附錄

貳、台日醫藥交流會議---健康保險類研討會資料

一.New Era of National Health Insurance in Taiwan—健保署署長　黃三桂

二. A Measure to Ensure Transparency and Efficiency in Drug Pricing System

Shinichi TAKAE, Deputy Director

Economic Affairs Division Health Policy Bureau,　MHLW, JP

三.Efficency and Transparency in pricing

健保署醫審及藥材組研究員　陳尚斌

四.Improvement in methodology of pricing for new drugs and orphan drugs

Yasuhiro Matsunaga,

Japan Pharmaceutical Manufacturers Association

五. Policy for reimbursing orphan drugs

健保署醫審及藥材組研究員　陳尚斌

六.Separation of Dispensing and Prescribing Drugs in Japan

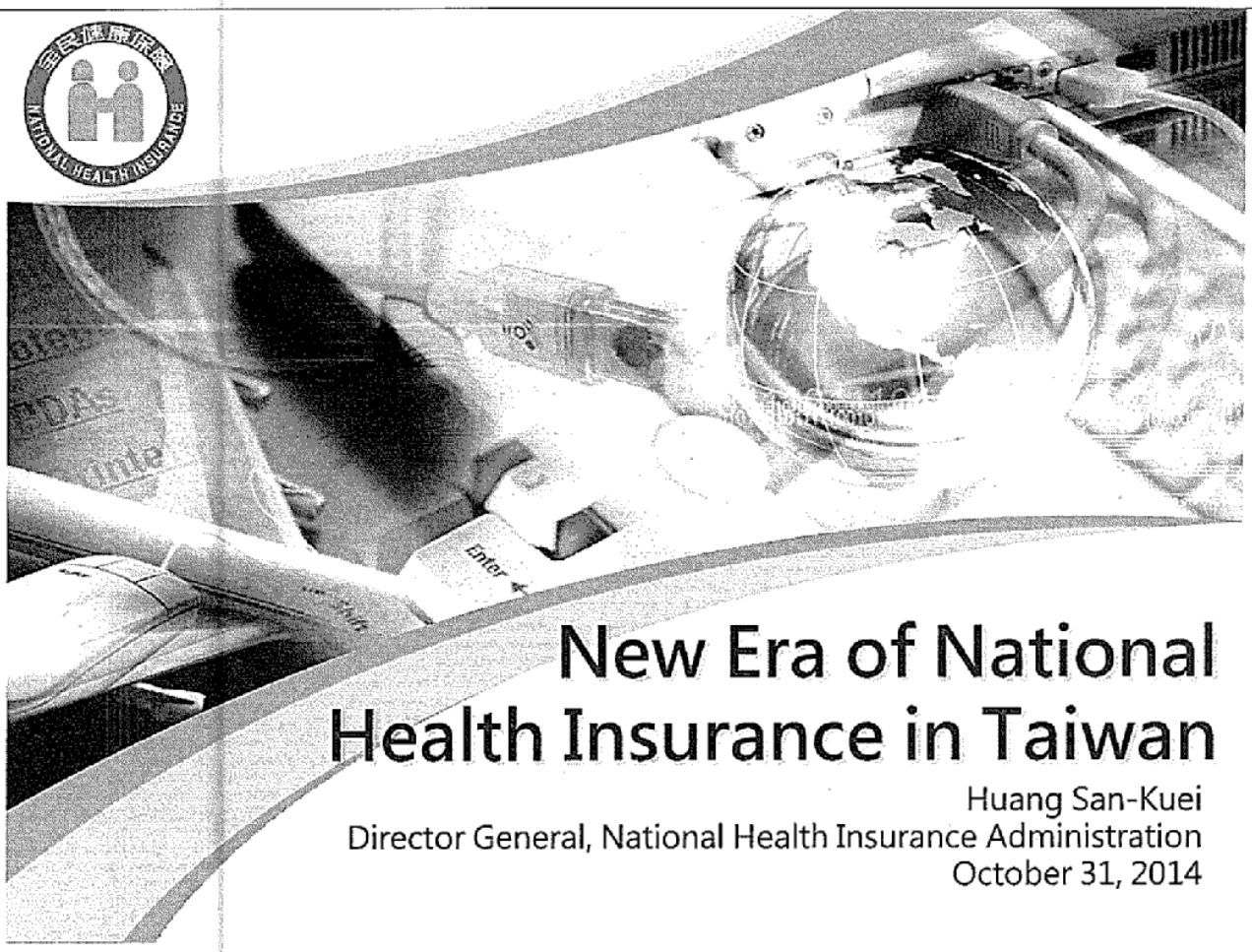
Katsuaki　Ura

General Affairs Division, Pharmaceutical and Food Safety Bureau ,

MHLW, JP

◎研討會資料已登載於日本独立行政法人医薬品医療機器総合機構網頁，供各界閱覽。（Pharmaceuticals and Medical Devices Agency，PMDA，似我國的財團法人醫藥品查驗中心)。

http://www.pmda.go.jp/kokusai/2014taiwan_sympo/2014taiwan_sympo_j.pdf



New Era of National Health Insurance in Taiwan

Huang San-Kuei
Director General, National Health Insurance Administration
October 31, 2014

Contents

Profile of Taiwan

Population	23 millions
Land Area	36,191 km^2
Population aged over 65	11.5%
GDP (2012)	US$20,423 Per Capita US$38,462 Per Capita (ppp)
NHE (2012)	US$1,350 Per Capita US$2,546 Per Capita (ppp)
NHE in GDP (2012)	6.6%
Life expectancy (2013)	76.69 (M) / 83.25 (F)

Source: Directorate-General of Budget, Accounting and Statistics; ROC; MOHW

3

Development of social insurance in Taiwan

- 1950 Labor Insurance(40.1%)
- 1958 Government Employees' Insurance(8.5%)
- 1985 Farmers' Insurance(8.5%)
- 1995 National Health Insurance(99%)
- 2013 2nd Generation NHI
- 2017 Long-term Care Insurance

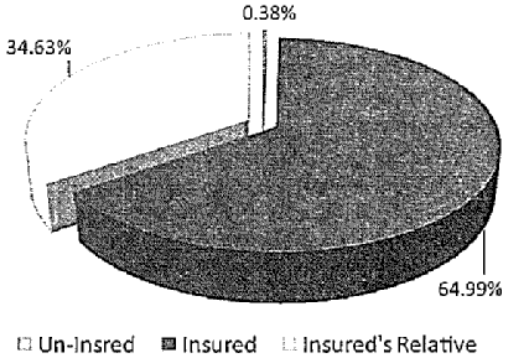
4

Current Development and Challenges

Current status of National Health Insurance in Taiwan

Compulsory program / single payer

- Universal coverage
- Guarantee equal access to health care service
- 20,325 contracted providers, including 493 hospitals (100% contracted) in 2013



- Coverage rate is 99.62%

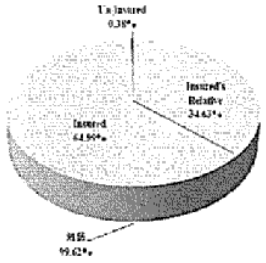
Advantage

- Low administrative costs
- Low co-payment, below 10% on average
- Comprehensive medical services, including outpatient services, inpatient services, dental, and traditional medicine, etc.
- Big database

Major NHI Achievements(1/2)

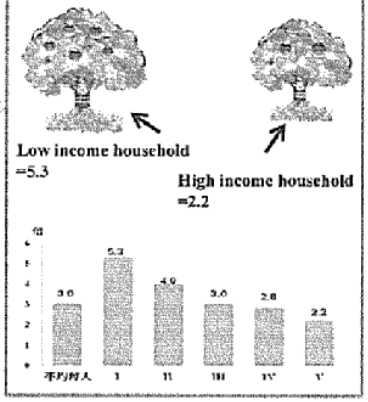
1.Universal coverage

Covered 23 millions population (coverage rate : 99.62%) , 2013



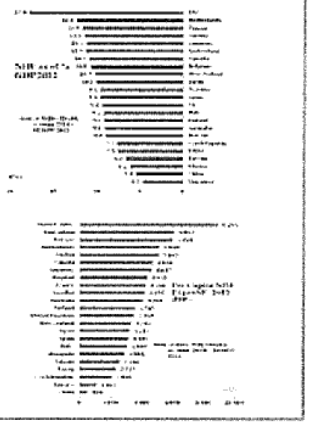
2.Easy & Equitable access

Benefit/Contribution Ratio for Low-income Households is Higher than 5.2



3. Affordable Cost

-NHE as to GDP : 6.6%
-Per capita NHE Expenses: US $2,546



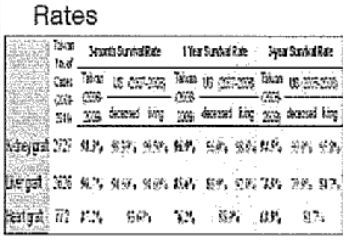
7

Major NHI Achievements(2/2)

4.Up-to-Standard Quality

➪ Five-year Survival Rates for Cancer

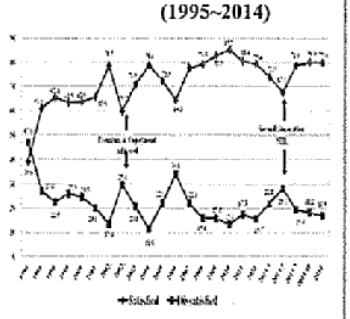
➪ Organ Transplant Survival Rates



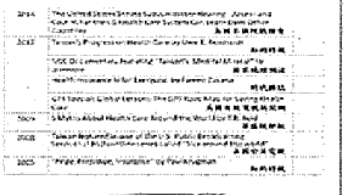
5.High Public Satisfaction

➪ The public satisfaction rate as improved from 39% in the first year of the program to 80% recently

(1995~2014)



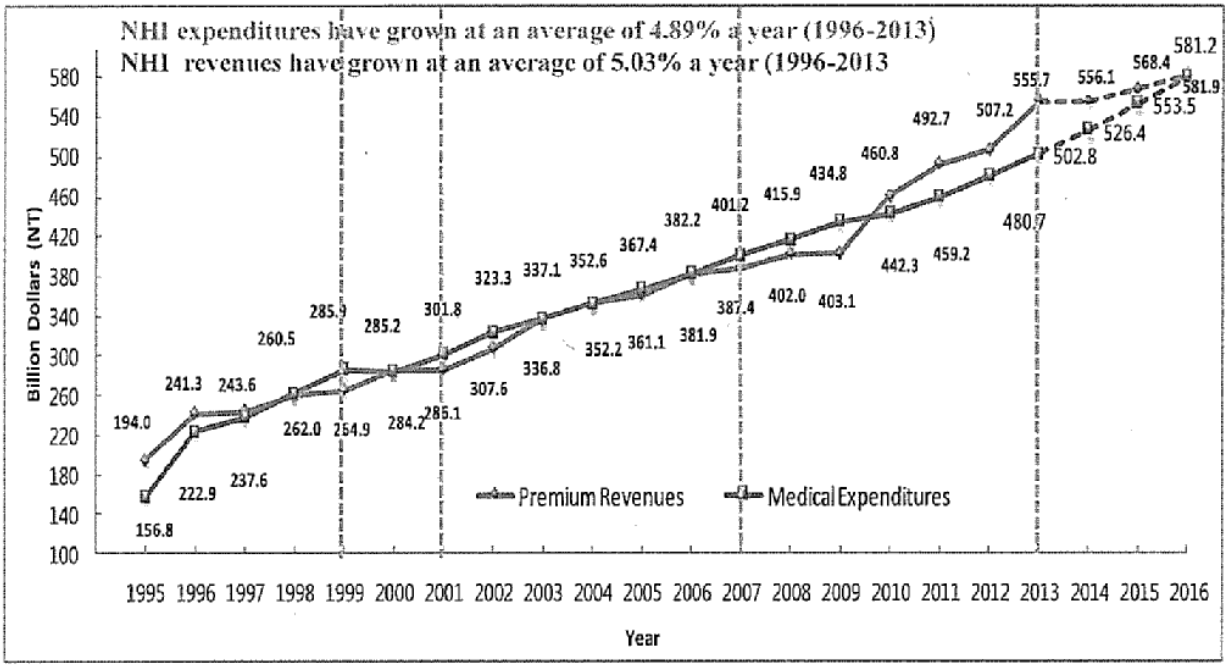
6.International Recognition



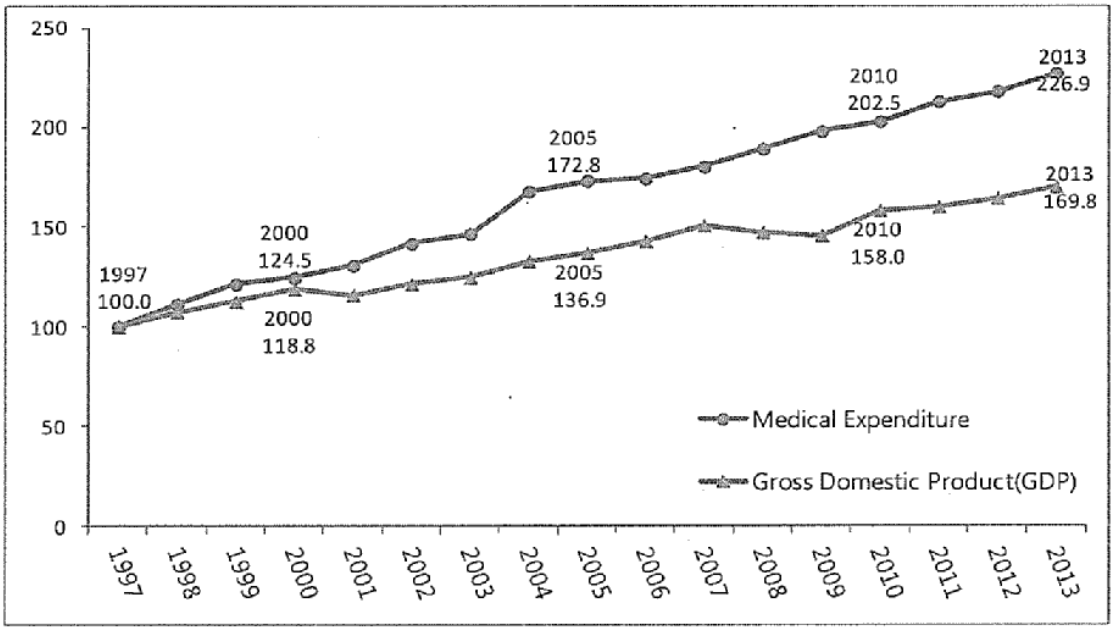
8

NHI revenues and costs

NT$ billion



Medical expenditure vs. GDP



Note1：GDP(1997) is reference year，Ratio=100x[GDP(Year)/GDP(1997)]。

Note2：GDP(1997) is 8.57T-NTD，2013 is 14.56T-NTD and growth rate is 69.8%；
Medical expenditure is 259.69B-P in 1997，589.27B-P in 2013 and growth rate is 126.9%。

Aging Across Region

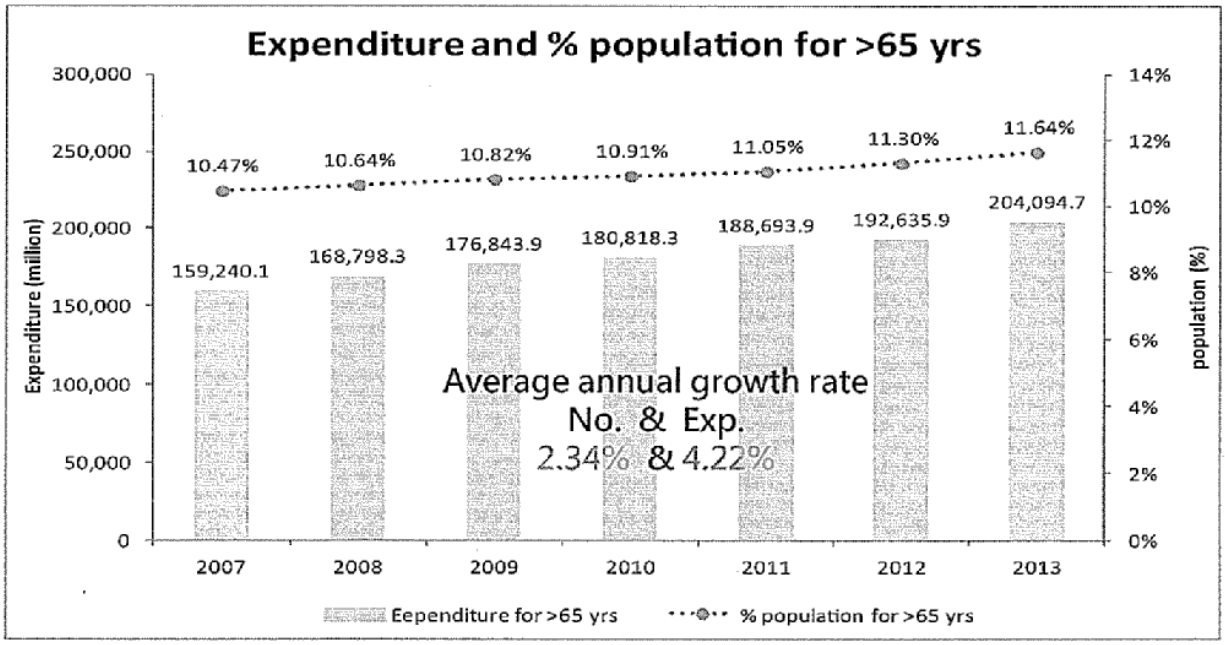
2009			2050		
Country	15-59:60+	Rank	Country	15-59:60+	Rank
Japan	1.92	1	Japan	1.01	1
Australia	3.24	2	Taiwan	1.14	2
USA	3.45	3	S.Korea	1.17	3
Hong Kong	3.97	4	Singapore	1.24	4
Singapore	4.51	5	Hong Kong	1.25	5
S.Korea	4.51	6	China	1.73	6
Taiwan	4.75	7	Australia	1.82	7
China	5.71	8	USA	2.03	8
Vietnam	7.63	9	Vietnam	2.13	9

Source:
Prof. Alan Cass
Senior Director
The George Institute for Global Health
Chair, Scientific Committee, Australasian Kidney Trials Network

11

Current Aging Trends and Impact to Healthcare

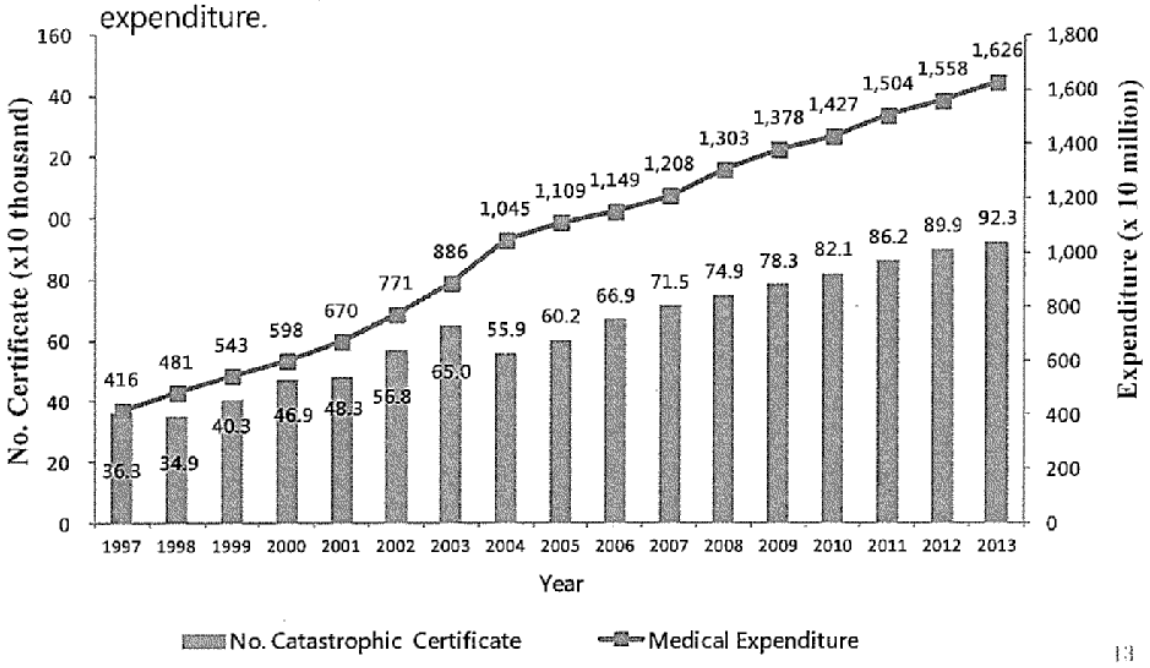
•The elderly people represent 11.6% of population, who used 34.6% NHI medical expenditures in 2013.



12

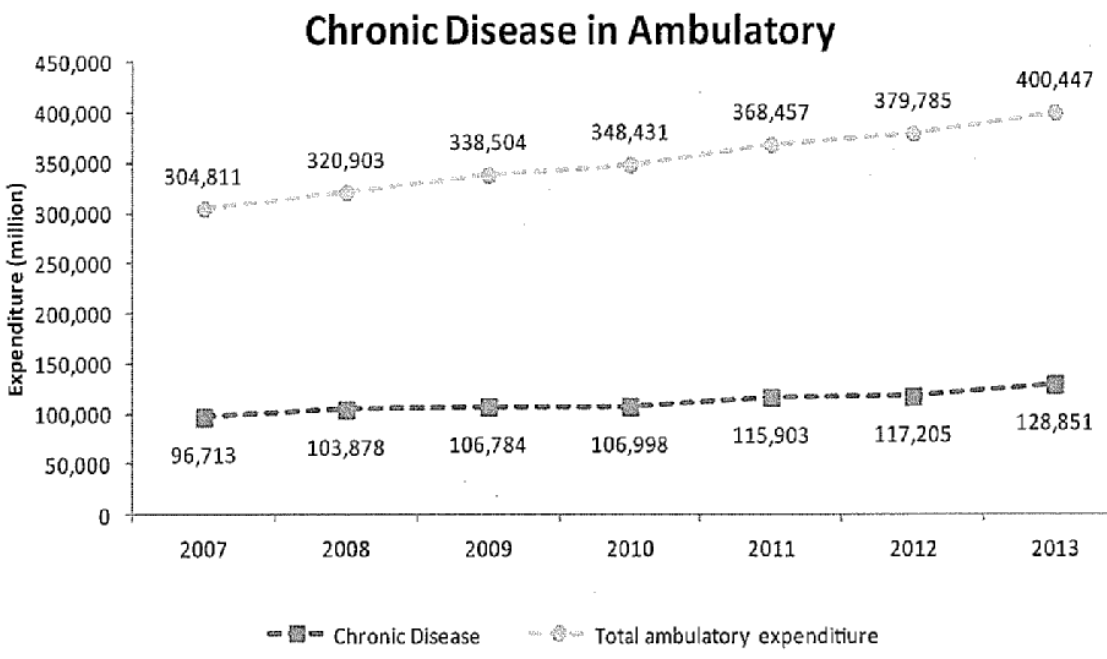
Catastrophic Illnesses

- There are more than 920 thousand catastrophically ill patients, or about 3.9% of all those insured under NHI program.
- Their medical expenditure in 2013 costs NT$ 162.6 billion, or 27.1% of all NHI expenditure.



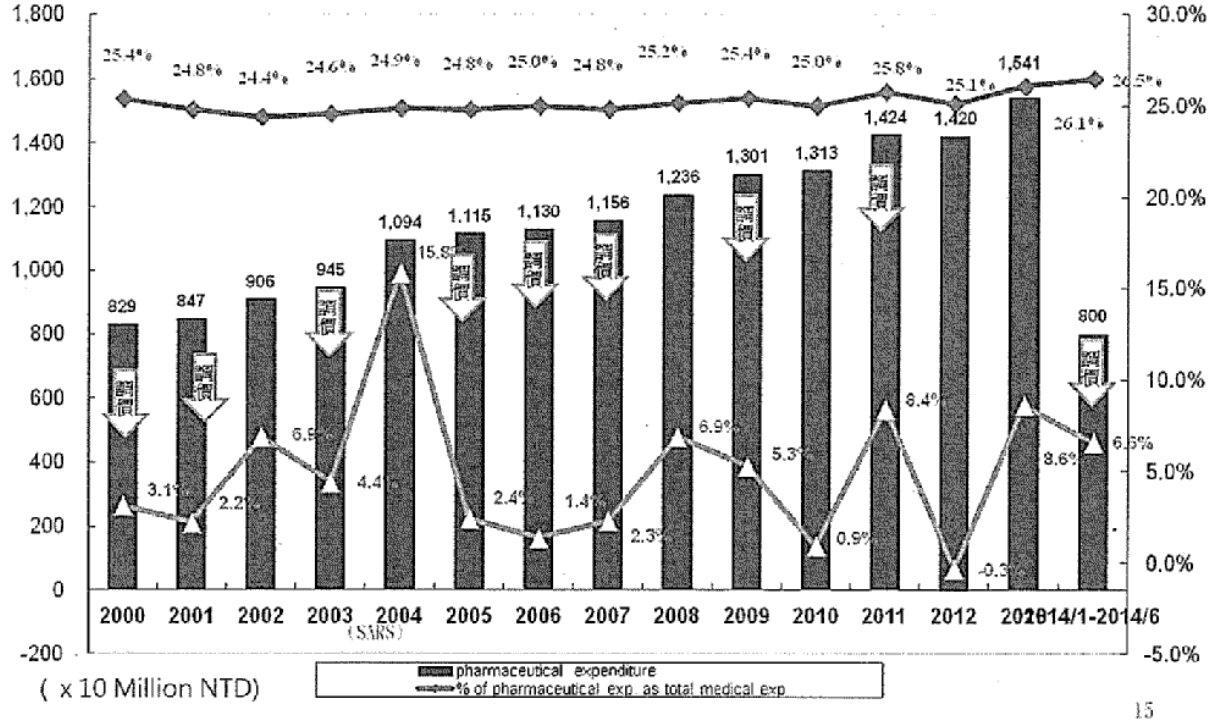
13

Medical Expenditure of Chronic Disease



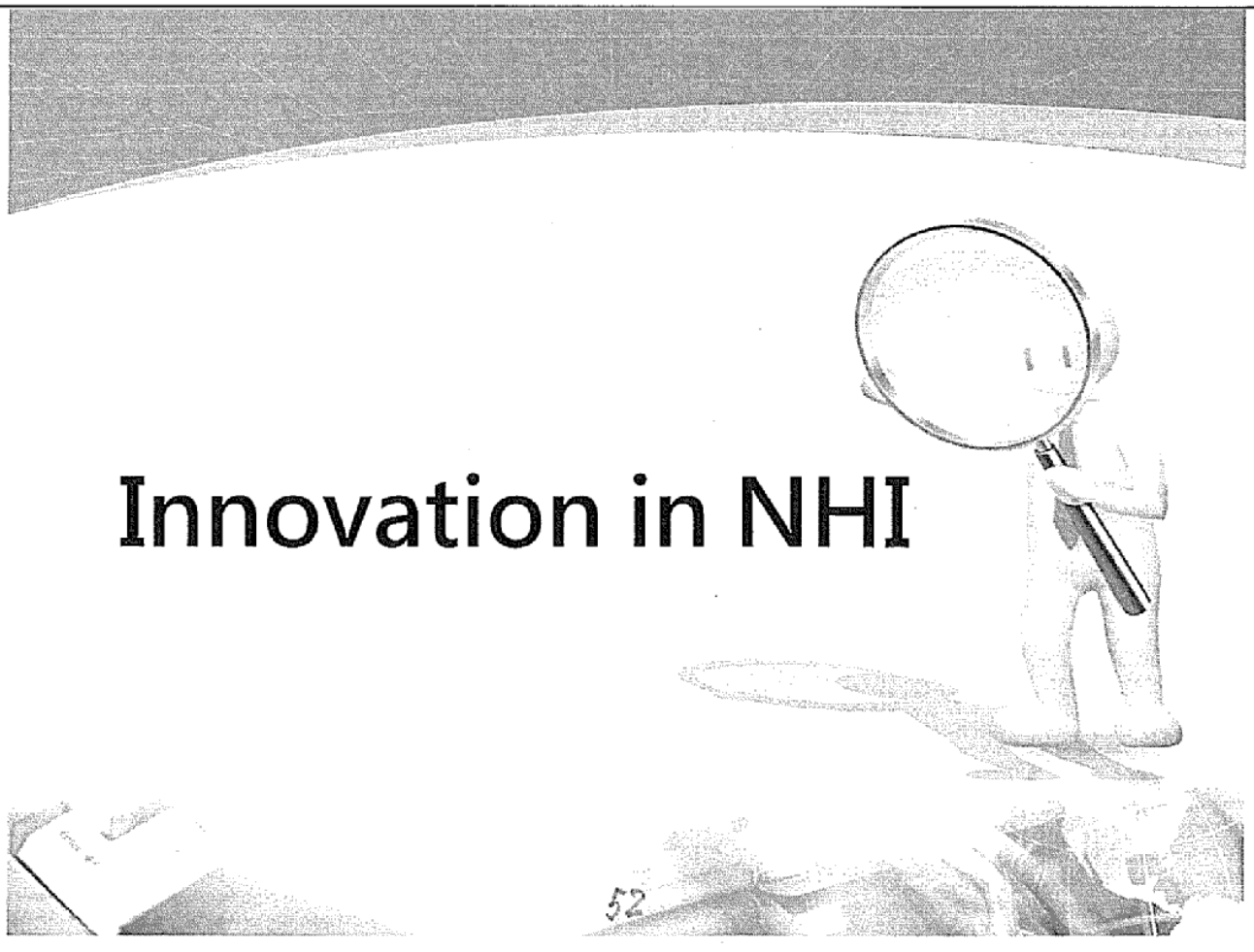
14

NHI Pharmaceutical Expenditure



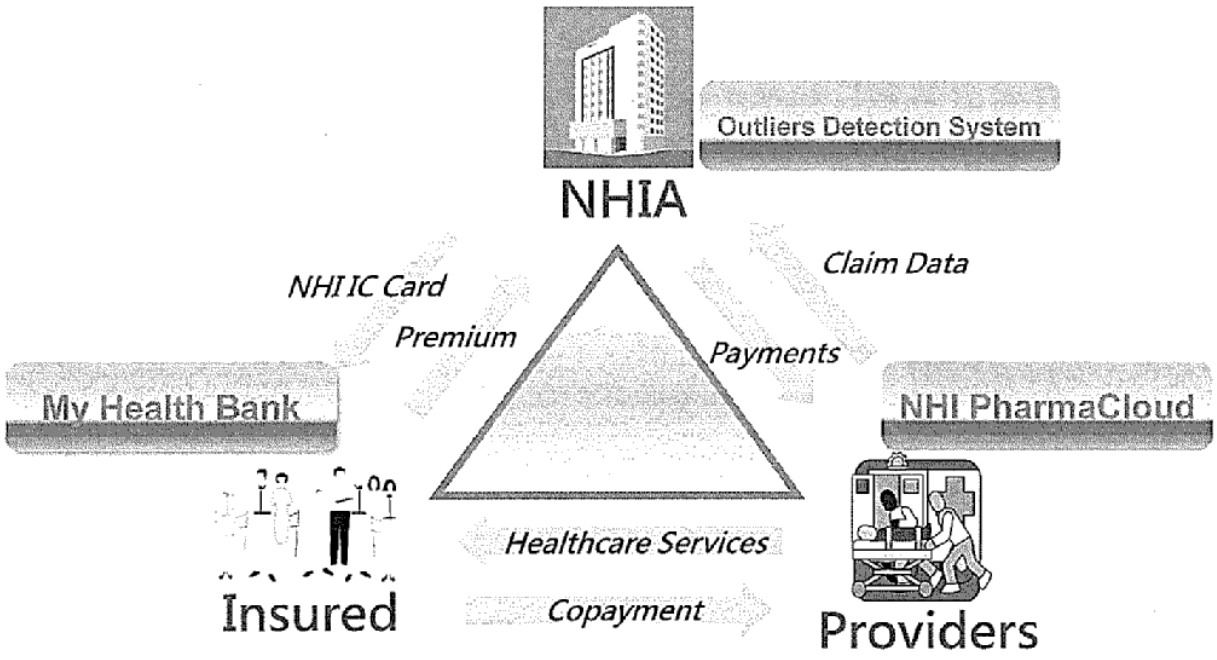
(x 10 Million NTD)

15



52

Healthcare Innovation 2014

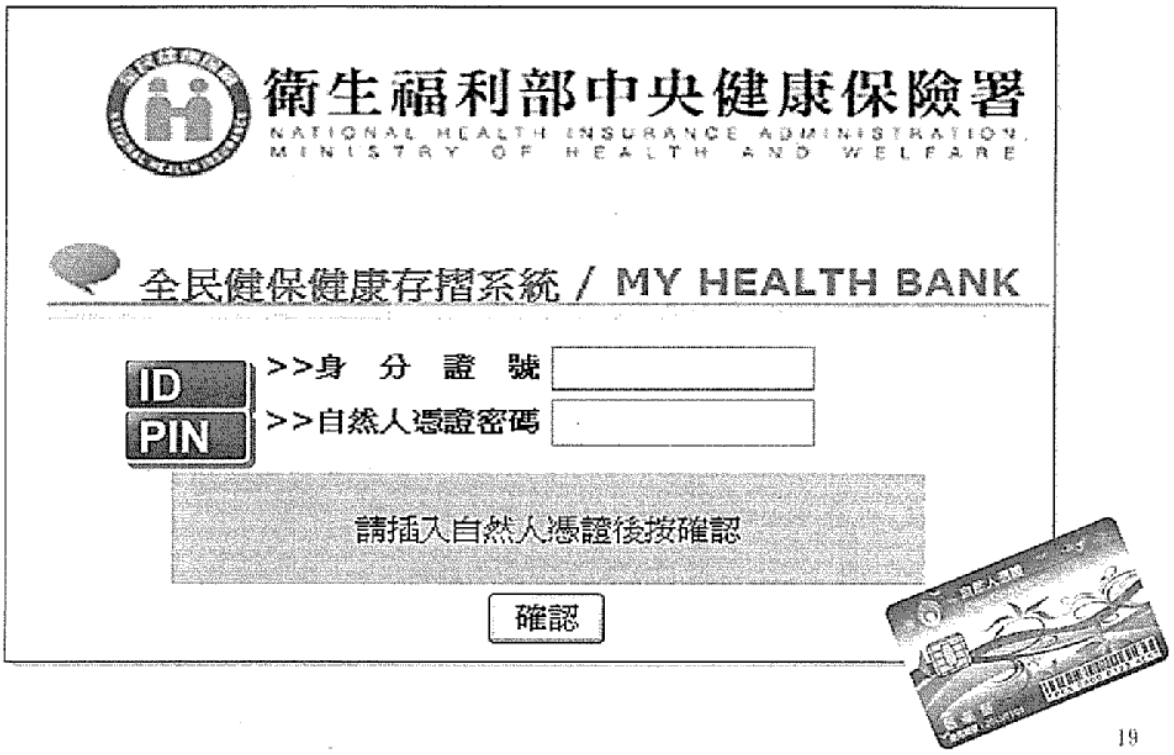


17

全民健保
健康存摺
MY
HEALTH
BANK

-My Health Bank-

My Health Bank

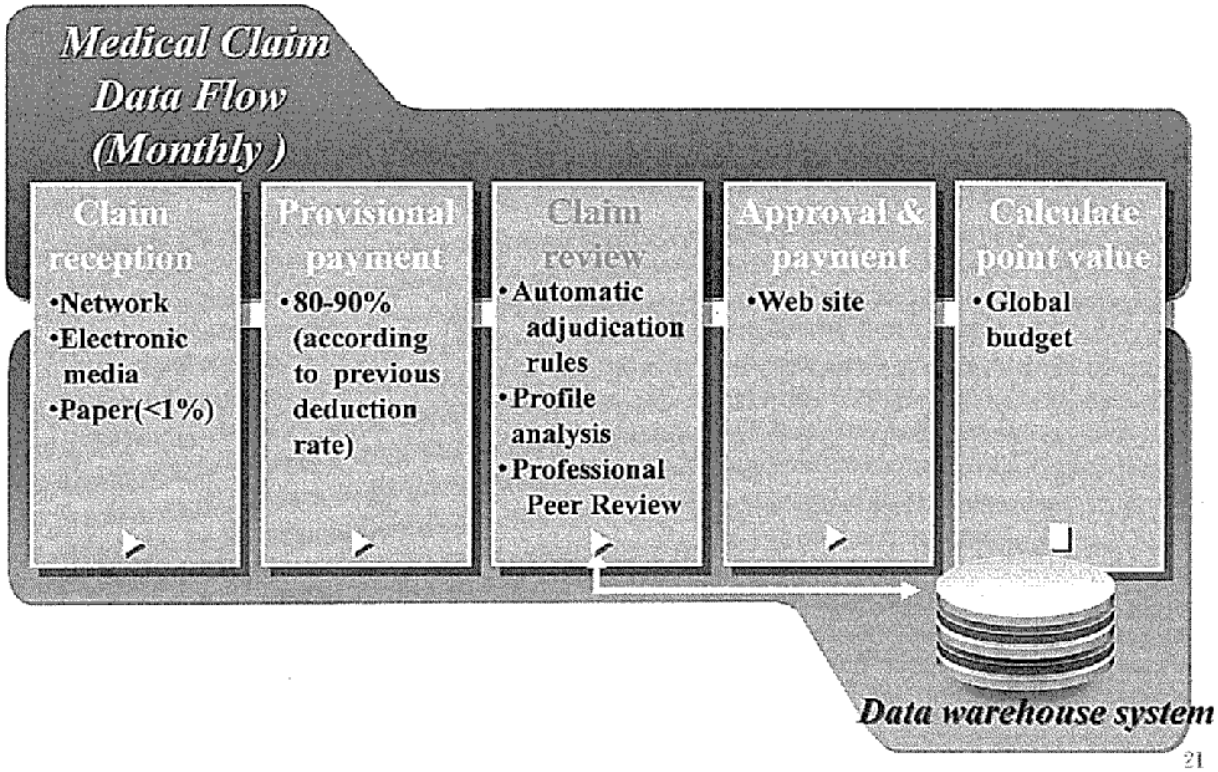


Multiple Sources

Scope of Benefits

- Inpatient care
- Outpatient care
- Prescription drugs and certain OTC drugs
- Dental services
  (orthodontics, prosthodontics excluded)
- Traditional Chinese medicine
- Day care for the mentally ill
- Home nursing care
- Allergy & Vaccine records*

High Quality-Medical Claim Data



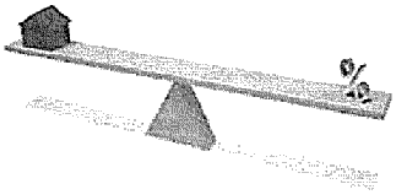
NHI IC Card for Each Patient

Functions of NHI IC Card

- Simplification of management process
- Daily update of medical visit data
- Infectious disease tracing & monitoring
- Heavy-user detection & management

Providing Personal Medical Data

- Personal medical data accessibility
  - Self-managing healthcare records
  - Alerting hospital to claim accurate data
  - Facilitating discussion between doctors and patients
- Personal privacy
  - Certificate identity
  - Security for downloading files



How soon to get the data?

全民健保健康存摺系統

- 本系統提供 台端自申請日前2日起近一年醫事機構申報及健保卡上傳之醫療資料，並於每日更新健保卡上傳資料之內容，例如：103年09月16日申請可查詢102年09月01日至103年09月14日之醫療費用申報及上傳資料，以此類推。全民健保健康存摺並非病歷，相關診斷及詳細罹病情形，請洽相關醫事機構。
- 請於申請日之隔日8時再至本網頁下載申請結果，本網站依據 台端申請產製資料後保留7日（例如：103年09月16日提出申請，請於103年09月17日8時至103年09月23日23時59分至本網站下載），下載檔案密碼為您的「身分證統」（首碼英文為大寫）。

Medical Data Period: 2013/9/1~2014/9/14

Apply Date: Sep 16, 2014 → **Download Date: Sep 17, 2014**

申請情形

	申請日期	資料起迄期間	可下載期間	狀態
	103/09/16	102/09/01 至 103/09/14	103/09/17 至 103/09/23	可下載

My Health Bank – Outpatient

NHI Service Office | Clinic/ Hospital | Visit Date/ Pharma Date | NHI IC Card Seq. No. | Diagnosis Procedure Operation | Copayment | NHI Expenditure

ID

Period

衛生福利部中央健康保險署 門診及交付藥情資料醫令明細表

身分證號：Z222***599
資料申請日期：103/07/02
資料起迄期間：103/05/01～103/05/31 (申報)

健保署服務單位	醫事機構	就醫日期	交付調劑、檢查或復健治療日期	健保卡就醫序號	疾病分類碼	疾病分類名稱	處置碼	處置名稱	部分負擔金額	健保支付點數
	醫囑代碼	醫囑名稱								醫囑總量
東區	***診所	103/05/14		0022	7140	類風濕性關節炎			250	1,438
	00110C	一般門診診察費－基層院所門診診察費１，每位醫師每日門診量在三十人次以下部分（3-1）未開處方或處…								1
	02011C	門診藥事服務費－慢性病處方給藥28天以上(山地離島地區每人每日100件內)								1
	05005C	紅血球沈降速度測定								1
	12015C	C反應性蛋白試驗 － 免疫比濁法								1
	1SC	肌肉注射								1
	A047570100	"汎亭"樂悠錠								56
	AC29575100	舒眠膠囊１０公絲（服納利林）								28
	AC316761G0	"柏理"康迴龍錠５毫克（培尼皮質醇）								56
	AC346701G0	"強生"萊歐莫衣錠５公絲								24
	AC367491G0	舒肌痛膠囊(鋁箔 膠箔)								56
	AC42899100	"健亞" 賜痛摸衣錠２００公絲（硫酸羥氨奎寧）								56
	AC47371100	"強生" 易除痛膠囊200毫克								56
	B022726100	滅殺除痛錠２．５公絲								24
南區	***檢驗所	103/05/14		0022	7140	類風濕性關節炎			0	275
	12015C	C反應性蛋白試驗 － 免疫比濁法								1

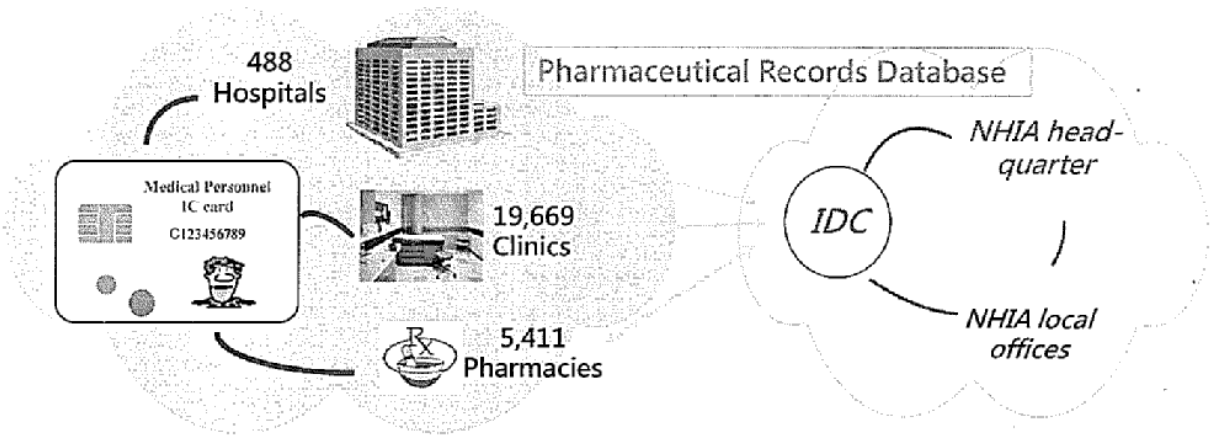
Detail Orders: Medicines Medical Devices

Order Quantity

23

-Pharma Cloud-

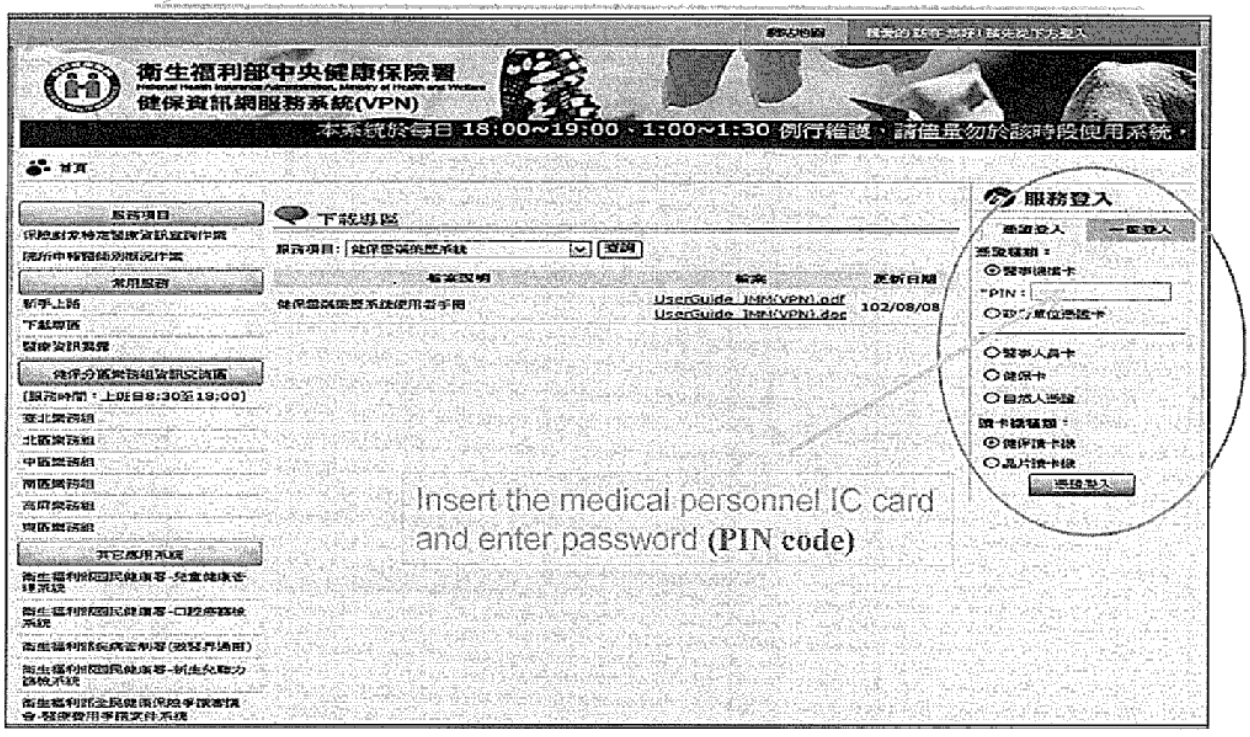
The NHI Pharma Cloud



- ✓ A patient-centered medication information system established in July 2013
- ✓ Information updated on a rolling daily basis
- ✓ Allowing practitioners to view real-time medication records with patient's consent
- ✓ Subject to strict privacy and security through VPN network

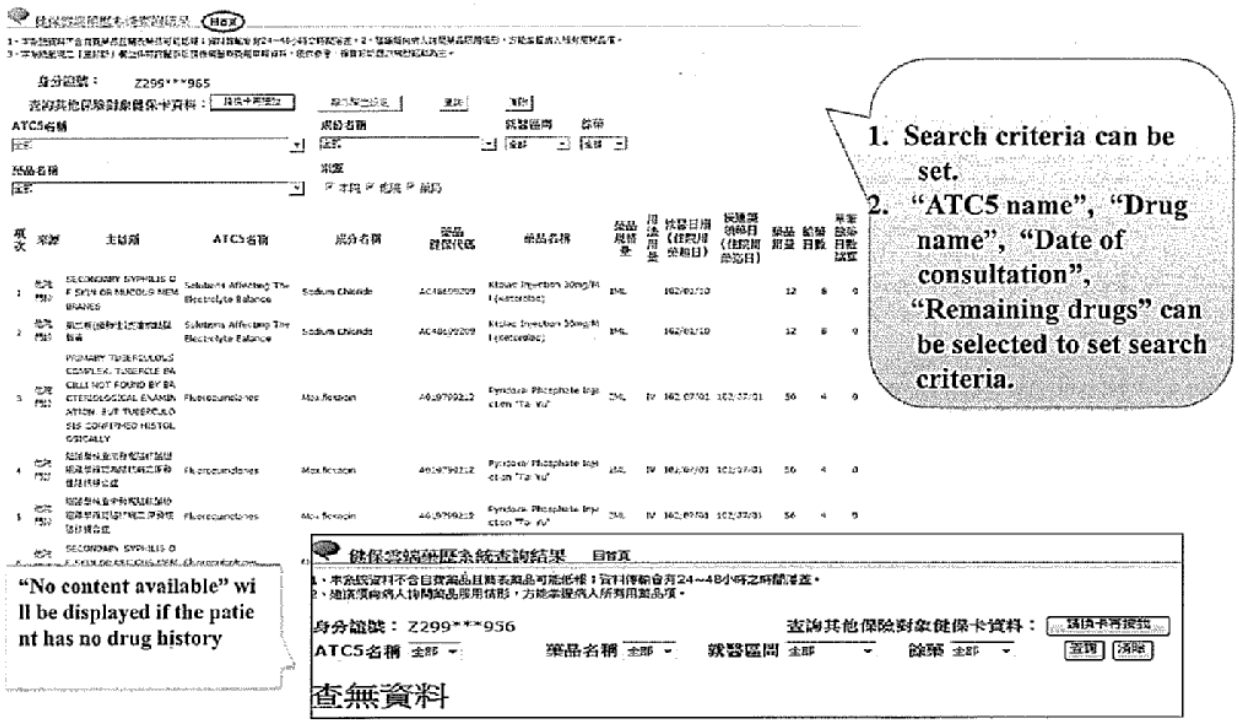
27

Inquiry Platform

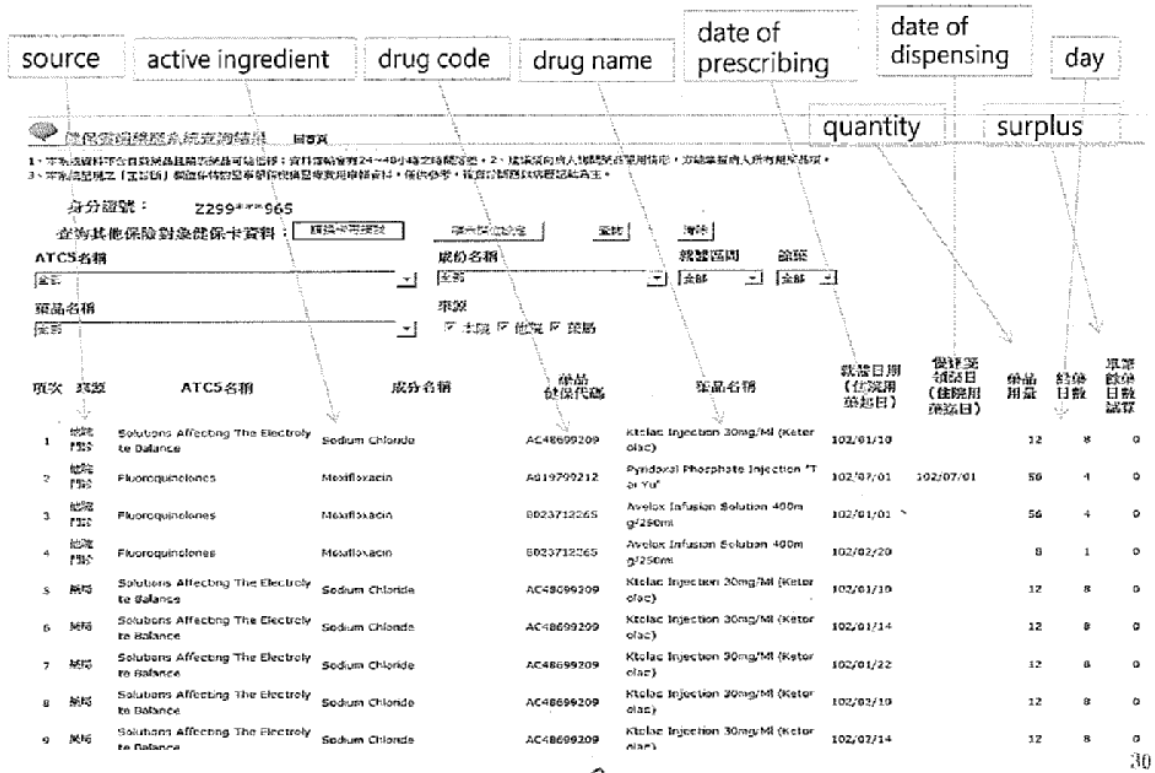


28

Inquiry Page of Hospital



Pharma Cloud Query Result



Pharma Cloud Benefits

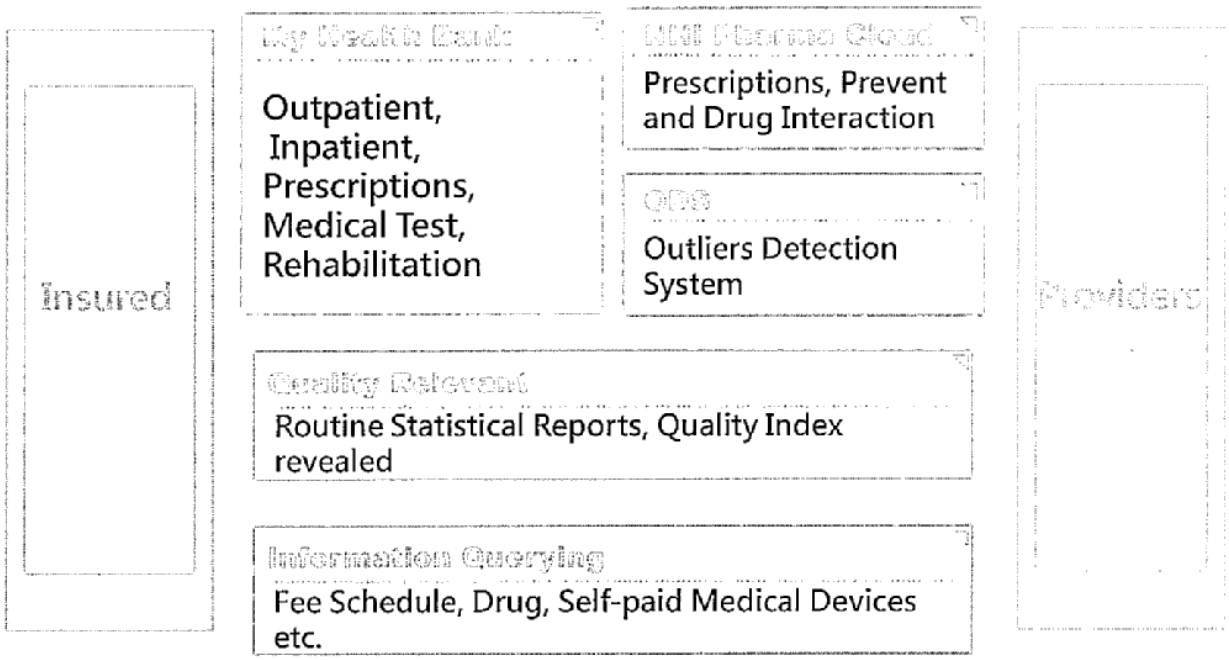
- Offer comprehensive medication information to healthcare professionals to provide patients with high quality care
- Prevent duplication of prescriptions and prescription fraud
- Protect patients from drug interactions and dosage errors
- Save the cost of drug expenditure

Development and applications

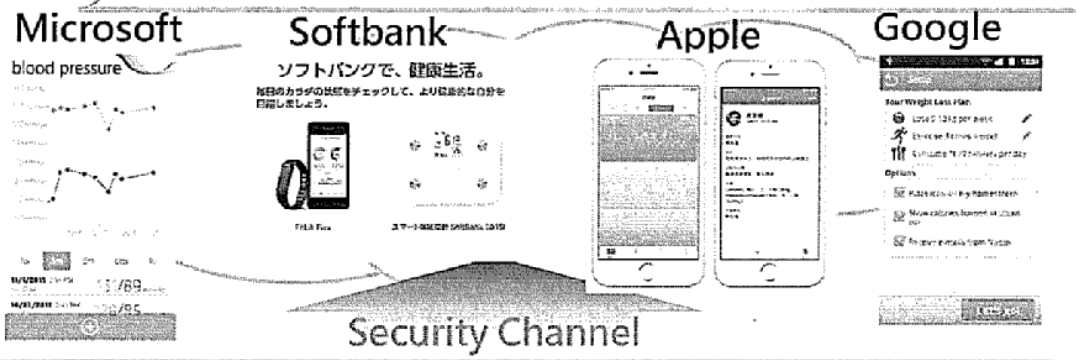
- Upgrade the bandwidth of the VPN
- Continuous improvement of system stability and inquiry efficiency
- Allow the information to be downloaded into hospitals' system if patient's consent was obtained.
  - Integrate patients' allergy history and drug interaction alarm check into the HIS system of hospitals
- The application of the system will be gradually expanded
  - **2,459 hospitals and clinics** have the access to the system so far and increases continuously.
  - **2,492,698 patients** were inquired until **September 2014**.

Future Perspectives

Solution for Healthcare



Next step in the Healthcare



Healthcare Platform

Prevention | Health Promotion | Medical Records | L.T.C. | Hospice

35

Vision to Holistic Care

Holistic Care

Health Maintenance	Health Insurance	Post Acute Care	Long Term Care
Self-Care, Wearable Devices, Innovative APP, Care Channel...etc	Health Improvement, Medical Promotion, Data Organization, Accessibility	Follow-up care, Medical Treatment, Secondary Care	Home Care Nursing Home E-health Pharma Cloud

My Health Bank (MHB)

36

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

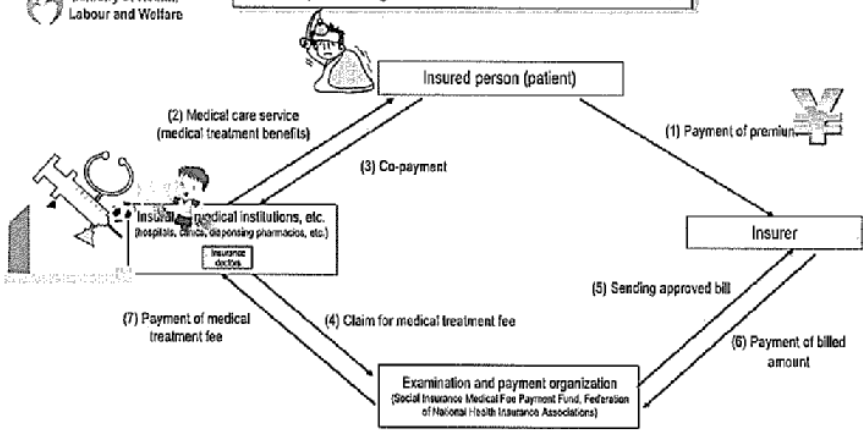
A Measure to Ensure Transparency and Efficiency in Drug Pricing System

31 October, 2014

Shinichi TAKAE
Deputy Director
Economic Affairs Division
Health Policy Bureau
Ministry of Health, Labour and Welfare

Ministry of Health, Labour and Welfare

Conceptual diagram of health insurance treatment



- 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.

Ministry of Health, Labour and Welfare

Outline of current drug price standard system

- **Drug price standard specifies the prices of drugs used for the payment by medical insurance to insurance medical institutions or insurance pharmacies (insurance medical institutions, etc.).**

  ⟹ **The prices should be appropriate.**

- **Drug price standard is based on "The Standard for Drug Pricing" developed by Central Social Insurance Medical Council on February 12, 2014 and announced by the Minister of Health, Labour and Welfare.**

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

||

Roughly biennially, recently

Ministry of Health, Labour and Welfare

What is adequacy of drug reimbursement price?

Requirements for reimbursement price specified in drug price standard

(1) Compensation of actual expense for medical institutions including hospitals and pharmacies that purchased drugs

(2) Reimbursement price must be fair and adequate.

Revision of price for already listed drugs

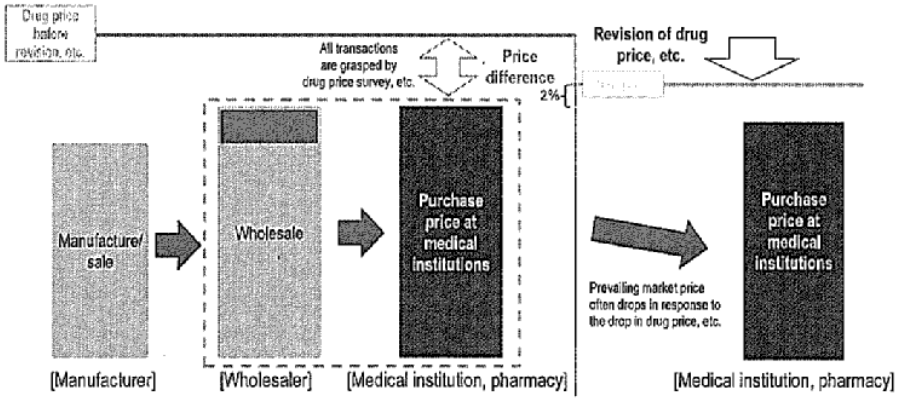
Bulk-line system → (1992) → Prevailing market price system (weighted average, fixed price range)

Pricing focused on (1) → Pricing focused on (2)

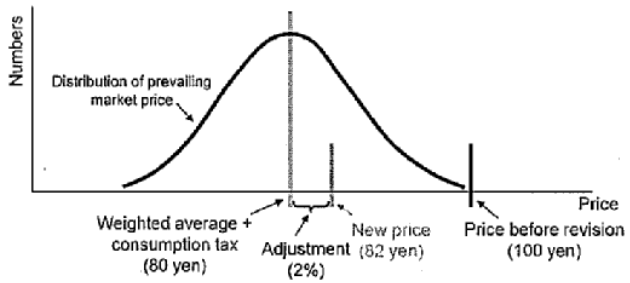
Assuming "market price = fair and adequate price"

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.



Pricing method of listed drugs



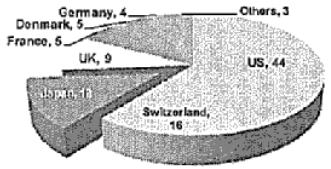
The new drug price is determined by adding consumption tax to the weighted average of sales price at which the drug was sold by wholesalers to medical institutions or pharmacies (prevailing market price before tax) and adjusting the resulting price (adding 2% of the price before revision) for stable distribution of drugs.

$$\text{New price} = \left[\begin{array}{c}\text{weighted average of sales price for}\\ \text{medical institutions/pharmacies}\\ \text{(prevailing market price before tax)}\end{array}\right] \times \begin{array}{c}\text{1 + consumption tax rate}\\ \text{(including local consumption tax)}\end{array} + \text{Adjustment}$$

Current status of pharmaceutical industry

■ While only a limited number of countries can continuously develop new drugs, Japan stands third in the world in drug development, contributing to the improvement of healthcare and public health in the world.

Number of top 100 drugs in global sales developed in each country (2010)



Source: prepared based on the data of Office of Pharmaceutical Industry Research

Number of drugs listed in drug price standard and market share by category

		No. of products	Share in No.	Share in amount
Brand name drugs	No generics	2,674	18.2%	49.3%
	With generics	1,562	31.2%	31.7%
Generics		8,038	27.6%	11.1%
Other products		3,629	20.8%	8.6%

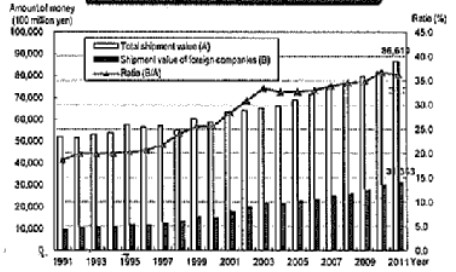
- Only the numbers of products are the data as of April, 2014.
- Share in number and share in amount are based on the numbers and drug prices at the time of the survey in September 2013.
- "Other products" include drugs, etc. (blood products, etc.) approved in 1967 or earlier that cannot be categorized into brand name drugs and generics in terms of Pharmaceutical Affairs Law.

Innovative drugs developed in Japan among top 100 drugs in global sales (2011)

Name	Company	Indication	Name	Company	Indication
Crestor	Shionogi	Hypodipidemia	Lowpin	Takeda	Prostate cancer
Abilify	Otsuka	Schizophrenia	Aricept	Eisai	Alzheimer-type dementia
Blopress	Takeda	Hypertension	Prograf	Astellas	Immune suppression
Actos	Takeda	Type II diabetes	Takepron	Takeda	Peptic ulcer
Olmetec	Daiichi Sankyo	Hypertension	Cravit	Daiichi Sankyo	Infection
Pariet	Eisai	Peptic ulcer	Vesicare	Astellas	Pollakiuria, urinary incontinence

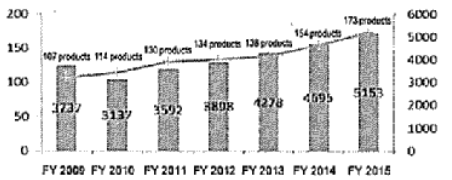
Source: Pharma Future, No. 265

Share of foreign companies in Japanese market



Recent trend in number of approval and listing of new drugs

Number of drugs approved



* The figures for FY 2014 and FY 2015 were estimated based on the mean growth rate from FY 2009 to FY 2013.

Number of new drugs listed

* The figures for FY 2013 to FY 2015 were estimated based on the mean growth rate from FY 2009 to FY 2012.

- ○ The number of listing tends to be increased as the number of approval is increased.
- ○ Products listed as new drugs was increased about 3.5-fold from 10 years ago.
- ○ Drugs are more actively developed.
- ○ Acceleration of approval review contributed.

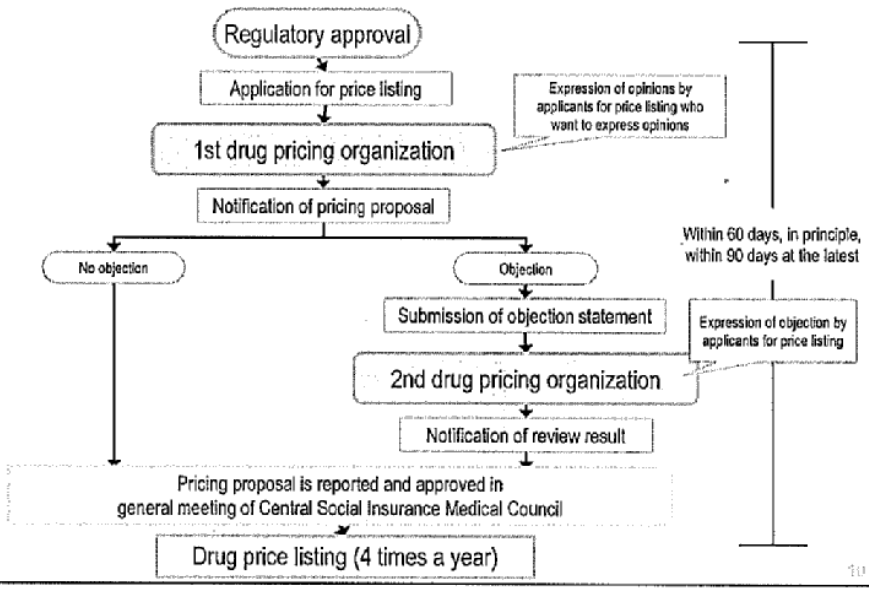
Timing of listing of new drugs

○ Basic rules
- Four times a year for new drugs (within 60 days in principle, within 90 days at the latest)
- Twice a year for report products and new kit products
- Twice a year for generics

● Timing of listing

New drugs	4 times a year	February, May, August, November (corresponding to approval timing based on Pharmaceutical Affairs Law)
Report products New kit products	Twice a year	May, November
Generics	Twice a year	June, December

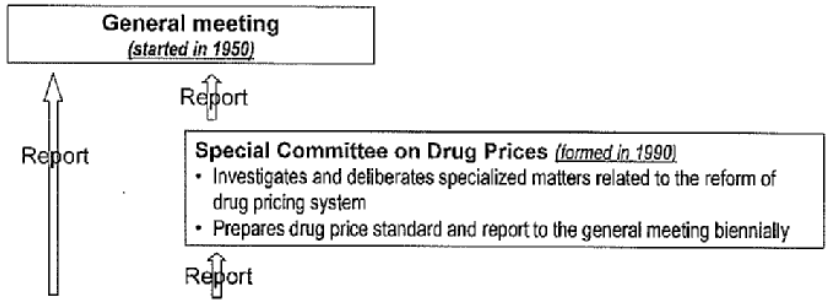
Pricing process of new drugs



Recent status of listing of generics

Listing date (announcement date)	Deadline of application for listing (deadline for approval)	Number of listed products
November 28, 2011	August 5, 2011 (July 15, 2011)	521
June 22, 2012	March 1, 2012 (February 15, 2012)	519
December 14, 2012	August 22, 2012 (August 15, 2012)	595
June 21, 2013	February 25, 2013 (February 15, 2013)	715
December 13, 2013	August 23, 2013 (August 15, 2013)	694
June 20, 2014	February 25, 2014 (February 17, 2014)	454

Organizations of Central Social Insurance Medical Council involved in drug pricing



Revision of medical treatment fee and drug price system in FY 2014 (summary)

Opinion regarding institutionalization of price premium for promotion of new drug development and resolution of off-label use, etc.

(Special Committee on Drug Prices, December 18, 2013)

(Proposal):

As shown in the attachment, how about institutionalizing the price premium for the purposes of stabilizing the profit from new drugs during patent term and promoting development of new drugs and resolution of off-label use, etc., assuming the introduction of the rule (Z2) requiring price reduction of brand name products that are not appropriately replaced by generics within a certain period?

In applying this premium, how about having Central Social Insurance Medical Council confirm whether research and development of unapproved drugs or drugs used off label are appropriately promoted by this premium upon every revision?

In addition, how about applying this premium to products of companies that conduct research and development for "the drugs that truly contribute to the improvement of quality of medical care ((1) drugs for pediatric use or in orphan disease areas, (2) drugs for diseases insufficiently treated by existing therapeutics (drugs for intractable diseases, drugs meeting unmet needs, etc.)"?

"Opinion No. 1" (opinion from payer side):

Although efforts to resolve the issue of unapproved drugs and drugs used off label seems to be going well, some companies have premium prices but do not request for them or respond to open recruitment for certain products.

In addition, the ratio between "development of drugs used off label, etc." and "development of drugs that truly contribute to improvement of quality of medical care" has been changing. Because there are problems including the criterion of average divergence rate or lower that does not represent the resolution of drug lag, further discussion is necessary

"Opinion No. 2" (opinion from care provider side):

Drugs that truly contribute to improvement of quality of medical care include unapproved drugs/drugs used off label for which requests were filed or public recruitment was implemented and drugs the development of which was requested by academic associations or other parties. Other than these, drugs that meet unmet medical needs, drugs for pediatric use and orphan drugs are acceptable. For drugs with new mechanism of action, there is room for discussion because they may improve the efficiency of treatment. Other drugs should not be accepted. Is institutionalization different from making it permanent?

(1) Price premium for promotion of new drug development and resolution of off-label use, etc. (exceptional price reduction, "Z" and "Z2")

Special Committee on Drug Prices, Central Social Insurance Medical Council
FPMAJ material (11/06/2013)

Survey results

- **The number of the drugs developed in response to requests or the developed drugs that truly contribute to improvement of quality of medical care exceeds 800 and many were developed simultaneously worldwide.**
- **For the development of the above drugs in Japan, approximately 290 billion yen is invested per year.**

1. Status of drugs developed in Japan and drugs developed simultaneously worldwide

The figures are number of products, some products are counted more than once in [A], [B] and [C].

Total number of developed products	Products developed in response to request [A]		Drugs that truly contribute to improvement of quality of medical care[B] (with duplication)					Prevention of drug lag[C]
	Public recruitment, unapproved, off-label	Others, developed at request of academic societies, etc.	Pediatric	Orphan	Meeting unmet needs (※2)	New mechanism of action	Others (new dosage form, etc.)	Drugs developed simultaneously worldwide
804	146	60	103	155	231	341	189	360

※1 Drug developed in Japan at the end of the most recent accounting period for each company (including drugs in PI to III, drugs in preparation for application, drugs being applied and approved drugs)
※2 Drugs for the diseases for which drugs contribute only to a minor extent to the treatment or similar diseases and drugs for the diseases that cannot be effectively treated by existing therapeutics, for example, intractable diseases shown in Slide 8 used for the statement of opinion of FPMAJ at the meeting of Special Committee for Drug Prices of Central Social Insurance Medical Council on September 25, 2013

2. Status of cost of development of the above drugs in Japan

Total development cost	Development cost related to drugs corresponding to products developed in response to request [A] (including products classified into[B])	Development cost for products classified only into drugs that truly contribute to improvement of quality of medical care [B]
2,906.2	387.9	2,518.3

Unit: 100 million yen

※ Approximate estimates of the following cost related to the development of concerned developed products in Japan for 1 year up to the end of the most recent accounting period of each company
Actual cost of studies/application (including all the cost related to studies including cost for outsourcing), labor cost (research and development division and regulatory affairs division), etc.

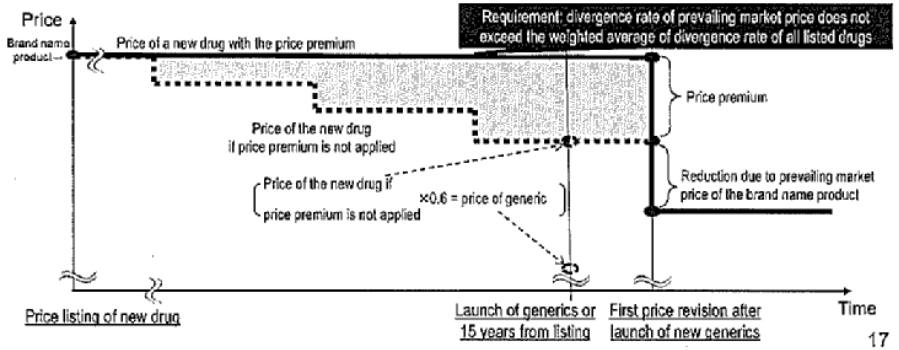
"Framework for the next reform of drug pricing system"

(approved in the general meeting of Central Social Insurance Medical Council on December 26, 2018)

Continued trial implementation of price premium for promotion of new drug development and resolution of off-label use, etc.

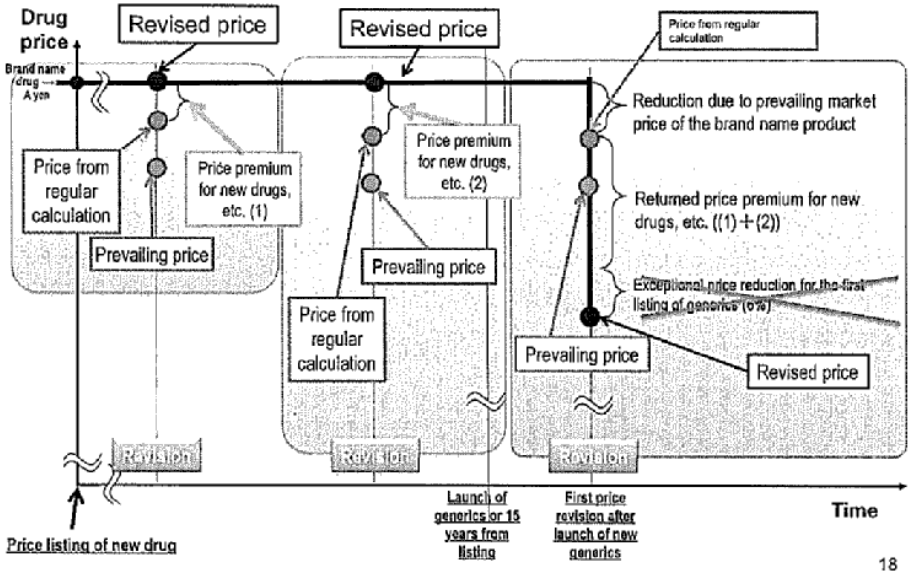
(Pharmaceutical companies shall accept the optimization of healthcare cost through replacement of brand name drugs with generics after the termination of patent term.)

- The rule (Z2) that requires price reduction of brand name drugs that are not appropriately replaced by generics within a certain period is introduced and the trial implementation of the price premium that stabilizes the profit from new drugs during patent term and promotes new drug development and resolution of off-label use, etc. is continued.
- The price premium is applied to the products of the companies that conduct research and development of "drugs that truly contribute to the improvement of quality of medical care" ((1) drugs for pediatric use or in orphan disease areas, (2) drugs for diseases insufficiently treated by existing therapeutics (drugs for intractable diseases or drugs meeting unmet needs))
- Confirmation and verification of the status of research and development in Japan of drugs that truly contribute to the improvement of quality of medical care shall be continued and the revision of the current system including the range of products to which this price premium is applied shall be discussed.



17

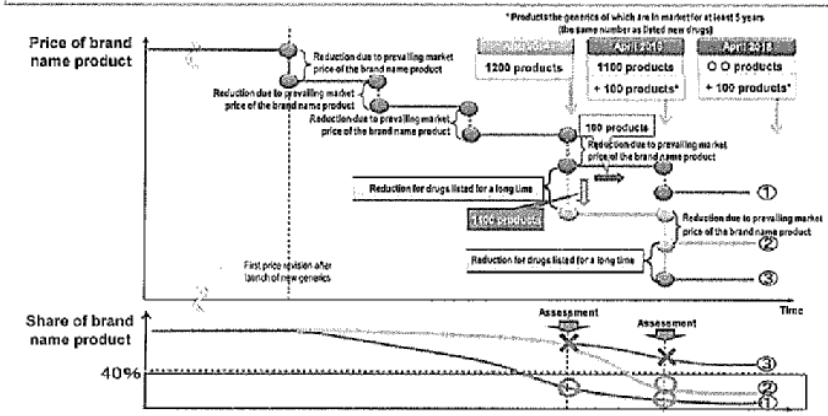
Image of price change of new drugs to which "price premium for promotion of new drug development and resolution of off-label use, etc." is applied at drug pricing



18

Revision of drug price that promotes replacement of drugs listed for a long time with generics

- "Exceptional reduction" shall be applied to individual brand name products that have not been appropriately replaced by generics even after 5 years of listing of these generics.
- The percentage of exceptional reduction is shown below.
  - Price reduction of brand name products with less than 20% of replacement rate by generics : 2.0%
  - Price reduction of brand name products with less than 40% of replacement rate by generics : 1.75%
  - Price reduction of brand name products with less than 60% of replacement rate by generics : 1.5%
- "Special provision for price revision of listed drugs the generics of which are listed for the first time" is abolished.



19

For people, for life, for the future

Ministry of Health, Labour and Welfare

Thank you for your attention!

EFFICIENCY AND TRANSPARENCY IN PRICING

SHANG-PING CHEN
RESEARCHER
DIVISION OF MEDICAL REVIEW AND PHARMACEUTICAL BENEFITS
NATIONAL HEALTH INSURANCE ADMINISTRATION (NHIA), TAIWAN

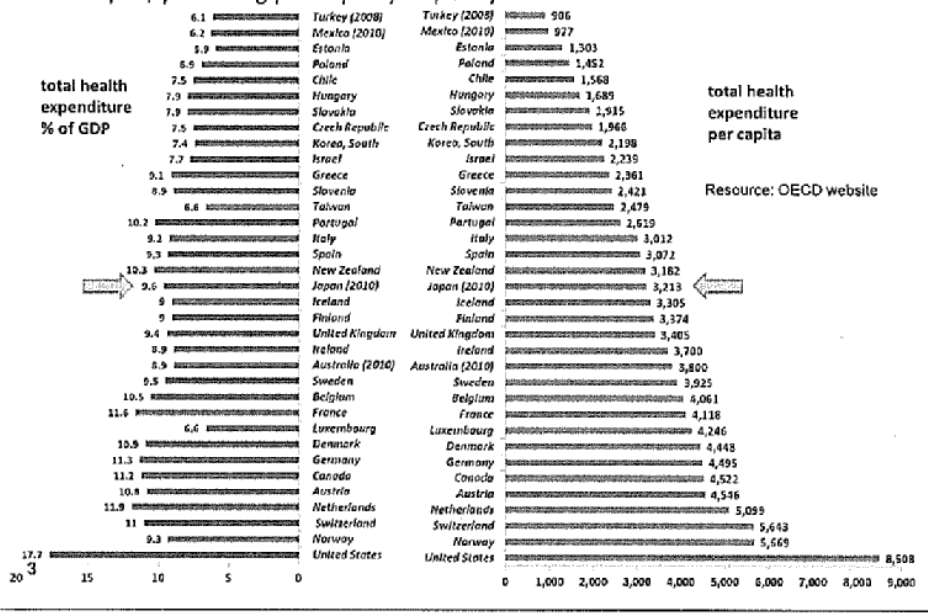
2014/10/31

Outline

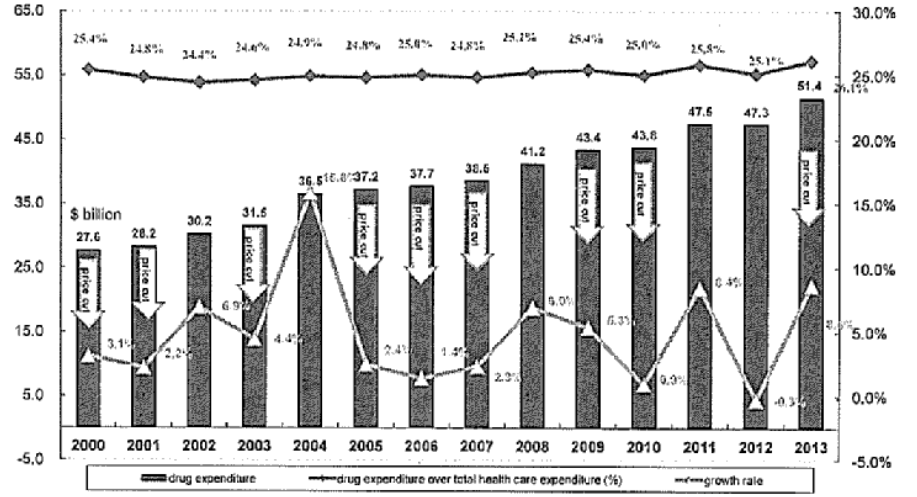
- Drug Expenditures Statistics
- Drug Payment System
- Pharmaceutical Benefits and Reimbursement Schedule (PBRS)
- Drug Listing and Pricing Rules
- Challenge and conclusion

2011 Total Health Expenditure per Capita

(US$ purchasing power parity-adjusted)



Trend of NHI Drug Expenditures



Analysis of the Drug Expenses (2012)

5

Classification	Subgroup	Drug expenditure ($ million)	Percentage
Catastrophic disease	Antineoplastic agents	78.3	16.5%
	Drugs used in blood disease	14.7	3.1%
	Drugs used in mental illness	12.7	2.7%
	others	39.3	8.3%
	subtotal	145.0	30.7%
Outpatient Chronic disease	Antihypertensive drugs	85.7	18.1%
	Drugs used in diabetes	29.0	6.1%
	Lipid modifying agents	8.3	1.8%
	others	104.0	21.9%
	subtotal	227.0	48.0%
Others	subtotal	101.0	21.4%
Total		473.3	100%

Drug Payment System

6

- Reimbursement for drugs is uniform nationwide and paid to the medical institution
- Fee-for-service
  - ✓ Reimbursement price per item* volumes prescribed
- Package payment
- Per diem
  - ✓ Chinese Medicines ($30 NTD per day)
  - ✓ Clinics and Pharmacies ($22 NTD per day, up to 3 days)

70

Outpatient Co-payment for Drugs

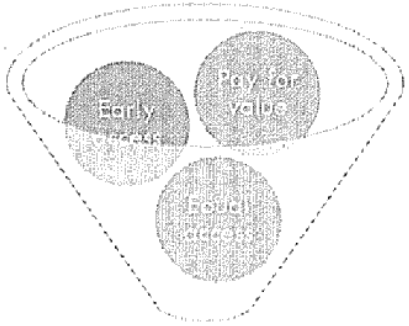
7

Drug Fee	Co-payment (NTD)	Drug Fee	Co-payment (NTD)
<=$100 NTD	0	$601~700	$120
$101~200	$20	$701~800	$140
$201~300	$40	$801~900	$160
$301~400	$60	$901~1000	$180
$401~500	$80	>=$1001	$200
$501~600	$100		

Exemption:
1. Refillable prescriptions for patients with chronic illnesses
2. Dental services
3. Case payment services

Principle of medication policy

8



Patient-oriented health care

2nd generation NHI

- Implemented in 2012
- 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

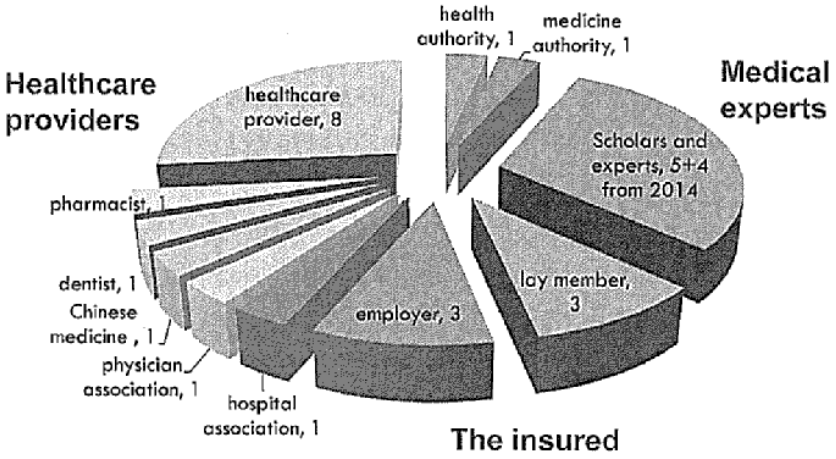
Difference between 1st & 2nd generation NHI

	Decision making	
	1st generation NHI	2nd generation NHI
New drugs	Expert committee	PBRS Joint Meeting (stakeholder committee)
New items (same ingredient/function with existent drugs/medical devices)	Price decided by the insurer	Price suggested by the insurer then decided by PBRS Joint meeting
HTA	Starting from 2007 by CDE	The NIHTA is established in 2013

Mission of PBRS Joint Meeting

- Make rules of drug listing
- Make principles of PBRS
- Decide to list & reimburse new drugs & medical devices
- Decide to list & reimburse new items with same ingredients or function of existing drugs or medical devices
- Review extension or change of existing PBRS items
- Other issue related to PBRS

Members of PBRS Joint Meeting



How to be a member?

13

Health and medicine 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 provider	• 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)

Transparency of decision making (1)

14

- Drug companies' representatives are allowed to make presentations at the Expert Advisory Meeting. Results of the initial review will be sent to the drug companies as well.
- PBRS Joint Meeting is composed of stakeholders and with three representing pharmaceutical industries sitting in.
- The agenda of the PBRS Joint Meeting and HTA report is made public 7 days before it meets.

Transparency of decision making (2)

15

- After meeting, the minutes, sound records, and interest disclosure declarations will be post on the NHIA website.
- If the suppliers did not agree with the preliminary price concluded by PBRS joint meeting, they can appeal for appraisal to give presentations at PRBS Joint Meeting before listing.

16 Listing and Pricing Rules

Around 16,700 items get listed by 2014

Factors of listing

17

- Safety
- Efficacy

} TFDA

- Relative effectiveness
- Budget impact analysis
- CBA/CEA/PE
- Ethical/Legal/Social/Political Impact

} NHIA

Pricing for brand drugs

18

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	Capped at A-10 median price • lowest price in A10 • 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.	
2B	Me-too		

13

A-10 reference countries

19

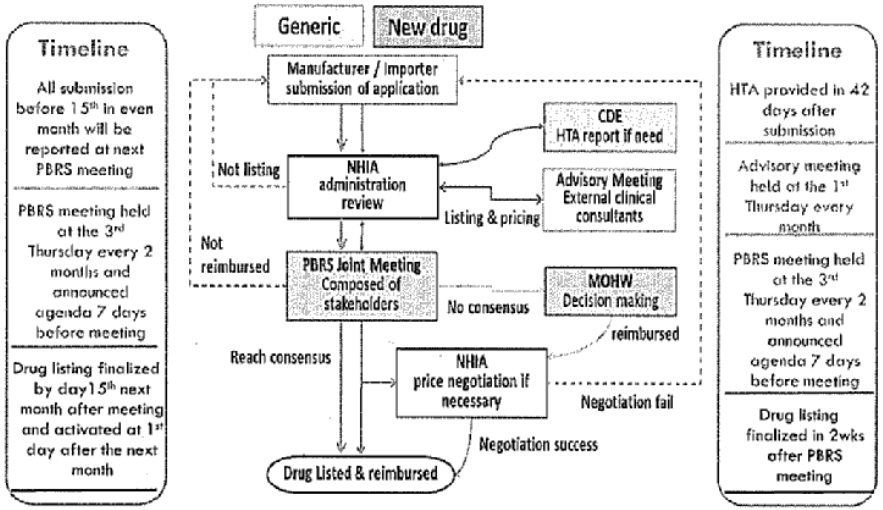
Country	Source of Reference	Pricing Structure
US	Red Book (not official publication)	Wholesale price
Japan	Drug price baselines (official website)	Ex-factory price + wholesale premium + drugstore premium + value-added tax
UK	NHS Prescription Service (official website)	Ex-factory price + wholesale premium
Canada	Saskatchewan Formulary (official website)	Wholesale price
Germany	ROTE LISTE (official website)	Ex-factory price + wholesale premium + drugstore premium + value-added tax
France	Base des Médicaments et Informations Tarifaires (official website)	Ex-factory price + wholesale premium + drugstore premium + value-added tax
Belgium	Centre Belge d'Information Pharmacothérapeutique (official website)	Ex-factory price + wholesale premium + drugstore premium + value-added tax
Sweden	Farmaceutiska specialiteter i Sverige (official website)	Wholesale price + drugstore premium
Switzerland	Arzneimittel kompendium der schweiz (official website)	Ex-factory price +logistics premium (shared by wholesalers and drugstores) + value-added tax
Australia	Pharmaceutical Benefits Scheme (official website)	Ex-factory price + wholesale premium + drugstore premium + dispensing fees

Pricing for generics

20

- For the 1st generic
  - * BA/BE generic —90% of the price of originator
  - * General generic —80% of the price of originator
- The 2nd forward generics are priced at the lowest price of the same category of generics.
- Add incentives to drugs comply with PIC/S GMP and other quality conditions

Pharmaceutical listing & pricing flowchart



21

Difference of reviewing results

22

1st NHI

2012

Expert committee (items)

Agree	Disagree	Total
66 (85.7%)	11 (14.3%)	77 (100%)

2nd NHI

2013

Expert committee (items)

PBRS Joint meeting		Agree	Disagree	Total
	Agree	41	0	41 (71.9%)
	Disagree	4	12	16 (28.1%)
	Total	45 (78.9%)	12 (21.1%)	57 (100%)

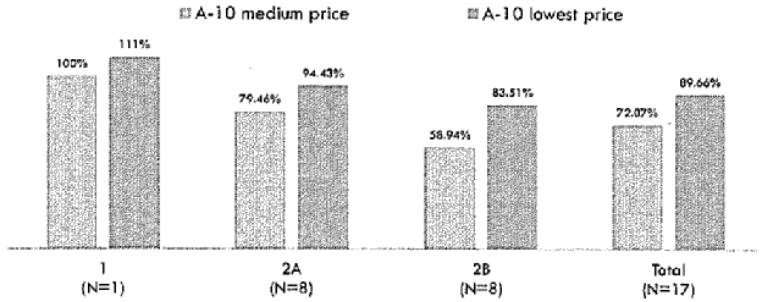
2014 (Jan.~Aug.)

Expert committee (items)

PBRS Joint meeting		Agree	Disagree	Total
	Agree	57	0	57 (86.4%)
	Disagree	4	5	9 (13.6%)
	Total	61 (92.5%)	5 (7.5%)	66 (100%)

Price of new drugs compared with A-10 reference countries

23



☐ New drugs listed during 2013/1/1~2014/06/01, not including domestic and those new drugs at self-cut price

30

Challenges

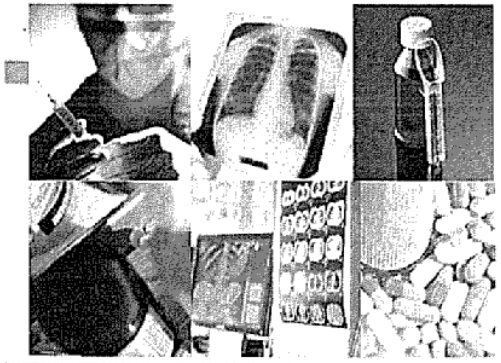
24

- ☐ Process control of PBRS Joint Meeting
- ☐ Reallocation of global budget and budget impact concern from healthcare providers
- ☐ Unbalance of medical information between representatives of the insured and healthcare provider

Conclusions

25

- Multiple participation
  - Involve more stakeholders to join PBRS Joint Meeting
- Increase transparency
  - Announced agenda and HTA report before PBRS Joint Meeting
- Introduce budget impact analysis
  - Through implementing HTA to determine budget impact for reasonable reallocating resources



衛生福利部
中央健康保險署

National Health Insurance (NHI) pricing formula in Japan

Improvement in methodology of pricing for new drugs and orphan drugs

October 31, 2014

Japan Pharmaceutical Manufacturers Association

Today's Topics

- Pharmaceutical industry of Japan
- Central Social Insurance Medical Council (CSIMC)
- Premium to promote the development of new drugs and eliminate off-label use
- NHI drug pricing formula for new drugs
- Recent cases
- Conclusion

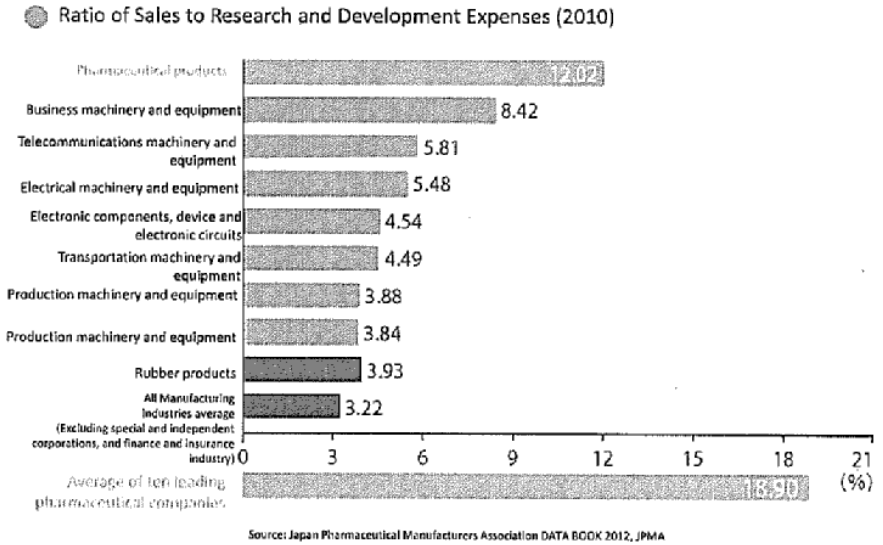
Summary of pharmaceutical industry in Japan

- **Number of pharmaceutical companies (2012 fiscal year)**[*1]: 349
  - Japan Pharmaceutical Manufacturers Association (JPMA) member companies (Research and development-oriented companies): 72[*4]
- **Number of employees (2012 fiscal year)** [*1]: 167,514
  - Vs total employees[*2]: 0.27%
- **Drug production revenue (2012 fiscal year)**[*3]: 6.9767 trillion yen
  - Production revenue versus GDP ratio: 1.48%
  - Prescription drugs value: 6.263 trillion yen (89.8%)

*1: 2012 fiscal year Pharmaceutical and medical device Industry Survey (Ministry of Health, Labor and Welfare) *2: 2012 fiscal year Labor force survey (Ministry of Internal Affairs and Communications) *3: 2012 Statistics of Production by Pharmaceutical Industry (Ministry of Health, Labor and Welfare) *4: As on April 1, 2014

Source: Transform the contribution of the drug industry and drugs

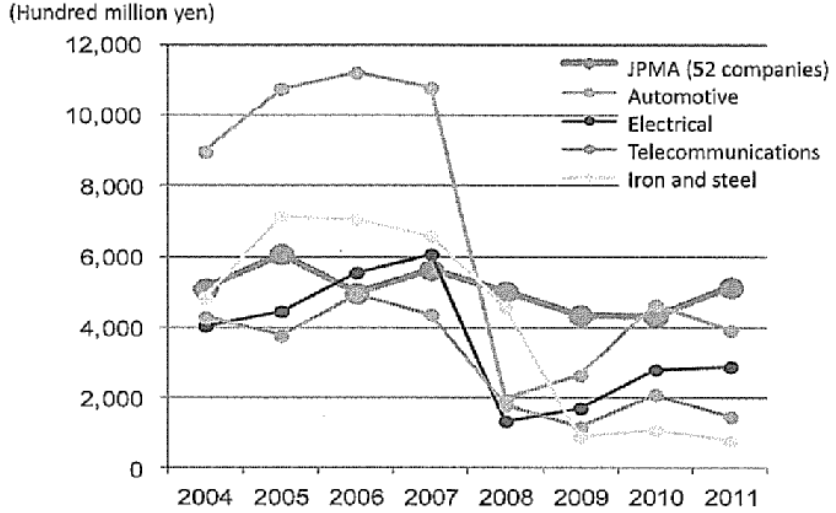
Research and development investment of top key industries



Source: Japan Pharmaceutical Manufacturers Association DATA BOOK 2012, JPMA

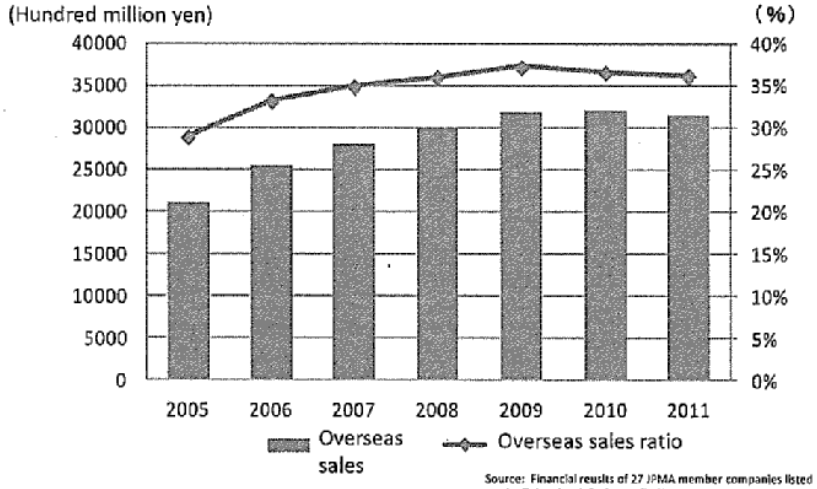
Stable high level tax bearing capacity

Transition of domestic tax payments of principal manufacturing industry



Source: Pharmaceutical industry vision 2013 Data Book Ministry of Health, Labor and Welfare Transformation

Overseas sales and transition of overseas ratio for Japanese companies



Source: Financial results of 27 JPMA member companies listed on the Tokyo Stock Exchange (TSE)
Prepared by: Office of Pharmaceutical Industry Research, Japan Pharmaceutical Manufacturers Association

Pharmaceutical industry vision 2013

Innovative new drugs from Japan contributing to the world's health

[Blockbuster products from Japan]

Position 2012	Position 2011	Product name	Company name	Drug efficacy	Sales (mil. $) 2,012	Sales (mil. $) 2011	Expansion rate
1	4	*Humira*	Abbott / Eisai	Rheumatoid arthritis treatment	9,611	8,216	17.0%
2	3	*Remicade*	J&J / Merck / Tanabe	Rheumatoid arthritis treatment	9,117	8,969	1.7%
3	6	*Enbrel*	Amgen / Pfizer	Rheumatoid arthritis treatment	8,512	7,877	8.1%
4	5	Seretide / Advair	GSK	Anti-asthma drugs	8,023	8,148	-1.5%
6	7	Crestor	Shionogi / AZ	Hypolipidemic agent	6,722	7,043	-4.6%
7	14	*Lantus*	Sanofi	Diabetes treatment drug	6,379	5,451	17.0%
10	15	Abilify	Otsuka / BMS	Schizophrenia treatment drug	5,433	5,102	6.5%
27	21	Blopress / Atacand	Takeda / AZ	Hypertension treatment drug	3,271	3,228	1.3%
30	31	Olmesartan	Daiichi Sankyo	Hypertension treatment drug	3,144	3,037	3.5%
41	43	Luprin / Lupron	Takeda / Abbott	Anti-cancer agents	2,250	2,327	-3.3%
42	34	Aciphex / Pariet	Eisai / J&J	Anti-ulcer agents	2,218	2,711	-18.2%
43	22	Actos	Takeda	Diabetes treatment drug	2,112	4,162	-49.3%
48	48	Prograf	Astellas	Immunosuppressive agent	1,917	1,991	-3.7%
61	37	Aricept	Eisai	Alzheimer's treatment drug	1,546	2,534	-39.0%
69	63	Takepron / Prevacid	Takeda	Anti-ulcer agents	1,440	1,512	-4.8%
80	94	Vesicare	Astellas	Hyperactive bladder drug	1,302	1,180	10.3%
100	102	MohrusTape / Pap	Hisamitsu	Anti-inflammatory agent	1,067	1,064	0.3%

New drugs from Japan

Source: "International Drug Information" (April 8, 2013 issue)

Central Social Insurance Medical Council (hereinafter referred to as CSIMC)

The price of new drugs is discussed and determined in a place open to the public called CSIMC.

CSIMC general meeting (January 22, 2014)

CSIMC members list (As on August 27th, 2014)

1. Payment side committee members

矢内　邦夫(全国健康保険協会東京支部長)
白川　修二(健康保険組合連合会専務理事)
花井　圭子(日本労働組合総連合会 総合政策局長)
花井　十伍(日本労働組合総連合会「患者本位の医療を確立する連絡会」委員)
石山　恵司(日本経済団体連合会社会保障委員会医療改革部会部会長代理)
田中　伸一(全日本海員組合副組合長)
榊原　純夫(愛知県半田市長)

2. Medical side committee members

鈴木　邦彦(日本医師会常任理事)
中川　俊男(日本医師会副会長)
松本　純一(日本医師会常任理事)
万代　恭嗣(日本病院会常任理事)
長瀬　輝諠(日本精神科病院協会副会長)
堀　　憲郎(日本歯科医師会常務理事)
安部　好弘(日本薬剤師会常務理事)

3. Public interest members

印南　一路(慶應義塾大学総合政策学部教授)
田辺　国昭(東京大学大学院法学政治学研究科教授)
西村　万里子(明治学院大学法学部教授)
野口　晴子(早稲田大学政治経済学術院教授)
松原　由美(明治安田生活福祉研究所主席研究員)
森田　朗　(国立社会保障・人口問題研究所所長)

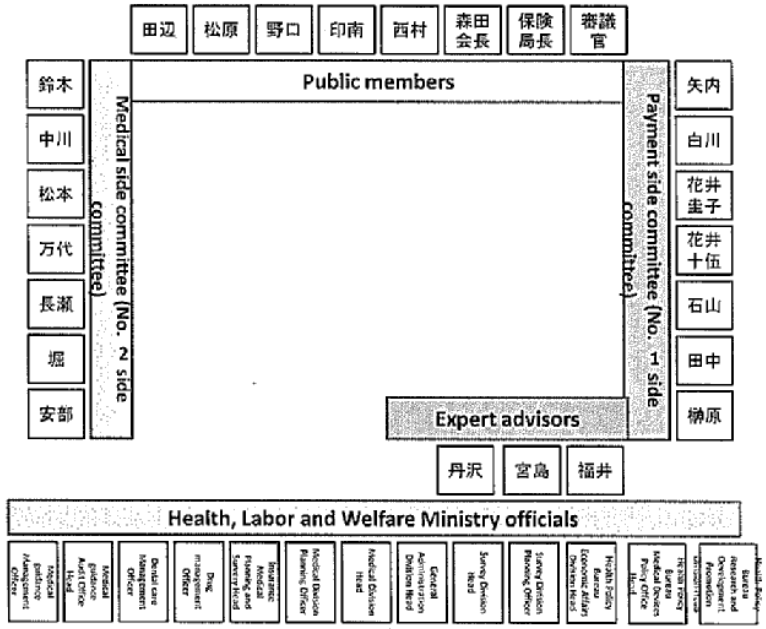
4. Expert advisors

藤原　忠彦(長野県川上村長)
福井　トシ子(日本看護協会常任理事)
宮島　喜文(日本臨床衛生検査技師会会長)
丹沢　秀樹(千葉大学医学部附属病院歯科・顎・口腔外科教授)

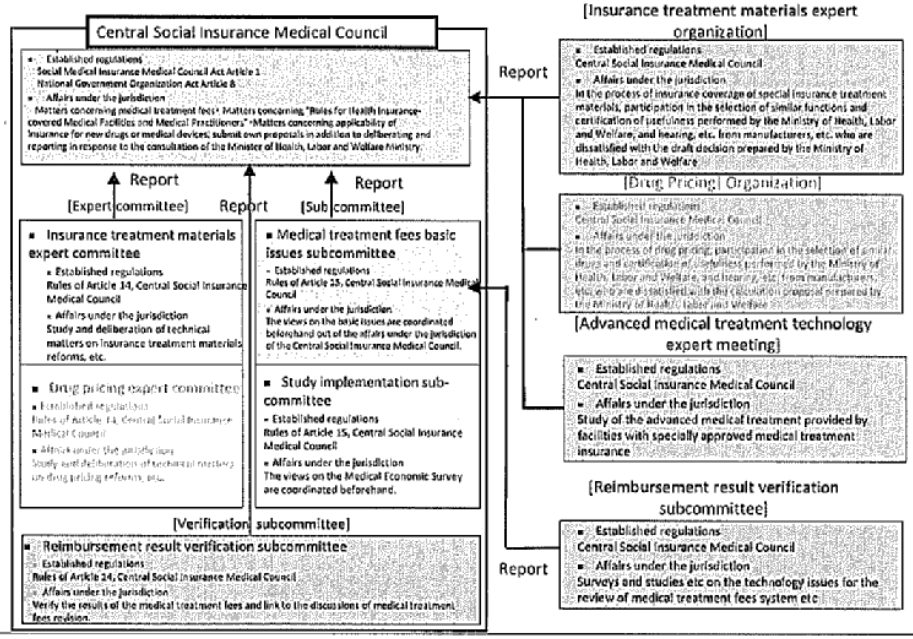
Drug pricing expert committee Expert advisors

加茂谷　佳明(塩野義製薬株式会社 常務執行役員)
土屋　裕(エーザイ株式会社代表執行役副社長)
吉村　恭彰(株式会社アステム代表取締役社長)
冨子　久仁子(テルモ株式会社取締役 上席執行役員)
田村　誠(アボットジャパン株式会社ガバメント アフェアーズバイスプレジデント)
十河　功二(株式会社イノメディックス統括営業本部 本部長代理)

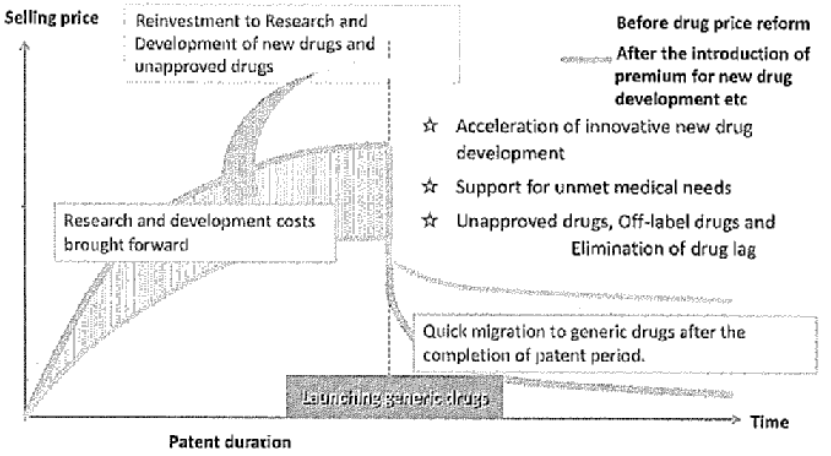
CSIMC General Assembly committee seating chart (As on October 8, 2014)



CSIMC organization chart

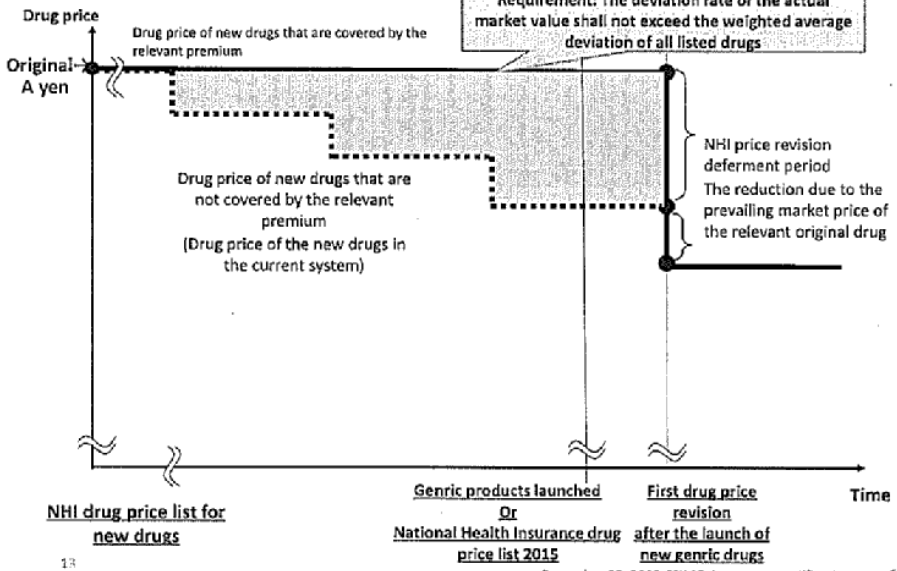


Concept of "premium to promote the development of new drugs and eliminate of off-label use"



The following development funds can be obtained more quickly by maintaining (premium) the drug price for new drugs during the patent period.
As a result, the development of new drugs and unapproved drugs is promoted and the needs of patients and medical professionals can be met quickly.

Example for drug pricing of new drugs covered by premium to promote the development of new drugs and eliminate off-label use



December 22, 2009 CSIMC document modification

13

Current state of Japan's pharmaceutical market

Number of articles and market share based on the classification of drug price standard list items.

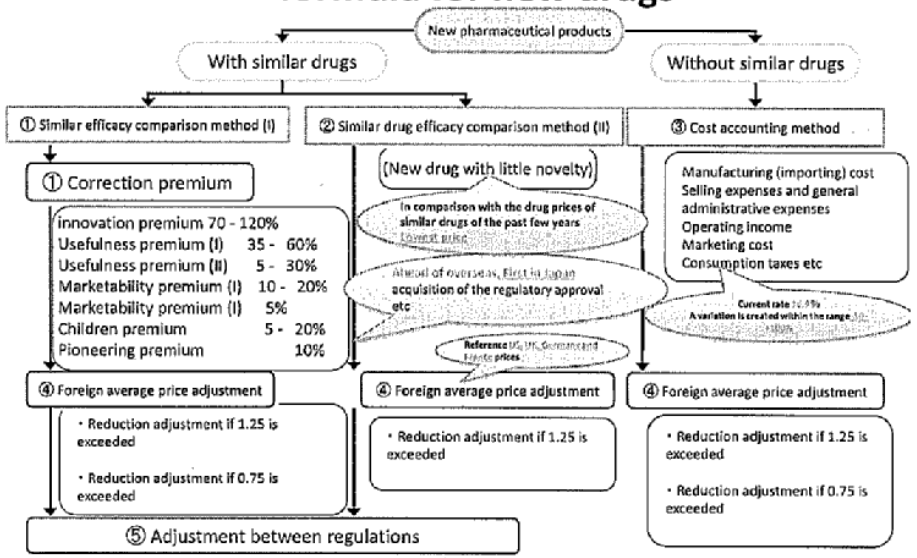
		Number of items	Quantity Share	Amount Share
Original drug	Generic drug not available	2,074	18.2%	49.3%
	Generic drug available	1,562	31.2%	31.7%
Generic drug		8,038	27.6%	11.1%
Other items		3,629	23.0%	8.0%

(Note) • Only number of items is as of April 2014
• Volume and revenue shares are based on the quantity and drug price at the time of survey in September 2013
• "Other items" are drugs (blood products) which have been approved before 1967 and cannot be separated into original drugs and generic drugs
• Share total need not be necessarily 100.0 since it is rounded off to 2 decimal places

Source : Ministry of Health, Labor and Welfare Japan

14

National Health Insurance (NHI) pricing formula for new drugs



(Note) Premium (5%) by adding the raw material cost of the kit characteristic parts after ⑤ of the above for highly useful kit products

① Similar drug efficacy comparison method (I)

~ Basic rules ~

- If similar drugs are available with same effectiveness, from the point of ensuring a fair competition in the market, the daily drug price is matched to the daily drug price of existing similar drugs. [Similar drug efficacy comparison method (I)]
  - As a rule, new drugs that are within 10 years after NHI drug price listing for which generic drugs have not been listed are used as the comparison drugs.

1 tablet = 50 yen
Daily 3 tablets

=

1 tablet = X yen
Daily 2 tablets

<Daily drug price matching>
50 yen X3 tablets = X yen X 2 tablets
X = 75 yen

Similar drugs refers to those drugs which have similarities when viewed from the following matters.
a Efficacy and effectiveness
b Pharmacological actions
c Composition and chemical structural formula
d Dosage form, dosage form classification, and dosage form and usage

- A premium correction is done to the above amount if high usefulness is observed for the relevant new drug after comparison with the similar drug.

[Innovation premium, Usefulness premium, Marketability premium, Children premium and Pioneering premium]

Innovation premium	70 - 120%	New action mechanism, high efficacy and safety, and improvement of disease treatment method
Usefulness premium	5 - 30%	High efficacy and safety, and improvement of disease treatment method
Marketability premium	5%, 10 - 20%	Orphan drug etc.
Children premium	5 - 20%	Matters pertaining to children have been explicitly included in the dosage and administration etc
Pioneering premium	10%	Obtained regulatory approval in Japan ahead of overseas

① Correction premium for similar drug efficacy comparison premium (I)

~ Basic rules ~

Innovation premium (70 - 120%)

Newly listed drugs meeting all of the following requirements
a Must have new action mechanism that is clinically useful.
b Must objectively show high usefulness and stability when compared to similar drugs.
c Improvement of the treatment methods for the disease or injury covered by the relevant newly listed drug must be shown objectively with the relevant newly listed drug.

Usefulness premium (I) (35 - 60%)

Newly listed drug satisfying two conditions out of the three conditions for innovation premium

Usefulness premium (II) (5 - 30%)

Newly listed drugs meeting any one of the following requirements
a Must have new action mechanism that is clinically useful.
b Must objectively show high usefulness and stability when compared to similar drugs.
c Improvement of the treatment methods for the disease or injury covered by the relevant newly listed drug must be shown objectively by the relevant newly listed drug.
d It must be objectively shown to have high medical usefulness compared to similar drugs by the improvement in the formulation.

Pioneering premium (10%)

Newly listed drugs meeting all of the following requirements
a Must have a different new mechanism of action compared to existing drugs that have been approved in either a foreign country (limited to United States, United Kingdom, Germany and France) or in Japan.
b. Drug which has obtained regulatory approval in Japan ahead of overseas.
c It must not be a drug that is expected to be distributed only in Japan and must have been confirmed overseas by either development status (including developmental planning) and clinical trial notification.
d The drug must have received innovation premium or usefulness premium (II).

+

Marketability premium (I) (10 - 20%)

Newly listed drugs meeting all of the following requirements
a It is a drug that can be used for rare disease based on the regulations of the Pharmaceutical Affairs Law, and the efficacy and effectiveness for the disease or injury covered must be the principal efficacy and effectiveness of the relevant newly listed drug.
b The comparison drug of the listed drug must not have been subject to the marketability premium (I).

Marketability premium (II) (5%)

Newly listed drugs meeting all of the following requirements
a The principal efficacy and effectiveness of the relevant newly listed product must correspond to the drug efficacy that is stipulated separately.
b The comparison drug of the listed drug must not have been subject to the marketability premium (I) or marketability premium (II).

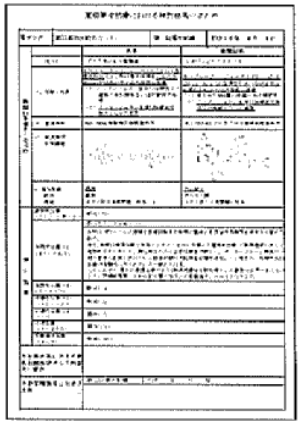
Children premium (5 - 20%)

Newly listed drugs meeting all of the following requirements.
However, this is excluded if clinical trials for pediatric efficacy have not been implemented in Japan.
a The principal efficacy and effectiveness or the relevant efficacy and effectiveness of the relevant newly listed product must explicitly include the usage and dosage of children (including young children, infants, newborns and low birth weight infants).
b The comparison drug of the listed drug must not have been subject to children premium.
(Note) If marketability premium (II) is also applicable, children premium is given priority.

Specific case A

Item: Daklinza 60mg
Constituent name: Daclatasvir Hydrochloride
Efficacy and Effectiveness: Chronic hepatitis C and compensated cirrhosis
Dosage and Administration : Generally, for adults 60mg of Daclatasvir is administered orally at one time once a day. The administration duration of this drug along with Asunaprevir is 24 weeks.

(From the documents of CSIMC April 27, 2014)



Specific case A

Pricing method: Similar drug efficacy comparison method (I)
Calculated drug price: 60mg 9,186.00 yen

Correction premium: Usefulness premium (I) 40%

<Basis>
This drug has been recognized to have a new action mechanism which is clinically useful **in directly inhibiting the proliferation of HCV virus.**

In addition, this drug has shown usefulness for patients who were disqualified, untreated or intolerant to Interferon therapy which is the standard treatment, **and** this drug makes treatment possible with oral administration alone **and does not require hospitalization as required by some of the patients during the initial administration period with Interferon therapy and therefore it is considered** that objective improvement of treatment method **has been shown**

(Omitted)

↓

<Quantitative evaluation>
Usefulness premium (I)
(5p + 3p) X 5% = 40%

(From the documents of CSIMC April 27, 2014)

② Similar drug efficacy comparison method (II)

~ Special rules ~

- For new drugs with little novelty, lowest price is used after comparison with the drug prices of similar drugs of the past few years.

[Similar drug efficacy comparison method (II)]

- For new drugs with little novelty: Those satisfying all the following conditions
  - Excluded from correction premium
  - Three or more similar drugs with same pharmacological action must exist
  - More than three years must have passed since the NHI drug price listing of a similar drug with the oldest pharmacological action

- The lower amount of ① or ② is used as a rule

① Cheapest daily drug price of the similar drug which has been listed in the past 6 years

② Average price of daily drug price of the similar drug which has been listed in the past 10 years

-If this exceeds -③ Premium amount (Drug price of the most similar drug) based on similar efficacy comparison method (I),

Further,

④ Cheapest daily drug price of the similar drug which has been listed in the past 10 years

⑤ Average price of daily drug price of the similar drug which has been listed in the past 15 years is calculated, and the lowest amount of ③ - ⑤ is considered.

③ NHI drug pricing formula for new drugs

~ Special rules ~

- If there are no similar drugs, cost of the raw materials and manufacturing are added. [Cost accounting method]

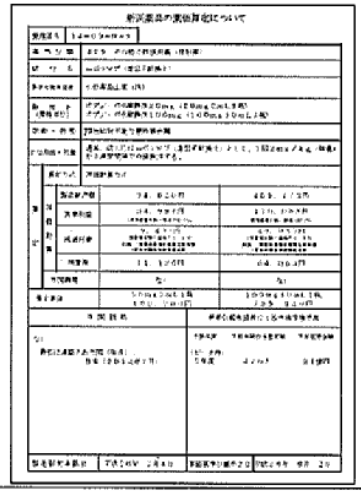
(Example)
① Raw material cost (Active ingredients, additives, containers and boxes)
② Labor cost (= 4,137 <Note 1> X Working hours)
③ Manufacturing cost (= ② X 3. 599 <Note 2>)
④ Product manufacturing (importing) cost
⑤ Selling expenses・research expenses (= (④ + ⑤ + ⑥) X 0. 462 <Note 2>)
⑥ Operating income (= (④ + ⑤ + ⑥) X 0. 169 <Note 2>)
⑦ Marketing cost (= (④ + ⑤ +⑥ + ⑦) X 0. 068 <Note 3>)
⑧ Consumption tax (8%)
Total: Calculated drug price

Strike a better balance for operating margin (current 16.9%) in the range -50 - +100% depending on the degree of innovativeness, usefulness and safety when compared with existing treatment

<Note 1> Labor cost unit price: "Monthly Labor Survey" (Ministry of Health, Labor and Welfare) Average from 2010 to 2012
<Note 1> Labor expense ratio, selling expenses and general administrative expenses ratio, and operating margin:
"Handbook of financial data of industries" (Japan Development Bank) 2010 - 2012 average
<Note 3> "Marketing cost ratio: Survey of the Prescription Pharmaceuticals Industry of Japan" Economic Affairs Division, Health Policy Bureau, Ministry of Health, Labor and Welfare) 2010 - 2012 average
As a rule the underlined values uses the average coefficient of pharmaceutical manufacturing industry (The most recent average value that can be obtained at the end of the previous fiscal year)

Specific case B

Brand Name: Opdivo drip injection 20mg/100mg
Constituent name: Nivolumab (Genetical recombination)
Efficacy and effectiveness: Malignant melanoma for which resection is not possible
Calculation method: Cost accounting method Premium results: operating margin 60%
(From the documents of CSIMC April 27, 2014)



28

Specific case B

Pricing method: Cost accounting method
Calculated drug price: 20mg 150,200 yen
100mg 729,849 yen (Adult 50kg: 34,755 yen)

Operating margin:
Average operating margin (16.9%) X 160% = 27.0%

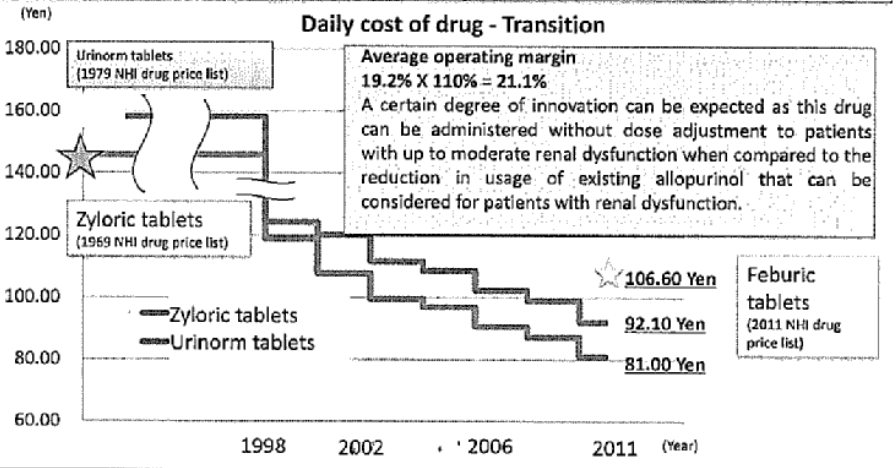
<Basis>
This drug has obtained regulatory approval in Japan ahead of the world, and has a new action mechanism with which it inhibits the proliferation of tumors by increasing the activation of cancer antigen-specific T cell and cytotoxic activity against cancer cells.

In the Japan Phase II trials, patients with advanced or recurrent malignant melanoma that cannot be subject to radical resection and with chemotherapy history which included Dacarbazine were covered, lower limit (13.4%) of the 90% confidence interval of the response rate (22.9%) for this drug based on the central review considered as the primary endpoint was above the threshold response rate (12.5%) which was set based on the clinical trial results of Dacarbazine, and the usefulness was confirmed.
In addition, it is considered reasonable to apply the +60% of the average operating margin since interferon beta and Dacarbazine after approval in the mid 80's have been evaluated to be clinically significant as a treatment option for malignant melanoma.

(From the documents of CSIMC April 27th 2014)

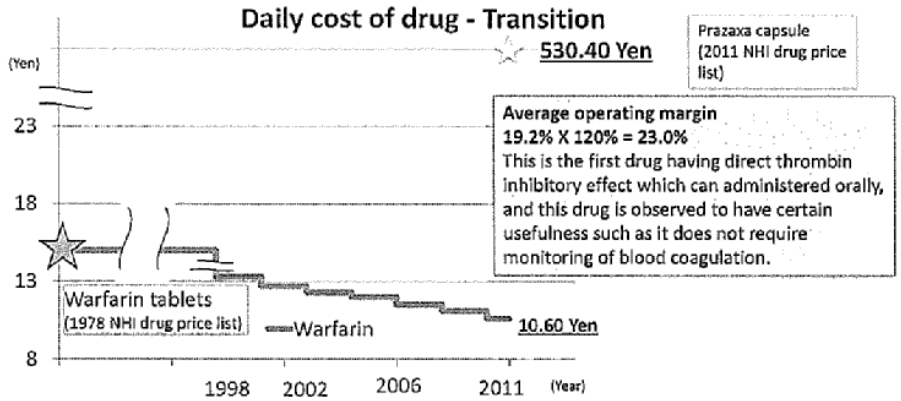
Specific case C

■ **Feburic tablets (Febuxostat)** **Efficacy and Effectiveness: Gout, hyperuricemia**
In this zone, no new drugs have been developed for almost 30 to 40 years following the listing of Allopurinol and Benzbromarone. This is a case in which the rule of "As a rule, new drugs that are within 10 years after NHI drug price listing for which generic drugs have not been listed are used as the comparison drugs" was applied and calculation has been done using the cost accounting format.



Specific case D

■ Prazaxa capsules (Dabigatran etexilate methanesulfonate)
Efficacy and Effectiveness: Inhibits the onset of thrombosis
In this zone, no new drugs have been developed for almost 30 years following the listing of the similar drug Warfarin potassium. This is a case in which the rule of "As a rule, new drugs that are within 10 years after NHI drug price listing for which generic drugs have not been listed are used as the comparison drugs" was applied and calculation has been done using the cost accounting format.



Conclusion

National Health Insurance (NHI) new drug pricing - Background

- Research and development type enterprises are present in Japan, the country is also boosting the development of Japanese companies from the point of view of industrial development
- The new drug development premium was proposed by the industry for the first time and it was introduced
- The drug prices for new drugs is calculated within the balance of the entire drug price system
- In principle, new drug prices are calculated matching to the prevailing market price (matched to the daily drug price)
- On the other hand, new drugs not in the long development zone are calculated without referring to the drug price of old pharmaceutical products
- Attempted to make the premium of usefulness system and adjustment premium of operating margin transparent

Policy for reimbursing orphan drugs

Shang-Ping Chen
Researcher
Division of Medical Review and Pharmaceutical Benefits
National Health Insurance Administration (NHIA), Taiwan

Outline

- The Rare Disease Prevention and Medication Act
- Organizations and statutory duties for rare disease prevention
- Designation of rare disease and orphan drugs
- Benefits of orphan drugs designation
- Reimbursement and logistic for orphan drugs
- Challenge and future vision

The Rare Disease Prevention and Medication Act

- Promulgated in 2000 and became the 5th country to make a law especial for rare disease prevention in the world
- Aims of the act
  - To prevent the rare disease
  - To early detect rare disease
  - To enhance healthcare for rare disease patients
  - To support rare disease patients for necessary treatment and nourishment
  - To promote and protect the aforementioned R&D and suppliers

Organizations and statutory duties for rare disease prevention

MOHW		
Health Promotion Administration	Food and Drug Administration	National Health Insurance Administration
• Designation • Prevention & promotion • Medical subsidization • R&D • Regulation	• Designation • Approval of orphan drugs • Publication for special nutrient food • Research promotion for orphan drugs research • Regulation	• Reimbursement • List in catastrophic disease field (Subsidized co-payment)

Determination of rare disease and orphan drugs

Committee of Rare Disease and Orphan Drugs (CRDOD)

- Designate rare disease
- Comments on approval of orphan drugs and special nutrient food

Medical Section, CRDOD

Comments on designate rare disease
- 201 rare diseases designated by 2013

Pharmaceutical Section, CRDOD

Comments on approval of orphan drugs and special nutrient food
- 86 orphan drugs listed and 40 special nutrient drugs published by 2013

Benefits of orphan drugs designation

- Reduce the fee for registration and review
- Simplify approval procedures, ex. cancel the adopting certificate of A-10 countries
- Drug certificate valid for 10 years, registration exclusive for same ingredients within terms
- Special application for prior use is allowed before approval, NHI reimbursement is applicable as well

Processes of listing orphan drug

Proprietor
requests for orphan drug appraisal

↓

Pharmaceutical Section, Committee of Rare Disease and Orphan Drugs
evaluates submission

→ **TFDA**
notifies proprietor to apply for NHI reimbursement

↓

Committee of Rare Disease and Orphan Drugs
review

Proprietor
submits for NHI reimbursement

↓

TFDA
orphan drug designation

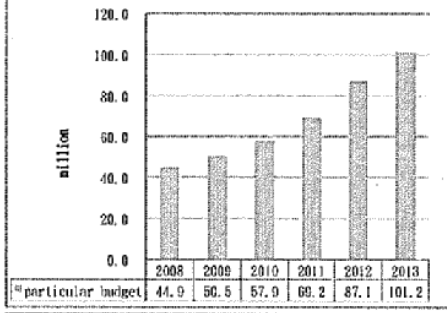
PBRS Joint Meeting
discussed by all stakeholders

↓

NHIA
Orphan drug listed & reimbursed

Logistics for reimbursing orphan drugs

particular budget for health care



*particular budget	2008	2009	2010	2011	2012	2013
	44.9	50.5	57.9	69.2	87.1	101.2

Co-payment

Co-payment subsidized

Beneficial pricing for orphan drugs

- *Pricing rule for new drugs
- *Cost based pricing(up to extra 25% of marketing fee)
- *International reference pricing

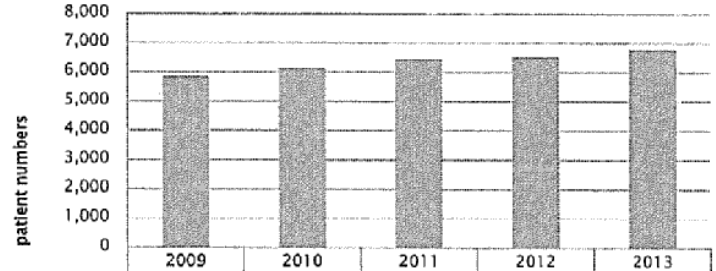
Monthly claimed expenditure ($US)	Upper limit
≦16,667	Medium price of A-10 countries*1.2
> 16,667 & ≦33,333	Medium price of A-10 countries*1.1
> 33,333	Medium price of A-10 countries

Reimbursement of orphan drugs(1)

- 75 orphan drugs are reimbursed by NHI, 27 items of them (36%) without approval.
- The claimed expense of those items without approval is around 50 million, which is half of the total expense for orphan drugs.

Reimbursement of orphan drugs(2)

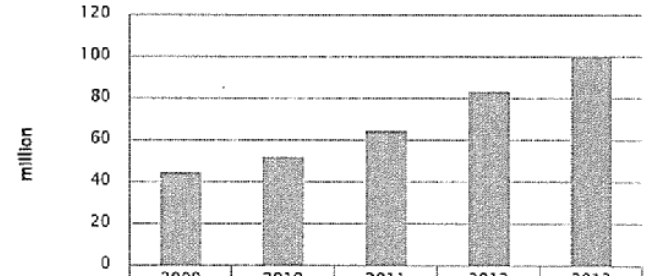
- There are 6,783 rare disease patients in 2013, which is 0.029% of the insured(around 23 million population)



	2009	2010	2011	2012	2013
patient numbers	5,869	6,151	6,459	6,543	6,783
growth rate		4.80%	5.00%	1.30%	3.70%

Reimbursement of orphan drugs(3)

- The expense of orphan drugs is around 100 million in 2013, which is 1.2% of total healthcare expenditure.
- If we calculate the average personal premium as $650 (NTD) , we have already pulled premiums from 150 thousands insured to cover the expense of treating rare disease in 2013.



	2009	2010	2011	2012	2013
expense of orphan drugs	44.4	51.8	64.4	83.5	100.2
growth rate		16.70%	24.40%	29.60%	20.00%

Challenges (1)

- Once the orphan drugs are designated, they are allowed to apply for reimbursement before approval. The suppliers are unwilling to complete the registration.
- 27 items of 75 orphan drugs reimbursed by NHI are still without approval. Only 4 of the 27 items are not approved in US, EU, Canada or Australia.

Challenges (2)

- Physicians and pharmacists can not get enough information of therapeutic effect and adverse effect of certain orphans drugs since the registration is not completed.
- The Drug Injury Relief Act is not applied for unapproved drugs, patient's right may be diluted in such case, and medical dispute may occur then.

Challenges (3)

- Monopoly market of orphan drugs
  - the drug company usually offers compassionate therapy before getting NHI reimbursed, and then cut supply afterword to raise humanity issues
  - Drug company appeals for increasing drug price.

Future vision

- Horizontal collaboration between medicine and insurance authorities
  - Simplify procedures to facilitate completing registration
- Principles for reimbursement
  - Reallocate budget
  - Conduct cost-effectiveness (ICER) analysis

Thanks for your attention!

31/ Oct/ 2014

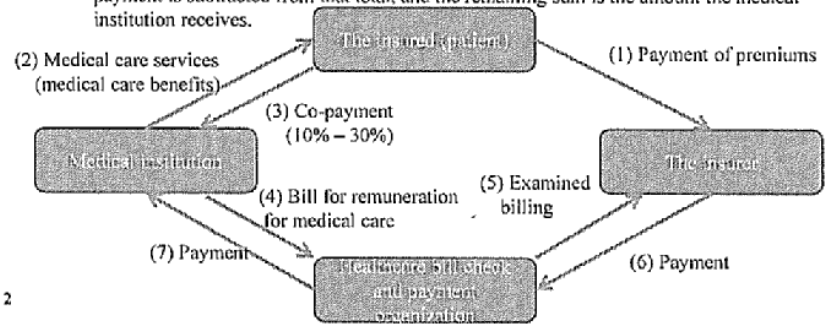
Separation of Dispensing and Prescribing Drugs in Japan

Katsuaki Ura
General Affairs Division
Pharmaceutical and Food Safety Bureau
Ministry of Health, Labour and Welfare

An Illustration of Health Care Services in Japan Provided by Health Insurance

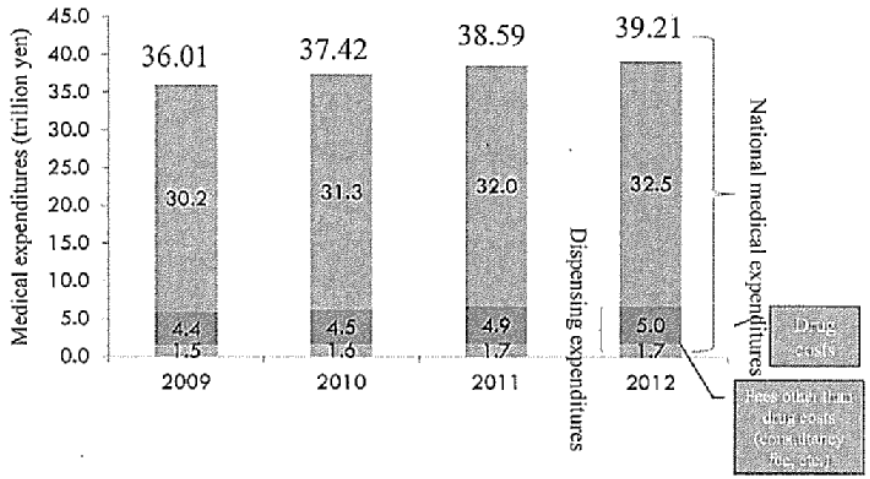
- Remuneration for medical care is determined for each medical practice and paid based on the medical practice carried out. It is a so-called "fee-for-service system."
- Remuneration for medical care is broadly classified into medical, dental, and pharmaceutical.

Example: If hospitalized for your appendix, items such as the fee for the first medical exam, hospitalization charges according to the hospitalization period, surgery costs for the appendix, laboratory fees, and pharmaceutical charges are added up. The patient's co-payment is subtracted from that total, and the remaining sum is the amount the medical institution receives.



2

Shifts in National Medical Expenditures and Pharmaceutical Expenditures



3 Source: Medical expenditure totals/Dispensing expenditures: National Medical Expenditures (Ministry of Health, Labour and Welfare)
Pharmaceutical charges for dispensing expenditures: Multiplication of dispensing expenditures by percentages of pharmaceutical charges in "Shifts in Recent Dispensing Expenditures (computerized processing)" (Ministry of Health, Labour and Welfare)

Legal Provisions

4

Medical Practitioners' Act (Act No. 201 of 1948) (excerpt)

Article 22 Where a medical practitioner finds it necessary to dispense and administer a medicine as a part of a patient's treatment, he/she shall issue a prescription to the patient or a person caring for the patient; however, this shall not apply where the patient or a person caring for the patient reports that it is not necessary to issue a prescription, or in any of the following cases:

(i) – (vii) (omitted)

Pharmacists Act (Act No. 146 of 1960) (excerpt)

Article 23 A pharmacist may dispense medicine for the purpose of sale or provision thereof only according to a prescription issued by a medical practitioner, dental practitioner or veterinarian.

2 (omitted)

Separation of Medical Practice and Drug Dispensing

Objective:
Medical practitioners and pharmacists share duties in each specialization to improve the quality of medical treatment.

Process:
(1) Medical practitioners provide medical services and issue prescriptions to patients.
(2) On that basis, pharmacists at pharmacies dispense drugs based on those prescriptions.

Merits:
(1) A medical practitioner can freely issue prescriptions without being restricted to the medicines he/she has on hand.
(2) A patient can confirm the prescription contents because the prescription is issued to the patient.
(3) A pharmacist can double check prescription contents from a position independent from the medical practitioner.
(4) Even if a patients is seeking consultation at several medical institutions, it is possible to confirm the interaction of medicines and prevent overlapping medications by dispensing medications at a single pharmacy (regularly visited pharmacy).
(5) Outpatient dispensing duties are reduced, and the ward activities of hospital pharmacists are expedited.

The Effectiveness of Separation of Medical Practice and Drug Dispensing (specific, easy-to-understand examples)

Case 1:
PL granulated medicine is prescribed to a patient receiving treatment for glaucoma. The prescription drug is cancelled due to questions about the prescription.

Case 2:
A medical examination is conducted because of recurring inflammation of the bladder, and a prescription issued. When previously examined, Meiact was prescribed, but there was a drug rash and the prescription was changed to Cravit. Because the history of drug rash was overlooked and Meiact was again prescribed, the pharmacist inquired about the prescription and it was changed to Cravit.

➡ Regular pharmacy functions link to the provision of appropriate medicines to patients.

Details of Separation of Medical Practice and Drug Dispensing (1)

7

September 1949

- The following recommendations are issued by a delegation of the American Pharmacists Association
  - All possible efforts should be made toward the early realization of the separation of medical practice and drug dispensing through legal, educational, and other means.
  - The job of the medical practitioner should be restricted to diagnosis, issuance of prescriptions, and emergency administration of medicines.
  - The job of the pharmacist should be to secure superior medicines, lawfully store them, and fulfill prescriptions issued by medical practitioners.
- Later, a review was carried out by a "sanshikai," a consortium comprised of doctors, dentists, and pharmacists, but no conclusion was reached. An investigating committee was established within the Ministry of Health and Welfare.

(From *Annotations to the Pharmacists Act 5th Revision* (Jiho))

Details of Separation of Medical Practice and Drug Dispensing (2)

8

February 1951

- The following report was submitted by the investigating committee to the Minister of Health, Labour and Welfare.
  - Obligate medical practitioners and dental practitioners to issue prescriptions.
  - Drugs dispensed by pharmacists must be in accordance with a prescription from a doctor, dentist, or veterinarian.

June 1951

- The "law revising portions of the Medical Practitioners' Act, Dental Practitioners Act, and Pharmacists Act" (the so-called Separation of Medical Practice and Drug Dispensing Act) is established (enforced from April 1, 1956).

Why the Separation of Medical Practice and Drug Dispensing is Presently Advancing (1)

9

- October 1971
  - Based on the recognition that issues concerning the separation of medical practice and drug dispensing will not be resolved simply by the heretofore assertion of the forced division of labor, the Japan Pharmaceutical Association decided on a policy shift from forced division of labor to discretionary division of labor.
- May 1973
  - In the 1974 revision to remuneration for medical care,
    - Prescription charges were raised (10 pts. → 50 pts.),

    and a foundation was established to promote the separation of medical practice and drug dispensing, meaning the issuance of outside hospital prescriptions and dispensing of drugs at health insurance pharmacies.
  - Even so, the separation of medical practice and drug dispensing did not thereafter advance to a great degree.
- In 1992 and 1998, prescription charges were raised.

16

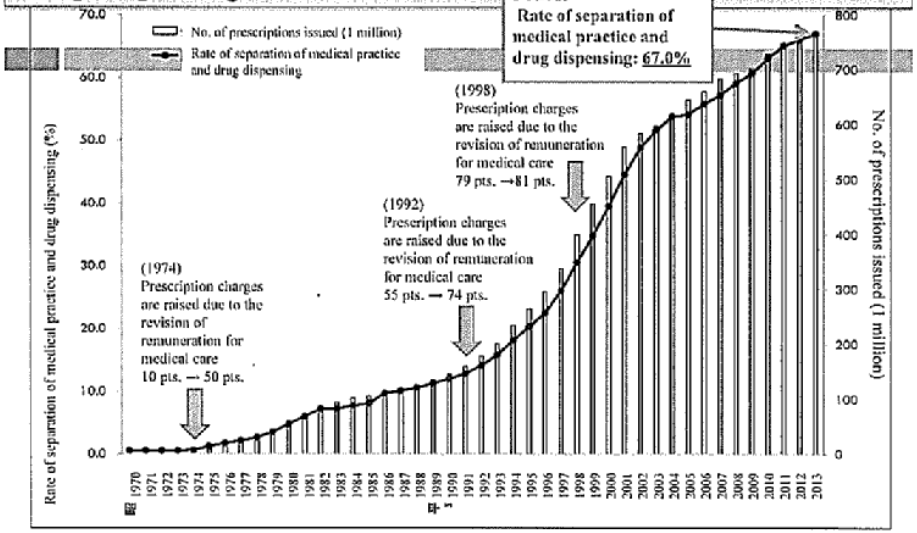
Why the Separation of Medical Practice and Drug Dispensing is Presently Advancing (2)

10

- From 1975
  - There was a growing opinion denouncing medical treatment that overprescribes medicines, and it was pointed to as the source of price disparities in medicines.
- Therefore, the Ministry of Health, Labour and Welfare successively reviewed the methods for drug price revisions from the 1980s. Drug price disparities were reduced, and doctors' technical fees were raised.
  - Drug price disparities (estimated rate of deviation)
    - 1991: 23.1%

      → 2009: 8.4%
- As a result, the issuance of outside hospital prescriptions gradually advanced.

Annual Shifts in the Rate of Separation of Medical Practice and Drug Dispensing



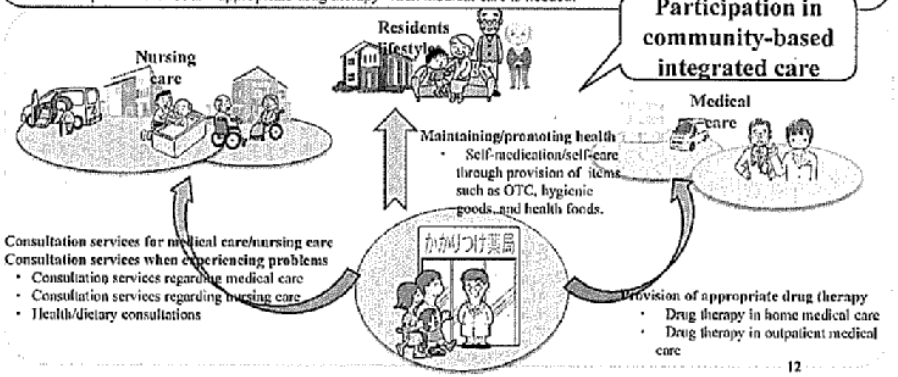
* Rate of separation of medical practice and drug dispensing (%) = No. of prescriptions issued (No. received at pharmacies) / No. of days of medical consultations (outside of hospitalization) × Rate of prescribed medical medicines ÷ No. of days of dental consultations x Rate of prescribed dental medicines × 100

An Illustration of the Functions of Pharmacies/Pharmacists in the Community-based Integrated Care System

- As an expert in drugs, they bear primary responsibility for providing general drug therapy for residents (outpatient, home medical care).
- They provide items such as OTC, hygienic goods, and health foods, and secure health through promotion of proper use to maintain/improve residents' health.
- They function as the initial access point allowing the most casual consultation, and are the first to field residents' inquiries regarding medical care/nursing care and various inquiries for advice from residents (consultations on health, dietary, nursing, medical care, etc.; they provide appropriate consultation services, etc.).

- While keeping in contact with the attending doctor, etc., the above is integrally provided to community residents to maintain/promote health and contribute to the assurance of safe living for residents through the provision of consultations when problems exist and appropriate drug therapy when medical care is needed.

Participation in community-based integrated care



12

Publication of Desired Functions in Pharmacies and Their Ideal Form

- "Desired Functions in Pharmacies and Their Ideal Form" was compiled by a Ministry of Health, Labour and Wealth Grants-in-Aid' project as a guideline for the promotion of the best regularly visited pharmacies based on changes in recent social circumstances (published by the Japanese Society of Pharmaceutical Health Care and Sciences (JSPHCS), January 2014).
  - "Assessment Study on Team Medical Care Undertaken by Pharmacists. Studies on Regional Medical Care, and Outcomes" (Primary Researcher: Masato Yasuhara, professor, Tokyo Medical and Dental University, Department of Hospital Pharmacy, University Hospital of Medicine; president, JSPHCS)
- The Ministry of Health, Labour and Welfare also made the above known to each municipality.
- Major points

Basic concept regarding desired functions in pharmacies/pharmacists

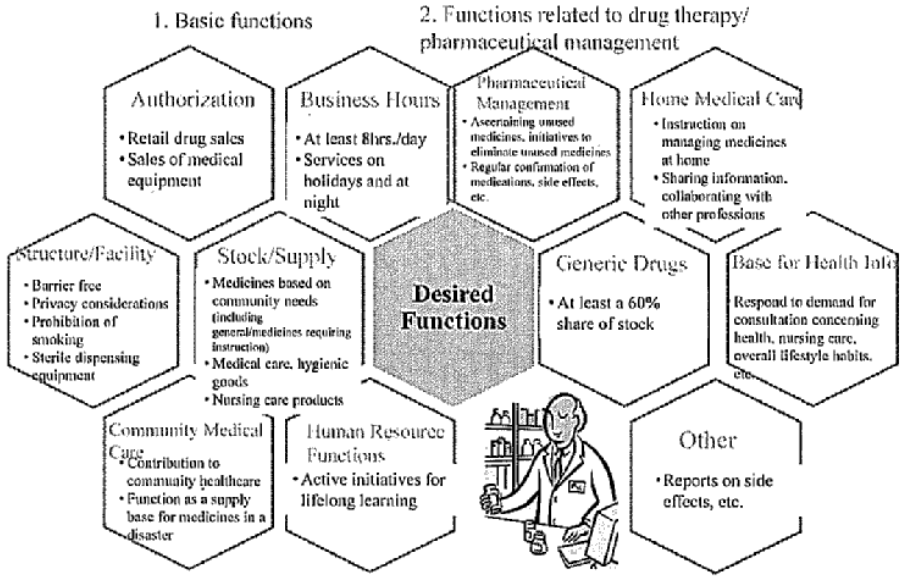
1. They are expected to bear responsibility for medical care offering optimum drug therapy.
2. From the perspective of ensuring/improving the quality of medical care and ensuring the safety of medical care, they are called on to proactively engage in team medical treatment in collaboration with medical facilities, etc.
3. In home medical care, they should ensure/enhance systems in the community that supply medicines, etc. and provide suitable support for taking medicines.
4. They are called on to not only fulfill the role as a base offering medicines and medical care/hygienic goods, but also more actively contribute to the promotion of generic drug usage, and the optimization of medical care that eliminates unused medications.
5. To promote self-medication, they should actively execute the role of serving as a base for community-based health information.
6. They should take responsibility for overall pharmaceutical management based on lifestyle habits, rather than just a patient's medical history.

⇒ This indicates matters under a basic concept that should be ensured or taken on in regard to fundamental systems that pharmacies should provide and the ideal state of pharmaceutical management.

2b

- Regarding publication of "Desired Functions in Pharmacies and Their Ideal Form," Japanese Society of Pharmaceutical Health Care and Sciences
  http://www.jsphcs.jp/cont/14/0107-1.html

Primary Functions Desired in Pharmacies



Promoting Health Information Bases that Utilize Pharmacies/Pharmacists

Requested Amount for FY2015: 250.795 million yen

• Revised Japan Revitalization Strategy 2014 mid-to-short term progress schedule (June 24, 2014 Cabinet decision: excerpt)
(1) Promote self-medication that utilizes pharmacies/pharmacists
(2) Review a framework that publicizes to residents pharmacies that have enhanced consultation systems, facilities, etc.

Problems with Current Pharmacies:

- Many do not handle general medicines
- Most pharmacists' businesses are dispensing based on prescriptions
- A lack of initiatives to become a base for community health development
- Lack of sufficient understanding of separation of medical practice and drug dispensing

Promoting model projects that utilize pharmacies/pharmacists

Outsourcing Contractors: Prefectures (re-entrustment possible)

○ Developing projects based on FY2014 projects
Enhancement/development of effective projects for self-medication

Examples of FY2014 Model Projects:
◇ Establishment of consultation points for the proper use of general medicines, etc., and creation/distribution of educational materials on proper use
◇ Holding seminars, etc. for the promotion of self-medication (dietary habits, no smoking, heart health, elderly, alcohol, home medical care)
◇ Provision of a system for health checks, such as blood pressure
◇ Popularization of "electronic medicine handbooks" that aid proper use of drugs, health, development, etc.

Project Examples:
Based on FY2014 projects,
• Improvement of recognized problems
• Enlargement of project scale (enlargement of content and number of targeted pharmacies, collaboration with other prefectures, etc.)
• Introduction of projects in other prefectures, etc.

Reviewing frameworks that publicize to residents pharmacies that have enhanced consultation systems, facilities, etc.

○ Pharmacies suitable as health information bases
Creation of standards for Health Navigation Stations (provisional name), etc.

Summary of Health Navigation Stations (provisional name)
(1) A base for supplying all medicines
(2) Support/consulting functions for creating health among residents
(3) Functions for residents to conduct health checks on their own to lead to medical examinations
(4) Collaboration with various professions
(5) Initiatives for home medical care
Proposed Criteria
• System/facility for health consultations
• Sales system for general medicines/medicines requiring instruction
• Collaboration with other organizations, etc.

Nationally develop even more effective initiatives to promote self-medication among Japanese by enabling citizens to easily access Health Navigation Stations (provisional name).