

出國報告（出國類別：開會）

參加第 13 屆亞洲製藥協會合作會議

服務機關：衛生福利部中央健康保險署

姓名職稱：李丞華副署長

派赴國家/地區：日本東京

出國期間：113.4.22 - 113.4.24

報告日期：113.6.18

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壹、摘要：

亞洲製藥協會合作會議 (Asia Partnership Conference of Pharmaceutical Associations, APAC)係由亞洲區11個國家中13個藥品研發協會所組成的組織，其宗旨為促進與加速亞洲區創新藥物的研發及上市。自2012年成立以來，APAC 每年舉辦年會，成為亞洲區產官學界溝通討論與意見交流的平台。

第13屆亞洲製藥協會合作會議(the 13th APAC conference)於113年4月23日在日本東京舉行，主題是為亞洲民族加速創新藥品的上市 (To expedite the launch of innovative medicine for the peoples of Asia)，本署李丞華副署長受邀於會中演講「台灣全民健康保險藥品給付(Taiwan's National Health Insurance Pharmaceutical Benefits)，分享我國健保制度與藥品給付機制。

貳、目的

亞洲製藥協會合作會議(Asia Partnership Conference of Pharmaceutical Associations, APAC) 係由亞洲地區 11 個國家共 13 個研發型製藥協會所組成的組織，其成員包含香港 HKAPI、印尼 IPMG、台灣 IRPMA、日本 JPMA、韓國 KPBMA、韓國 KRPIA、印度 OPPI、馬來西亞 PhAMA、菲律賓 PHAP、中國 PhIRDA、泰國 PReMA、中國 RDPAC 及新加坡 SAPI，其宗旨為促進與加速亞洲區創新藥物的研發及上市，其下包含數個工作組：藥品研發、法規與核准、電子仿單、市場與法規環境。

自 2012 年成立以來，APAC 每年舉辦年會，成為亞洲區產官學界溝通討論與意見交流的平台，其宗旨為促進與加速亞洲地區創新藥物的研發及核准上市，本署參加第 13 屆亞洲製藥協會合作會議，除分享臺灣實務經驗，並與各國交流製藥科技的新發展現況及未來趨勢，以作為我國推動藥品給付與相關政策之思考。

參、過程

第13屆亞洲製藥協會合作會議(the 13th APAC conference)於113年4月23日在日本東京舉行，主題是為亞洲民族加速創新藥品的上市 (To expedite the launch of innovative medicine for the peoples of Asia)，內容以藥品與保險給付為核心，亞洲共有來自美國、英國、瑞士、日本、韓國、新加坡、泰國、菲律賓、馬來西亞、印尼、越南、臺灣等超過1,000名藥品與健保的專家顧問、業者/供應商、醫護人員、政府部門等相關人員參與。主題包括：法規與核准、藥品研發聯盟、電子仿單、製造-品質管制-供應、亞洲全民健康覆蓋，進行方式包括專題演講及圓桌論壇等，共同討論製藥產官學三方的未來趨勢與前景，以及可能面臨的挑戰。

本次會議援例分為五個部分：一、法規與核准(Regulations and Approvals, RA)；二、藥品研發聯盟 (Drug Discovery Alliances,DA)；三、電子仿單 (e-labeling)；四、製

造-品質管制-供應(Manufacturing-Quality Control-Supply, MQS)；五、亞洲全民健康覆蓋(Asian Universal Health Coverage, aUHC)。

本署李丞華副署長受邀參加「亞洲全民健康覆蓋」的場次，並分享「台灣全民健康保險藥品給付(Taiwan's National Health Insurance Pharmaceutical Benefits)，分享我國健保制度與藥品給付機制。

在此場次中，主持人首先介紹，日本自 1927 年開始邁向全民健康覆蓋(UHC)，當時的公共保險系統僅限特定族群加入，隨後，被保險範圍逐步擴展，並於 1961 年 4 月全面修訂了國民健康保險法，確立了保障公民的公立健康保險系統，除了全民健康保險制度外，醫療照護的改善及初級醫療保健的完成，都成就了日本世界第一的健康壽命。

自第 11 屆亞洲製藥協會合作會議 (APAC) 開始，大會即新增「亞洲全民健康覆蓋(aUHC)」的議題，討論亞洲的全民健康保險，這個會議旨在探討亞洲國家全民健康保險的現狀和問題，並找出它們未來所需的條件。迄今與會者已瞭解到各國對全民健康保險定義的差異以及資金支持的重要性。今年，大會將討論公共保險的重要性，以及如何通過利用私人保險來補充公共無法資助的部分。此外，亦希望確認包括創新藥物在內的基本藥物應如何由公共和私人保險支付。

馬來西亞講者 ProtectHealth Corporation 代表說明，馬來西亞在健康領域的投資不足，當前健康支出 (CHE) 僅占 GDP 的 4.1%，公共部門支出僅占 GDP 的 2.2%，而中等收入國家 (UMIC) 為 4.4%，高收入國家 (HIC) 為 6.4%，自費健康支出高達 2020 年 CHE 的 34.2%。在人加與結構方面，公共醫院和診所存在擁擠和長時間等待問題，許多醫療設施和設備陳舊，醫療人員配置不足，醫療資源配置不均，公共和私營部門未能得到最佳利用。

在過去 20 到 30 年間，馬國衛生部進行了多次系統分析和改革建議，然而，過去的結構性改革嘗試被證明具有挑戰性，政府和社會各層面的支持對於改革成功至

關重要。自 2019 年以來，衛生改革計畫的工作已經啟動，並與第 12 馬來西亞計畫保持一致 - “馬來西亞醫療系統改革藍圖” 將作為國家醫療系統轉型的新方向引入。新冠疫情的爆發測試了馬國的醫療系統容量，並使其不堪重負。

這一大流行也為馬國實施系統性改革提供了機遇之窗。因此，醫療改革對確保國家醫療系統未來的可持續性和抗災能力至關重要。ProtectHealth Corporation Sdn Bhd (ProtectHealth) 成立於 2016 年 12 月 19 日，是馬來西亞衛生部 (MOH) 全額補助的 ProtectHealth Malaysia (PHM) 的子公司。

Protect Health Malaysia 為非營利公司，根據衛生部的要求，負責協調、管理和執行與衛生保健服務財源籌措相關的各項計畫，因其有足夠的採購和談判能力，Protect Health 成功地以較低價格戰略性地購買了健康篩查服務和健康設備，Protect Health 確保在現有資源的基礎上，提供具品質的健康服務。

例如以協商談判降低了 TBP 價格：

1. 心臟藥物釋放支架 (DES)：將中位支付從 RM5,000 降低到 RM3,000 (降低 40%)
2. 眼內透鏡 (IOL)：將中位支付從 RM490 降低到 RM440 (降低 10%)

議價談判得到競爭性市場價格：

1. 健康篩查服務：RM60
2. 實驗室服務：RM30

品質保證措施包括：

1. 供應商管理：為供應商提供入職培訓和定期/有針對性的複訓輔導
2. 索賠審核：拒絕不合格的護理/索賠 (如不完整、漏診/漏轉診)
3. 醫療審計：提供品質警報，進行檔和現場審計，進行欺詐索賠調查

4. 結果：篩查後診斷和轉診的改善

接著由我國衛生福利部中央健康保險署李丞華副署長出席，並演講「台灣全民健康保險藥品給付(Taiwan's National Health Insurance Pharmaceutical Benefits)，會中對我國醫療制度、健保制度與藥品給付詳加介紹討論。

首先李副署長說明我國全民健保制度給付內容，包括住院、門診、處方藥、牙科服務（不包括矯正與假牙）、傳統中醫藥、精神病日間護理、居家護理等，並說明大部分的處方藥都有給付。

對於藥價核定，專家/PBRS 聯合委員會做出三個決定：

1. 上市：新藥是否將列入藥物支付標準？
2. 定價：新藥將支付多少？
3. 限制：是否需要對藥物適應症進行限制或進行事前審查？

接著，李副署長以數據統計說明藥品給付品項增長趨勢、新藥核價的依據、學名藥核價的方法、藥價調查原則、藥費占比的年成長趨勢(報告投影片如附錄)。會場討論熱烈，與會者對於我國藥品核價方法面面俱到，邏輯及層次清楚，感到欽佩。討論時段專家學者就「是否所有藥品均應由政府負擔」進行交流討論。

肆、心得及建議

一、 APAC 大會就創新藥物之研發與審查相關事宜提供產官學界溝通交流之平台，且每年皆舉辦年會活動，建議未來持續參與相關會議，有助於了解國際最新法規科學及業界技術發展之趨勢，並可增進與亞太地區各國之實質互動，有機會進一步建立合作伙伴關係，宜持續參與。

二、 我國目前正面臨人口老化及少子化的衝擊，在提高醫療照護品質須兼顧效

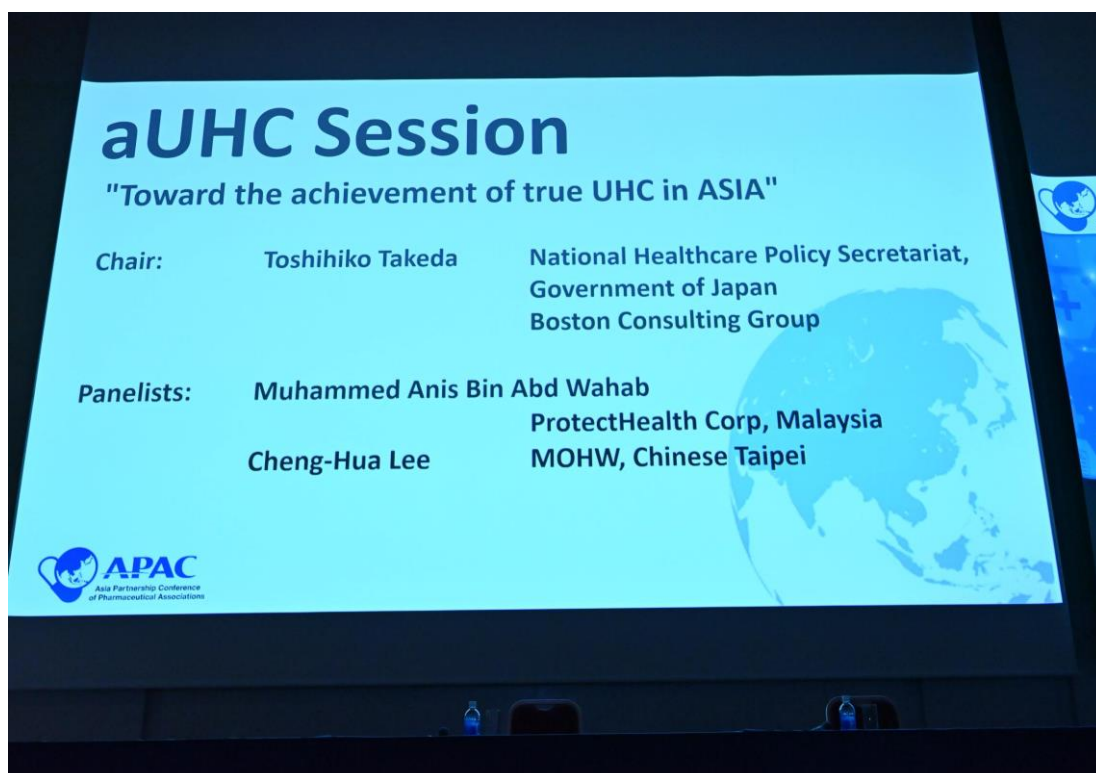
率與安全，是各級政府急需面對的議題。我國已推行全民健康保險制度多年，如何與時俱進，納入新藥新材，以協助降低民眾自費負擔，並協同促進製藥產業發展，應為未來繼續努力目標。

伍、議程及會議照片

| Program | | | |
|---------------|--|--------------------------------|--|
| 08:30 ▶ 08:45 | Come-in | | |
| 08:45 ▶ 08:50 | Opening Remarks | Hiroaki Ueno | JPMA |
| 08:50 ▶ 09:00 | Congratulatory Speech | David Reddy | IFPMA |
| 09:00 ▶ 09:20 | Keynote Lecture | Yasuhiro Fujiwara | PMDA |
| 09:20 ▶ 09:35 | < Picture taking & Break > | | |
| 09:35 ▶ 11:15 | RA Session: Further Promotion of Reliance through International Collaboration ~ Examples from WHO and ASEAN initiatives and the path we should take ~ | | |
| 09:35 ▶ 09:40 | Introduction | Naoyuki Yasuda Janis Bernat | PMDA IFPMA |
| 09:40 ▶ 09:55 | WHO Good Reliance Practices and support to ASEAN joint assessment procedures | Marie Valentin | WHO |
| 09:55 ▶ 10:10 | Forthcoming strategy of ASEAN Joint Assessment | Azuana Ramli | Malaysia NPRA |
| 10:10 ▶ 10:20 | Indonesian Experience in Reliance System and Asean Joint Assessment | Ria Christine Siagian | BPOM |
| 10:20 ▶ 10:30 | Philippine Reliance Experience through the ASEAN Joint Assessment | Jesusa Joyce Cirunay | Philippines FDA |
| 10:30 ▶ 11:10 | Panel discussion "Further promotion of reliance through international collaboration and the path we should take" | All speakers plus: KC Wong | SAPI |
| 11:10 ▶ 11:15 | Closing | Naoyuki Yasuda Janis Bernat | PMDA IFPMA |
| 11:15 ▶ 11:20 | < Preparation > | | |
| 11:20 ▶ 11:50 | DA Session: The microbiome research in Asia | | |
| 11:20 ▶ 11:24 | Introduction of DA-EWG | Megumi Ikemori | JPMA |
| 11:24 ▶ 11:37 | Introduction of Microbiome based drug discovery including recent topics and attractiveness of this modality | Jun Terauchi | Japan Microbiome Consortium (JMBC) / Metagen Therapeutics Inc. |
| 11:37 ▶ 11:50 | Introduction of Taiwanese activities and APAC region initiatives | Chun-Ying Wu | National Yang Ming Chiao Tung University |
| 11:50 ▶ 12:50 | < Lunch Break > | | |

| | | | |
|---------------|--|---|------------------------------------|
| 12:50 ▶ 14:30 | e-labeling Session: Asian e-labeling strategy for digital health ~What to do now and future~ | | |
| 12:50 ▶ 13:00 | Opening with progress sharing of APAC e-labeling EWG initiatives for APAC regions | Rie Matsui | JPMA |
| 13:00 ▶ 13:10 | Medical digital transformation and product information for patients in Japan | Takayuki Okubo | MHLW |
| 13:10 ▶ 13:20 | Updates of e-labeling initiatives in Malaysia | Azuana Ramli | NPRA |
| 13:20 ▶ 13:30 | E-labeling Update in Taiwan | Po-Wen Yang | Taiwan FDA |
| 13:30 ▶ 13:40 | E-labeling Pilot Project in Indonesia | Rita Endang | BPOM |
| 13:40 ▶ 13:50 | Update on e-labeling for pharmaceuticals in Korea | Yeonhae Han | MFDS |
| 13:50 ▶ 14:25 | Panel discussion | All speakers plus: Jesusa Joyce Cirunay Worasuda Yoongthong Luong Thu Vinh | Philippines FDA Thai FDA DAV |
| 14:25 ▶ 14:30 | Closing | Takayuki Okubo | MHLW |
| 14:30 ▶ 14:35 | < Break > | | |
| 14:35 ▶ 16:05 | MQS Session: Short time frame for additional supplier procedures | | |
| 14:35 ▶ 14:40 | Opening and presenter introduction | Shinichi Okudaira Makoto Ono | PMDA JPMA |
| 14:40 ▶ 14:55 | Introduction of session | Aya Shoda | JPMA |
| 14:55 ▶ 15:10 | Presentation: Introduction of PQ KMP in ICMRA | Shinichi Okudaira | PMDA |
| 15:10 ▶ 15:20 | Presentation: Case study in Malaysia | Nur'Ain Shuhaila | MOH Malaysia |
| 15:20 ▶ 15:30 | Presentation: Case study in Thailand | Chaiporn Pumkam | Thai FDA |
| 15:30 ▶ 16:00 | Panel discussion | All speakers | |
| 16:00 ▶ 16:05 | Summary and Closing | Shinichi Okudaira Makoto Ono | PMDA JPMA |
| 16:05 ▶ 16:25 | < Break > | | |
| 16:25 ▶ 18:05 | aUHC Session: "Toward the achievement of true UHC in ASIA" | | |
| 16:25 ▶ 16:45 | Opening | Toshihiko Takeda | Boston Consulting Group |
| 16:45 ▶ 16:55 | Strategic Purchasing to Achieve UHC in Malaysia | Muhammed Anis Abd Wahab | ProtectHealth Corp |
| 16:55 ▶ 17:05 | Taiwan's National Health Insurance: Pharmaceutical Benefits | Cheng-Hua Lee | MOHW, Chinese Taipei |
| 17:05 ▶ 18:00 | Panel discussion "Can all drugs be covered by public insurance?" | All Speakers | |
| 18:00 ▶ 18:05 | Closing | Toshihiko Takeda | Boston Consulting Group |
| 18:05 ▶ 18:10 | < Preparation > | | |
| 18:10 ▶ 18:40 | Special Lecture | Keizo Takemi | MHLW |
| 18:40 ▶ 18:50 | Wrap-up for all program and session | Nobuo Murakami | JPMA |
| 18:50 ▶ 18:55 | Closing Remarks | Sunao Manabe | JPMA |

場次：aUHC Session: “Toward the achievement of true UHC in Asia



本場次由 Toshihiko Takeda 博士主持










衛生福利部中央健康保險署李丞華副署長演講中



專家小組討論



李丞華副署長答詢中

|  <h3>Taiwan's National Health Insurance: Pharmaceutical Benefits</h3> <p>Cheng-hua Lee M.D., Dr.P.H. Deputy Director General National Health Insurance Administration Taiwan, ROC</p> |  <h3>Benefits Package</h3> <div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid green; border-radius: 50%; padding: 5px; text-align: center;">Disease</div> <div style="border: 1px solid green; border-radius: 50%; padding: 5px; text-align: center;">Injury</div> <div style="border: 1px solid green; border-radius: 50%; padding: 5px; text-align: center;">Maternity Care</div> </div> <ul style="list-style-type: none"> » Inpatient care » Outpatient care » Prescription drugs » Dental services(orthodontics & prosthodontics excluded) » Traditional Chinese medicine » Day care for the mentally ill » Home health care | | | | | | | | | | | | | | | | | | | |
|---|--|--|----------------|--------------------------------|--------------|---|--------------------------------------|--|--|--------------------|--------------|-------------|---|---|--|--------|------|--------|--------|--------|
|  <h3>Pharmaceutical Pricing & Reimbursement</h3> <ol style="list-style-type: none"> Most of the prescription drugs are covered. Expert/PBRS joint committee makes 3 decisions: <ol style="list-style-type: none"> <u>Listing</u>: Whether the new drug will be listed in drug formulary? <u>Pricing</u>: How much will the new drug be paid? <u>Restriction</u>: Whether the restriction in drug indication or pre-utilization review is needed? |  <h3>Drug Listing Status</h3> <table border="1"> <thead> <tr> <th rowspan="2">Year</th> <th colspan="3">Covered Drugs</th> </tr> <tr> <th>western medicine (items)</th> <th>traditional Chinese medicine (items)</th> <th>total</th> </tr> </thead> <tbody> <tr> <td>2021</td> <td>16,810</td> <td>10,140</td> <td>26,950</td> </tr> <tr> <td>2022</td> <td>15,225</td> <td>10,311</td> <td>25,536</td> </tr> <tr> <td>2023</td> <td>14,744</td> <td>10,377</td> <td>25,121</td> </tr> </tbody> </table> | Year | Covered Drugs | | | western medicine (items) | traditional Chinese medicine (items) | total | 2021 | 16,810 | 10,140 | 26,950 | 2022 | 15,225 | 10,311 | 25,536 | 2023 | 14,744 | 10,377 | 25,121 |
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| 2023 | 14,744 | 10,377 | 25,121 | | | | | | | | | | | | | | | | | |
|  <h3>Pricing of New Drugs</h3> <table border="1"> <thead> <tr> <th>Category</th> <th>Pricing</th> </tr> </thead> <tbody> <tr> <td>1 Breakthrough</td> <td>Median price of A-10 countries</td> </tr> <tr> <td>2A Me-better</td> <td>Capped at A-10 median price <ul style="list-style-type: none"> lowest price in A10 price in original country international price ratio </td> </tr> <tr> <td>2B Me-too</td> <td> <ul style="list-style-type: none"> 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. </td> </tr> </tbody> </table> <p>A-10 reference countries: Australia, Belgium, Canada, France, Germany, Japan, Sweden, Switzerland, US, UK.</p> | Category | Pricing | 1 Breakthrough | Median price of A-10 countries | 2A Me-better | Capped at A-10 median price <ul style="list-style-type: none"> lowest price in A10 price in original country international price ratio | 2B Me-too | <ul style="list-style-type: none"> 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. |  <h3>Pricing for off-patented drugs</h3> <table border="1"> <thead> <tr> <th>BA/BE Generic drug</th> <th>Generic drug</th> <th>Biosimilars</th> </tr> </thead> <tbody> <tr> <td> <ul style="list-style-type: none"> First BA/BE generic drug priced at 80%-90% of brand-name drug. The following BA/BE generic drug priced at the lowest price in the same chemical group. </td> <td> <ul style="list-style-type: none"> First generic drug priced at 80% of brand-name drug. The following generic drug priced at the lowest price in the same chemical group. </td> <td> <ul style="list-style-type: none"> Biosimilars priced at 85% of brand-name drug or reference listed drug. </td> </tr> </tbody> </table> | BA/BE Generic drug | Generic drug | Biosimilars | <ul style="list-style-type: none"> First BA/BE generic drug priced at 80%-90% of brand-name drug. The following BA/BE generic drug priced at the lowest price in the same chemical group. | <ul style="list-style-type: none"> First generic drug priced at 80% of brand-name drug. The following generic drug priced at the lowest price in the same chemical group. | <ul style="list-style-type: none"> Biosimilars priced at 85% of brand-name drug or reference listed drug. | | | | | |
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| 2B Me-too | <ul style="list-style-type: none"> 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. | | | | | | | | | | | | | | | | | | | |
| BA/BE Generic drug | Generic drug | Biosimilars | | | | | | | | | | | | | | | | | | |
| <ul style="list-style-type: none"> First BA/BE generic drug priced at 80%-90% of brand-name drug. The following BA/BE generic drug priced at the lowest price in the same chemical group. | <ul style="list-style-type: none"> First generic drug priced at 80% of brand-name drug. The following generic drug priced at the lowest price in the same chemical group. | <ul style="list-style-type: none"> Biosimilars priced at 85% of brand-name drug or reference listed drug. | | | | | | | | | | | | | | | | | | |
|  <h3>Price Survey and Adjustment</h3> <ul style="list-style-type: none"> Price-volume survey every year. Both hospital pharmacies and drug companies should submit transaction data. Price adjustment to reduce the gap between NHI reimbursement and actual transaction price. | <h3>Stable Share of Pharmaceutical Expenses</h3> | | | | | | | | | | | | | | | | | | | |