



# **Program to Promote Use of Generic Drugs in Japan**

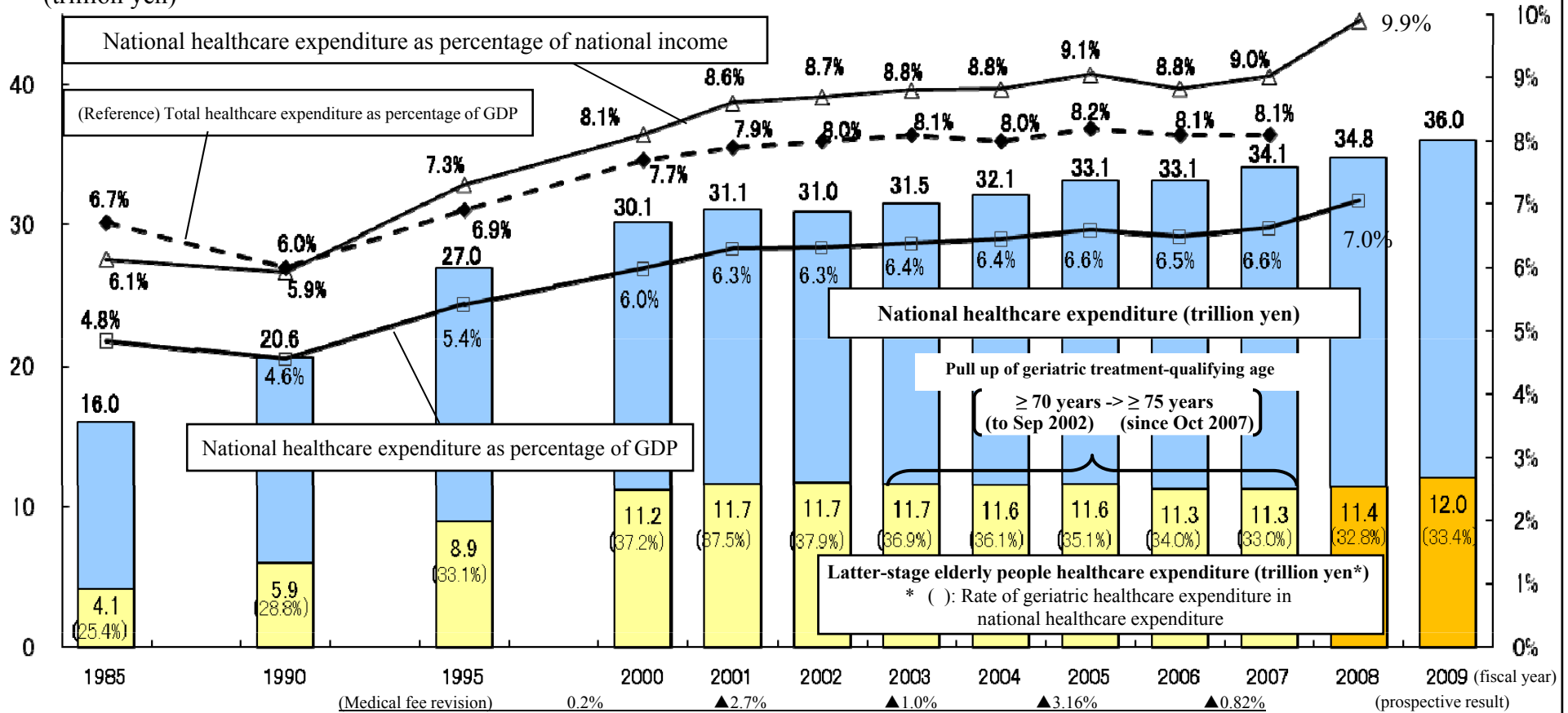
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Tsuyoshi Matsuno  
Economic Affairs Division, Health Policy Bureau,  
Ministry of Health, Labour and Welfare

\* A Japanese translation is the official edition.

# Trend of healthcare expenditure

(trillion yen)



<Increase rate from previous fiscal year>

	1985 (S60)	1990 (H2)	1995 (H7)	2000 (H12)	2001 (H13)	2002 (H14)	2003 (H15)	2004 (H16)	2005 (H17)	2006 (H18)	2007 (H19)	2008 (H20)	2009 (H21)
National healthcare expenditure	6.1	4.5	4.5	▲1.8	3.2	▲0.5	1.9	1.8	3.2	0.0	3.0	2.0	3.5
Latter-stage elderly people healthcare expenditure	12.7	6.6	9.3	▲5.1	4.1	0.6	▲0.7	▲0.7	0.6	▲3.3	0.1	1.2	5.5
National income	7.2	8.1	▲0.3	2.0	▲2.8	▲1.5	0.7	1.6	0.5	2.6	0.9	▲7.1	-
GDP	7.2	8.6	1.7	0.9	▲2.1	▲0.8	0.8	1.0	0.9	1.5	0.9	▲4.2	-

Note 1 National income and GDP: national economic accounting (Dec 2009).

The total healthcare expenditure is the healthcare expenditure used on comparing the healthcare expenditures of OECD countries and has a wider range than the national healthcare expenditure since preventive services, etc. are included. In 2008, the healthcare expenditure is 9.0% of GDP in average in the OECD countries.

Note 2 The national healthcare expenditure and the latter-stage elderly people healthcare expenditure in fiscal 2009 are the prospective results calculated by multiplying each value in fiscal 2008 by the increase rate. The increase rate from the previous fiscal year in 2009 is the increase rate of approximate healthcare expenditure

## Meaning of use promotion of follower drugs (generic drugs)

In the current situation where the healthcare expenditure is increasing,

- the efforts to reduce the supply costs by promotion of efficiency, etc. are necessary
- with securing the necessary services and aiming at quality maintenance / improvement

### \* What is generic drug?

A generic drug is a drug which contains **the same active ingredient** at the same content, which is administered through **the same route**, which has basically **the same indication and which is used with the same dosage and administration** as the forerunner drug. Therefore, a generic drug is equivalent to the **forerunner drug in efficacy and safety** and can be positioned as an **interchangeable drug**.



By promoting use of generic drugs,

**(1) each patient's self burden of drug expense can be reduced**

**(2) more efficient healthcare can be achieved without deteriorating the quality of healthcare.**

## Program for improvement of quality and efficiency of healthcare / nursing-care services (summary)

Effort	Major goal/target	Policy measures
<b>(2) Viewpoint of improving quality and efficiency of services</b>		
<b>8. Use promotion of follower drugs</b>	<ul style="list-style-type: none"> <li>▪ To increase the share of follower drugs (16.8% on the amount base in fiscal 2004) to <b>30% or more (doubling from the present) by fiscal 2012</b></li> </ul>	<ul style="list-style-type: none"> <li>○ Thorough instructions to follower drug manufacturers about information provision and stable supply, information provision and enlightening to people and healthcare professionals about equivalency to forerunner drugs, etc.</li> <li>○ Investigation of effective measures for use promotion based on the results of checking the effect of prescription format change</li> </ul>

**This program was included in “Large-Boned Policy 2007” and decided at the Cabinet Meeting in June 2007.**



# Dissemination of generic drugs (follower drugs)



## ○ Consciousness of healthcare professionals

- (1) Healthcare professionals are generally uneasy about the quality and stable supply and do not feel sufficient necessity of using generic drugs in place of familiar forerunner drugs.
- (2) Burden of assortment of many products at pharmacy, difficulty in selection of generic drugs (for a certain antihypertensive drug, 34 companies are supplying generic drugs)

## ○ Consciousness of patients

- (1) Awareness of generic drugs has been improved to some extent .
- (2) There is a merit of lower drug expenses for patients. But, on the other hand, a sufficient feeling of security that familiar forerunner drugs can be safely switched to follower drugs has not been obtained from healthcare professionals.



## Major countermeasures



Goal: Achievement of **30%** amount share of generic drugs by fiscal 2012 (**22.8%** as of September 2011)

(1) Measures mainly targeting medical institutions and pharmacies



▪ **“Action program for promotion of easy-mind use of follower drugs”**

(Specific efforts related to environment arrangements for securement of stable supply , quality and information provision system and use promotion)

▪ **Environmental arrangement related to medical fee** (Gradual appreciation of pharmacies depending on the amount rate of prescribed follower drugs and environment arrangement for prescription switching, appreciation of medical institutions using follower drugs proactively, insurance physicians’ obligation to check patient’s intention to select follower drugs, etc.

▪ **Disclosure of list of follower drugs adopted at National Hospital Organizations**

(2) Measures mainly targeting patients



▪ **Holding of “generic drug easy-mind use promotion seminar”**

▪ **Delivery of generic drug-wishing card**

▪ **Notification of cost difference on switching to generic drugs**

▪ **Publicity activities by preparation and delivery of posters and leaflets, etc.**

# Action program for promotion of easy-mind use of follower drugs (outline)

Toward the government's goal of "30% or more amount share of follower drugs (doubling from the present percent) by fiscal 2012", the efforts to be made by the Government shall be clarified in relation to **(1) stable supply, (2) quality securement, (3) information provision by follower drug manufacturers, (4) environment arrangement for use promotion and, (5) items related to healthcare insurance system** so that patients and healthcare professionals can use follower drugs with easy mind.

## (1) Stable supply

Opinion from clinical practice site

Example: The time from order to delivery is sometimes long.

Government

### ○ Thorough instructions for stable supply

- Reception of complaints from healthcare professionals, disclosure of instructions to manufacturers, etc.

Follower drug manufacturer

### ● Shortening the time until delivery

- 100 % delivery to wholesalers by the next day (within fiscal 2007)
- In a case of no stocks at wholesalers, 75% delivery to wholesalers within the day (within fiscal 2008)

### ● Stock securement

- In-house stock / distribution stock: At least one-month portion (within 2007) • Zero products out of stock (within fiscal 2009)

## (2) Quality securement

Opinion from clinical practice site

Example: Some follower drugs may be different from the forerunner drug in dissolution and blood concentration achieved.

Government

### ○ Test/analysis conduct and result disclosure related to follower drug quality

- Conduct of **impurity test** targeting injectable preparations
- **Collection and assortment of research articles** related to follower drug quality, **investigations of quality-related opinions presented to the "Follower Drug Consultation Window"**, and the conduct of **test/analysis** as necessary

Follower drug manufacturer

### ○ Expansion of simultaneous vigilance/instruction and result disclosure

- GMP-based instruction through on-site inspection by **Prefectural Government and Central Government**
- **Expansion of products designated for testing**

### ● Quality test/analysis conduct and result disclosure

- By-batch conduct of product test (within fiscal 2007)
- Also the tests not required as conditions for approval (such as long-term storage test) are to be started, if not started yet, within the fiscal year (within fiscal 2007).

### ● Survey of relevant literatures

- The industry association shall survey and evaluate the follower drug-related literatures and take necessary measures (within fiscal 2007).

### (3) Information provision by follower drug manufacturer

Opinion from clinical practice site

Example:

- No MR's visits
- Relying on the forerunner manufacturer for information provision like saying "Ask the forerunner manufacturer"



Government

Follower drug manufacturer

#### ○ Instructions toward improvement of package insert

- The package insert shall describe additives, bioequivalence study data, stability study data, contact information for asking literatures, etc.
- **Revision by the end of March 2008 -> Follower drug manufacturers shall finish by December 2007.**

#### ○ Instruction toward reinforcing the information provision system of follower drug manufacturer

- Reinforcing the system to assort and evaluate the research and development data, collected ADR information and relevant literatures and provide information healthcare professionals

#### ● Information provision to healthcare professionals

- Posting the test data, ADR data, etc. in the home page, prompt responses to requests for materials (within fiscal 2007)

### (4) Environment arrangement for use promotion

Government

#### ○ Set-up of prefecture-level committee

- To set up a committee consisting of healthcare professionals and prefectural government officers for preparation/dissemination/enlightenment of use promotion measures at prefecture level

Follower drug manufacturer

#### ○ Dissemination and enlightening with posters and pamphlets

- Preparation and delivery of posters and pamphlets for healthcare professionals and people (from fiscal 2007)

#### ● Delivery of "Generic Drug Q & A" to medical institutions / newspaper advertisement of it

### (5) Items related to healthcare insurance system

Previous efforts

#### ○ Appreciation of prescription including a follower drug in medical fee (from fiscal 2002)

- **Appreciation in dispensing fee in a case where a follower drug is dispensed** under the agreement of the patient obtained after providing the information on follower drug quality in addition to the information on the price difference between the forerunner drug and the follower drug to the patient in writing (from fiscal 2006)

- **The prescription format was revised again to enable prescribing a follower drug in a case where there is no signature of physician in the box of "No change allowed"** (from fiscal 2008).

- **At pharmacy, gradual appreciation in dispensing fee depending on rate of prescribed amount of follower drugs** (from fiscal 2010)

- **At medical institution, appreciation in medical fee in a case where the system to use follower drugs proactively is established** (from 2010)

- **The MHLW ordinances, etc. specified insurance pharmacist's obligations to make explanations related to follower drugs to patients and make efforts to dispense follower drugs as well as insurance physician's obligation to check patient's intention to use a follower drug** (from 2010)



# Conduct status of “Action program for promotion of easy-mind use of follower drugs” (summary)

July 29 2011

- For the major items raised in the “Action program for promotion of easy-mind use of follower drugs” (enacted on October 15 2007), the conduct status is shown below (as of the end of March 2011)
- For the effort items of follower drug manufacturers, the conduct status at each member company of the Japan Generic Medicines Association (JGMA) was summarized under cooperation of JMGA (number of target companies: 43, survey period: April 1 2010 to March 31 2011)

## Efforts of follower drug manufacturers

	Effort item	Effort content in the action program	Conduct status
Stable supply	Shortening the time until delivery	In case of no stock at wholesaler, 75% within-day delivery to the wholesaler (end of fiscal 2008)	○ Number of events needing urgent delivery: 826 Among those, number of events with successful within-day delivery: 820 (99.3%)
	Stock securement	Zero products out of stock (end of fiscal 2009)	○ Occurrence of “out of stock” 6 companies, 14 events (accumulation in 1 year) * The number of events of “out of stock” is decreasing surely (2008: 14 companies, 34 events; 2009: 10 companies, 22 events), but further efforts will be made toward achievement of the goal.
Quality securement	Conduct of quality test, etc.	The tests not required as conditions for approval (such as long-term storage test) are to be 100% started, if not started yet, within the fiscal year and the test results are to be provided per request of healthcare professionals, etc. (end of fiscal 2007)	○ Number of products to be subjected to long-term storage test 5,177 products (all started) Among those, number of products for which the test was finished 3,064 products (59%) ○ Number of products to be subjected to stability test in non-packaged state 3,149 products (all started) Among those, number of products for which the test was finished 3,089 products (98%)
	Securement of dissolution at the time of quality reevaluation	For the products designated to undergo quality reevaluation, it will be confirmed periodically that the dissolution profile of such product is equivalent to that of the standard preparation for quality reevaluation, and the test results will be provided promptly per request of healthcare professionals.	○ Number of products to be subjected to quality reevaluation 1,892 products Among those, number of products for which dissolution profile was confirmed 1,881 products (99%) Among those, number of products for which dissolution profile is being confirmed 11 products (1%)
Information provision	Information provision to healthcare professionals	For interview form and compounding change test data, to secure prompt responses to requests for materials including posting in the company’s own home page (end of fiscal 2008)	○ For 8 information items raised in the action program including the interview form and compounding change test data, 100% information provision system was secured for material requests from healthcare professionals. ○ Operation of “Generic Drug Information Provision System” was started, and the system enabling prompt and smoother information provision was secured.

## Efforts of government

	Effort item	Conduct status
Item related to quality securement	Conduct of tests related to impurities contained in injectable preparations among follower drugs, collection and assortment of research articles related to follower drug quality, and conduct of necessary tests/analyses	○ Based on the quality-related research articles, dissolution tests were conducted at the National Institute of Health Sciences and others, and the test results were announced in the home page.
Environment arrangement related to use promotion	<ul style="list-style-type: none"> <li>• Preparation of posters and others contributing to dissemination of follower drugs</li> <li>• Enactment of use promotion measures at the prefecture level</li> <li>• Promotion of sharing the follower drug list used at the district level, among healthcare professionals</li> </ul>	<ul style="list-style-type: none"> <li>○ Public announcement through the government internet television</li> <li>○ Committees were set up in 42 prefectures, and deliberations and efforts related to use promotion of follower drugs were performed.</li> <li>○ About the examples of advanced efforts in prefectures, the contents and effects were surveyed and studied.</li> <li>○ In 11 prefectures, the “Follower Drug Adoption Know-How Dissemination Program” was performed to share the follower drug adoption standards in each district.</li> </ul>



## **[(1) Stable supply ]**

### Example efforts related to stable supply

#### **Shortening the time to delivery**

**(Goal : At least 75% delivery within the day by March 2009)**

Latter half of fiscal 2007(the first fiscal year of the action program)

Rate of within-day delivery among the requests for urgent delivery - **54.7%**



Fiscal 2010: Improved to **99.3%**!

#### **To eliminate products out of stock**

**(Goal : Zero products out of stock by March 2010)**

Latter half of fiscal 2007 37 products of 9 companies (in a 6-month period)



Fiscal 2010

**14 products of 6 companies** (in 12-month period)

## [(1) Stable supply ]

# Major examples of “out of stock” seen actually

### (1) Injectable Preparation A

(Cause) There was a flaw in data management of laboratory at the overseas manufacturing site, and product release was voluntarily stopped until the completion of investigation. => (Major preventive measure) Grasping the data management status of the

(Duration of no supply) About one month overseas manufacturing site and close communication/coordination

### (2) Tablet Preparation B

(Cause) The same as Injectable Preparation A => (Major preventive measure) Grasping the data management status of the

(Duration of no supply) About three months overseas manufacturing site and close communication/coordination

### (3) Injectable Preparation C

(Cause) The order volume exceeded the capacity of freeze-drying machine. => (Major preventive measure) Establishment of in-

(Duration of no supply) About half month house liaison system

### (4) Capsule Preparation D

(Cause) Approval was delayed due to a flaw in procedures to change the drug product manufacturing site.

(Duration of no supply) About half month => (Major preventive measure) Action on changing the approval contents

### (5) Slow-release Tablet Preparation E

(Cause) Difficulty in obtaining raw materials => (Major preventive measure) Securement of alternative supply

(Duration of no supply) About half month source for raw materials

### (6) Ophthalmic Solution F

(Cause) Delay of manufacturing due to component breakdown of manufacturing equipment => (Major preventive measure) Maintenance/inspection of

(Duration of no supply) About half month manufacturing facility

**When an alternative product of another company is available, the ordering party shall make arrangements to promptly secure the alternative product before falling in the state of “out of stock”.**

**[(1) Stable supply ]**

# Countermeasures toward stable supply

## Efforts of Japan Generic Medicines (JGA)

- Set-up of Product Inventory Manager Liaison Committee
- Measures to secure stable supply of raw materials such as drug substance
- Disclosure of information on supply
  - Posting the effort-taking status in the home page of JGA
  - Disclosure of information on supply of each product
- Exemplification of events easily resulting in “out of stock”
- Preparation and revision of “Points to Consider” for prevention of “out of stock”

(From the material prepared by JGA)

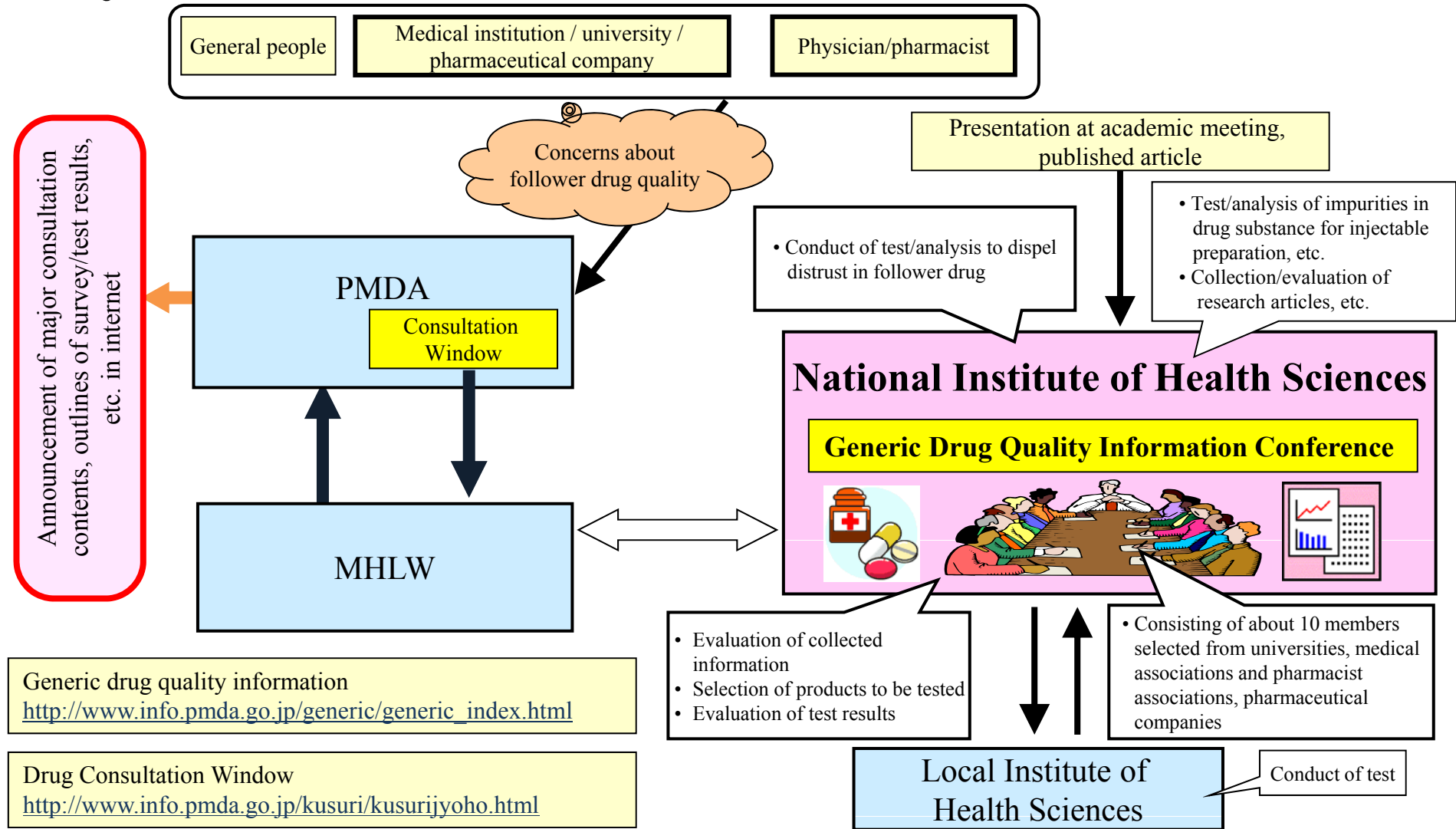
## [(2) Quality securement]

### ○ Opinions related to generic drug quality expressed at the meeting of Central Social Insurance Medical Council

- It is all that we request the MHLW to make further efforts to secure the follower drug quality at the same level as the forerunner drug quality.
- Physicians are concerned about the quality of follower drugs. Some patients say that “if the quality is equivalent, a lower price is better”.
- The problem in follower drugs is efficacy. Since the efficacy is not sufficiently examined, 31% of physicians have a sense of distrust.
- The final difference in stability due to difference in solid-phase synthesis may result in by-batch differences and data showing ineffectiveness in spite of the equivalent results obtained at the time of approval.
- Physicians will be convinced of the quality if the data are presented in comparison with non-active substance. We would like the MHLW to sufficiently present correct data of equivalency and quality.
- The number of problematic cases handled at the meeting of Japanese Society of Clinical Pharmacology and Therapeutics is also decreasing. If there is a problem with follower drugs, it may be good for us to receive explanations on each occasion.
- It is difficult to scientifically show the rate of follower drugs doubted in efficacy since clinical studies are necessary. When even one follower drug gives bad impression, physicians will have bad impression about the entire follower drugs.
- How about making the follower drug manufacturer describe that “the contained excipient is not the same between this drug and the forerunner drug” in the package insert of the follower drug.

## [(2) Quality securement]

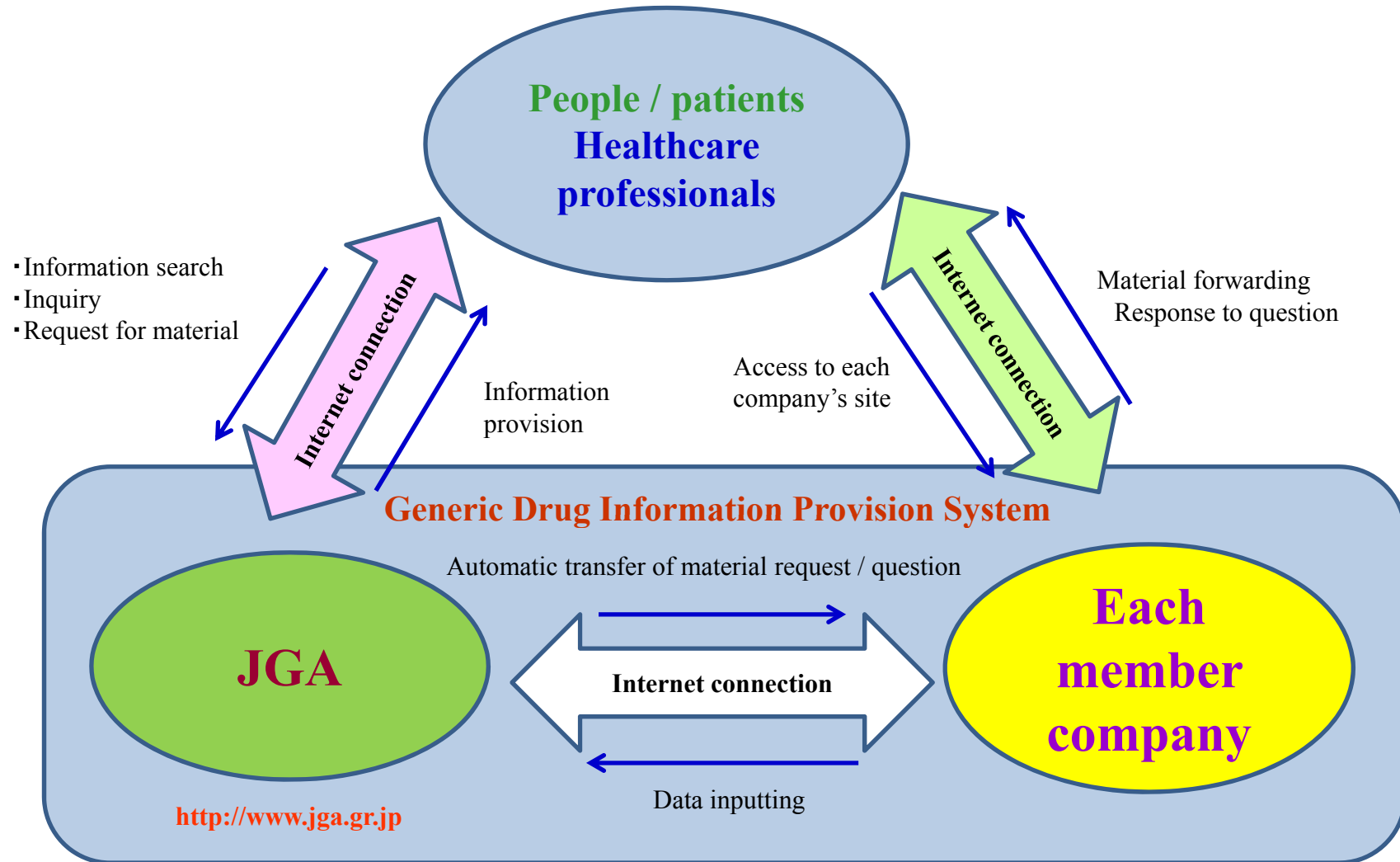
### Quality securement by conduct of test/analysis of generic drugs



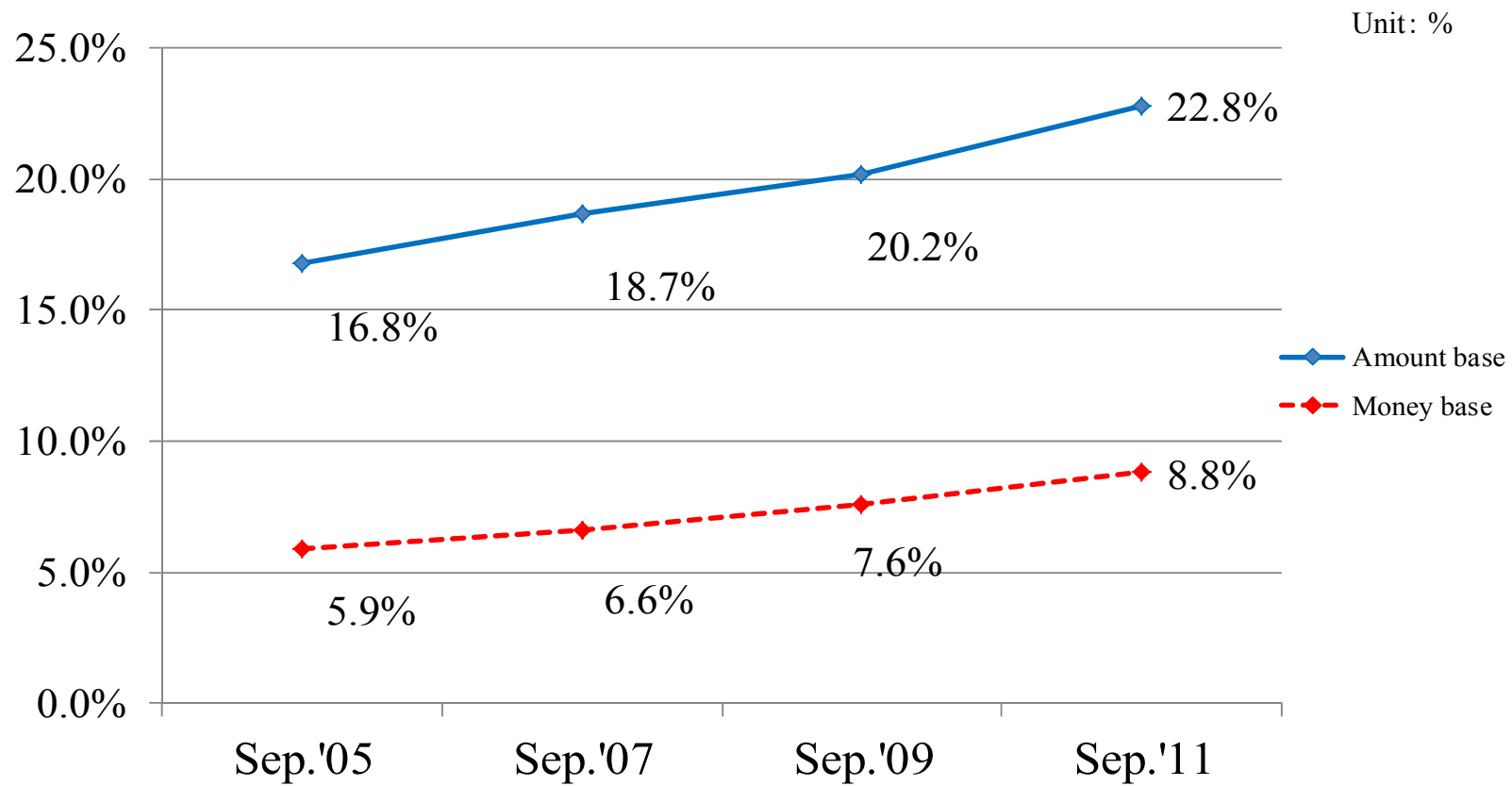
Scientific analysis, test/examination, evaluation => Formation of trust basis

### [(3) Information provision by generic drug manufacturer ]

## Generic Drug Information Provision System of JGA



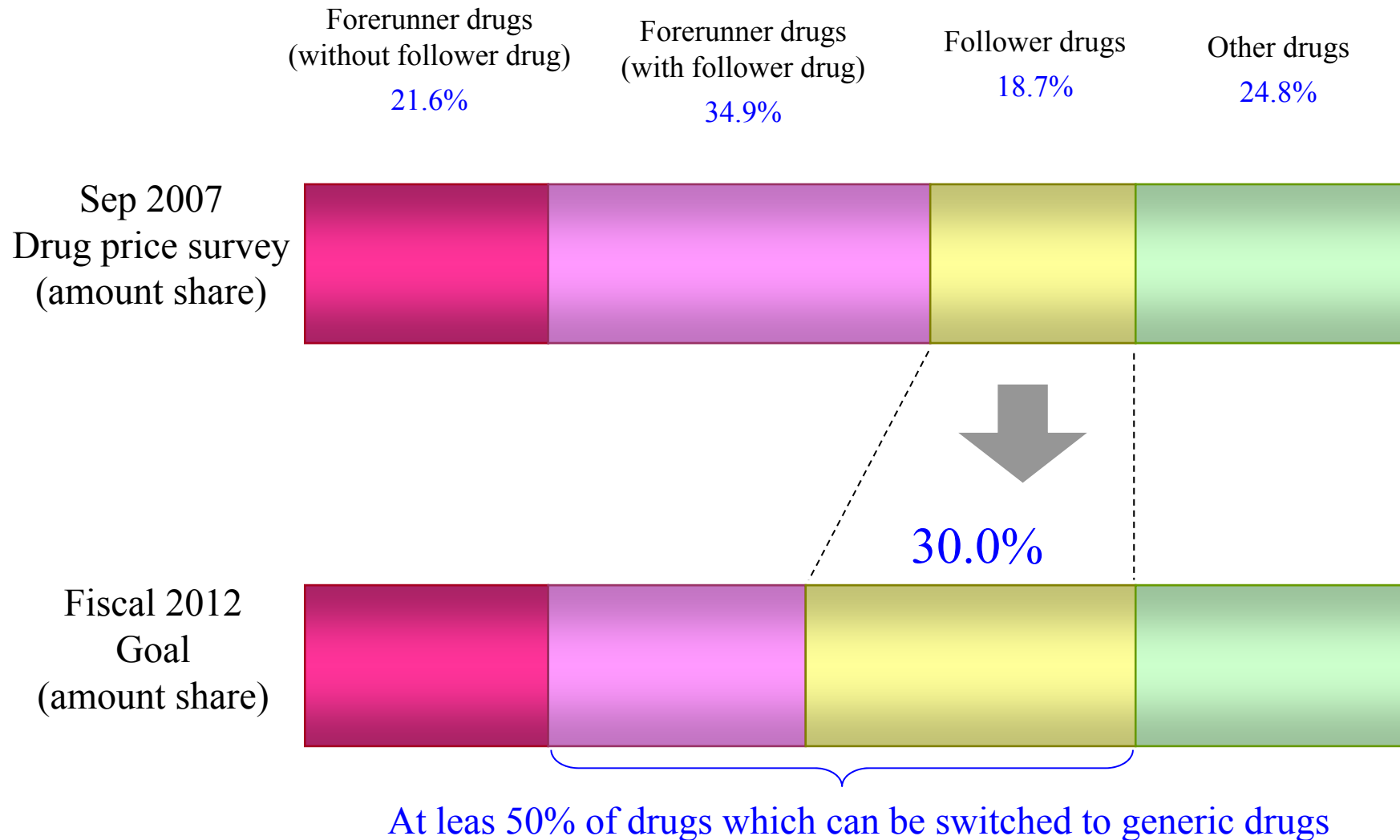
## Changes of generic drug market share



Survey by MHLW



# Goal of generic drug use promotion



\* Other drugs: Drugs approved in or before 1967, Kampo extract preparations, crude drugs, biological preparations (vaccines, blood preparations), JP drugs

# Environment arrangement for use promotion of follower drugs (outline)

## Detailed contents

### **1 Review of premium for follower drug dispensing system in basic dispensing fee of insurance pharmacy**

The requisite for premium, i.e., use rate of follower drugs (amount base) will be changed from the conventional “not less than 20%”, “not less than 25%” and “not less than 30%” to “not less than 22%”, “not less than 30%” and “not less than 35%”, and the appreciation rate will also be graded.

### **2 Information provision related to follower drugs utilizing the Drug Information Provision Sheet**

When the information on follower drugs (presence/absence, prices and inventory information of follower drugs) is provided with the “Drug Information Provision Sheet” at a pharmacy, appreciation will be made in the pharmaceutical management fee.

### **3 Appreciation of the system to proactively use follower drugs at medical institutions**

To the conventional requisite for premium (numerical rate of follower drugs in adopted drugs: not less than 20%), appreciation of “not less than 30%” will be added.

### **4 Promotion of prescription with nonproprietary name, change of prescription format, etc.**

- To promote prescription with nonproprietary name, when physicians issue prescriptions.
- To change the current prescription format so that it can be shown clearly for each drug whether switching to a follower drug is allowed .

### **5 Quality securement of follower drugs**

- (1) To prepare scientific opinions on follower drugs for healthcare professionals and people
- (2) To make proactive information provision for the discussion results at the Generic Drug Quality Information Conference

(Prepared according to the handouts at the meeting of Central Social Insurance Medical Council held on Dec 21 2011)

## Information provision related to follower drugs utilizing the Drug Information Provision Sheet

### ○ Conventional problems

- The “Notification of cost reduction by using generic drug” performed by the insurer has shown a certain level of effect, but the number of patients receiving it actually is still small.
- As the trigger which actually drove the patients to switching to follower drugs, the explanations by the pharmacists and the advertisements of follower drugs account for a high rate.
- On the other hand, some of the patients who wish switching to follower drugs at a pharmacy do not know that “there are no generic drugs for the drug concerned” or that “a follower drug has already been prescribed”.

### ○ New Countermeasures



- ◆ As the measure to improve information provision related to follower drugs, the information provision utilizing the “Drug Information Provision Sheet” handed to patients at an insurance pharmacy will be appreciated as a requisite for premium in dispensing fee.
- ◆ The information related to follower drugs includes the following:  
(1) the presence/absence of follower , (2) price, (3) inventory information

## Promotion of prescription with nonproprietary name

In order to further promote use of follower drugs and reduce the burden of stock management of follower drugs at an insurance pharmacy, a new premium will be set for physician's prescription with the nonproprietary name issued for drugs with follower drugs.

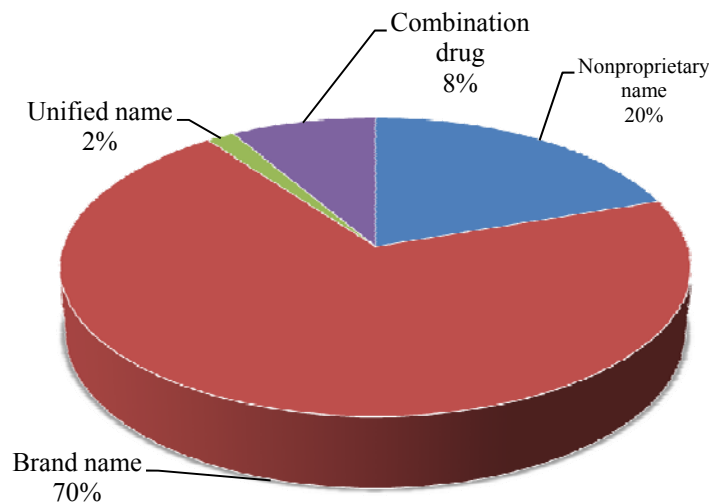
Current system	Proposed revision
[Prescription fee]	[Prescription fee]
1 A case where 7 or more kinds of drugs are administered (except drugs administered transiently for less than two weeks) 40 points	1 A case where 7 or more kinds of drugs are administered (except drugs administered transiently for less than two weeks) 40 points
2 Other than 1 above 68 points	2 Other than 1 above 68 points
	(Addition of Note) <u>In a case where a prescription including a nonproprietary name is issued, 2 points will be added for each issue of the prescription.</u>

# Rate of follower drugs having a brand name based on the nonproprietary name

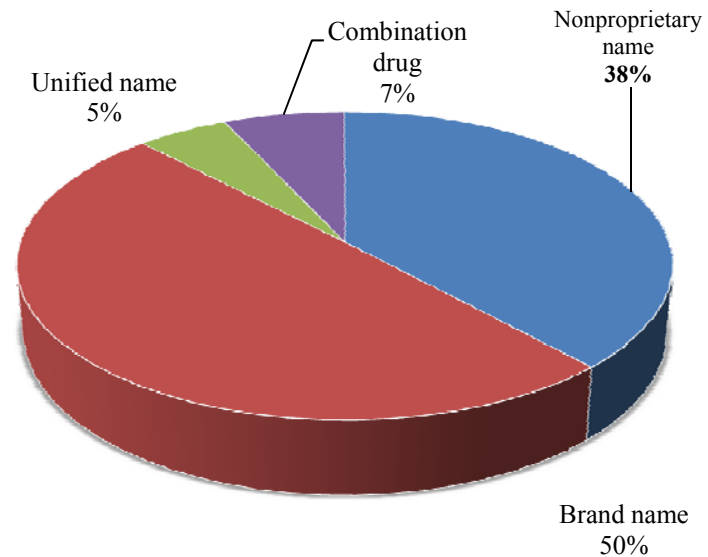
(Survey by Japan Generic Medicines Association)

Among the follower drugs in medical fee, the rate of those having a brand name based on “nonproprietary name” is increasing, being 38% at present.

## As of June 2008



## As of October 2011



	June 2008		October 2011	
	Number of products	Share	Number of products	Share
Nonproprietary name	1,324	20%	2,946	38%
Brand name	4,687	70%	3,835	50%
Unified name	110	2%	404	5%
Combination drug	570	8%	530	7%
Total	6,691	100%	7,715	100%

# Social Security / Tax Integrated Reform Draft (Extract)

(Decided on January 6 2012 by Government / Ruling Party Social Security Reform Headquarter)

## Chapter 3 Specific Reform Contents (Reform Item and Process)

**3. Healthcare・nursing-care (2) (Reinforcement of safety net function of healthcare /nursing-care insurance through reinforcement of insurer function and benefit prioritization, low-income class measures)**

**(9) Further promotion of use of follower drugs, review of patient's burden of drug cost, etc.**

- **To prepare a road map for promotion of follower drugs and take comprehensive measures for use promotion such as appreciation in medical fee calculation, information provision to patients, change of prescription format, quality securement for improved confidence of healthcare professionals. In addition, to reduce the prices of forerunner drugs with follower drugs with giving consideration to the viewpoint of innovation.**
- As for the review of patient's burden of drug cost, make deliberations based on “To review patient's burden of drug cost taking consideration the price levels of marketed drugs” described in the “Social Security / Tax Integrated Reform Draft”.

## To promote use of generic drugs

It is important for both healthcare professionals and people to place confidence in generic drugs and have a mind to proactively use generic drugs through the following efforts:

- (1) securement of reliability of generic drugs in the aspects of quality, stable supply and information provision, and thorough notification thereof
- (2) appreciation in calculation of medical fee and dissemination/enlightenment from insurers to the insured



**Thank you!**



Central Joint Government  
Building No. 5 (MHLW)