衛生福利部出國報告（出國類別：會議）

參加 2018 年「第六屆臺日醫療交流會議」

服務機關：行政院衛生福利部中央健康保險署
姓名職稱：專門委員黃兆杰
派赴國家：日本
出國期間：107.10.10-107.10.13
報告日期：107.12.24

摘 要

「臺日醫療交流會議」係源於 102 年 11 月 5 日台日雙方簽署「台日藥物法規合作框架協議」後，為進一步加強彼此間之醫藥相關法規合作及分享管理經驗，所建立的長期溝通交流平台。本次為第 6 屆會議，由日方於東京主辦。雖然雙方溝通之內容以醫藥法規為主，惟醫藥法規常與健保藥品給付息息相關，且台日雙方均屬全民健康保險制度，彼此多有能夠互相分享、借鏡與學習之處，因此，每屆會議主辦單位均會邀請本署與日本厚生勞動省負責健保業務之單位派員與會進行演說與討論。

本次交流有關健保議題部分，對外會議係分別由本署針對「台灣健保的藥品給付與藥價調整（Drug Reimbursement & Drug Price Adjustment Under Taiwan's NHI System）」進行介紹，及由日方針對「日本藥品核價系統的更新（Update of Drug Pricing System in Japan）」進行介紹。另為更深入了解與溝通，本署與日本厚生勞動省官員進一步舉辦閉門會議，雙方除就最新規劃之藥品核價及調整等制度交換意見外，本署亦就風險分攤、精準醫療、基因檢測、癌症免疫及學名藥核價等向日方請益。

透過本次會議，雙方都有不少收穫，特別是有關日本目前對於藥品核價系統所進行的改革，包括：為鼓勵創新所設計的加成或公司指標制度、美國藥價由參考 red book 改為參考美國大眾健康保險系統的公告藥價、鉅額增長的藥品價格調整方式等，都是台灣未來可以思考的方向，建議納入本署未來健保藥品核價制度改革的參考。

台灣與日本健保的藥品給付制度多有類似的地方，也同樣面臨新藥昂貴、藥費高漲及人口老化等問題，建議未來本署能夠透過各種交流或研討會議，持續與日本進行溝通學習，以建構符合台灣需求的健保藥品給付制度。

目　　錄

壹、目的

為因應全球化的發展，各國無不極力推展雙邊或多邊的協議及溝通平台，「臺日醫療交流會議」即在此浪潮下台日雙方共同推出的溝通平台，該會議是在 102 年 11 月 5 日台日雙方簽署「台日藥物法規合作框架協議」後，為進一步加強彼此間之醫藥相關法規合作及分享管理經驗，所建立的長期溝通交流平台。會議每年舉辦一次，並輪流由台方或日方主辦，本次為第 6 屆會議，由日方於東京主辦。雙方溝通之內容係以醫藥法規為主，因此台方主要由食品藥物管理署派員與會，惟醫藥法規常與健保藥品給付息息相關，且台日雙方均屬全民健康保險制度，彼此多有能夠互相分享、借鏡與學習之處，因此，每屆會議主辦單位均會邀請本署與日本厚生勞動省負責健保業務之單位派員與會，進行演說與討論。

本次本署派員參與會議，除了希望能夠持續分享全民健康保險制度中藥品給付的最新發展及規劃外，亦希望能夠就台灣目前擬發展的項目向日方請益，因此，除了對外會議外，亦與日本厚生勞動省官員進行閉門會議。對外會議部分，分別由本署針對「台灣健保的藥品給付與藥價調整（Drug Reimbursement & Drug Price Adjustment Under Taiwan’s NHI System）」進行介紹，及由日方針對「日本藥品核價系統的更新（Update of Drug Pricing System in Japan）」進行介紹。閉門會議部分，則由雙方就最新規劃之藥品核價及調整等制度交換意見，本署另就風險分攤、精準醫療、基因檢測、癌症免疫及學名藥核價等向日方請益。

貳、行程及會議議程

一、行程表

日期	行程
10/10	台北出發往日本東京
10/11	臺日醫療交流會議
10/12	閉門會議
10/13	返台

二、會議議程

6th Joint Conference of Taiwan and Japan on Medical Products Regulation

Date: October 11, 2018

Place: Kaiun Club Building (2-6-4, Hirakawa-Cho, Chiyoda-ku, Tokyo)

*Simultaneous interpretation (Chinese - Japanese) provided

Joint Session (Main Hall. 2F) *MC: Mr.Katsuaki Ura, MHLW*	
8:30-9:00	**Registration**
9:00-9:40	**Opening remarks** (40 min) *5min each 1. Representative from the Japan-Taiwan Exchange Association 2. Dr. Jiun-Rong Chen, Director, Science & Technology Division, Taipei Economic & Cultural Representative Office in Japan 3. Mr. Kazuhiko Mori, MHLW 4. Dr. Shou-Mei Wu, Director-General, TFDA 5. Mr. Tadaharu Goto, Director General, JPMA 6. Mr. Tung-Mao Su, TPMA 7. Mr. Seiichi Mori, JFMDA 8. Mr. Francis Hong, TMBIA
9:40-10:00	**Memorial photo taking (including MOC celebration and group photo)**
10:00-11:00	**Keynote speeches** (60 min) -Regulatory updates in Japan, MHLW/PMDA (25min) Dr. Nobumasa Nakashima, Associate Executive Director, PMDA -Regulatory updates in Taiwan, TFDA (25min)

	Dr. Jo-Feng Chi, Deputy Director, Division of Medicinal Products, TFDA Q&A (10min)
11:00-11:20	**Break**

【Parallel session (Pharmaceutical)】

Pharmaceutical (Main Hall)	
11:20-12:15	**Regulatory progress for innovation / International trend on pharmaceutical regulatory convergence** (55min) Moderator: Mr. Katsuaki Ura ,MHLW - Introduction of Horizon Scanning – sharing ICMRA progression -, MHLW/PMDA (20min) Mr. Naoyuki Yasuda, Director, Office of International Regulatory Affairs, MHLW - Regulatory progress for innovation – Taiwan bio's perspectives- (20min) Ms. Carol Cheng, Chief Operating Officer, TRPMA Q&A (15min)
12:15-13:00	**Lunch Break**
13:00-13:50	Moderator: Dr. Junko Sato, Office Director, Office of International Programs, PMDA **E2B** (50min) - Japan's experience (25min) Mr. Iku Mitta, Director, Office of Safety I, PMDA - ADR Reporting System progress and E-submissions in Taiwan (10min) Mr. Po-Wen Yang, Section Chief, Division of Medicinal Products, TFDA Q&A (15min)
13:50-14:40	Moderator: Dr. Jo-Feng Chi, Deputy Director, Division of Medicinal Products, TFDA **Recent Trend on Utilization of Real World Data** (50min) - Challenges in Japan (20min) Mr. Takashi Ando, Office of Medical Informatics and Epidemiology, PMDA - Using Real World Evidence in Regulatory Decision Making (20min) Chi-Hsun Chen, M.D. Senior Team Leader, Division of New Drugs, Center for Drug Evaluation (CDE) Q&A (10min)
14:40-15:00	**Break**
15:00-15:50	Moderator: Dr. Junko Sato, Office Director, Office of International Programs, PMDA **Further collaboration from Industry's view** (50min) - Japan's industry perspectives (ICH-E17) Mr. Osamu Komiyama, JPMA - TFDA's industry perspectives Q&A (20min)
15:50-16:20	**Break**

Health Insurance (Main Hall) / Self-care (Room 306)		
16:20-17:20	**Drug price adjustment under health insurance system** (60min) Moderator: Mr. Akihiko Matsubara, Managing Director, JPMA - MHLW (20min) - Mr.Jau-Jic Huang, Senior Executive Officer, Medical Review and Pharmaceutical Benefits Division, National Health Insurance Administration (20mim) Q&A (20min)	**Self-care initiative** (60min) Moderator: Mr. Katsuaki Ura, MHLW - OTC accessibility to consumer, MHLW (15min) Dr. Hikoichiro Maegawa, Deputy Director, Pharmaceutical Evaluation Division - OTC accessibility to consumer and expansion of monograph, TFDA (15min) Ms. Hui-Ping Chang, Section Chief, Division of Medicinal Products, TFDA - Q&A (10min each)
17:20-17:30	**Closing Remarks (pharmaceuticals)** - PMDA Mr. Yoshikazu Hayashi, Executive Director, PMDA - TFDA Dr. Shou-Mei Wu, Director-General, TFDA	
Reception (18:00-)		

【Parallel session (Medical Devices)】

Medical Devices (Room 303/304, 3F) *MC: Mr. Masayoshi Naito, JFMDA*	
11:20-12:15	**WG report & future image** (55min) Moderator: Dr. Madoka Murakami (PMDA) 1. Product registration WG, TFDA (20min) Mr. Ta-Jen Wu, Technical Specialist, Division of Medical Devices & Cosmetics, TFDA 2. QMS WG and MOC, MHLW(15min) and TFDA (5min) Ms. Yumiko Aoyagi, MHLW, Ms. Lee, Szu Yu, TFDA 3. Q&A (15min)
12:15-13:00	**Lunch**
13:00-14:50	Moderator: Dr. Madoka Murakami (PMDA) **1. Prospective of regulation for cutting-edge technology** (55min) - Regulatory progress of Artificial Intelligence, PMDA (20min) Mr. Kentaro Kato, Regulatory progress of Artificial Intelligence, PMDA - Regulatory progress of 3D Printing,TFDA (20min) Mr. Cheng-Wen Lan, Senior Reviewer, TFDA - Q&A (15min) **2. Strategies for regulatory convergence including Asian region** (55min) - Japan's perspectives, PMDA (20min) Dr. Mari Shirotani, PMDA - Taiwan's perspectives, TFDA (20min) Ms. Cheng-Ning Wu, Section Chief, Division of Medical Devices & Cosmetics, TFDA - Q&A (15min)
14:50-15:00	**Closing Remarks (medical devices)** -Dr. Mari Shirotani, PMDA -TFDA -Ms. Yu-Roo Chu, TFDA
15:00-15:20	**Break**
15:20-17:30	WG Closed meeting (Reg. + Industry) *(Consecutive interpretation provided)* • Product registration WG • QMS WG
Reception (18:00-)	

參、對外會議內容摘要（健保相關）

時間：2018/10/11 16:20-17:20

地點：Kaiun Club Building (2-6-4, Hirakawa-Cho, Chiyoda-ku, Tokyo) (Main Hall)

議程：Drug price adjustment under health insurance system (60min)

主持：Mr. Akihiko Matsubara（松原 明彦）, Managing Director, JPMA

一、日方報告部分（詳如附件）：

（一） 報告人：Takafumi Yumoto（湯本 貴文），Section Chief Economic Affairs Division Health Policy Bureau Ministry of Health, Labour and Welfare

（二） 報告摘要：

1、 湯本先生的報告，主要分為 2 個部分，分別為日本健保的藥品核價系統介紹及藥品核價系統的改革。

2、 藥品核價系統介紹部分：

(1) 支付的藥品品項和價格係由厚生勞動省核定，核價的標準是依據 2016 年 2 月 10 日訂定的「Drug Pricing Standard」，核價後定期依據價量調查進行調整。

(2) 鉅額增長的藥品，定義及調整方式於 107 年增修：

A. 原制度：a.定義：超過 150 億日圓及預期的 2 倍，或超過 100 億日圓及預期的 10 倍；b.調整方式：最高調降 25%。

B. 新增制度：a.定義：超過 1,000 到 1,500 億日圓及預期的 1.5 倍，或超過 1,500 億日圓及預期的 1.3 倍；b.調整方式：前者最高調降 25%，後者最高調降 50%。

(3) 新藥核價依照是否有對照品分別訂定：

A. 有對照品：看是否具創新性，若無：則以對照品最低價核定；若有，則可考量創新、實用、市場規模、兒童及是否符合「SAKIGAKE Review and Designation System」等，予以加乘。

B. 無對照品：則依成本（製造、行政、銷售、配送）、營業利潤及消費稅等核定，再依上述 A 的情形考量是否調整。

(4) 藥價計算完成後，會再參考美、英、德、法等四個國家的藥價依公式酌予調整。

(5) 學名藥的核價為原廠的50%，當品項數大於10個後則為原廠的40%；生物相似性藥品的核價為原廠的 70%，當品項數大於 10 個後則為原廠的 60%，但可依臨床結果酌予加成最高 10%。

(6) 新藥價格的核定，是在中央社會保險醫療協議會（Central Social Insurance Medical Council, CSIMC，以下稱中醫協）的一般會議中決定。該會議一年舉辦 4 次。

3、 藥品核價系統改革部分：

(1) 改革目標是希望達到系統的持續、鼓勵創新、降低財務及改善醫療品質。

(2) 改革的重點大致包括：

A. 反映藥品市場擴張部分：利用新藥每年 4 次核價的機會檢視藥品列項後的市場擴張情形，重新檢討支付價。

B. 2 年藥價調整期間的檢討部分：對於價差過大的藥品，於 2 年調價的中間年，也進行檢討；

C. 評估創新部分：從根本檢討新藥的發展、消除非適應使用及引進全面的成本效益評估等。

(3) 有關新藥核價的改革部分，包括：

A. 依據創新性和實用性評估新藥加成，並依據公司達成創新之情形設定公司指標。

B. 針對每年申報金額大於 350 億日圓之藥品，利用新藥每年 4 次核價的機會，檢視藥品列項後因適應症變更至市場擴張的情形，重新檢討支付價。除適用原規定，申報超過 150 億日圓且為原估計 2 倍以上，或超過 100 億日圓且為原估計 10 倍以上，調降幅度最高 25%之外，新增列申報超過 1,000 至 1,500 億日圓且為原估計 1.5 倍以上，或超過 1,500 億日圓且為原估計 1.3 倍以上，調降幅度最高為 25%或 50%。

C. 參考國外價格部分，美國藥價由參考 red book，改為參考美國大眾健康保險系統的公告藥價。

D. 引進成本效益評估，107 年 4 月先針對 13 項產品進行試辦，107 年底完成全面導入的評估。

(4) 有關藥價調整中間年檢討的部分：配合日本稅制變更的確認，預計於 2020 年確認檢討的品項後，於 2021 年針對部分價差過大的藥品進行調整（註：依據 2018 年 12 月相關新聞，此制度將提前實施，預計於 2019 年進行中間年的藥價調整），範圍如下：

A. 年申報 500 億至 800 億，價差超過平均 2 倍者。

B. 年申報 750 億至 1,100 億，價差超過平均 1.5 倍者。

C. 年申報 1,200 億至 1,800 億，價差超過平均 1.2 倍者。

D. 年申報 1,900 億至 2,900 億，價差超過平均 1 倍者。

(5) 有關專利藥品價格暫緩調整之條件及比例部分：

A. 目標為正確識別和評估真正有用的藥物創新，限縮適用在具有真正創新/實用性的藥品，以促進研發投資。

B. 引進公司指標（Company indicators），依據指標計算進行分類（Categorization），再依分類 I、II、III 分別設定暫緩調整係數為 1、0.9、0.8。

(6) 為確保創新藥物的創新得到適當評估，成本計算的方法也進行了修訂：

A. 溢價計算由依營業利潤改為依總成本計算。

B. 溢價率的差異，依據各藥品共應商可披露的製造成本項目的百分比（披露水平 Disclosure level）進行設定。

(7) 有關老藥（long-listed products）改革的部分，為了將依賴老藥的產業結構，轉變為具有更大藥物開發能力的產業結構，進行以下修定：

A. 修改 Z2 期間（學名藥收載 5 年後至 10 年期間）的規定：為於 2020 年 9 月之前實現學名藥數量的占比達 80%之目標，修改 Z2 期間三種替代率類別的標準，並依修改後比率調整支付價：

原替代率	修改後替代率	調降比率
50% ~ 70%	60% ~ 80%	▲1.50%
30% ~ 50%	40% ~ 60%	▲1.75%
< 30%	< 40%	▲2.00%

B. 引進新的方案，Z2 期間後接續 G 期間的檢討，並將 G 期間的產品區分為 G1 及 G2，G1 為學名藥替代（80％或以上）的產品，G2 為學名藥替代差（低於 80％）的產品。G1 產品，若老藥價格為學名藥的 2.5 倍或以上，則 6 年內調為同價，即每兩年分別調降為 2 倍、1.5 倍及 1 倍；G2 產品，若老藥價格為學名藥的 2.5 倍或以上，則 10 年內調降至 1.5 倍，即每兩年分別調降為 2.3 倍、2.1 倍、1.9 倍、1.7 倍、1.5 倍。

(8) 有關參考國外價格調整部分的修改：

A. 對於引用美國 RED BOOK 價格部分，因為 RED BOOK 是製造商推薦價格（免費價格）的清單，是否適合在日本官方定價決策中進行比較引起爭議，但美國為世界上最大的藥物開發國，亦不應在參照國中排除，因此建議參考用於美國公共醫療保健計劃 Medicare 和 Medicaid 的價格表 ASP（Medicare Part B Drug Average Sales Price）和 NADAC（National Average Drug Acquisition Cost）。

B. ASP 是醫療中心內部處方藥的平均銷售價格，是 Medicare B 部分報銷（醫院門診服務等）的支付價格，相關藥物用於診所醫生非固定費用報銷的臨床治療；NADAC 是透過調劑藥局獲得內部處方藥的平均成本，是 Medicaid 的支付價格，相關藥品包括已列於 CMS 門診處方藥列表的產品或批准的新產品。

C. 2016 年 4 月～2017 年 8 月在日本上市的新藥，上市時可獲得美國 RED BOOK 價格的有 55 項，ASP/NADAC 則有 19 項；平均 ASP/NADAC 價格為 RED BOOK 的 0.77 倍。

4、 對於未來展望，湯本先生表示已分別記載在 2 分報告附帶的補充意見中，分述如下：

(1) 2018 財年醫療費用修訂的報告附帶的補充意見部分：藥品定價體系的基本改革，將根據「藥品價格體系基本改革綱要」，繼續探討核實藥品價格體系基本改革，對利害關係者影響的必要行動和措施，此外，也將繼續討論如何處理基本藥物。

(2) 藥品定價系統基本改革綱要附錄部分（2017 年 12 月 20 日在 Chuikyo 批准）

A. II.適當的創新評估部分：將對新藥開發和取消適應症外藥物使用的保費進行基本審查，並透過對公司的要求和相對應的公司指標來達成。

B. VI.未來的考慮部分：下一次修訂將討論新適應症的創新性和有用性是否須列入創新評估；對於老藥的降價將依據（1）學名藥的替代率，（2）學名藥的發展狀況，以及（3）穩定供應情形，重新評估檢查理想的時間設定

C. 對此次藥品核價系統修訂後的影響進行研究，作為下一次修訂的考量。

二、台方報告部分：

（一） 報告人：黃兆杰專門委員（中央健康保險署醫審及藥材組）

（二） 報告摘要：針對台灣健保的藥品給付與藥價調整的相關規定進行說明，並說明「全民健康保險藥物給付項目及支付標準」107 年 9 月 19 日修訂時新增的藥品給付協議（MEA），以及相關內容介紹。

肆、閉門會議內容摘要（健保相關）

時間：2018/10/12 10:00-12:00

地點：Shin-Kasumigaseki Building Pharmaceuticals and Medical Devices Agency(PMDA) meeting room No.12（12th floor）

出席人員

日方：日本厚生勞働省醫政局經濟課藥價係 Takafumi Yumoto（湯本 貴文）先生、醫藥生活衛生局國際藥事規制室 Noriko Saruta（猿田 紀子）小姐

台方：中央健康保險署醫審及藥材組黃兆杰專門委員

一、本署提問部分

本署於會前已向日方提出 7 項問題，日方於會中之說明摘要如下：

（一） 有關日本的藥品核價制度是否有更新部分，日方表示，相關更新內容已於對外簡報中說明。

（二） 有關日本的藥價調整制度是否有更新部分，日方表示，相關更新內容已於對外簡報中說明。

（三） 有關日本對於高價新藥是否有研議採風險分攤制度部分，日方表示，日本對於高價新藥的管控，係透過核價及調整來進行，特別是針對高費用且申報超出預計許多的藥品，支付價最高調降 50%，且每年持續檢討。至於台灣所採行的藥品給付協議（MEA）方案，日本目前並未採用。

（四） 有關日本健保對於精準醫療的政策和規劃為何？日方表示，各種藥物的使用，臨床醫師均依據相關學會制訂之指引執行，若需進行檢測確認後方建議使用，亦會依據指引於檢測後用藥，目前並未針對精準醫療特別訂定規範。

（五） 有關日本對於癌症免疫療法的給付方式及規劃？日方表示，在日本，藥品納入健保給付都是透過中醫協會議討論，並同時訂定藥品支付價格，而適用的範圍則是依據藥品許可證核准的適應症，健保未再另外規範。對於癌症免疫治療藥品並無特殊對待，惟如前述，若該藥品屬高費用且申報超出預計許多，則將透過價格調整方式因應處理。例如：Opdivo，因為給付後藥品許可證核准的適應症擴增，造成申報費用大增，所以支付價格被調為原來的 1/2，若後續核准的適應症持續擴增，申報費用超過預期，則仍可能會繼續調降。

（六） 有關日本健保對於基因檢測的給付方式為何？日方代表表示，因為此項目非其單位負責，僅能就其所知提供參考，目前日本對於基因檢測的給付係分別以技術費及藥劑費 2 種項目進行給付，至於有哪些檢測已經列入給付，其目前無法提供。

（七） 有關日本健保對於學名藥的核價趨勢和方法？日方代表表示，已於對外簡報中說明有關日本學名藥核價制度的更新情形，此外，對於處方學名藥的醫療機構，日本有依學名藥佔比給予不同程度的獎勵點數的制度。依據 2017 年 9 月資料顯示，目前日本學名藥使用的佔率約 65.8%。

二、日方提問部分

會中日方向本署提出 4 項問題，摘要說明如下：

（一） 日方詢問目前新藥納入健保給付的時間，日本是 60 到 90 天，台灣部分似乎需要較久的時間，請問台灣是否有規劃改善的方式。本署說明，台灣新藥納入健保給付的時間，經統計中位數約 8.7 個月、平均約 9.7 個月，與其他 OECD 國家相較尚屬合理。台灣因為實施總額支付制度，預算有限，新藥是否納入給付，必須由利害關係人組成的共同擬訂會議決定，而多元參與難免需要較長的時間進行溝通。至於對於新藥給付的改善，台灣已於 2018

年 9 月修訂時新增的藥品給付協議（MEA），透過 MEA 的協商可以減少財務衝擊，將有利於新藥納入給付。本署亦請問日方，有關新藥預算部分，日方如何編列及超出後如何處理？日方代表僅說明，會儘量將預算估計準確，並未說明超出後的處理方式。

（二） 承上，日方再詢問新藥遲遲無法納入給付，台灣民眾是否會抱怨。本署說明，醫療屬於稀缺資源，無法無限制的供應，台灣健保考量新藥是否納入，會進行醫療科技評估，就新藥的相對療效、成本效益、財務衝擊及政治、倫理、社會等提出科學的證據，最後再由共同擬訂會議統合考量後進行決定。當然，資源有限，難免還是會有民眾提出質疑，對於各種不同的聲音，本署也會在共同擬訂會議中提出，供所有代表參考，做出最後的決定。

（三） 日方詢問台灣學名藥占比較高的原因和做法為何？本署說明，台灣學名藥用量較高的原因，推測可能和台灣學名藥的核價相對其他國家較高，約原廠的 8 折有關，據觀察，較高的核價的確促使了學名藥能夠快速進入市場與原廠藥競爭；此外，台灣健保收載 15 年以上非專利期藥品，健保係以成分別訂價，亦即同成分、劑型、規格的藥品，無論原廠或學名藥支付價均相同，此一加速學名藥競爭的方式，亦可能為學名藥用量較高的原因。本署另補充說明，透過此一市場競爭，本署也會適時地進行價量調查及藥價調整，進一步減少健保負擔。

（四） 日方詢問台灣醫療院所是否較為強勢，因此有較高的議價空間？本署說明，自由市場競爭可能會受到的影響因素很多，例如：醫療院所或銷售單位規模、競爭者的數量，以及採購量的大小等，都可能會造成影響而有不同的結果。相較日本藥品的銷售大多經由大型批發商統一銷售，台灣大部分還是由原廠或製造廠和醫院進行議價，此外，學名藥的競爭也會促使醫療院所有較大的議價空間。

伍、心得與建議

本次交流透過對外會議，台日雙方分享了彼此健保藥品給付的最新發展及規劃，並交換彼此意見，而透過閉門會議溝通，本署也進一步了解日方對於風險分攤、精準醫療、基因檢測、癌症免疫及學名藥核價等目前的做法，本署也說明了台灣的有關學名藥及 MEA 等相關制度的規畫及執行情形供日方參考，雙方都有不少收穫。

有關日本目前對於藥品核價系統所進行的改革，包括：為鼓勵創新所設計的加成或公司指標制度、美國藥價由參考 red book 改為參考美國大眾健康保險系統的公告藥價、鉅額增長的藥品價格調整方式等，都是台灣未來可以思考的方向，建議納入本署未來健保藥品核價制度改革的參考。

台灣與日本健保的藥品給付制度多有類似的地方，也同樣面臨新藥昂貴、藥費高漲及人口老化等問題，建議未來本署能夠透過各種交流或研討會議，持續與日本進行溝通學習，以建構符合台灣需求的健保藥品給付制度。

陸、活動照片

與本次會議主辦單位日本製藥工業協會（JPMA）國際委員會 副委員長 Akihiko Nagaoka（長岡 邱広）先生合影

與對外會議主持人 JPMA 常務理事 Mr. Akihiko Matsubara（松原 明彦）先生合影並獲贈 JPMA 50-Year History 刊物一份

與日本厚生勞働省醫政局經濟課 Takafumi Yumoto（湯本 貴文）先生及醫藥生活衛生局國際藥事規制室 Noriko Saruta（猿田 紀子）小姐進行閉門會議及合影，並代表本署致贈禮物

職於對外會議中介紹台灣健保藥品相關制度

附件

For people, for life, for the future
Ministry of Health, Labour and Welfare

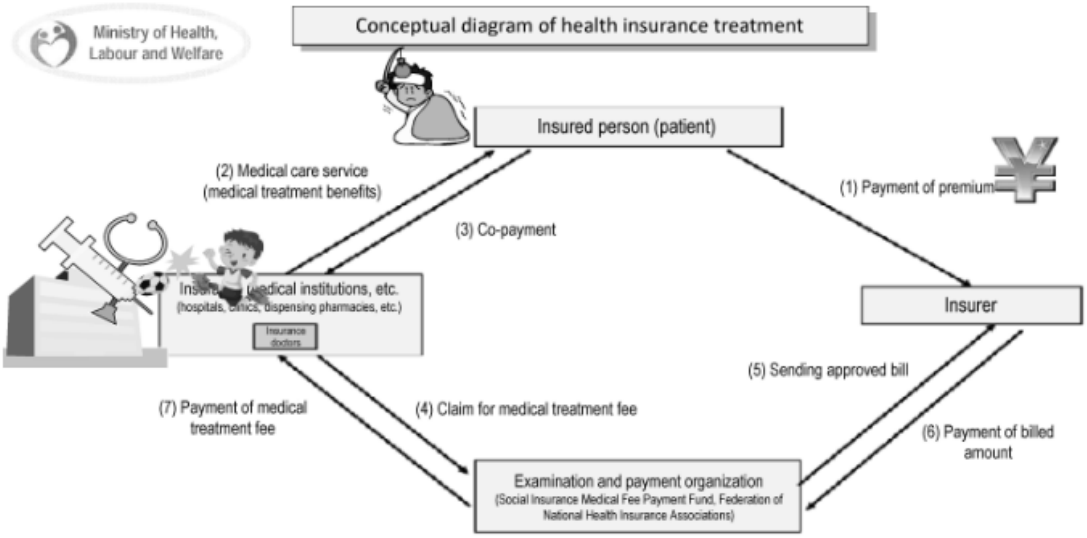
Update of Drug Pricing System in Japan

Takafumi Yumoto
Section Chief
Economic Affairs Division
Health Policy Bureau
Ministry of Health, Labour and Welfare

Outline of Today's presentation

1. Drug Pricing System in Japan
2. Reform of Drug Price System

1. Drug Pricing System in Japan



- Medical treatment fee is classified into medical, dental and dispensing fee.
- Specifically, medical fee is calculated by adding the scores given to individual medical actions that were provided, converting 1 point to 10 yen, in principle (so called, "fee-for-service system").
- For example, when a patient is hospitalized for appendicitis, the first visit fee, hospital fee according to the number of days of hospitalization, surgery fee for appendicitis, test fee, drug fee, etc. are added. The insurance medical institution will receive the total amount less the co-payment charged to the patient from the examination and payment organization.

National Health Insurance Drug Price Standard

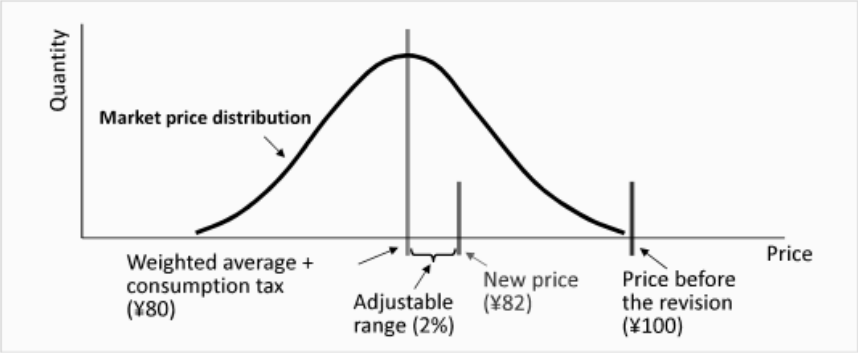
Items and prices of drugs usable in insurance-covered healthcare, specified by the Minister of Health, Labour and Welfare
(common for all medical insurance systems, including health insurance, National Health Insurance (NHI), and various mutual aid systems)

- Item list
  - A doctor or pharmacist operating under the health insurance program, in principle, must not use drugs other than "Drugs the Minister of Health, Labour and Welfare specifies".
  - Items listed in the NHI Drug Price Standard are stipulated as "Drugs the Minister of Health, Labour and Welfare specifies".
  - = NHI Drug Price Standard specifies drugs usable in insurance-covered healthcare, and functions as an item list.
- Price table
  - When an authorized medical institution or pharmacy operating under the health insurance program makes insurance claims, the drug charge shall be calculated based on the price specified in the NHI Drug Price Standard.
  - = NHI Drug Price Standard specifies the claimable amount of drugs used in insurance-covered healthcare, and functions as a price table.

Outline of current drug price standard system

1. The Drug Price Standard specifies the price of drugs when paid from medical insurance to authorized medical institutions or pharmacies operating under the health insurance program (insurance medical institutions).
2. The Drug Price Standard is announced by the Minister of Health, Labour and Welfare, based on "Drug Pricing Standards" issued by the Central Social Insurance Medical Council on February 10, 2016.
3. Prices specified by the Drug Price Standard is periodically revised based on the results of a survey (drug price survey) on the actual selling price (market price) to medical institutions and pharmacies.

Pricing method for listed drugs

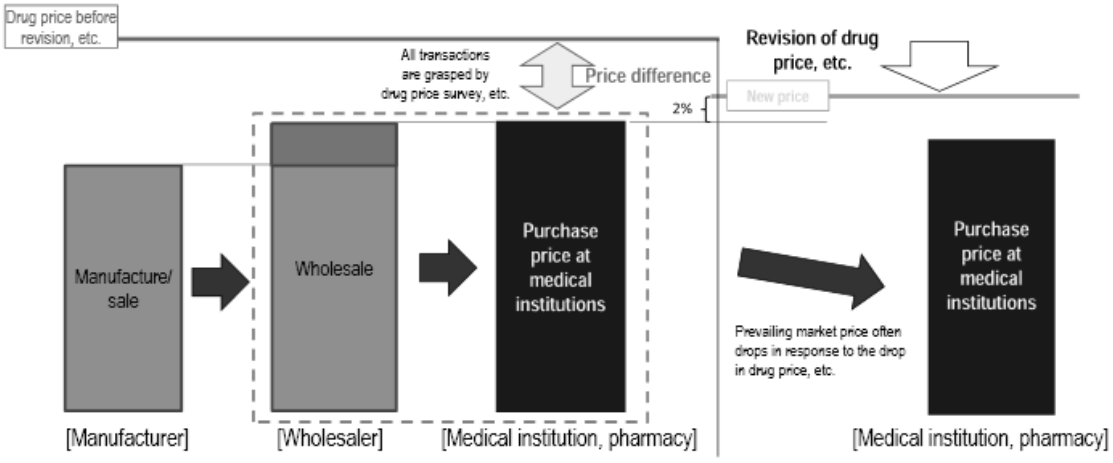


The new drug price is the weighted average of the wholesaler's selling price to medical institutions and pharmacies (market price excluding tax), with consumption tax added as well as the span of the adjustable range (2% of drug price before the revision) for stabilizing drug distribution.

New drug price = [Weighted average of selling price to medical institutions and pharmacies (market price excluding tax)] × 1 + consumption tax rate (incl. local consumption tax) + Span of adjustable range

Revision of price of listed drugs

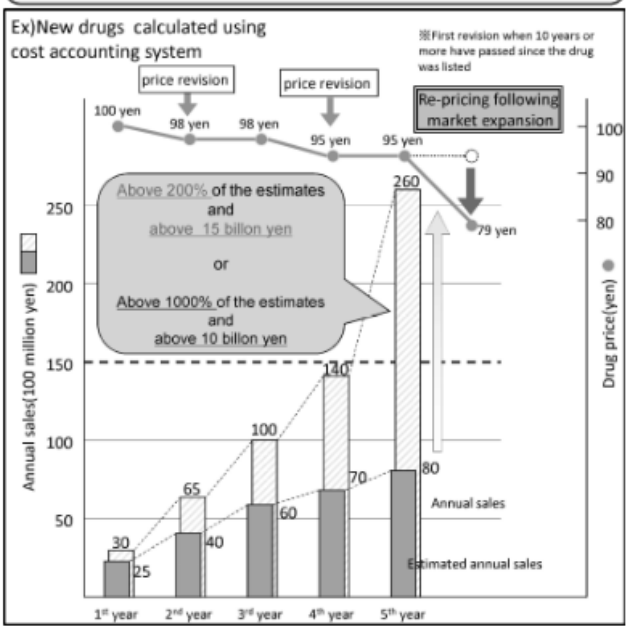
The actual purchase prices paid by medical institutions and pharmacies (prevailing market price) are surveyed (drug price survey) and the prices specified in the drug price standard are revised periodically based on the results of the survey.

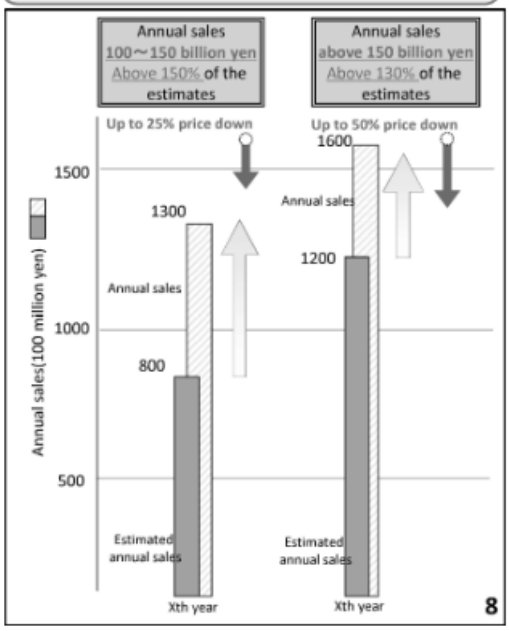


“Re-pricing following market expansion” for the drugs with huge annual sales

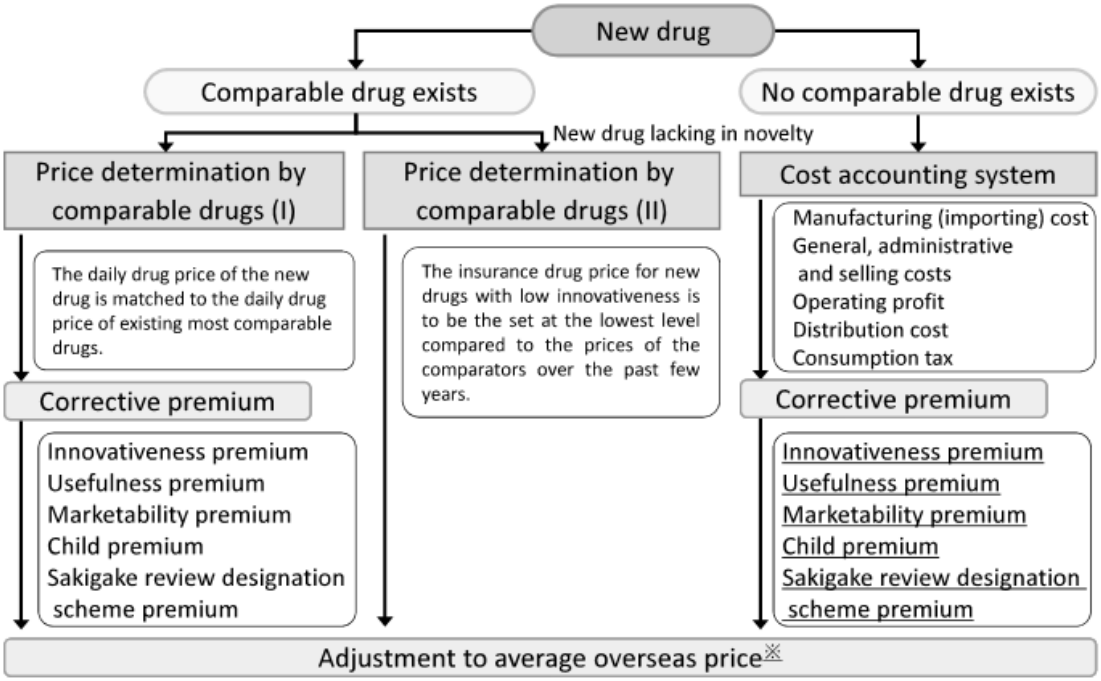
【Now（Previous）】
Price will be reduced when annual sales of a drug exceed its estimated figure to some extent.

【Revised】
The drugs with huge annual sales will be treated as an exception of the current rule.





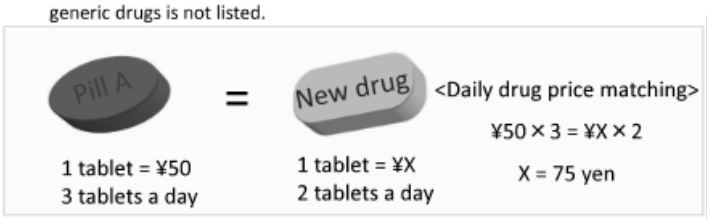
New drug price determination method



※Only those to be priced with the cost accounting method or the comparator pricing method for which no drugs with similar pharmacological action exist

Price determination by comparable drugs

- When there are comparable drugs with similar efficacy, the daily drug price of the new drug is matched to the daily drug price of existing comparable drugs from the viewpoint of ensuring fair competition in the market. [Price determination by comparable drugs (I)]
  - A comparable drug shall be, in principle, a new drug within 10 years after NHI price listing and the drug price of generic drugs is not listed.



Comparable drugs refer to those similar in the following aspects.

A Efficacy and effect
B Pharmacological action
C Composition and chemical structure
D Dosage form, division and use

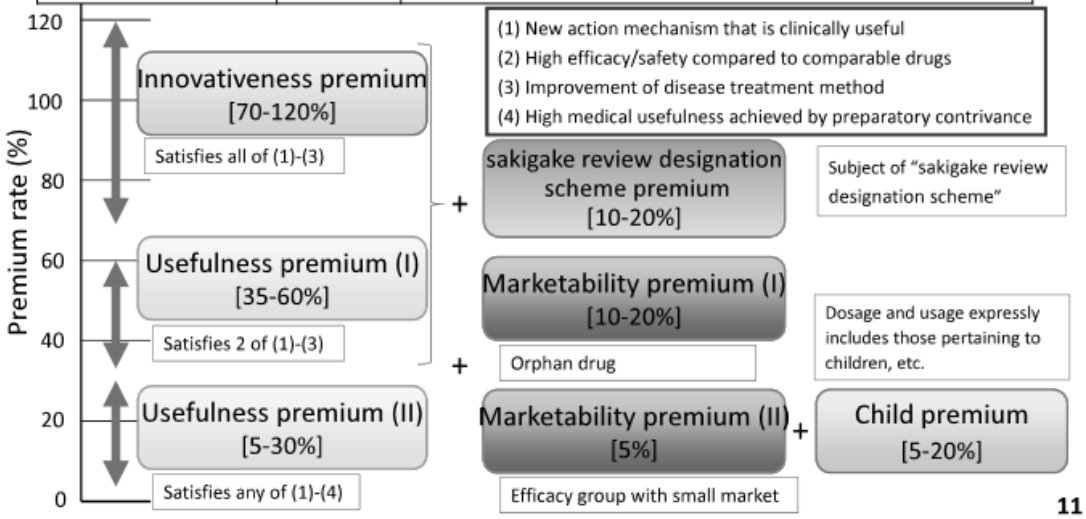
- For the relevant new drug, when higher efficacy is identifiable compared to comparable drugs, a corrective premium is applied to the above amount. [Innovativeness premium, usefulness premium, marketability premium, child premium, and sakigake review designation scheme premium]

Innovativeness premium	70-120%	New action mechanism, high efficacy/safety, improvement of disease treatment method
Usefulness premium	5-60%	High efficacy/safety, improvement of disease treatment method
Marketability premium	5%, 10-20%	Orphan drug, etc.
Child premium	5-20%	Dosage and usage expressly includes those pertaining to children, etc.
sakigake review designation scheme premium	10-20%	Pharmaceutical approval was obtained in Japan ahead of other countries, etc.

Usefulness premium

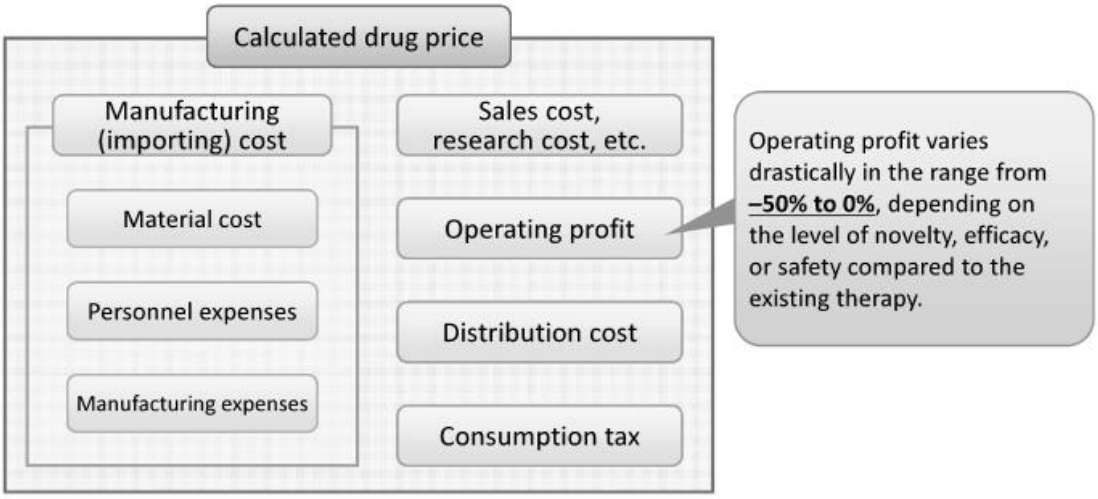
* Usefulness premium for the case where high usefulness, etc., is identified compared to comparable drugs

Innovativeness premium	70-120%	New action mechanism, high efficacy/safety, improvement of disease treatment method
Usefulness premium	5-60%	High efficacy/safety, improvement of disease treatment method
Marketability premium	5%, 10-20%	Orphan drug, etc.
Child premium	5-20%	Dosage and usage expressly includes those pertaining to children, etc.



Cost accounting system

Add up material cost, manufacturing expenses, etc., if there is no comparable drug



In principle, in case of exceeding the average coefficient for the pharmaceutical industry, calculation is performed using a coefficient.

Adjustment to average overseas price

- For either price determination by comparable drugs (I) or cost accounting system, an adjustment is made if the deviation from the overseas price is large. [Adjustment to average overseas price]

1. Average overseas price (AOP): Average of prices in the US, UK, Germany and France
   (Make adjustment if there is a large discrepancy among overseas prices)
2. Adjustment requirement: (1) When above 125% of AOP → Downward adjustment
   (2) When below 75% of AOP → Upward adjustment

(1) When above 125%

$$\left(\frac{1}{3} \times \frac{\text{Calculated value}}{\text{AOP}} + \frac{5}{6} \right) \times \text{AOP}$$

(2) When below 75%

$$\left(\frac{1}{3} \times \frac{\text{Calculated value}}{\text{AOP}} + \frac{1}{2} \right) \times \text{AOP}$$

The upper limit is 200% of the calculated value.

To solve the problem about unapproved and off-label drugs, the items whose development were requested to the private or public sectors,and satisfy all the requirements below, should be excluded from the adjustment.

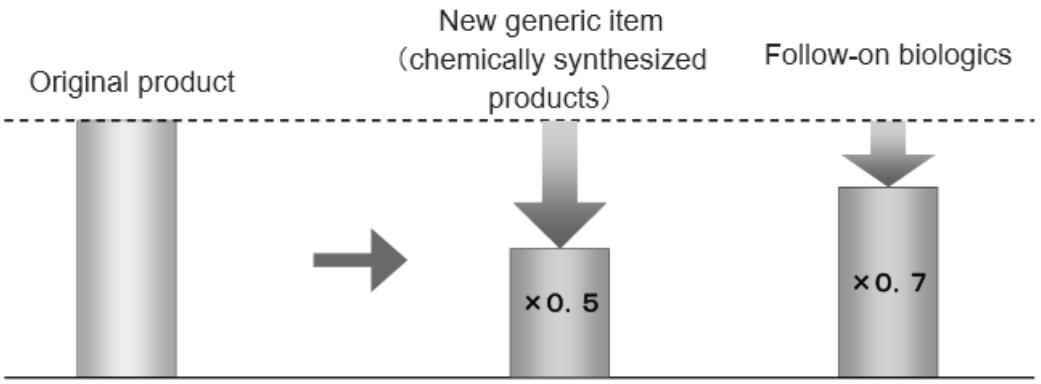
① The latest date a drug was approved in any of the 4 countries is more than 10 years before the approval date in Japan.

② AOP is less than one third of the calculated value.

Exception: The development costs the manufactures and retailers shouldered are not considered to exceed certain level.

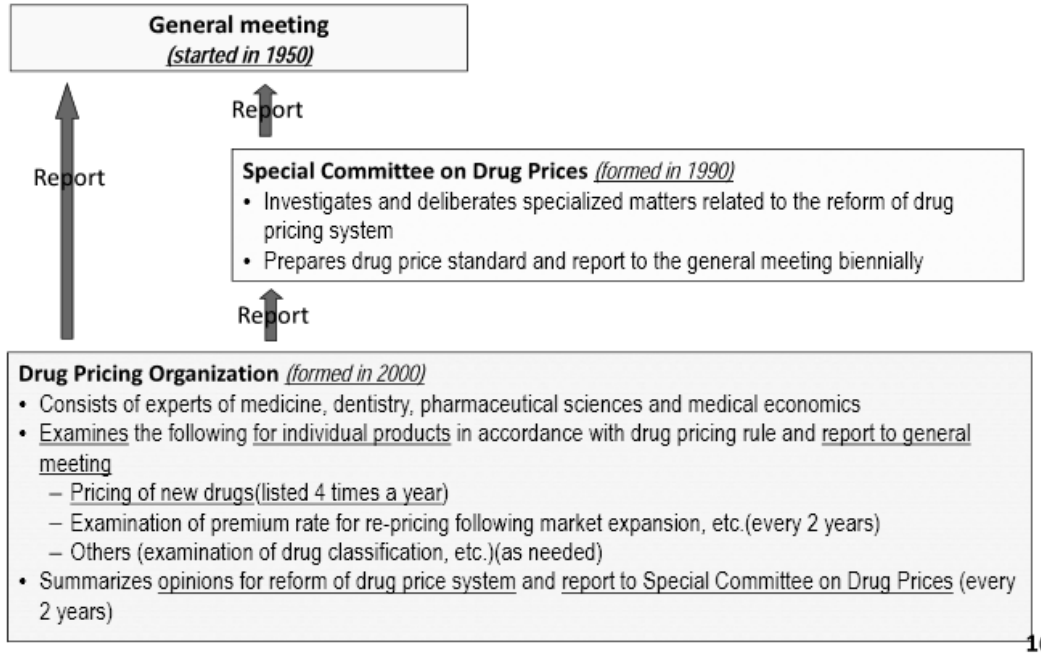
The drug price of the follow-on biologics (biosimilars)

- Case of follow-on products of biotechnology
  : **0.7 multiplication of the drug price of the original product**
  ※If the medicine is more than 10 items, 0.6 multiplied
  ※Depending on the degree of clinical trial, up to 10% addition is allowed
- Case of chemically synthesized products
  : **0.5 multiplication of the drug price of the original product**
  ※If the medicine is more than 10 items, 0.4 multiplied



New drugs price determination process

Organizations of Central Social Insurance Medical Council involved in drug pricing



2. The reform of drug price system

Basic Policy for Fundamental Reform of the Drug Pricing System (Overview Version)

(Decided by the related Chief Cabinet Secretary, Minister of State for Economic and Fiscal Policy, Minister of Finance, and Minister of Health, Labour and Welfare on December 20, 2016)

Achievement of both "Sustainability of the universal healthcare system" and "Promotion of innovation" to realize "Reduction of public financial burden" and "Improvement in the quality of medical care"

Response to a market expansion after drug price listing

○ **In order to promptly respond to a market expansion beyond a certain extent associated with an additional indication, etc., utilize the new drug listing opportunity (four times a year) to review the drug price.**

Drug price survey and drug price revision in the in-between year

○ **In addition to a drug price revision every two years, also conduct a drug price survey in the in-between year for all products, and based on the survey results, conduct a drug price revision for products with large price discrepancies.**

Evaluations of innovation (Review of the premium for new drug development and elimination of off-label drug use and introduction of cost-effectiveness evaluations)

○ **In order to promote the discovery of innovative new drugs, fundamentally review, on a zero basis, the premium for new drug development and elimination of off-label drug use.**

○ **Along with this, introduce full-scale cost-effectiveness evaluations, including a price increases for drugs with high cost-effectiveness. (Also consider the modality of implementation, including organization and system.)**

◆ Future efforts in line with reform

- Thorough implementation of accuracy and transparency of the drug price calculation method
- Improvement of the foreign price adjustment method
- Expeditious understanding of stakeholders' actual business situation and necessary action
- Prompt provision of new health technologies
- Transformation from a model depending on long-listed products to an industrial structure with stronger drug discovery capabilities
- Expansion of strategies/measures to support the R&D of innovative biopharmaceuticals and biosimilars
- Promotion of support for venture companies and market competition of generic manufacturers
- Improvement of distribution efficiency, promotion of distribution improvements, and appropriate responses to the profit structure associated with the market environment
- Promotion of unit price-based by-product contracts and promotion of early price settlements

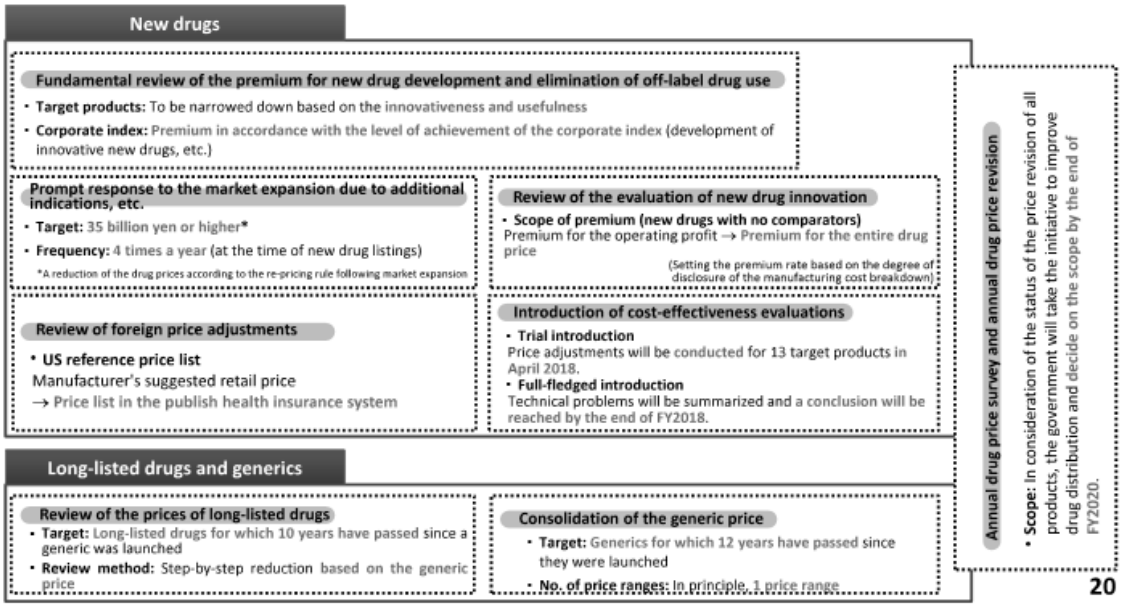
Discussions regarding the Fundamental Reform of the Drug Pricing System

○ Based on the "Basic Policy for Fundamental Reform of the Drug Pricing System" (December 20, 2016), the Special Committee on Drug Prices initiated specific discussions in January 2017 and held 17 meetings throughout the year until December. Meetings to hear the opinions of the related industries were held three times.

Jan. 11	Responses to market expansions associated with additional indications, etc.
Jan. 25	Modality of foreign price adjustment
Feb. 8	Drug price surveys
Feb. 22	Accuracy and transparency of the drug price calculation method (comparator price method)
Mar. 15	Drug price survey and drug price revision in the in-between year
Mar. 29	Drug price survey
Apr. 12	Accuracy and transparency of the drug price calculation method (cost calculation method)
Apr. 26	Modality of the drug prices of generics
May 17	Opinion-hearing from the related associations
May 31	Modality of the drug prices of long-listed drugs
Jun. 14	Modality of the premium for new drug development and elimination of off-label drug use
Jun. 28	Evaluations of innovation
Jul. 26	Summary of discussions up to now (1)
Aug. 9	Summary of discussions up to now (2)
Sept. 13	Opinion-hearing from the related associations
Oct. 27	Other matters
Nov. 22	Fundamental reform of the drug pricing system (Draft)
Nov. 29	Opinion-hearing from the related associations
Dec. 13	Fundamental reform of the drug pricing system (Draft) (Part 2)
Dec. 20	Outline for the Fundamental Reform of the Drug Pricing System (Approved at the Chuikyo)

Fundamental Reform of the Drug Pricing System

● Based on the "Basic Policy for Fundamental Reform of the Drug Pricing System" (December 20, 2016), achieve both "Sustainability of the universal healthcare system" and "Promotion of innovation" to realize "Reduction of public financial burden" and "Improvement in the quality of medical care."



Handling of market expansion following addition of indications etc.

Direction of reform

（Provisional translation by PhRMA）

○ Drugs with additional indications etc. of which the market has expanded over and above a certain level shall be revised in price taking maximum advantage of the (four times a year) new drug listings.

＜Scope of drugs for data extraction＞

○ In order to capture products with market expansion over and above a certain level, the market size of the following products shall be identified through the National Database (NBD).

	Drugs for data extraction	Notes
(1)	Drugs with additional indications etc.	To identify those of which the market has expanded substantially due to the addition of indications etc.
(2)	Products for which on listing the sales in the second fiscal year were projected to be at least 10 billion yen*1 or 15 billion yen*2	To identify those of which the market has expanded substantially since marketing over the initial projection

*1 Cost calculation method, *2 Comparator pricing method

Market size over a two-year period to be identified for (1) and (2) respectively

＜Drugs subject to repricing＞

○ Those of the above drugs that correspond to the conditions for the current repricing for market expansion rule (including special cases) shall be repriced in accordance with the current method. However, since quarterly repricings will impose a tremendous burden on medical institutions, pharmacies and pharmaceutical companies, as the certain level of market expansion, drugs with annual sales in excess of 35 billion yen shall be targeted.

○ In addition, the (four times a year) new drug listings shall also be used for repricing for dosage and administration changes.

Annual drug price surveys and revisions

Direction of reform

（Provisional translation by PhRMA）

<Scope of application of drug price survey>

○ To control the national burden through the timely reflection of market prices in NHI prices, all-product drug price surveys shall be conducted in the off-year of the biennial drug price revision (the 'drug price revision off-year') based on extraction of survey subjects from all drug wholesalers including major companies. Prices shall be revised on the basis of the results.

<Scope of applicable products>

○ From the perspective of reducing the national burden while continuing to establish the infrastructure for the proper conduct of drug price surveys, it is valid to set the scope of applicable products as widely as possible. To this end, ahead of FY 2021* the government shall take initiatives to improve drug distribution through proactively promoting single-product, single-price contracts, early price settlements and the correction of negative primary margins on sales so as to maintain stable drug distribution.

* Since a consumption tax hike is scheduled for FY 2019, which shall involve the price revision of all products, the initial drug price revision off-year shall be FY 2021.

○ Prices shall be revised for all products for three consecutive years from FY 2018 to FY 2020. Therefore, the specific scope of applicable products shall be set during 2020 taking comprehensive account of identified market price trends, the status of price gaps ('yakkasa') and the impact of these revisions on wholesalers, medical institutions and pharmacies during this period.

(Ref.) Scope of applicable products and impact on healthcare expenditure (estimates*)

a) Products with a price discrepancy rate of 2 times or higher the average (approximately 3,100 products, approximately 20% of all products) ▲ 50 ~ 80 billion yen

b) Products with a price discrepancy rate of 1.5 times or higher the average (approximately 5,000 products, approximately 30% of all products) ▲ 75 ~ 110 billion yen

c) Products with a price discrepancy rate of 1.2 times or higher the average (approximately 6,600 products, approximately 40% of all products) ▲ 120 ~ 180 billion yen

d) Products with a price discrepancy rate of over 1 times the average (approximately 8,100 products, approximately 50% of all products) ▲ 190 ~ 290 billion yen

* The estimates were calculated from the FY 2015 drug price survey data on the assumption that half to three-quarters of the price discrepancies that occurred during the previous two years would occur in the drug price revision off-year.

Revision of price maintenance premium

Direction of reform

（Provisional translation by PhRMA）

<Product requirements>

○ In applying the premium to on-patent new drugs etc., eligible products shall be limited to the following that have genuine innovativeness/utility so as to identify properly and evaluate the innovation of genuinely useful drugs and promote R&D investment.

Scope of application	Eligible products	
*New drugs with no generic launches	Orphan drugs	
	Products publicly offered for development	
	Products awarded premiums	Innovation, Utility I or II
		Operating profit adjustment
		Verification of genuine clinical utility
* In such cases, new drugs for which 15 years have passed since listing	Drugs with a novel mechanism of action etc. (only those with innovativeness/utility) etc. * Details given on following page	

○ In addition, in view of the following issues, the product requirement for the price discrepancy rate to be the average or below shall be withdrawn:

(1) That it is not necessarily an indicator for the evaluation of innovativeness/utility

(2) That it leads to prices remaining at a high level through the setting of high invoice prices

Revision of price maintenance premium

Direction of reform

（Provisional translation by PhRMA）

○ Innovativeness/utility criteria such as the following shall be set out for drugs with a novel mechanism of action and such drugs shall be limited to those fulfilling any of these criteria.

Proposed criteria	
Demonstration of efficacy against diseases not adequately responsive to current therapies through the novel mechanism of action	That following the demonstration of efficacy etc. in clinical studies that include cases that are inadequately responsive to or intolerant of standard therapies for the respective disease (only industry-sponsored clinical trials conducted with the objective of obtaining initial approval and for which the target number of cases inadequately responsive to or intolerant of standard therapies has been pre-set,) it is explicitly stated in the Indications, Precautions and Clinical Studies sections that the drug can be administered to these patients.
Demonstration through comparative studies of supremacy over current therapies through the novel mechanism of action	That clinical studies (only industry-sponsored clinical trials conducted with the objective of obtaining initial approval based on the hypothesis of verifying supremacy) have been conducted in which current therapies for the target disease (only those valid as therapeutic modalities in Japan) were set as the control (excluding placebos) and in which the primary endpoint was met through demonstration of supremacy of the agent over the current therapies. In addition, post-marketing clinical studies conducted on the disease specified on initial approval shall be handled similarly.
No other drugs available with the indications acknowledged through the novel mechanism of action	Agents for which at the time of regulatory approval no products were available with matching indications and effects and that offered the first therapeutic option for the target disease; or that clearly expand the scope of treatable cases to a greater extent than current drugs with similar indications and effects.

○ In addition to the above, the following products shall be eligible for the PMP since their level of innovativeness/utility is deemed to be equivalent to that of first-in-the-class products.

- Those listed within three years of the listing of a drug with a novel mechanism of action (only up to the third-in-the-class) of which
- The drug with a novel mechanism of action has been awarded a premium or correspond to the above criteria.

Revision of price maintenance premium

Direction of reform

（Provisional translation by PhRMA）

○ The specific categorization of the company indicators based on the total respective points shall be as follows.

○ Further, given that the company indicators are to be newly introduced, in the FY 2018 revision it shall be ensured that inter-company differentials arising from the difference in the scope and premium coefficient of Categories I and III are limited. For subsequent revisions too, and with reference to the status of new drug development etc., there shall be ongoing examination of the validity of these indicators for evaluating the initiatives and performance of pharmaceutical companies in respect of the development of innovative new drugs and elimination of drug lags, and their revision or the reflection of the findings in the respective revisions shall be discussed.

<Company indicators>

	Details			
A - 1	Domestic studies (including global studies including Japan) (no. conducted) (Phase II ~)	Top Median	25% 50%	4 pts 2 pts
A - 2	New drug listing performance (no. of listed ingredients) (past 5 years)	Top Median	25% 50%	4 pts 2 pts
B - 1	Products publicly offered for development (no. of starts) (past five years) (excluding B – 2)	2 pts per product		
B - 2	Products publicly offered for development (no. of approvals) (past 5 years)	2 pts per product		
C	First-in-the-world new drug developments (no. of products) (past 5 years)	2 pts per product		

The A – 1 figures are those as at the end of September 2017 and the values of other indicators are the figures up to that date.

In addition, the A – 1 figures are per ingredient and include additional indications. (Studies underway for several indications for one ingredient are counted as '1'.)

The no. of studies conducted for A – 1 include products such as HIV agents for which applications for approval based solely on the results of overseas studies are exceptionally permitted.

The number of products referred to in C is the number designated under the *sakigake* review designation scheme.

<Categorization>

Category	I	II	III
Scope	Top 25%*	Other than I and III	Minimum no. of points
Premium coefficient	1.0	0.9	0.8

* Where there are several companies in the top 25th percentile of company indicator points, companies with the respective points shall be handled as Category I, with the ceiling set at the number of companies within the respective points percentile that do not exceed 30% of the total number of PMP-eligible companies.

<Handling of medical ventures>

Companies fulfilling the following criteria shall be placed in Category II.

- Is an SME
  (A company with 300 or fewer employees or stated capital of 300 million yen or less)
- The share-holding or capital contribution of another corporation does not exceed 1/2 of the total no. of shares or total capital
- The share-holding or capital contribution of several corporations does not exceed 2/3 of the total no. of shares or total capital
- Has only one ingredient eligible for the PMP and has posted no current profits or did so but had no business income in the fiscal preceding the year of the respective product approval (only over the past five years)

Revision of price maintenance premium scheme (overall image)

(Provisional translation by PhRMA)

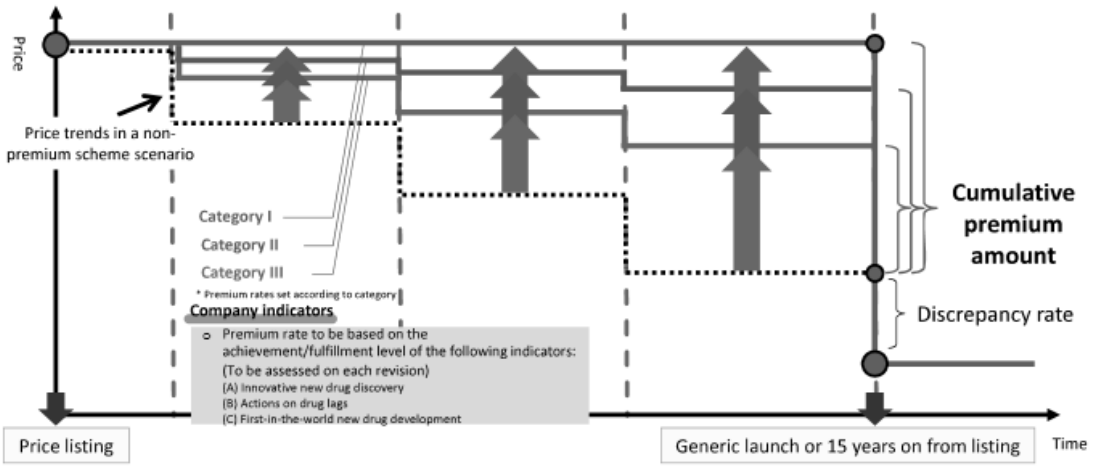
Position of scheme

- Institutionalization to be discussed following fundamental revision to establish an efficient and effective mechanism for the promotion of breakthrough new drug discovery.

Product requirements

- Decision based on intrinsic drug innovation and utility

Limited to drugs awarded an innovation/utility premium and operating profit rate adjustment, orphan drugs, products publicly offered for development and drugs with a novel mechanism of action (only those deemed under the pricing rules to have innovation and utility) etc.



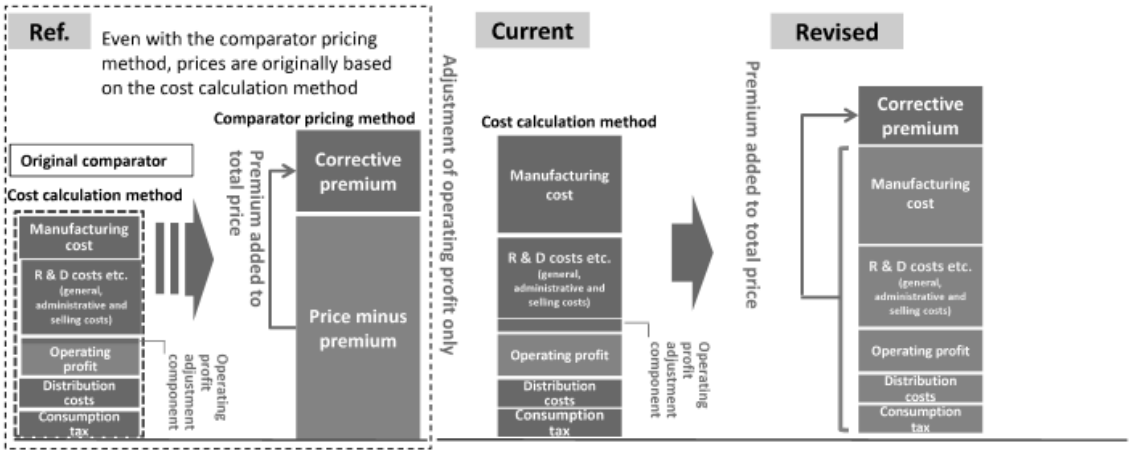
* Ceiling premium amounts also set according to the discrepancy rate

Evaluation of innovation

Direction of reform

(Provisional translation by PhRMA)

- To ensure that the innovation of innovative drugs is properly evaluated, with the cost calculation as well as the comparator pricing method, premiums shall be applied to the total price (the calculated price minus the premium).



Evaluation of innovation

Direction of reform

（Provisional translation by PhRMA）

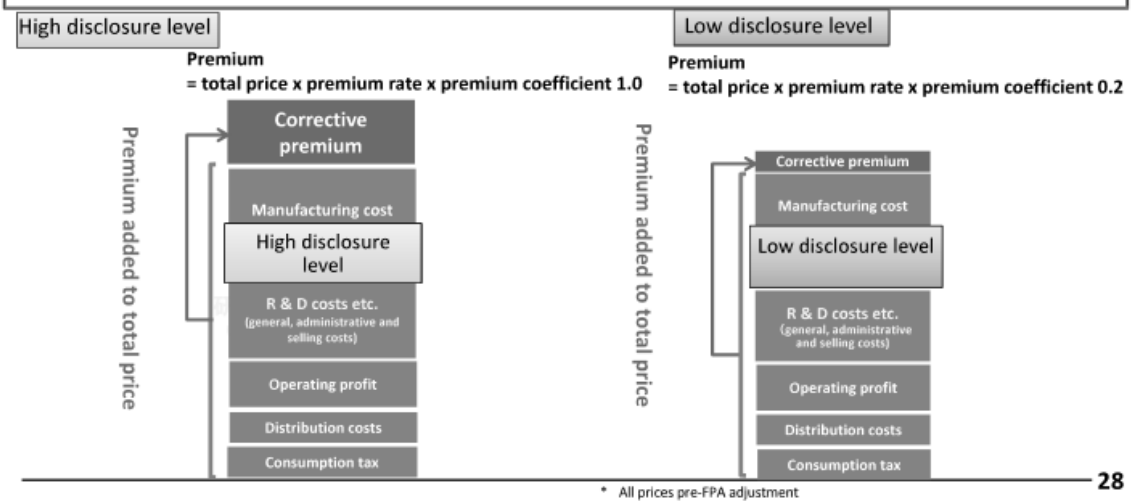
○ To promote the transparency of drug pricing, premium rate differentials shall be set for the cost calculation method according to the percentage of manufacturing cost items disclosable by the Drug Pricing Organization (the disclosure level)*

Premium＝total price×premium rate×premium coefficient

(price minus premium) (0 ~ 120%) (0.2 ~ 1)

Disclosure level	80% ~	50～80%	< 50%
Premium coefficient	1.0	0.6	0.2

* Disclosure level = (disclosable price components) ÷ (manufacturing cost)



* All prices pre-FPA adjustment

Revision of prices of long-listed products etc.

Direction of reform

（Provisional translation by PhRMA）

<Outline of scheme>

○ To promote a shift from an LLP-dependent industry structure to one with greater drug development capability, LLPs shall be positioned as follows and their prices revised at the respective timings.

(1) The generic substitution timing shall be up to ten years after generic launch

(2) The timing of the reduction of LLP prices to the generic level shall be ten years on from generic launch

<Generic substitution timing: revision of the Z2 rule>

○ The Z2 rule for generic substitution timing shall be maintained. However, in view of the government target for the achievement of an 80% volume-based generic share by September 2020, the criteria for the three substitution rate categories under this rule shall be revised as follows.

Substitution criteria (current)	Reduction rate
50% ~ 70%	▲1.5%
30% ~ 50%	▲1.75%
< 30%	▲2.0%

⇒

Substitution criteria (revised)	Reduction rate
60% ~ 80%	▲1.5%
40% ~ 60%	▲1.75%
< 40%	▲2.0%

<Timing of reduction to generic price : introduction of new scheme>

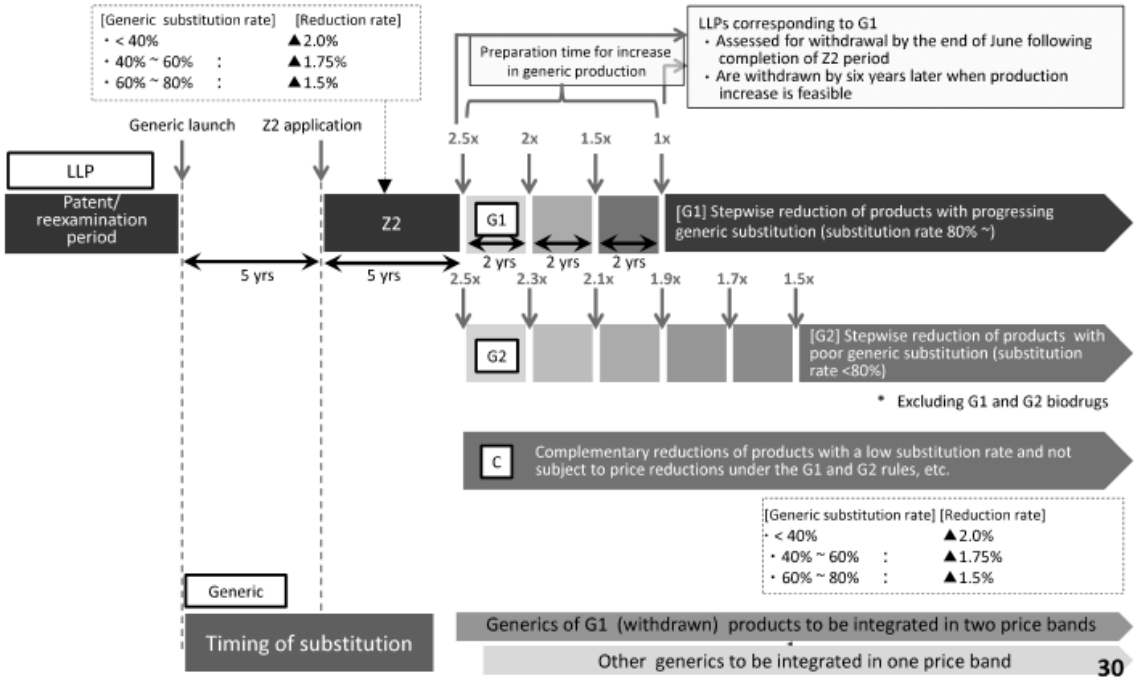
○ A new scheme for reducing the prices of LLPs shall be introduced based in principle on their categorization as follows:

(1) Products with progressing generic substitution (80% or above) **(G1)**

(2) Products with poor generic substitution (less than 80%) **(G2)**

（Provisional translation by PhRMA）

Revision of prices of long-listed products etc. (overall image)



Revision of foreign price adjustment

Direction of reform

（Provisional translation by PhRMA）

<Reference price list>

○ In the US the RED BOOK prices are currently referenced. However,

(1) Some have taken the view that, being a list of the manufacturers' recommended prices (free prices), the RED BOOK is inappropriate for comparative use in drug pricing decisions in Japan, a country that has official prices.

(2) Whereas others have take the view that, being the world's largest drug discovery country, it is not valid to exclude the US from the reference countries.

○ In view of these points, the price lists ASP and NADAC* used for the US public healthcare schemes Medicare and Medicaid shall be referenced.

<Scope of applicable new drugs>

○ Currently, FPA is applied both to drugs priced with the cost calculation and the comparator pricing methods. However, to assure fair market competition, FPA shall not be applied in the comparator pricing of new drugs but shall be applied to the following:

(1) New drugs to be priced with the cost calculation method

(2) New drugs to be priced with the comparator pricing method for which no drugs with similar pharmacological action exist

* ASP：Medicare Part B Drug Average Sales Price
NADAC：National Average Drug Acquisition Cost

Re: NADAC and ASP

Overview

	ASP	NADAC
Overview	● Average sales price of in-house prescription drugs to medical centers ● Reimbursement price for Medicare Part B coverage (hospital outpatient services etc.)	● Average cost for acquisition of in-house prescription drugs by dispensing pharmacies ● Used as basis for Medicaid reimbursement prices
Applicable drugs	Drugs principally used as part of treatment administered by physicians in clinics that are not reimbursed on a flat-fee basis.	Products included in the CMS outpatient prescription drug list or new products approved as outpatient prescription drugs by the CMS under the provisions of Section 1927 of the Social Security Act.

* Extract from data distributed to Expert Advisors of the Expert Committee on Drug Pricing on August 9 2017

Comparison with RED BOOK

	ASP/NADAC (New reference price lists)	RED BOOK (Reference price list used to date)
No. of listed products *	19 products	55 products
Price relative to RED BOOK (average)	0.77	–

* New drugs listed in Japan April 2016 ~ August 2017 for which US RED BOOK prices were available at the time of listing (55 products in total)

Future Considerations

● **Supplementary comments attached to the report concerning the FY2018 medical fee revision (excerpt)**

(Fundamental reform of the drug pricing system)
16 Based on the "Outline for the Fundamental Reform of the Drug Pricing System," continue discussing the necessary actions and measures upon verifying the impact of the fundamental reform of the drug pricing system on the stakeholders.
In addition, continue to discuss how to handle basic drugs.

● **Outline for the Fundamental Reform of the Drug Pricing System Appendix (Approved at the Chuikyo on December 20, 2017) (excerpt)**

II. Appropriate evaluations of innovation
1. Fundamental review of the premium for new drug development and elimination of off-label drug use
2) Corporate requirements and corporate index
○ Since the corporate index is to be introduced for the first time on this occasion, in the FY2018 revision, the disparity among companies due to the scope of Classifications I and III and differences in the premium will be limited, and after the FY2018 revision, pharmaceutical companies' efforts and the results of innovative drug development and drug lag elimination will continued to be examined in terms of whether they are appropriate as evaluation criteria while taking into consideration the actual situation surrounding new drug development, etc. in order to discuss the review of and reflection onto the next or later revision.

VI. Future considerations
○ For the next revision, examine the evaluations of innovation in terms of whether or not it is necessary to evaluate the innovativeness and usefulness due to additional indications, etc.
○ For the next revision, examine the ideal time period until the step-by-step price reduction of long-listed drugs based on (1) the replacement rate to generics, (2) status of generic launches, and (3) responses to stable supply, among other things, after the price reductions of long-listed drugs on this occasion.
○ Upon examining the impact of the fundamental reform of the drug pricing system this time, such as review of the premium for new drug development and elimination of off-label drug use and review of the drug price of long-listed drugs, on the development, manufacture, distribution of drugs, when deemed necessary, consider the necessary measures for the next revision.