JKS READING ROOM

Generics Asia Conference

JGPMA Presentation

Singapore, November 2006

Japan's Healthcare System and Generic Drug Industry

Secretary General
Japan Generic Pharmaceutical Manufacturers Association (JGPMA)

In Singapore, 23 November 2006

Main Theme

- I'll show you that Japan's generic drug industry has just entered a new era due to generic substitution, which was introduced this April, and various encouraging factors.
- This is the today's main theme.

Japan Generic Pharmaceutical Manufacturers Association (JGPMA)

- Established: 1968
- Head Quarters: Tokyo, Japan
- President: Itsuro Yoshida (President of Towa Pharmaceutical Co. Ltd.)
- Member: 38 companies, which have about 80% share of generic drug sales in Japan
- International Generic Pharmaceutical Alliance (IGPA) Observer (joined in 2005)

Japan's Healthcare System

- Free Practice System

  and

- Universal Health Insurance System

Free Practice System

- In general, practitioners can freely open their clinics
- Hospitals are established without restraint, although some restrictions have been introduced in recent years

Universal Health Insurance System

- All Japanese people are covered by one of the public health insurance programs
- Japan does not have a family doctor system
- Patients can receive treatment (including dental care) in any clinic or hospital across the country by simply presenting their health insurance certificates and with some money for co-payment

Strong point　Weak point

- Japanese people can easily access healthcare services, making it possible for them to receive early diagnosis and treatment. It supports them to maintain good health. They have the longest healthy life expectancy in the world.
- It leads to excessive consumption of healthcare services and materials.

Healthcare System

- Health Insurance Program: aged 0-74 old (about 110 million people are covered)
- Special Healthcare System for Seniors (SHSS): aged 75 or older and bedridden patients aged 65 or older (total 16 million people are covered)

Main Health Insurance Programs

(excluding for teachers, sailors, etc.)

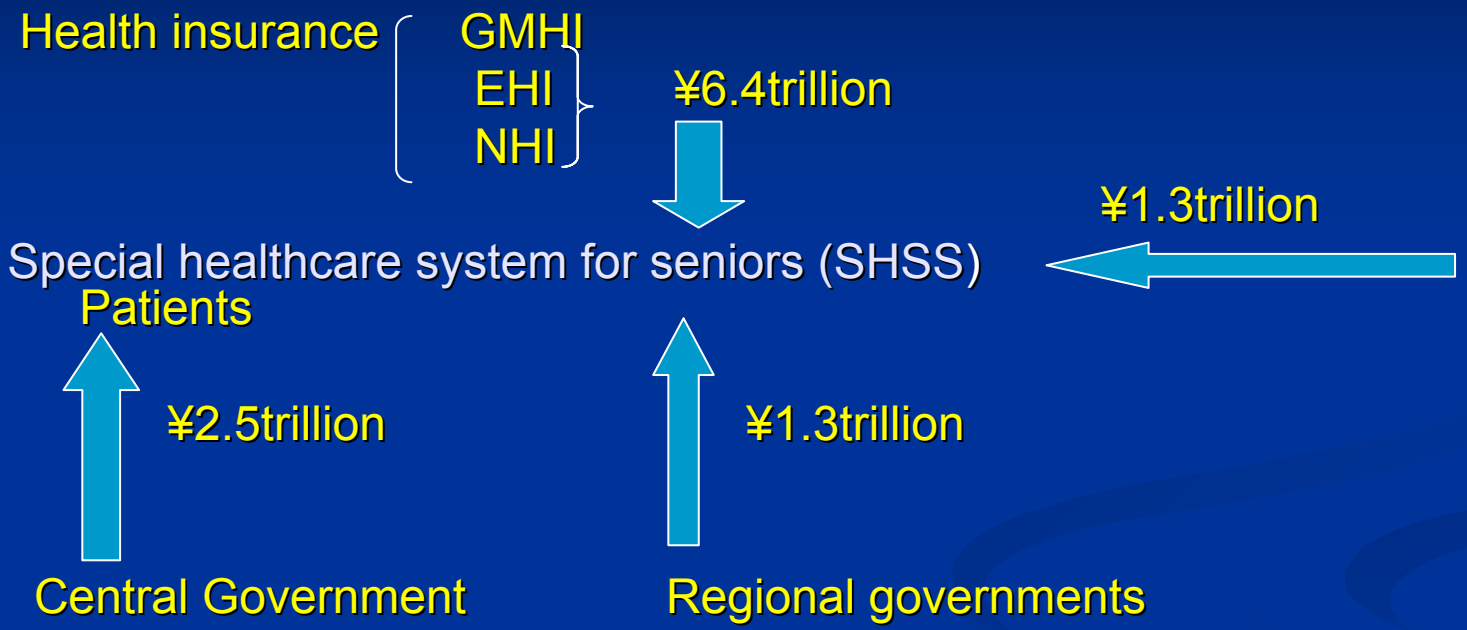
Type	Insured persons	Premium rate	Cost sharing
Government-managed health insurance (GMHI)	Employees of small businesses	8.2 %	4.1 % by employees 4.1 % by employers
Employees' health insurance (EHI)	Employees of large corporations	7.6 % (average)	3.8 % by employees 3.8 % by employers
National health insurance (NHI)	Self-employed individuals, small farmers, retired persons, etc.	Variable by region	Shared by insured persons and central/regional governments on a 1:1 basis

Government Subsidy to health insurance programs (FY2005)

Type	Government spending (billion yen)
Government-managed health insurance (GMHI)	796.7
Employees' health insurance (EHI)	11.5
National health insurance (NHI)	3,371.5
Total	4,179.7

Contributions to SHSS

(FY2004)



SHSS total cost=¥11.5trillion

Source: MHLW

Government's heavy financial burden

- Health Insurance Subsidy ¥4.2 trillion
- Contribution to SHSS ¥2.5 trillion
- Total per year ¥6.7 trillion

(US$ 60 billion)

Japanese government's huge cumulative financial deficit ¥500 trillion

(US$ 4.5 trillion)

Target from the government's healthcare cost cut policy

- National Health Expenditure ¥30 trillion
- Drug Cost ¥6 trillion (20 %)
- Drug Cost is more likely to be targeted from the government's cost cut policy.
- Drug Price Revision is the most effective cost control step.

Drug Price Revision

- Drug Price is the reimbursement price paid by insurers to medical institutions under the public health insurance system.
- Drug Price Revision is designed to control drug cost by reducing the spread between the reimbursement prices and actual purchase prices of medical institutions surveyed regularly, which are otherwise appropriated by them as a profit.
- Revised every other year

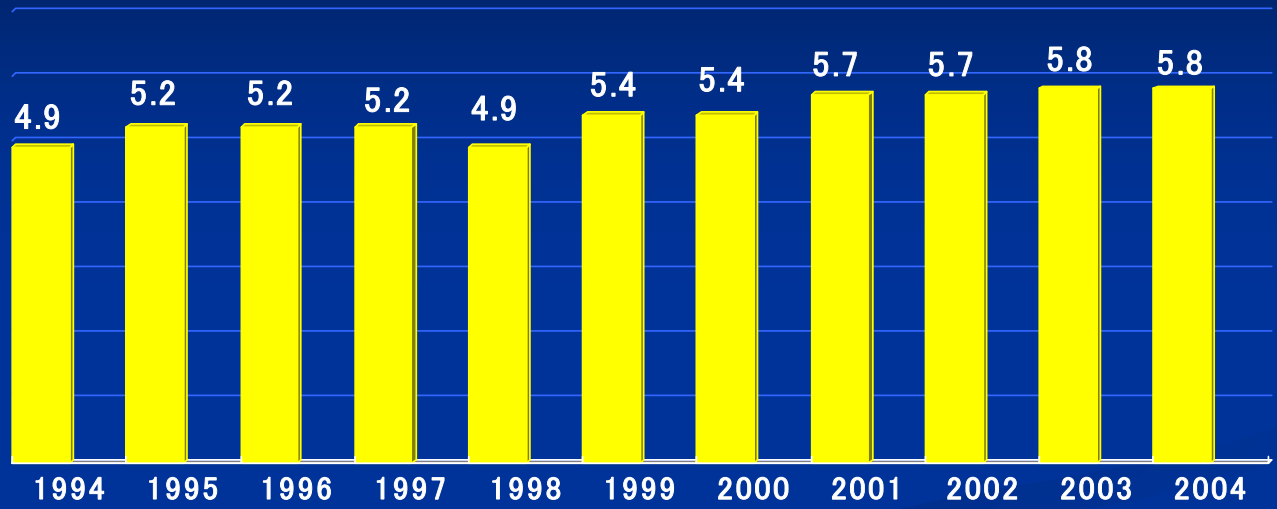
Price Cut Pressure

Drug Price Revision
every other year

Japanese Prescription Drug Market

Sluggish production of prescription drugs

source: MHLW (¥ trillion)



Price Cut (%)

*1997: with VAT revised

1994	1996	1997	1998	2000	2002	2004
6.6	6.8	4.4	9.7	7.0	6.3	4.2

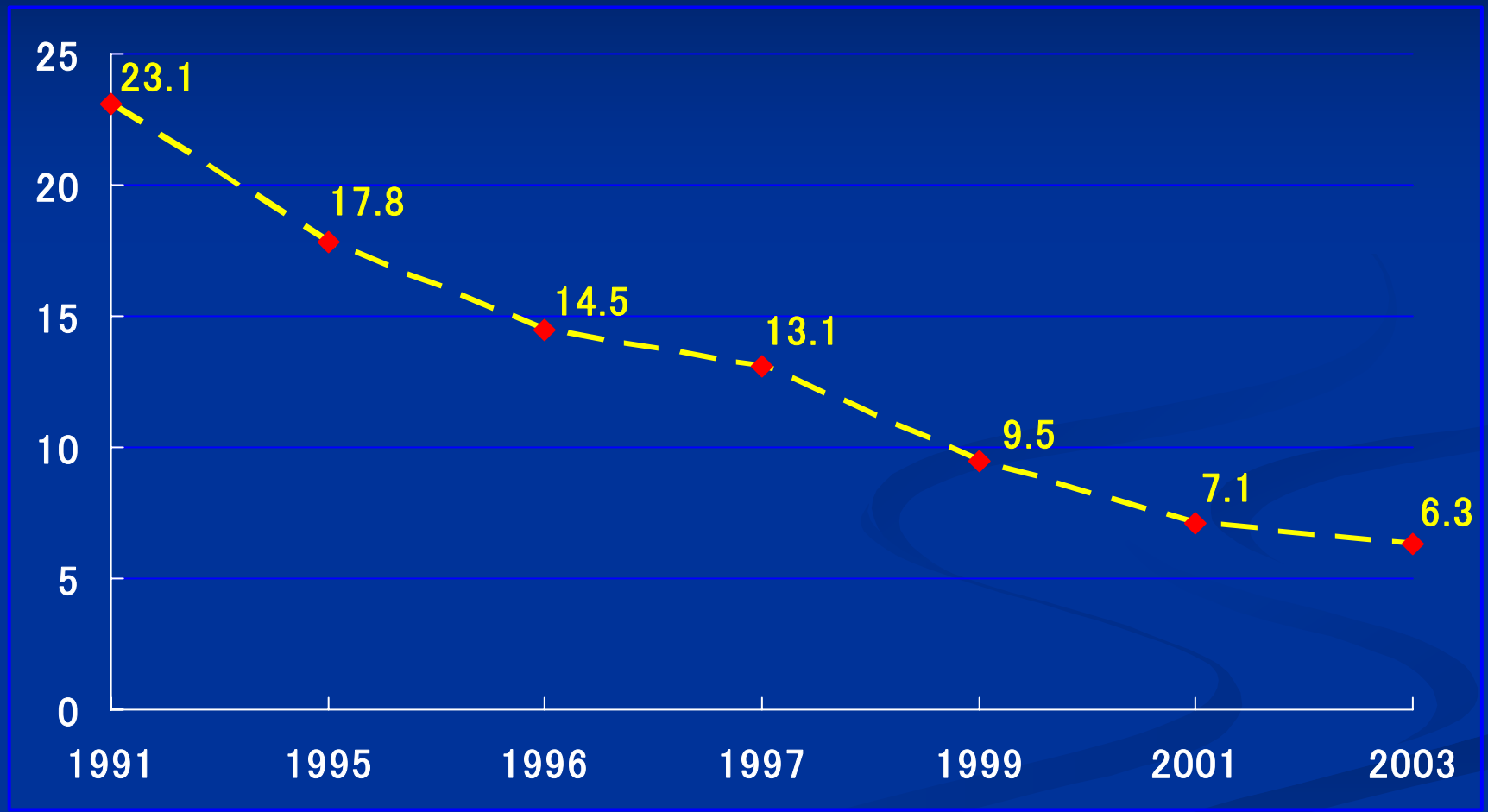
Previous Government Policy

- Previous Policy were focused on cutting prices of brand drugs and controlling their sales volume
- This approach has become less effective for controlling total drug cost year by year
- On the other hand, the spread between the reimbursement prices and actual purchase prices of medical institutions, which is potential for savings, has been significantly reduced in the last decade

“ Spread” reduced significantly

spread between the reimbursement prices and actual purchase prices (%)

source: MHLW



Government Policy Changed

"Promoting use of affordable Generic Drugs should be a more effective measure, so it must be one of the main policies for controlling drug cost"

This idea was suggested in "The Final Report on Japanese Pharmaceutical Industry in 21st Century" in 1993 and has been adopted step by step by the Ministry of Health, Labour and Welfare (MHLW) since the early 2000s

The Report "Vision for the Japanese Pharmaceutical Industry"

- The report was released by the MHLW in 2002
- Four business models were formally proposed

*Mega-Pharma : Internationally competitive R&D Pharma

* Specialty Pharma: Specialized R&D Pharma

*Generic Pharma: Pharma with stable supply of high-quality generics

* OTC Pharma: Pharma concentrated on OTCs

Importance of Generic Pharma has been realized !

Government's measures for promoting use of generics (1)

In 2002

New fees at Revision of medical service fee (Incentives for promoting use of generics)

(1) generic prescribing fee for doctors ¥20 / prescription

(2) generic dispensing fee for pharmacists ¥20 / transaction

(3) fee for explanation about generics for pharmacists ¥100 / prescription

Government's measures for promoting use of generics (2)

In 2003

(1) Patient co-payment (including drug cost)
20% ⟹ 30%

(2) Introduction of DPC (Diagnosis Procedure Combination, Japanese version DRG) in selected Major Hospitals: 82 hospitals in 2003 ⟹ 360 hospitals in 2006

In 2004

National Hospitals ⟹ Independent Administrative Corporations (more cost conscious bodies)

Government's measures for promoting use of generics (3)

In 2006

(1) Generic Substitution introduced !

New prescription form put with column indicating "Substitution allowed"

For substitution, doctor has to sign !

(2) Incentive to doctor

¥ 20 to doctor for allowing generic substitution

Government's measures for promoting use of generics (4)

In 2006

(3) MHLW notification to generic companies in order to secure stable supply of generic drugs (requiring at least a 5 year supply from launch, etc.)

(4) Mandatory supply of all the strengths

MHLW requires generic companies to supply all the strengths (e.g.10 mg, 20 mg, 30 mg…)corresponding to originator drugs to assure that substitution can be achieved without problems

(5) Generics Listing on the Drug Price List

1 ⇨ 2 times/year (under discussion)

Changed situation of medical institutions for using generics

(1) Ratio of separation between prescribing and dispensing reached 53.8% in 2004

Doctors and medical institutions are increasingly reluctant to get money from dispensing

(2) DPC hospitals began to use generics after they completed arrangements including evaluation and selection of generics, changed doctors view about generics and clear-cut role of pharmacists for using them

(3) DPC system is adopted in 360 hospitals in 2006 of which 180,000 beds are covered by this system

(4) Community pharmacists have changed view on generics and made arrangements for using them

Activities of generic drug industry (1)

(1) JGPMA has been taking efforts for enlightening doctors, pharmacists and consumers about generics.

(2) “Generic Drug Consultation” Card

Patient shows this Card before consultation.

JGPMA supplied 300,000 copies of the Card to insurance bodies, pharmacists and member companies.

(3) JGPMA joined IGPA in 2005

→ enhanced activity for ICH promotion activities through exchange of information worldwide

Activities of generic drug industry (2)

(4) Generic drug companies have increased detail persons for promoting to doctors and medical institutions.

(5) Generic drug companies began to supply products to large hospitals through large national wholesalers.

Previously, they supplied products mainly to clinics and small hospitals through small community wholesalers.

(6) 3 major generic companies are using mass media (e.g. TV, newspaper) for explaining consumers about generics.

Main hurdles to prevent use of generics

(1) Multiple patent extension

(2) Re-examination System, which has similar functions of Data Exclusivity

(3) Pharmaceutical Regulation, which in general forbids generic application with only off–patent indications

(4) Insufficient information provided for medical professions by generic drug companies

Multiple Patent Extension

Patent Term: 20 years from date of filing → maximum protection 25 years

	Japan	US	EU
Introduction	1988	1984	1993
Maximum period	5 years	5 years	5 years
No. of extensions	Multiple possible	Only once	Only once
No. of patents eligible for extension	Multiple possible	Only one	Only one

Patent Term Extension

- It is possible to extend basic patent term multiple times e.g. by adding new indications
- Also, multiple related patents (use of product, method of manufacturing, etc.) can be extended multiple times

JGPMA has requested the Patent Office

Limit the extension to only one patent and once

Evergreening of Patent !

Multiple patent extension of levofloxacin

1st Staphylococcus and other 30 bacteria → June 2006

2nd Anthrax, Pest, etc. → October 2006

3rd Typhoid Fever, Paratyphoid Fever → November 2007

4th Legionella ⇢ June 2011 (under examination)

Re-examination System

The system to re-examine the efficacy and safety of New Drug

- Based on the results of Post Marketing Surveillance
- Obliged for a given period (4-10 years, normally 6 years) after the approval of New Drugs
- No approval of generic drugs before the end of Re-examination period, even in case of no patent infringement
- This system's function is similar to Data Exclusivity
- Introduction of 8 years of Japanese version Data Exclusivity is now under discussion. Relation between Re-examination and Data Exclusivity will be clarified

Pharmaceutical Regulation

- In principle, the regulation forbids generic application with only off-patent indications.
- In exception, the regulation allows it ,if the indication protected by patent is/was in Re-examination.
- In the levofloxacin case, any generic application cannot be filed until the last patent extension term ends because the supplemental indications are not in Re-examination.

JGPMA has requested

Allow generic application with only off-patent indications with no condition.

Insufficient information provided for medical professions by generic drug companies

- Japanese Pharmaceutical Law does not regard labeling information as a review matter.
- Usually, the originator companies insist labeling information is a property belonging to them.
- Generic companies cannot have and provide sufficient labeling information, in particular information on frequency of adverse effects .

Move of Foreign Companies

Business operating

Sandoz K.K. (subsidiary of Sandoz),
Merck Seiyaku (subsidiary of Merck KGaA)

Establishment of subsidiary

Teva, Torrent, Zydus Cadila

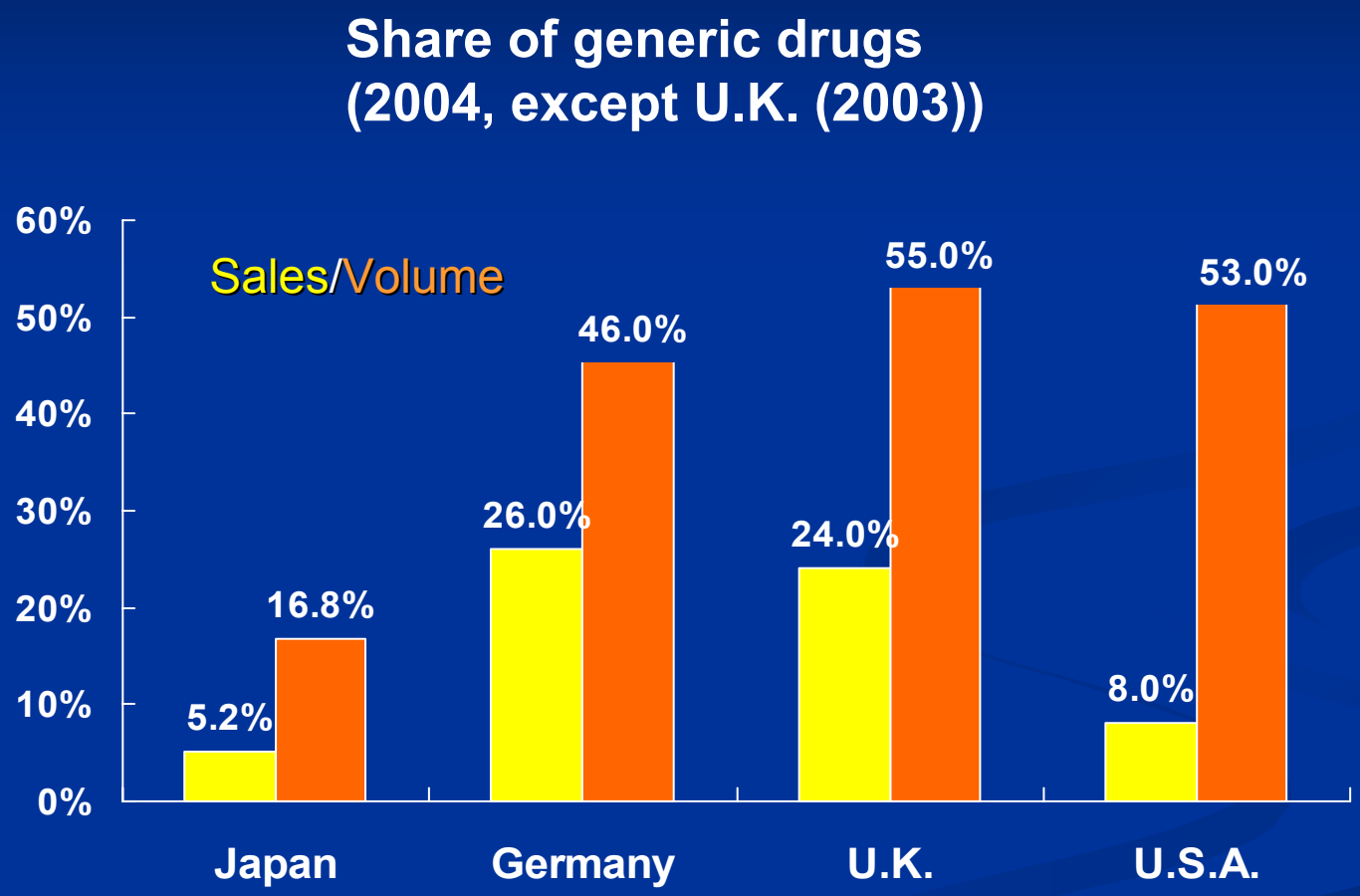
Collaboration with local company

Ranbaxy : Nippon Chemiphar

Lupin : Kyowa Pharmaceutical

Hospira Japan (subsidiary of Hospira): Taiyo Yakuhin

Share of generic drugs in Japan is still low



Source: JGPMA, ProGenerika, BGMA, GPhA

Prospect of Japanese generic market

- Share of generic drugs in Japan is still low. That is a fact.
- However, if you change a point of view, you can find that Japan has a huge potential to extend the use of generic drugs.
- Generic substitution which was introduced in April this year will be a key engine to expand Japan's generic drug market.

Good News !

- On 27th September 2006, JGPMA 37 companies reported the fiscal 2005 year results as follows;
- Sales 9.2%up 338.1 ¥billion
- Operating Profit 14.3%up 35.9 ¥billion
- Ordinary Profit 18.3%up 36.2 ¥billion
- These results were achieved even without Generic Substitution.
- Now, JGPMA companies' sales are increasing more than 10% with Generic Substitution, while total market in Japan is growing only 3% according to IMS data.
- A new era of Japan's generic drug industry has just started !

Thank you for your kind Attention !