出國報告（出國類別：會議）

參加第 3 屆亞洲藥物市場年會 (The 3rd Annual Pharma Market Access Asia)

服務機關：衛生福利部中央健康保險署
姓名職稱：林宜潔 科員
派赴國家：新加坡
出國期間：106 年 9 月 19 日至 106 年 9 月 22 日
報告日期：106 年 12 月 19 日

摘要

本次「第 3 屆亞洲藥物市場年會(Annual Pharma Market Access Asia)」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，常舉辦各項會議和課程，並提供學術期刊、即時新聞、商業情報等之資訊服務。IBC 公司的亞洲總部位於新加坡，每年都會在亞洲地區辦理許多會議和培訓課程，涉足領域廣泛，包含企業、商品、金融、生命科學、電信等多個領域；常邀請國際商界領袖、國際專家、傑出人士等參加，使該會議做為知識交流和提供商業資訊的平台。

本次會議時間共兩天，在大會(4TH Annual Phamacon Aisa)之下，按不同主題分為 3 場會議同步舉行，分別為討論亞洲地區藥品市場開發及保險給付制度的「Pharma Market Access and Pricing Summit」、討論各國藥品管理法規的「Pharmaceutical Regulatory Affairs Asia」及討論藥品臨床試驗「Accelerating Clinical Trials in Asia」。本次本署參加的為「Pharma Market Access and Pricing Summit」會議，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與未來趨勢、以及保險給付制度等，本署並受邀於會上報告臺灣健保藥品收載流程及核價制度，讓其他國家亦能藉此機會瞭解臺灣的健保制度。

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。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，有助於累積促進我國醫藥產業發展之能量。

壹、會議目的

因應全球化的發展，如今亞洲國家已成為全球重要的藥物臨床開發和製造基地，但各國在醫藥品的生產、交易和銷售上都有很不同的進展，相關法規及制度的發展亦不盡相同，又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變得非常重要。

本次由 IBC Asia 公司舉辦之「第 3 屆亞洲藥物市場年會(Annual Pharma Market Access Asia)」，以亞洲地區各國的市場為主題，邀集臺灣、新加坡、馬來西亞、大陸、菲律賓、印尼、日本、韓國及歐美地區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 19 日	去程，台北→新加坡
9 月 20-21 日	參加會議
9 月 22 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

亞洲地區的人口數眾多，且有許多為開發中的國家。近來在各國經濟發展快速、政府對於醫療健康照護的日益重視，以及隨著社會轉型而來的人口老化之下，各國對於醫療及用藥的需求急速提升。相較於日趨飽和的歐美市場，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。

然而，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。對於經濟相對發展較落後的國家，例如印尼、菲律賓等，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；故開發較慢的國家大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)臺灣

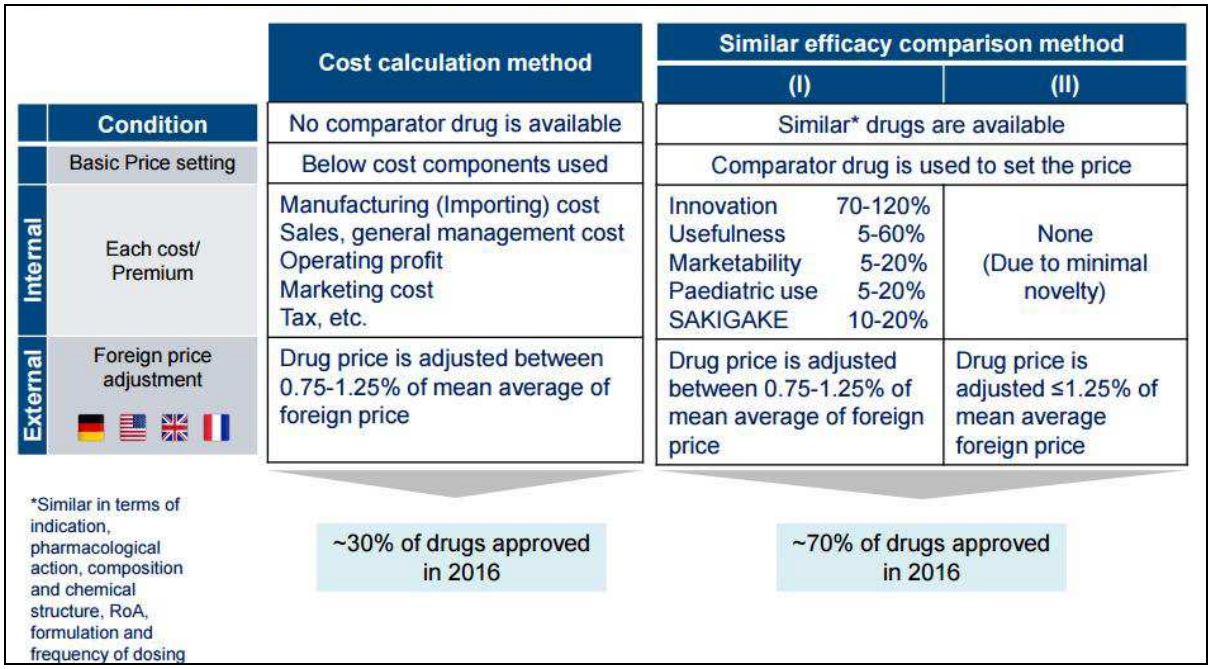
由本署負責介紹在臺灣健保制度下新藥的收載流程及核價方式、藥品共同擬訂會議的組成及運作方式、醫療科技評估(HTA)在新藥核價程序所扮演的角色，以及學名藥的核價原則等，報告資料如附錄三。

(三)日本

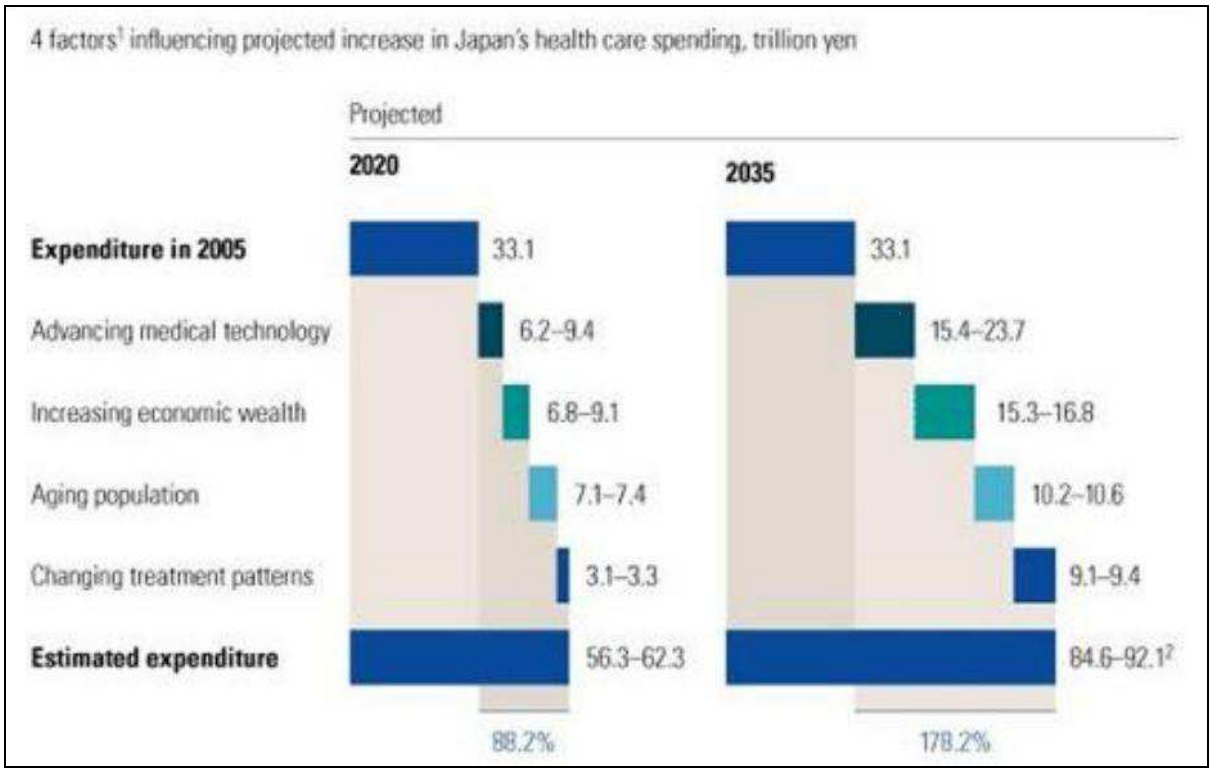
本次會議負責分享日本健保藥品給付制度的講者為諾華公司日本地區健康經濟及市場開發部的 Mr. Jean-Francois Baladi 及 Deallus Consulting 公司的 Mr. Neal Somchand，報告重點摘要如下：

1. 日本健保也是全民納保，其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，惟部分負擔的比例會隨著病人族群的不同 (如年紀)而有所調整。

2. 日本新藥核價方式主要分為「成本計算法 (cost calculation method)」及「類似療效比較法 (similar efficacy calculation method)」。「成本計算法」適用於新藥沒有核價參考品的情況，所採計的成本包含製造或進口成本、管銷費用、營業利潤、行銷成本及稅等；「相似療效比較法」適用於新藥具類似品的情況，依據核價參考品核算藥價，並按新藥的創新性、方便性、兒童用藥、在日本第一個上市且用於治療 unmet medical need 的新藥理類別新藥 (SAGIKAKE)等條件給予加算。依上述方法核算出來的藥價，還會再參考美國、英國、德國及法國的藥價進行校正，目的是為了使核定支付價更接近國際藥價。根據統計，2016 年中約佔 3 成的新藥係以「成本計算法」核價，約 7 成的藥品以「類似療效比較法」核價。



3. 人口老化是近年來日本所面臨最大的問題之一，它不僅成為日本社會日益沉重的負擔，亦造成醫療費用逐年攀升。其他造成日本醫療費用增加的因素尚包含新興醫療科技的引進、經濟發展、疾病治療方式改變等。



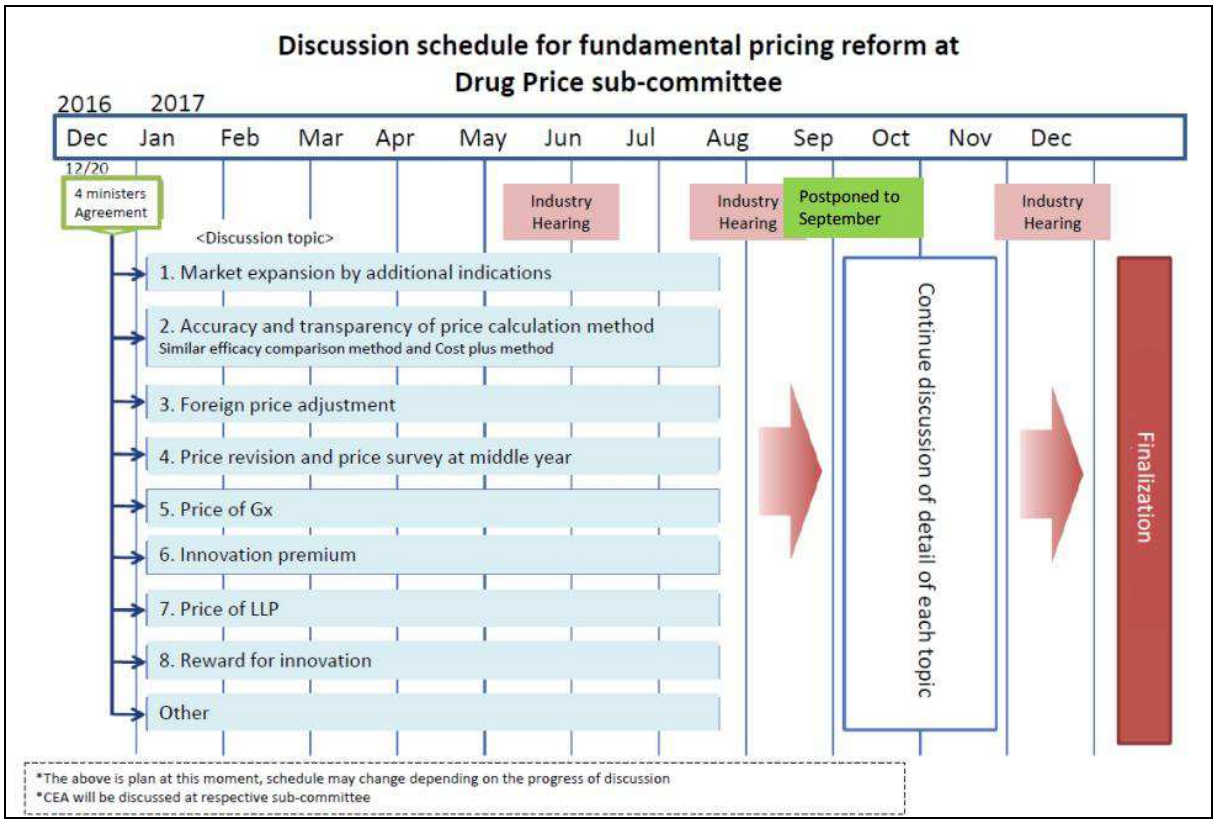
4. 為了因應快速成長的藥費支出，並避免新藥納入收載後因市場快速擴張(如用藥人數遽增、適應症擴增等)，導致實際藥費支出大幅超出原預估之藥費，目前日本政府採取的主要策略之一為每兩年檢討一次藥費支出，當新藥的實際年度藥費支出超出一定的限量額度，並超出原預估年度藥費一定的倍數以上時，則調降該藥品支付價格 25%至 50%，而其同成分之其他品項或核價參考品亦一併納入調整。

		Market Expansion Repricing		Special Expansion Repricing		Out-of-cycle repricing for market expansion
Annual sales	JPY	10 BN	15 BN	100 – 150 BN	150+ BN	100 BN
	USD	89.2 MN	134 MN	892 MN – 1.34 BN	1.34 BN +	892 MN
Sales forecast threshold		X 10	X 2	X1.5	X1.3	X 10
Reduction		Upto 25%*	Upto 15%** Upto 25%*	Upto 25%	Upto 50%	Upto 50%
Target products		Similar MoA; same chemical composition		Pricing comparator; same chemical composition		Indication expansion between Oct 2017 –Mar 2018
Reasons for exemption from repricing		Size of market of similar MoA products; listed a long time ago; different indication / line of treatment; different RoA^		Size of market of comparator products; listed a long time ago; different indication / line of treatment		Indication expansion is after the biannual pricing survey (September 2017)

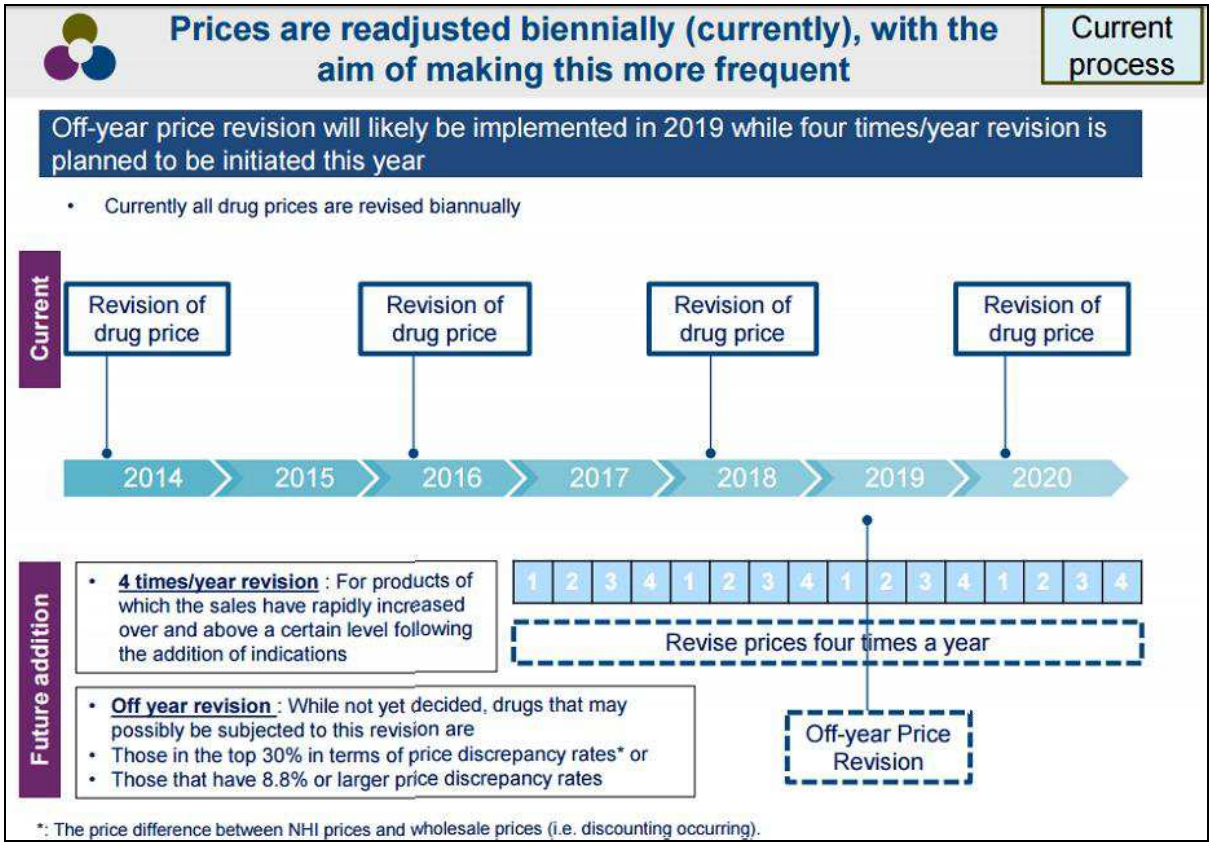
MHLW took the strictest criteria from both rules and combined → **Resulting in Opdivo repricing out-of-cycle**

*only for drugs priced by cost calculation method
**only for drugs priced by comparator method
^not in official rules, but have analogue example

5. 除了上述策略之外，目前日本也正在規劃對健保藥價制度進行大幅改革，現正研議中的議題涵蓋因應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，將後續收集各界意見，研修相關法規。



(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，除了目前例行性兩年一次的藥價調整，將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，並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，目前日本還在以試辦計畫辦理的階段，僅針對少數高價藥品(如用於照療 C 型肝炎的口服藥品 Sovaldi、Harnovi、Viekirax、Daclinza 及 Sumbepra，用於治療癌症的 Opdivo、Kadcyla)進行 HTA 評估，但已規劃未來將對所有新藥均進行 HTA 評估。日本的 HTA 制度整體而言可能會和法國的 HTA 制度較為類似，並會在 HTA 中建立 cost-effectiveness threshold 系統，根據藥品的 ICER 值及臨床治療地位將其成本效果程度(cost-effectiveness)分為 5 級，以

評估新藥納入給付的效益。

(3)此外，日本在進行上述藥價制度改革的同時，對於一些新的給付制度，如依適應症核價(pricing by indication)、依治療效果給付 (pay for performance)等，陸續也有所討論。可見面臨健保財務壓力日益沉重的情況下，日本正很努力地從多方面尋求解決因應策略。

(四)韓國

本次會議由百靈佳公司韓國地區市場開發部的 Ms. Megan Kim 分享韓國健保藥品給付情形及對於高價藥品的核價策略，報告重點摘要如下：

1. 目前韓國新藥核算支付價約為 OECD 國家的 45%。韓國 2016 年的總藥費約佔整體醫療支出的 24.6%，較 OECD 國家的平均值為高。另外，在韓國除了癌症藥品或罕見疾病用藥，病患使用一般藥品需自付的部分負擔不低。
2. 為了控制新藥納入給付後對於健保藥費支出之財務衝擊，目前韓國對於納入給付後之新藥訂定有藥價調整方式如下：
    (1) PVA-linked price cut：藥費超出價量協議之限量額度時調降藥價
    (2) Expansion-linked price cut：藥品擴增給付適應症時調降藥價
    (3) Generics entry：學名藥進入市場時調降藥價
    (4) ATP-linked price cut：依據藥價調查結果調降藥價
3. 韓國新藥核價時間約 12 至 18 個月，如果是癌症用藥通常會更久，例如有些高價的癌症藥品核價時間會長達 4 年之久。

4. 目前韓國針對部分癌症或罕見疾病新藥，另建立有特殊的收載機制，稱為「風險分攤協議管道(Risk Sharing Agreement Track)」和「免除成本效果分析資料管道(Cost-Effectiveness Exemption Track)」：

(1) 風險分攤協議管道(Risk Sharing Agreement Track)：適用於治療沒有其他替代藥品可用之威脅生命疾病之新藥，且該藥品必須為癌症或罕見疾病用藥。此管道主要是廠商需要和國民健康保險公團(NHIS)簽訂風險分攤協議，可採用之協議方式如下：

A. Conditional treatment continuation：根據病人用藥後的治療效果決定是否繼續給付；如有效則繼續給付，如沒效則廠商需還款。

B. Expenditure cap：設定年度藥費限量額度，如實際藥費支出超出限量額度，則廠商需按公告之比例還款。

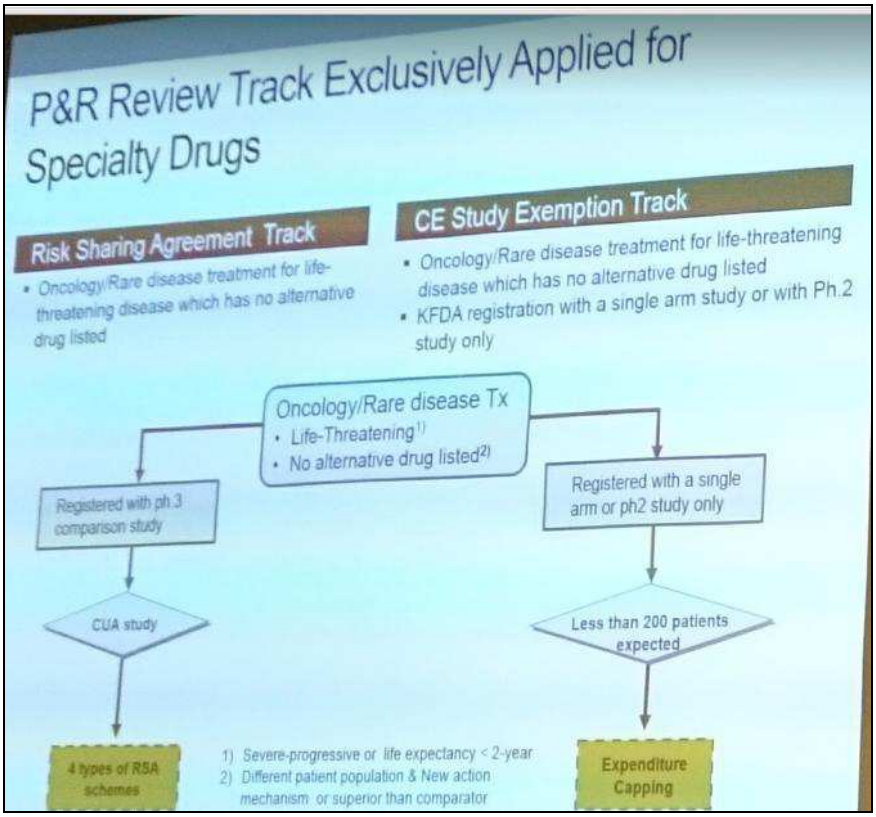
C. Refund：廠商根據實際藥費支出返還一定比例的藥費。

D. Utilization cap/Fixed cost per patient：設定每位病人的限制用量，如病人使用超出限制用量則廠商需還款。

E. Coverage with Evidence Development：在臨床試驗的架構下進行給付，一邊給付一邊蒐集病人的資料。

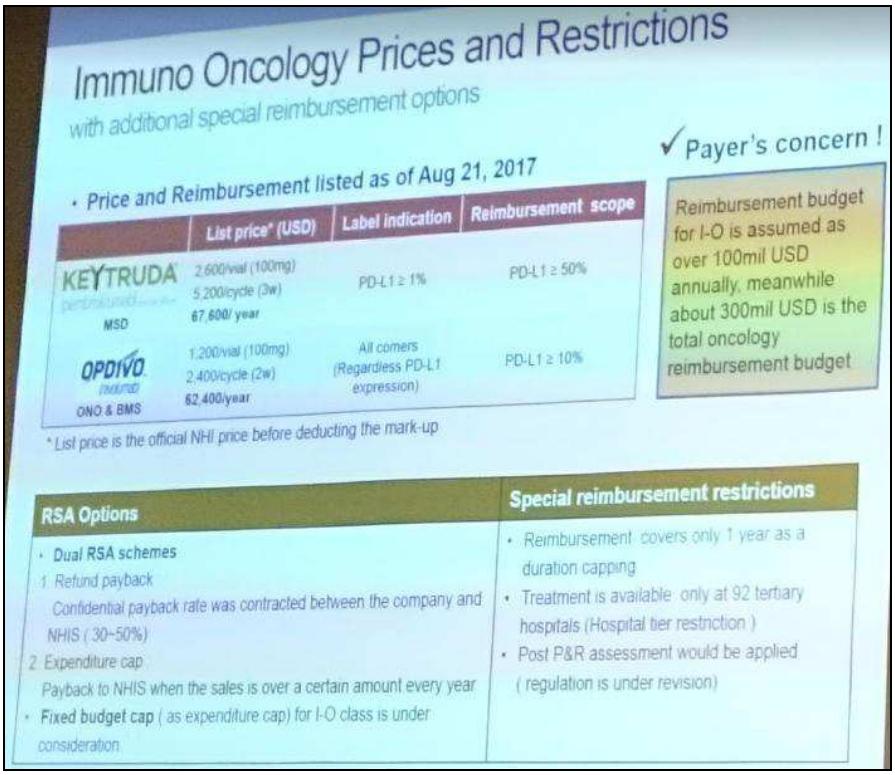
(2) 免除成本效果分析資料管道(Cost-Effectiveness Exemption Track)：適用於治療沒有其他替代藥品可用之威脅生命疾病之新藥，且該藥品必須為癌症或罕見疾病用藥，惟此類藥品係以單臂研究(single arm study)或第二期臨床試驗向韓國食品藥物管理局(KFDA)申請查驗登

記，且病人數少於 200 人。此類藥品以上述條件納入給付時，需設定 Expenditure cap，如年度藥費支出超出限量額度則廠商需還款。

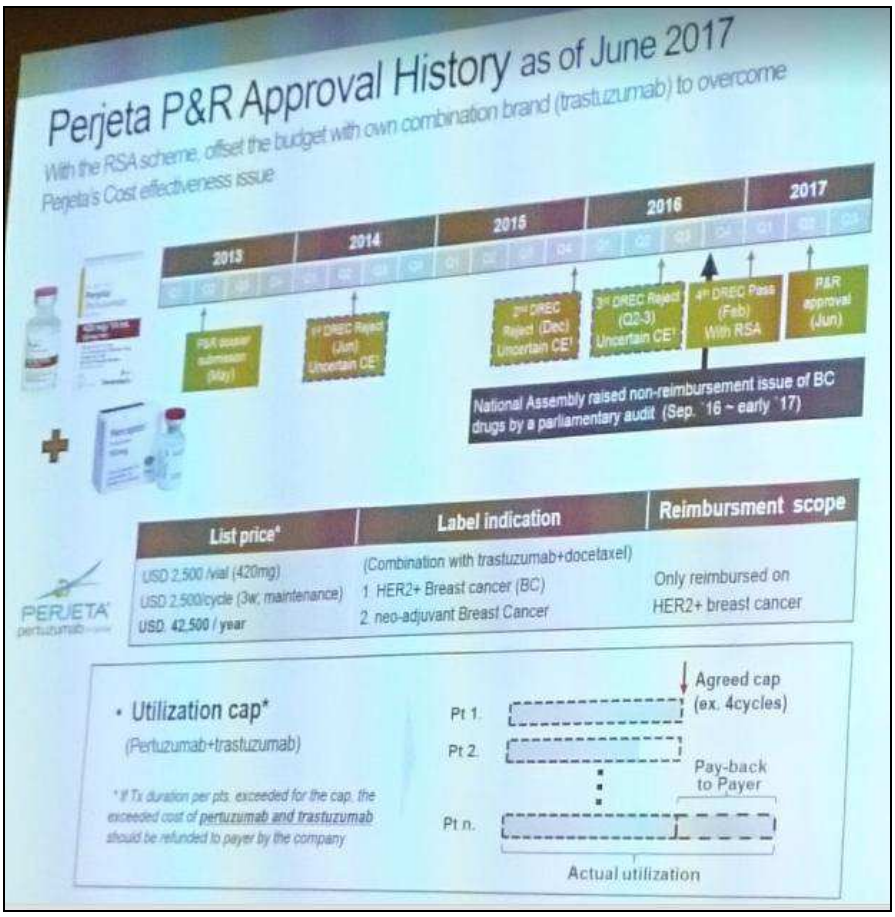


5. 案例分享：

(1) 癌症免疫療法藥品 Keytruda 及 Opdivo：韓國為癌症免疫療法藥品所編列之年度預算約為一億美元，佔整體癌症藥品預算的三分之一。Keytruda 及 Opdivo 皆同時採用還款(Refund)和藥費限量額度(Expenditure cap)之風險分攤協議方案。還款方案(Refund)的還款比例約落在藥費的 30%至 50%之間，係廠商與國民健康保險公團(NHIS)經機密協訂協議之比例。此二項藥品並訂定有給付規定，包含每位病人以給付一年為限，且限特定的醫院層級才能開立。



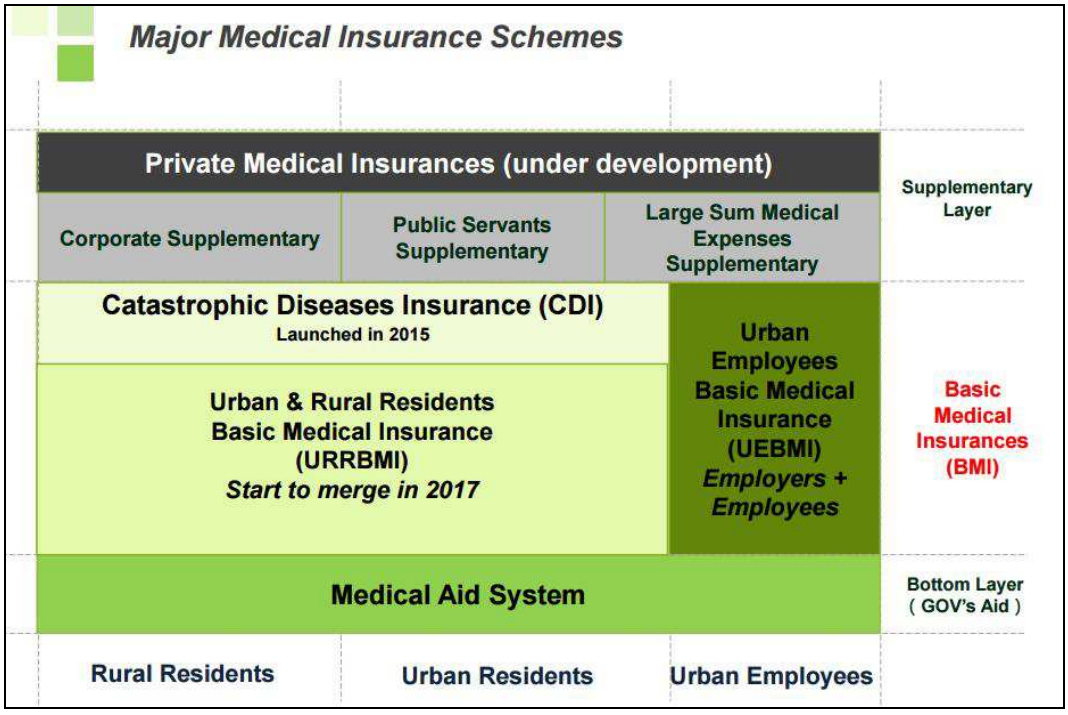
(2)用於治療轉移性乳癌之藥品 Perjeta：採 utilization cap，每位病人僅給付 4 個療程，如病人使用超過 4 個療程，超出部分的藥費廠商需還款給 NHIS。



(五)中國大陸

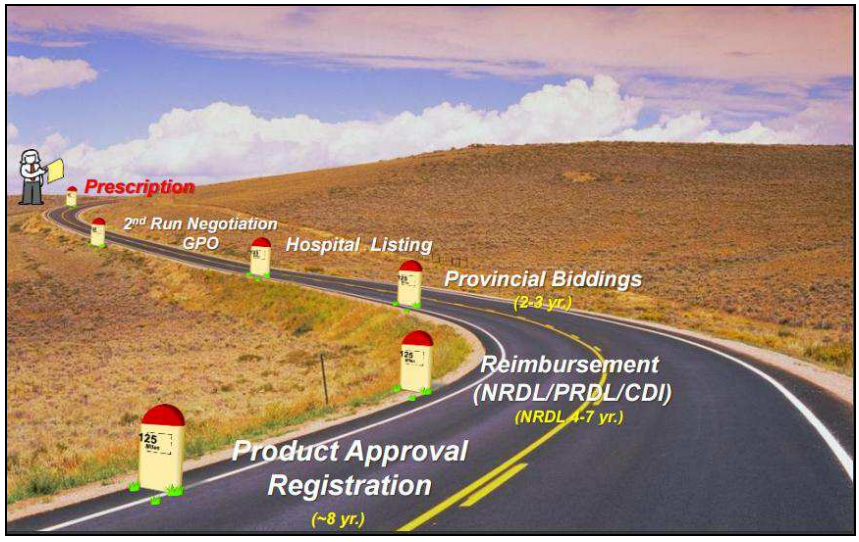
本次會議負責分享中國大陸健保藥品給付制度的講者為惠氏藥廠中國地區政府事務部席慶先生(Mr. Qing Xi)，報告重點摘要如下：

1. 中國大陸醫療保險以國營醫療保險為主，而國營醫療保險制度分為三種，分別為「新農合」、「城居保」及「城職保」。「城職保」類似勞保，在城鎮的就業單位必須幫員工投保，企業和員工共同繳保費，每個月直接從員工的工資扣繳，繳納的保費會撥至個人帳戶，帳戶內的資金可用來在醫療機構支付醫療費用。「新農合」及「城居保」則是農村人口及無業的城市居民可自由納保，其保險基金主要用於給付住院及大病的醫療費用，然為縮減保險項目的城鄉差距，自 2017 年起中國大陸政府開始整合「新農合」及「城居保」為一更統一的城鄉居民保險制度。



2. 在中國醫療保險的納保率達 95%以上，但納入給付的藥品有限，且通常高價或創新的藥品都不在給付範圍。此外，在中國大陸主要的醫療服務

者為公立醫院，藥品必須先被列入中國醫療保險目錄並經各省政府納入收載，各省中的公立醫院才能採購藥品供醫師開方使用。然而，新藥在中國大陸從申請審批、納入國家醫療保險收載、各省納入收載和議價、公立醫院納入處方集，到醫師可開立供病人使用為止，整體的時程非常冗長；通常新藥從國外上市至在中國申請審批核准需耗時約 8 年、保險收載(列入中國醫療保險目錄)需耗時約 4 至 7 年、各省納入收載和議價需耗時約 2 至 3 年。因此，一個新藥在被納入健保給付前的銷售通常很難成長，且在中國的銷售生命週期通常較在西方國家延遲很多。



3. 由於中國大陸人本身口數眾多，且在一胎化政策下人口老化的問題日益嚴重，導致整體醫療需求逐年在上升，故近來中國大陸被各大國際藥廠視為重要市場。雖然近年間中國的醫療費用支出逐年上升，經濟成長速度卻有逐年趨緩的現象，但在財源有限之下，中國政府也開始積極地從各方面著手控制藥費支出，相關策略如下：

(1) 加強管控學名藥的品質，要求的國產學名藥(包含已上市者)必須做生物相似性試驗(Bioequivalence)，以縮減學名藥和原廠藥之品質落差。

(2) 不論是專利期內或逾專利期的藥品，藥商在申請審批時必須承諾在中國的售價不能比在原產國或和中國相當的鄰近國家的價格高。

(3) 改革藥品採購制度，採行「兩票制」壓縮藥品流通環節，避免藥品在藥品供應鏈中被代理商層層轉介加價，造成藥品售價虛高的現象。在「兩票制」之下，藥廠直接將藥品交給醫院，或將藥品交給一家藥品代理公司，而代理公司必須直接將藥品交給醫院。交貨過程必須驗證發票，確定發票、貨物和帳款一致，以確保其間的交易價格透明化。

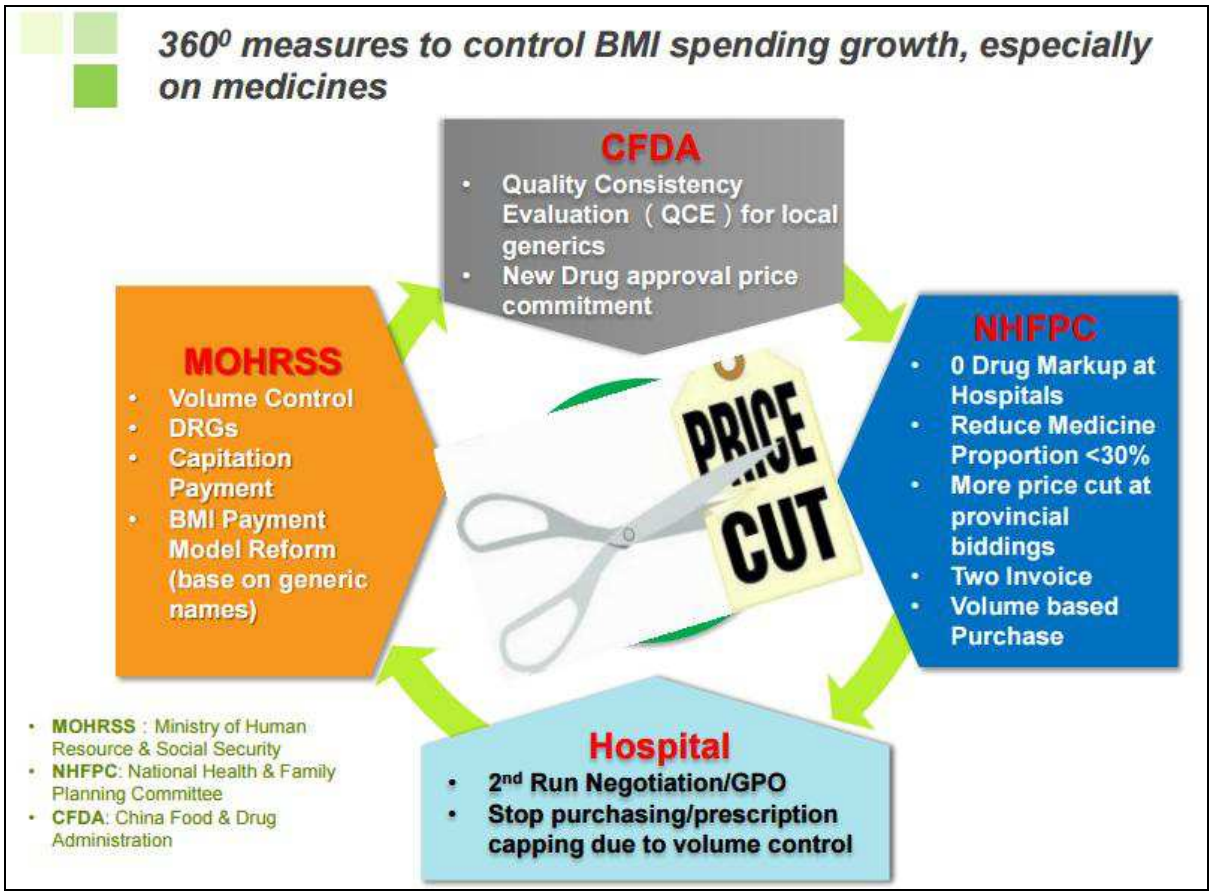
(4) 各省級藥品管理機構招標及審定價格時，應盡可能殺低藥價，特別是針對原廠藥。

(5) 公立醫院採購時再次進行議價，並設定採購量或處方量的上限。

(6) 規劃針對藥品給付制度進行改革，例如僅以學名藥的價格支付且不同廠牌的學名藥均同一價格，如病人欲使用更貴的藥則需自付差額。

(7)設定藥費或使用量之限量額度。

(8)縮減藥價差。



備註：國家衛生和計劃生育委員會(NHFPC)：負責藥品供應的管理和議價。人力資源和社會保障部(MOHRSS)：負責辦理醫療保險及藥物給付項目。

(六)馬來西亞

馬來西亞的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，提供民眾收費低廉的醫療服務，屬於社會福利取向的系統，並以一般稅收做為主要財源。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並不多。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。

(七)菲律賓

1. 目前菲律賓醫療照護的重點在於必要藥品的給付，如何讓民眾在可負擔的情況下取得具醫療急迫性或維持生命所需之用藥，包括傳染病用藥、胰島素、EPO….等，目前政府還沒有足夠的財力可給付昂貴的藥品，例如癌症用藥等。
2. 此外，由於較為貧窮，為了減少藥費支出，菲律賓比美國更早訂定學名藥法，強制醫師必須使用學名藥，故菲律賓是目前亞洲地區使用比率最高的國家，更甚於中國大陸。經統計，學名藥的藥費支出佔了菲律賓整體藥費支出約 85%左右。

(八)印尼

印尼的藥品以自費市場為主，國營醫療保險僅給付少數品項，皆為學名藥且不同廠牌均同一價格；藥品由政府直接向藥廠購買再供應醫院，醫院無藥價差，藥品如走國營醫療保險給付市場也較沒賺頭。

參、心得與建議

透過本次會議與其他亞洲國家藥品給付制度的經驗交流，發現儘管亞洲各國現階段經濟發展的程度不同，醫療照護體系及藥品給付制度亦不盡相同，然各國均陸續面臨人口結構改變及醫療需求增加等問題，使得各國政府皆越來越重視如何讓醫療資源更有效且合理地分配，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。在發展醫療保險給付的路上，雖然各國現今位處的階段不同，但均循著相同的方向在演進，在各階段中所遇到的問題亦十分類似，故實宜多加利用交流的機會瞭解鄰近國家的做法，從其他國家汲取經驗，以提早瞭解未來可能會遇到的問題並著手研議解決之道，例如臺灣可多向鄰近的日本或韓國等國情較為類似之國家學習相關經驗。

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，對於鎖定亞洲地區廣大新興市場的國際藥廠而言，因為瞭解其他國家可能將臺灣視為重要參考對象，臺灣制度動態更是各藥廠密切關注的重點。由此可見，儘管臺灣藥品市場在亞洲地區已相對飽和，然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，故國際藥廠在關注臺灣健保制度同時，可能未必是以拓展臺灣市場

為主要考量，其更重要的考量點可能在於臺灣的制度易間接影響到亞洲地區其他更廣大的市場。

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

CONFERENCE DAY ONE

WEDNESDAY 20 SEPTEMBER, 2017

08:00 **Main Conference Registration and Morning Coffee**

08:50 **Welcome Address and Ice Breaker from IBC Asia**

OPENING KEYNOTE SESSIONS
Joint Plenary Sessions with Clinical Trial and Pharma Regulatory Affairs Conferences

09:00 **Chairperson's Opening Remarks**

09:10 **KEYNOTE:**
From Trials to Table – The Move Towards a More Patient-Centric Approach

John Wilbanks
Chief Commons Officer, Sage Bionetworks, Senior Fellow, **Ewing Marion Kauffman, Foundation and FasterCures, USA,** TEDGlobal 2012 Speaker on "Let's Pool Our Medical Data"

John Wilbanks seeks to transform and innovate medical research by accelerating data sharing between clinical studies. As the Chief Commons Officer at Sage Bionetworks, he is in-charge of figuring out how to design policies and technologies that allow health and biological data to be broadly share between patients, clinicians and data analysis. Sage Bionetworks has put their open source toolkit innovation to the test by designing an application to conduct a set of Sage Bionetworks mobile research studies enrolling more than 100,000 participants in less than two years and integrated into more than 25 studies outside of Sage, including the US Precision Medicine Initiative.

To view John's talk at TEDGlobal 2012, click here

09:50 **INDUSTRY ROUNDTABLE: Drug Development, Pricing and Access – Bringing Together the Technical, Regulatory and Economic Considerations**

- Patient centric drug development and access
- ROI drivers, and outlook for the clinical research and drug development market
- Regulatory priorities across the pharma value chain
- Drug pricing developments
- Regulatory updates - harmonization, new policy, clarity and speed in licensing, submission and approval
- What are drug development ROIs looking like, and new partnership models for better harnessing ROIs

Panelists:

Li Ling Liu, Director, Good Registration Management (GRM), Researcher, Deputy Director General Minister Office, **Chinese Taipei Food and Drug Administration (TFDA),** Taiwan

Eva Kopecna, Senior Director Generics Regulatory Affairs Global OTC, **Teva Pharmaceuticals International GmbH,** Switzerland

Qing Xi, Sr. Director, Government Affairs, Market Access & Communications, **Pfizer,** China

Jean-François Baladi, Senior Executive, Health Economics and Market Access, **Novartis Pharma K.K.,** Japan

PJ Chen, Vice President, Head of Medical and Clinical Affairs Centre, **United BioPharma,** Taiwan

10:20 **Morning Networking and Refreshment Break**

11:10 **Chairperson's Introduction**

PATIENT-CENTRIC APPROACH AND ACCESS STRATEGY

11:20 **Improving Patient Access and Real-World Outcomes in Asia**

- Patient access challenges and treatment barriers
- Creative access strategies to increase market reach by removing financial barriers while maintaining price
- Disease management solutions that improve adherence and compliance to treatment

Michael Hofer, Regional Business Development Manager, **DKSH,** Asia

Co-presenters:

Dr. Joseph Saba, Co-Founder and Chief Executive Officer, **Axios International**

Maryline Marquet, APAC Managing Director, **Human Care Systems (HCS)**

11:55 **Importance of Patient-Centric Approaches in Defining Access Strategy**

- Why Patient-centric is crucial
- How can integrate all difference needs into one goal
- What Access strategy can be defined

Sittipong Liamsuwan, Policy & Market Access Director, **MSD (Thailand) Ltd.,** Thailand

12:30 **Networking Lunch**

13:30 **A Patient-Centric Model for Access to Unregistered Therapeutic Products**

- Today's challenges in drug development and access to pre-approval medicines
- A digital access model for patients with unmet medical needs globally
- Real-world evidence to improve healthcare decision making for all stakeholders
- Turn-key solution for Asian drug developers to bring medical innovations to the rest of the world

Robert Kraal, Chief Operations Officer, **myTomorrows,** Netherlands

14:00 **Translating Rare Disease Therapies for Improved Patient Care and Outcomes**

- Examining the challenges of bringing rare disease therapies to market, and its impact on patients
- Navigating complex regulatory and policy environments, to ensure patient access
- Communication strategies, advocacy and partnering for rare disease treatments

Cameron Milliner, Head Public Affairs and Patient Advocacy - APAC, **Shire,** Singapore

A NEW THINKING ON PRICING AND REIMBURSEMENT

14:30 CASE STUDY **Innovative Pricing Strategies for Expensive Therapeutics or Drugs**

- Budget and Reimbursement for expensive therapeutics in Korea
- Reimbursement policies to enable the product launching of costly drugs/ treatment
- Improved access and pitfalls to market and patient to ensure the economic outcome
- Strategies of market access in South Korea

Megan Kim, Head of Market Access Korea, **Boehringer Ingelheim Pte Ltd,** Korea

15:00 **Implementation of Integrated Market Access Strategy for Negotiation of Better Pricing and Reimbursement**

- Formulating a Market Access Strategy with real-world data
- Aligning your data to evidence requirements in HTA markets
- Usage of evidence for pricing and reimbursement negotiations

Chris King, Real-World Insights Principal, **QuintilesIMS,** Singapore

15:30 **Afternoon Networking & Refreshment Break**

16:00 **Taiwan's Reimbursement Model and Drug Price Review**

- Taiwan's healthcare system, national insurance program and getting market access
- Reimbursement and pricing approval process
- Timelines
- Health Technology Assessments (HTA) on new drugs
- Pricing recommendations by Drug Benefit Committee

Yi-Chieh Lin, Officer, Medical Review and Pharmaceutical Benefits Division, National Health Insurance Administration, **Ministry of Health and Welfare,** Taiwan

16:30 **Impact of Drug Price Review in Japan - Opportunities and Challenges for Drug Pricing & Reimbursement**

- Current outlook of Japan's healthcare pricing & reimbursement reform and future impact
- Key ingredients for future success - The win-win situation for government and pharma companies
- Innovative pricing and reimbursement strategies after implementation of pricing reforms
- The role of outcome research and pharmacoeconomic evaluations post pricing and healthcare reform

Jean-François Baladi, Senior Executive, Health Economics and Market Access, **Novartis Pharma K.K.,** Japan

17:00 CASE STUDY **A Strong Pricing Strategy for Universal Health Coverage in Indonesia**

- Examining the overall healthcare and current reimbursement situation in Indonesia
- Overcoming the challenges for Indonesia's road to Universal Health Coverage
- Key pricing strategies to understand and undertake for successful UHC

Rosalina Saleh, Market Access Lead, **PT Boehringer Ingelheim** Indonesia

17:30 **Chairperson's Summary and End of Main Conference Day One**

CONFERENCE DAY TWO

THURSDAY 21 SEPTEMBER, 2017

09:00 **Chairperson's Opening Remarks**

GROWTH MARKETS AND STRATEGY SPOTLIGHT

09:10 **HTA is Japan – Where Are We Now, and Where Are We Going?**
- A look at what we know and what we don't know about Japan's HTA
- A discussion on where we think HTA is heading, and what it could potentially mean for manufacturers

Neal Somchand, Senior Consultant, **Dealius Consulting,** Japan

09:40 **Philippines Market**

Embracing the Challenges of Implementing Universal Health Coverage and Pharma Market Access in the Philippines
- Mitigation of high out-of-pocket expense in health care due to costly medicine
- Benefits and risks to look out for while implementing pharma market access
- Leveraging the proven solutions to improve access – What has been done and challenges remain ahead?
- Exploring more innovative market access strategies in public and private sectors

Enrique A. Tayag, Assistant Secretary, Office for Policy and Health Systems, **Department of Health,** Philippines

10:10 **Morning Networking and Refreshment Break**

10:40 **Indonesia Spotlight**

How to Integrate Market Access Internally and Externally in Indonesia
- Examining the current public immunization policy landscape within Indonesia
- Sustaining and driving policies through effective advocacy strategies and broad internal and external engagements to maximize immunization benefit
- Achieving better market access for business growth, sustainability and public healthcare

Farida Malawi, Head of Public Sales and New Channels, Vaccine Policy & Advocacy and Market Access, **Sanofi Pasteur,** Indonesia

11:10 **Malaysia Outlook**

Strategies to Integrate Pharma Market Access in Malaysia
- Market access environment in Malaysia
- Challenges in market access for innovative medicines in Malaysia
- Strategies in consideration that may improve access to innovative medicines

Nathan Kothandaraman, Lead, Market Access, **Johnson & Johnson Sdn Bhd,** Malaysia

11:40 **China Case Study**

Innovative Strategies to Integrate Market Access Internally and Externally in China
- The overall healthcare and reimbursement investment/situation in China
- Current pharma market access environment and future trend in China
- Key challenges and opportunities for MNC pharma companies
- Suggested strategies

Qing Xi, Head of Government Affairs, Market Access & Communications, **Pfizer,** China

12:10 **Networking Lunch**

LEVERAGING HEOR AND RWE TO ENHANCE MARKET ENTRY

13:10 **Leveraging RWE for Market Access in Asia-Pacific**
- Growing interest of RWE in Asia-Pacific
- Leveraging RWE for Market Access strategies
- Challenges and opportunities in the region

Anh Bourcet, Associate Director, ASPAC Health Economic & Market Access, Orthopedics, **Johnson & Johnson,** Singapore

13:40 **Connecting with Patients through Digital Data Collection to Support HEOR**
- Collaborating with patients on digital health projects
- Digital data collection to control costs
- Digital data collection to transform the patient journey

Colette Hamilton, Chief Operating Officer, **RWE Genosys,** United Kingdom

14:10 **Are We Ready for a Cure? - Key Value Demonstration and Policy Considerations for the New Wave of Potentially Curative Therapies from Industry Perspective**
- What does the emerging Cell and Gene therapies landscape look like?
- What does this mean for patients with unmet needs?
- Opportunity to shape new value based reimbursement

Tay Salimullah, Global Strategic Projects Leader, Real World Evidence, **Novartis,** Switzerland

15:10 **Afternoon Networking & Refreshment Break**

15:40 **Country Specific Pricing and Market Access Strategies that work**
- Working with regulatory bodies
- Pricing opportunities and strategies
- Common market access strategy downfalls, and remedies
- Making local country partnerships work

Philippines: Enrique A. Tayag, Assistant Secretary, Office for Policy and Health Systems, **Department of Health,** Philippines

Malaysia: Nathan Kothandaraman, Lead, Market Access, **Johnson & Johnson Sdn Bhd,** Malaysia

China: Qing Xi, Sr. Director, Government Affairs, Market Access & Communications, **Pfizer,** China

Indonesia: Farida Malawi, Head of Public Sales and New Channels, Vaccine Policy & Advocacy and Market Access, **Sanofi Pasteur,** Indonesia

16:20 **Chairperson's Summary and End of Main Conference**

*Session outline may change to accommodate market-specific or company development.

附錄二、會議照片

一、臺灣健保藥品核價制度專題報告



Pricing Process of New Drugs (2G NHI)
PHARMA MARKET ACCESS AND PRICING SUMMIT
DKSH


Why Need HTA ?
Decision-making Processes:
1. Assessment: objective collection and evaluation of evidence
2. Appraisal: considers and weighs the summarized evidence in order to render a recommendation
3. Decision
PHARMA MARKET ACCESS AND PRICING SUMMIT

二、會議討論情形


This session uses Pigeonhole Live for interactive Q&A and Poll.
Logon to www.pigeonhole.at
Event Passcode:
PHARMACON2017
PHARMACON
ASIA
20 - 22 September 2017
[Thought Leadership Roundtable] Drug Development, Pricing and Access – Bringing Together the Technical, Regulatory and Economic Considerations
Patient centric drug development and access
ROI drivers, and outlook for the clinical research and drug development market
Regulatory priorities across the pharma value chain
Drug pricing developments
Regulatory updates - harmonization, new policy, clarity and speed in licensing, submission and approval
What are drug development ROIs looking like, and new partnership models for better harnessing ROIs
Moderator
Alex Matter, CEO, Experimental Therapeutics Centre & D3, A*STAR, Singapore
Panellists:
Eva Kopecna, Sr Dir Generics Reg Affairs Global OTC, Teva Pharmaceuticals International GmbH, Switzerland
PHARMACON
ONE-FARRER
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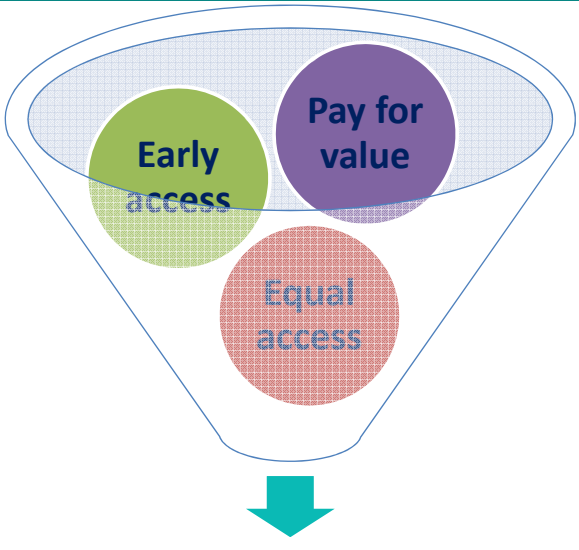
Event
PHARM

Taiwan’s Reimbursement Model and Drug Price Review

Yi-Chieh Lin
Officer
Medical Review and
Pharmaceutical Benefits Division
NHIA, MoHW/ Taiwan

Principle of Medication Policy



Patient-oriented health care

Outline

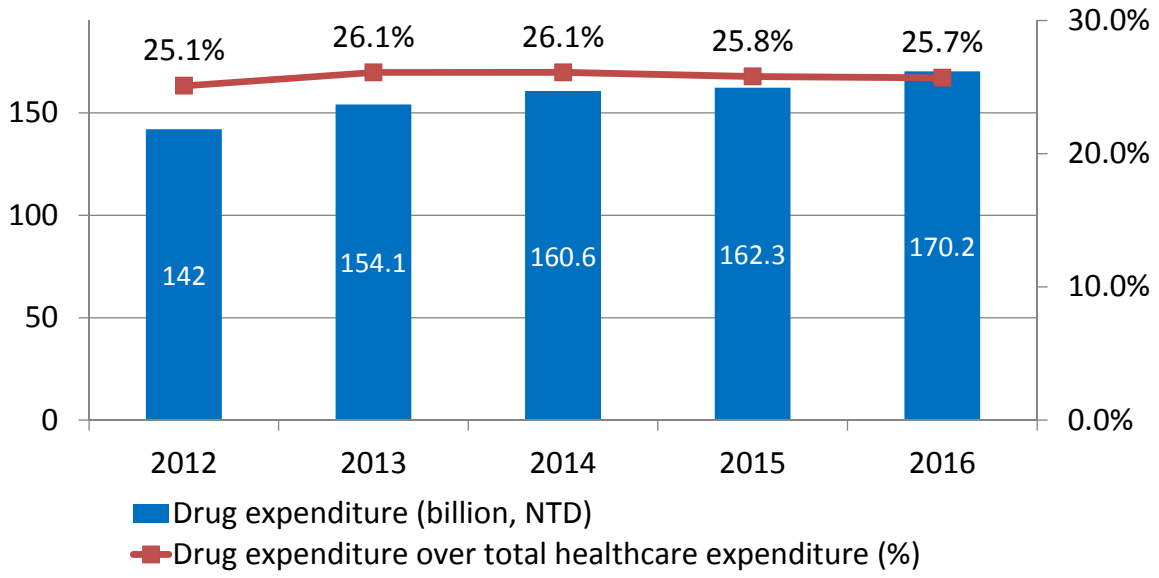
- Payment system and pharmaceutical expense
- Pharmaceutical Benefits and Reimbursement Schedule (PBRS)
- Pricing process
- Health Technology Assessment in NHI

Global Budget Payment System

The global budget payment system was adopted to constrain the rapid growth in costs under the fee for-service model and institute a system of financial accountability.

Medical providers and payers negotiate overall caps on total medical payments with the NHI system prior to the beginning of a fiscal year based on a fixed volume and range of medical services.

Trend of NHI Drug Expenditures



Principles of Pharmaceutical Reimbursement

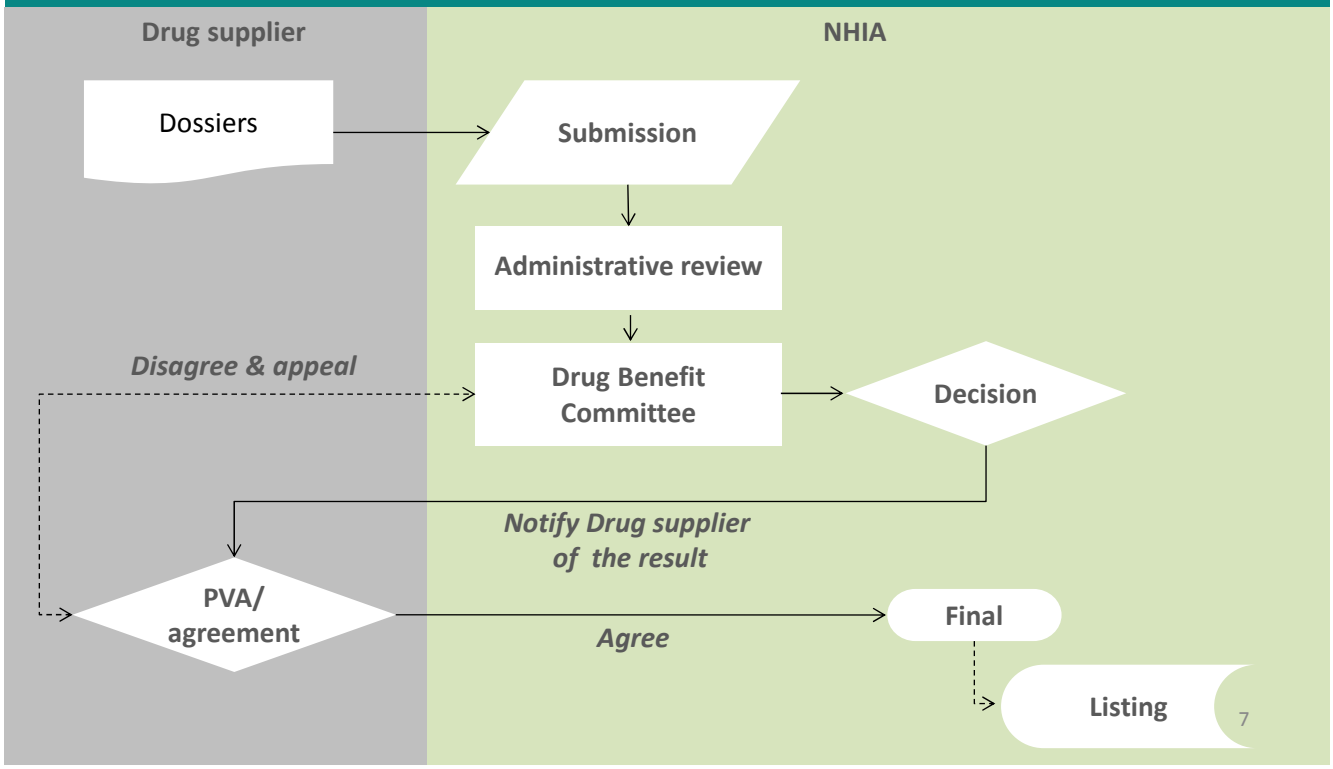
Positive Listing

The National Health Insurance Pharmaceutical Benefits and Reimbursement Schedule (>15,000 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

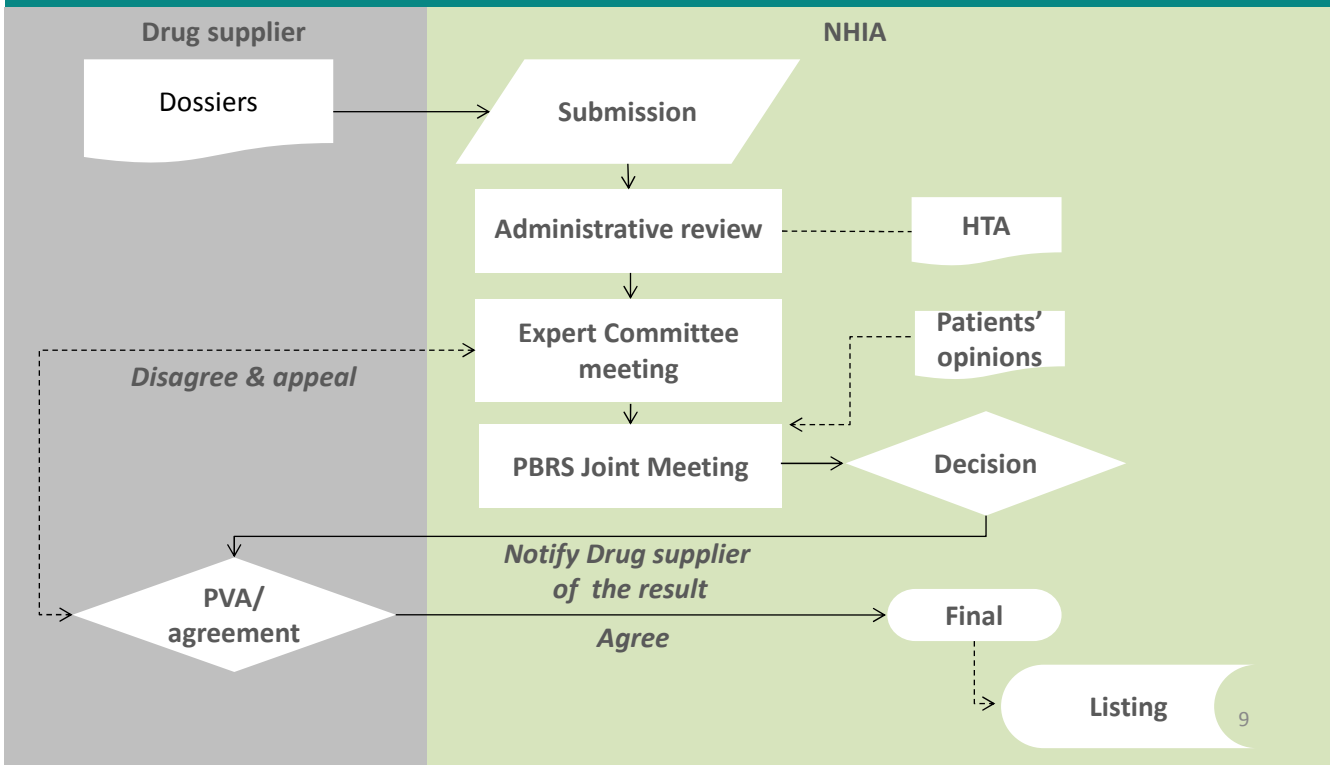
Pricing Process of New Drugs (1G NHI)



2nd generation NHI

- **Implemented in 2013**
- **More transparent and predictive**
  - **Pharmaceutical Benefits and Reimbursement Schedule (PBRS)**
    - as the principle for drug listing and fee schedule
  - **PBRS Joint Meeting**
    - composed of stakeholders to ensure decision making for drug listing and reimbursement

Pricing Process of New Drugs (2G NHI)



PBRS Joint Meeting

composed of stakeholders to ensure decision making for drug listing and reimbursement

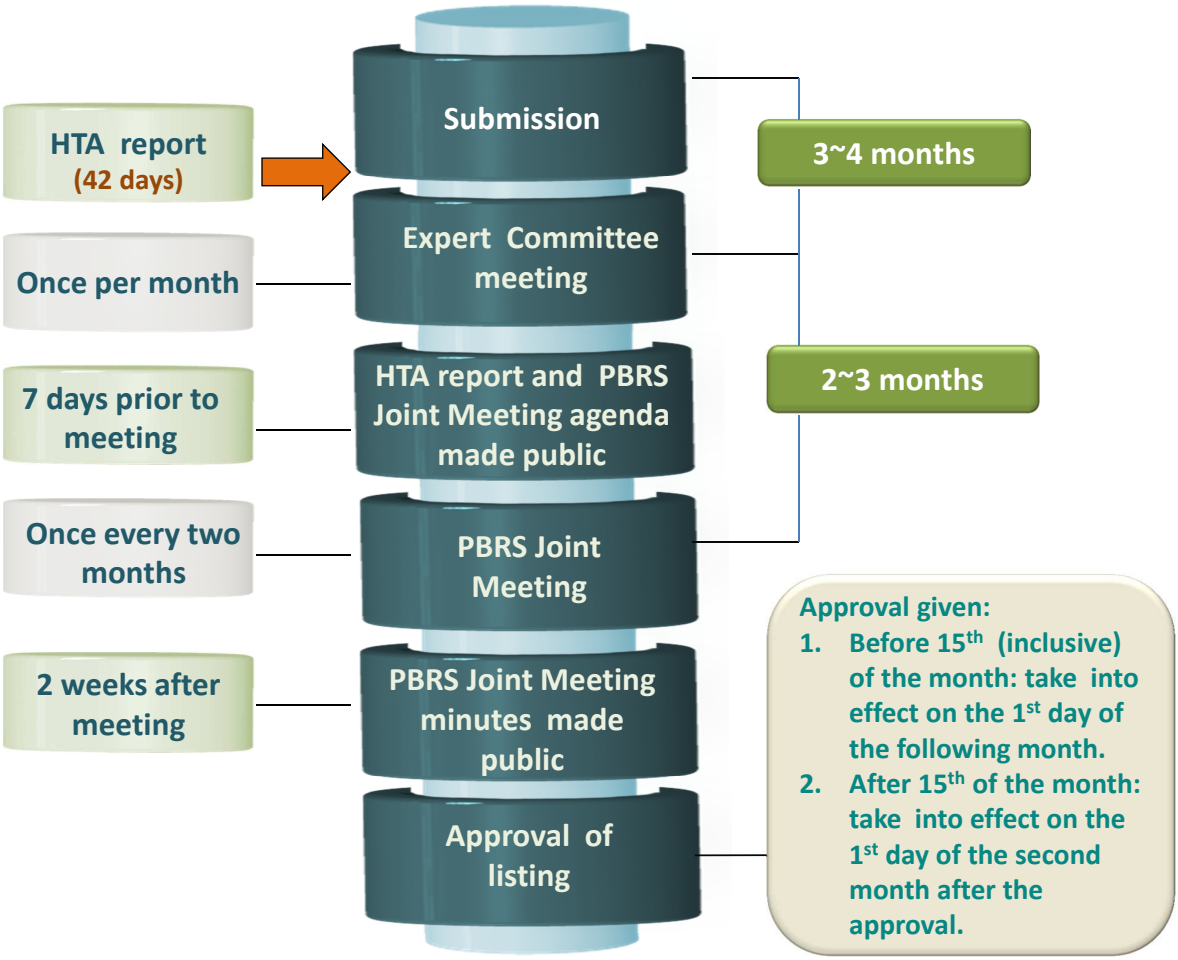
Healthcare Providers	13	
Scholars and Experts	9	
The Insured	3	
Employer	3	
Health Regulatory Authority (MoHW)	1	
Drug Regulatory Authority (TFDA)	1	

Participants of PRBS Joint Meeting

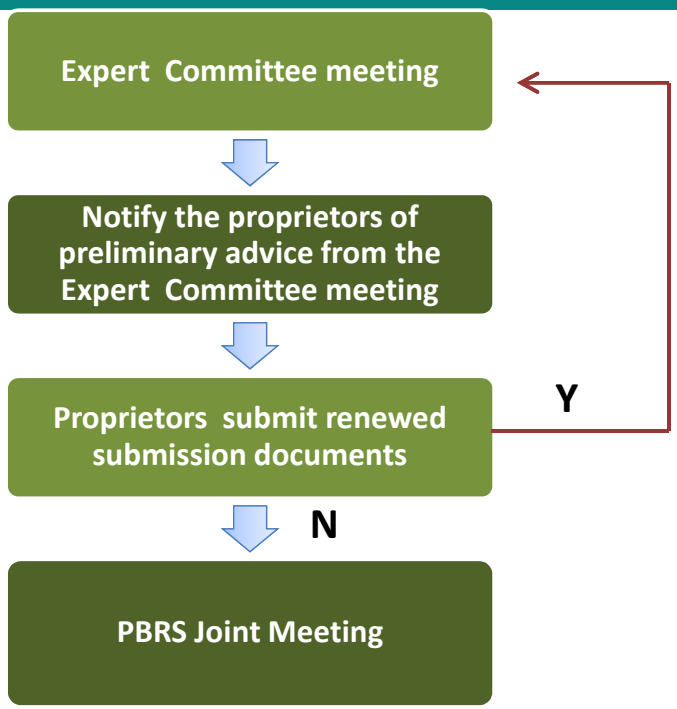
Health and drug regulatory authority	• assigned by competent authorities
Scholars and experts	• designated by insurer
The Insured (employer and lay member)	• recommended by related association then designated by insurer
Healthcare providers	• assigned by related association
Pharmaceutical industry	• 3 representatives may assigned by related association to seat in the PBRS Joint Meeting (although they have no right to vote for cases)

Missions of PBRS Joint Meeting

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



Notification of the Preliminary Advices from the Expert Committee Meeting



Two-level of Pricing & Reimbursement Decision

1. **Expert committee: initial proposal**
2. **Stakeholder Committee: final decision**

Three decisions of pricing & reimbursement

1. **Listing:** whether the new drug will be listed in pharmaceutical benefits scheme?
2. **Pricing:** how much will the new drug be paid?
3. **Restriction:** whether the restriction on reimbursed indication or pre-utilization review is needed?

Four Criteria of Pricing & Reimbursement

Safety/efficacy/quality: by Taiwan's FDA

1. Relative effectiveness
2. CBA/CEA/PE
3. Budget impact analysis
4. Ethical/Legal/Social/Political Impact

Pricing of New Drugs

Items with new active ingredient(s), new dosage form, new route of administration or a new combination of listed ingredients.

Category		Pricing	Mark-ups
1	Breakthrough	Median price of A-10 countries	• local clinical trials (10%) • local 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		

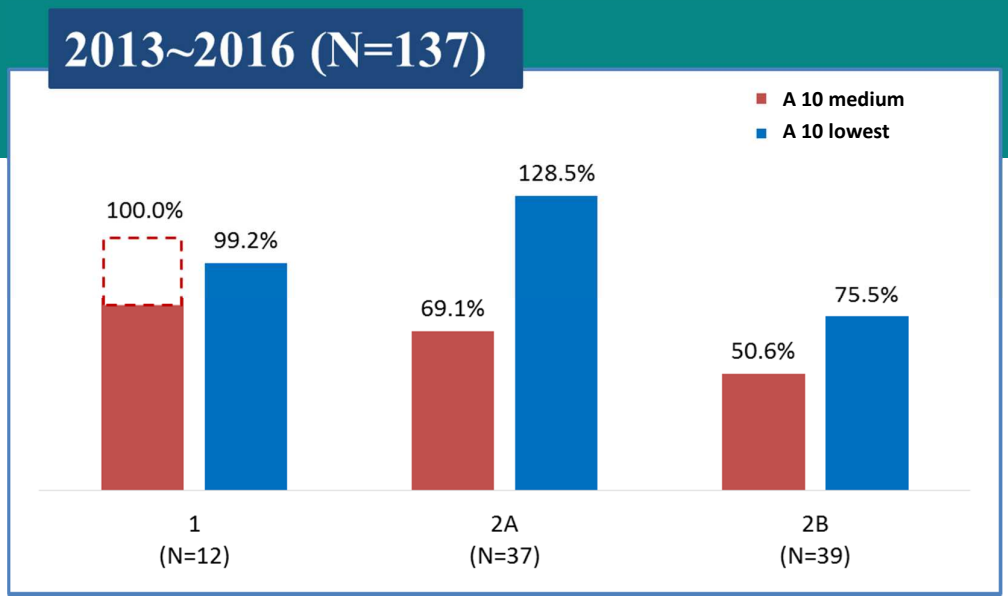
Selection of comparators

- 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

A-10 reference countries

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)

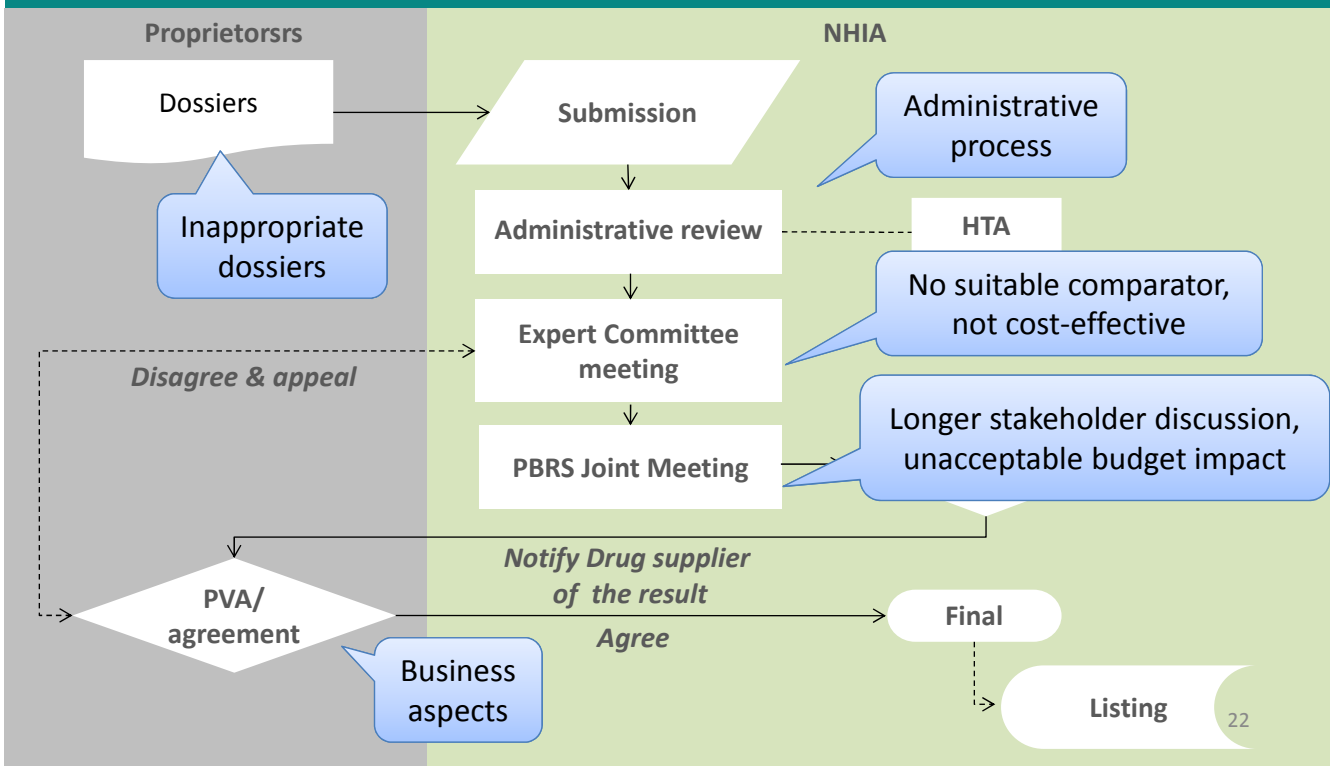
Price of new drugs compared with A-10 reference countries



Not including:

1) None of reference countries listed. (N=22)
2) Only 1 reference countries listed, reimbursement price/ Price submitted by the supplier. (N=22，92.5%)
3) Price submitted by the supplier (2A&2B). (N=5，100%)

Interfering Factors of pricing process



Strategies for improvement

Factors	Solutions
Inappropriate dossiers	Create check list
Administrative process	1. Establish electronic tracking system 2. Allow drug supplier to make submission by approval letter.
No suitable comparator, Not cost-effective	1. Pricing Category 2A new drugs with reference comparators listed in the past five years 2. Giving the proprietors a 10-minute hearing in the Expert Committee meetings as requested 3. Notify the proprietors of preliminary advice from the Expert Committee meeting
Longer stakeholder discussion, Unacceptable budget impact	1. Pre-meeting briefs to consumer representatives 2. Adding 4 expert representatives to the PBRS Joint Meetings 3. Giving the proprietors a 10-minute hearing in the PBRS Joint Meetings as requested 4. Allocate more budget for new drugs 5. Request submissions to attach budget impact analysis in file. 6. Regularly report the expenditure regarding newly listed items and items subject to expansion of reimbursed indication on the PBRS Joint Meetings.
Business aspects	More communication

Why Need HTA ?

Decision-making Processes:

1. **Assessment: objective collection and evaluation of evidence**
2. **Appraisal: considers and weighs the summarized evidence in order to render a recommendation**
3. **Decision**

Contents of HTA Report

1. Comparator
2. Relative effectiveness
3. Cost effectiveness
4. Budget impact analysis
5. Summary of HTA reports from UK, Canada and Australia

Comparator

What are the existing treatment options?

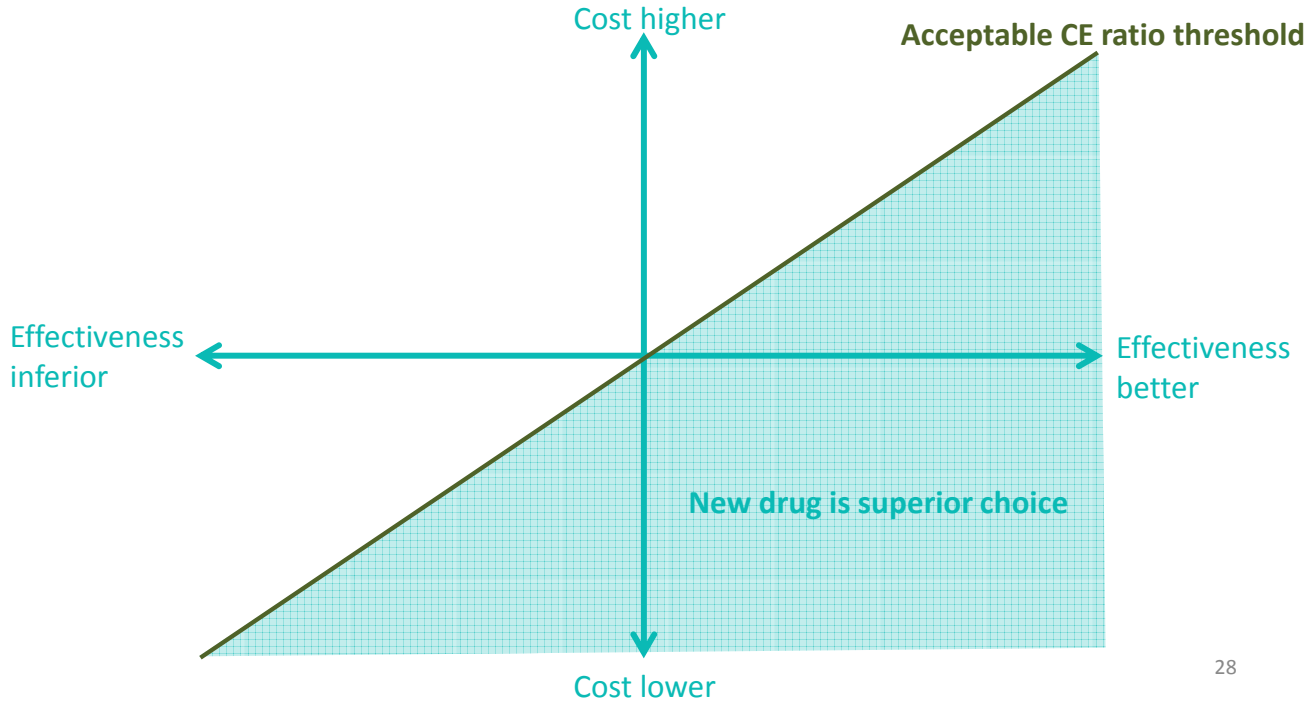
- Principle of selection → drug
- Clinical guideline
- Payment status
- Clinical practice

Relative Effectiveness

Is the new drug better than the existing option? How much better?

- Systemic review
- Head-to-head comparison is preferred
- Indirect comparison is also accepted
- Outcome indicator
- Safety consideration
- Target population

Cost Effectiveness



Cost Effectiveness

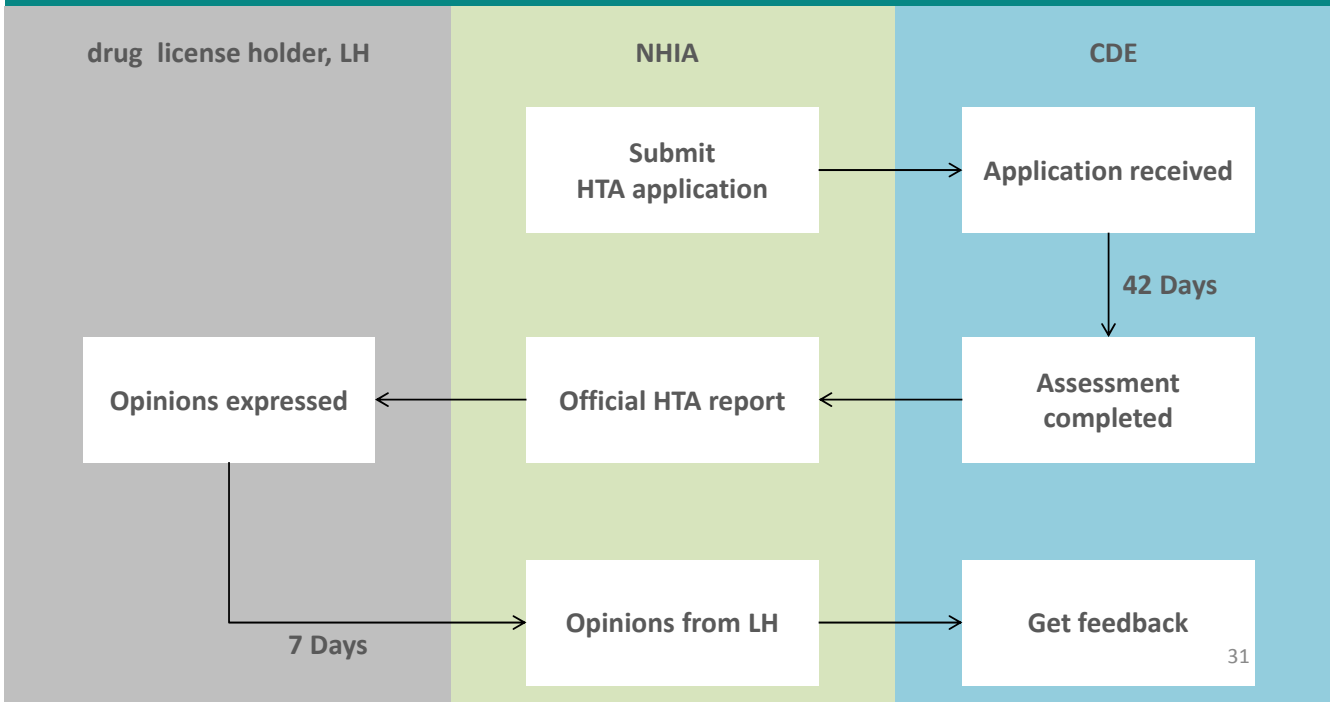
- Still in the stage of capacity building (lack of local clinical epidemiological data and cost data)
- CE assessment results from UK, Canada and Australia as reference data
- Up to 10% price plus for conducting local PE study

Budget Impact Analysis

How much is the total expenditure? Is that affordable?

- Verification of financial forecast provided by new drug supplier
- Financial forecast include:
  - Total new drug expense in five years of listing
  - Substitution effect on other drug expense
  - Saving effect on other medical claims

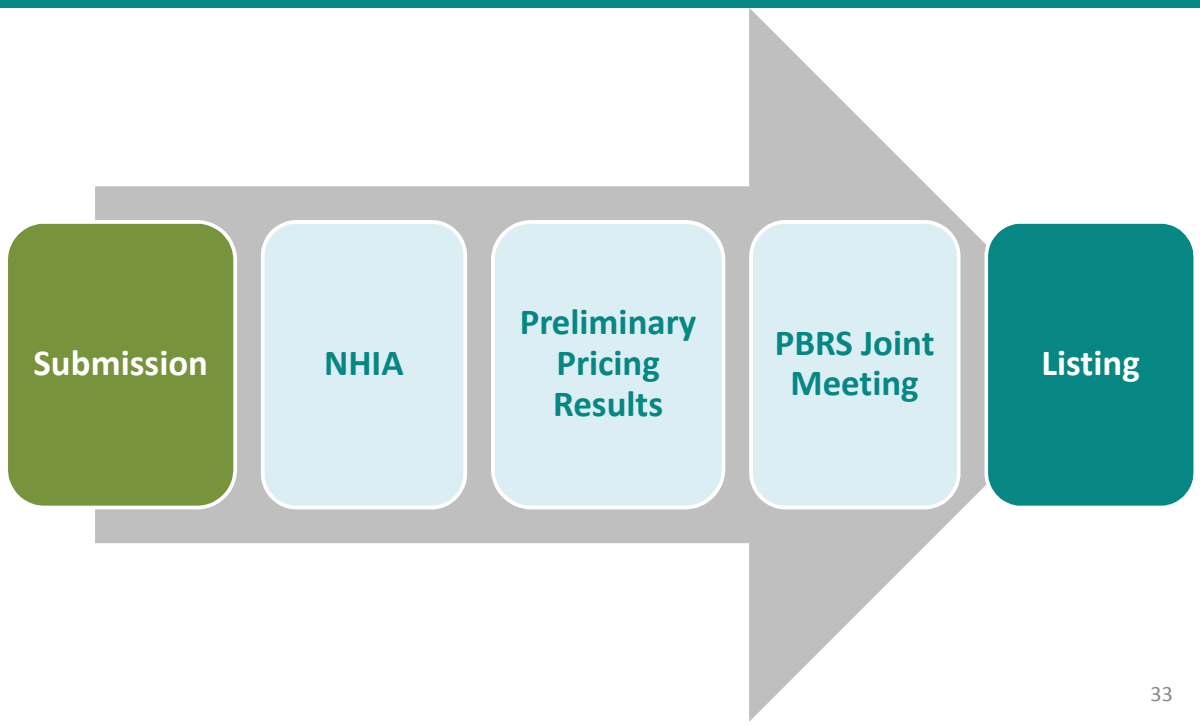
HTA Process for New Drug Listing Application



Pricing of Other New Items

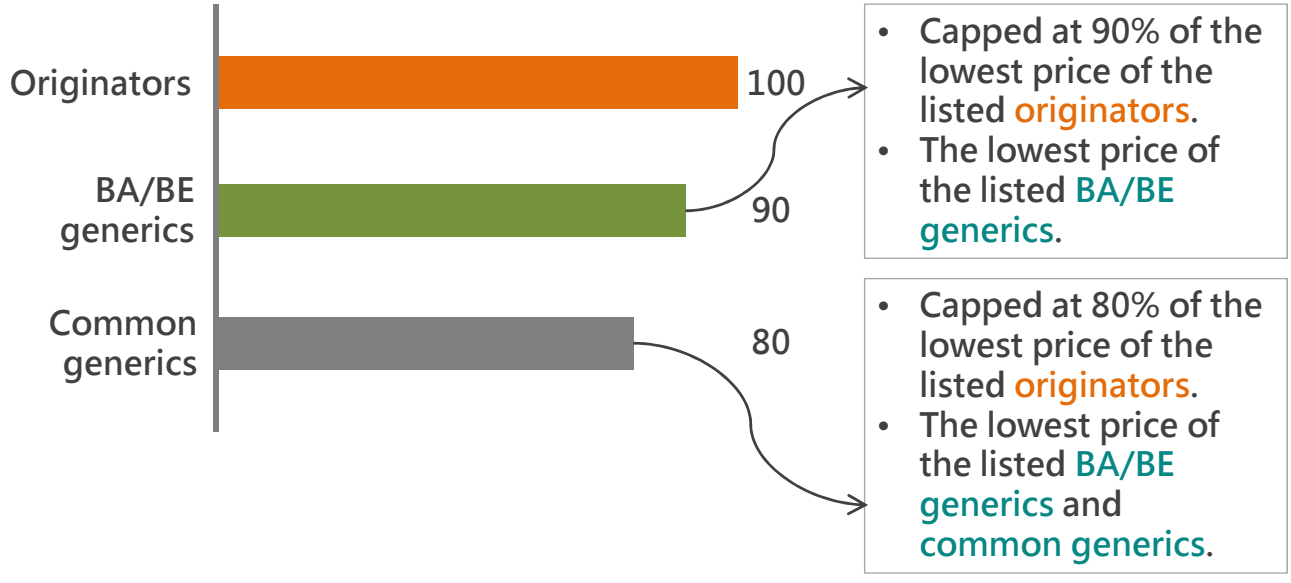
- **New items of the same ingredient(s) and dosage form as those listed in the Schedule can be classified into:**
  1. **Originators:** drugs with patented active ingredients
  2. **BA/BE generics:** generic drugs which have been subject to BA/BE studies and approved by the competent authority.
  3. **Common generics:** generics drugs other than the above

Pricing Process of Other New Items



Principle of Pricing Other New Items

By classification (originators, BA/BE generics or common generics)



Principle of Pricing Other New Items

By active ingredient(s)

- **When the first item with the same ingredient(s) and dosage form has been listed more than 15 years**
  - **Items with the same ingredient(s), dosage form and specification are listed with the same price.**

Conclusions

- **Multiple participation**
  - Involve more stakeholders to join PBRS Joint Meeting
- **Implement budget impact analysis**
  - Implementing HTA to determine budget impact for reasonable reallocating resources
- **Multi-way communication**
  - Use multi-way communication to balance cognition between the insured and healthcare provider or the payer and the seller
- **International harmonization**
  - Harmonize regulation to join worldwide partnership


Thank you for your attention!