出國報告（出國類別：會議）

參加第 2 屆亞洲藥物市場暨核價高峰會
(The 2nd Pharma Market Access & Pricing Summit Asia)

服務機關：衛生福利部中央健康保險署

姓名職稱：黃育文 專門委員

派赴國家：新加坡

出國期間：107 年 9 月 18 日至 107 年 9 月 21 日

報告日期：107 年 12 月 19 日

摘要

本次「第 2 屆亞洲藥物市場暨核價高峰會 (the 2nd Annual Pharma Market Access and Pricing Summit Asia 2018)」係由 IBC 公司舉辦，該公司是 Informa plc 公司的亞洲部門，而 Informa plc 公司是目前提供世界各國市場趨勢及知識分享的最大平台，舉辦各項會議和課程，邀請各國法規主管機關之演講者，或產業/企業界領導階層人士與會，除蒐集各國家醫藥領域相關之產品管理法規最新資訊，並提供學術期刊、即時新聞、商業情報等服務。也藉此建立企業、商品、金融、生命科學、電信等多個領域之領袖、專家、傑出人士等交流和提供商業資訊的平台。

本次會議時間共 2 天，在大會(4TH Annual Phamacon Aisa)之下，按藥品上市管理法規趨勢(11th Annual Pharmaceutical Regulatory Affairs Asia)、藥品製造准入市場與藥價給付制度(2nd Pharma market Access and Pricing Summit)、製藥數位化(Digital Pharma Asia)及加速臨床試驗(2nd Accelerating Clinical Trials)等不同主題分為 4 場會議同步舉行。本次本署受邀於「2nd Pharma Market Access and Pricing Summit」場次下，一場演講講題為「Accelerating Patient Access throughout HTA reimbursement Process in Taiwan」，一場主題訪問「Fireside Chat: Payer insights from Government Perspective」，該會議邀請到藥品產業人士及官方代表，分享亞洲地區各國藥品市場現況，未來趨勢以及保險給付制度等。藉此機會，讓其他國家瞭解臺灣的健保制度，擴展臺灣的能見度。

透過本次會議與各國講者及與會者的分享及交流，除可瞭解亞洲地區藥品市場的概況、鄰近國家保險給付制度的最新進展，以及發展保險給付制度上所面臨的問題及考量點，並可同時瞭解臺灣及臺灣的健保制度之於亞洲地區藥品市場的地位。有利於國外藥品進入臺灣市場先行了解。全球國際化，法規調和是普遍共識，在新南向政策的推展下，我國與東南亞地區國家之經濟貿易夥伴發展連結日益緊密，藉由此機會進行國際交流並瞭解鄰近國家地區的現況，有助於累積促進我國醫藥產業發展南向之能量。

壹、會議目的

因應全球化的發展，亞洲國家已成為全球重要的藥物臨床開發和製造基地，但各國主管機關對於醫藥品的生產、交易和銷售上相關的管理規定仍然有很大的差異，相關法規及制度的發展亦不盡相同，調和進展空間還很大。又因應數位化與大數據的應用全球發展趨勢，今年新增一場 Digital Pharma Asia 並行會議。亞洲地區特別是東南亞地區的區域整合經濟網絡日益緊密，故各國間的交流及資訊分享極為重要。

本次由 IBC Asia 公司舉辦之「第 4 屆亞洲藥物市場年會(Annual Pharmacon Asia)」，以亞洲地區各國的市場為主題，邀集臺灣、日本、韓國、新加坡、馬來西亞、大陸、菲律賓、印尼、印度、越南及歐美澳等國之專家及企業代表等進行交流，旨在讓與會者瞭解各國藥品市場及保險給付制度的現況與未來發展趨勢。

貳、行程及會議內容

一、行程：

日期	行程內容
9 月 18 日	去程，台北→新加坡
9 月 19-20 日	參加會議
9 月 21 日	返程，新加坡→台北

二、會議內容：(議程如附錄一)

(一)亞洲地區藥品市場概況

亞洲地區，包括臺灣、日本、澳洲、紐西蘭、韓國、中國大陸及新加坡等東南亞國協(Association of Southeast Asian Nations, ASEAN)10國，不僅人口數眾多，且有許多為開發中的國家，在製藥產業上具有市場開發潛力，因此深深吸引先進國家製藥業。近來各國經濟發展快速，醫療科技進步，人民的平均餘命延長，隨著人口老化後，慢性病與癌症治療耗費醫療資源年年增長，各國對於醫療器材及藥品的需求急速提升，各國政府對於醫療健康照護也日益重視。相較於先進的歐美市場日趨飽和，對於製藥產業而言，亞洲地區是一充滿商機的重要新興市場，故跨國藥廠均在密切關注亞洲地區藥品市場的動態，並積極研究如何開發亞洲市場的商機。

由於亞洲地區同國家經濟發展的程度及人口結構不同，對於醫療及用藥的需求亦不盡相同。日本、臺灣、韓國、香港和新加坡等國家對於醫療

照護系統比較先進發達，法規也較為完整，但在其他國家多在起步階段，因此在醫藥管理法規上，雖有調和機制但也因各國之文化差異與基本需求不盡相同，其國家主權管理上也都有區別。對於經濟相對發展較落後的國家，例如印尼、菲律賓、越南等，國家醫療資源的照護重點在於盡可能提供所有國人基本的醫療需求，或是基於公共衛生的考量把傳染病的防治列為醫療照護之基礎重點。對於醫療用藥，這些國家的重點在於確保基本醫療需求或防治傳染病所需之必要藥品的穩定供應，以及民眾能在經濟可負擔的情況下適時取得所需的藥品，故政府僅給付少數的藥品，其他都必須由民眾自付。對於已歷經經濟快速發展且人口數眾多的國家，例如中國，由於近來經濟成長速度開始出現逐年趨緩的現象，人口卻持續成長並有邁向老化的趨勢，在醫療需求快速增加之下，現行的醫療保險給付制度面臨了日益沉重的財務壓力，於是紛紛開始尋求改革，變得更加重視醫療資源的有效分配及以價值效益為導向的給付制度，以減少保險給付制度的財務負擔並確保永續發展。對於已高度開發的國家，例如日本，由於人口老化問題較嚴重，且對於高價藥品的需求較高，保險給付制度所面臨的財務壓力更為沉重，政府更積極於尋求減緩財務負擔的因應策略。儘管不同國家因經濟發展的程度不同，各國醫療照護體系所面臨的挑戰及考量點亦不盡相同，然綜觀而言各國的醫療照護體系仍循著相同的脈絡在演進，只是位處於不同的階段；故開發較慢的國家可以從較先進的國家學習經驗，以提早瞭解未來可能會遇到的問題並提早因應。

(二)醫藥界發展趨勢

由新加坡 A*STAR 的 Biomedical Research Council 資深總監 Dr. Danny Soon 報告最近產業發展趨勢，在醫藥品研發領域，法規變革趨勢，核價機制都與過去傳統製藥和醫療器材發展有很大轉變；全球藥業市場趨勢主導者為美國和歐洲，美國 FDA 近幾年核准的產品可以看出端倪， 2017 年 4 月核准第一個直接由民眾使用的體外診斷試劑醫療器材(IVDs) direct-to-consumer (DTC)基因檢測，檢測結果透過專業諮詢輔助臨床醫師疾病診斷或治療追蹤等，以期達到更大的治療效益；2017 年 8 月核准第一個細胞治療產品 CAR-T 細胞，Kymriah ™用於治療小孩或青少年之 B 細胞急性淋巴癌；2017 年 9 月也核准了第一個移動式醫療軟體應用(mobile medical application)，利用智慧型手機下載醫療應用軟體幫助毒品依賴者(substance use disorder, SUD)的戒斷行為治療，讓數位科技實際應用於醫療跨下一大步。隨著新科技產品問世，醫藥品的市場價格也有了大的轉變，市場主流變成是生物製劑(參考表一)。

表一

Bump from Biologics

Top Selling Drugs 2006			Top Selling Drugs 2016		
Name	Revenue in millions (USD)	Monthly WAC	Name	Revenue in millions (USD)	Monthly WAC
Lipitor	$12,886	$105	Humira	$16,499	$4,480
Advair	$6,104	$150	Enbrel	$9,234	$4,480
Plavix	$6,056	$119	Harvoni	$9,081	$34,448
Nexium	$5,182	$128	Rituxan	$8,583	$7,529
Norvasc	$4,866	$60	Remicade	$7,561	$3,215
Zyprexa	$4,364	$447	Avastin	$7,053	$11,657
Diovan/Co-Diovan	$4,223	$105	Herceptin	$7,052	$6,732
Aranesp	$4,121	$1,333	Revlimid	$6,974	$16,931
Rituxan	$3,863	$4,438	Lantus	$6,343	$2,283
Effexor XR	$3,722	$181	Prevnar	$5,718	$174
Average monthly WAC		**$707**	**Average monthly WAC**		**$9,193**

Table 1. Monthly wholesale acquisition cost (WAC) prices in the US of top-selling drugs in 2006 and 2016. **Notes:** Global revenue for top-selling drugs according to PharmaCompass.com and GlobalData.com. 2006 monthly WAC prices calculated based on 20% discount to Red Book-reported average wholesale price (AWP). 2016 monthly WAC prices calculated based on Medi-Span PriceRx-reported WAC prices for the first year of treatment.

(三)亞洲罕藥發展與給付制度

目前罕見疾病的定義隨著各國家的人口及遺傳流行病學有不同的定義，台灣是以萬分之一發生率來認定，美國的定義是少於 20 萬個病人的疾病，歐洲是以 1/2000 人中有 1 的發生率，日本是以少於 5 萬個病人的疾病(依其總人口數計算約 1/2600)，南韓以少於 2 萬人(依其總人口數計算約 1/2600)，而 ASEAN 中只有新加坡、菲律賓、馬來西亞和印尼有罕見疾病的定義，其發生率如表二。

表二

In ASEAN 6:	
Country	**Definition of Rare Disease**
Singapore	Life-threatening and severely debilitating illness affecting less than 20,000 people in its population of 5.5 million. (**~1 in 275**)
Philippines	A genetic disorder which affects less than **1 in 20,000** people in the country.
Malaysia	One which affects less than **1 in 4,000** people in the country.
Thailand	**No definition** of a rare disease and no specific rare disease policies. (Thailand use "shortage of medicine" as a criteria for orphan drug designation.)
Vietnam	**No definition** of a rare disease. (Rare disease management was made a priority in the new Pharmaceutical Law. Currently no specific orphan drug legislation in Vietnam.)
Indonesia	Less than 200,000 patients in Indonesia. (**~1 in 1,300**)

而真正有特別法規可遵循的只有醫療先進國家如日本、台灣、韓國、香港和新加坡，而菲律賓 2016 年才有罕見疾病法，其他國家則尚在發展中。在健保給付制度上，就臺灣、日本、韓國有較健全的國家預算支付，新加坡和香港主要是靠私人保險，不可諱言，罕見疾病的治療，不論是在診斷或是治療上都是醫療預算上很大的支出，對於財政有衝擊，對於罕藥市場也較缺少吸引力。

(四)風險分擔合約的藥品給付模式

為了讓病人及早(early access)使用具有潛力效益的新藥品，為了橋接新藥 added value 與 alternatives 之間的時差，在新藥證據尚不足以讓主管機關評估該付多少錢給付於新增加的醫療價值而收載於健保給付列項，(cost-)effectiveness still unknown，但是病人想要用，臨床上想要有新的選擇。風險分擔合約給付(managed entry agreement, MEA 或 risk-sharing agreement, RSA)是一個方式。這些新藥的特點是，雖僅具有潛在效益但通常很貴，在國家醫療有限資源(limited public resources)，要滿足病人對於新藥的可近性，於是利用各種 risks sharing scheme 來給付這些具潛力的新藥，. 病人及早取得這個具有潛在效益的昂貴新藥 (early access), 再利用上市後同時蒐集真實世界資料，在合約到期時，分析評估這些數據，期望評價這些具潛在藥品的實際臨床價值。

採用風險分擔之藥價管理給付策略已成為新藥(尤其腫瘤治療新藥)快速進入市場的機制之一，優點是: (1)病人可以提早選用具有潛力的藥品，(2)藥廠會較願意研發創新藥品，且節省藥廠產品上市的研發成本，(3)對於整體臨床而言，藉由真實世界的資料蒐集，較明確證實新藥的臨床效益。但是缺點包括: (1)政府財政衝擊很難預估，(2)缺少療效的臨床試驗證據，而臨床實證資料並不那麼容易蒐集分析或評估，導致新藥上市時的不確定性，在新藥上市數年後仍然不確定，(3)因為缺少 robust researches 藥品的副作用或不良反應難以掌握，所帶來的醫療支出無法估算，(4)保險人與藥廠

的協商合約隱密性，導致公開價格常常是很昂貴，反而讓新藥真正的價值估算出現偏差，(5)大數據的建立，通常在合約結束，分析資料時才發現不足，對於合約的延續多了變數。

韓國是亞洲國家中較早引進 RSA 給付機制，主要形式有還款機制、藥品項目支出總額限制、每個病人治療總額限定機制、有條件治療機制、藉由上市後證據蒐集計畫納入治療病人給付方式(coverage with evidence development)，最長合約是 4 年。必須符合下列幾種狀況中至少兩種以上的條件才能採用 RSA 的合約方式進入市場，(1)臨床上無替代療法。(2)治療嚴重疾病或威脅生命之疾病(如生命存活期少於二年)，(3)罕見疾病治療藥物，(4)可利用的臨床試驗證據證明可以延長病人的存活期。如果採用 RSA 方式進入市場，必須要有 pharmacoeconomic evidence 來支持健保給付。儘管 RSA 可以讓藥廠研發的新藥有及早進入市場的機制，但仍然有不少藥品因為不確定的 cost-effectiveness 而被 HIRA 拒絕(參考表三)。

表三

The rejections by HIRA were mainly due to the uncertainty in cost-effectiveness

Drug name	Indications	Indications
Cetuximab	• Advanced head and neck squamous cell carcinoma • Colorectal cancer	Uncertainty in cost-effectiveness given higher drug costs than its comparator, and uncertainties around evidence development, resource selection, and modelling process to derive the ICER.
Crizotinib	Locally advanced or metastatic NSCLC	Uncertainty in cost-effectiveness given higher drug costs than its comparator and based on the ICER demonstrated by the submitted PE.
Pertuzumab	HER2+ EBC and MBC	Same as above
Trastuzumab emtansine	Recurrent HER2+ MBC	Same as above
Elosulfase alfa	Morquio A syndrome	Same as above
Regorafenib	Metastatic colorectal cancer	Uncertainty in cost-effectiveness based on drug costs per cycle.
Vemurafenib	Unresectable or metastatic melanoma	Uncertainty in cost-effectiveness given higher drug costs than its comparator and the weighted price based on prices in A7 countries.
Carfilzomib	Multiple myeloma	Uncertainty in cost-effectiveness given higher drug costs than its comparator (the manufacturer did not submit a PE due to the small patient population).

Source: Costello Medical (2018)

(五)真實世界資料應用的挑戰

真實世界資料(real world data, RWD)的蒐集作為實際臨床效益評估已成為新藥品或創新醫療器材上市後要求的趨勢。由於科技的進步，很多新創產品尤其是高價昂貴之新科技產品陸續上市，且是在安全性評估許可，僅具可能的臨床效益(unmet medical needs)，但卻還無法評估其 cost-effectiveness。在此種狀況下，主管機關多會要求藥(材)商須在產品上市一段期間內蒐集實際臨床上使用的相對數據，完成 Health Economics and Outcomes Research (HEOR)與 RWD 的評估，產出 real world evidence (RWE)支持可能的臨床效能以協助保險人評估 cost-effectiveness。各國落實 HEOR

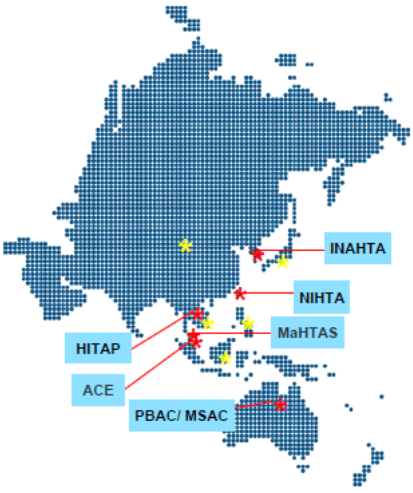
& RWE 的作法不是很一樣，澳洲、臺灣、泰國、南韓、馬來西亞、新加坡之國家健康保險決定是不是要收載一項新醫療科技產品時，會要求廠商檢送 cost-effectiveness analysis (CEA)和 budget impact analysis (BIA)的報告，並進行 HTA 評估後才決定是否要收載，核予合理價錢，作為臨床支付之依據。我國中央健康保險署相較於其他國家，擁有較完整的申報資料庫，因此對於收載產品後續的追蹤資料蒐集較其他國家有優勢。但是 RWD/RWE 的資料，不能單靠保險人，最關鍵的是醫療院所實際使用情形，必須完整的上傳數據資料，且這些數據資料庫必須要在新品項開始在臨床端使用時即提出具體的目的，架構資料庫的雛型，要求醫療院所上傳病人使用的治療反應與健康狀態時的品質，所蒐集的資料經過適當的確效與對的統計方法分析，才能得出可用準確/精確的結果。亞洲各國對於真實世界資料的使用情形詳參表四，資料蒐集的關鍵步驟如圖一。

普遍各國都認同 RWD/RWE 是需要在上市產品的全生命週期間，動態評估，且要將病人使用後的經驗也一併納入 RWE 的評估報告，動態監測新科技產品於實際臨床上的效益情形，根據這些真實世界數據評估的結果調整產品給付價格或給付範圍，直到穩定的臨床效益結果呈現。

表四

Evidence requirement for reimbursement

HTA requirement/ consideration



Established HTA Agencies	Evidence requirement/ in consideration
Australia: MSAC/ PBAC	CEA and BIA required for decision
Thailand: HITAP	CEA, BIA are compulsory for some high cost treatment
Taiwan: NIHTA	Comparative effectiveness and BIA are required
South Korea: INAHTA	CEA and BIA required for decision
Malaysia: MaHTAS	BIA required
Singapore: ACE	CEA and BIA for full review and BIA for expedited review

Pending HTA Establishment	Evidence requirement/ in consideration
China	Has decision making framework
Japan	Value based pricing, Inclusion of cost-effectiveness analysis is in pilot phase
Indonesia	Has expressed intent to develop HTA decision making framework
Philippines	Has expressed intent to develop HTA decision making framework
Vietnam	Has expressed intent to develop HTA decision making framework

CEA = cost-effectiveness analysis
BIA = budget impact analysis

★ represent countries without established HTA agency; ★ represent countries with established HTA agency

圖一

(六) 臺灣

由育文以「Accelerating Patient Access throughout HTA reimbursement Process in Taiwan」介紹臺灣健保制度下新藥的收載流程及核價方式，醫療科技評估(health technology assessment, HTA)如何協助臺灣健保縮短新藥核價程序，增加病人對於新藥可近性所扮演的角色等，報告資料如附錄二。另外在主題訪問「Fireside Chat: Payer Insights from Government Perspective」，以個人觀點分享單一健保制度的經驗，育文以署長接受 Huff post 記者訪問，由 Mr. Jonathan Cohn 主筆發表的文章「If You Don't Believe Single Payer Can Work, See How They Do it in Taiwan」為基礎，將臺灣健保的獨特性和幾項重要改革，包括雲端藥歷(PharmaCloud)到醫療雲(MediCloud)，分級醫療的推動與落實，利用大數據檢核重複用藥機制，健康存摺讓民眾為自己的健康把關等分享與會者，並推薦與會者下載讀此文，與談資料如附錄三。

(七)日本

本次會議負責分享日本健保藥品給付制度的講者為 Deallus Consulting Japan K. K.的 Representative Director, Mr. Yuki Sato，報告針對罕藥的給付變革，摘要如下：

1. 日本健保是全民納保的國家，主要財源來自被保險人繳納的保費及稅收等；大部分的國民需負擔醫療費用 30%的部分負擔(co-payment)，惟部分負擔的比例會隨著病人族群的不同 (如年紀)而調整。

2. 近幾年，日本政府在新創藥品上，鼓勵基因治療和細胞治療。主管機關厚生勞動省(MHLW)不僅在 2014 年特別制定再生醫療法規，以有條件式的核准方式，加速上市審查核准程序(SAGIKAKE)，鼓勵安全性經審查符合法規的創新產品，如細胞製劑產品，先讓臨床治療癌症上有新的選擇，要求醫院及業者蒐集臨床實際治療經驗資料，在一定時間內分析這些上市後的 phase IV study 或 real world data，評估實際臨床效益。尤其是創新性、方便性、兒童用藥、在日本第一個上市且用於治療 unmet medical needs 製劑，也會要求實際臨床資料的蒐集與分析評估，因此真實世界資料(real world data & real world evidence)的重要性及其作法也成為醫藥品核准上市後，主管機關、醫療機構與藥廠的共同責任義務。

3. 因應快速成長的藥費支出，以避免新藥納入收載後，市場快速擴張(如用藥人數遽增、適應症擴增等)，導致實際藥費支出大幅超出原預估之藥費，目前日本厚勞省正在規劃健保藥價制度改革，包括擴增新適應症調整藥價、提升新藥核價方法(成本計算法、類似療效比較法)的透明性及正確性、依國際藥價調整支付價格、藥價調查及調整的方式、學名藥的核價方式、研發創新的獎勵、正式施行 HTA 等。

(1) 有關藥價調查及調整，日本正在規劃增加調查及調整的頻次，目前例行性兩年一次的藥價調整之外，對於因擴增適應症藥費支出快速成長的藥品每年進行 4 次藥價調查；自 2019 年開始，將對於藥價差過高的藥品，額外增加非例行性的調查。

(2) 有關醫療科技評估(HTA)制度，日本是以試辦計畫方式，針對少數高價藥品(如用於治療癌症的 Opdivo、Kadcyla 等)進行 HTA 評估，但已規劃未來將對所有新藥均進行 HTA 評估。

(八)馬來西亞

馬來西亞近幾年很活躍，衛生主管機關對於各項管理法規包括健保給付制度，都很有企圖心想要超越新加坡成為 ASEAN 主導者。其醫療照護體系主要分為兩個系統，一個是為以公立醫院為主的醫療福利體系，以一般稅收為主要財源，提供民眾收費低廉但是等待時間長的醫療服務，屬於社會福利取向的系統。民眾就醫時只需負擔約 0.3 美元的掛號費，即可在公立醫院獲得醫療服務，但公立醫院往往就診人數眾多，就醫等待時間很長。此外，公立醫院只能開立經政府列入公定處方集(Blue Book)的藥品，惟因藥品列入 Blue Book 的條件十分嚴格，故病患在公立醫院能使用的藥品選擇很有限。馬來西亞的另一個醫療照護系統則是私人醫療保險，病患如欲接收較高品質的醫療服務或使用較昂貴的藥品，通常必須透過私人醫療保險才能夠取得。

儘管公私立醫療照護體系差異大，馬來西亞近幾年，一方面建設制定醫藥相關管理法規與民眾基本醫療照護基礎，同時也著重於如何提升新藥與新醫療科技的可近性，加強適當的病人參與並與醫療機構成為合作夥伴，期望建造公私醫療網絡，應用大數據，執行以病人為中心的醫療照護計畫，讓馬來西亞的民眾取得新醫療科技產物的距離不再那麼遙遠。但是

法規制度的建立仍然有一大步的空間需要主管機關去跨越。

(九) 澳洲

澳洲一直是我國收載藥品或特材時核價的參考國家之一。本次會議由AstraZeneca 的 Greg O'Toole 藥師分享「價格管理策略與澳洲健保給付模式(Cost Management Strategies and Australia's Pharmaceutical Benefits Scheme)」，Greg 藥師曾經在澳洲的衛生部工作 7 年，負責藥品與醫療服務收載計畫(Parmaceutical Benefits Scheme, PBS)的評估委員會(Pharmaceutical Benefits Advisory Committee, PBAC)。澳洲政府將醫療科技評估(health technology analysis, HTA)納入是否要收載一個新醫療科技產品已經行之有年，為了避免健保福利財物損失，也採用風險分析，將要不要收載一個新藥品或特材的主因素與其關鍵因子分別列出來並依其權重逐步分析(詳表五)。

1.政治因素:政治的干擾，對於福利結果無法明確了解或資料不足以評估，公眾對醫療健保的期望，是否公平的資源分配等綜合分析。

2.經濟: 財務預算控制和可能給付了效益結果不好的品項。

3.社會文化: 是否為普遍可獲得的健保照護，政府支出的優先順序，可得的最新醫藥品或材，公平性等。

4.科技:先進且用於緊急醫療，醫療科技評估還是過時的藥材。

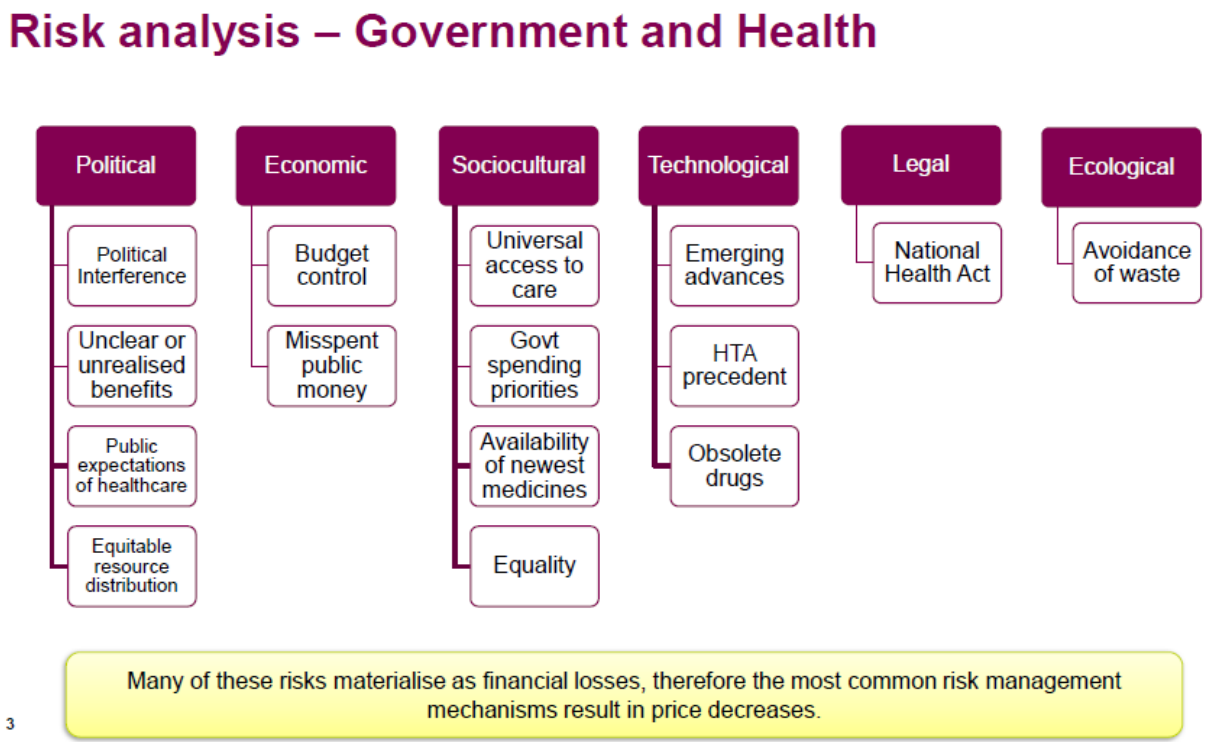
5.法規:國家健康保險法。

6.醫療生態:避免浪費，訂定相對地合理的給付規定。

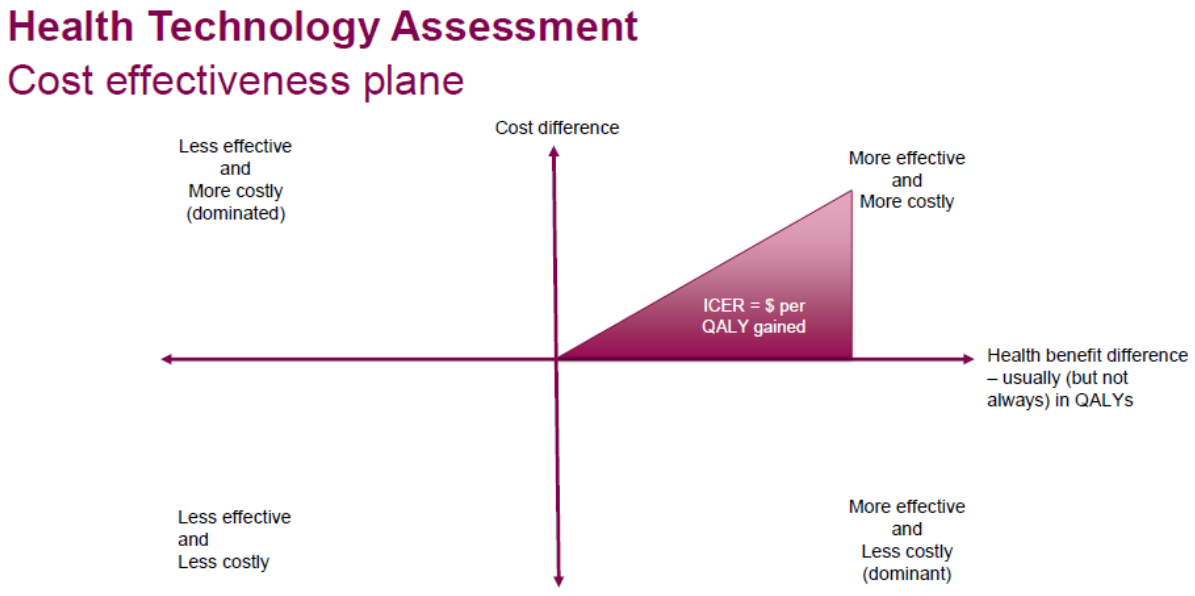
綜整以上分析每一個風險因子項下的影響後，可以做出一個如圖二的

cost-effectiveness plane，並訂出國家財政可負擔的閥值和 QALY 和 ICER 值，輔助 PBAC 做出是否收載和給付價錢之建議報告予衛生福利部。

表五



圖二



一般健保評估委員會針對臨床上擴增適應症或新科技產品，討論是否近

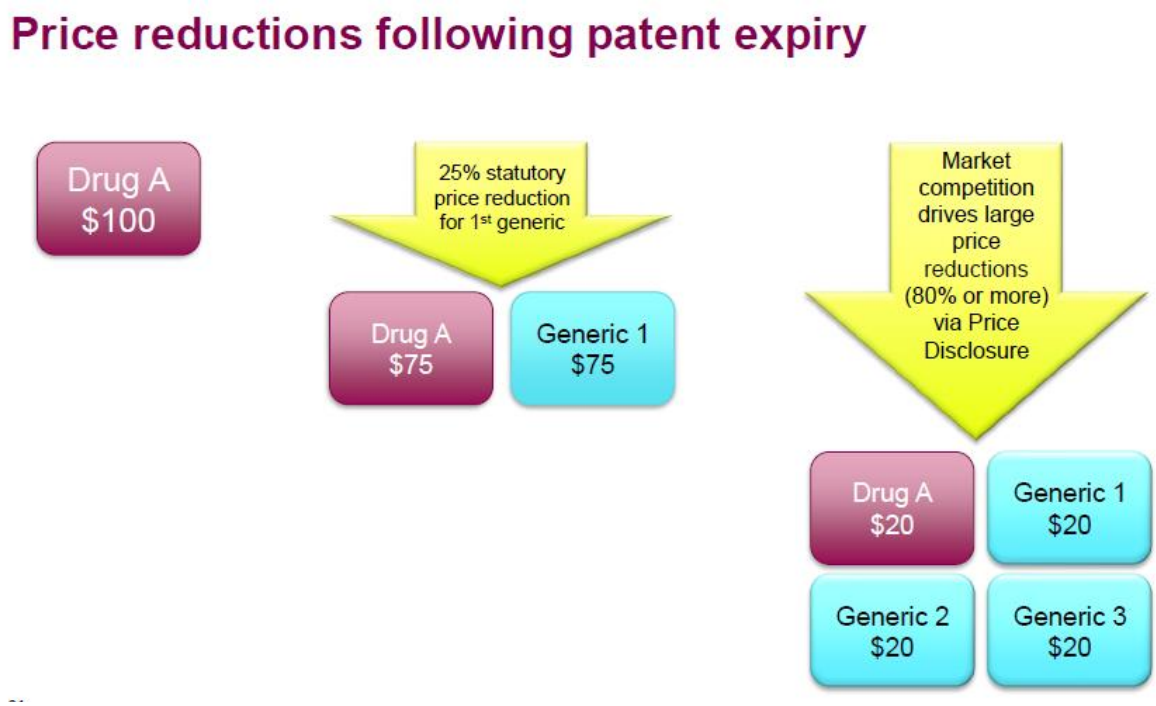
期內可能可以得到可更充分的證據，而這些證據是否可以回應不確定的效益，根據分析結果可能做出下列幾種建議:

1. Managed Entry Scheme:上述問題是肯定(Yes)，就做出 MES 的建議。
2. Pay for Performance Agreement: 上述問題是否定(No)，當一個藥物的成本效益取決於實際臨床中所觀察到的健康效益時，就會採取 PfP 的給付建議。
3. Risk Share Agreement (RSA)，如果評估中的治療族群單純，易於預估，則會建議 RSA，依據新藥的治療療程，如果花費超過年度支出預算時，由廠商還款與政府。
4. Restricted listing，如果新藥的治療劑量、療程，併用治療或不合格病人用藥等資訊可以很有把握做出結論，則會建議訂定給付規定的方式。
5. Post market review，任何一個新藥被列項給付，都可能被要求上市後/給付後再次評估。

健康保險的財政一值都不足，澳洲也一樣，尤其人民的平均餘命延長，慢性病隨著人口老化，治療的花費逐年攀升，澳洲政府為了讓藥價更合理的提供給國人，根據藥品的專利來調整價格。其價格調整方式是以藥品專利為考量基礎的調整方式: (1)當新藥的專利期一過，且有第一個學名藥上市，則藥價隨即折扣 25%，且第一個學名藥的價格也跟這個降價的原廠藥同享原價的 75%為健保給付價格。(2) 倘若陸續有第二或第三個學名藥被

核准上市，市場競爭程度藥價最多可能被調整為 20%，亦即打八折。(參考圖三)

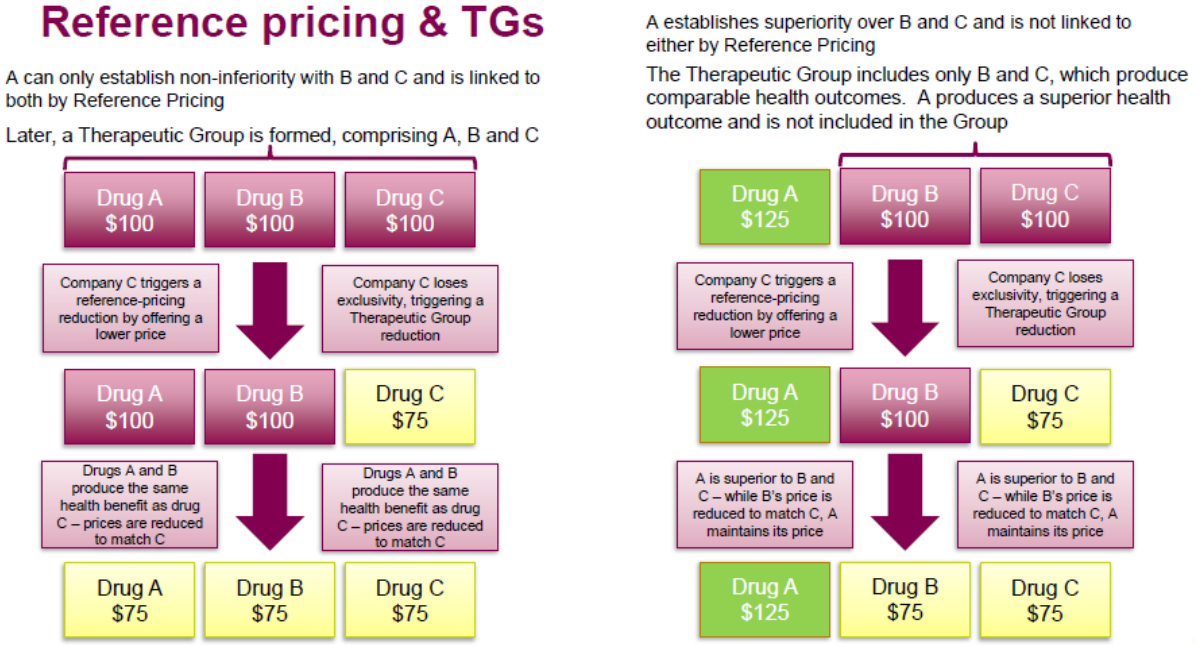
圖三



另外以臨床治療結果(health outcome or health benefit)為考量基礎。(1)A 藥藉由參考定價建立不劣於(non-inferior) B 藥與 C 藥的評估模型:因為 A 不劣於 B 藥和 C 藥，所以，三個藥品形成一個治療群(therapeutic group, TG); 隨後因為市場競爭，如果 C 藥廠提供較低的價格，那麼促使主管機關進行同治療群中各藥品所呈現健康福利(health benefit)的比較，如果 A、B 藥與 C 藥的 health benefit 一樣，那麼這個治療群中的 A、B 藥品價格也會被降成與 C 藥同。(2) A 藥建立一個優於其他藥(comparable health outcomes)且享有較高價格，而且與參考價無關聯的價格調整模式:一開始 A 藥優於 B、C 藥，所以在這個治療群中只有包括 B 藥和 C 藥，不包括 A 藥，所以 A 藥的價格較 B、C 藥的價格高一些，而 B、C 藥屬於同一治療群所以訂一樣的給付

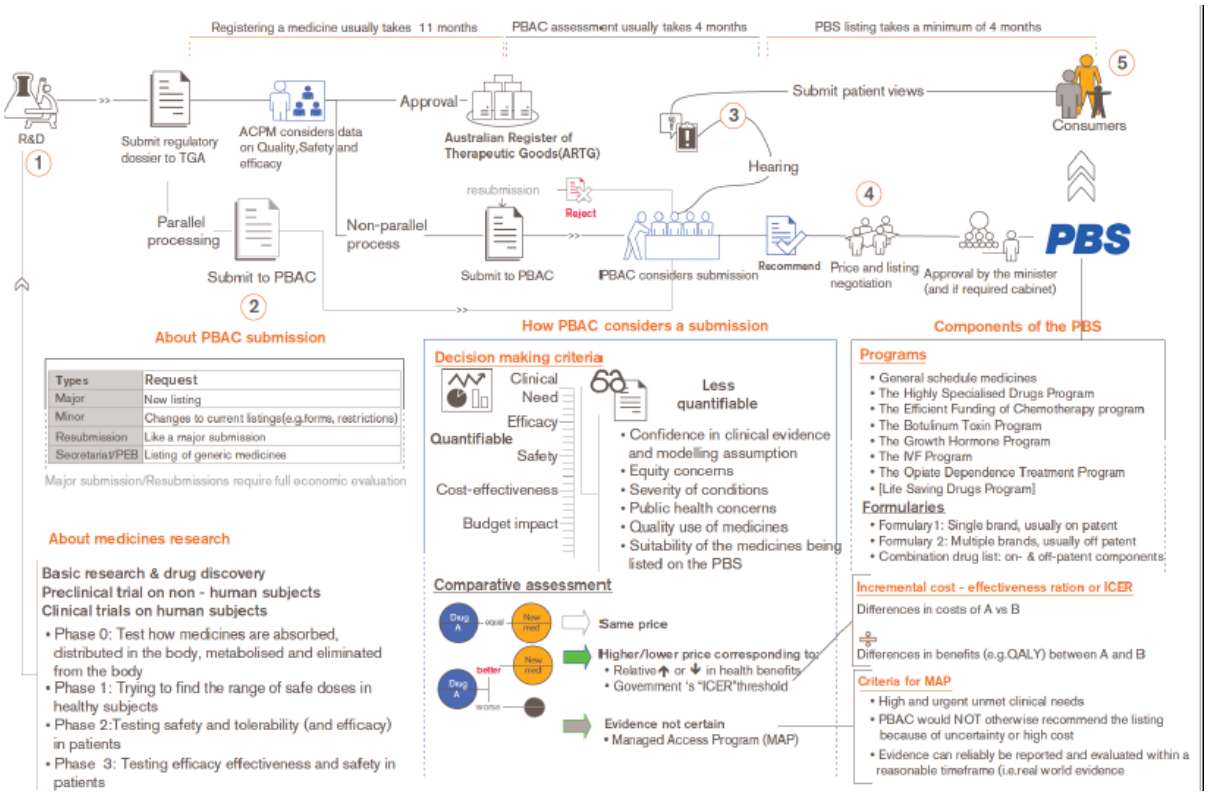
價。然而一樣的，可能因為市場競爭，如果 C 藥降價，則驅使主管機關再次評估 A 藥的是否仍較優於 B、C 藥，如果是，則 B 藥也會被降成跟 C 藥一樣的給付價。參考流程圖四。

圖四



此外澳洲政府允許廠商申請藥品上市許可的申請與健保收載給付的申請同步送件，只是在審查過程中，因為該藥品的適應症是掌握在澳洲 TGA (Therapeutic Goods Agency)，所以當健保收載與否審查進度到了蒐集公眾意見時，PBAC 會與 TGA 對話，最後的審查結果會等 TGA 同意該藥品上市及其上市適應症為何。雖然雙向並行表面上看起來似乎較節省時間，但是在澳洲，廠商向政府申請健保收載是要付審查費的，而且萬一最後藥品沒有被核准就全部重來。所以澳洲廠商多數案件還是先向 TGA 申請核准上市後再向 PBAC 申請健保收載審核；只有很少的案子是走雙向並行申請(圖五)。

圖五

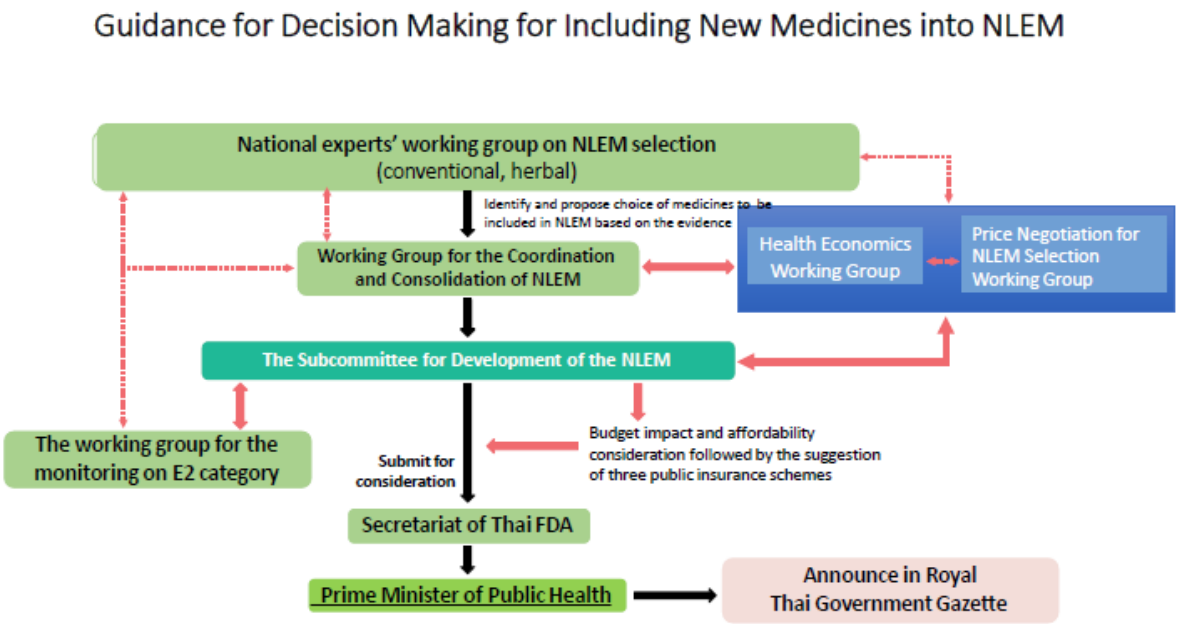


(十)泰國

泰國的全民健保是從 2002 年才開始，在 2002 年之前，政府撥預算予醫療機構，治療特定目標受益人，1960 年開始有部分(約 7%)公保由政府編列預算支應，另 13%左右私人保險。泰國的全民健保主要是給付高單價昂過藥品，門住診病人和診斷關聯群等。醫療費用支出也是每年成長威脅全民健保的永續經營，所以政府從 2010 年開始利用 HTA，從藥物經濟學、臨床必需性、臨床效益(含安全與療效)和政治社會因素等評估一個藥品的價值，協助衛生署決定是否要收載列項給付和支付價格。由於科技評估的責任與工作逐漸加重，所以另外成立一個半官方的法人機構 HITAP (Health Intervention and Technology Assessment Program) 協助執行 HTA 的評估作

業，也是健康經濟工作組和議價工作組的祕書處。被泰國衛生署全民健保收載的藥品，the National List of Essential Medicines (NLEM)會對外公布。新藥從申請到增列於 NLEM 表中的程序可參考圖六。只是要特別提醒泰國衛生署所公布的全民健保收載給付之全國必須醫藥品表(NLEM)與世界衛生組織所列的必須性藥品(essential drug list)意涵不同。另外 HTA 評估須遵循 7 程序步驟和方法學，期間也多次跟利益團體和專家，學會醫療服務提供者溝通討論(流程參考圖七)。

圖六



圖七


All HTA studies need to follow methodological and process guidelines
Thailand HTA process guidelines
Step 1
*Stakeholders' meeting on scope of the study
Step 2
Researchers present proposal to the Health Economic Working Group
Step 3
Researchers conduct studies
Step 4
*Stakeholders' meeting on the preliminary results of the study
Step 5
Research quality inspection: internal and external reviewers
Step 6
Researchers present the results to the Health Economic Working Group
Step 7
Writing up the study report that include executive summary and policy recommendation
*Stakeholders include medicine nominators, practitioners and all clinical experts in the field, and pharmaceutical representatives

參、心得與建議

藉由本次會議與其他亞洲國家藥品給付制度的經驗交流，本次會議的討論主題有三，(1) 醫療科技在藥價審核上的落實；(2) 藉重 HTA 評估報告加速病人使用新藥的可近性，各國家施行風險分擔機制的經驗；(3) 真實世界資料蒐集的基礎建設需要產官學合作。

一個國家的醫療照護網絡的完整性與該國家的法規健全有絕對的關係，法規的完整、制度的透明是吸引跨國醫藥公司投資的意願。亞洲各國現階段經濟發展的程度不同，醫療照護體系與國際調和化程度，醫藥品給付制度均不相同，然而不論各國醫療照護體系如何發展，大家都面臨相同的問題: (1) 新藥上市核准速度太慢，尤其是治療癌症藥物；(2) 醫療費用成長威脅健保制度的永續發展，首重節省浪費；(3)新的藥價管理機制加速病人使用新藥的機會已然成為趨勢；(4)真實世界資料的蒐集挑戰。雖然各界都重視，然而至今仍然沒有一個國家藉由真實世界資料的蒐集系統化，成功的回答 uncertainty cost-effectiveness。進而面臨人口結構改變及慢性病與癌症醫療需求增加等問題，使得各國政府也越來越重視合理公平的分配醫療資源，包括引進醫療科技評估制度、尋求控制醫療費用成長的方法及因應昂貴新興醫療科技的策略。臺灣的健保制度普及率和 health benefit，尤其是罕藥的給付更是東南亞國家驚嘆羨慕。然而我國還是有精進的空間，如(1) 核准藥材支付點數可以參考澳洲 reference pricing 方式和往後調整藥價的策略。(2) 我們的 HTA 雖然已行之多年，但仍然有很多需要強化，

尤其如何及早介入評估國內投資某一特定新藥材的環境，提供中央健康保險署及其他目的事業主管機關及早在法規環境和審查制度上因應，可以加速藥材審核價格的效率。甚至對於已經收載藥材的給付效益評估(health outcome)都可以再多向先進國家取經。(3) 此外病人參與藥材審核過程也是大家討論的重點，健保署建制的病人意見分享平台應可以再優化，讓病友的意見轉換成可評估的報告中。當然教育病人也是很重要的功課。(4) RWD/RWE 的部分，韓國和澳洲都有失敗的例子，我國擁有相較其他國家更為完善的健保資料庫，可以藉由經驗交流從他們的案例中更為妥善規劃我們要蒐集真實世界資料的基礎建設。(5)多數國家要求藥/材商要負起醫藥品上市後蒐集臨床使用資料的責任，所以在建構蒐集資料庫所需的財源，廠商責無旁貸負責一部分，資料庫的管理則由主管機關或委託學會來執行維運。韓國是直接由 NHIS (National Health Insurance Service)來主導，向廠商收取部分經費，澳洲則是由 TGA 要求廠商執行 phase IV 臨床試驗方式蒐集資料，數據評估則由主管機關與廠商合作完成。因為，從不同的觀點(如保險人觀點、付費者觀點還是病人觀點)評估數據會得到不一樣的結果。這方面我國也是要再多琢磨。

雖然臺灣並非亞洲國家中最早開辦健保制度者，然而相較於大多數的亞洲國家，臺灣的健保制度已經算是發展得很完善，不論是新藥的收載流程、核價方式、多元參與且公開透明的共同擬訂會議討論機制等，均是鄰近國家亟欲做為參考的典範。對於制度發展較臺灣落後的國家政府而言，

臺灣是個重要的參考對象，國際大藥廠瞭解台灣健保核價具有進軍其他國家市場的參考價值，所以對於臺灣醫藥管理法規和健保審核制度的動態更是密切關注。由此可見臺灣健保制度對於整個亞洲地區的藥品市場而言仍具相當大的影響力，而公平、公開、透明的協商機制更是其他國家想要效仿學習。

本次會議透過各講者的交流分享，可瞭解亞洲地區藥品市場的概況、鄰近國家保險給付制度的最新進展，以及發展保險給付制度上所面臨的問題及考量點，並可同時瞭解臺灣及臺灣的健保制度之於亞洲地區藥品市場的地位。此外，在當今我國與東南亞地區國家之經濟發展連結日益緊密之際，藉由此機會進行國際交流並瞭解鄰近國家地區的現況，亦有助於累積促進我國醫藥產業發展之能量。

肆、附錄

附錄一、會議議程

MAIN CONFERENCE DAY ONE | 19 SEPTEMBER 2018 | WEDNESDAY

08:00	Main Conference Registration and Morning Coffee
08:55	Chairperson's Opening Remarks **Danny Soon**, Senior Director, Health and Biomedical Cluster, Biomedical Research Council (BMRC), **A*STAR**, Singapore
	5th Annual PharmaCon Asia 2018 Combined Opening Plenary
09:00	**KEYNOTE ADDRESS:** **Singapore – a Leading Innovation and Commercialization Hub in Asia** Addressing on skilled talent, strong manufacturing capabilities and thriving research ecosystem in pharmaceutical firms to set up to serve patients and connect with the growing Asian market **Weng Si Ho,** Director, Biomedical Sciences Group, **Economic Development Board**, Singapore
09:30	**INDUSTRY ADDRESS:** **Integrating Silicon with Drugs: Pushing the Boundaries of Pharma Manufacturing with Digital Medicines** **Kurt Scheinpflug**, Senior Director, Digital Medicines Engineering, **Proteus Digital Health**, USA
10:00	**PANEL DISCUSSION:** **Industry Think Tank: Pharma 2030 – Envisioning the Future** • Drug pipeline growth areas • Regulatory trends • Innovation in pricing and market access • The most significant industry trends in the long term, and how should Pharma respond Moderator: **Danny Soon**, Senior Director, Health and Biomedical Cluster, Biomedical Research Council (BMRC), **A*STAR**, Singapore Panellists: **Enver Erkan,** Country Manager, **Pfizer**, Singapore **Alexis Serlin,** Asia Cluster Head, **Novartis**, Singapore **Miguel Rivera**, Global Digital Innovation Lead, **Ferring Pharmaceuticals,** Switzerland **How Ti-Hwei**, Country President, **AstraZeneca**, Singapore
10:40	**End of Plenary Session, Followed by Morning Networking and Refreshment Break**

11TH ANNUAL PHARMACEUTICAL REGULATORY AFFAIRS ASIA		2ND ANNUAL PHARMA MARKET ACCESS AND PRICING SUMMIT ASIA		DIGITAL PHARMA ASIA		2ND ANNUAL ACCELERATING CLINICAL TRIALS IN ASIA	
11:10	**Chairman's Opening Remarks** **Shun Jin**, Head, Regulatory Affairs, APMA, **Sandoz**, Singapore	**11:10**	**Chairman's Opening Remarks** **Jie Shen**, Corporate Global Head of Pricing and Value Policy, **Novartis**, Switzerland	**11.10**	**Chairman's Opening Remarks** **Charmaine Soon**, Associate Director, Multi-Discipline Asia-Pacific Team Lead, Bioresearch Quality & Compliance, **Janssen – A Company of Johnson & Johnson**, Singapore	**11:25**	**Chairman's Opening Remarks** **Fuqu Wang**, Director, Clinical Innovation, **The Janssen Pharmaceutical**, United States
11:15	**Updates on Regulatory Harmonisation Efforts in Asia for Pharmaceutical Products** **Finny Liu**, Lead of APAC Regional Regulatory Policy, PDR, **Roche**, Singapore	**11:20**	**Emerging Market Access Panel: Expanding Access in Emerging Markets in Asia** **Moderator:** **Jeff Weisel**, Director, Life Sciences & Healthcare, Transaction Advisory Services, **EY**, Singapore	**11:15**	**CIO Interview: Progressing Digital Transformation in Pharma** **Interviewer:** **Charmaine Soon**, Associate Director, Multi-Discipline Asia-Pacific Team Lead, Bioresearch Quality & Compliance, **Janssen – A Company of Johnson & Johnson**, Singapore	**11:30**	**Tech in Trials Round Table: Implementing a Digital Clinical Trial – Design, Start Up and Close Out** **Moderator:** **Fuqu Wang**, Director, Clinical Innovation, **The Janssen Pharmaceutical**, United States

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			Cont.' **Panellists:** **Kathleen Yeoh,** Director, Corporate Affairs and Market Access, ASEAN, **Eli Lilly & Company,** Malaysia **Jie Shen,** Corporate Global Head of Pricing and Value Policy, **Novartis,** Switzerland **Cameron Milliner,** Head of Public Affairs and Patient Advocacy - APAC, **Shire,** Singapore **Gregory O'Toole,** Reimbursement Strategy Specialist, **AstraZeneca,** Australia		***Cont.'*** **Interviewee:** **Bruce Shi,** Chief Information Officer, Asia, **Sanofi,** Singapore		***Cont.'*** **Panellists:** **Dennis Teng,** JAPAC Immunology Gastro TA Assoc. Director, **AbbVie,** Singapore **Stephanie Liu,** Medial, Regulatory and Clinical Quality Assurance Lead, **Lundbeck,** Singapore **Mrunalini Jagtap,** Data Management Lead, Singapore Institute for Clinical Sciences, **Agency for Science, Technology and Research,** Singapore
11:50	**Navigating the Regulatory Environment in EU with Introduction of New Clinical Trial Regulation (536/2014)** **Hye Jin Choi,** Principal, Strategic Clinical Development Consulting Asia Pacific, **IQVIA,** South Korea	**12:00**	**Launch Excellence Planning for New Products** **Evelyn Pang,** Head of Operations, **Sanofi,** Singapore	**11:45**	**The Impact of Technology in Reshaping the Thinking of Pharma Leaders – Transformation, Investments, Business Strategies** **Tamsin Greulich-Smith,** Chief, Smart Health Leadership Centre, Institute of Systems Science, **National University of Singapore,** Singapore	**12:20**	**Digitally Enabled Trials Should not be the Exception but the Norm** **Robert Kerle,** Senior Director, Clinical Operations, Asia Pacific, **IQVIA**
12:30	**AI, the New Solution to Global Regulatory Operations** **Bruce Sun,** Publishing Team Lead (Established Markets), Worldwide Regulatory Operations, **Pfizer,** China	**12:30**	**Implementing Integrated HEOR & RWE Strategy Across Pharmaceutical Product Lifecycle** **Sirinthip Petcharapiruch,** Head of HEOR, Real-World Insights, **IQVIA Asia Pacific**	**12:20**	**Applications of Digital Technologies to Solve Big Barriers – Delivery, Access, Financing, Customer Experience** **Amkidit Afable,** Director Business Model Innovation – Asia Pacific, **Johnson & Johnson,** Singapore		
13:00	**Networking Lunch**						
14:00	**PANEL DISCUSSION: e-Emerging: Global eCTD Transition on the Way** **Moderator:** **Shun Jin,** Head, Regulatory Affairs, APMA, **Sandoz,** Singapore **Panellists:** **Silke Nolkemper,** General Manager, Director Consulting APAC, **EXTEDO,** China	**14:00**	**Progress and Challenges for Orphan Drug Access Procedures in Asian Markets** **Yuki Sato,** Representative Director, **Deallus Consulting,** Japan	**14:00**	**Developing Innovative Technological Solutions to Improve Patient Outcomes** **Aaron Tian,** Head of Neuroscience Patient Innovation, **UCB,** China	**14:00**	**Patient-Centric Digital Capabilities for Clinical Trials** **Fuqu Wang,** Director, Clinical Innovation, **The Janssen Pharmaceutical,** United States

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	Cont.' **Bruce Sun**, Publishing Team Lead (Established Markets), Worldwide Regulatory Operations, **Pfizer**, China **Cindy Huang**, Senior Technical Specialist, Division of Medicinal Products, **Taiwan Food & Drug Administration**, Taiwan	**14:30**	**Evidentiary Equilibrium: Balancing Real World Evidence Development with Stakeholder Needs** **Bruce Crawford**, Vice President, Real-World & Late Phase, **Syneos Health**	**14:30**	**Big Data and Bottom Line – Impact on Sales, Marketing & Consumer Analytics** **Allan Marx Ancheta**, Business Unit Director Diversified Brands/Hospital & Special Care/Oncology, Strategy Lead, **MSD**, Philippines	**14:30**	**Singapore: Succeeding in Investigator-led Oncology Trials** **Teoh Yee Leong**, Chief Executive Officer, **Singapore Clinical Research Institute**
14:40	**Pharmaceutical Regulation & GMP Updates in Taiwan** **Cindy Huang**, Senior Technical Specialist, Division of Medicinal Products, **Taiwan Food & Drug Administration**, Taiwan						
15:05	**Biologics Registration & Approvals in Malaysia** **Chua Hui Ming**, Senior Principal Assistant Director, Biologics Section, Center for Product Registration, **National Pharmaceutical Regulatory Division (NPRA), Ministry of Health Malaysia**	**15:00**	**Fast-Tracking Market Access Through Negotiating Effective Risk-Sharing Agreements** **Xingzhi Wang**, Oncology HEOR Lead (Asia & Oceania), **Astellas Pharma**, Singapore	**15:00**	**Digitalisation of Pharmacovigilance and Adverse Effects Monitoring** **Jean-Christophe Delumeau**, Head of Pharmacovigilance Policy Strategy, **Bayer**, Singapore	**15:00**	**Philippines – An Emerging Destination for Global Clinical Trials** **Hazel Dy Tioco**, Asia Pacific Regional Director, Study Management and Logistics, **Sanofi**, Philippines
1530	**Afternoon Networking and Refreshment Break**						
16:00	**Drug Registration in Myanmar – E-Submission System** **Theingi Zin**, Director (Drug Control), **Food & Drug Administration, Ministry of Health & Sports**, Myanmar	**16:00**	**Addressing Payer Needs: Payer Insights from An Insurer's Perspective** **PART I:** **Enhancing Real-World Value and Health Outcomes for Healthcare Insurers and Pharma Partnerships** **Min Su**, Director, Healthcare Analytics – Group Healthcare, **AIA**, Hong Kong	**16:00**	**Digital Health: Delivering Personalized Medicine through Technology** **Miguel Rivera**, Global Digital Innovation Lead, **Ferring Pharmaceuticals**, Switzerland	**16:00**	**Indonesia – Business Case of Approval and Hospital Permit Highlight** **Dr. Martin Hertanto**, Dept. of Ophthalmology, Faculty of Medicine **Universitas Indonesia**

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16:30	**Quality Medicine Regulation from Compendial Standards Usage** **Sherry Wang**, Associate Director, Public Policy & Regulatory Affairs - Southeast Asia, Global External Affairs, **United States Pharmacopeia (USP)**, Singapore		***Cont.'*** **PART II:** **A Reimbursement & Claims Perspective** **Chan Wing Sze Cherry**, Group Medical Advisor, **AIA**, Hong Kong	16:30	**Enabling Singapore to ride the AI Wave in Pharma** **Laurence Liew**, Director, **AI Singapore**, Singapore	16:30	**Malaysia Challenges and Opportunities for Clinical Research in Malaysia** **Tah Pei Chien**, Principal Investigator, **University Malaya Medical Centre**, Malaysia
		16:50	**PANEL DISCUSSION: Beyond Drugs Access: Converging Medical Devices, Therapeutics and Technology for a New Direction** **Moderator:** **Yoshihiro Suwa**, Partner, Head of Healthcare Southeast Asia, **PT Roland Berger**, Indonesia Panellists: **Nathan Kothandaraman**, Market Access & Government Affairs, **Johnson & Johnson**, Malaysia **Teck Jack Tan**, Medical Director, **Northeast Medical Group**, Singapore **Timothy Low**, Board of Director, **Farrer Park Hospital** I APAC Medical Head, **Shire** I Board of Director, **PACRA**, Singapore **Evelyn Pang**, Head of Operations, **Sanofi**, Singapore	17:00	**INDUSTRY PANEL: Digital Transformation in the Asian context** **Moderator:** **Charmaine Soon**, Associate Director, Multi-Discipline Asia-Pacific Team Lead, Bioresearch Quality & Compliance, **Janssen – A Company of Johnson & Johnson**, Singapore **Panellists:** **Vishal Doshi**, Chief Executive Officer, **AUM Biosciences**, Singapore **Prabhuram Krishnan**, Medical Director (South Asia – Hong Kong, ASEAN, India), **Ipsen**, Singapore **Jason Tamara Widjaja**, Associate Director, Global Data Science (AI & Data Products), **MSD**, Singapore **Stan Bilinski**, Director Multi-Channel Marketing APAC Lead, **Takeda**, Singapore	17:00	**PANEL DISCUSSION: Trials and Tribulations in Emerging Markets** **Moderator:** **Hazel Dy Tioco**, Asia Pacific Regional Director, Study Management and Logistics, **Sanofi, Philippines** **Panellists:** **Dr. Anggun Ramayudantha**, Vitreoretina Specialist and Lecturer in Dept. of Ophthalmology, **Faculty of Medicine Universitas Indonesia** **Tah Pei Chien**, Principal Investigator, **University Malaya Medical Centre**, Malaysia **Robert Kerle**, Senior Director, Clinical Operations, Asia Pacific, **IQVIA**
17:00	**Chairperson's Summary and End of Conference Day One**	17:30	**Chairperson's Summary and End of Conference Day One**	17:40	**Chairperson's Summary and End of Conference Day One**	17:30	**Chairperson's Summary and End of Conference Day One**
17:35	**Networking Cocktail**						

MAIN CONFERENCE DAY TWO | 20 SEPTEMBER 2017 | THURSDAY

11TH ANNUAL PHARMACEUTICAL REGULATORY AFFAIRS ASIA		2ND ANNUAL PHARMA MARKETACCESS AND PRICING SUMMIT ASIA		DIGITAL PHARMA ASIA		2ND ANNUAL ACCELERATING CLINICAL TRIALS IN ASIA	
08:50	**Chairman's Opening Remarks** **Rie Matsui**, Director, Regional Labeling Head for Asia, **Pfizer**, Japan	**08:50**	**Chairman's Opening Remarks** **Gregory O'Toole**, Reimbursement Strategy Specialist, **AstraZeneca**, Australia	**08:50**	**Chairman's Opening Remarks** **Charmaine Soon**, Associate Director, Multi-Discipline Asia-Pacific Team Lead, Bioresearch Quality & Compliance, **Janssen – A Company of Johnson & Johnson**, Singapore	**09:00**	**Chairman's Opening Remarks** **Dr. Nishant Sangole**, Head of Medical Affairs, ASEAN, **Mitsubishi Tanabe Pharma Singapore**
09:00	**PANEL DISCUSSION: Enhancing Launch Excellence: A Regulatory Perspective for Global & Regional Strategies** **Moderator:** **Rie Matsui**, Director, Regional Labeling Head for Asia, **Pfizer**, Japan **Panellists:** **Koichi Miyazaki**, Senior Director, Clinical Development Group, Asia Development Department, R&D Division, **Daiichi Sankyo**, Japan **Catherine Clemente**, Associate Drug Regulatory Affairs & Pharmacovigilance Lead, **Sandoz**, Philippines	**09:00**	**Health Technology Assessment and Value Based Pricing - A Global View** **Jie Shen**, Corporate Global Head of Pricing and Value Policy, **Novartis**, Switzerland	**09:00**	**Digitalising Pharma - HCP Engagement: Challenges, Opportunities and Benefits** **Julie Olszewski**, Executive Director, MSD Global Innovation Hub, **MSD**, Singapore	**09:05**	**Optimising Trial Outcomes via a Patient Centric Approach** **Dr. Nishant Sangole**, Head of Medical Affairs, ASEAN, **Mitsubishi Tanabe Pharma Singapore**

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09:40	**Regulatory Environment on Botanical Drug Development** **May Wei**, Vice President, Head of Regulatory, CMC & Production, **Moleac**, Singapore	**09:30**	**Accelerating Patient Access Through HTA and Reimbursement Processes in Taiwan** **Yu-Wen Huang**, Senior Executive Officer, Medical Review and Pharmaceutical Benefits Division, **National Health Insurance Administration, Ministry of Health and Welfare**, Taiwan	**09:30**	**How Digital Solutions Can Enhance the Patient, Doctor, and Pharma Pathways Experience** **Paul Tan**, Director, **KPMG Healthcare & Life Sciences**, Singapore	**09:30**	**PANEL DISCUSSION: Future of Patient Centric Clinical Trials Operations** **Moderator:** **Dr. Nishant Sangole**, Head of Medical Affairs, ASEAN, **Mitsubishi Tanabe Pharma Singapore** **Panellists:** **Sow Wei Wong**, Legal Counsel, **Takeda Global Research & Development Centre (Asia)**, Singapore **Alex Goh**, Head, Regional Clinical Quality and Medical Quality, Asia Pacific, **GSK**, Singapore **Stephanie Liu**, Medial, Regulatory and Clinical Quality Assurance Lead, **Lundbeck**, Singapore
10:10	**China's Regulatory Environment: An Update** **Lu Bihong**, Head, Regulatory Affairs APAC, **UCB Pharmaceuticals**, China	**10:00**	**Cost Management Strategies and Australia's Pharmaceutical Benefits Scheme (PBS)** **Gregory O'Toole**, Reimbursement Strategy Specialist, **AstraZeneca**, Australia	**10:00**	**Digital Pharma and Precision Medicine in the Age of Data Science, Machine Learning and Real Time Analytics** **Yaron Turpaz**, Chief Data & Technology Officer, Managing Director, **Global Gene Corp.**, Singapore	**10:10**	**Outsourcing and Global Clinical Trials Project Management** **Yongho Oh**, Regional Clinical PM and ISS PM for Asia, JPAC & China, **Sanofi Pasteur**, Singapore
10:30	**Morning Networking & Refreshment Break**						
11:00	**Product Lifecycle Management** **Anuradha Arunachalam**, Regulatory Affairs and Pharmacovigilance Specialist, **Novo Nordisk**, Singapore	**11:00**	**Evidence - Based HTA for Evaluation and Economic Assessment of New Drugs in Thailand** **Waranya Rattanavipapong**, Head of International Unit, **Health Intervention and Technology Assessment Program (HITAP)**, **Ministry of Public Health**, Thailand	**11:00**	**Case Study: Embracing Digitalisation- Creating a Value Chain in Pharma & Healthcare** **Mrunalini Jagtap**, Data Management Lead, Singapore Institute for Clinical Sciences, **Agency for Science, Technology and Research**, Singapore	**11:10**	**Fireside Chat Session: Transforming Clinical trials through Digitalization-Case studies** **Interviewer:** **Dr. Nishant Sangole**, Head of Medical Affairs, ASEAN, **Mitsubishi Tanabe Pharma Singapore** **Interviewee:** **Valerie Tan**, Trial Monitoring Cluster Head, Asia, Global Drug Development, **Novartis Asia Pacific Pharmaceuticals**, Singapore

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11:30	**The Impact of ICH-E17 on Drug Development Strategy in Asia** **Koichi Miyazaki**, Senior Director, Clinical Development Group, Asia Development Department, R&D Division, **Daiichi Sankyo**, Japan	11:30	**A Look at Lifetime Costs of High-Priced Drugs** **Neal Somchand**, Principal, **Deallus Consulting**, Japan	11:30	**Use & Perception of Scientific Medical Reprints and Opportunities in Digital Marketing** **Amit Singh**, Director - Pharma Business, **Elsevier**, India	11:40	**Clinical Studies and Conditional Approval** **Vincenzo Teneggi**, Senior Medical Director, **D3 (Drug Discover & Development) A*STAR**, Singapore
12:00	**Digitalisation of Pharmacovigilance and Adverse Effects Monitoring: A Regulatory Perspective** **Jean-Christophe Delumeau**, Head of Pharmacovigilance Policy Strategy, **Bayer**, Singapore	12:00	**Driving Transformation in Cancer Care: Optimizing Patient-Access to Personalised Healthcare** **Hang Le**, APAC Regional Market Access Lead, **Roche**, Singapore	12:00	**Emerging Medical Technologies and New Opportunities for Digital Pharma** **Dr. Dinesh Visva Gunaskeran**, Steering Committee (Head, Big Data Protocol), **Collaborative Ocular Tuberculosis Study**, Singapore		
12:30	**Networking Lunch**						
13:30	**e-Labelling: A Global & Regional Outlook** **Rie Matsui**, Director, Regional Labeling Head for Asia, **Pfizer**, Japan	13:30	**Fireside Chat: Payer Insights from Governments' Perspective** **Gregory O'Toole**, Reimbursement Strategy Specialist, **AstraZeneca**, Australia And **Yu-Wen Huang**, Senior Executive Officer, Medical Review and Pharmaceutical Benefits Division, **National Health Insurance Administration, Ministry of Health and Welfare**, Taiwan	13:30	**Case Study: Preventing the Risk of Cardiovascular Disease via a Doctor – Patient – Consumer Digital Platform** **Dr. Peter Ting**, Co-Founder, **Cardiatrics**, Senior Consultant Cardiologist, **Gleneagles and Mt. Elizabeth Hospital**, Singapore	13:30	**Therapy for Diabetic Macular Edema: from Trials to Practice** **Dr. Anggun Ramayudantha**, Vitreoretina specialist and lecturer in Dept. of Ophthalmology, **Faculty of Medicine Universitas**, Indonesia
14:10	**Post-Marketing Surveillance & Safety in Philippines** **Catherine Clemente**, Associate Drug Regulatory Affairs & Pharmacovigilance Lead, **Sandoz**, Philippines	14:00	**Optimising Patient Access in APAC Through Multi-Stakeholder Engagement** **Manoj Saxena**, Director Regional Market Access, Asia-Pacific, **Bayer**, Singapore	14:10	**Pharma Case Study: Why Analytics Projects Fail?** **Jason Tamara Widjaja**, Associate Director, Global Data Science (AI & Data Products), **MSD**, Singapore	14:00	**Case Study in Infectious Disease: Using Molecular Endpoints to Accelerate Clinical Trials through the Development of Molecular Endpoints** **Raphael Zellweger**, Scientific Director, The Viral Research and Experimental Medicine Centre @ **SingHealth Duke-NUS (ViREMiCS)**, Singapore

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14:50	**Improving Compliance in Clinical Research – According to ICH GCP & HBRA** **Yeo Jing Ping**, Director of Research Integrity, Compliance & Ethics, **Singapore Health Services (SingHealth)**, Singapore	14:30	**Expanding Market Access for Next-Generation Medicines to Patients of Tomorrow** **Kathleen Yeoh**, Director, Corporate Affairs and Market Access, ASEAN, **Eli Lilly & Company**, Malaysia	14:50	**Data Storage, Data Integrity, Privacy and Protection** **Winston Chew**, Director, Regional Information Security Officer, **GlaxoSmithKline**, Singapore	14:30	**Moving Beyond Immuno-Oncology: a small molecule strategy** **Harish Dave**, Chief Medical Officer, Executive Director, **AUM Biosciences**, Singapore
		15:00	**Improving Orphan Drug Accessibility and Affordability in Asia** **Mathew Thomas**, Head, Public Affairs, Value Demonstration and Access - SEA, **Shire**, Singapore			15:00	**Regulatory Know-How, New Drug Development is Accelerating in China** **May Wei**, Vice President, Head of Regulatory, CMC & Production, **Moleac**, Singapore
1530	**Afternoon Networking & Refreshment Break**						

5th Annual PharmaCon Asia 2018 *Closing Plenary Sessions*	
16:00	**PharmaCon Asia 2018 Round-Up Panel:** **Closing Plenary Roundtable: Evolving Scenarios for the Asian Pharma Market** • Top line innovation trends and implications • Drug research and development environment in the long-term Impact of M&A activity and investment on industry • Emerging pharma business models, broadening value propositions, and sustainable revenue models **Moderator:** **Manoj Saxena**, Director Regional Market Access, Asia-Pacific, **Bayer**, Singapore **Panellists:** **Hazel Dy Tioco**, Asia Pacific Regional Director, Study Management and Logistics, **Sanofi**, Philippines **Yaron Turpaz**, Chief Data & Technology Officer, Managing Director, **Global Gene Corp**, Singapore **Harish Dave**, Chief Medical Officer, Executive Director, **AUM Biosciences**, Singapore
17:00	**Chairperson's Summary and End of Conference**

附錄二、本署報告檔

Accelerating Patient Access Through HTA and Reimbursement Processes in Taiwan

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Senior Executive Officer, Medical Review and Pharmaceutical Benefits Division, NHIA, MOHW/Taiwan

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Outline

Taiwan National Health Insurance Administration

- Taiwan's National Health Insurance (NHI)
- Payment system and pharmaceutical expenditure
- Listing process & fee schedule of medical products
- Accelerating patient access through HTA
- Conclusion

2

Taiwan's National Health Insurance

Taiwan National Health Insurance Administration

1. Profile of Taiwan
2. Health care in Taiwan
3. Value for the reimbursement of medical products

3

1. Profile of Taiwan

Taiwan National Health Insurance Administration

- **Population**
  - ✓ 23.5 million
  - ✓ Aged society (14.13% of population was 65+ in 2018)
  - ✓ Expected life years at birth: 76.81 years for male and 83.42 years for female in 2016
- **2017 GDP per capita** (IMF estimated)
  - ✓ nominal : US$ 24,030
  - ✓ PPP: US$ 49,900

PPP: purchasing power parity (購買力平價)

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2. Health care in Taiwan

Taiwan National Health Insurance Administration

- **National Health Expenditure (NHE) is 6.3% of GDP in 2016**
- **Compulsory Contributory Health Insurance Schemes is 52.8% of NHE in 2016**
  (https://dep.mohw.gov.tw/DOS/lp-2156-113.html)
- **National Health Insurance (NHI)**
  - ✓ Instituted 1995
  - ✓ Mandatory, single-payer social health insurance
  - ✓ Comprehensive
  - ✓ Low premium & low co-payment
  - ✓ US$ 20 billion budget per year
    - 26.2 % for drugs in 2017
    - 3.7 % for medical devices in 2017
    - 60.1 % for medical services in 2017
      (include diagnosis, examination, lab test, consultation, surgery, anesthesia, etc.)

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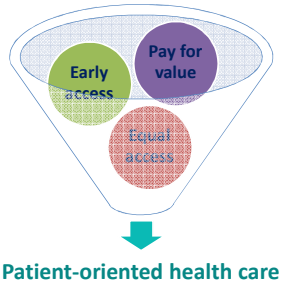
3. Value for the reimbursement of medical products

Taiwan National Health Insurance Administration



Patient-oriented health care

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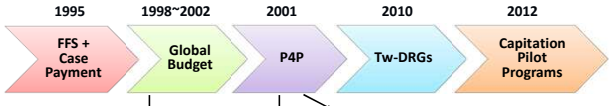
Payment system and pharmaceutical expenditure

Taiwan National Health Insurance Administration

1. Diversified Payment Systems
2. Global Budget Payment System
3. Pre-negotiated, fixed NHI expenditure
4. Distribution of global budget system of NHI (2018)

1. Diversified payment systems

Taiwan National Health Insurance Administration



- **5 + 1 sectors**
  - Dental care (1998)
  - Traditional Chinese Medicine (1999)
  - Clinics (2001)
  - Hospitals (2002)
  - OPD Dialysis (2003)
  - Other (2004)
- **3 Integration Plans (2002-)**
- **12 Pay for Performance Plans**
  - (DM、Asthma、Breast Cancer)

RBRVS(2004)

FFS: Fee-for-Service
P4P: Pay-for-Performance
Tw-DRGs: Taiwan Diagnosis Related Groups

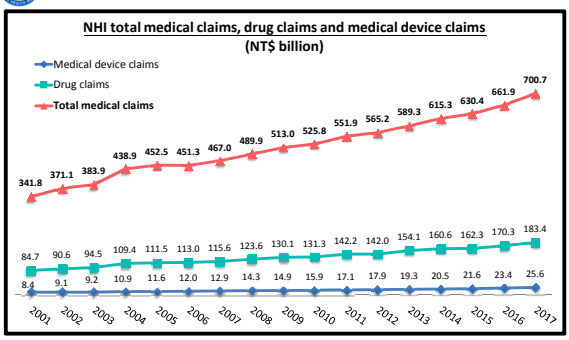
2. Global budget payment system

Taiwan National Health Insurance Administration

- Adopted since 1998 to control the rapid growth in costs under the fee for-service model
- A fixed volume and range of medical services, financial accountability
- Negotiating overall caps on total medical payments between medical providers and payers prior to the beginning of a fiscal year

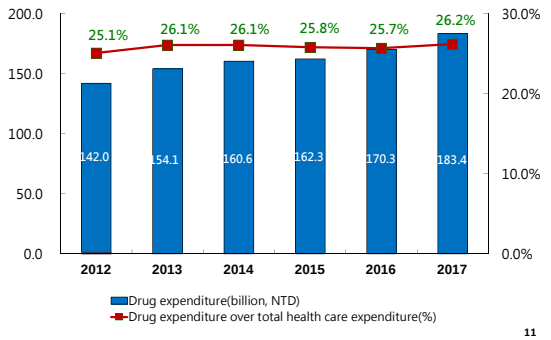
3. Pre-negotiated, fixed NHI expenditure

Taiwan National Health Insurance Administration



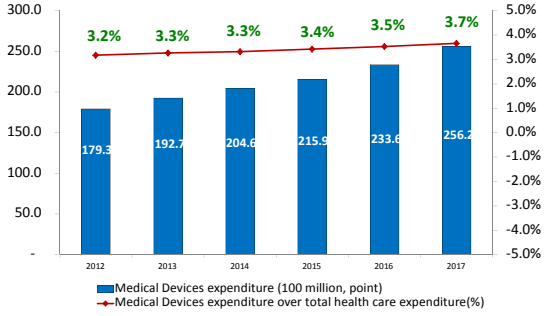
Trend of NHI drug expenditures

Taiwan National Health Insurance Administration



Trend of NHI medical device expenditures

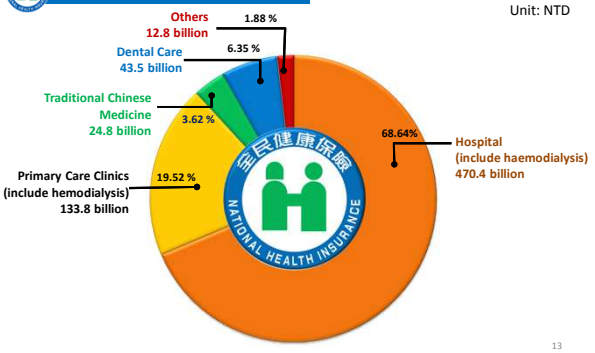
Taiwan National Health Insurance Administration



4. Distribution of global budget system of NHI (2018)

Taiwan National Health Insurance Administration

Unit: NTD



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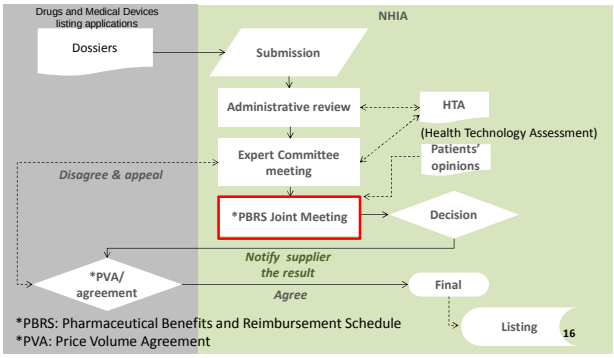
2. Pricing process of new drugs and innovative medical devices

Taiwan National Health Insurance Administration



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Listing process & Fee schedule of medical products

Taiwan National Health Insurance Administration

1. Principles of pharmaceutical reimbursement
2. Listing and pricing process of new medical products
3. Stakeholders and missions of PBRS joint meeting
4. Criteria of pricing & reimbursement
5. Managed entry agreement, MEA

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3. Stakeholders of PBRS joint meeting

Taiwan National Health Insurance Administration

The PBRS joint meeting is composed of diverse representatives of stakeholders that makes decisions regarding the reimbursement of medical products under consensus agreement.

Healthcare Providers	13	
Scholars and Experts	9	
The Insured	3	
Employer	3	
Health Regulatory Authority (MOHW)	1	
Drug Regulatory Authority (TFDA)	1	

PS：法規 - 全民健康保險法 第 41 條
全民健康保險藥物給付項目及支付標準共同擬訂辦法條文 第4條

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1. Principles of pharmaceutical reimbursement

Taiwan National Health Insurance Administration

Positive Listing

The National Health Insurance Pharmaceutical Benefits and Reimbursement Schedule (For Drugs >16,000 items；for Medical Devices > 8,900 items)

Items not covered

A. OTC/non-prescription drugs
B. Not clinically essential (contraceptives、hair restorers、shampoo…).
C. Immunization
D. Not complying with approved indications or reimbursement restrictions
E. For Medical Devices, e.g. dentures, artificial eyes, spectacles, hearing aids, wheelchairs, canes

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Missions of PBRS joint meeting

Taiwan National Health Insurance Administration

- Make rules of Medical products listing
- Make principles of PBRS
- Decide the listing & reimbursement of new medical products
- Decide the listing & reimbursement of new items with same active ingredients or function of existing medical products
- Decide the amendment of reimbursement restrictions
- Other issues related to PBRS

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4. Criteria of pricing & reimbursement

Taiwan National Health Insurance Administration

- Free sale certificated by TFDA, MOHW
  Quality/Safety/efficacy or effectiveness
- PBRS Joint Meeting
  - ✓ Relative effectiveness
  - ✓ *CBA/CEA/PE
  - ✓ Budget impact analysis
  - ✓ Ethical/Legal/Social/Political Impact

*CBA: cost benefit analysis
CEA: cost effectiveness analysis
PE: pharmacoeconomics

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A-10 reference countries

Taiwan National Health Insurance Administration

Country	Source of Reference
US	Red Book (not official publication)
Japan	Drug price baselines (official website)
UK	NHS Prescription Service (official website)
Canada	Saskatchewan Formulary (official website)
Germany	ROTE LISTE (official website)
France	Base des Médicaments et Informations Tarifaires (official website)
Belgium	Centre Belge d'Information Pharmacothérapeutique (official website)
Sweden	Farmaceutiska specialiteter i Sverige (official website)
Switzerland	Arzneimittel kompendium der schweiz (official website)
Australia	Pharmaceutical Benefits Scheme (official website)

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Pricing of new drug

Taiwan National Health Insurance Administration

Items with new active ingredient(s), new dosage form, new route of administration or a combined preparation with new effect.

Category		Pricing	Mark-ups
1	Breakthrough	Median price of A-10 countries	• domestic clinical trials (10%) • domestic pharmaco-economic study (up to 10%) • better therapeutic effects (up to 15%) • greater safety (up to 15%) • more convenient (up to 15%) • pediatric preparations with clinical implications (up to 15%)
2A	Me-better	• lowest price in A-10 • price in original country • international price ratio • treatment-course dosage ratio • a combination drug is priced at 70% of the sum of each ingredient's price, or at the price of the single active ingredient. Capped at A-10 median price	
2B	Me-too		

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Listing by function of new medical device

Taiwan National Health Insurance Administration

- **Improved function**
  The new medical device shows functional improvement in clinical practice compared to existed medical device.
- **Innovative function**
  The clinical function or effectiveness of the new medical device is breakthrough or innovative.

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Selection of comparators

Taiwan National Health Insurance Administration

- Based on ATC classification
- Drugs of the same pharmacological effects or in the same treatment category
- Drugs with head-to-head comparisons shall be regarded as important comparators
- In the case of Category 2A new drugs:
  - Based on the originator which has the same active ingredient(s) and specifications
  - Drugs listed in the past five years

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3. International price by reference countries

Taiwan National Health Insurance Administration

Country	Source of Reference
US	Red Book (not official publication)
Japan	Drug price baselines (official website)
Korea	Drug price baselines (official website)
Australia	Pharmaceutical Benefits Scheme (official website)

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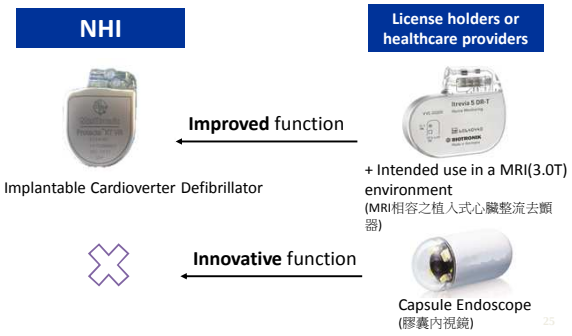
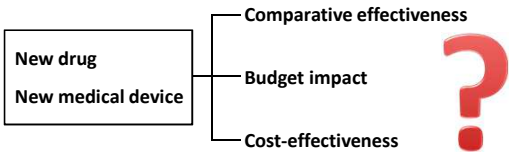
Implementation (for example)

Taiwan National Health Insurance Administration



Taiwan National Health Insurance Administration



5. Managed Entry Agreements (MEAs) 1/2

Taiwan National Health Insurance Administration

- Rapid access to new potentially beneficial pharmaceuticlas,
- Challenges:
  - ✓ Insufficient cost-effectiveness of innovative treatments at the time of licensing
  - ✓ Budget impact very high
  - ✓ Early accessing for patients wanted
- MEA , sharing the risks and uncertainties arising from public coverage
  - ✓ Collecting the relevant data to access (cost-) effectiveness, controlling the budget impact, monitoring the rational use in clinical practice or generating real life data on effectiveness

Accelerating patient access through HTA

Taiwan National Health Insurance Administration

1. Why and When to conduct HTA?
2. Contents of HTA report
3. Impact of HTA on PBRS

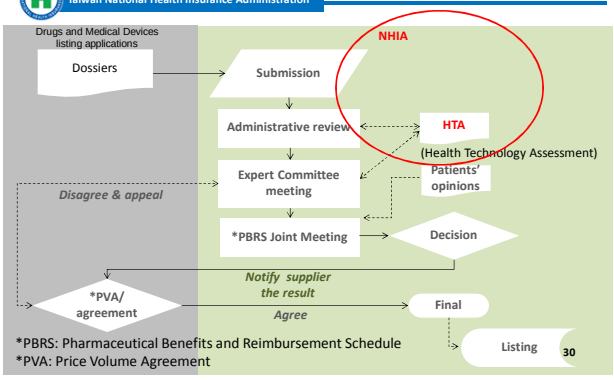
5. Managed Entry Agreements (MEAs) 2/2

Taiwan National Health Insurance Administration

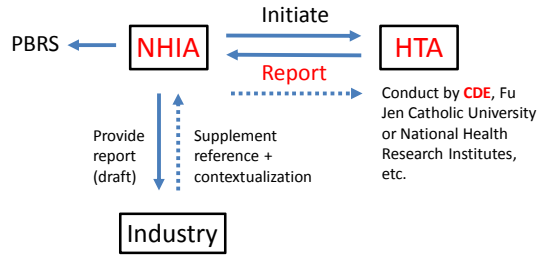
- Taiwan National Health Insurance is working on establishing a diversified risk sharing scheme.
- A public notice on the draft of the amendment of “The National Health Insurance Pharmaceutical Benefits and Reimbursement Schedule” was issued on July 2nd 2018.
- After collecting comments from the public, the MEAs scheme will be sent to the MOHW for final approval.

HTA in reimbursement process of NHIA

Taiwan National Health Insurance Administration



Taiwan National Health Insurance Administration



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When to conduct HTA?

Taiwan National Health Insurance Administration

Decision-making Processes

Assessment → **Appraisal** → **Decision**

Assessment: objective collection and evaluation of evidence (include HTA report)

Appraisal: considers and weighs the summarized evidence in order to render a recommendation

Drugs	* Newly applied items (large budget impact, over 100 millions NTD/year) * Reassessment of listed items (widely used or large expansion rate)
Medical devices	* Budget impact over 30 millions NTD * Requested by the expert committee
Medical services	Depend special case (ex. Transcatheter Aortic Valve Implantation(TAVI))

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INAHTA definition of HTA

Taiwan National Health Insurance Administration

- HTA is the systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies.
- HTA is conducted by interdisciplinary groups that use explicit analytical frameworks drawing on a variety of methods.

(www.inahta.org)

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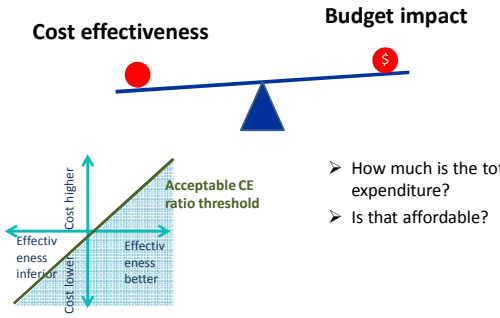
2. Contents of HTA report

Taiwan National Health Insurance Administration

- Subject
- Comparative effectiveness
- Budget impact
- Cost-effectiveness
- Legal, ethical, social impacts, etc.

1.Why to conduct HTA?

Taiwan National Health Insurance Administration



- How much is the total expenditure?
- Is that affordable?

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3. Impact of HTA on immune-oncology (IO)drugs (1/2)

Taiwan National Health Insurance Administration

- **Evaluation of IO drugs**

The HTA team conducted comparative effectiveness and economic assessment of four IO drugs in the class of immune checkpoint inhibitors, including pembrolizumab (Keytruda), nivolumab (Opdivo), and ipilimumab (Yervoy), to assist policy-making.

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Impact of HTA on immune-oncology (IO) drugs (1/2)

Taiwan National Health Insurance Administration

- **Six steps of the study**
  - ✓ Selecting one reimbursed indication from one reference country (UK, Canada, and Australia) as the reference case and collecting data from available clinical trials
  - ✓ Based on the reference case, estimating the user population, annual drug expenditure, and drug expenditure per person per year
  - ✓ Developing substitution scenarios if the four IO drugs would be reimbursed
  - ✓ Evaluating local incremental cost-effectiveness ratio (ICER) of the reference case
  - ✓ Comparing local ICER to those in reference countries
  - ✓ Accessing the copayment rates of the reference countries and discussing the feasibility of the copayment policy

Taiwan National Health Insurance Administration

Muse of cancer drugs

Impact of HTA on Medical devices– cochlear implant(CI) (1/2) (人工電子耳)

Taiwan National Health Insurance Administration

- **Evaluation of CI**
  - ✓ This study conducted in 2015 aimed to assess cochlear implant care program by evaluating the current clinical efficacy data, regulations from other countries, and patient evidence.
  - ✓ According to the opinions of the patient groups and HTA evaluation, **CI is safe, efficient, and cost-effective for adults and children with severe deafness.**
  - ✓ Additionally, it facilitates the education of hearing-impaired children in general schools and helps adult patients back to the society, thereby reduces social burden.

Do cancer drugs improve survival or quality of life?

Taiwan National Health Insurance Administration

- Between 2008 and 2012 the US FDA approved most uses of cancer drugs without evidence of survival or improved quality of life (67%, 36/54).
- Among the 36 such approvals, only five (14%) uses were shown later to improve survival compared with existing treatments or placebo after a median of 4.4 years on the market.


EDITORIALS

Do cancer drugs improve survival or quality of life?

Vinay Prasad, Do cancer drugs improve survival or quality of life? BMJ 2017; 359

Impact of HTA on Medical devices– cochlear implant(CI) (2/2)

Taiwan National Health Insurance Administration

- **Impact on policy**
  - ✓ In 2017, cochlear implant along with speech processors was incorporated into the NHI reimbursement scheme in the category of medical devices with innovative function.
  - ✓ The payment-restriction was below：
    1. Patients aged <18 years
    2. For unilateral only
    3. Limited for once in a lifetime

Availability of evidence of benefits on overall survival and quality of life of cancer drugs approved by European Medicines Agency

Taiwan National Health Insurance Administration

- Cancer drugs approved by the European Medicines Agency (EMA) between 2009 and 2013, 57% (39/68) had no supporting evidence of better survival or quality of life when they entered the market.
- After a median of 5.9 years on the market, just six of these 39 (15%) agents had been shown to improve survival or quality of life.


Availability of evidence of benefits on overall survival and quality of life of cancer drugs approved by European Medicines Agency: retrospective cohort study of drug approvals 2009-13

Courtney Davis, Availability of evidence of benefits on overall survival and quality of life of cancer drugs approved by European Medicines Agency: retrospective cohort study of drug approvals 2009-13. BMJ 2017; 359

Majority of recent cancer drugs approved for use in UK show no survival benefits

Taiwan National Health Insurance Administration

- Although we are approving cancer drugs at a rapid pace, few come to market with good evidence that they improve patient centered outcomes.
- Most approvals of cancer drugs are based on flimsy or untested surrogate endpoints, and post-marketing studies rarely validate the efficacy and safety of these drugs on patient centered endpoints.
- Add to this that the average cancer drug costs in excess of $100 000 (£75 000; €85 000) per year of treatment.


News

UK World Politics Science Education Health Brexit Royals

Majority of recent cancer drugs approved for use in UK show no survival benefits, study finds

Vinay Prasad, Do cancer drugs improve survival or quality of life? BMJ 2017; 359

What is the effective indicator of cancer drugs?

Taiwan National Health Insurance Administration

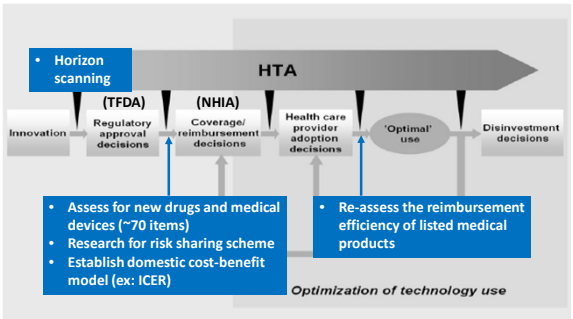
- surrogate endpoint (RR, PFS, tumor shrinkage…) ? clinical endpoint (OS)
- Statistically significant ? clinical meaningful
- Clinical benefit ? cost effectiveness (Expedited review by FDA)

Uncertain ?

Real world data needed !

Conclusion (1/3)

Taiwan National Health Insurance Administration



Conclusion (2/3)

Taiwan National Health Insurance Administration

- MEA, risk sharing scheme makes patients early accessing costly potentially beneficial innovative treatments.
  - ✓Domestic pharmacoeconomic analysis and HTA prior to reimbursement
  - ✓Real world data collection and reassessment post reimbursed products

Conclusion (3/3)

Taiwan National Health Insurance Administration

- To assess the Real-World Evidence (RWE)
  - ✓NHI MediCloud system
  - ✓Pre-authorization reviews mechanism
  - ✓Data linking between NHIA-MediCloud and *HPA-Taiwan cancer registry

*HPA: Health Promotion Administration (國民健康署)

THANK YOU FOR YOUR ATTENTION

附錄三 Fireside Chat: Payer Insights from Government Perspective

1. How is the landscape looking like for local pharmaceutical companies vs international big pharmaceutical companies in Taiwan/Thailand?

My opinions: The products manufactured by big pharma and domestic manufacturers are different.

For pharmaceuticals:

- Most new drugs are imported from foreign countries, e.g. USA, Europe etc.
- Most domestic manufacturers produce generic drugs or biosimilar products.
- Taiwan's competent health authority desperately builds up an good circumstance for conducting clinical trials, including both for pharmaceuticals and medical devices. We have advanced medical system.

For medical devices:

- Most high technical products and implantable medical devices are imported from international big companies.
- The well-known brands of Taiwan are contact lens, check system for blood sugar and blood pressure and lipid.
- Most domestic manufacturers are small business.

2. What role does the Taiwanese/Thailand government play in ensuring fast and affordable access to drugs to patients who need it most?

My opinions:

- Taiwan's national health insurance is a true singly payer system, which the government provides insurance directly.
- Taiwan's health care insurance system is universal, comprehensive, mandatory and with low premium and modest copayment. However we cover hospital, hemodialysis, primary care clinics, traditional Chinese medicine, dental care etc.
- We develop the national health care system as "global budget payment" to control the rapid growth in costs under the fee for-service model.
  - ✓A fixed volume and range of medical services, financial accountability
  - ✓Negotiating overall caps on total medical payments between medical providers and payers prior to the beginning of a fiscal year
- Taiwan's health care system is positive listing items for reimbursement.
- According to article 51 of the National Health Insurance Act, the following categories are not covered:
  - ✓OTC/non-prescription drugs
  - ✓Non clinically essential (contraceptives、hair restorers、shampoo…)
  - ✓Immunization
  - ✓non approved indications or not comply with reimbursement restrictions
  - ✓For Medical Devices, e.g. dentures, artificial eyes, spectacles, hearing aids, wheelchairs, canes etc.

3. At this point, what are some of the most difficult/challenging issues that the Taiwanese/Thailand government is having to tackle?

My opinions:

- New risk sharing scheme, MEA for costly new drugs, uncertain effectiveness but potentially effective new treatments on clinics.
- Precision medicine related genetic examinations, biomarkers.

4. Tell us more about the different Health Technology Assessment (HTA) models taking place in Taiwan vs Thailand. Are there useful models/practices to be adopted from other neighbouring countries?

My opinions:

- Newly applied drugs (large budget impact, over NTD 100 millions /year)
- For medical devices, budget impact over NTD 30 millions
- Reassessment of listed items (widely used or large expansion rate)
- Requested by the expert committee
- For medical services, depend special case (ex. Transcatheter Aortic Valve Implantation(TAVI)

5. Please share with us your opinion on what the future for drug market access & pricing looks like in your respective country.

My opinions:

- Risk sharing scheme or managed entry agreement
- Prospectively, we hope to introduce HTA through whole product life cycle. Horizon scanning at the very early stage, cost-effectiveness analysis before reimbursement decision made and reassessment post reimbursement.
- According to HTA, reallocate resources on coverage
- NHI MediCloud system prevents from duplicate prescriptions and examinations, furthermore saves unnecessary medications.
- Pre-authorization reviews mechanism makes probable reimbursement.
- Inspection mechanism