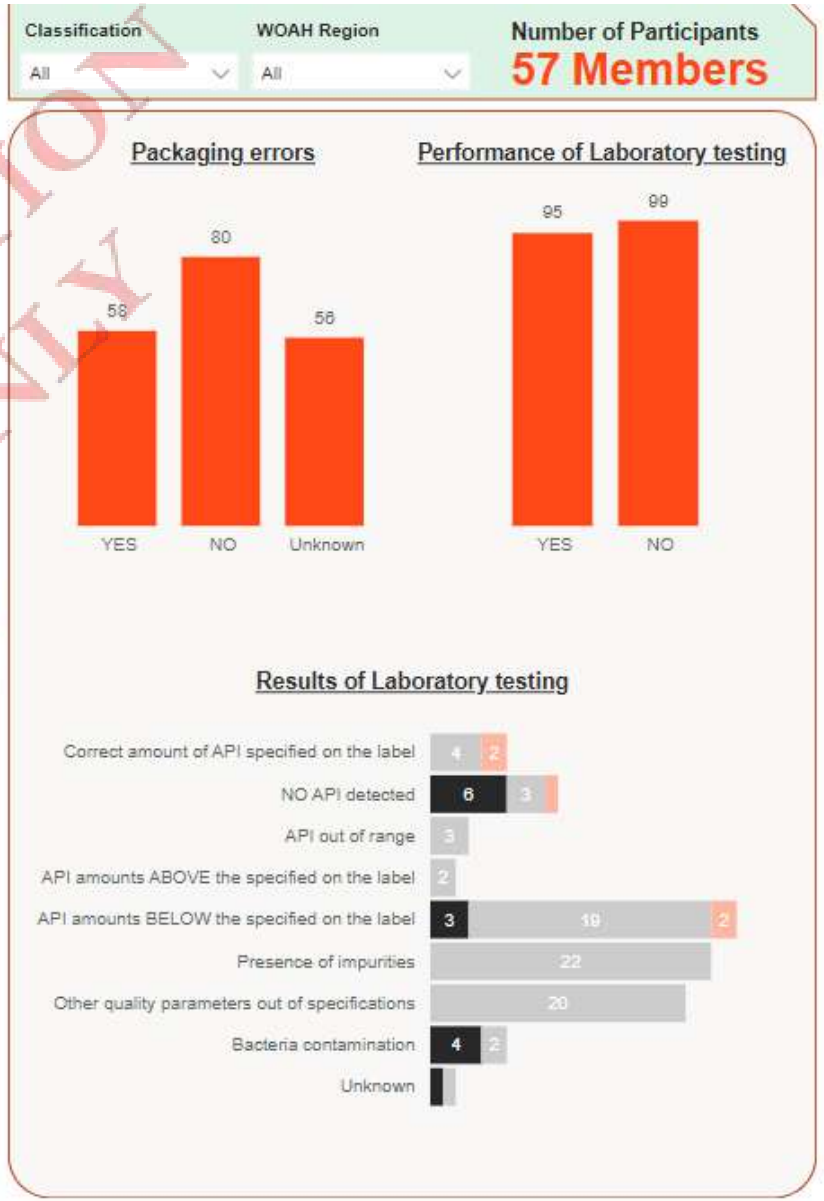
Current response

Confirmation no incidents to report

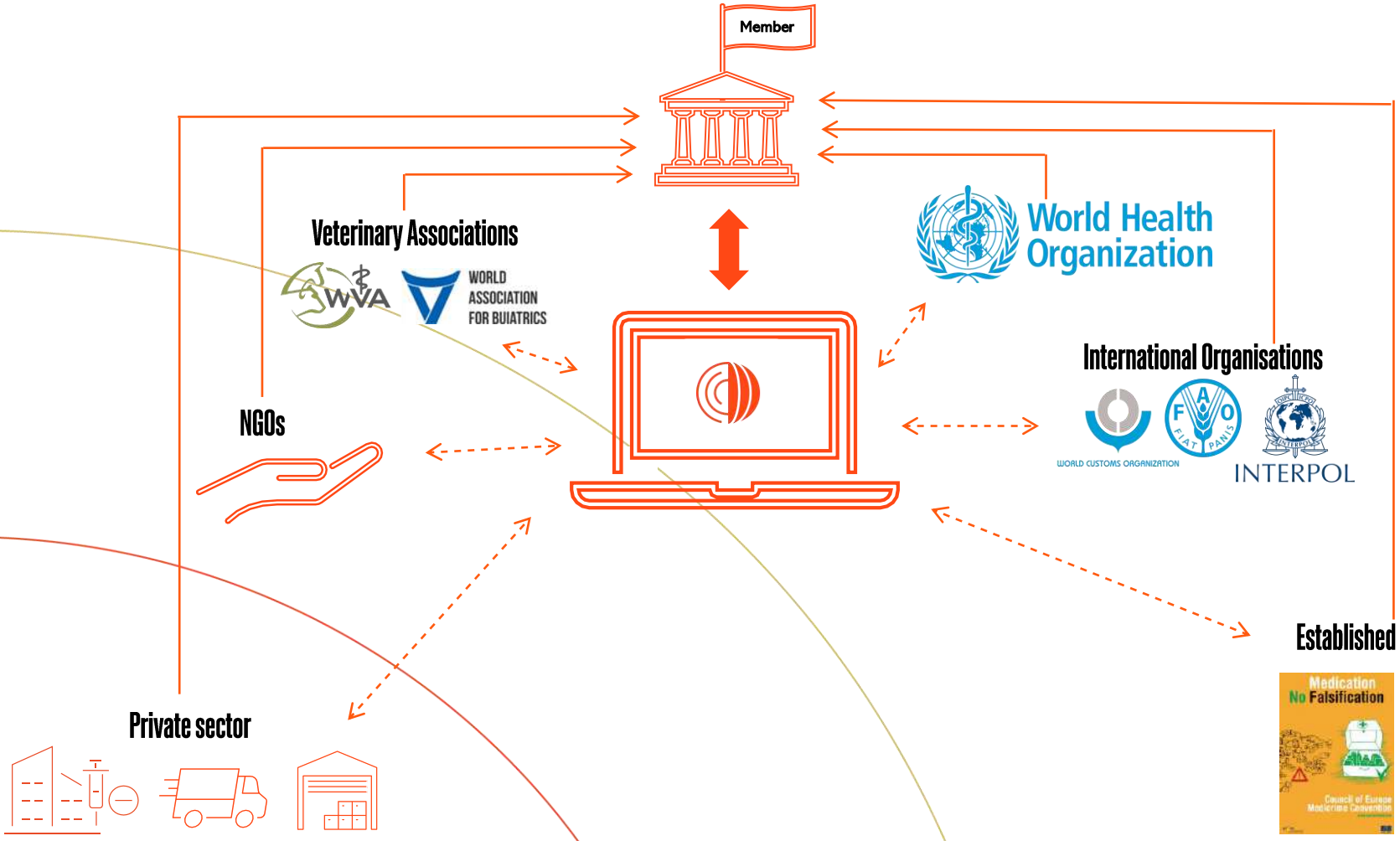
Main Benefit (but not the only one)

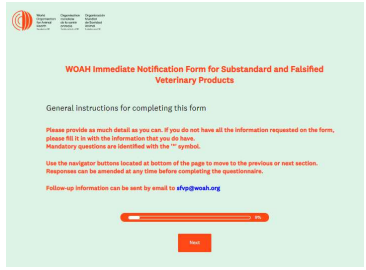






FINAL GOAL





Support communication with Members for validation

Leverage for encouraging participation to Members

Better understanding of the Situation in the field

VSAFE – IT Tool Development

World Health Organization

+

Pilot Experiences

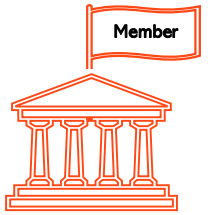
90 Functional Requirements

&

29 Technical Requirements

- **Security** – no data breach
- Different levels of **Access** for Members and external stakeholders
- Individual Country Portal - **more than one agent** per portal
- Engine **Search Tool** for suspect 'VMP' already reported
- **Autosave** reporting and updates on same immediate notification
- **Automated** notifications & subsequent **follow-up** of incidents
- **Image gallery** of suspect reported if available
- **Upload** own **existing template/s** already in use nationally
- Direct upload from **screening devices** used in field (in the future)

Benefits and accessibility to VSAFE – WHY you should join ?

Features		WOAH Partners & direct stakeholders	
Access to own portal / profile	✓	✓	✓
Public alerts	✓	✓	✓
Annual Report	✓	✓	✓
Own reporting	✓	✓	✓
Main contact for final validation	✓	✓	✗
Search tool of all VMPs reported available	✓	✗	✗

Benefits and accessibility to VSAFE – WHY you should join ?

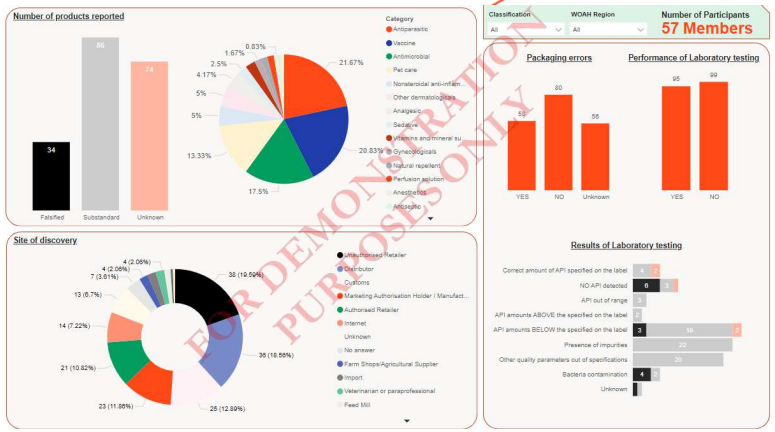
YOUR FEEDBACK MATTERS

My country does not have a system …

VSAFE can be used as model to establish your system

My country does have a system already …

Share any reports/forms to reduce your work burden



Let's explore VSAFE !!

Veterinary Surveillance System for Substandard And FalsifiEd VMP

Experiences in using Pilot Veterinary Monitoring and Surveillance System for Substandard & Falsified Veterinary Medicinal Products (VSAFE)

Dr. Swe Lynn Htet
Assistant Director
Livestock Breeding and Veterinary Department

12-14 July 2024
Bangkok, Thailand

World Organisation for Animal Health
Founded as OIE

Introduction

- During the Regional ANIMUSE Training for WOAH Focal Points for Veterinary Products which was held on 22-24 February 2023, Bangkok, Thailand, WOAH introduced about the SFVP as the first time
- Proposed and sent the confirmation letter to WOAH to participate in the 2nd Pilot Phase of the WOAH Global Information and Alert System of Substandard and Falsified Veterinary Products
- Myanmar is part of the pilot VSAFE since February 2023
- Reference Numbers of the incident (just sample);
  - DA0107MMR (June 2023)
  - DA050124MMR-01 (December 2023)
  - DA010224MMR-01 (January 2024)
  - DA040324MMR-01 (February 2024)
  - DA020524MMR-01 (April 2024)

THE REPUBLIC OF THE UNION OF MYANMAR
MINISTRY OF AGRICULTURE, LIVESTOCK AND IRRIGATION
LIVESTOCK BREEDING AND VETERINARY DEPARTMENT
DIRECTOR GENERAL OFFICE, NAY PYI TAW, MYANMAR
Tel: +95 67 408056, Fax: +95 67 408342
Email: ir.lbvd@gmail.com

Ref no; Sayapa/3/SFVP(100)/Makanyakakha-2023
Date: 12 March 2023

Dr Andrés García Campos
Programme Manager
Antimicrobial Resistance & Veterinary Products Department
Email: sfvp@woah.org

Subject; **Confirmation Letter as new participant for 2nd Pilot Phase of the WOAH Global Information and Alert System of Substandard and Falsified Veterinary Products**

Dear Dr Andrés García Campos,

We would like to express our sincere appreciation and many thanks for inviting Livestock Breeding Veterinary Department, Myanmar to participate in as a new participate for the 2nd Pilot Phase of the WOAH Global Information and Alert System of Substandard and Falsified Veterinary Products.

In this regards, we would very pleasure to participate as a new participant in this pilot phase 2 project so as to performed the purpose of this pilot project.

Thank you for your kind consideration.

If you have any queries or needs more information regarding with the cited matter, please feel free to contact us.

Sincerely yours,

Dr Ye Htun Win
WOAH Delegate
Director General
Livestock Breeding and Veterinary Department, Myanmar
Email: ytwvet84@gmail.com
Hotline: +95 9 5029759

Working plan for Participants

- Complete a 5-10 min WOAH Baseline Reporting Form for SFVP once a year, which should be submitted between 15th January and 1st April 2024.
- Submit a 10-15 min WOAH Immediate Notification Form for SFVP, as soon as they are aware of a suspected/confirmed incident of SFVP. When all information is not available, minimum reporting should contain
  - Name of the product and Registration Number as stated in the packaging,
  - Manufacturer as stated in the packaging,
  - Batch number as stated in the packaging,
  - Date and site of discovery.

  An open text box is available at the beginning of the Immediate Notification Report to allow participants to write a description of the remaining information relevant of every incident (i.e., quantities, reasons of suspicious, lab testing conducted, adverse reactions detected, etc.) to facilitate reporting in case of lack of resources or time.

Source: VSAFE ToR

Working plan for Participants

- Following receipt of an incident by the Team, an email including the reference number will be provided. The reference number can be used in case participants would like to update the information provided in the incident before, or to follow up.
- Revise the WOAH Immediate Notification Form for SFVP – even if no incidents are reported - to verify that all specifications and options required are well reflected and is designed fit-for-purpose.
- Provide any template that they currently use if they have already a system in place for the notification of SFVP at national level. The purpose is to work on a final system that allows us to pre-populate information of the forms to our system directly hence reducing administrative burden to the reporter.
- If no incidents are received in a calendar month, participants must complete the 1-min WOAH Monthly Declaration Form for the Absence of SFVP. This must be submitted within 7 days after the end of the calendar month.
- Provide feedback on the data collection tools on, at least, an annual basis for refinement, improvement, and for indicating other issues that should be considered.

Source: VSAFE ToR

Definition and Classification Criteria

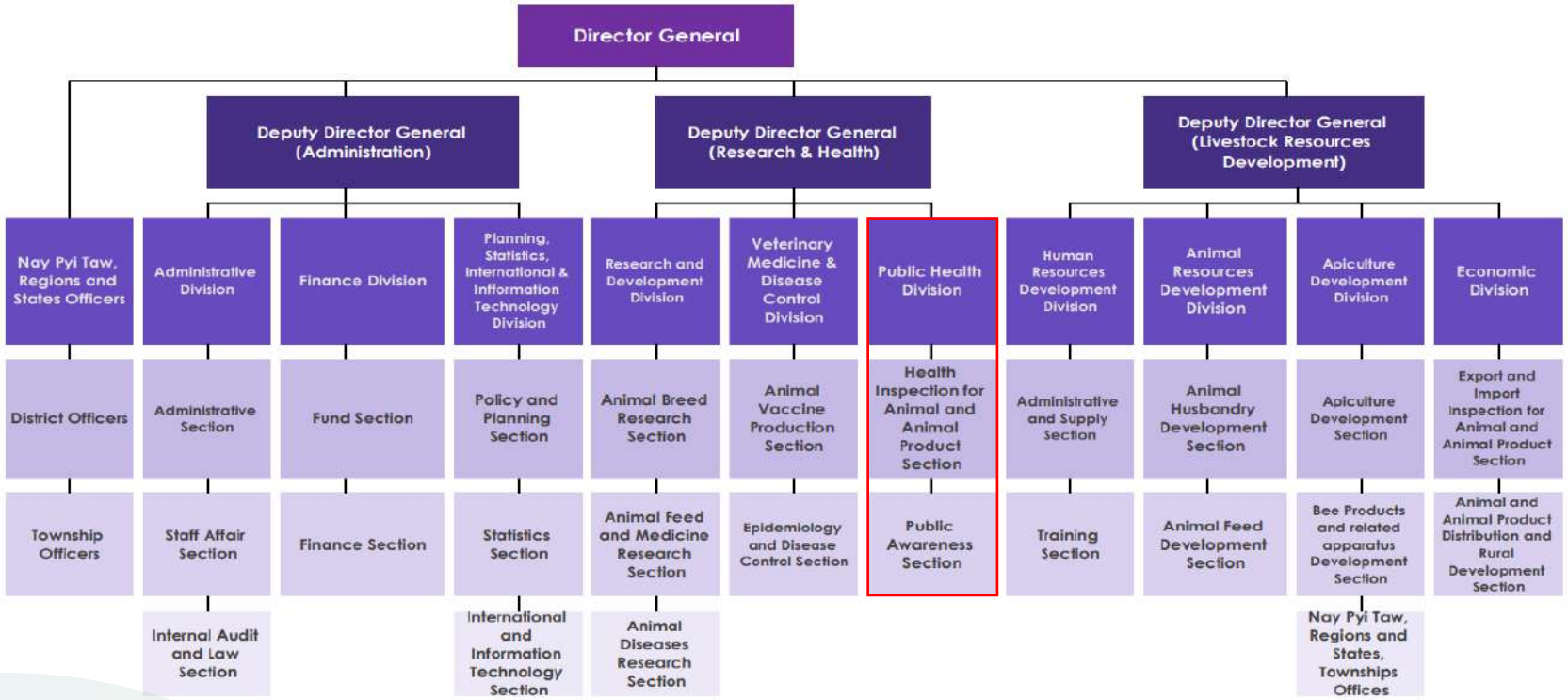
Adapted from the WHO's definitions and criteria

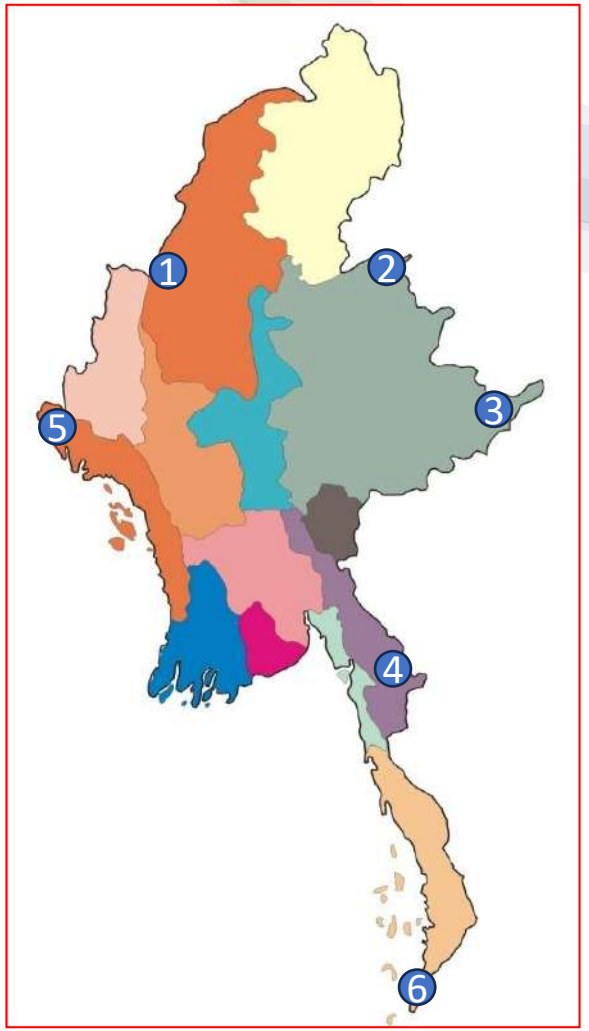
		Substandard	Falsified	Unregistered / Unlicensed
Definition		Authorised VP* that fail to meet either their quality standards or their specifications, or both	Unauthorised VP that deliberately or fraudulently misrepresent their identity	VP that has not undergone evaluation and/or approval by the national or regional regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.
Incident criteria	Suspect	The VP appears to be registered in the country where it is found AND The VP failed field screening examination, and/or local laboratory testing	The VP failed field screening examination, and/or local laboratory testing	The VP does not appear to be registered in the country where it is found
	Confirmed	The veterinary authority has confirmed that the VP is registered in the country where it was found AND The stated manufacturer or MAH** has confirmed that they did make the product AND The stated manufacturer or MAH has confirmed that the results of laboratory testing do not correspond to their records	The stated manufacturer or MAH has confirmed that they did not make the product	The veterinary authority has confirmed that the VP is not registered in the country where it was found AND The stated manufacturer or MAH has confirmed that they did make the product

* VP = veterinary products, **MAH = manufacturing authorisation holder

Source: https://oieoffice365.sharepoint.com/sites/SFVPPilot

LBVD Organization chart





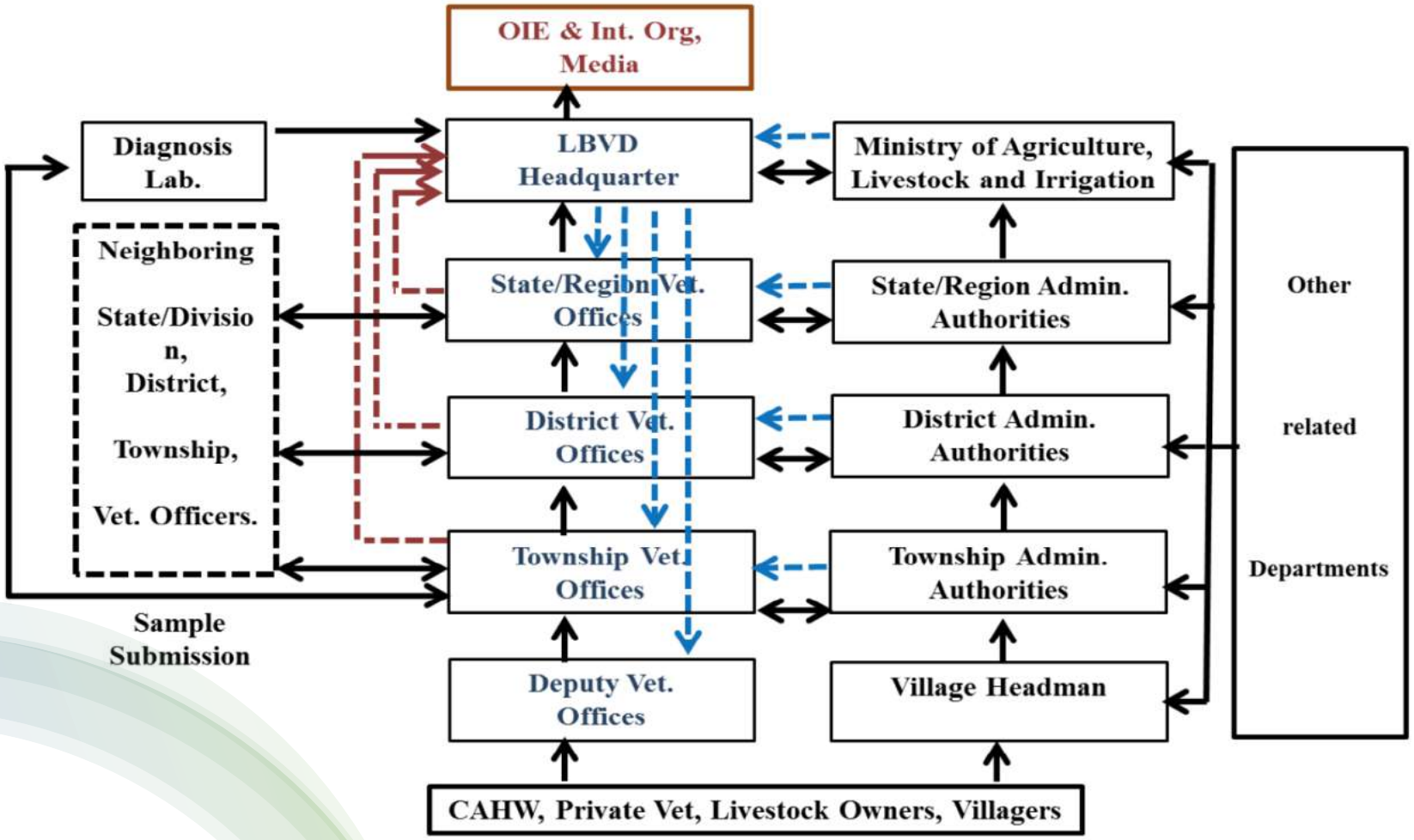
There are 6 check points in Myanmar which are situated in the border areas and quarantine laboratories.

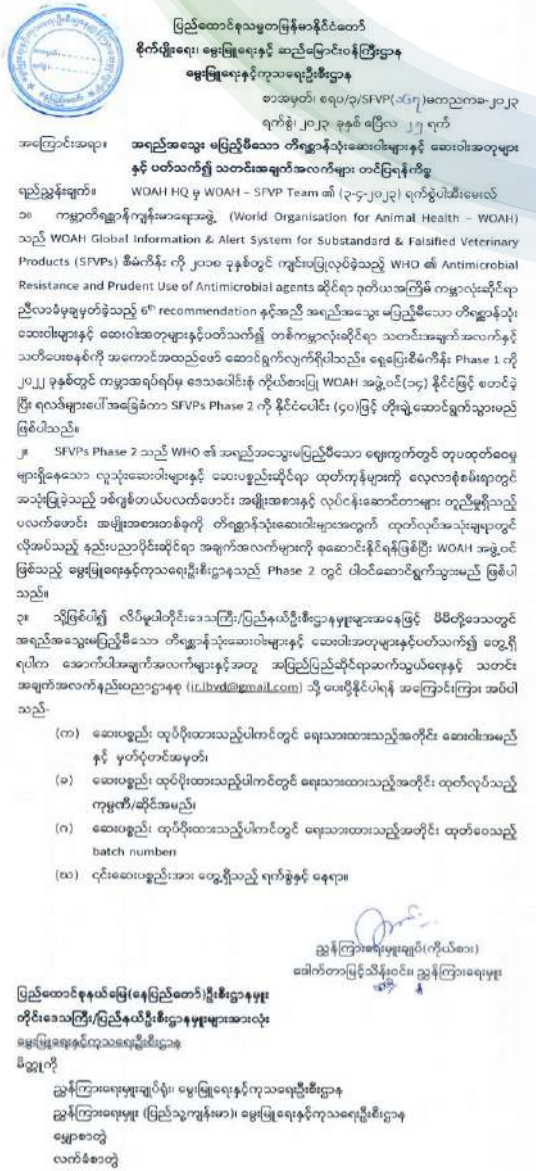
Mission

12 missions including;

- To produce biologics for the protection of infectious diseases and undertaking disease control and animal health care
- Control of animal diseases through animal movement across border by establishing check points

Information Flow and Chain of Command





ပြည်ထောင်စုသမ္မတမြန်မာနိုင်ငံတော်
စိုက်ပျိုးရေး၊ မွေးမြူရေးနှင့် ဆည်မြောင်းဝန်ကြီးဌာန
မွေးမြူရေးနှင့်ကုသရေးဦးစီးဌာန
စာအမှတ်၊ ရရဝ/ခ/SFVP(၁၆၇)ကညကခ-၂၀၂၃
ရက်စွဲ၊ ၂၀၂၃ ခုနှစ် ဖေဖော်ဝါရီလ ၂၅ ရက်

အကြောင်းအရာ။ အရည်အသွေး မပြည့်မီသော တိရစ္ဆာန်သုံးဆေးဝါးများနှင့် ဆေးဝါးအတုများနှင့် ပတ်သက်၍ သတင်းအချက်အလက်များ တင်ပြရန်ကိစ္စ

ရည်ညွှန်းချက်။ WOAH HQ မှ WOAH – SFVP Team ၏ (၃-၄-၂၀၂၃) ရက်စွဲပါအီးမေးလ်

၁။ ကမ္ဘာတိရစ္ဆာန်ကျန်းမာရေးအဖွဲ့ (World Organisation for Animal Health – WOAH) သည် WOAH Global Information & Alert System for Substandard & Falsified Veterinary Products (SFVPs) စီမံကိန်း ကို ၂၀၁၈ ခုနှစ်တွင် ကျင်းပပြုလုပ်ခဲ့သည့် WHO ၏ Antimicrobial Resistance and Prudent Use of Antimicrobial agents ဆိုင်ရာ ဒုတိယအကြိမ် ကမ္ဘာလုံးဆိုင်ရာ ညီလာခံမှချမှတ်ခဲ့သည့် 6th recommendation နှင့်အညီ အရည်အသွေး မပြည့်မီသော တိရစ္ဆာန်သုံး ဆေးဝါးများနှင့် ဆေးဝါးအတုများနှင့်ပတ်သက်၍ တစ်ကမ္ဘာလုံးဆိုင်ရာ သတင်းအချက်အလက်နှင့် သတင်းပေးစနစ်ကို အကောင်အထည်ဖော် ဆောင်ရွက်လျက်ရှိပါသည်။ ရွေးပြေးစီမံကိန်း Phase 1 ကို ၂၀၂၂ ခုနှစ်တွင် ကမ္ဘာအရပ်ရပ်မှ ဒေသဝေါင်းနဲ့ ကိုယ်စားပြု WOAH အဖွဲ့ဝင်(၁၄) နိုင်ငံဖြင့် စတင်ခဲ့ပြီး ရလဒ်များပေါ်အခြေခံကာ SFVPs Phase 2 ကို နိုင်ငံပေါင်း (၄၀)ဖြင့် တိုးချဲ့ဆောင်ရွက်သွားမည်ဖြစ်ပါသည်။

၂။ SFVPs Phase 2 သည် WHO ၏ အရည်အသွေးမပြည့်မီသော ဂျေးကွက်တွင် တုပထုတ်ဝေမှုများရှိနေသော လူသုံးဆေးဝါးများနှင့် ဆေးပစ္စည်းဆိုင်ရာ ထုတ်ကုန်များကို လေ့လာစုံစမ်းရာတွင် အသုံးပြုခဲ့သည့် ခစ်ဂျစ်တယ်ပလက်ဖောင်း အမျိုးအစားနှင့် လုပ်ငန်းဆောင်တာများ တူညီမှုရှိသည့် ပလက်ဖောင်း အမျိုးအစားတစ်ခုကို တိရစ္ဆာန်သုံးဆေးဝါးများအတွက် ထုတ်လုပ်အသုံးချရာတွင် လိုအပ်သည့် နည်းပညာပိုင်းဆိုင်ရာ အချက်အလက်များကို ခုဆောင်းနိုင်ရန်ဖြစ်ပြီး WOAH အဖွဲ့ဝင်ဖြစ်သည့် မွေးမြူရေးနှင့်ကုသရေးဦးစီးဌာနသည် Phase 2 တွင် ပါဝင်ဆောင်ရွက်သွားမည် ဖြစ်ပါသည်။

၃။ သို့ဖြစ်ပါ၍ လိပ်မူပါတိုင်းဒေသကြီး/ပြည်နယ်ဦးစီးဌာနမှူးများအနေဖြင့် ဗီဗီတို့ဒေသတွင် အရည်အသွေးမပြည့်မီသော တိရစ္ဆာန်သုံးဆေးဝါးများနှင့် ဆေးဝါးအတုများနှင့်ပတ်သက်၍ တွေ့ရှိရပါက အောက်ပါအချက်အလက်များနှင့်အတူ အပြည်ပြည်ဆိုင်ရာဆက်သွယ်ရေးနှင့် သတင်းအချက်အလက်နည်းပညာဌာနစုရုံ (ict.lbwd@gmail.com) သို့ ပေးပို့နိုင်ပါရန် အကြောင်းကြား အပ်ပါသည်-

(က) ဆေးပစ္စည်း ထုပ်ပိုးထားသည့်ပါကင်တွင် ရေးသားထားသည့်အတိုင်း ဆေးဝါးအမည်နှင့် မှတ်ပုံတင်အမှတ်၊

(ခ) ဆေးပစ္စည်း ထုပ်ပိုးထားသည့်ပါကင်တွင် ရေးသားထားသည့်အတိုင်း ထုတ်လုပ်သည့် ကုမ္ပဏီ/ဆိုင်အမည်၊

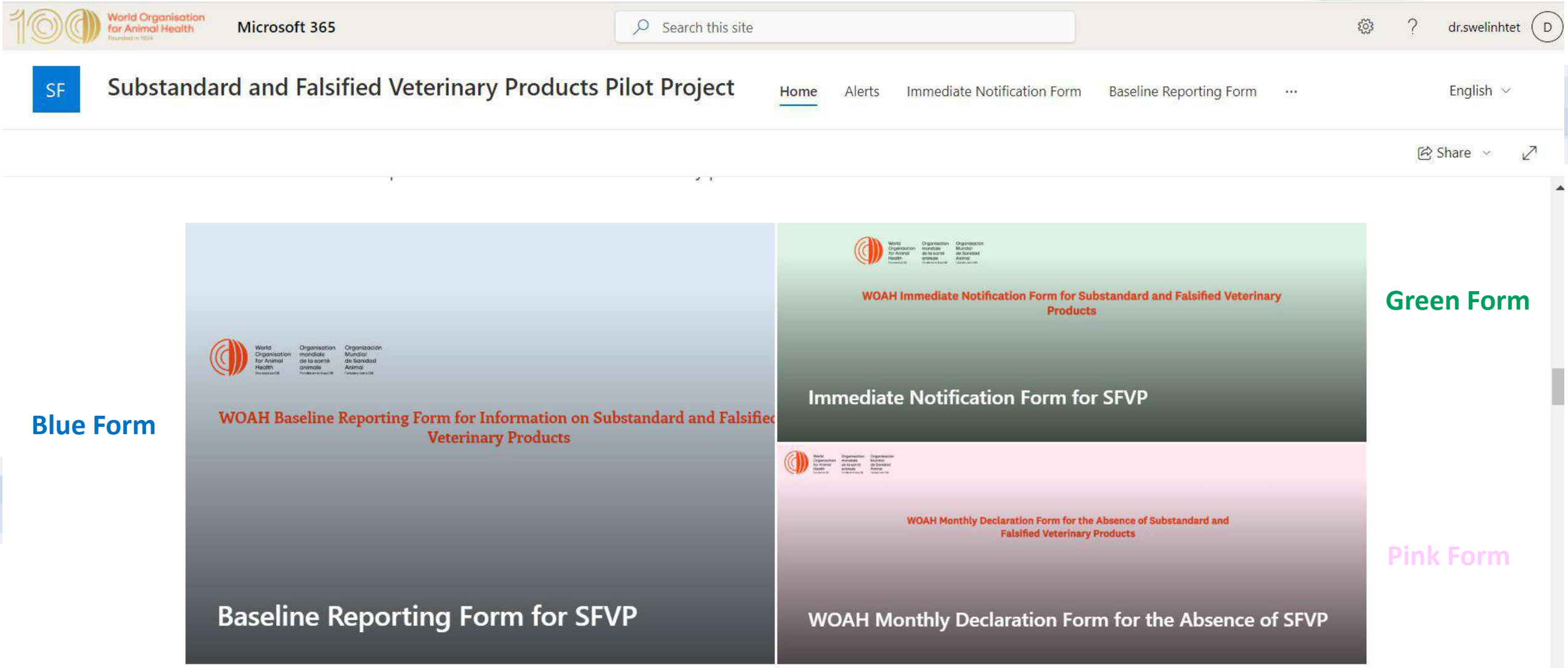
(ဂ) ဆေးပစ္စည်း ထုပ်ပိုးထားသည့်ပါကင်တွင် ရေးသားထားသည့်အတိုင်း ထုတ်ဝေသည့် batch number၊

(ဃ) ၎င်းဆေးပစ္စည်းအား တွေ့ရှိသည့် ရက်စွဲနှင့် နေရာ။

ညွှန်ကြားစီမံမှုးချုပ် (ကိုယ်စား)
ဒေါက်တာမြင့်သိန်းဝင်း၊ ညွှန်ကြားရေးမှူး

ပြည်ထောင်စုနယ်မြေ(နေပြည်တော်)ဦးစီးဌာနမှူး
တိုင်းဒေသကြီး/ပြည်နယ်ဦးစီးဌာနမှူးများအားလုံး
မွေးမြူရေးနှင့်ကုသရေးဦးစီးဌာန
မိတ္တူကို
ညွှန်ကြားရေးမှူးချုပ်ရုံး၊ မွေးမြူရေးနှင့်ကုသရေးဦးစီးဌာန
ညွှန်ကြားရေးမှူး (ပြည်သူ့ကျန်းမာ)၊ မွေးမြူရေးနှင့်ကုသရေးဦးစီးဌာန
မျှော်စာတွဲ
လက်ခံစာတွဲ

Declaration of Myanmar



Blue Form

Green Form

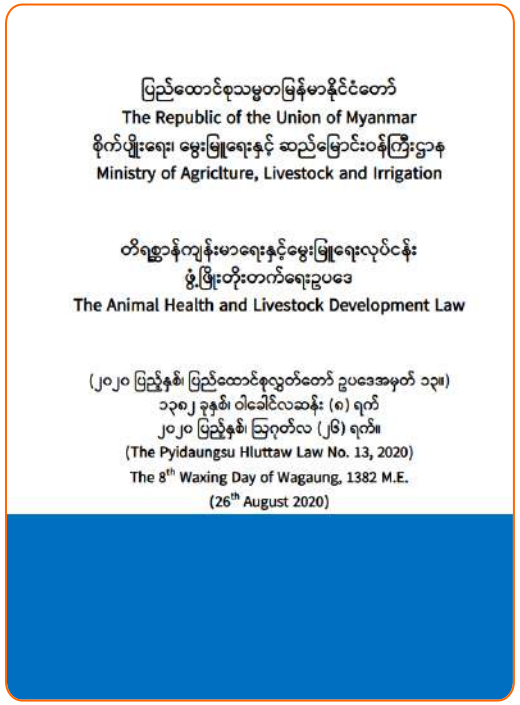
Pink Form

Myanmar always submitted monthly the absence of SFVP using Pink Form starting from February 2023.

Legislation

Animal Health and Livestock Development Law

- was enacted since 26th August 2020 by Union Parliament (Pyidaungsu Hluttaw)
- In accordance with the sub-section (g) of section 10, department shall:
  - *carry out the registration process of animal, livestock farm, breeder farm, hatchery, apiculture, domestic production, processing or sale of animals, animal products, genetically modified organisms, animal feed, veterinary medicinal products and animal equipment;*
- In accordance with the sub-section (d) of section 11, department shall:
  - *inspect whether animals, animal products, genetically modified organisms, animal feed, animal equipment or veterinary medicinal products to be imported or exported or domestically produced or processed are complied with the specifications;*
- In accordance with the section 26:
  - *The person who wants to export or import animals, animal products, genetically modified organisms, animal feed, animal equipment or veterinary medicinal products shall apply for the recommendation certificate to the Director General in accordance with stipulations before applying for an export or import license or a permit to the relevant government department.*


ပြည်ထောင်စုသမ္မတမြန်မာနိုင်ငံတော်
The Republic of the Union of Myanmar
စိုက်ပျိုးရေး၊ မွေးမြူရေးနှင့် ဆည်မြောင်းဝန်ကြီးဌာန
Ministry of Agriculture, Livestock and Irrigation

တိရစ္ဆာန်ကျန်းမာရေးနှင့်မွေးမြူရေးလုပ်ငန်း
ဖွံ့ဖြိုးတိုးတက်ရေးဥပဒေ
The Animal Health and Livestock Development Law

(၂၀၂၀ ပြည်နှစ်၊ ပြည်ထောင်စုလွှတ်တော် ဥပဒေအမှတ် ၁၃။)
၁၃၈၂ ခုနှစ်၊ ဝါခေါင်လဆန်း (၈) ရက်
၂၀၂၀ ပြည်နှစ်၊ သြဂုတ်လ (၂၆) ရက်။
(The Pyidaungsu Hluttaw Law No. 13, 2020)
The 8th Waxing Day of Wagaung, 1382 M.E.
(26th August 2020)

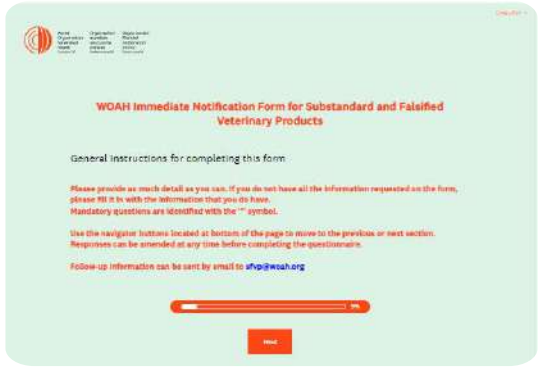
Legislation

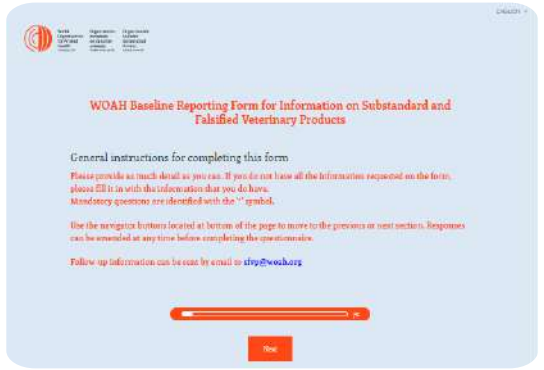
Animal Health and Livestock Development Law

- In accordance with the sub-section (e) of section 42, Any person without a permit or recommendation certificate shall not:
  - *export or import animals, animal products, genetically modified organisms, animal feed, livestock equipment or veterinary medicinal products;*
- In accordance with the sub-section (d) of section 47, Whoever:
  - *violates the prohibition of subsection (d), (e) or (f) of section 42 shall, on conviction, be punished with a fine from a minimum of three million kyats to a maximum of ten million kyats. If that person violates such prohibition again, he or she shall, on conviction, be punished with imprisonment for a term not exceeding one year and shall also be liable to a fine from a minimum of five million kyats to a maximum of 15 million kyats.*
- In accordance with the sub-section (a) of section 43, any person who is the holder of a permit or recommendation certificate shall not:
  - *export, import, domestically produce, process or distribute animals, animal products, genetically modified organisms or animal feed, animal equipment or veterinary medicinal products that do not meet the specified quality standards;*
- In accordance with the sub-section (a) of section 48, If any person who is the holder of a permit or recommendation certificate:
  - *violates the prohibition of sub-section (a) of section 43, he or she shall, on conviction, be punished with a fine from a minimum of two million kyats to a maximum of seven million and five hundred thousand kyats. If that person violates such prohibition again, he or she shall, on conviction, be punished with imprisonment for a term not exceeding six months and shall also be liable to a fine from a minimum of three million kyats to a maximum of ten million kyats;*

Current Experience on WOAH VSAFE Pilot Phase 2

- Current platform is overall good acceptable situation.
- Design of reporting forms (blue, green, pink form) are easy to follow and very user friendly. However, monthly declaration for the absence of SFVP (pink form) from Myanmar was usually submitted because any incident of suspect/confirmed Substandard and Falsified Veterinary products circulating in Myanmar during the reporting month.
- So, we have not experience with the suspected/confirmed incident of SFVP in Myanmar.
- We are closely cooperating and coordinating with other relevant departments and organizations in order to reduce and disseminate the illegal trade including substandard and falsified animal and animal related products such as veterinary products.





Thank you for your kind attention

Dr. Swe Lynn Htet

Assistant Director

Livestock Breeding and Veterinary Department

Ministry of Agriculture, Livestock and Irrigation, Myanmar

Mobile: +95 9 420726727

Email: dr.swelinhtet@gmail.com

https://lbvd.gov.mm/

New Zealand Food Safety
Haumaru Kai Aotearoa

ACVM Regulatory Regime
- WOAH Workshop on SFVPs

Warren Hughes
Assurance Directorate

Ministry for Primary Industries
Manatū Ahu Matua

The ACVM Team

- Part of New Zealand Food Safety in MPI, and in the Assurance Directorate
- Responsible for the administration of the ACVM Act 1997
    - Registration of agricultural compounds: veterinary medicines, agricultural (horticultural) chemicals, vertebrate toxins (pest control products)
    - Independent scientific assessment and review of all technical aspects of product management – manufacturing, importing, sale, and use
    - Policy and standard setting including inputs into international forums (VICH, OECD, & OIE)
- Also responsible for assessment and setting of Maximum Residue Levels (MRLs) under the Food Act 2014

The ACVM Act and ACVM Regulations: A Brief Overview

Ministry for Primary Industries
Manatū Ahu Matua

New Zealand Food Safety
Haumaru Kai Aotearoa

The ACVM Act and Regulations

The Agricultural Compounds and Veterinary Medicines Act 1997

The ACVM (Exemptions and Prohibited Substances) Regulations 2011

- **ACVM Act**: Rules for import, manufacture, registration, and sale of ag compounds, recognition (including vets), offences
- **ACVM Regulations**: Rules for import, manufacture, sale, and use of exempt products, list of prohibited substances

➢ **Establish the risk management framework for exemption and registration**

What is an Agricultural Compound?

"Any substance or mixture of substances … for the purposes of:"

- Managing or eradicating **pests**
- Maintaining, promoting, or regulating **productivity** and **reproduction**
- Fulfilling **nutritional** requirements
- **Marking**, **manipulation**, **capture**, or **immobilisation**
- **Diagnosis**, **treatment** and **prevention** of conditions
- Any substance used for **post-harvest treatment** of raw primary produce

➢ **Anything used in, on, or around an animal to directly manage the animal or its produce**

The ACVM Act and Regulations

The purpose of the ACVM Act is to:

a) Prevent or manage risks associated with the use of agricultural compounds, being –

   (ia) risks to public health; and

   (i) risks to trade in primary produce; and

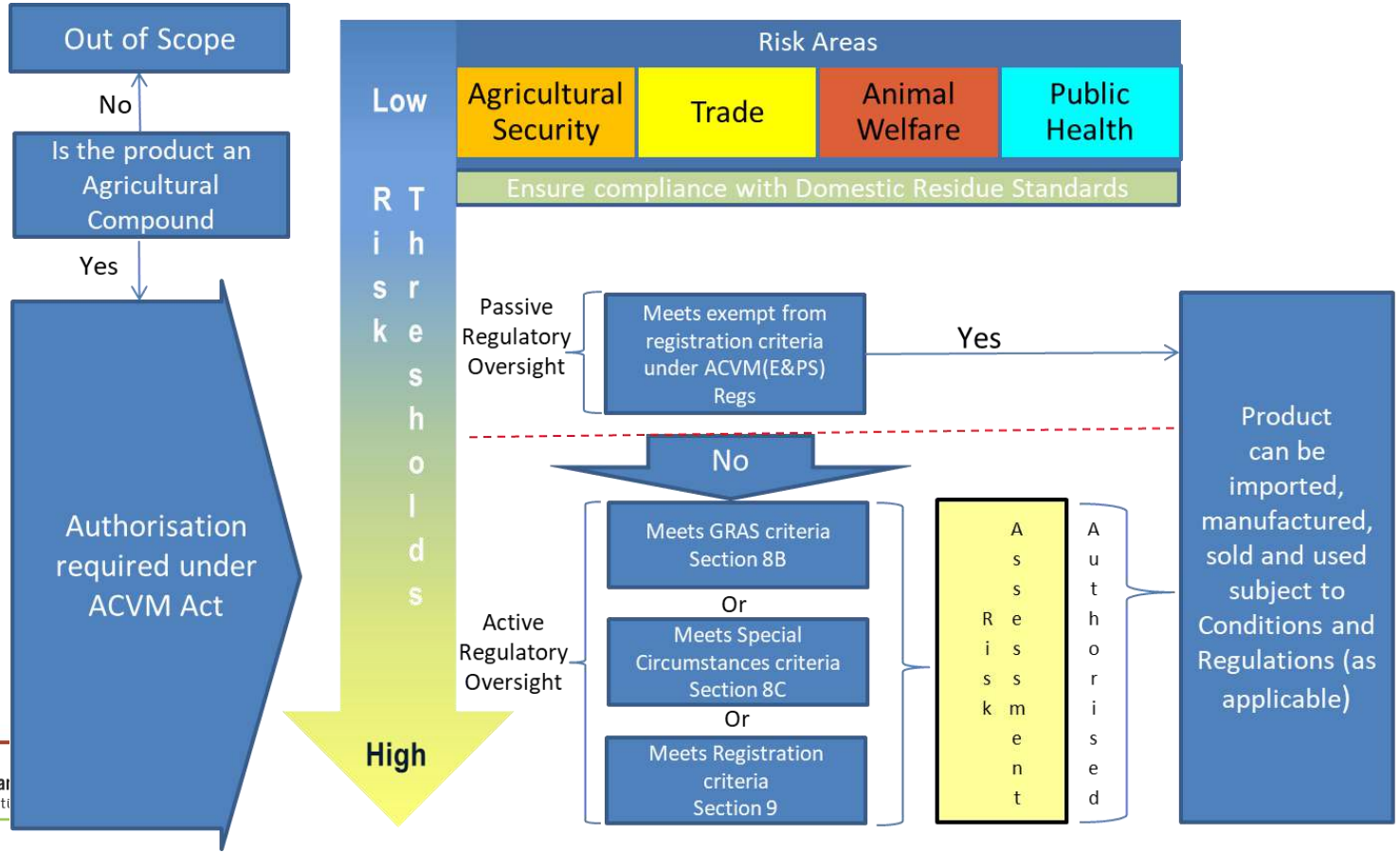
   (ii) risks to animal welfare; and

   (iii) risks to agricultural security

b) Ensure that the use of an agricultural compound does not result in breaches of domestic food residue standards

c) Ensure the provision of sufficient consumer information about agricultural compounds

ACVM Risk Framework



Risk Management by Exemption

- Risk profile for certain products is at level that registration is not required

Exempt from Registration via Regulations

- Exempt from registration products are specified by categories in schedule 2 of the ACVM (Exemptions & Prohibited Substances) Regulations
- The Regulations state general requirements for the exempt product categories:
  - a) Documented systems
  - b) Labelling
  - c) Fit for Purpose
  - d) Advertising

The ACVM Act and Regulations

Registration of ACVMs

The goal of ACVM risk assessment is:

- To determine whether sufficient information has been provided to ensure the benefits of registration always outweigh the risks, and

- To determine whether the risks can be managed with the application of conditions of registration

Regulatory Tools – Conditions of Registration

Section 23 of the Act allows conditions to be set on:

- Use
- Specifying standards in many areas including:
    - Competence
    - Quality and purity
    - Labelling
    - Advertising
    - Testing methods
- Restrictions on who can manufacture, import, or use

Risk Management by Registration

Veterinary Medicines are registered as either **Restricted Veterinary Medicines (RVMs)** or **Unrestricted Veterinary Medicines**

Unrestricted Veterinary Medicine	Restricted Veterinary Medicine
Risks require active regulatory control, but **owners can manage use including residue risks if all label instructions are followed**	Risks require active regulatory control AND **veterinary oversight needed for diagnosis, treatment, and monitoring,** in addition to label instructions
Off-label use can be directed by user, but only with expert advice regarding welfare	All use is directed by the authorising vet, and all risks managed by vet
Can be sold “over the counter”	Can only be sold under veterinary authorisation

Registration Process

Registration Information Requirements

All products requiring registration undergo risk assessment and approval process evaluating:

- Formulation chemistry and manufacturing
  - Good Manufacturing Practice
- Efficacy
- Target animal/Plant safety
- Residues (if applicable)
- Product/risk-specific data as needed (AMR)

Registered pursuant to the ACVM Act 1997, No. A7085
See www.foodsafety.govt.nz for registration conditions

Post-Registration Regulation

Post-Registration Regulation

Products are maintained and updated by both the registrant companies and ACVM for the life of the product

Companies must maintain their product registrations by:

- Keeping all product information and labelling up to date through approval for changes before they are actioned
- Report all AERs from field use, and advise major AERs from overseas
- Provide all new information that may impact the product's registration or risk profile

Post-Registration Regulation

ACVM Act allows ACVM to:

- Recall Products
- Suspend registrations
- Issue prohibition notices

❖ **Evaluation of adverse events**

❖ **Reassessments**

Post-Registration Regulation

This means ACVM can:

- Enforce compliance to approval, including advertising
- Evaluate domestic and international issues with products and/or ingredients as they occur
- Work with other parts of MPI (residue monitoring programmes, Animal Products, Market Access) to indirectly monitor product use through verification and monitoring

Adverse Events

- An **adverse event** is any observation in animals or plants that is **unfavourable** and **unintended**, including:
    - Side effects after application or treatment
    - An animal or crop safety issue
    - A residue issue
    - Lack of efficacy
    - Interactions with other products

Reassessments

Reassessments can be driven by:

- MPI post-registration monitoring findings - AERs, GMP audits, residues monitoring
- Emerging domestic risk – industry-detected residues or other issue with product use
- Emerging international risk – overseas compound ban, use restrictions that change trade risk

The Reassessment Process

- **Potential outcomes**
  - Status quo
  - Revision of product information (claims, label statements/warnings, WHPs)
  - Revision of registration controls (new conditions of registration, change of status, more/less restriction)
  - De-registration

WOAH SFVP System

- **Potential outcomes**
  - Status quo
  - Revision of product information (claims, label statements/warnings, WHPs)
  - Revision of registration controls (new conditions of registration, change of status, more/less restriction)
  - De-registration

Our non-compliance monitoring and reporting tools

- Notification forms for registrants (MAH) to notify us of their own non-compliant products
- Public online form to report potential non-compliant product or activities
- Adverse event reporting
- Audits and Inspections of premises
- Routine local verification testing of products is not usually conducted unless an investigation on non-complying or falsified product indicates additional testing is necessary.

VSAFE Pilot System

- We’ve received minimal reports of substandard and falsified products circulating in New Zealand to date, and none since the initiation of VSAFE. Note: we do not perform routine additional testing.
- Therefore, New Zealand has not needed to report a Substandard or Falsified Veterinary Product.

VSAFE Pilot System

- **Comments/feedback:**
  - As we haven't completed the immediate notification form, we cannot comment on the use of this form.
  - The monthly declaration form for the absence of incidents is straightforward to complete.
  - Would be useful to have bullet points outlining the key points and summary at the beginning of the Alert to assist with a quick triage/risk assessment of the Alert.
  - Does VSAFE propose to work alongside the Rapid Alert System (RAS), or will Regulatory Authorities need to use both systems?

Thank you!

Any Questions?

WOAH Immediate Notification Form for SFVP

1st Workshop on Substandard and Falsified Veterinary Products (SFVP)
and WOAH pilot Veterinary Monitoring and Surveillance System for SFVP (WOAH - VSAFE)
Asia and Pacific Region

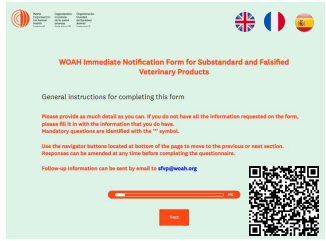
Andrés García Campos
Programme Manager - AMR & VP Department

13th June 2024 - Bangkok

World Organisation for Animal Health
Founded in 1924
Organisation mondiale de la santé animale
Fondée en 1924
Organización Mundial de Sanidad Animal
Fundada en 1924

Veterinary Monitoring and Surveillance System for Substandard and Falsified VMPs

Member



VSAFE

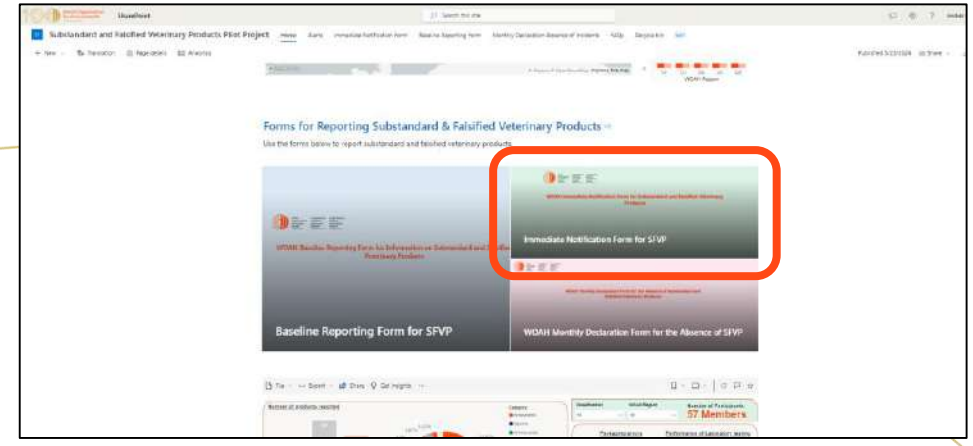
Members with access, control and analysis of their own data

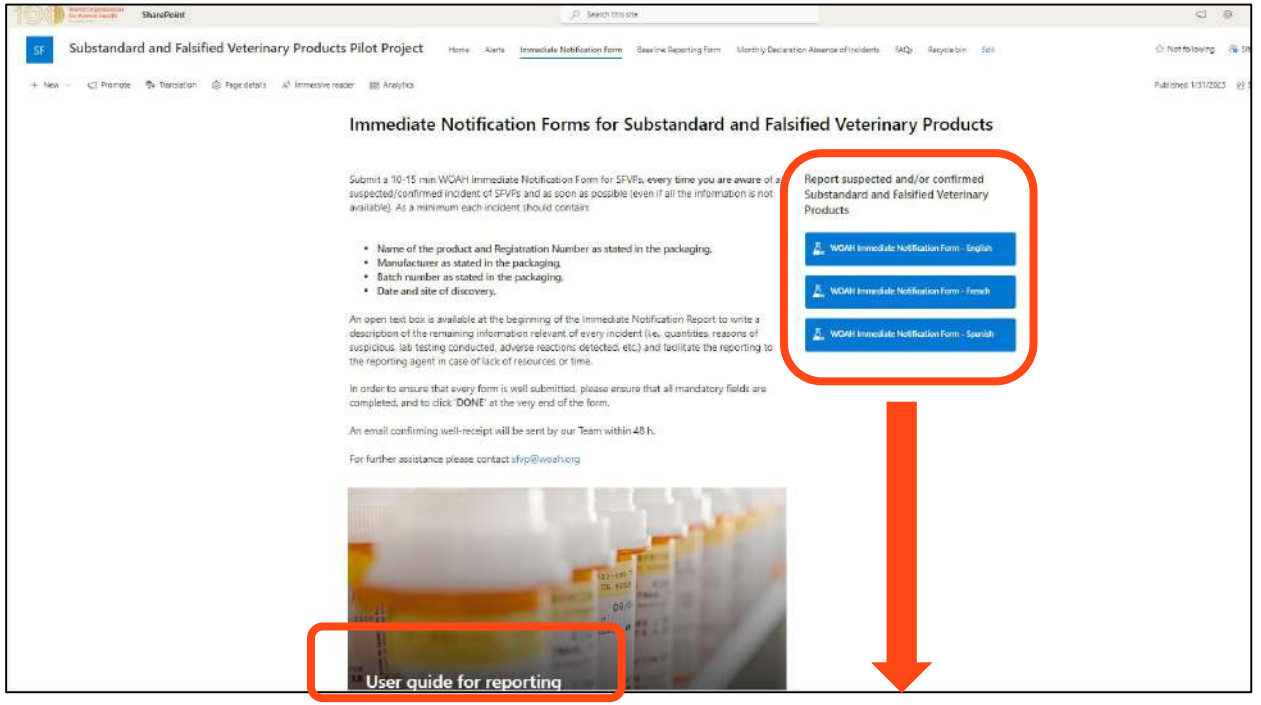
Repository of incidents available at regional level

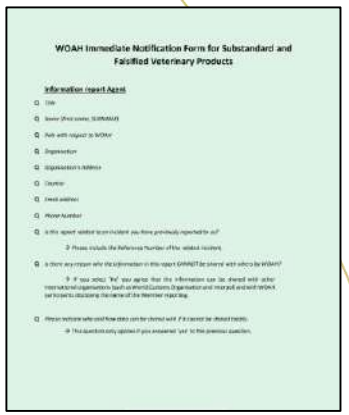
Public Alerts with recommendations (subject to conditions to fulfill)

Annual report

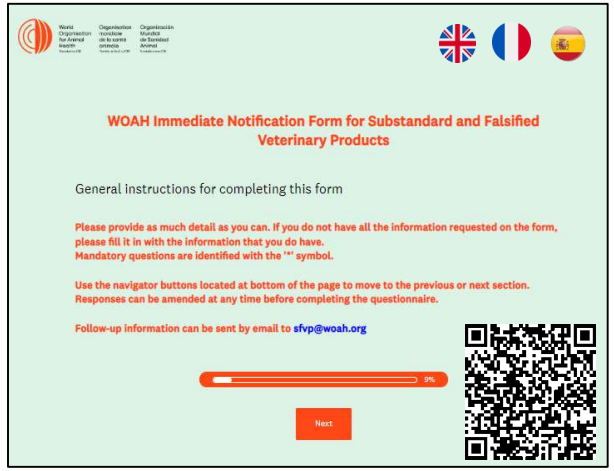
Location of WOAH Immediate Notification Form in VSAFE



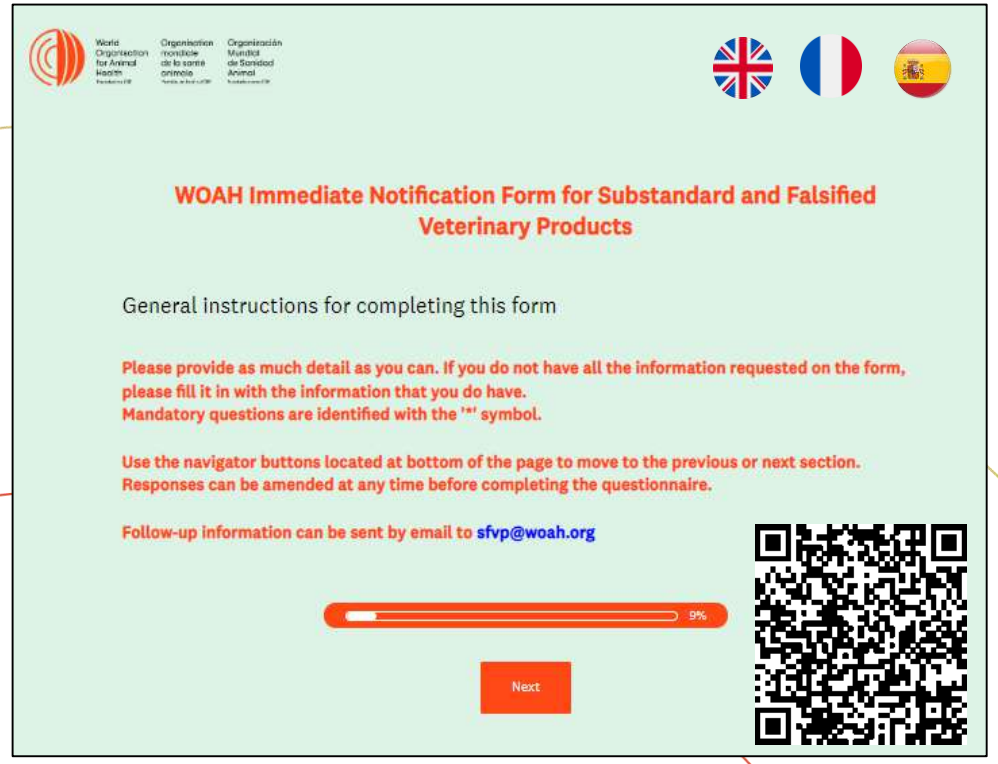




Instructions valuable before starting reporting



WOAH Immediate Notification Form



To be completed every time a Member has an incident to report

General Information

Is there any reason why the incident cannot be shared with others ?

Details of suspect

Brand Name

Name & strength of Active Ingredient/s

Pharmaceutical form & route of administration

MAH / manufacturer

Product Identification :

- Registration Number
- Batch Number
- Expiry date
- Date of manufacturing

Target species (on and off-label if known)

Photographs available

Details of Discovery

Date of discovery

Date notification to Authorities

Type of units & quantities

Reason of discovery

Site of discovery

Data source

Preliminary Assessment

Is product registered ?

Errors in packaging /labelling ?

Laboratory testing undertaken ?

Current Response

Recall ?

Alert ?

Adverse reactions ?

Consent to share data with others – mandatory question

* 10. **Is there any reason why the information in this report CANNOT be shared** with others by WOAH?

If you select 'No' you agree that the information can be shared with other international organisations (such as World Customs Organisation and Interpol) and with WOAH participants disclosing the name of the Member reporting.

○ **No**

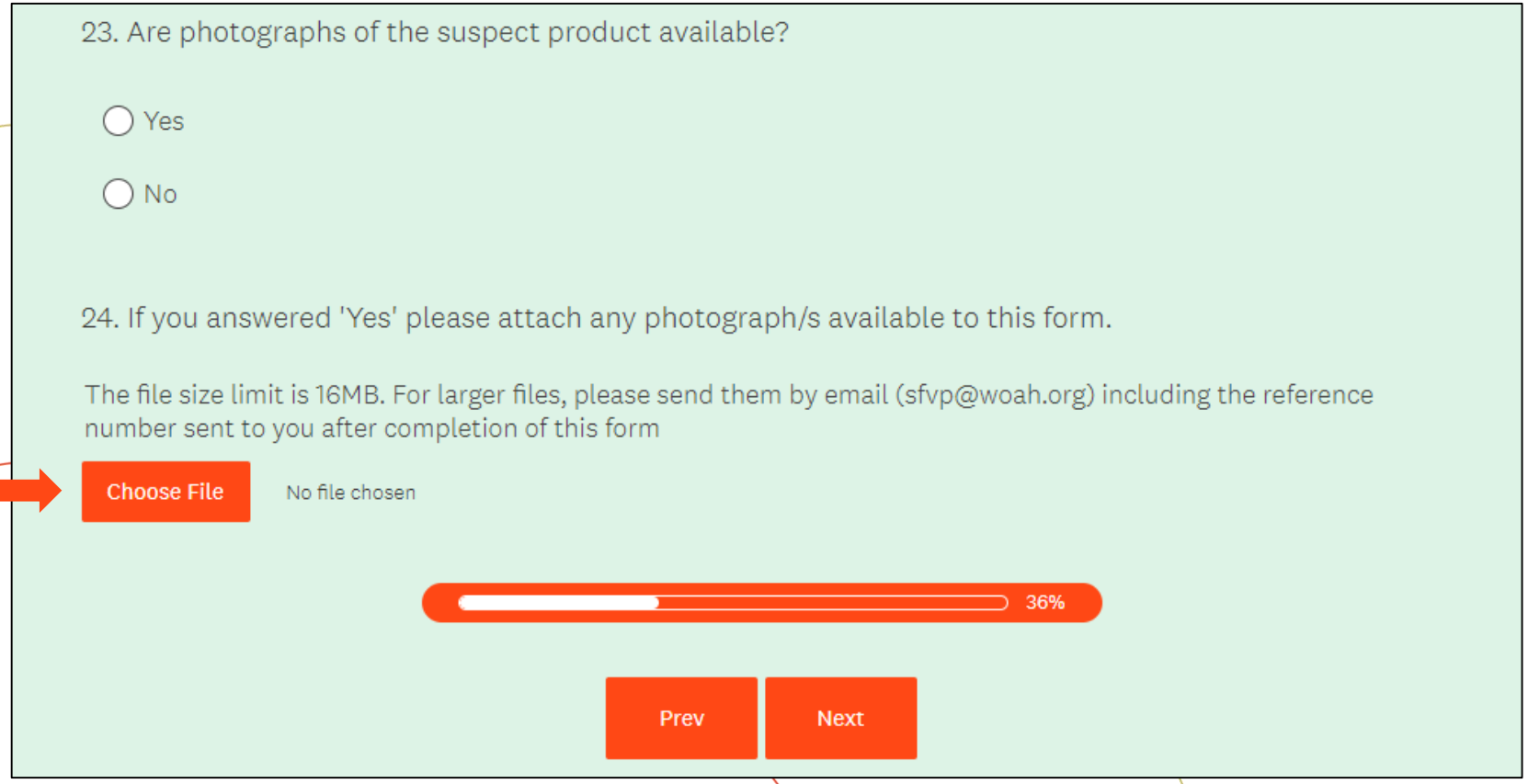
◉ **Yes**

11. Please indicate who and how data can be shared with if it cannot be shared totally

- ○ It can be **shared with other international organisations** (such as World Customs Organisation and Interpol) **and** with **WOAH participants** at regional level without disclosing the name of the Member reporting the incident but indicating the region affected.
- ○ It cannot be shared with other international organisations (such as World Customs Organisation and Interpol) but it can be **shared with WOAH participants only**, without disclosing the name of the Member reporting the incident but indicating the region affected.
- ○ It cannot be shared with other international organisations (such as World Customs Organisation and Interpol) but it can be **shared with WOAH participants only**, disclosing the name of the Member reporting the incident.
- ○ Other (please specify)

In all instances, participants consent that the information can be used for writing the annual public report describing the presence of SFVPs regionally and globally anonymously (that is, no disclosing the country reporting)

Upload files : for example, photographs (if available)



Ideally

Focused with reference size of size

Minimum information shown

Brand Name

Name & strength of API

Name of MAH / manufacturer

Product Identification :

- Registration Number
- Batch Number
- Expiry date
- Date of manufacturing

Inconsistencies in label/packaging detected

Type of responses

Multiple selection

30. If laboratory testing was undertaken, what were the results?

- [ ] Correct amount of API specified on the label
- [x] **API amounts ABOVE the specified on the label (overdose)**
- [ ] API amounts BELOW the specified on the label (underdose)
- [ ] API other than that specified on the label detected
- [ ] No API detected
- [x] **Presence of impurities out of the specifications**
- [ ] Bacteria contamination
- [ ] Other (please specify)

Single selection

27. Has the manufacturer or marketing authorisation holder (MAH) been contacted to confirm if they produced the veterinary product?

- ( ) Yes, and they confirmed they did NOT make the product
- (•) **Yes, and they confirmed they did make the product**
- ( ) Yes, but a response has not yet been received
- ( ) No, they have not been contacted
- ( ) Unknown

even if the manufacturer is located outside of your country

Type of responses

Field text

Abcdefghijklmnopqu ...

31. **Date of discovery** (*DD/MM/YYYY*) if known

32. **Date of notification to the veterinary authority** (*DD/MM/YYYY*) if known

Respect format proposed

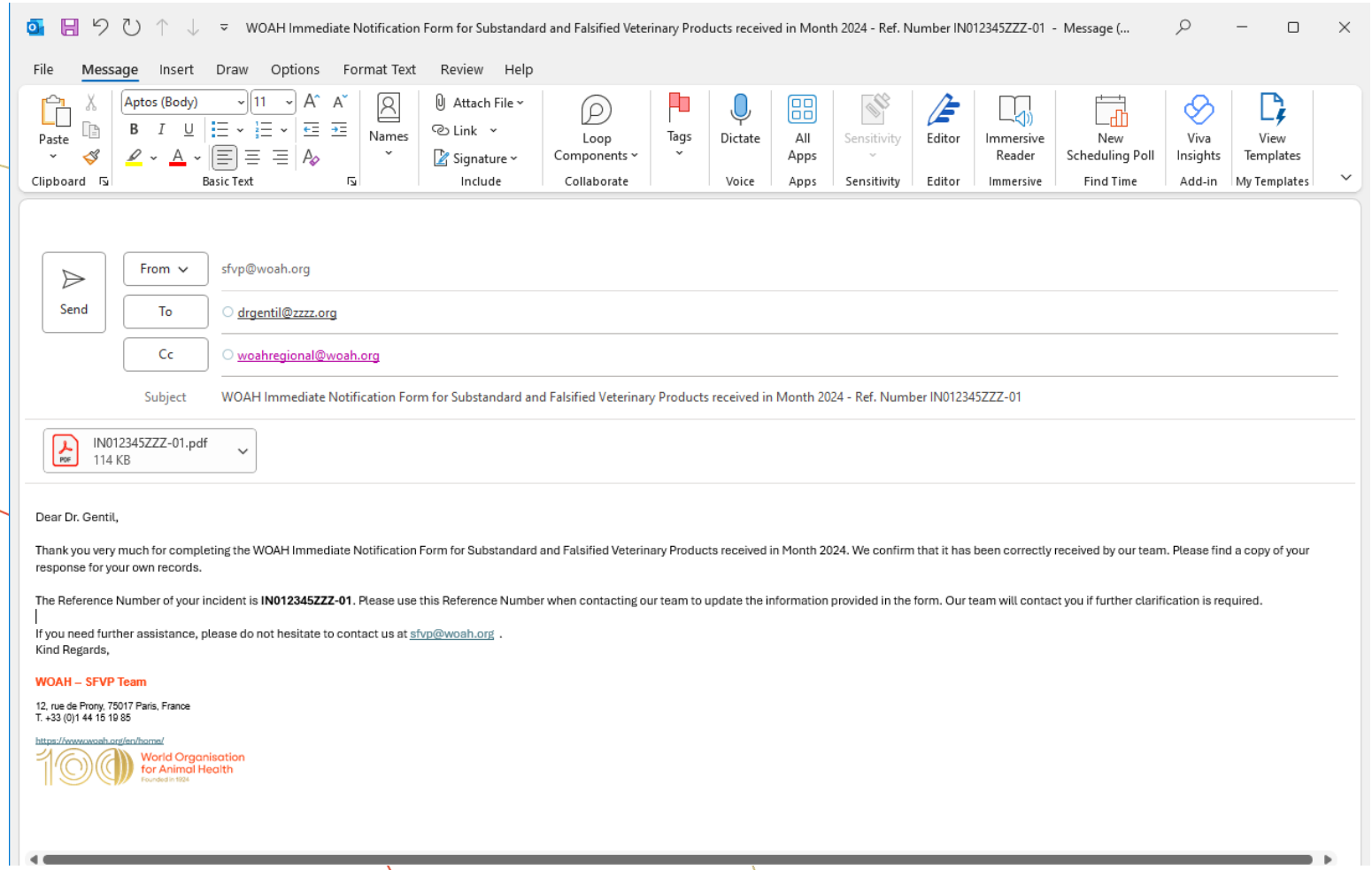
Dropdown

37. Site of discovery of suspect veterinary product(s) (i.e., where in the supply chain was the suspect veterinary product found/purchased)

- Customs
- Distributor
- Farm Shops/Agricultural Supplier
- Feed Mill
- Importer
- Internet
- Marketing Authorisation Holder or Manufacturer
- Pharmacy
- Retail store (authorised to sell veterinary products)
- Retail store (unauthorised to sell veterinary products e.g. street vendor)
- Veterinary clinic
- Wholesaler
- Other
- Unknown

Avoid blank responses as much as possible

Acknowledgement with Reference Number – within 48 h



It's your time ...

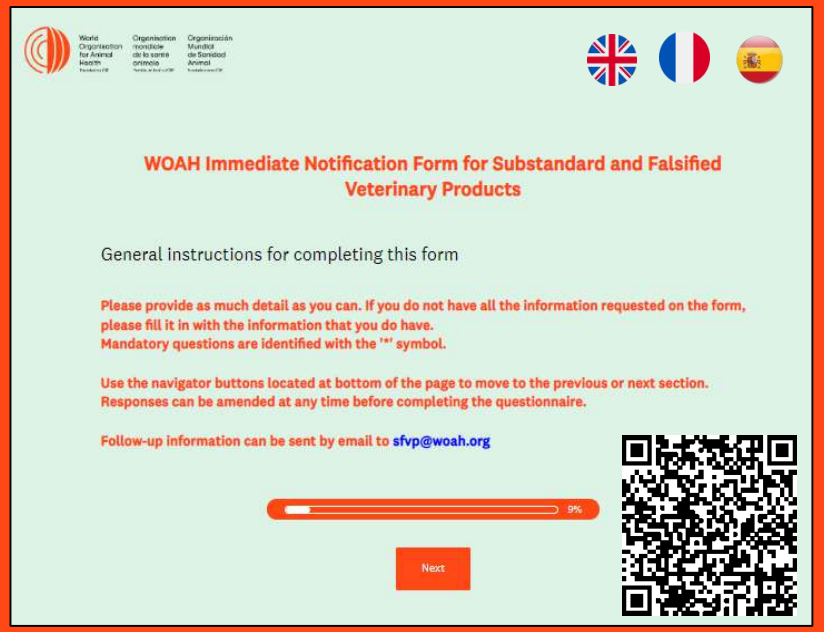
Until 1 pm

Use the case scenario 1 presented for the following :

1. Join and get familiarised with VSAFE

2. Complete as many WOAH Immediate Notification Forms for SFVP as required

3. Use the Feedback and suggestions form to highlight
   - any improvements for VSAFE
   - any improvements for the immediate notification form



Thank you

Merci

Gracias

sfvp@woah.org

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
Founded in 1924

Organisation mondiale de la santé animale
Fondée en 1924

Organización Mundial de Sanidad Animal
Fundada en 1924

Case Scenario 2

1st Workshop on Substandard and Falsified Veterinary Products (SFVP) and WOAH pilot Veterinary Monitoring & Surveillance System for SFVP (WOAH - VSAFE) for WOAH Focal Points for Veterinary Products and Regulators of Veterinary Medicinal Products in Asia and Pacific

Bangkok 12-14 June 2024

World Organisation for Animal Health
Founded in 1924
Organisation mondiale de la santé animale
Fondée en 1924
Organización Mundial de Sanidad Animal
Fundada en 1924

Special Acknowledgement

World Health Organization

Rutendo Kuwana
Anita Sands
Naseem Hudroge
Pernette Bourdillon
Esteve

ISF Team

Meeting of focal points for WHO Global Surveillance and

World Organisation for Animal Health
Founded in 1924

Disclaimer

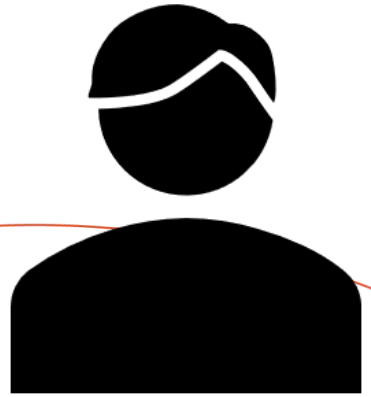
The case presented is not real and created only for demonstration purposes.

Names, numbers and incidents are the products of the author's imagination.

Any resemblance to actual events is purely coincidental

Instructions

Divide in 5 groups



Each group elects one rapporteur

Instructions

- Each rapporteur completes the tables included in the presentation sent in you email
- Send the presentation completed at sfvp@woah.org
- Each rapporteur will present a piece of the updates
- WOAH will wrap the session with main points of reflection

Instructions

- You will receive 5 updates
- Each update contains limited information
- Use this information to decide the enquires, investigations you pursue, and next steps
- 10-15 min for each update

What facts can you establish?	What information are you missing?	What risks did you identify?	What action did you take?

There is no wrong answer. There can be multiple solutions

Update 1 | Update 2 | Update 3 | Update 4 | Update 5

You work as part of the inspection team of veterinary products in the national competent authority (NCA) in Easos.

On 10 June 2024 you receive a call from someone in your Customs Authority. The caller says she is a Customs officer based at the Port.

They have stopped a container that contains boxes of vials of vaccines for veterinary use, and they are unsure if the medicines are authorised for import and what the legal requirements are.

According to the Port Authority the container must leave the port and be delivered to the importer within 24 hours.

The NCA is invited for an urgent inspection early next day. The container must leave the premises by 16:00 that day.

When opening the cargo, you estimate a total of 50 boxes of inactivated rabies vaccine for dogs CLEARRABIES. Each box contains 10 bottles (= 10 doses) of ≥1 I.U. inactivated G52 strain rabies virus / dose. At closer inspection, you note that there are some inconsistencies between the colour for some boxes.

- **Name: CLEARRABIES**
- **Registration number : 1108-VC**
- **Batch Number : 69007-ADF**
- **Manufacturing date : 12/2022**
- **Expiry Date : 12/2025**
- **Manufacturer : Vaccbest S.A.**
- **Marketing Authorisation Holder (MAH) : PHARMVACDOG LIMITED**
- **Special precautions for storage : Store and transport refrigerated (2 °C to 8 °C)**

Documentation of the cargo only provides the address where the vaccines are to be delivered ‘Plot 253, Arya’s Industrial State, City of Brayes, Eases’. There is no named importer nor of the exporter.

When you drive back to the NCA, you pass in front of Plot 253, Arya's Industrial State by chance. You notice it is a medium-size well-fenced warehouse, with no signs outside.

According to the National Database of registered veterinary medicinal products, it is confirmed that CLEARRABIES has PHARMVACDOG LIMITED as MAH. You speak to the PHARMVACDOG LIMITED responsible person, and they confirm the company is not responsible for the container inspected.

Vaccine boxes are confiscated by the authorities until further clarification. The container has been cleared and has left the port.

The Veterinary Services of the country are currently working towards the endorsement of official control programme for dog-mediated rabies.

On 12 June 2024, the NCA decides to initiate an inspection at the warehouse located at Plot 253, Arya's Industrial State. From the outside it appears empty. You are given access by a security guard of the Industrial State.

The warehouse lacks ventilation, windows or cooling system. You find several veterinary medicinal products, including :

- 1,000 boxes of CLEARRABIES with the same details and stored at room temperature.
- 30 bottles (1L) of TICKATIK pour-on solution for use in cattle for tick control.

Following your communication with the genuine manufacturer of CLEARRABIES (Vaccbest S.A.) it is confirmed that the pictures of the products in the photos you shared are falsified.

In the warehouse you find a rental agreement and is rented to 'Tyrion Lannister'.

You identify Dr Tyrion Lannister as an authorised veterinary practitioner operating at SERVIAGRO S.L. His premises are located at Lot 266, Arya's Industrial State, just 2 blocks aways from the warehouse inspected.

SERVIAGRO is not an authorised wholesaler, and there are no import notifications. Dr Lannister is not named as a responsible person for any authorised importer of veterinary products.

Your NCA now conducts an inspection of SERVIAGRO S. L. The inspection finds 25 packs of CLEARRABIES and 75 bottles of TICKATIK in a storage unit at the back of the premises. All products present similar irregularities to those confiscated from Plot 253, Arya's Industrial State, City of Bravos.

Following your reporting through VSAFE, WOAH SFVP Team notes that falsified versions of CLEARRABIES were reported in two other countries, and TICKATIK was reported in seven other countries.

Points for reflection

Important of coordination with stakeholder and Authorities – particularly in situations under pressure

Importance of visual examination of products (outer cartons, labels, etc.) and good quality of pictures for confirmation from manufacturer

Importance of impacts of Falsified Vaccines in Global control programmes for animal health, and One-Health – use VSAFE as tool to support and to achieve Goals. Consider Practical Guidelines for National Procurement of Veterinary Vaccines from WOAH

Importance of follow-up cases : More falsified products detected following one case – organised criminals

Thank you

Merci

Gracias

sfvp@woah.org

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
Founded in 1924

Organisation mondiale de la santé animale
Fondée en 1924

Organización Mundial de Sanidad Animal
Fundada en 1924

Case Scenario 2

1st Workshop on Substandard and Falsified Veterinary Products (SFVP) and WOAH pilot Veterinary Monitoring & Surveillance System for SFVP (WOAH - VSAFE) for WOAH Focal Points for Veterinary Products and Regulators of Veterinary Medicinal Products in Asia and Pacific

Bangkok 12-14 June 2024

Group Number : X

World Organisation for Animal Health
Founded in 1924

Organisation mondiale de la santé animale
Fondée en 1924

Organización Mundial de Sanidad Animal
Fundada en 1924

Instructions

- You will receive 5 updates
- Each update contains limited information
- Use this information to decide the enquires, investigations you pursue, and next steps
- 10-15 min for each update

What facts can you establish?	What information are you missing?	What risks did you identify?	What action did you take?

There is no wrong answer. There can be multiple solutions

Instructions

- Elect a rapporteur for completion of the tables
- Each rapporteur will present a piece of the updates
- Send presentation at sfvp@woah.org
- WOAH will wrap the session with main points of reflection

Disclaimer

The case presented 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

Update 1 | Update 2 | Update 3 | Update 4 | Update 5

What facts can you establish?	What information are you missing?	What risks did you identify?	What action did you take?

Update 1 | Update 2 | Update 3 | Update 4 | Update 5

What facts can you establish?	What information are you missing?	What risks did you identify?	What action did you take?

Update 1 | Update 2 | Update 3 | Update 4 | Update 5

What facts can you establish?	What information are you missing?	What risks did you identify?	What action did you take?

Update 1 | Update 2 | Update 3 | Update 4 | Update 5

What facts can you establish?	What information are you missing?	What risks did you identify?	What action did you take?

Update 1 | Update 2 | Update 3 | Update 4 | Update 5

What facts can you establish?	What information are you missing?	What risks did you identify?	What action did you take?

Thank you

Merci

Gracias

sfvp@woah.org

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
Founded in 1924

Organisation mondiale de la santé animale
Fondée en 1924

Organización Mundial de Sanidad Animal
Fundada en 1924

INTERPOL




Illicit Goods & Global Health Programme (IGGH)

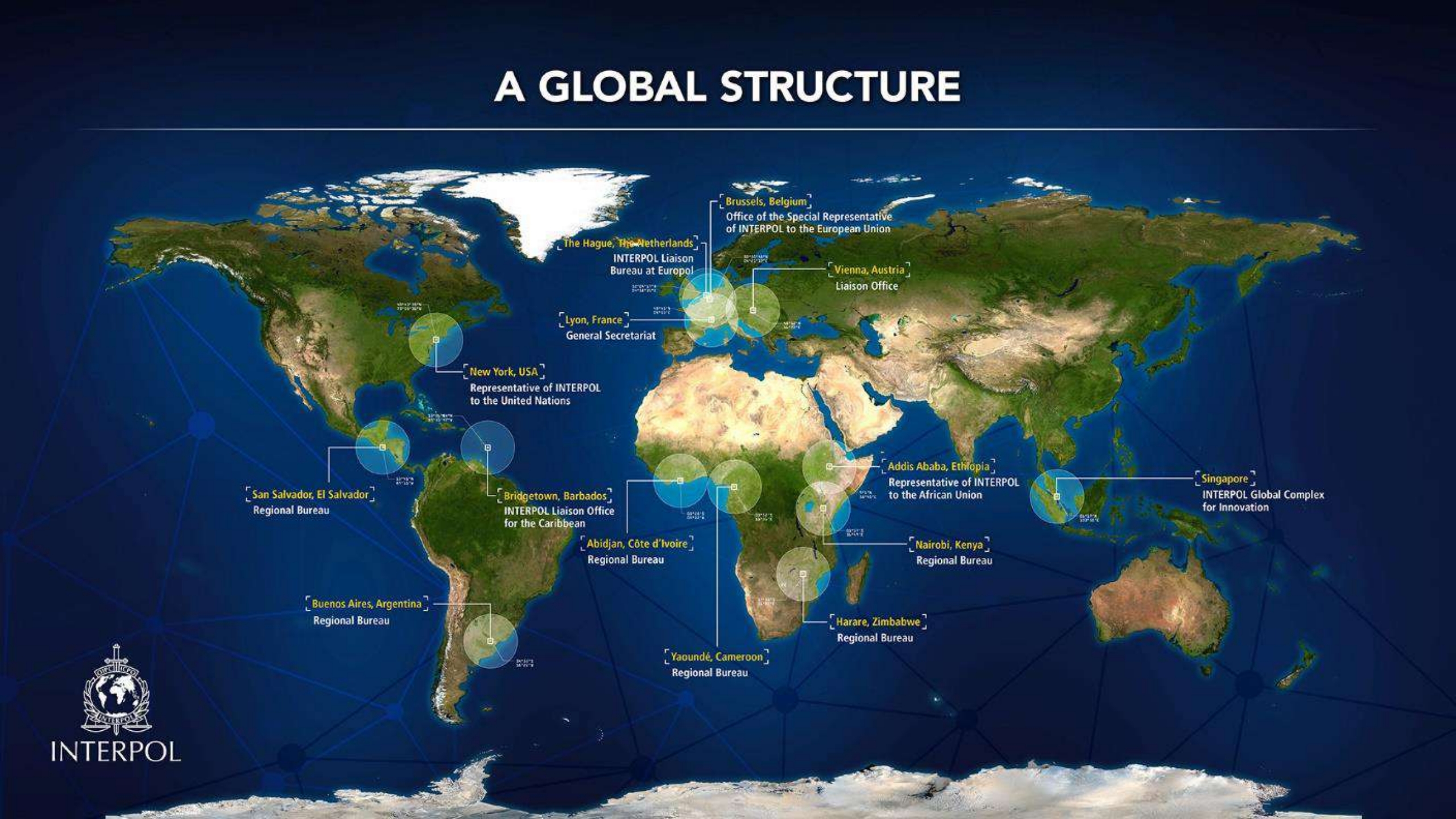
Public Health and Pharmaceutical Crime

Operation PANGEA – a way to react towards SFVPs

Chi Wang LAM, Coordinator

13 June 2024

A GLOBAL STRUCTURE



196 MEMBER COUNTRIES CONNECTED
THROUGH A SECURE NETWORK

INTERPOL

The National Central Bureau is a country's focal point for all INTERPOL activities.

Each of our member countries hosts an INTERPOL National Central Bureau (NCB). This connects their national law enforcement with other countries and with the General Secretariat via our secure global police communications network called I-24/7.

Many crimes today have an international aspect; think of cybercrimes, fugitives, or stolen or illicit goods that are driven by organized crime groups. When a crime goes beyond their national jurisdiction, a country needs international support to solve it.

The heart of INTERPOL

NCBs are at the heart of INTERPOL and how we work. They seek the information needed from other NCBs to help investigate crime or criminals in their own country, and they share criminal data and intelligence to assist another country.

As part of their role in global investigations, NCBs work with:

- Law enforcement agencies in their own country
- Other NCBs and Sub-Bureaus around the world
- The General Secretariat's offices worldwide

NCBs can also develop training programmes for their national police to raise awareness on INTERPOL's activities, services and databases.

Sharing criminal data

NCBs contribute national crime data to our global databases, in accordance with their respective national laws. This ensures that accurate data is in the right place at the right time to allow police to identify a trend, prevent a crime, or arrest a criminal. For example, our Red Notices alert police in all countries to wanted persons.

INTERPOL

INTERPOL CONNECTS

We connect police around the world – both technically and in person – bridging jurisdictions, time zones and languages.

INTERPOL is unique. It is the only organization with the mandate and technical infrastructure to share police information globally.

All 195 member countries are connected to each other and to the General Secretariat via a secure communications system called I-24/7. It also allows them to access our databases and services in real-time, from both central and remote locations.

We also coordinate networks of police and experts in different crime areas, who come together through working groups and at conferences to share experiences and ideas.


INTERPOL
INTERPOL
CONNECTING POLICE
REAL-TIME ACCESS TO CRITICAL CRIMINAL DATA
DAY AND NIGHT

INTERPOL

INTERPOL EMPOWERS

We empower law enforcement agencies to make a long-term difference to their national security.

We provide police with the knowledge, skills, and sustainable tools needed to meet today's challenges.

We offer investigative support, such as forensics and assistance in locating fugitives around the world, as well as coordination support for on-the-ground operations.

Training is an important part of what we do so that officials know how to work efficiently with our services and embed best practices into their ongoing work.

The National Central Bureaus in our member countries are at the heart of how we work. By accessing INTERPOL's global capabilities they can make a difference to their regional, national and local communities.

INTERPOL ALERTS

We are the global hub for criminal data, with mechanisms for alerting our member countries when action is needed.

Police need up-to-date global data on criminals in order to carry out successful international investigations. Our 19 databases contain millions of records with information on people, stolen property, weapons, and more. Every hit can help move an investigation forward. This can happen in real-time as a database search will return a result in just 0.5 seconds on average.

Our flagship system of notices enables countries to share alerts and requests for information worldwide, while criminal intelligence analysis joins gives insight into the the inner-workings and driving factors of crime phenomena and criminal enterprises.

INTERPOL NOTICES

RED NOTICE
WANTED PERSONS

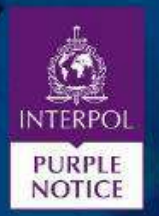
YELLOW NOTICE
MISSING PERSONS

BLUE NOTICE
ADDITIONAL INFORMATION

BLACK NOTICE
UNIDENTIFIED BODIES

GREEN NOTICE
WARNINGS AND INTELLIGENCE

ORANGE NOTICE
IMMINENT THREAT



PURPLE NOTICE
MODUS OPERANDI

INTERPOL–UN SECURITY COUNCIL SPECIAL NOTICE
ENTITIES AND INDIVIDUALS SUBJECT TO UNSC SANCTIONS

INTERPOL

INTERPOL INNOVATES

We constantly innovate to stay on top of policing issues in today's fast-changing world.

Technology, such as artificial intelligence, can be a threat to security but can also be a tool for police and a source of evidence.

Since crimes evolve, we keep an eye on the future through research and development in international crime and trends.

INTERPOL has been a constant presence in international security over the last 100 years, evolving and innovating continually, and will remain relevant in the future.

INTERPOL

INTERPOL ADVOCATES

As the voice of global law enforcement, we represent police in the international arena.

INTERPOL gives a voice to its membership on the global stage while maintaining its neutrality and inspiring trust.

Our seven Global Policing Goals form the basis for advocacy before national governments. The goals are aligned with the United Nations 2030 Agenda for Sustainable Development.

We champion the cause of policing with governments, international organizations and regional bodies in order to effect change.

Looking to the future, we also invest in the next generation of global police leaders, to ensure fresh and relevant voices continue to be heard.

INTERPOL

OUR EXPERTISE TO SUPPORT MEMBER COUNTRY INVESTIGATIONS

- CRIMINAL ANALYSIS
- INNOVATION
- FUGITIVE INVESTIGATIVE SUPPORT
- POLICE DATA MANAGEMENT
- FORENSIC SUPPORT
- CAPACITY BUILDING AND TRAINING
- COMMAND AND COORDINATION CENTRE
- SPECIAL PROJECTS

INTERPOL

TRAINING AND OPERATIONAL SUPPORT TO MEMBER COUNTRIES

Pharmaceutical crime operations

OPERATION PANGEA

- **INTERPOL led Global Operation;**
  (Pre , Operational and Post)
- **Targets the online sales of illicit pharmaceutical products;**
- **Remove from circulation;**
- **Raise awareness.**

Pharmaceutical crime operations

OPERATION PANGEA

- Collection of Data and Disseminate Intelligence;
- Identify cases and coordinate international investigations;
- Provide recommendations;
- Enhance Capacity Building;
- Strengthening Partnership.

Our response

RAISING AWARENESS

"A significant challenge is too many people still think of counterfeiting and piracy as a victimless crime, but these are serious transnational organized crimes run by extensive and complex criminal enterprises."

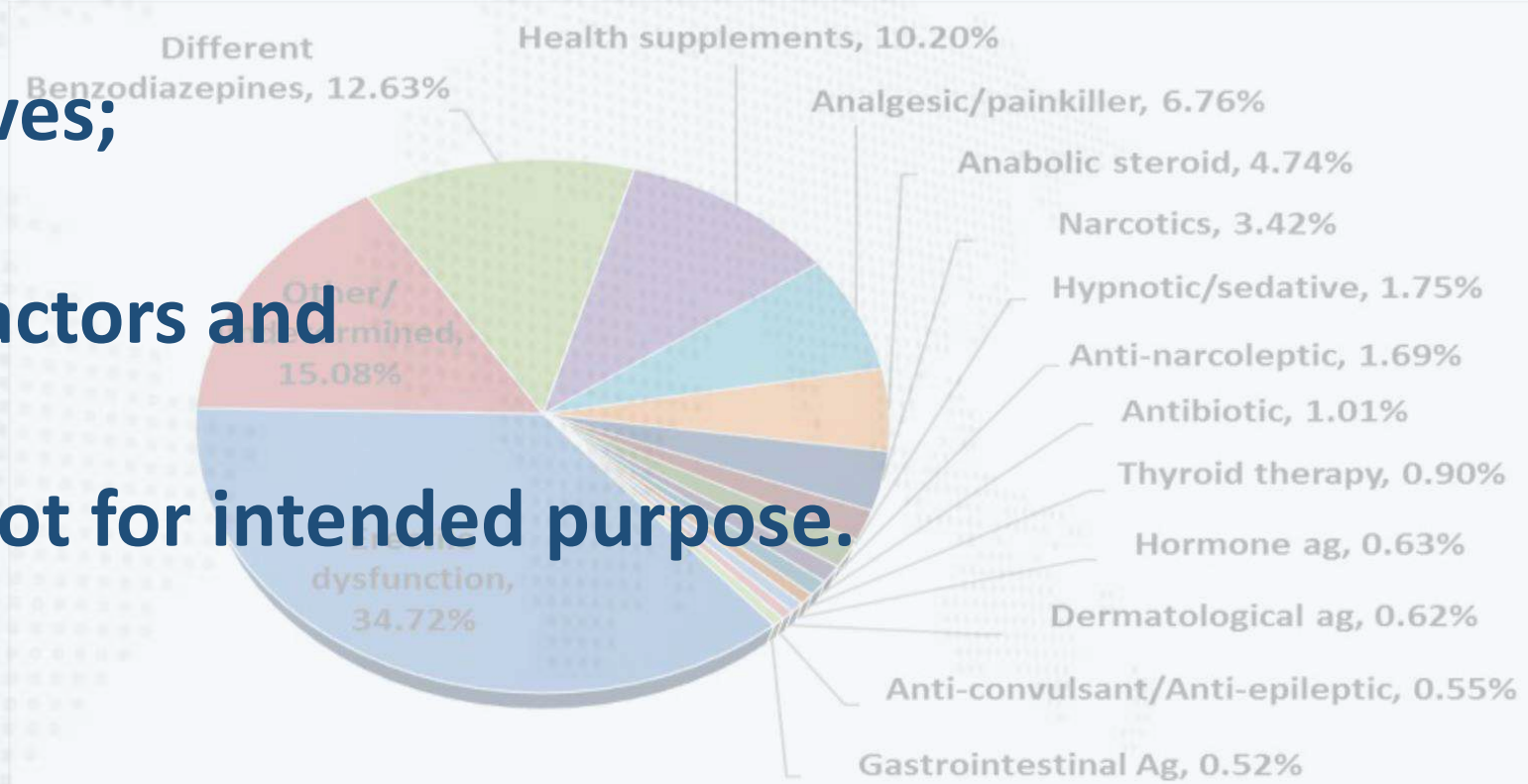
Jürgen Stock, INTERPOL Secretary General

Public Awareness helps to educate and keep consumers' safe and informed!

Pharmaceutical crime operations

COMMONLY SEIZED

- **Trends of seizures evolves;**
- **Impacted by external factors and**
- **To misuse and abuse, not for intended purpose.**



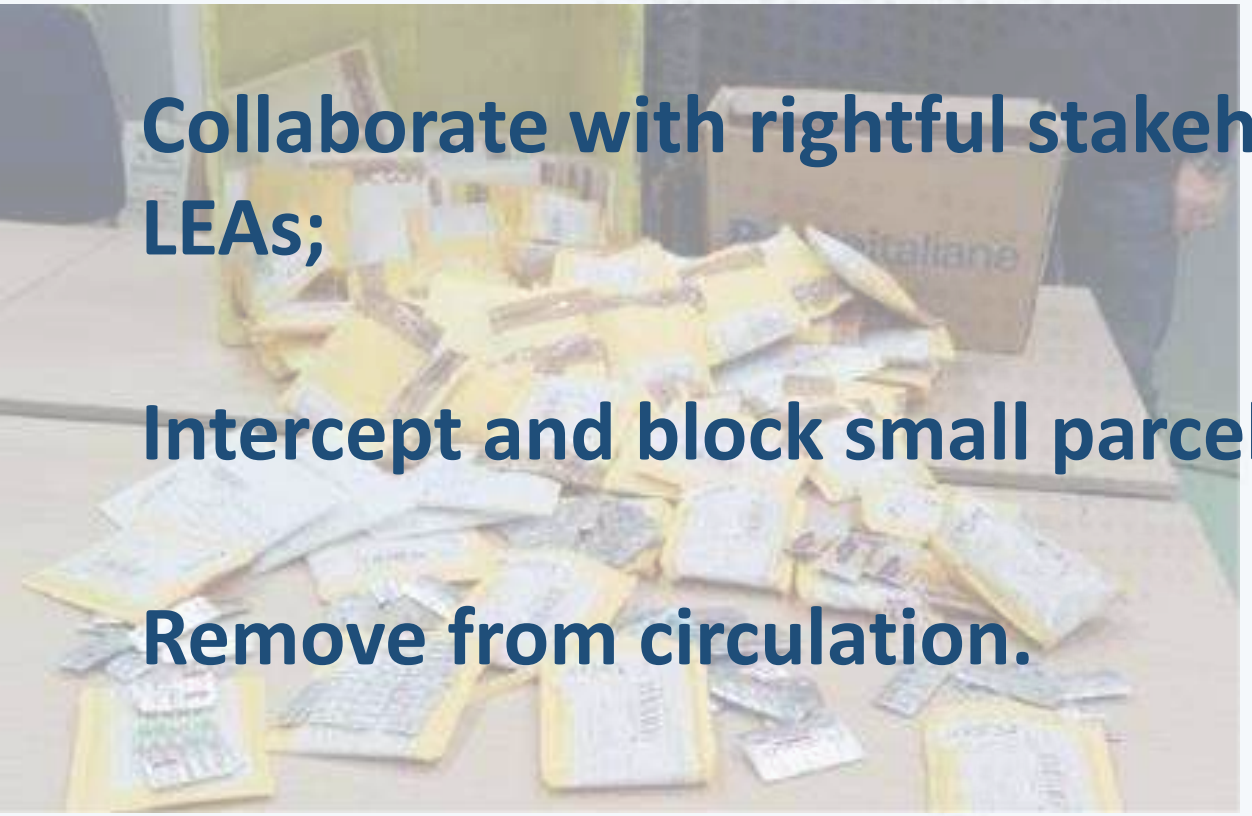
Pharmaceutical crime operations

Observations…

- Increase in unauthorised and unregulated online pharmacies;
- Shipping packages containing smaller quantities;
- Trend of using PO Boxes for rerouting the products is continuing;
- International shipping companies or national post services are misused;
- Mis-declared.

Pharmaceutical crime operations

Deploying New Initiatives…



Collaborate with rightful stakeholders – Industries based and LEAs;

Intercept and block small parcels containing counterfeit goods;

Remove from circulation.

Pharmaceutical crime operations

OPERATION PANGEA ED

- Global Criminal Phenomenon

Significant seizures reported in past editions of Operation Pangea

- 2018 – accounted for 5.1 million units
- 2019 & 2020 – 38% and 56% of total seizures
- 2021 – higher quantities and accounted for 54% of total seizures

- Distribution of illicit EDs through unauthorized and unregulated websites, e-commerce platforms, marketplaces, etc., have become a global and continually expanding problem

Pharmaceutical crime operations

OPERATION FLASH-IPPA

2 million illicit anti convulsing tablets
300 000 other epilepsy treatment tablets
1,600 rapid COVID tests
More than 208,000 COVID-19 protection masks
antibiotics, anti-inflammatories, analgesics and medication used to correct erectile dysfunction, rheumatism and epilepsy.
More than 2000 arrested.

INTERPOL

AFRIPOL

COLLABORATION IS KEY TO SUCCESSFUL OUTCOMES

Exchange Information timely

Strengthening Partnership

United and Collective Approach

Challenges

Illicit goods - partners

STRENGTHING PARTNERSHIP

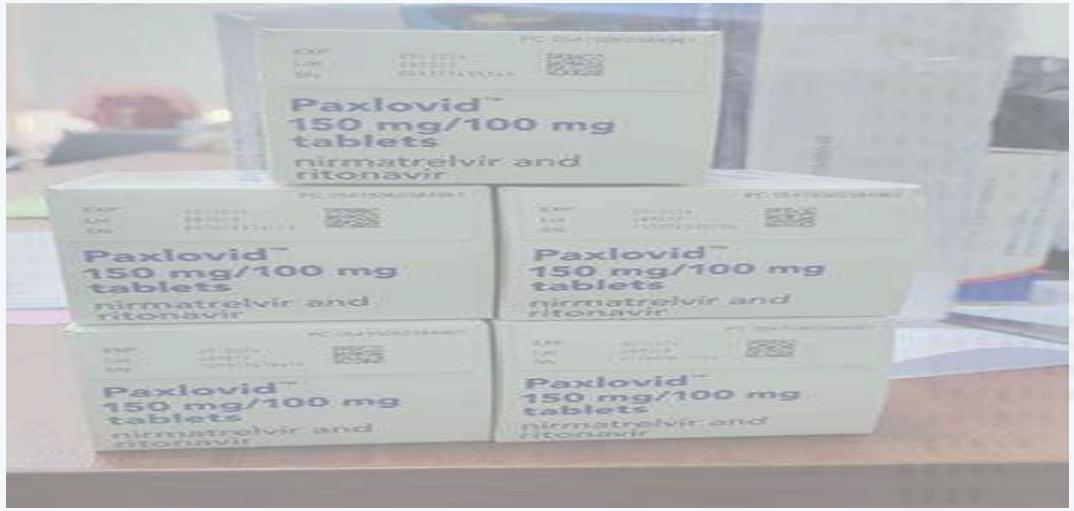
Cross Border Cooperation– Weight loss pills

Malaysia – INTERPOL – Thailand

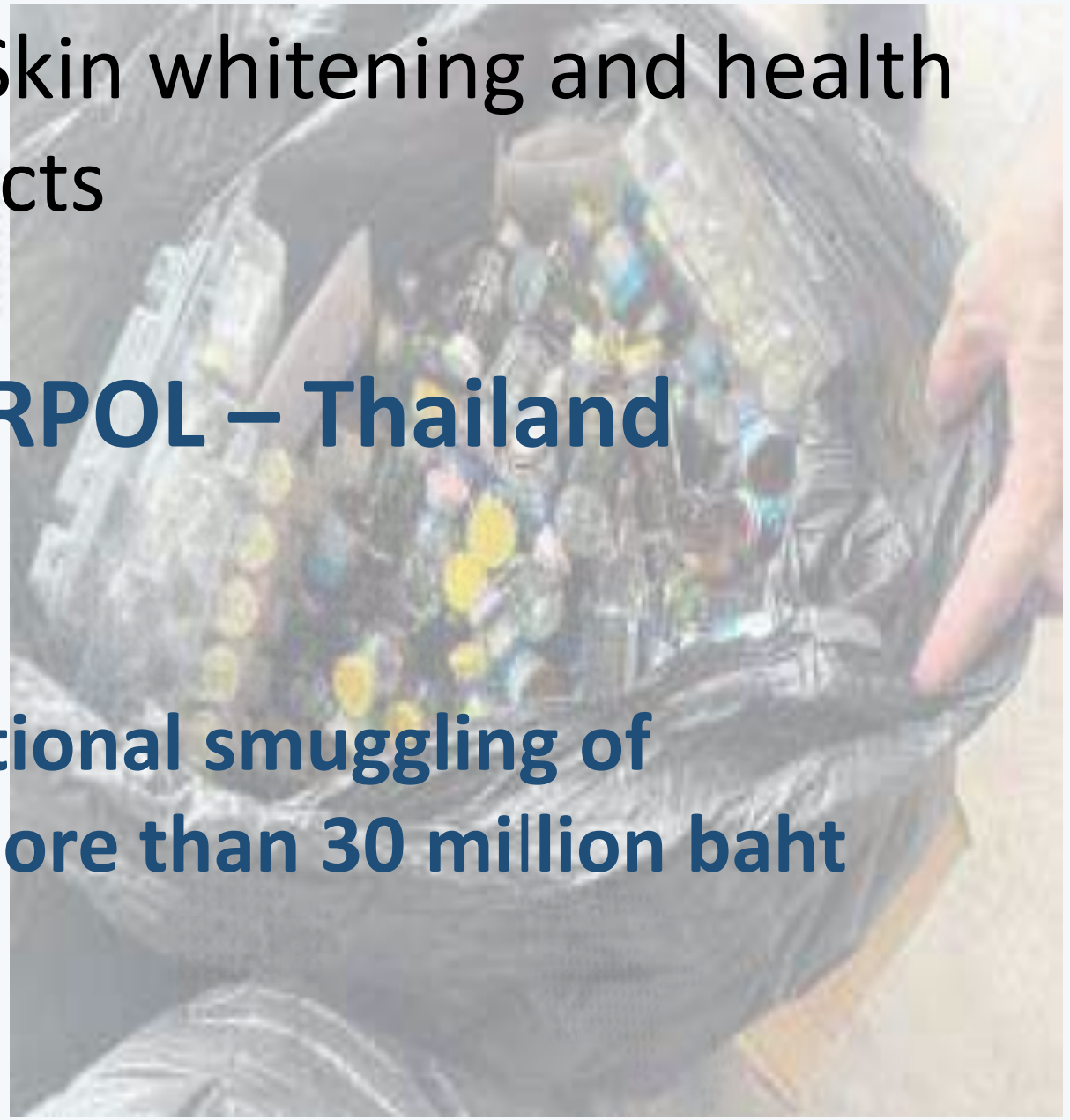
Transnational Gang dismantled and disrupted their criminal activities…

Cross Border Cooperation – Paxlovid

Private Sector – INTERPOL – Cambodia



Cross Border Cooperation– Skin whitening and health products



Singapore – INTERPOL – Thailand

Breaking down the transnational smuggling of counterfeit fillers, seizing more than 30 million baht

Published: 19 Feb 2024 By: Crime News Team

INTERPOL

Thank You

INTERPOL Illicit Goods & Global Health Programme

oec-ilm-iggh@interpol.int

My email:

C.LAM@INTERPOL.INT

SFVP Perspective

Nackanun C.

Advisor

AHPA

SFVP

- Substandard
- Falsified
- Veterinary
- Products

Substandard

Thai Drug Act $\pm$ 25% of L/A

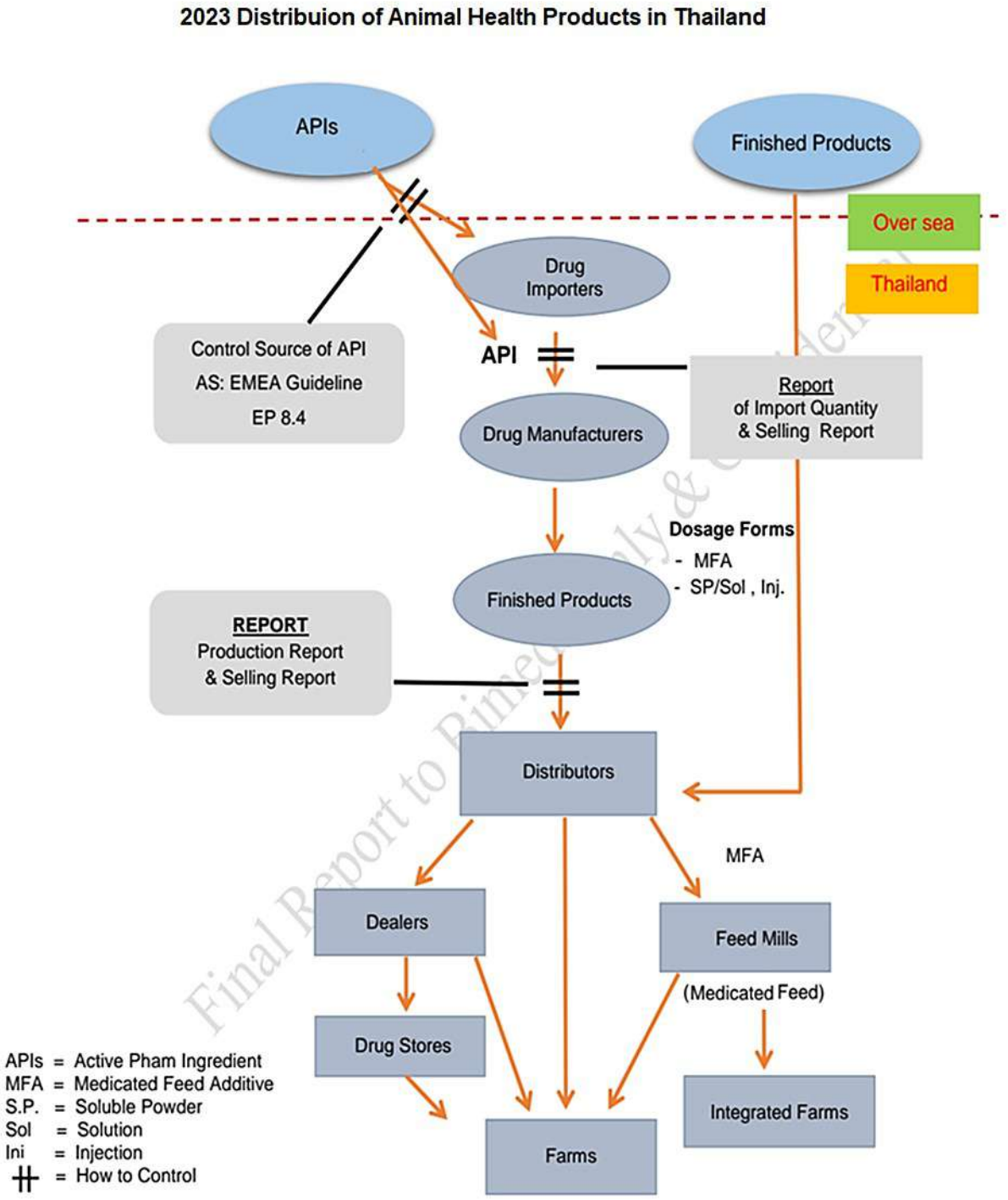
Falsified

- Counterfeit
- Illegal Drug

VP Registration

Category	Regulator
- Vet Drug	- FDA
- Feed Additives	- DLD
- Disinfectants	- DLD / DF

Fate of VP


2023 Distribuion of Animal Health Products in Thailand
APIs
Finished Products
Over sea
Thailand
Drug Importers
Control Source of API
AS: EMEA Guideline
EP 8.4
API
Report
of Import Quantity
& Selling Report
Drug Manufacturers
Dosage Forms
- MFA
- SP/Sol , Inj.
Finished Products
REPORT
Production Report
& Selling Report
Distributors
MFA
Dealers
Feed Mills
(Medicated Feed)
Drug Stores
Integrated Farms
Farms
APIs = Active Pham Ingredient
MFA = Medicated Feed Additive
S.P. = Soluble Powder
Sol = Solution
Ini = Injection
= How to Control

Responsibilities from Different Entity

Prescriber	Dispenser	Regulators	Consumer
Only prescribe legal drug	P.O.M. (not 100% implemented)	Post Marketing Activities	Educate
Vet	Vet / Pharmacist	FDA / DLD /DF	Farmers

Strategies to Handle SFVP

- Increase post marketing action from regulators
- Educate consumers
- Check and balance via prescription
- Improve VP Registration process / lead time
- Increase more qualified lab test


AHPA
สมาคมธุรกิจเวชภัณฑ์สัตว์
ANIMAL HEALTH PRODUCTS ASSOCIATION

Thailand Veterinary Pharmaceuticals Market 2023

1. Introduction to AHPA
2. Total Animal Health Market Potential
3. Animal Health Market by Category
   - Dosage Form
   - ATC Vet Code
4. Fate of Pharm Ingredients
5. Law & Regulation

1. Introduction to AHPA

สมาคมธุรกิจเวชภัณฑ์สัตว์
ANIMAL HEALTH PRODUCTS ASSOCIATION

Profile and Industry

AHPA

Thailand AHPA

Animal Health Products Association

- Established since 1983
- Current members 67 companies
- Market share > 90%
- www.thaiahpa.com

ANIMAL HEALTH PRODUCTS ASSOCIATION

The committee 2022-2023

Dr.Sombat Rojasawasatera

president

Dr.Narong Suthumnathpong

Vice-precident

Dr.Phaiwan Siphua

secretary

Dr.Eagaluk Theerakornsakul

committee

Dr.Siwichai Tonyiwinyoopong

committee

Dr.Narong Buasom

committee

Dr. Teerayoot Chaionnom

committee

Dr. Chompunut Pungthong

committee

Dr. Olan NiyomSuknirun

committee

Dr.Verachart Chaicumpa

adviser

Dr.Chatchawan Orawannukul

adviser

Mr.Nackanun Chitaroon

adviser

Mr.Chayanon Kittayachaweng

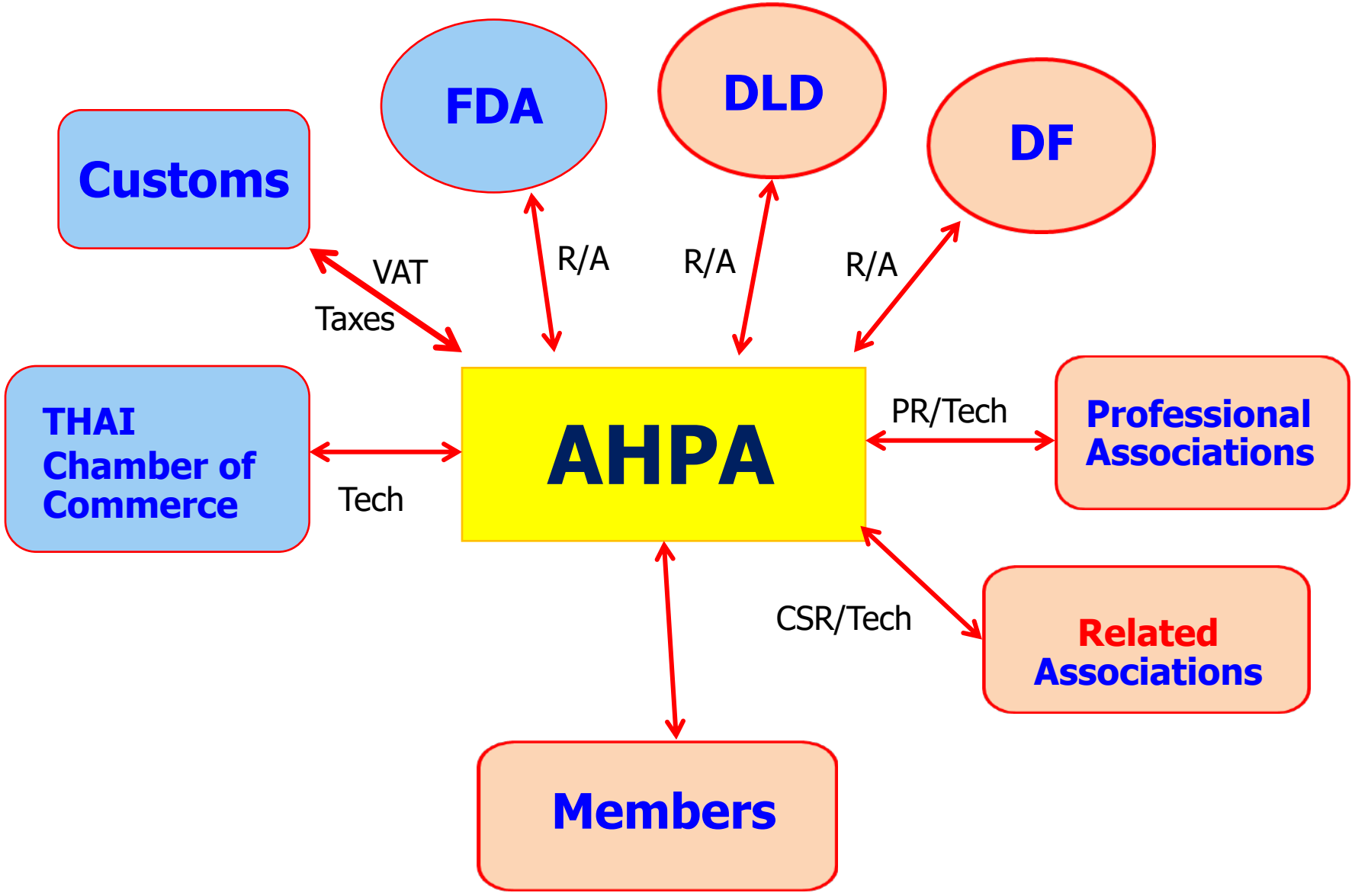
adviser

Dr.Sumeth Sapchukun

adviser

Dr.Tienchai Paitoonvongvira

adviser

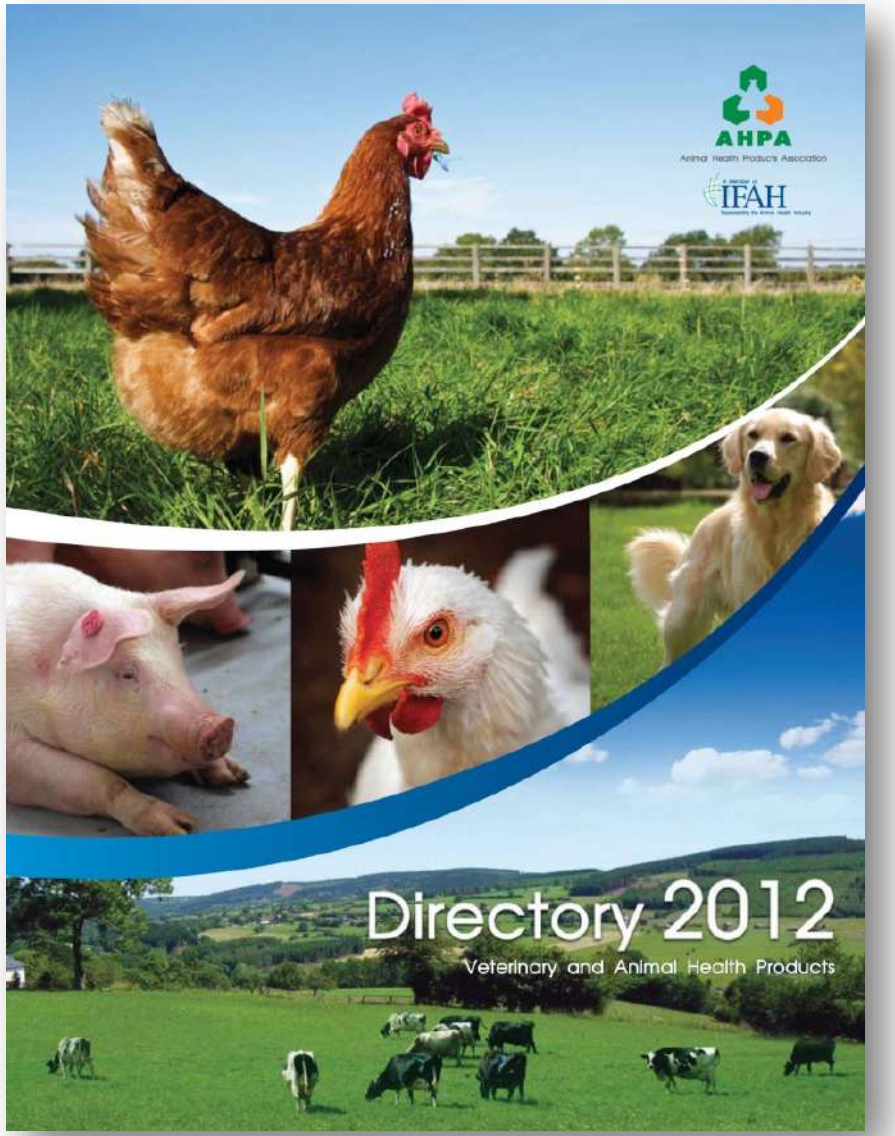

FDA
DLD
DF
Customs
VAT
Taxes
R/A
R/A
R/A
THAI Chamber of Commerce
Tech
AHPA
PR/Tech
Professional Associations
CSR/Tech
Related Associations
Members

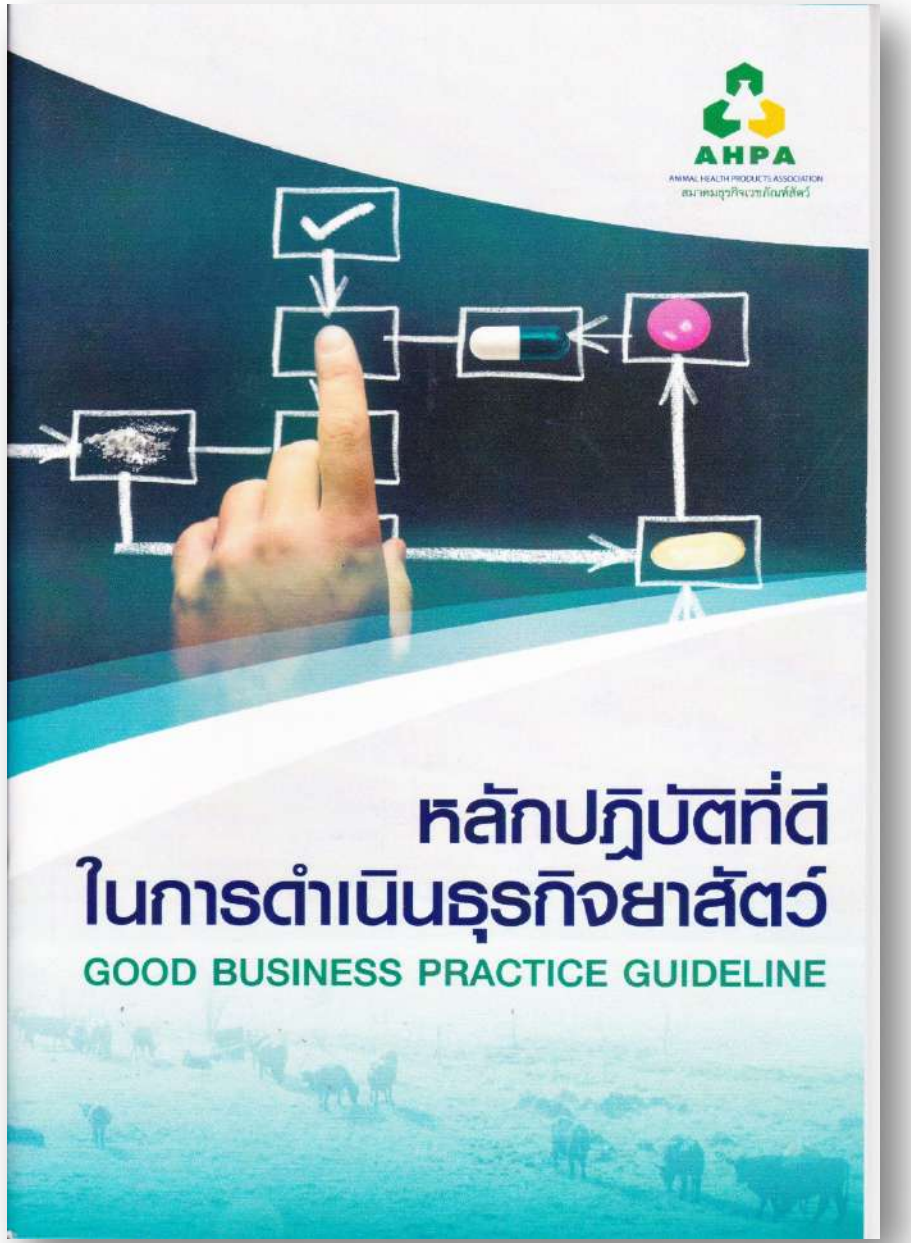
AHPA
MARKET INFORMATION

AHPA

สมาคมธุรกิจเวชภัณฑ์สัตว์

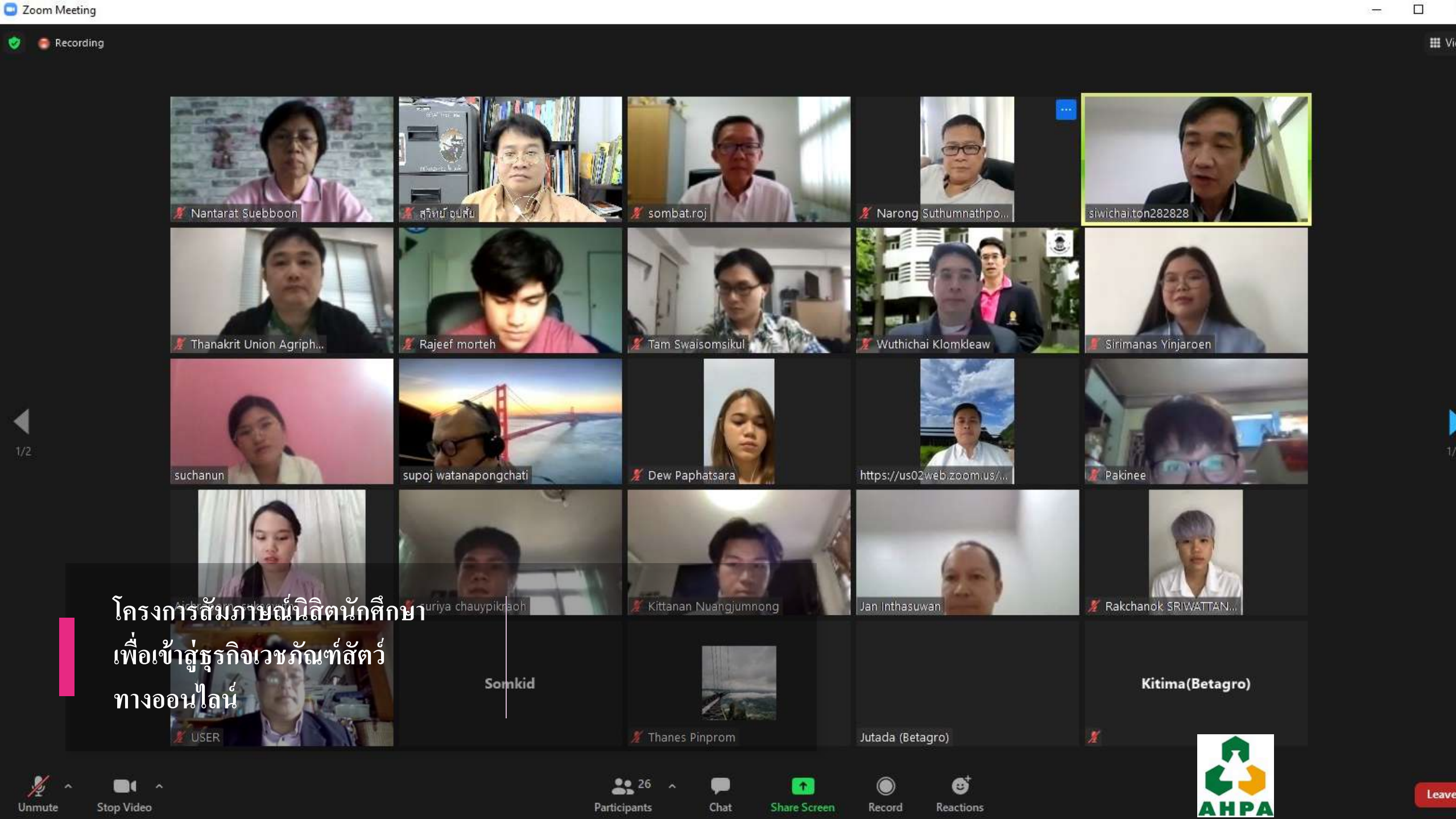
ANIMAL HEALTH PRODUCTS ASSOCIATION


AHPA
Animal Health Product's Association
IFAH
Directory 2012
Veterinary and Animal Health Products


AHPA
ANIMAL HEALTH PRODUCTS ASSOCIATION
สมาคมธุรกิจเวชภัณฑ์สัตว์
หลักปฏิบัติที่ดี
ในการดำเนินธุรกิจยาสัตว์
GOOD BUSINESS PRACTICE GUIDELINE

การประชุมใหญ่สามัญประจำปี 2565

โครงการอบรม “สุดยอดการเจรจาต่อรองทางธุรกิจ”


Zoom Meeting
Recording
Nantarat Suebboon
สุทิษย์ อุปลัย
sombat.roj
Narong Suthumnathpo...
siwichai.ton282828
Thanakrit Union Agriph...
Rajeef morteh
Tam Swaisomsikul
Wuthichai Klomkleaw
Sirimanas Yinjaroen
suchanun
supoj watanapongchati
Dew Paphatsara
https://us02web.zoom.us/...
Pakinee
suriya chauypikraoh
Kittanan Nuangjumnong
Jan Inthasuwan
Rakchanok SRIWATTAN...
โครงการสัมภาษณ์นิสิตนักศึกษา
เพื่อเข้าสู่ธุรกิจเวชภัณฑ์สัตว์
ทางออนไลน์
Somkid
USER
Thanes Pinprom
Jutada (Betagro)
Kitima(Betagro)
Unmute
Stop Video
Participants
26
Chat
Share Screen
Record
Reactions
AHPA

ประชุมเครือข่ายวิจัยนโยบายและระบบสุขภาพการดื้อยาต้านจุลชีพ

(HPSR-AMR network)

ประชุมเพื่อซักซ้อมความเข้าใจการปฏิบัติตามประกาศกระทรวงเกษตรและสหกรณ์ว่าด้วยอาหารสัตว์ที่ผสมยา

2. Total Animal Health Market Potential

Total Animal Health Market Potential

ANIMAL HEALTH MARKET 2023

MARKET SIZE CLASSIFIED BY PRODUCT GROUP

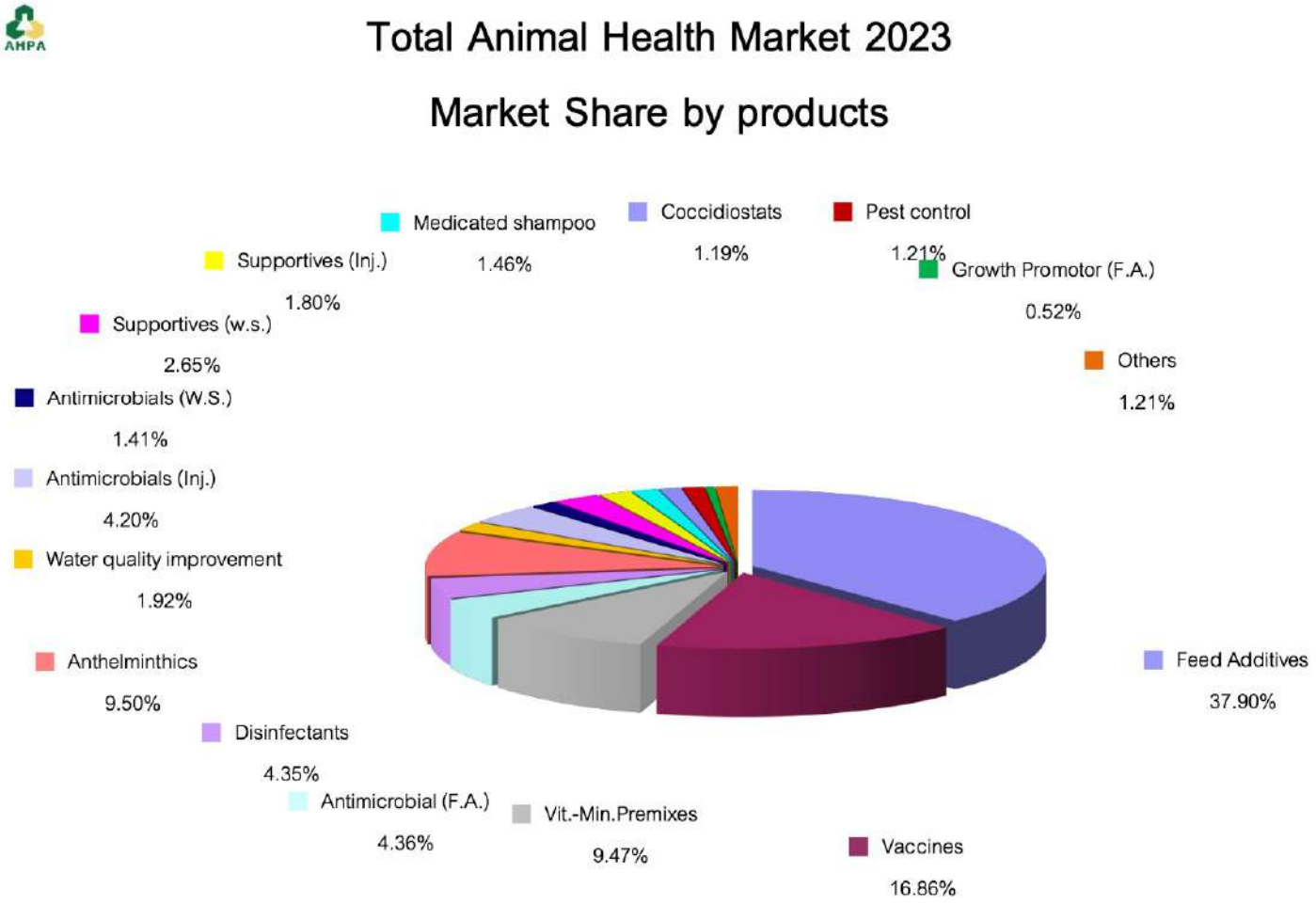
POPULATION /PRODUCTION (Million)	LAYER	BROILER	BREEDER	MEAT D.	PIG	DAIRY	DOG	SHRIMP(Ton)	FEED MILL (M.Ton)
	51.04	1,741.49	16.91	59.0	17.20	0.68	7.80	0.28	20.73
			Duck BREEDER	LAY.DUCK	SOW ON	BEEF	CAT	FISH (Ton)	
			0.47	10.50	0.79	4.10	5.30	0.39	

Products	TOTAL	Market Size Baht/Year	Market Size Baht/Year	Market Size Baht/Year	Market Size Baht/Year	Market Size Baht/Year	Market Size Baht/Year	Market Size Baht/Year	Market Size Baht/Year	Market Size Baht/Year
1. Vit.-Min.Premixes	3,552,563,354	360,573,122	978,701,522	135,816,029	189,071,399	1,117,761,282			770,640,000	
2. Coccidiostats	447,250,871	21,512,623	368,895,189	2,663,059		54,180,000				
3. Antimicrobial (F.A.)	1,634,773,310					1,492,623,310			142,150,000	
4. Feed Additives (G.P.)	193,591,332					193,591,332				
5. Feed Additives	14,209,857,893	219,014,785				774,365,328	482,640,000	359,700,000	298,600,000	12,075,537,780
6. Vaccines	6,321,814,581	363,999,415	1,339,469,165	587,225,731	102,218,897	3,000,121,373	0	928,780,000		
7. Antimicrobials (W.S.)	526,938,390	168,281,664	188,081,219	83,357,986	87,217,520					
8. Antimicrobials (Inj.)	1,572,986,837					913,401,905	365,584,932	294,000,000		
9. Supportives (W.S.)	995,189,302	269,250,663	609,522,470	67,633,254	48,782,915					
10. Supportives (Inj.)	673,813,333					373,813,333	300,000,000			
11. Endoparasiticides	948,774,164	84,140,832		43,285,283	16,458,214	120,009,835		684,880,000		
12. Ectoparasiticides	1,369,676,913	42,070,416		33,816,627		125,749,870	238,700,000	929,340,000		
13. Endectocides	1,243,600,000						573,600,000	670,000,000		
14. Disinfectants	1,629,909,224	100,968,998	522,447,831	30,434,964	22,558,945	313,248,485			640,250,000	
15. Water quality improvement	718,956,000								718,956,000	
16. Pest control	453,651,752	100,968,998	313,468,699	25,362,470		13,851,584				
17. Medicated shampoo	546,000,000							546,000,000		
18. Others	455,268,000						260,568,000	194,700,000		
TOTAL	37,494,615,258	1,730,781,517	4,320,586,096	1,009,595,405	466,307,890	8,492,717,638	2,221,092,932	4,607,400,000	2,570,596,000	12,075,537,780
Percentage	100.00	4.62	11.52	2.69	1.24	22.65	5.92	12.29	6.86	32.21

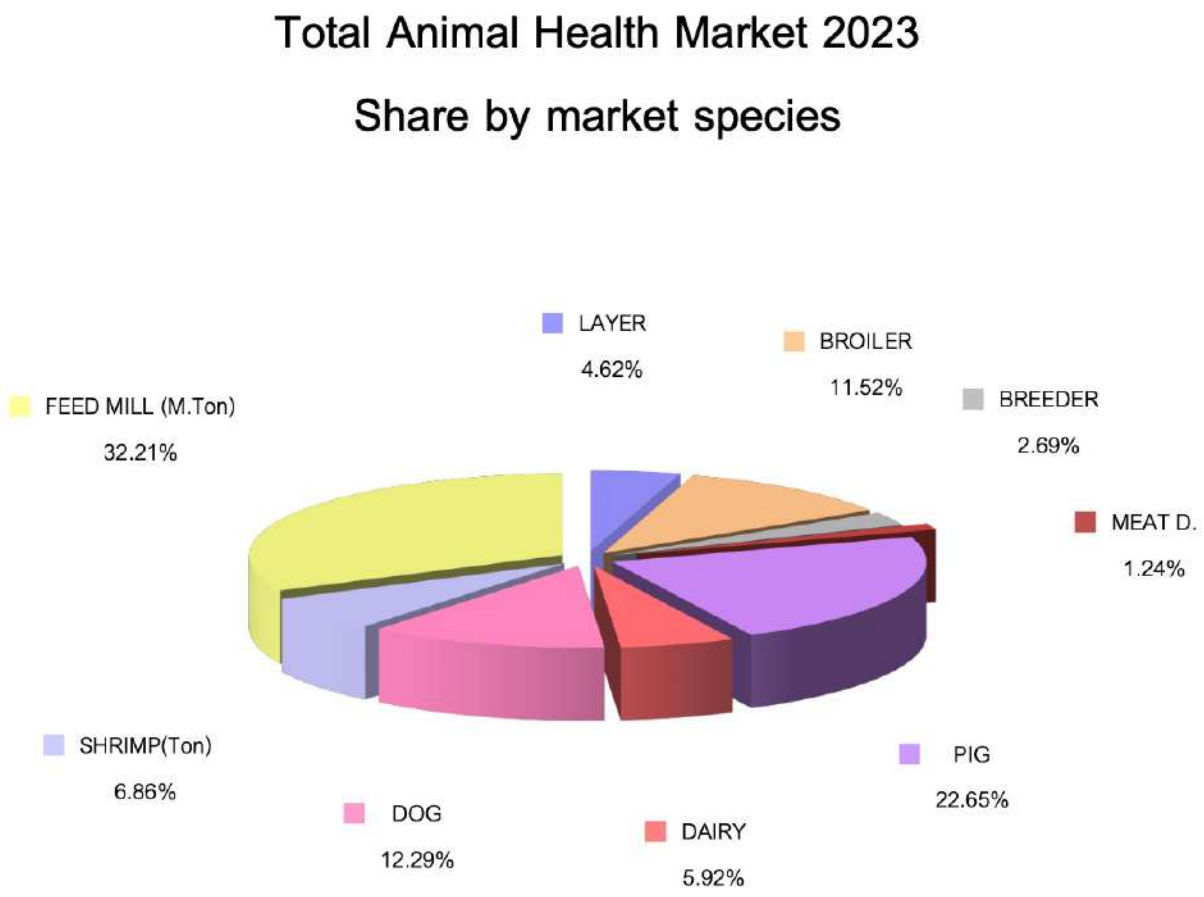
Total Animal Health Market Potential

Products	TOTAL	Percentage
Feed Additives	14,209,857,893	37.90
Vaccines	6,321,814,581	16.86
Vit.-Min.Premixes	3,552,563,354	9.47
Antimicrobial (F.A.)	1,634,773,310	4.36
Disinfectants	1,629,909,224	4.35
Anthelminthics	3,562,051,078	9.50
Water quality improvement	718,956,000	1.92
Antimicrobials (Inj.)	1,572,986,837	4.20
Antimicrobials (W.S.)	526,938,390	1.41
Supportives (w.s.)	995,189,302	2.65
Supportives (Inj.)	673,813,333	1.80
Medicated shampoo	546,000,000	1.46
Coccidiostats	447,250,871	1.19
Pest control	453,651,752	1.21
Growth Promotor (F.A.)	193,591,332	0.52
Others	455,268,000	1.21
TOTAL	37,494,615,258	100.00

Total Animal Health Market Potential



Total Animal Health Market Potential



3. Animal Health Market by Category

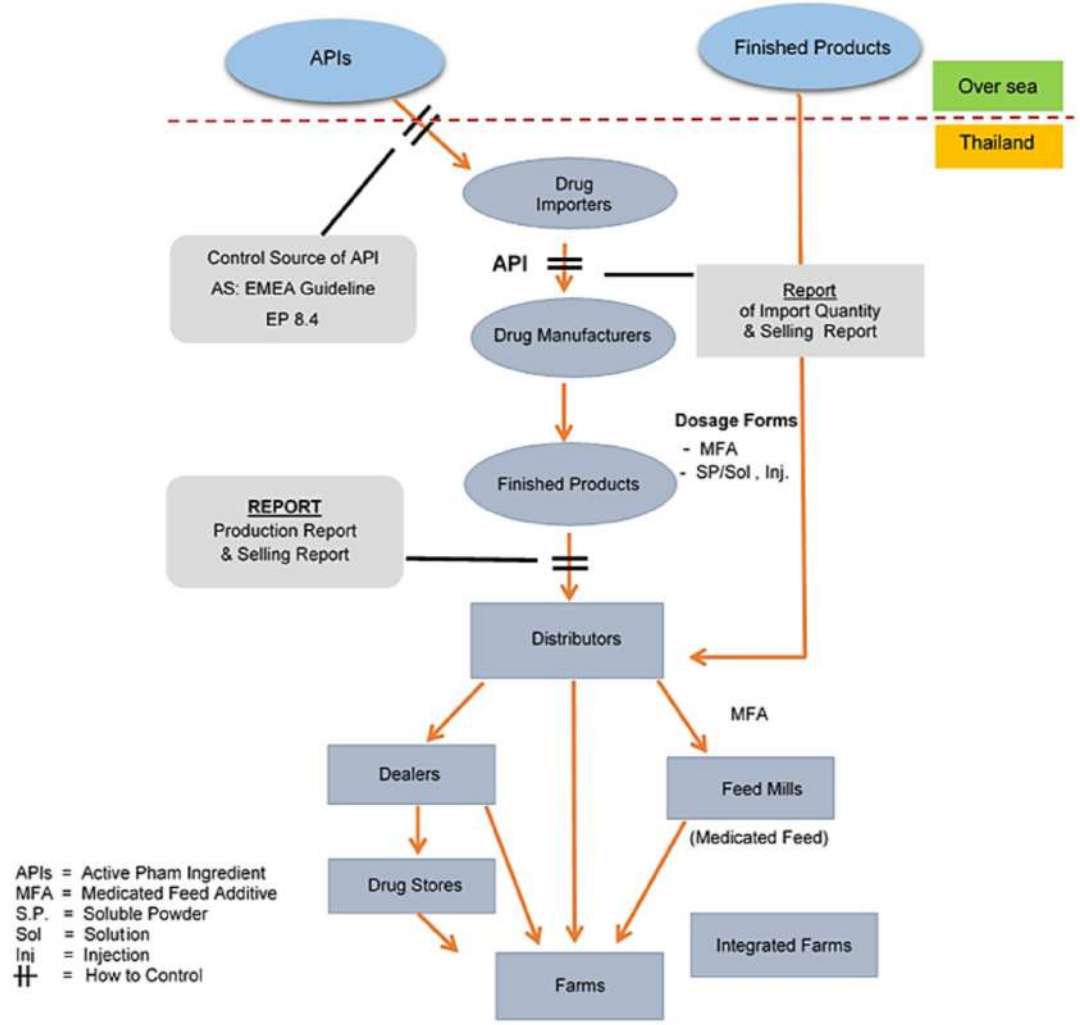
Animal Health Market by Category

- Dosage From
- ATC* Vet Code

*Anatomy Therapeutic Category

4. Fate of Pharm Ingredients

Fate of Pharm Ingredients



5. Law & Regulation

Law & Regulation

Drug FDA, MOPH, พรบ.ยา

Feed DLD, MOAC, พรบ.ควบคุมคุณภาพอาหารสัตว์

Disinfectants DLD, MOAC…พรบ.วัตถุอันตราย

(Under authorized Law from MOI)

Fisheries DOF, MOAC….พรบ.ควบคุมคุณภาพอาหารสัตว์

Thank You

Illegal veterinary medicines

-observations from the animal health industry-

WOAH Workshop on Substandard and Falsified Veterinary Products

Bangkok, June 2024

Carel du Marchie Sarvaas, Executive Director
HealthforAnimals (global animal health association)

Presence

26 Regional & National Associations
Working in **~40 countries**

Ten Largest Animal Health Companies
Working in **100+ countries**

zoetis
Boehringer Ingelheim
Virbac
vetoquinol
ACHIEVE MORE TOGETHER
IDEXX
MSD Animal Health
ZENOAQ
Phibro
ANIMAL HEALTH CORPORATION
Elanco
ceva

Parasite control products, vaccines, antibiotics, diagnostics, digital products, genetics, other (topics, dental, etc)

All companies and associations members = about 85% + of global market

Health for Animals
global animal health association

What we know. How we know it. What we don't know.

What we know

- criminal activity in all countries - some more, some less
- different levels of counter-activity (enforcement) per country
- illegal products smaller problem than in human medicine due to economics
- problem smaller in food-exporting countries - higher enforcement/compliance

How we know it

- law enforcement data and actions
- testing in some markets – extrapolation
- industry/veterinarian's experiences in the marketplace

What we don't know (enough)

- size of the problem
- who is involved (beyond criminals)
- exact impacts on animal human and environmental health

Types of illegal veterinary medicines

Not legally authorized in a country

Illegal supply/use of an unauthorized veterinary medicine (f.e. no prescription)

Abuse of preparation regulations (f.e. compounding)

Counterfeit (falsified) medicines (non authorized use of trademarks/ violation IP rights, f.e. false labeling, different ingredients)

All illegal, but with varying levels of negative animal, human, environmental, business impacts.

Characteristics of markets with illegal products

Farmers and veterinary services

- access to quality medicines is poor in remoter areas
- lack of awareness among livestock farmers - focus on price

Distributors/importers

- weak distribution channels + poor financial capacity of importers
- interest of small distributors is financial, not quality or return customers
- administrative procedures for imports long and bureaucratic

Authorities

- inadequate regulations and enforcement - lack of governance
- limited awareness (beyond ag. ministry) of threat to public animal health
- limited government policies or resources

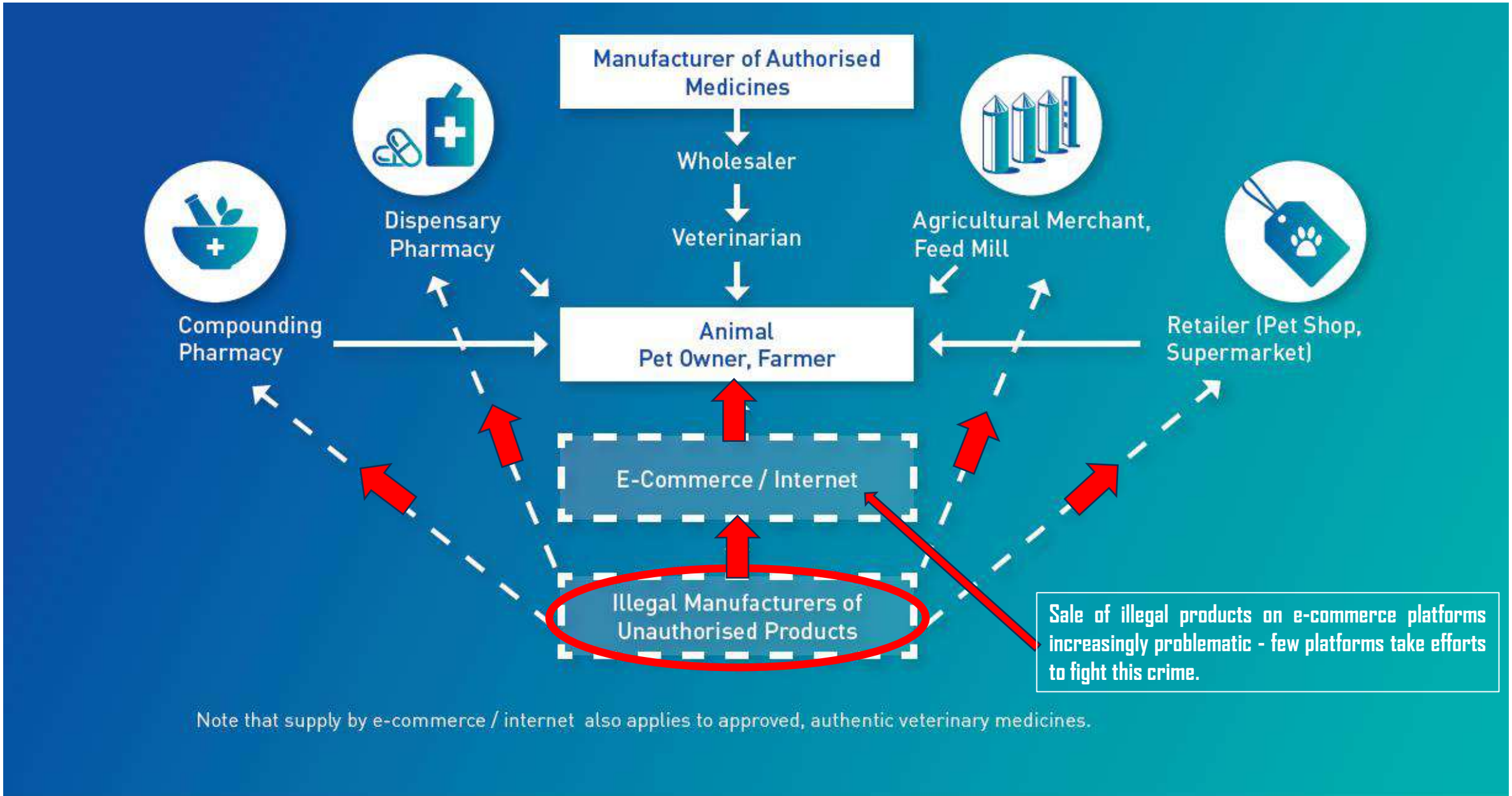
Animal Health companies

- concerned about illegal animal medicines - threat to public, animal, environmental health and businesses
- committed to controlling its legitimate supply chain
- supportive of WOAH to assess magnitude/nature of challenge
- all companies work with competent authorities on suspected cases
  - but challenging to share info during investigation/judicial procedure)
- supportive of efforts by national and global authorities to:
  - collect information about cases (VSAFE)
  - coordinate and exchange information
  - take active measures to pursue/prosecute

Observations

- regulatory agencies' resources (human+financial) are barrier to action
- animal health not seen as significant, in comparison to human health
- potential negative impact on human health is often not understood
  - food contamination
  - lack of efficacy of products when zoonosis
  - antiparasitic and antimicrobial resistance development
- legal manufacturers will keep their products away from markets where enforcement authorities do not undertake enough efforts

How products are accessed – legally vs. illegally



What actions should be taken?

Regulation & Enforcement Agencies

- Effective regulation
  - Necessary government resources
- Rigorous enforcement
- Collaboration
  - Police
  - Customs
  - Regulatory agencies
  - Professional bodies
  - Manufacturers
- Private prosecution, legal action

E-Commerce & Internet Sites

- Raise awareness
- Cease or comply
- Popup warning on legitimate sites
- Full compliance with legal requirements

Manufacturers of Authorised Medicines

- Raise awareness
- Collect data
- Leadership in working with enforcement agencies
- Evaluate technology to support enforcement
- Protect patents and trademarks
- Protect reputation

Veterinarians, Retailers, Wholesalers, Feed Mills

- Raise awareness
- Report illegal products
- Work with enforcement agencies
- Be alert and informed
- Do not encourage illegal compounded products and vaccines

Farmers

- Awareness of risks of illegal products:
  - Efficiency
  - Safety
  - Residues
  - Environment
- Business risk if illegal products are used
- Report illegal products

Pet Owners

- Awareness of risks of illegal products to efficiency and safety
- Report illegal products

Extensive report available

- HealthforAnimals global study
- Learn lessons from pharma, pesticide industries
- Actions and ideas

https://healthforanimals.org/resources/publications/publications/new-report-illegal-veterinary-medicines-impact-and-effective-control/

Thank you

Facebook.com/HealthfrAnimals

Twitter.com/Health4Animals

Linkedin.com/company/HealthforAnimals

HealthforAnimals.org

RAGNA- Strengthen the international collaboration, identify concrete actions, and exchange experiences between human- and veterinary medicines

Katarina Lönnquist

Swedish Medical Products Agency

Swedish Medical Products Agency (SMPA)

Is the national authority responsible for **regulation and surveillance of the development, manufacturing and sales** of pharmaceuticals and other medicinal products for **humans and animals** including environmental aspects

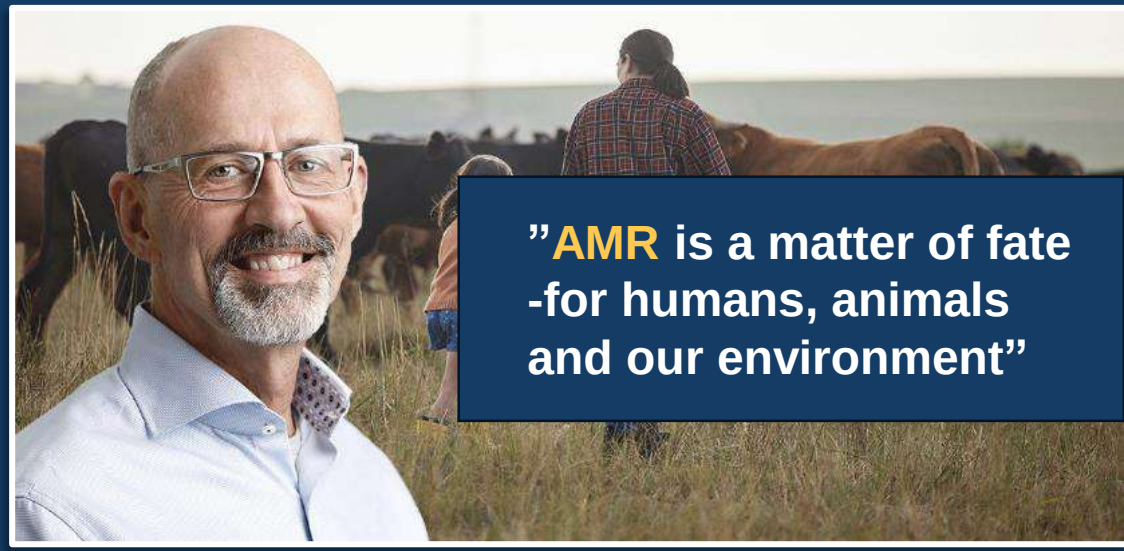
AMR has high priority at SMPA

Our AMR experts

- Human, Veterinary and Environment
- AMR experts meet every week to share information

We focus on

- One Health perspective
- Access to safe and effective antibiotics
- Prudent and responsible use of antibiotics
- Low impact on the environment



Fredrik Hultén, Veterinary, AMR expert, SMPA

We act for human and animal health

Activities within the entire lifecycle of antibiotics

- Scientific Advice
- Approve Clinical trials
- Assess documentation for registration
- Approve special permissions
- Managing shortages
- Perform inspections
- Pharmacovigillance
- Develop National treatmentrecommendations
- Waste management of medicines
- Review marketing material for medicines
- Falsified and substandard medicines

RAGNA

”The global regulatory agencies have an important role to play

both in combatting antimicrobial resistance (AMR)

and in contributing to global solutions”

Haileyesus Getahun, WHO

RAGNA background

5 May 2023

The 1st Global Joint Summit Human & Veterinary Medicines Regulatory Authorities

10 May 2023

Haileyesus Getahun, WHO visits the Swedish Medical Products Agency (SMPA)

25 May 2023

Director General, SMPA, gives OK to start up RAGNA

28 June 2023

1st **RAGNA** meeting is held

sweden 2023.eu

RAGNA

Regulatory Agencies Global Network against AMR

- An initiative by the Swedish Presidency of the Council of the European Union
- In collaboration with the Quadripartite (FAO, UNEP, WHO & WOAH)
- Consists of global representatives from human and veterinary medicines regulatory agencies
- Voluntarily and free of charge

RAGNA objectives

Strengthen the international collaboration between regulatory agencies against AMR

Identify concrete actions that regulatory agencies can contribute with against AMR

Exchange experiences and good practices between regulatory agencies, human- and veterinary medicines, against AMR

During our first year

- Invited over 500 international representatives
- Established a digital platform to share documents
- Conducted 6 digital meetings
- Established Terms of Reference
- Performed a mapping of regulatory measures
- Produced and launched **RAGNA** call to Action
- Compiled a plan for 2024-2025

RAGNA- Call to Action

The UNGA AMR meeting in September 2024 is an opportunity to bring forward concrete feasible measures within the mandate of regulatory agencies

RAGNA Call to Action is a document consisting of prioritized regulatory measures against AMR

- High impact on AMR
- Feasible in all countries
- Low cost
- One Health perspective

Regulatory Agencies Global Network against AMR | RAGNA

Who is RAGNA?

The Regulatory Agencies Global Network against AMR (RAGNA) is an initiative by the Swedish Medical Products Agency (Läkemedelsverket) during the Swedish Presidency of the Council of the European Union, in collaboration with the Quadripartite Organizations (FAO, UNEP, WHO & WOAH). RAGNA, which consists of global representatives from human and veterinary medicines regulatory agencies, facilitates collaboration and knowledge sharing among agencies and advocates for the regulatory perspective in the global One Health response to combat AMR.

RAGNA

a global forum of regulators, key players in combating antimicrobial resistance (AMR) and contributing to global solutions

There are strong links between AMR, the antimicrobial cycle, the role of regulators, and international instruments on antimicrobial usage. Effective regulation and responsible use of antimicrobials throughout their life cycle – from production to disposal – is paramount to effectively address AMR. Regulatory agencies, particularly those overseeing human and veterinary medicines, have significant influence in ensuring good manufacturing processes, facilitating controlled access to safe, effective and high-quality antimicrobials, while also preventing their disposal into the environment. The UNGA High-Level Meeting on AMR in September offers a great opportunity to boost this agenda. To better inform Member States as they craft this meeting's political declaration, Regulatory Agencies Global Network Against AMR (RAGNA) has prepared a list of key recommendations voicing the joint inputs of international regulators across the human and animal veterinary medicines sectors:

RAGNA recommendations to prevent and mitigate impacts due to AMR

1 Countries should strengthen One Health multisectoral regulatory governance of medicines.

As a multi-sectoral challenge, AMR demands a One Health lens when applying regulatory frameworks. Similarly, National Action Plans on AMR (NAPs) should be multi-sectoral and multi-disciplinary with coordination mechanisms that are sustainable, accountable, and appropriately equipped with human and financial resources. To facilitate communication and aid coordination, countries are encouraged to develop robust regulatory networks across human, animal, plant, and environmental sectors, incorporating international guidance in the management of human and veterinary medicinal products throughout their lifecycle, and in other areas relevant to AMR.

The Quadripartite Joint Secretariat (FAO, UNEP, WHO, WOAH) supports the work of RAGNA to advocate for strategic and political action for AMR.

RAGNA meetings

- Meetings are held every other month
- Digitally for 1,5 hour
- Presentaions mixed with breakout groups
- Recording of the meetings are available for 14 days

Next meeting 19 June 2024 at 13.00 CET

- How make impact with RAGNA Call to action
- Country presentation on AMR situation
- Breakout groups - How could contries support eachother and share experience

Welcome to join RAGNA

Join RAGNA by contacting us via Ragna@lakemedelsverket.se

Visit our digital platform to read more about **RAGNA**

Falsified and substandard medicines in Europe

Substandard and falsified medicines in EU

Harmonised European measures to fight medicine falsifications and ensure that medicines are safe and that the trade in medicines is rigorously controlled which includes

- Obligatory safety features on the outer packaging of medicines
- A common, EU-wide logo to identify legal online pharmacies
- Tougher rules on import of active pharmaceutical ingredients
- Strengthened record-keeping requirements for wholesale distributors

Substandard and falsified medicines in EU

At the end of the distribution chain, **only licensed pharmacies and approved retailers are allowed to offer medicines for sale**, including the legitimate sale via the internet.

Revised **good-distribution-practice guideline** includes specific provisions for brokering activities

From July 2013, **all active substances manufactured outside the EU and imported into the EU** have had to be accompanied by a written confirmation from the regulatory authority of the exporting country

Internet sales of veterinary medicines

National regulatory authorities in the EU / EEA **are obliged to list all registered online medicine retailers** in their country on their websites

All online medicines retailers registered in the EU / EEA **should display the common logo and link to the relevant national authority website**

Common EU symbol is indicating websites approved to sell veterinary medicines within EES

European reporting system

Marketing and manufacturing authorisation holders are **obliged to report to EMA** if they detect any (suspected) falsification of a centrally authorised medicine that could pose a risk to public and animal health.

EU network for regulatory agencies

- Established EU network
- Representatives from national competent authorities within EU
- Share information on reported falsified medicines
- Both for human and veterinary medicines

Thank you

MOTT MACDONALD

Results in Phase I Quality and Coordination in Phase II

Robert Rosenthal
Asia Regional Director
Robert.Rosenthal@mottmac.com

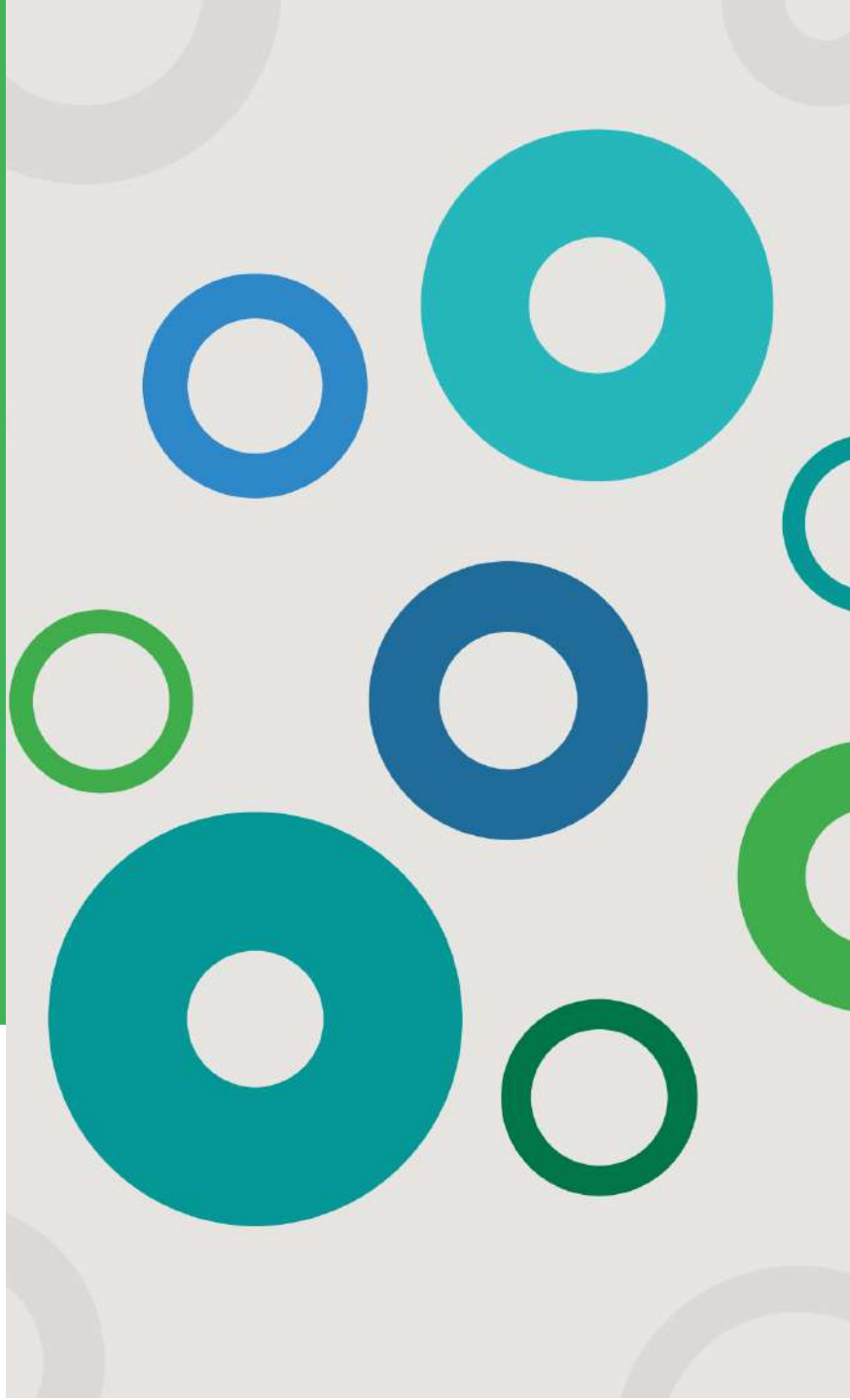
Mott Macdonald
Fleming Fund Management Agent

The Fleming Fund

Fleming Fund is a UK aid programme

Department of Health & Social Care

UKaid from the British people



The Fleming Fund

UKaid from the British people

The Fleming Fund is a UK Aid programme by **the UK Department of Health and Social Care** that seeks to gather and share antimicrobial resistance data.

<u>Phase I (2017-2023):</u>

- Global portfolio: £200 million

<u>Phase II (2023-2025):</u>

- Global portfolio: £133 million
- 58 grants in 26 countries
- SEA Region portfolio: £24.7 million (country grants and Fellowships)

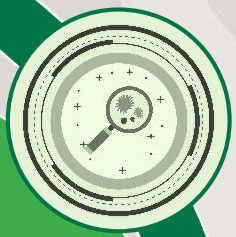
- The UK Department of Health and Social Care's Fleming Fund currently supports **21 countries** across Asia and Africa to tackle antimicrobial resistance (AMR).
- The Fund invests in **strengthening AMR surveillance systems** through a portfolio of country and regional grants, global projects and fellowship schemes.
- The programme focuses on **low- and middle-income (LMIC) countries** because they are expected to bear the heaviest consequences of the spread of AMR.

The Fleming Fund

UKaid from the British people

Fleming Fund approaches

Establishing laboratory capacity and AMR surveillance



Laboratory capacity

Funding: Country Grants & Central Procurement

Infrastructure, Equipment & Reagents, Microbiology Capacity, QMS, LIMS, Biosafety & Biosecurity, Sample Collection & Transport, Biorepository

Workforce capacity

Funding: Fellowship Scheme & Open U. Course

AMR Laboratory, AMR/U/C surveillance, Antimicrobial Stewardship,

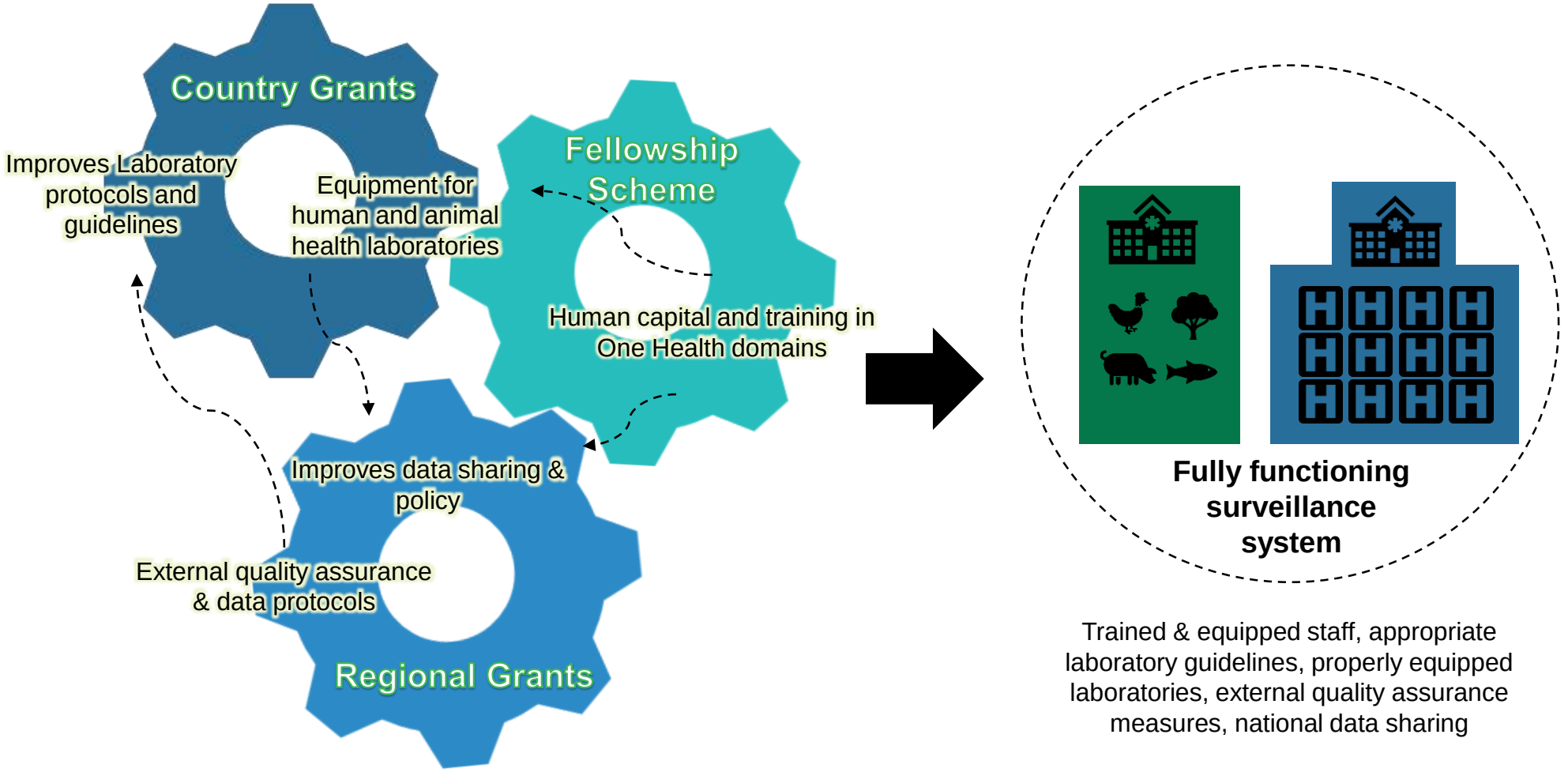
AMR Advocacy, AMR Health Economics

Regional capacity

Funding: Regional Grants

Regional quality assurance networks, Data & information sharing platforms, Quality & use of surveillance data, Advanced testing of AMR pathogens

How the programmes work together

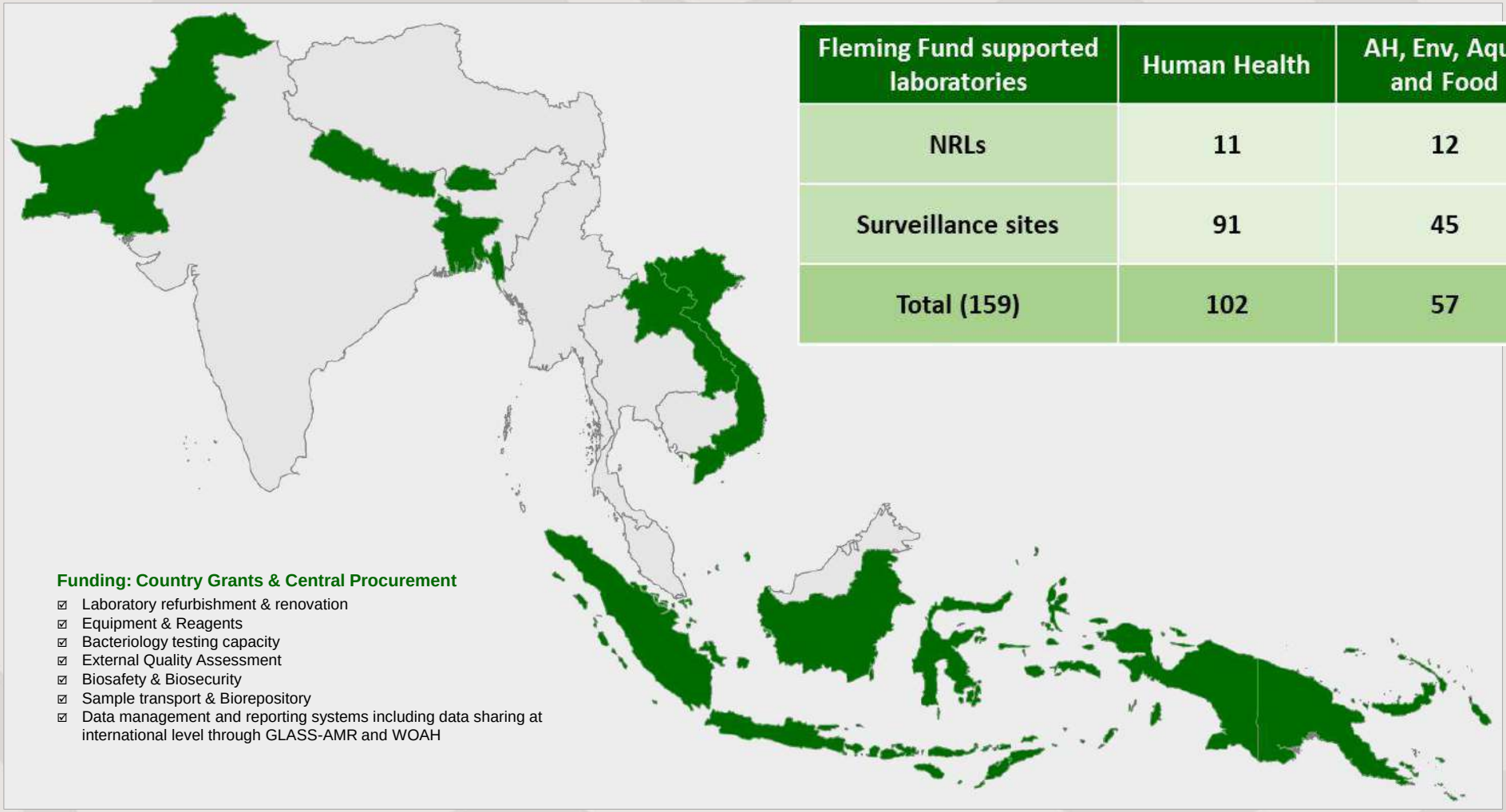


Phase I (2017-2023):

How did we do?

What kinds of results were achieved for AMU in animal health?

AMR surveillance laboratory network: Asia

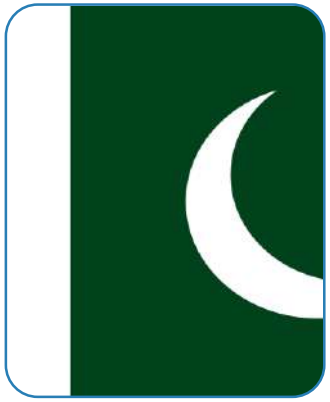
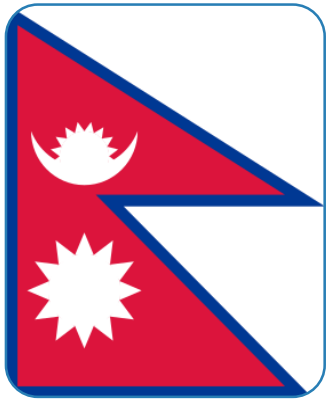
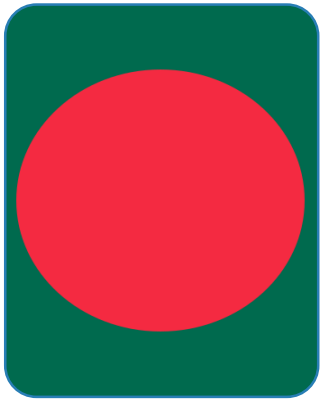


Fleming Fund supported laboratories	Human Health	AH, Env, Aqua and Food
NRLs	11	12
Surveillance sites	91	45
Total (159)	102	57

Funding: Country Grants & Central Procurement

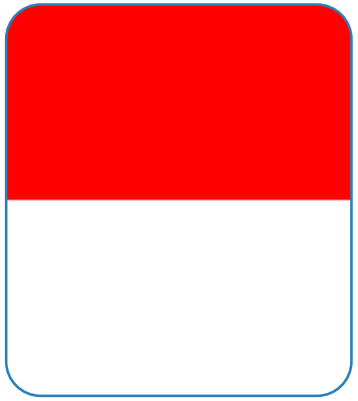
- ☑ Laboratory refurbishment & renovation
- ☑ Equipment & Reagents
- ☑ Bacteriology testing capacity
- ☑ External Quality Assessment
- ☑ Biosafety & Biosecurity
- ☑ Sample transport & Biorepository
- ☑ Data management and reporting systems including data sharing at international level through GLASS-AMR and WOAH

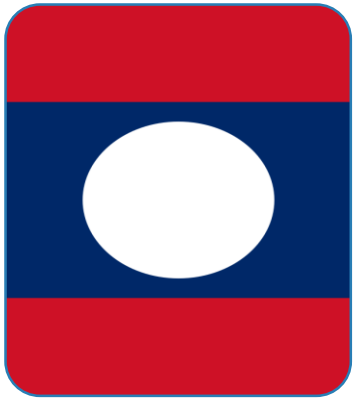
Phase I partnerships South Asia


India	Pakistan	Nepal	Bangladesh	Bhutan
Country Grant: CG1: £652k	**Country Grants:** CG1: £2.8m CG2: £6.49m	**Country Grants:** CG1: £1.41m CG2: £2.7m	**Country Grant:** CG1: £4.99m	**Country Grant:** CG1: £2.4m
Country Grantee: WHO India	**Country Grantee:** DAI	**Country Grantee:** FHI 360	**Country Grantee:** DAI	**Country Grantee:** Bhutan Govt.
	Fellowship Host: American Society of Microbiology	**Fellowship Host:** Doherty Institute, University of Melbourne	**Fellowship Host:** International Livestock Research Institute	**Fellowship Host:** Doherty Institute, University of Melbourne

Phase I partnerships Southeast Asia




Timor-Leste

Country Grants:
CG1: £4m
CG2: 2.86m

Country Grantee:
Menzies School of Health Research

Fellowship Host:
Doherty Institute, University of Melbourne

Indonesia

Country Grant:
CG1: £8.6m

Country Grantee:
DAI

Fellowship Host:
Erasmus MC (University Medical Center Rotterdam)

Vietnam

Country Grant:
CG1: £8.8m

Country Grantee:
FHI 360

Fellowship Host:
Erasmus MC (University Medical Center Rotterdam)

Lao PDR

Country Grant:
CG1: £2.15m
CG2: £2.2m

Country Grantees:
UNOPS / FAO, Fondation Merieux

Fellowship Hosts:
Mahidol University, Fondation Merieux

Papua New Guinea (PNG)

Country Grant:
CG1. £7.7m

Country Grantee:
Burnet Institute

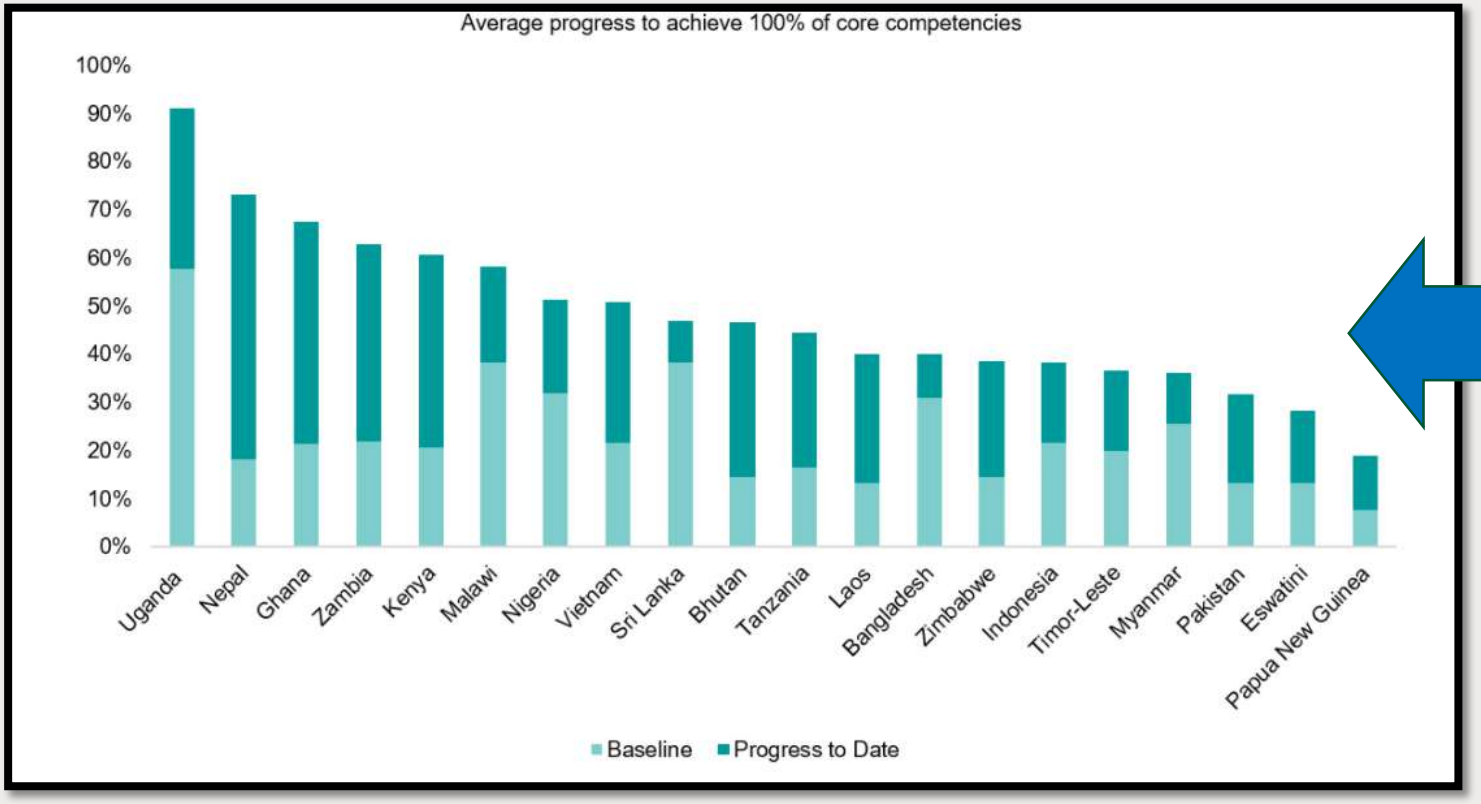
Fellowship Host:
Doherty Institute, University of Melbourne

Phase I Highlights

- Over **75 National Action Plans on AMR** developed or implemented.
- **WOAH reporting improvements on AMU in 3 countries in SEA.**
- **181 fellows** improving technical skills in microbiology and epidemiology and over **3,000 healthcare workers trained** in AMS principles
- Over **240 labs supported.**
- **22,713 training attendees** were supported via country and regional grants
- **17** Fleming Fund countries enrolled in **WHO's Global AMR Surveillance System (GLASS),** up 2 from 2017.
- **11 regional grants** improving the quantity and quality of national data, EQA for labs, and new whole genome sequencing capacity for AMR in Africa

Measuring success in Phase I

Improvement in quality of data

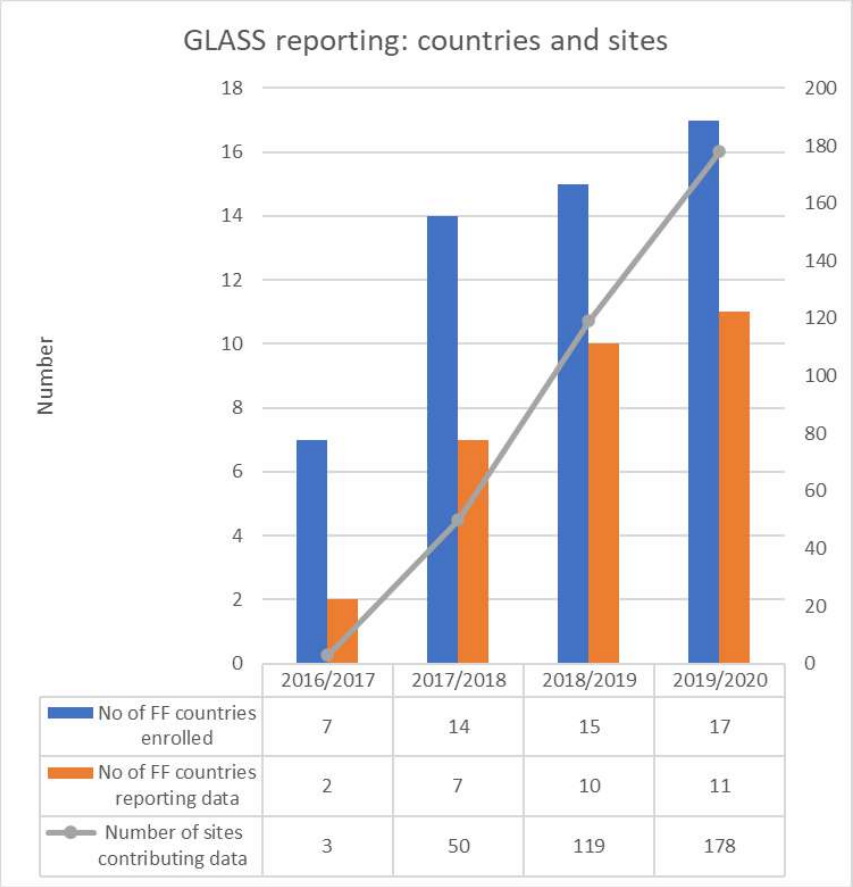


- Increased number of laboratories / AMR surveillance sites
- Across sectors: Human Health. Animal Health, Food safety.
- Improved competencies of the healthcare facilities to perform better
- Guided by periodic healthcare facility (lab) assessments and site reports

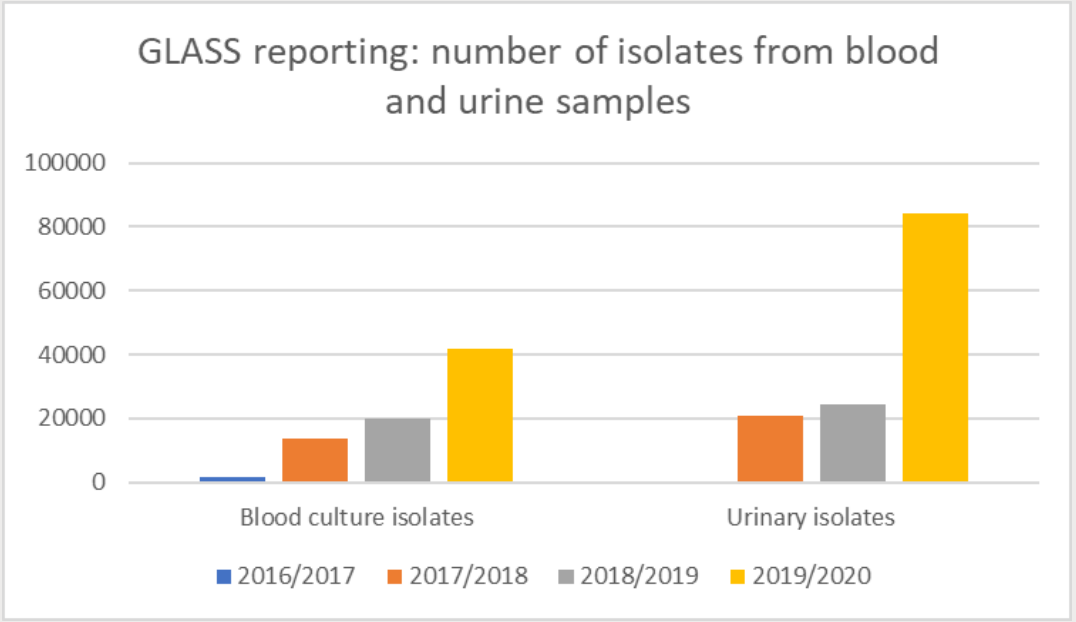
** Per The London School of Hygiene & Tropical Medicine (LSHTM)*

Measuring success in Phase I

Improvement in quantity of data



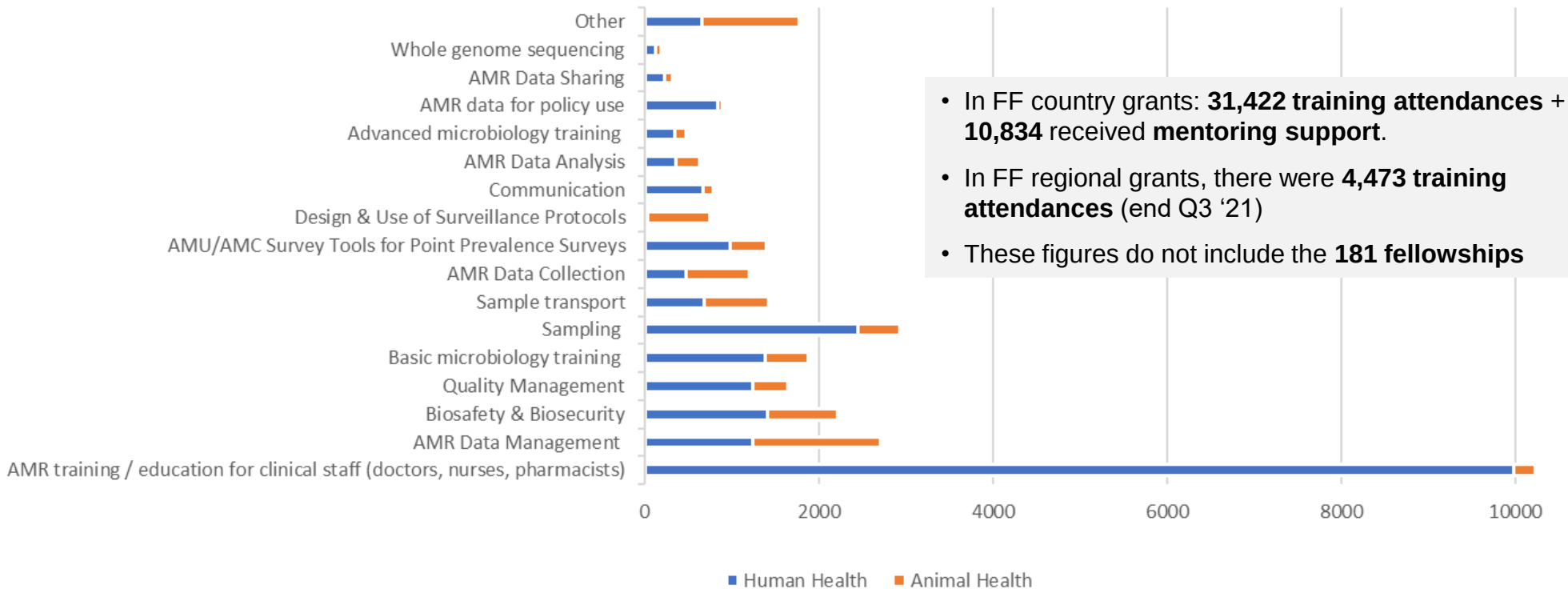
	2016/2017	2017/2018	2018/2019	2019/2020
No of FF countries enrolled	7	14	15	17
No of FF countries reporting data	2	7	10	11
Number of sites contributing data	3	50	119	178



** Using the WHO Global Antimicrobial Resistance and Use Surveillance (GLASS) system*

Measuring success in Phase I

Improvement in workforce capacities



- In FF country grants: **31,422 training attendances** + **10,834** received **mentoring support**.
- In FF regional grants, there were **4,473 training attendances** (end Q3 '21)
- These figures do not include the **181 fellowships**

AMU in Animals Highlights

Support for WOAH reporting in ANIMUSE

Country	FF support for WOAH reporting in Asia	WOAH AMU Reporting Option
Laos	Developed national AMU surveillance and increased quality and quantity of data	**2**
Vietnam	Established national AMU data collection system and provided training on data analysis.	**1**
Pakistan	Provided authorities with training and TA on AMU surveying at farm level	**3**
Timor-Leste	Established national AMU surveillance and increased quality and quantity of data	**3**
PNG	Developed the national AMU data collection system	**1**
Bangladesh	Increased the quality and quantity of AMU data. Provided PPS survey and data analysis training	**1**
Bhutan	Increased the quality and quantity of data. Provided AMU survey and data analysis training	**1**
Indonesia	Increased the quality and quantity of data; AMU survey and data analysis	**1**
Nepal	Increased quality and quantity of AMU data; AMU survey, data collection and data analysis	**3**

AMU in Animals Highlights

- Overall Improved quality and quantity of data submitted to WOAH (Bhutan, Bangladesh, Indonesia, Nepal, Timor-Leste, Pakistan and Laos)
- Global Support for WOAH's "Quality of Veterinary Products" Programme

Nepal: Two rounds of quantitative AMU data collected from poultry farms; Software developed to collect and manage AMU/AMC data from hospitals and farms.

Bangladesh: One Health PPS on AMU was conducted across HH sites, poultry and aquaculture farms.

Indonesia: The AMU surveillance expanded for wider coverage, data analysis and interpretation.

AMU in Animals Highlights

Pakistan: Software for a dashboard of multisectoral AMR/AMU indicators; 1st AMU surveillance in AH (poultry, cattle); KAP surveys on-farm AMU, animal husbandry, and prescriptions; AMR awareness for veterinary students and veterinary professionals

Timor-Leste: National AMU surveillance in AH; Standard Treatment Guidelines; Essential Medicines List and antibiotic guidelines; Implementation and training on mSupply.

Vietnam: Supported establishment of e-portal system. Private sector directly feeds the data of imported drugs, antimicrobial sales, antimicrobial uses in AH.

Laos: National AMU surveillance in AH in 2022, including 1) assessment of AMU data collection in AH sector, 2) consultation meetings on assessment findings, and 3) Implementation of surveillance;

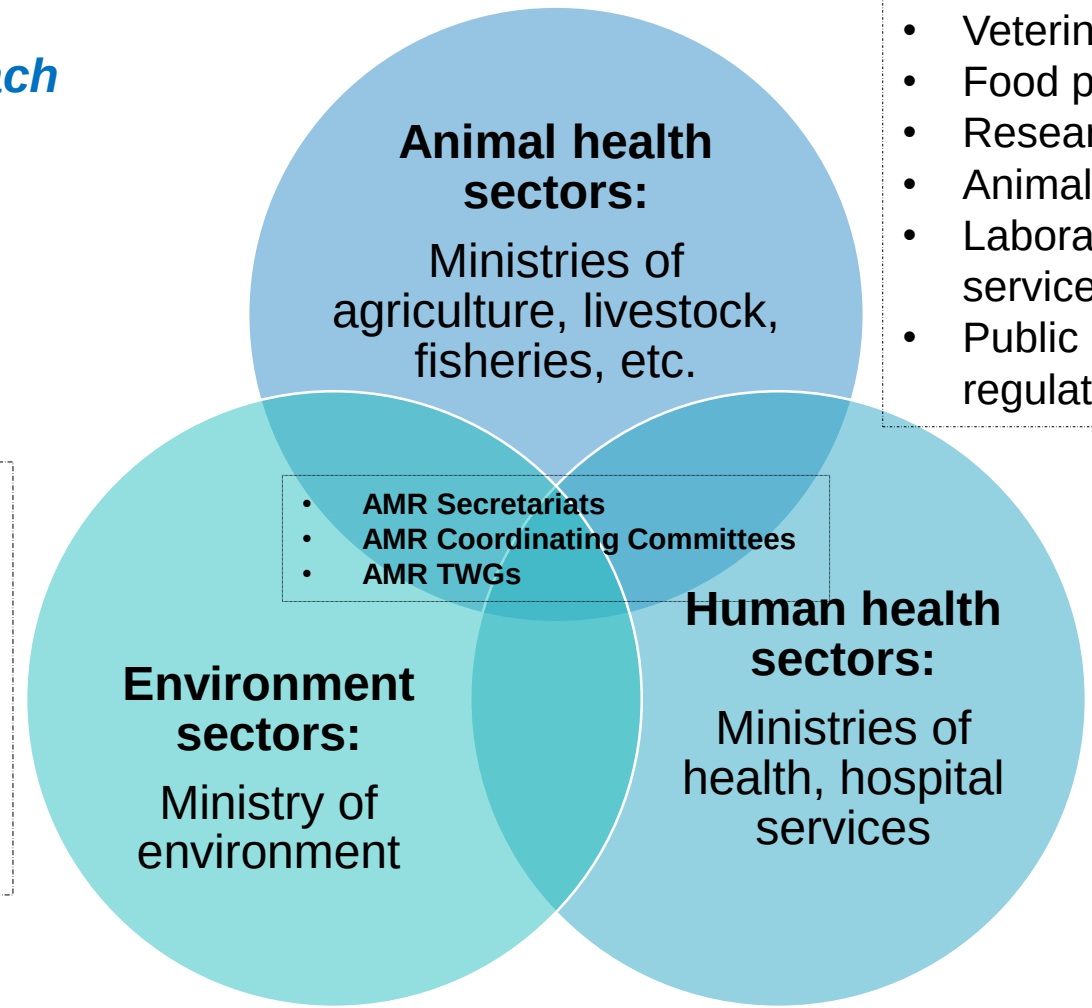
Phase II (2023-2025):

How will we promote quality?

How will we promote coordination?

Phase II: Ensuring Quality

Our OH approach invests in coordination



- Veterinary
- Food production
- Research
- Animal drugs
- Laboratory services
- Public health regulation

- Water authorities
- Protection and conservation
- Climate change offices
- Planning and development

- Public health
- Food safety
- Human drugs
- Research
- Laboratory services
- Public health regulation

Phase II: Ensuring Quality

There are 4 outcomes in Phase II. 3 of them focus on Quality.

	Outcome Area	Examples relevant to AMU in Animal Health
1	**Quality AMR/AMU/AMC data produced**	Support development/ revisions of AMU surveillance strategy, plans and protocols, farm level AMU surveillance (qualitative/ quantitative)
2	**Quality data analysis**	LIMS, data management software
3	**Quality data transmitted for analysis**	Data analysis and reporting (national/International), development / upgrading of prescription guidelines for veterinary practice
4	**Sustainability**	Support the establishment of functional AMU technical working groups; AMU fellows in key govt institutions; costing, economic value, evidences for policy making

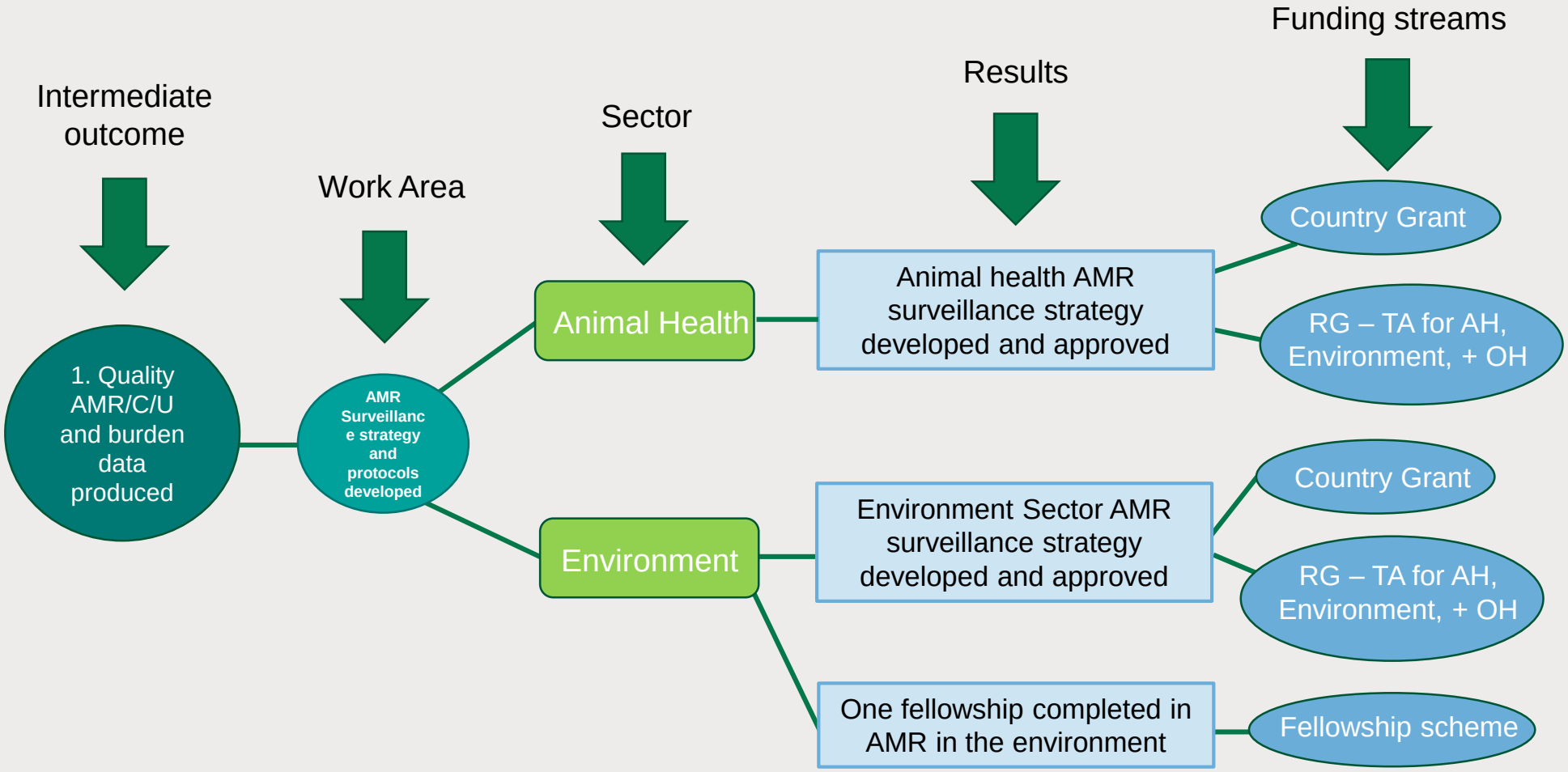
Phase II: Ensuring Quality

Country level Investment Strategies ensure alignment

- Highly consultative across ministries
- Ensures strategic alignment
- Comprehensive programming across sectors
- Generates alignment across countries and programmes
- Improved reporting, M&E
- Stronger local coordination

Phase II: Ensuring Quality

Funds and sectors are aligned to outcomes



Phase II: Ensuring Quality

Tools are promoted for standardisation and measuring progress

- Grantees are advised to follow WOAH guidelines for AMU data collection and reporting (eg: *OIE Standards, Guidelines and Resolutions on Antimicrobial Resistance and the use of antimicrobial agents, 2020*).

- Two standards are used for AMR surveillance:
  - In HH, **LSHTM core standard** for technical capacity review and GLASS reporting.
  - In AH, **Massey poultry protocol** for AMR surveillance on farms.

- Surveillance site and surveillance system planning and monitoring tools for grantees have been developed by the Fleming Fund.

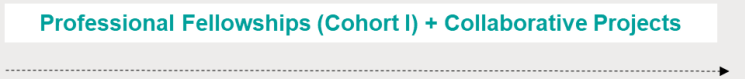
More support for Multi-sectorial Governance

Prioritization of initiatives that require inter-ministerial coordination

- NAP planning and revision
- Fleming Fellowship Scheme
- Integrated surveillance
- Institutionalization of surveillance governance and leadership (TWGs, AMRCCs, Secretariats)
- Institutionalization of the surveillance system in the greater health system
- Costed operational plans

Measuring success in Phase I

Fleming Policy and Professional Fellows learn to work together as AMR champions



Collaborative Training

Community of practice - Fellows from multiple sectors in one country communicate during their fellowships.

Activities - Fellows develop integrated, cross-sectoral projects

Policy - Policy fellows have the component of intersectoral coordination, facilitation of OH and cross cutting issues around health sector inbuilt in their work plan.

Thank you!

The Fleming Fund

Fleming Fund is a UK aid programme

Department of Health & Social Care

UKaid from the British people

Results of survey for the management of quality of VMPs in WOAH Asia and Pacific Region

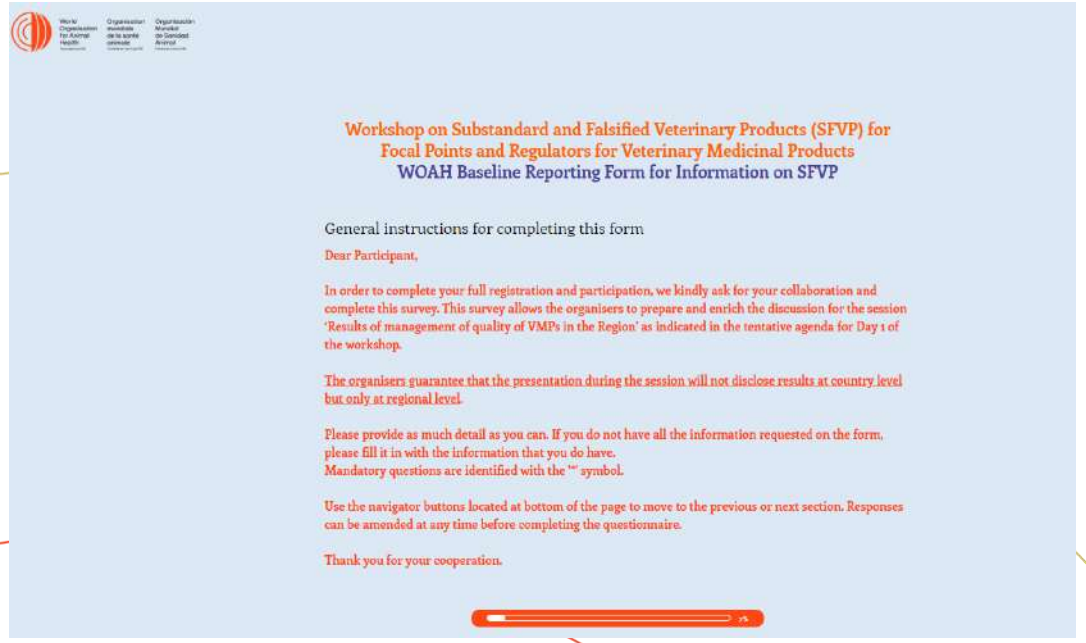
1st Workshop on Substandard and Falsified Veterinary Products (SFVP)
and WOAH pilot Veterinary Monitoring and Surveillance System for SFVP (WOAH - VSAFE)
Asia and Pacific Region

Andrés García Campos
Programme Manager - AMR & VP Department

14th June 2024 - Bangkok

World Organisation for Animal Health
Founded in 1924
Organisation mondiale de la santé animale
Fondée en 1924
Organización Mundial de Sanidad Animal
Fundada en 1924

Prior to attend the workshop ...



Workshop on Substandard and Falsified Veterinary Products (SFVP) for Focal Points and Regulators for Veterinary Medicinal Products
WOAH Baseline Reporting Form for Information on SFVP

General instructions for completing this form

Dear Participant,

In order to complete your full registration and participation, we kindly ask for your collaboration and complete this survey. This survey allows the organisers to prepare and enrich the discussion for the session 'Results of management of quality of VMPs in the Region' as indicated in the tentative agenda for Day 1 of the workshop.

The organisers guarantee that the presentation during the session will not disclose results at country level but only at regional level.

Please provide as much detail as you can. If you do not have all the information requested on the form, please fill it in with the information that you do have.
Mandatory questions are identified with the '*' symbol.

Use the navigator buttons located at bottom of the page to move to the previous or next section. Responses can be amended at any time before completing the questionnaire.

Thank you for your cooperation.

Information of previous incidents

Where there any incidents of suspect or confirmed SFVPs last year?

Have they been reported to WOAH?

Did you cooperate with any other countries?

Access to Laboratory Testing

Does your country have access to a laboratory, or have access to a laboratory from another country for testing VMP Quality?

Management of Quality of VMPs

Competent authority responsible for registration

Competent authority responsible for monitoring & surveillance of product quality

System in place for monitoring and/or surveillance already established?

Does the system involve laboratory testing?

Recall & Traceability

Legislation in place for recalls ?

Traceability systems in place? which ones?

Disclaimer

24 out of **32** Members

for Asia and the Pacific

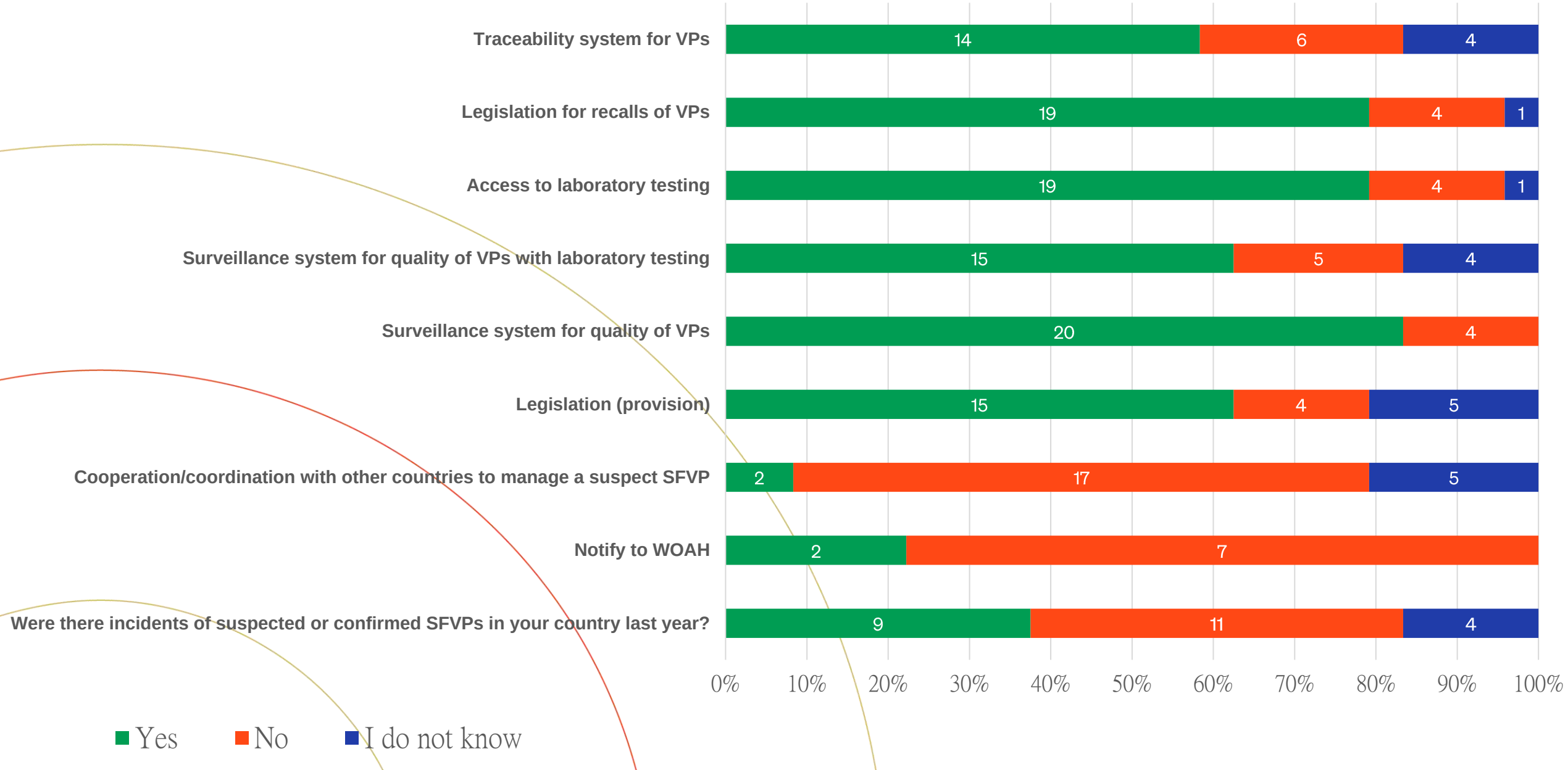
THANK YOU !!

Responses verified by **participants** to their best of their knowledge

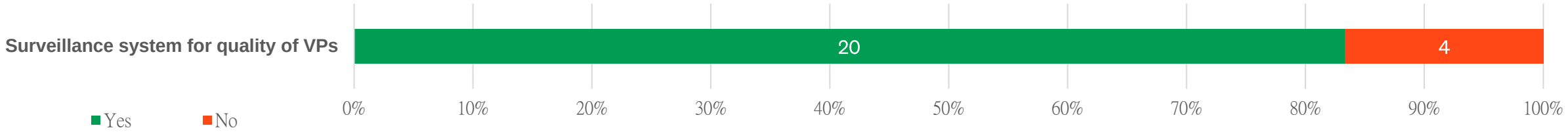
More in-depth assessment may be required for final validation

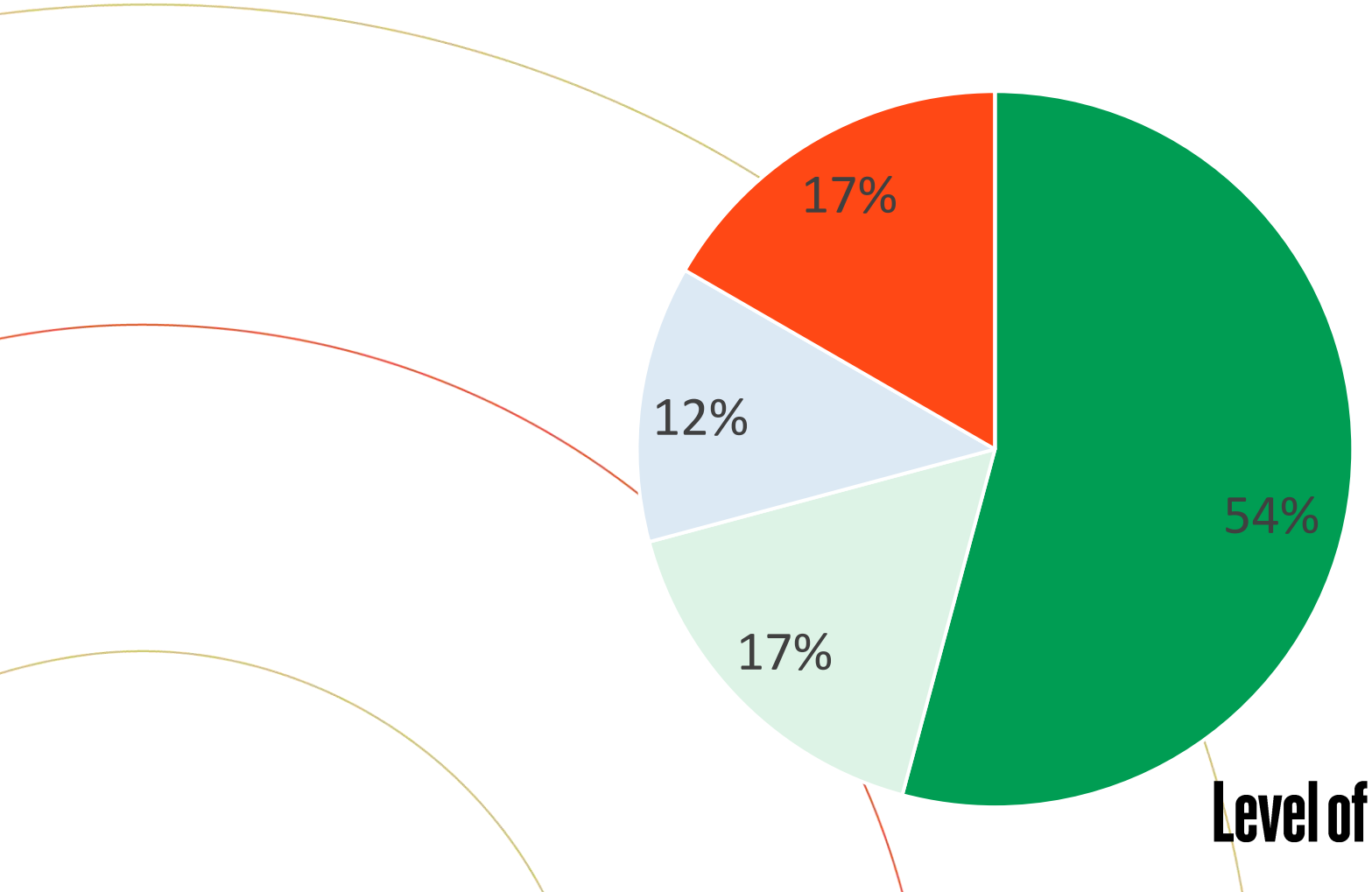
Responsibilities		Ministry of Agriculture	Ministry of Health	Both	Other/None
Registration		15	8	0	1
		16	5	2	1
	PREMIX	20	1	2	1
Monitoring & surveillance		15	6	2	1
		16	6	1	1
	PREMIX	20	1	2	1

Overall responses (N = 24 out of 32 Members from A&P Region)



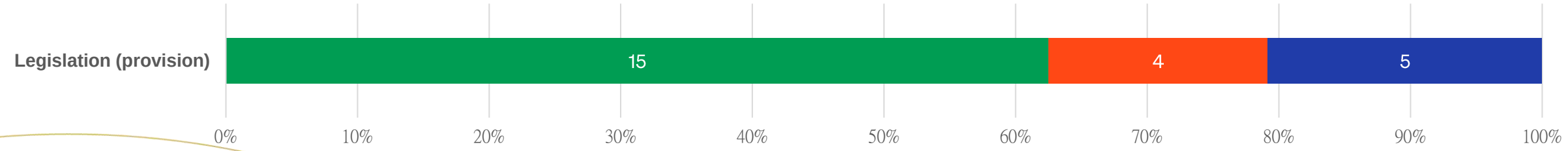
Surveillance system for quality of Veterinary Products

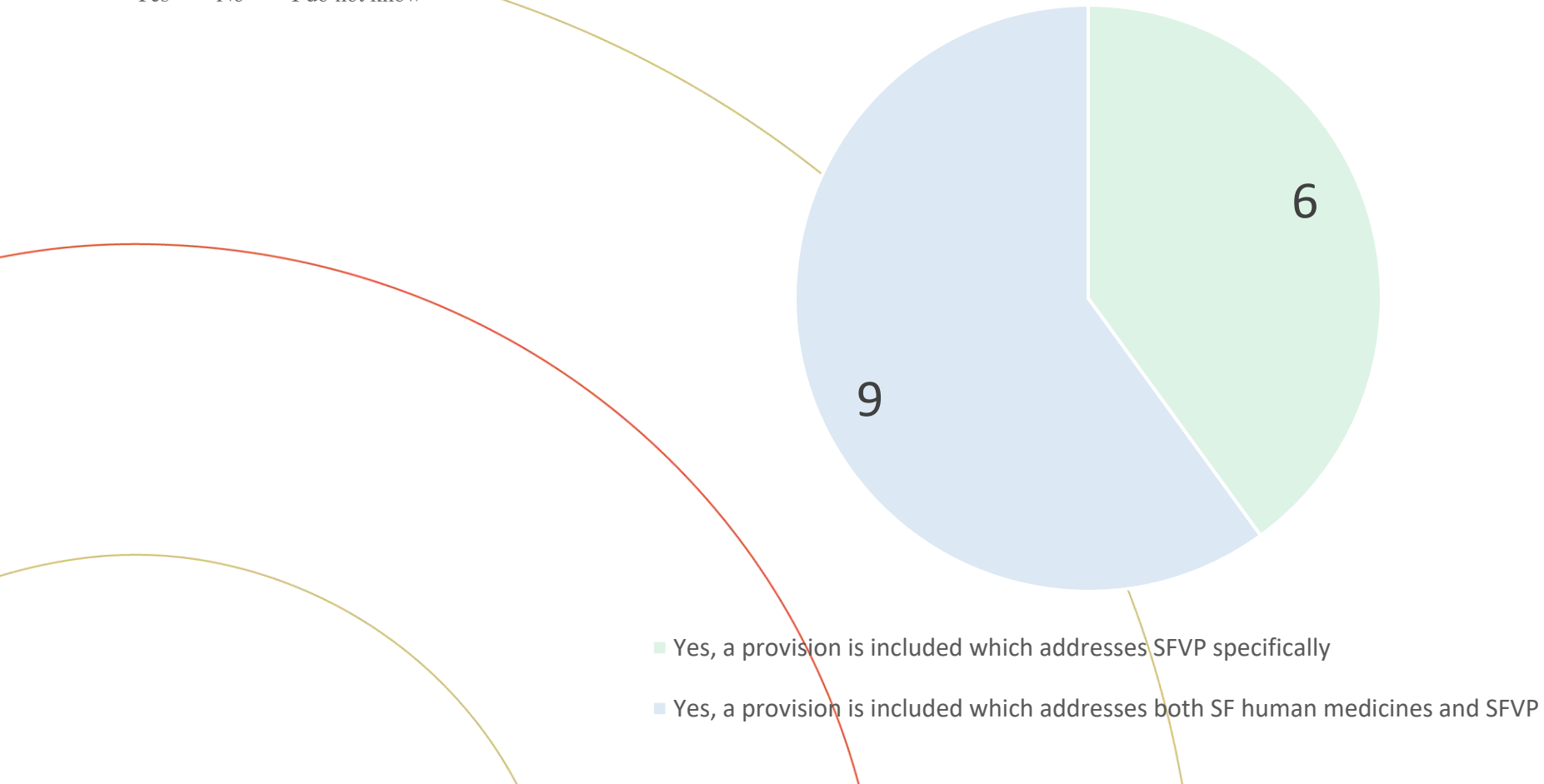




Level of surveillance of VMPs not very consistent

Is there a legislation in place which includes a provision to identify SFVP?






Let’s hear your
reactions !!!

Thank you

Merci

Gracias

sfvp@woah.org

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
Founded in 1924

Organisation mondiale de la santé animale
Fondée en 1924

Organización Mundial de Sanidad Animal
Fundada en 1924

Post-workshop

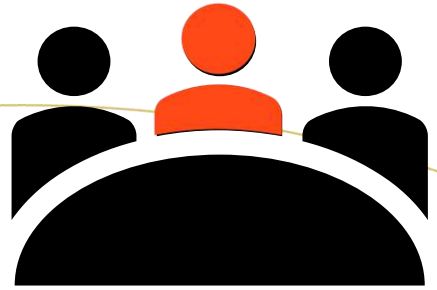
1st Workshop on Substandard and Falsified Veterinary Products (SFVP)
and WOAH pilot Veterinary Monitoring and Surveillance System for SFVP (WOAH - VSAFE)
Asia and Pacific Region

Andrés García Campos
Programme Manager - AMR & VP Department

14th June 2024 - Bangkok

World Organisation for Animal Health
Founded in 1924
Organisation mondiale de la santé animale
Fondée en 1924
Organización Mundial de Sanidad Animal
Fundada en 1924

All CURRENT Member Participants with access to VSAFE

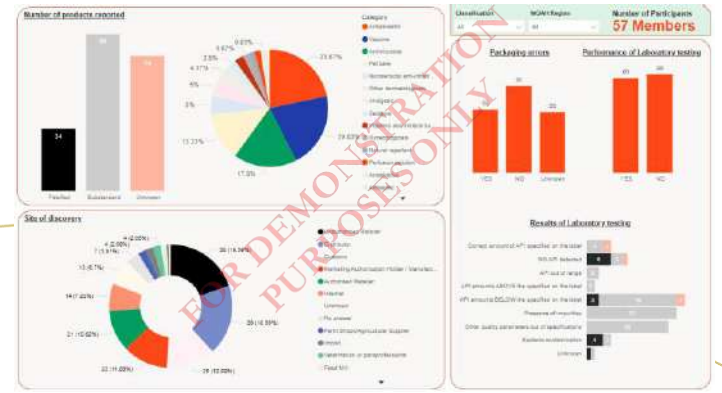


Discuss with team & Delegate in case that users from Reg. authority are needed

Email sfvp@woah.org if:

- Name and email of new user/s
- Any Changes in Focal Points

All NEW Member Participants will have access to VSAFE until 25th June 2024



Continue to use all portal, including dashboards

25 June

Share any additional feedback

Discuss with team & Delegate, Coordinate with Reg. authority if needed

Email from Delegate sfvp@woah.org if agreed to enroll VSAFE


SFVP Post-Workshop Evaluation
Please give us feedback!
World Organisation for Animal Health
Founded in 1924
Organisation mondiale de la santé animale
Fondée en 1924
Organización Mundial de Sanidad Animal
Fundada en 1924

Thank you Gracias Merci ขอบคุณ

sfvp@woah.org

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
Founded in 1924

Organisation mondiale de la santé animale
Fondée en 1924

Organización Mundial de Sanidad Animal
Fundada en 1924

Who is RAGNA?

The Regulatory Agencies Global Network against AMR (RAGNA) is an initiative by the Swedish Medical Products Agency (Läkemedelsverket) during the Swedish Presidency of the Council of the European Union, in collaboration with the Quadripartite Organizations (FAO, UNEP, WHO & WOAH). RAGNA, which consists of global representatives from human and veterinary medicines regulatory agencies, facilitates collaboration and knowledge sharing among agencies and advocates for the regulatory perspective in the global One Health response to combat AMR.

RAGNA

a global forum of regulators, key players in combating antimicrobial resistance (AMR) and contributing to global solutions

There are strong links between AMR, the antimicrobial cycle, the role of regulators, and international instruments on antimicrobial usage. Effective regulation and responsible use of antimicrobials throughout their life cycle – from production to disposal – is paramount to effectively address AMR. Regulatory agencies, particularly those overseeing human and veterinary medicines, have significant influence in ensuring good manufacturing processes, facilitating controlled access to safe, effective and high-quality antimicrobials, while also preventing their disposal into the environment. The UNGA High-Level Meeting on AMR in September offers a great opportunity to boost this agenda. To better inform Member States as they craft this meeting's political declaration, Regulatory Agencies Global Network Against AMR (RAGNA) has prepared a list of key recommendations voicing the joint inputs of international regulators across the human and animal veterinary medicines sectors:

RAGNA recommendations to prevent and mitigate impacts due to AMR

1 Countries should strengthen One Health multisectoral regulatory governance of medicines.

As a multi-sectoral challenge, AMR demands a One Health lens when applying regulatory frameworks. Similarly, National Action Plans on AMR (NAPs) should be multi-sectoral and multi-disciplinary with coordination mechanisms that are sustainable, accountable, and appropriately equipped with human and financial resources. To facilitate communication and aid coordination, countries are encouraged to develop robust regulatory networks across human, animal, plant, and environmental sectors, incorporating international guidance in the management of human and veterinary medicinal products throughout their lifecycle, and in other areas relevant to AMR.

The Quadripartite Joint Secretariat (FAO, UNEP, WHO, WOAH) supports the work of RAGNA, to advocate for strategic and political action for AMR.

2 Medicines registration and authorization processes should ensure quality, efficacy and safety of antimicrobials and protect the environment.

Benefits of regulatory registration and authorization procedures are numerous, and given their importance, should be coordinated by National Regulatory Authorities (NRAs). Application of good manufacturing practices is key, ensuring safety, efficacy, and quality of antimicrobials while reducing environmental impact by minimising antimicrobial discharge to the environment through waste and wastewater management interventions. To promote responsible and prudent use of antimicrobials, and to reduce the likelihood of AMR development and spread, several considerations should be covered in the registration process. These should include an assessment of environmental risks from human and veterinary medicinal products, relevant restrictions or precautions for use of the medicinal products, and admission of only registered products to market. To improve access, countries may wish to employ mutual recognition, harmonization, or regulatory reliance strategies to increase product registration. Where this is not possible, countries should utilise existing tools and support mechanisms to facilitate registration. Countries are also urged to enable product registration to assist the development of alternatives to antimicrobials, and to encourage manufacturers to expand applications to smaller markets. Regulatory frameworks should include the surveillance and reporting of substandard and falsified antimicrobials of human and veterinary use.

3 Managing access and promoting prudent and responsible use of antimicrobials to reduce their need and use and preserve efficacy for future generations.

Access to antimicrobial products should be ensured for prudent, responsible, and sustainable use. Countries are encouraged to develop national lists of essential medicines using tools such as the WHO Essential Medicines List; access to these medicines should be guaranteed. Development and implementation of diagnostic testing and access to relevant and correct information are both key for the prudent and responsible use of antimicrobials. Countries should implement legislation on appropriate labelling (including the correct dosage regimen, expiration, directions to contact the authorized professional in cases of treatment failure, safe and proper disposal, and withdrawal periods for food-producing animals) to ensure that such information is available to prescribers and users of antimicrobials. Legislation reserving the prescription of antimicrobials to authorized professionals only and restricting the over-the-counter sale and unauthorized sales of antimicrobials (including over the internet) should be implemented and enforced, without compromising human and animal health. Similarly, since antimicrobials should be used only when necessary, countries are encouraged to prevent the marketing or advertising of antimicrobials to the public and remove incentives to those prescribing and using antimicrobials, whilst promoting sustainable public procurement practices. Regulatory frameworks should impose restriction on the use of critically important antimicrobials for humans and animals (based on WHO Medically important Antimicrobials and the WOAH list of Antimicrobials of Veterinary Importance) to safeguard access to quality and efficacious products. Countries should actively act towards ending non-veterinary medical use.[1]

4 Multisectoral monitoring and surveillance efforts to support AMR policies and interventions.

Countries are urged to allocate financial resources in national budgets to establish, improve, and maintain national AMR monitoring and surveillance systems for informed decision-making processes. Collaboration across the One Health spectrum is key to surveillance efforts, and this should be reflected in the creation of national integrated surveillance mechanisms as part of multi-sectoral National Action Plans for AMR, with all actors and sectors sharing responsibility for data collection and use, and information sharing. Countries should continue the reporting of imports and sales data of antimicrobials and commit to move towards the reporting of antimicrobial use and adverse reactions to treatment - including treatment failures - by those who administer antimicrobials in the future. This stepwise approach aims to facilitate monitoring of antimicrobial consumption in humans and animals and to allow a post-marketing authorization regulatory assessment to evaluate benefit/risk and recommendations for use.

5 Equitable research and development of antimicrobials and alternatives to antimicrobials including vaccines and diagnostic tests across sectors.

Preventative actions for infectious diseases should be put in place to preserve the effectiveness of antimicrobials, while development of new antimicrobials and alternatives to antimicrobials is also urgently needed. Collaboration between actors in the research and development process is essential to expediate timelines. Regulators should actively facilitate the development of new and alternative human and veterinary medicinal products, whilst ensuring infection prevention and control, and promoting biosecurity and biosafety measures to reduce the need for antimicrobials and avoid discharges into the environment.

1 'Non veterinary medical use of antimicrobial agents': means the administration of antimicrobial agents to animals for any purpose other than to treat, control or prevent infectious disease; it includes 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. (WOAH Terrestrial Animal Health Code, Chapter 6.9, Article 6.9.2)