出國報告（出國類別：開會）

（裝釘線）

赴韓國參加「亞太罕見疾病管理之政府倡議」研討會

服務機關：衛生福利部中央健康保險署
姓名職稱：署長　　李伯璋
　　副組長　張惠萍
　　視察　　杜安琇
派赴國家：韓國
出國期間：111 年 11 月 30 日至 111 年 12 月 3 日
報告日期：112 年 3 月 1 日

摘　要

近年來，新興且價格昂貴之癌症藥品及罕見疾病藥物陸續研發上市，帶給病人治療的希望，然而長期安全療效、治療效益及財務衝擊具高度不確定性，是健保面臨的艱鉅挑戰。醫界反映新醫療科技快速發展且價格昂貴，明顯壓縮醫療服務的合理給付，而國內病友團體們則認為罕病及癌症等新藥納入健保給付之速度慢或給付條件太嚴格。

本次會議係由韓國漢陽大學主辦，會議主題為「亞太罕見疾病管理之政府倡議(Government Initiatives for Rare Disease Management in Asia Pacific Region)」。主辦單位邀請來自亞太地區之醫療從業人員、公衛學者或行政管理者，分別就罕見疾病之政策面及臨床面分享經驗。

由於各國醫療保健制度、經濟條件各不相同，對於罕見疾病照顧有各自的難處，亦有共同的挑戰。我國早於 2000 年立法通過罕見疾病藥物及防治法，內容結合罕病防治與罕藥法，涵蓋罕見疾病之預防、篩檢、診斷及治療，透過跨署合作，集結各署資源，共同照顧罕見疾病病人。未來除了每年積極爭取罕藥預算，合理給付有效益的新罕藥，另善用健保大數據分析，持續利用真實世界數據評估健保給付效益。

目　次

壹、會議目的：

韓國漢陽大學醫學院全球衛生及發展系(Department of Global Health and Development, College of Medicine, HANYANG UNIVERSITY)每年就衛生政策相關議題舉辦國際研討會，本年度會議與韓國疾病管理廳(Centers for Disease Control and Prevention)、韓國國立研究基金會(National Research Foundation of Korea)合辦，會議主題為「亞太罕見疾病管理之政府倡議(Government Initiatives for Rare Disease Management in Asia Pacific Region)」。主辦單位邀請來自香港、日本、馬來西亞、尼泊爾、新加坡、台灣及南韓等之醫療從業人員、公衛學者或行政管理者，分別就罕見疾病之政策面及臨床面分享經驗，與會者約 50 人，期能藉由本次研討會，建立亞太地區治療罕見疾病的專家群網絡，分享政府在罕見疾病（如硬皮病和肺纖維化等自身免疫性疾病）政策和項目方面的經驗，以及就診斷和治療、國際合作和研究等面向，提供學術和政策啟示，以增進獲得全面、高品質、有效的醫療保健服務和罕見疾病管理。

貳、會議過程

一、行程

日期	活動
111 年 11 月 30 日(三)	離台/抵韓國首爾
111 年 12 月 1 日(四)	參加會議
111 年 12 月 2 日(五)	參加會議
111 年 12 月 3 日(六)	返台/抵台

二、會議內容(議程詳附錄一)

（一）全世界對於罕見疾病並無一致的定義，有些國家是以盛行率、有些國家則以罹病人數計算，例如：美國為罹病人數低於 20 萬人、歐盟為盛行率低於 5/10,000，WHO 則建議每萬人盛行率低於 10 人則可定義為罕病；依前述定義，全球估計將近 7000 種疾病定義為罕病，影響人數約為 4 億人，80%之罕病與遺傳有關，可能導致慢性病且具生命危險。罕見疾病雖然盛行率較低、相對罹病人數較少，然而 95%以上的罕病未能有有效的治療方式，或是治療方式昂貴，對於病人、家屬、社會造成巨大的疾病負擔、人力損失和社會成本，是當前世界各國皆面臨的問題，因此許多國家紛紛設立專法或制定獎勵措施，以保障病人治療權益及鼓勵藥物研發。所以主辦單位邀請香港、日本、馬來西亞、尼泊爾、新加坡、臺灣、南韓、美國、巴西及祕魯等國之醫療從業人員、公衛學者或行政管理者，分別就罕見疾病之政策面及臨床面分享經驗。

（二）香港

香港之醫療保健模式承襲英國，財源以稅收為基礎，主要用於住院照護，90%之病床由公立醫院提供服務，而超過 70%之門診服務由私部門之家庭醫師或專科醫師提供服務，主要由私人醫療保險或病患自費。香港未就罕見疾病有官方定義，亦未立罕病或罕藥專法，多數罕病病人之醫療照護仰賴公立醫院服務，

其診斷及醫療服務費用，然而，因公立醫院之處方集收載極度重視成本效益資料，導致罕見疾病藥物多被排除於公立醫院之處方集，病人需仰賴其他財源(self-financing drugs)或是自費用藥。其中，self-financing drugs 包括補助低收入病人之 Samaritan Fund，以及在社會安全網之外的醫療補助計畫 Community Fund，經統計 2020~2021 年之資料，納入 Samaritan Fund 之藥品計 9 項，Community Fund 之藥品計 11 項，仍然面臨治療可近性之議題。對於高價罕見疾病用藥，亦採取個案審查、與廠商進行風險分擔或設定支出上限協議之策略，以加速病人用藥可近性。

（三）韓國

韓國之健保制度與台灣類似，財源以收取健保費為主。韓國於 2000 年 8 月由企劃及預算部公告，於次年起對於罕見難治疾病之醫療費用由政府預算支持，包括慢性腎衰竭、血友病、高雪氏症及肌肉相關疾病等。

韓國對於罕見疾病之定義為人數少於 20,000 人，或適當的治療方式尚未被研發出來的疾病。依 2016 年韓國健保資料的統計，罕病人數約有 33 萬 5500 人，分布於 89 類疾病。為了進一步照顧罕病病人，韓國於 2003 年訂定罕藥指引，透過給予 6 年市場獨佔權鼓勵罕藥研發；2013 年推動罕見疾病生物資料庫計畫；2015 年南韓議會罕見疾病管理法，要求衛生福利部應推動罕見疾病之預防、診斷、治療及研究。此外亦透過跨部會分工合作，將罕藥納入健保給付及編列國家基金補助研究等，期能更周全照顧罕病病人。

（四）臺灣

本署李署長受邀於會議演講「Challenges of National Health Insurance Benefits for Rare Diseases in Taiwan」，演講中介紹臺灣罕見疾病現況、健保對於罕見疾病之照顧、本署以真實世界數據分析罕見疾病用藥之成果，以

及未來面臨的挑戰。演講內容摘要如下，簡報詳見附錄二。

1.我國於 2000 年立法通過罕見疾病藥物及防治法，僅次於美國、日本、澳洲、歐盟，成為全球第五個立法保障罕見疾病醫療權利的國家，內容結合罕病防治與罕藥法，為世界首見。此專法之立法精神包括：預防罕見疾病之發生、及早診斷及篩檢罕病、加強照顧罕病病人、協助病人取得罕病藥物及維生所需特殊營養食品，以及鼓勵與保障該藥物及食品之供應、製造與研究發展。

2.我國對於罕見疾病的照顧為國民健康署、食品藥物管理署及中央健康保險署跨署分工合作，國民健康署負責罕病預防、醫療照護及防治工作補助、教育宣導等；食品藥物管理署負責罕藥法規、認定、查驗登記、製造研發獎勵，以及罕見疾病藥物、特殊營養食品專案申請；中央健康保險署則負責罕病患者就醫之醫療費用給付、核發罕病重大傷病證明、就醫免部分負擔等。

3.我國對於罕見疾病之認定則為盛行率低於 1/10,000，加上治療及診斷困難且必須由罕見疾病及藥物審議委員會逐一審議；依我國國民健康署及食品藥物管理署統計資料，台灣已有 240 種疾病公告為罕病，通過罕藥認定計 97 種藥品，其中 64 種罕藥獲得健保給付。另依健保重大傷病領證資料，因罕見疾病領有重大傷病卡之人數約為 12,500 人。自 2002 年起，經衛生福利部公告之罕見疾病，列為健保重大傷病範圍，罕病病人可免除健保之部分負擔，減輕經濟負擔。2005 年起於全民健康保險醫療費用總額編列罕見疾病專款專用項目，此專款係用來照顧所有罕病病友的藥費支出，包括既有罕病病友用藥費用之成長、擴增罕藥的給付範圍以及收載新的罕藥，避免罕見疾病個案因使用高額醫療費用，而受到總額醫療費用排擠。

4.考量健保資源有限，台灣善用真實世界數據，滾動式評估健保給付效益，以龐貝氏症和脊髓性肌肉萎縮症(簡稱 SMA)為例進行說明。目前台灣約有 207 位龐

貝氏症病人，根據文獻記載，未接受藥物治療的嬰兒型龐貝氏症病人 18 個月的存活率約僅有 2%；根據台灣健保真實世界數據分析，接受由中央研究院陳垣崇院士研發 alpha-glucosidase 藥品治療的嬰兒型龐貝氏症病人，18 個月的存活率可高達 97%，顯示我國政府、醫界及專家對龐貝氏症病人提供最妥適的照顧。另一實例，治療 SMA 藥品由於單價高昂（第一年每人每年藥費約一千四百萬，五年平均每人每年藥費約八三五萬），健保署建立登錄系統，追蹤病人治療效果，結果顯示，接受健保給付藥物 nusinersen 治療的個案，其運動功能有所改善且均存活，佐證健保給付於最具治療效益的族群，後續將會進一步評估擴增給付範圍，以減輕病人之醫療負擔。

5. 近年來新醫療科技快速發展，一次性高價基因治療產品陸續上市，尤其罕見疾病藥品上市時臨床試驗人數不多，缺乏長期療效及安全性資料，且單價高昂，財務負擔巨大，均是我們目前及未來所面臨之挑戰。

(五)其餘亞太國家對於罕見疾病之重要衛生政策

1. 日本：該國於 1970 年代即有罕見疾病相關政策，1983 年正式入法，甚至於 2015 年 Agency of Medical Research and Development(AMRD)將罕見疾病及疑難雜症列為 9 大優先研究領域之一。

2. 中國：該國於 2016 年成立罕見疾病治療及照顧專家委員會，2017 年公布罕見疾病清單，隨後於 2019 年核准罕藥上市並將其納入醫療保險給付範圍。

3. 菲律賓：該國於 2016 年通過罕見疾病法，內容包括罕見疾病之管理、登記、研究及新生兒篩檢。

4. 印度：該國於 2021 年公布罕見疾病國家政策。

參、心得與建議：

一、本次會議與會者來自不同國家，由於各國醫療保健制度、經濟條件各不相同，對於罕見疾病照顧有各自的難處，亦有共同的挑戰。例如：部分國家對於罕病之早期發現、早期診斷有其障礙，自發病至確立診斷甚至需要好幾年的時間，導致病患及家屬勞心勞力、耗費醫療資源並錯失了治療的時機。

二、我國早於 2000 年立法通過罕見疾病藥物及防治法，內容結合罕病防治與罕藥法，涵蓋罕見疾病之預防、篩檢、診斷及治療，且透過跨署(國民健康署、食品藥物管理署及中央健康保險署)合作，集結各署資源，共同照顧罕見疾病病人。相較於其他國家之作法，我國照顧罕病病人不落人後。

三、我國現今面臨的挑戰在於近年來新醫療科技快速發展，新興且價格昂貴之基因檢測技術及罕見疾病藥物陸續研發上市，帶給病人治療的希望，然而長期安全療效、治療效益及財務衝擊具高度不確定性。經分析近年收載新罕藥，自其受理至生效之時間約為 12 個月，尚稱合理，其中有些藥品審查時間較長係因為財務衝擊大，尚須費時與廠商議價。另健保未來將採有條件給付，且建置個案登錄系統，蒐集並分析真實世界數據後，再決定是否持續給付。

四、我國是單一保險人制度，且善用健保大數據分析，滾動式利用真實世界數據評估健保給付效益，此部分為他國講者印象深刻之處，甚至有與會講者建議未來可評估在不侵犯個人資料保護之前提下研究跨國合作之可行性。

五、最後，本署贈送各國講者全民健康保險年報及 Digital health Care in Taiwan 兩本出版品，分享台灣全民健康保險制度與經驗，除了增加臺灣的國際能見度外，各國亦對於英文專書 Digital health Care in Taiwan 之作者均為本署同仁感到驚艷。

附錄

一、會議議程

The 7th GHD International Symposium

Government Initiatives for Rare Disease Management in Asia Pacific Region

- Date : Dec 01st, 2022 09:00~18:00 / Dec 02nd, 2022 09:00~13:00
- Place : Sansoo Hall (B1), Grand Hyatt Seoul
- Host : Dept. of Global Health and Development, Hanyang University
- Support : Boehringer Ingelheim, Iksan City, IRIC PNU, NRF

Day	Time	Contents
1st	08:30 - 08:50	Registration
	08:50 - 09:00	Opening Remark
	09:00 - 10:50	Session I Dr. Jun / Dr. Salmo / Dr. Cheng
	10:50 - 11:00	Break Time
	11:00 - 12:00	Session II Dr. Lee(Korea) / Dr. Hasegawa
	12:10 - 13:30	Lunch
	13:30 - 16:00	Session III Dr. Yuen / Dr. Aflah / Dr. Lee(Taiwan) / Dr. Baral / Dr. Koju
	16:00 - 16:20	Break Time
	16:20 - 17:20	Session IV Dr. Accinelli / Dr. Kim / Dr. Gyanwali
	17:20 - 18:00	Discussion & Closing
2nd	08:30 - 08:50	Registration
	08:50 - 09:00	Opening
	09:00 - 10:30	Session V Dr. Phua / Dr. Liu / Dr. Wieland
	10:30 - 10:50	Break Time
	10:50 - 11:20	Session VI Dr. Han
	11:20 - 12:00	Wrap Up & Closing
	12:00 - 13:30	Lunch

CONTENTS

Presentation II

◆ Challenges and Opportunities in Management of Interstitial Lung Disease in Malaysia
: Dr. Aflah, Syazatul Syakirin Binti Sirol
Institut Perubatan Respiratori, Malaysia

Presentation III

◆ Challenges of National Health Insurance Benefits for Rare Diseases in Taiwan
: Dr. Lee, Po-Chang
National Health Insurance Administration, Taiwan

Presentation IV

◆ Challenging Issues on Rare Diseases Management in Nepal
: Dr. Baral, Gehanath
Nepal Health Research Council (NHRC), Nepal

Presentation V

◆ Challenges to Address Rare Diseases in Resource Limited Countries
: Dr. Koju, Rajendra
Kathmandu University, Nepal

Session 4 : Presentation

Presentation I

◆ Pulmonary Fibrosis: an Orphan Disease with Treatment and Also Prevention?
: Dr. Accinelli, Roberto Alfonso
Universidad Peruana Cayetano Heredia (UPCH), Peru

Presentation II

◆ Adventure for Clinical Trials of Mecasin (KCHO-1): Rare Disease with ALS & PMD
: Dr. Kim, Sung Chul
Wonkwang University,
Global Rare Disease Network Research Institute, South Korea

Presentation III

◆ Addressing Rare Disease Management in Asia Pacific Region
: Dr. Gyanwali, Pradip
Nepal Health Research Council (NHRC), Nepal

Session 5 : Presentation

Presentation I

◆ The Healthcare System of Singapore and Management of Rare Diseases
: Dr. Phua, Kai Hong
National University of Singapore, Singapore

Presentation II

◆ The Management of Rare Diseases in Hong Kong
: Dr. Liu, Shao Haei
Hong Kong College of Health Service Executive, Hong Kong

Presentation III

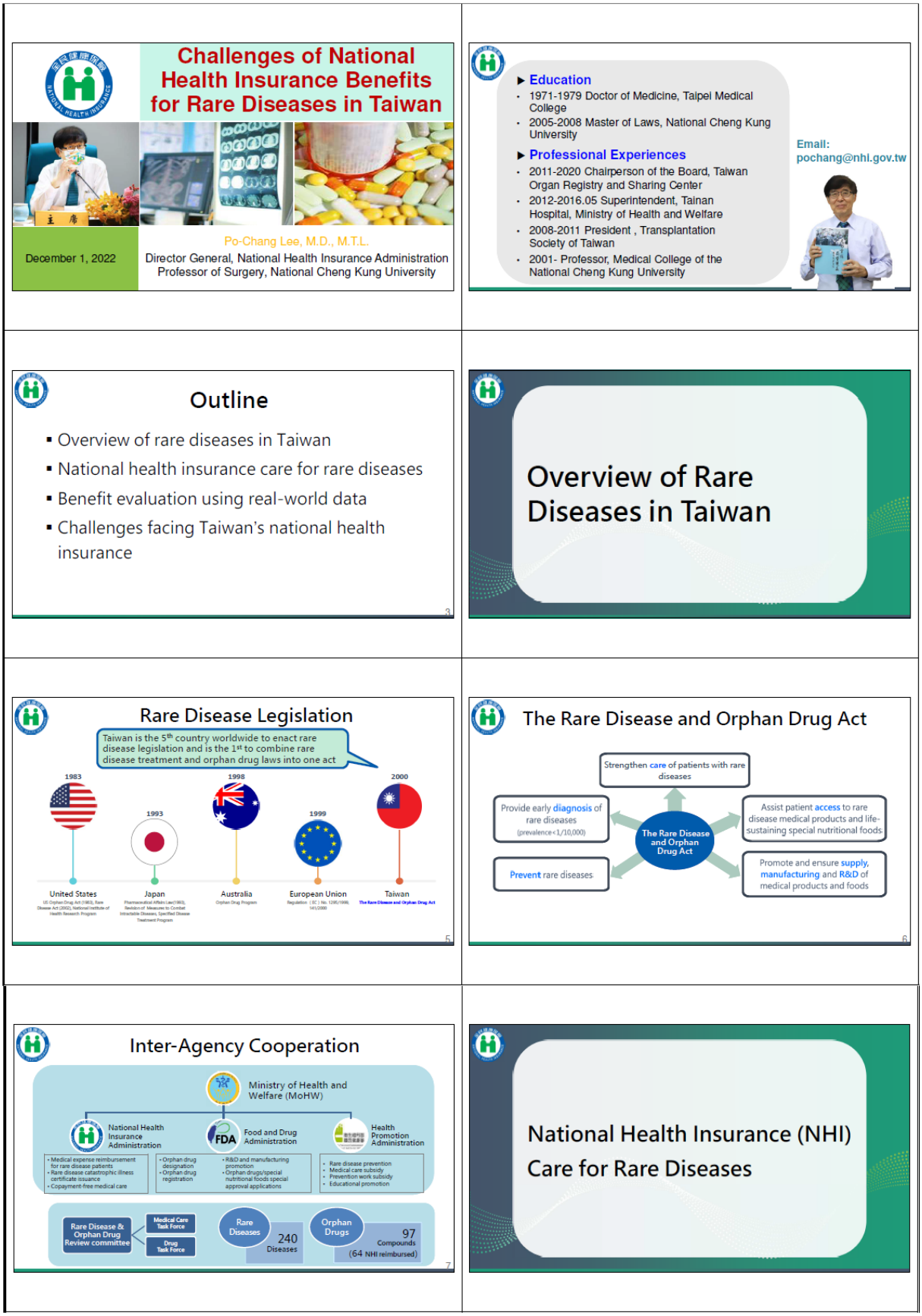
◆ Complementary Therapies for Rare Disease: Current Situation and Future Possibilities
: Dr. Wieland, Lisa Susan
University of Maryland, USA

Presentation IV

◆ Government Initiatives for Rare Disease Management in Asia Pacific Region
: Dr. Han, Dong Woon
Hanyang University, South Korea

Discussion

二、本署李署長演講內容


Challenges of National Health Insurance Benefits for Rare Diseases in Taiwan
December 1, 2022
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1971-1979 Doctor of Medicine, Taipei Medical College
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Outline
Overview of rare diseases in Taiwan
National health insurance care for rare diseases
Benefit evaluation using real-world data
Challenges facing Taiwan's national health insurance
Overview of Rare Diseases in Taiwan
Rare Disease Legislation
Taiwan is the 5th country worldwide to enact rare disease legislation and is the 1st to combine rare disease treatment and orphan drug laws into one act
1983
United States
1993
Japan
1998
Australia
1999
European Union
2000
Taiwan
The Rare Disease and Orphan Drug Act
Strengthen care of patients with rare diseases
Provide early diagnosis of rare diseases (prevalence<1/10,000)
Assist patient access to rare disease medical products and life-sustaining special nutritional foods
The Rare Disease and Orphan Drug Act
Prevent rare diseases
Promote and ensure supply, manufacturing and R&D of medical products and foods
Inter-Agency Cooperation
Ministry of Health and Welfare (MoHW)
National Health Insurance Administration
Food and Drug Administration
Health Promotion Administration
Medical expense reimbursement for rare disease patients
Rare disease catastrophic illness certificate issuance
Copayment-free medical care
Orphan drug designation
Orphan drug registration
R&D and manufacturing promotion
Orphan drugs/special nutritional foods special approval applications
Rare disease prevention
Medical care subsidy
Prevention work subsidy
Educational promotion
Rare Disease & Orphan Drug Review committee
Medical Care Task Force
Drug Task Force
Rare Diseases
240 Diseases
Orphan Drugs
97 Compounds
(64 NHI reimbursed)
National Health Insurance (NHI) Care for Rare Diseases

NHI Characteristics

Coverage
Compulsory enrollment for all citizens (23 million) and legal residents

Administration
Single-payer system run by the government

Financing
Premiums

Providers
93.03% of healthcare providers contracted with NHI

Payment
Plural payment programs under the global budget payment

Privileges
Premium subsidies and co-payment waivers for the disadvantaged

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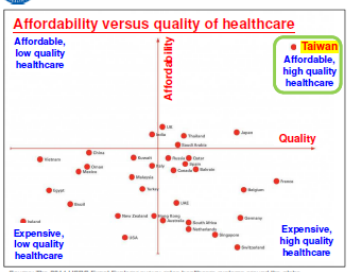
Affordable and High Quality Healthcare in Taiwan



- Good accessibility
- Low cost
- Short waiting times
- Comprehensive population coverage
- National data collection systems

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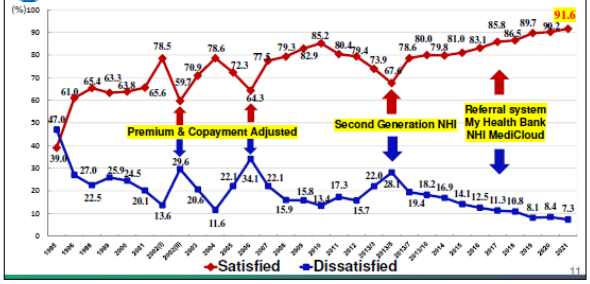
High Public Satisfaction



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Rare Disease:
Special Fund Creation/Expedited Drug Approval/Home Nursing Care

Copayment exemption	Since 2012, patients with a rare disease listed by the MoHW as a catastrophic illness are exempt from NHI copayment
Drug expense special fund	Since 2005, special funding has been allocated and designated for rare diseases
Orphan drug expedited reimbursement	Drugs for rare diseases, as designated by the Rare Disease and Orphan Drug Review Committee, can be considered for reimbursement by the NHIA prior to licensing
Ventilator+ Hospice home care	•Rare disease patients with amyotrophic lateral sclerosis (ALS), congenital muscular dystrophy, spinal muscular atrophy (SMA), or Pompe disease are eligible for home ventilator care •Since June 2022, home hospice care eligibility includes rare disease or other life-limited patients

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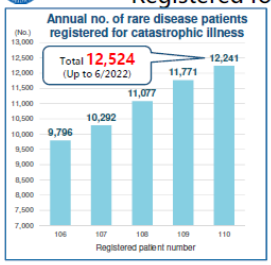
12,524 Rare Disease Patients Registered for Catastrophic Illness



Rank	Disease	Registered patients
1	Multiple sclerosis	1,636
2	Spinocerebellar ataxia	950
3	Tuberous sclerosis complex	680
4	Wilson's disease	564
5	Amyotrophic lateral sclerosis (ALS)	556
6	Charcot-Marie-Tooth disease	431
7	Achondroplasia	414
8	Spinal muscular atrophy (SMA)	411
9	Fabry disease	377
10	Idiopathic/heritable pulmonary arterial HTN	362
-	Other	6,143
	Total	12,524

Data source: NHIA Registry for Catastrophic Illness Patients (accessed 2022/7/4); registered patient number excludes cases of death and cancelled registration.

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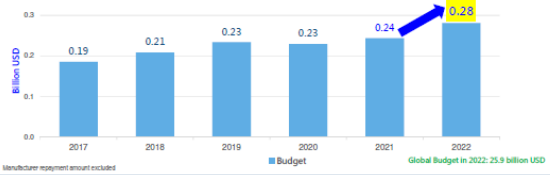
Continued Increase in Special Fund Budget

Rare disease's drug expense special fund budget in recent years

Special fund utilization:
- Rising drug costs for existing rare disease patients
- Expand reimbursement of existing orphan drugs
- Inclusion of new orphan drugs

Continued yearly budget increase



Manufacturer repayment amount excluded

Global Budget in 2022: 25.9 billion USD

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Benefit Evaluation Using Real-World Data

Real-World Data of Pompe Disease Treatment

According to literature of infantile Pompe disease, only 2% of untreated patients survive to 18 months; from Taiwan's real-world data, 97% of patients treated with Myozyme survive to 18-months.

- Myozyme discovered by Dr. Yuan-Tsong Chen of Taiwan Academia Sinica
- Myozyme reimbursed from 2005
- Newborn screening for Pompe disease from 2008

	Infantile Pompe Disease						Non-infantile Pompe Disease			
	Median survival			(median not reached)			180 mo.			
Survival (mo.)	6	12	18	24	30	36	42	48	54	60
Infantile Pompe Disease n=76	99%	97%	97%	97%	97%	97%	92%	91%	91%	91%
Non-infantile Pompe Disease n=72	100%	99%	99%	97%	96%	96%	96%	95%	94%	94%

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Real-World Data of SMA Treatment (1)

7/2020 — 12/2021 — 2022-

Nusinersen Reimbursed → Usage overview → Reimbursement expansion?

- Reimbursement prioritized for:
  - Disease onset and diagnosis within 12 months of birth AND
  - Treatment initiation prior to age 7 yrs
- 39 patients treated at declared cost: 15.89 mil USD
- Ave. annual cost per patient: 0.28 mil USD (range 0.23-0.47 mil USD)

SMA Patient Registry

Collect patient data → Track treatment effect → Periodic review of reimbursement

- ✓ Basic patient data
- ✓ Treatment info
- ✓ Results of each clinical evaluation
- ✓ Reason for treatment discontinuation

Registry system site

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Real-World Data of SMA Treatment (2)

SMA patients treated with Nusinersen showed motor function improvement, and all patients survived. Data support that NHI reimbursement has been applied to the patient group with the most potential for therapeutic benefit. Expansion of reimbursement scope will be evaluated to further reduce patients' financial burden.

Improvement in motor function

Measure	n	Baseline score	Change from baseline in score	p
CHOP INTEND	7	34.6 (25.5)	8.4 (11.9)	0.0469
HINE-2	9	5.8 (9.5)	10.3 (8.6)	0.0078
HFMSE	21	26.4 (17.2)	7.4 (5.7)	<0.0001
RULM	21	20.8 (10.1)	2.2 (3.5)	0.0098

- CHOP INTEND: Children's Hospital of Philadelphia Infant Test of Neuro-muscular Disorders
- HINE-2: Hammersmith Infant Neuromuscular Examination Section 2: Motor Milestones
- HFMSE: Hammersmith Functional Motor Scale Expanded
- RULM: Revised Upper Limb Module

- 37 patients
- Median follow-up duration: 336 days
- Mean age at treatment initiation: 4.3 yrs
- Results:
  - All 37 patients survived
  - All motor function measures showed trend of improvement or stabilization through follow-up
  - Most patients experienced significant improvement from baseline to last study assessment

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Challenges Facing Taiwan's National Health Insurance

One-Time High-Priced Gene Therapy Drugs (not yet reimbursed)

Zolgensma® (Onasemnogene abeparvovec)

- Treat Spinal Muscular Atrophy
- Vector containing the cDNA of the human SMN gene, that product that expresses the human survival motor neuron (SMN) protein
- Price: about 2 million USD per dose

Luxturna® (Voretigene neparvovec)

- Treat Leber congenital amaurosis
- Treat children and adult patients with an inherited form of vision loss that may result in blindness
- Price: about 0.32 million USD per dose

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the Challenges

- Few clinical trials
- Lack of long-term efficacy data

→ Safety? / How long effect

- Expensive
- Huge budget impact

→ Drug prices justified? / Uncertain cost-effectiveness

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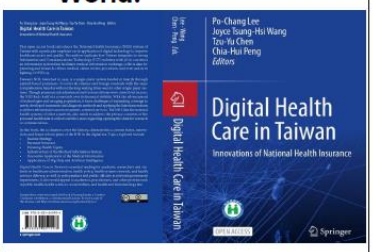
Sharing Taiwan's Experiences with the World!

Facing the Challenges of Health Care System in Taiwan

Taking Patient's Best Interest as the First Priority for Medical Treatment



Open Access — Purchase Now

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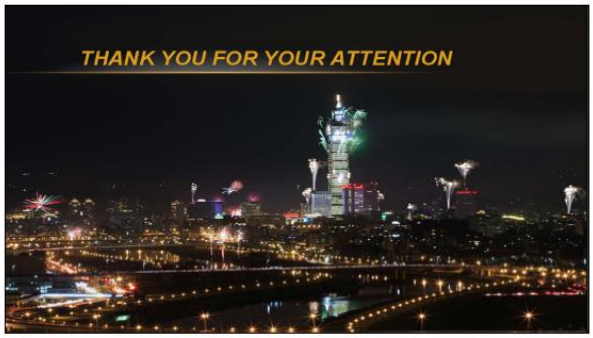

三、會議照片

李署長演講分享台灣經驗

致贈本署全民健康保險年報及英文專書 Digital Health Care in Taiwan 予主辦單位漢陽大學 Professor Han, Dong-woon


The 7th GHD International Symposium
Government Initiatives for Rare Disease Management
in Asia Pacific Region

講者合影


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