A reform proposal for a new drug pricing system consistent with fiscal sustainability

–Centered around the assessment of priorities for drug benefits based on a philosophy of insurance benefits and macroeconomic indexing of drug costs–

INES New Drug Innovation Study Group

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Table of contents

Preface

As the response to the recent outbreak of the novel coronavirus infection has shown, pharmaceuticals have an important role to play in protecting the health and lives of people from danger in various situations. However, there is also a lack of transparency in the pharmaceutical manufacturing field due to the frequent changes to the drug pricing system. In recent years, the sophistication of medical care has led to the development of innovative drugs. Even though they fulfill the healthcare needs of people, they are often accompanied by high drug prices, and there are concerns about the momentary increase in drug costs and their fiscal impact.

In order for innovative drugs to be provided in Japan on a priority and continuous basis, ahead of the rest of the world, the Japanese market should remain stable and attractive. This will be of great benefit to the Japanese people, especially patients. The Institute for New Era Strategy (INES), with the cooperation of experts and companies, established the New Drug Innovation Study Group to examine various issues and propose a framework for a new drug pricing system in order to ensure an environment in which innovative drugs can continue to be provided in Japanese healthcare.

With the premise of maintaining universal health insurance in Japan, in order to balance the burden of medical costs, which are expected to increase in the future, with the priority and continuous provision of innovative drugs, it is necessary to introduce a dynamic drug pricing system which balances the appropriate evaluation of the value of innovative drugs with the management of drug costs commensurate with the level of medium- and long-term economic growth.

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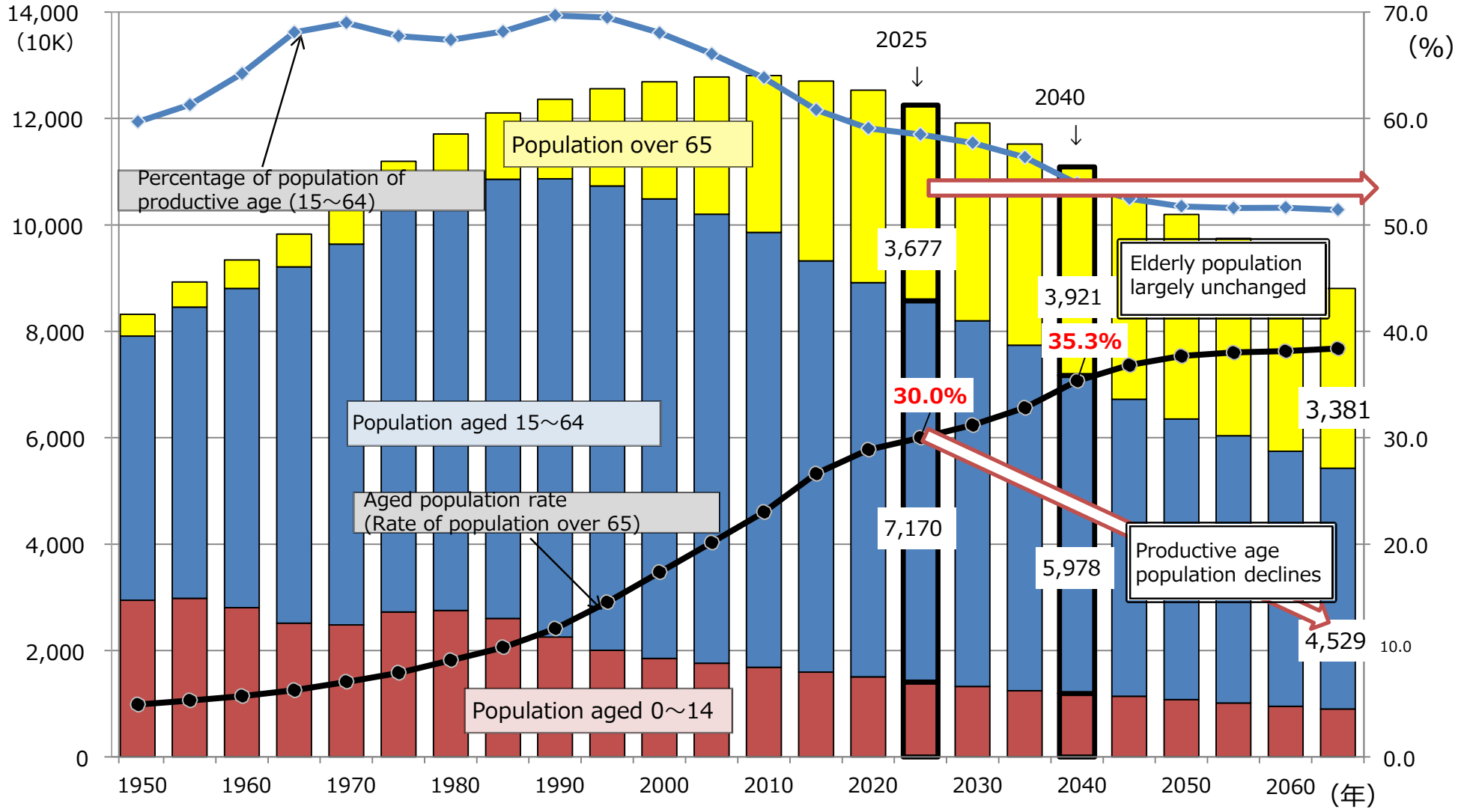
Secretariat

The Institute for New Era Strategy (INES)

Fundamental issues① : Demographics

Declining birthrate and aging population; rapid decline in working-age population

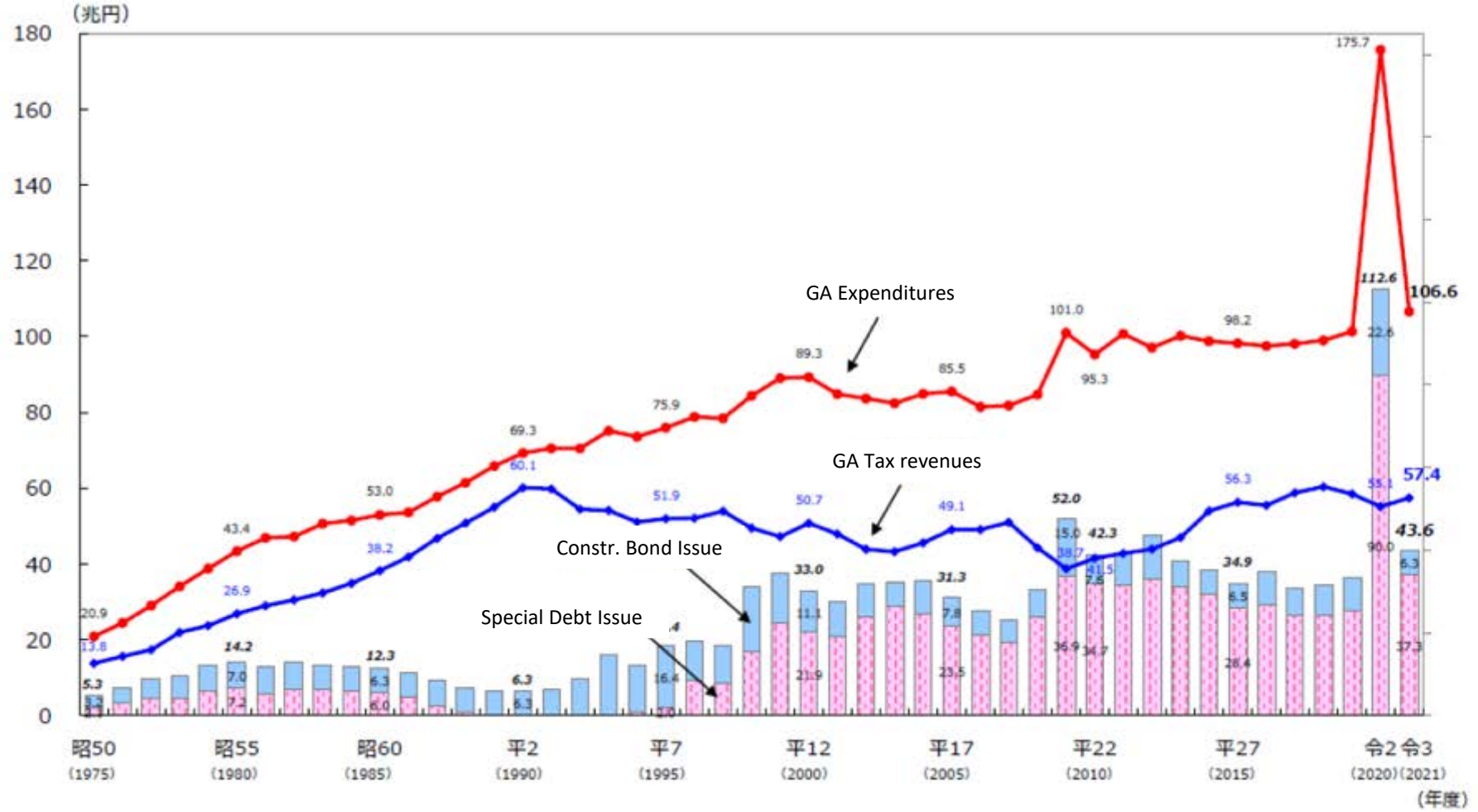


Sources: ~2015=actual data of Census; 2020~=Estimated populations in 2017 by IPSS (Estimate based on medium-fertility and medium-mortality)

Fundamental issues② : Public finances

On the other hand, the fiscal situation is feared to be even more critical due to the COVID-19 disaster

General account tax revenues, expenditures and issuance of public bonds

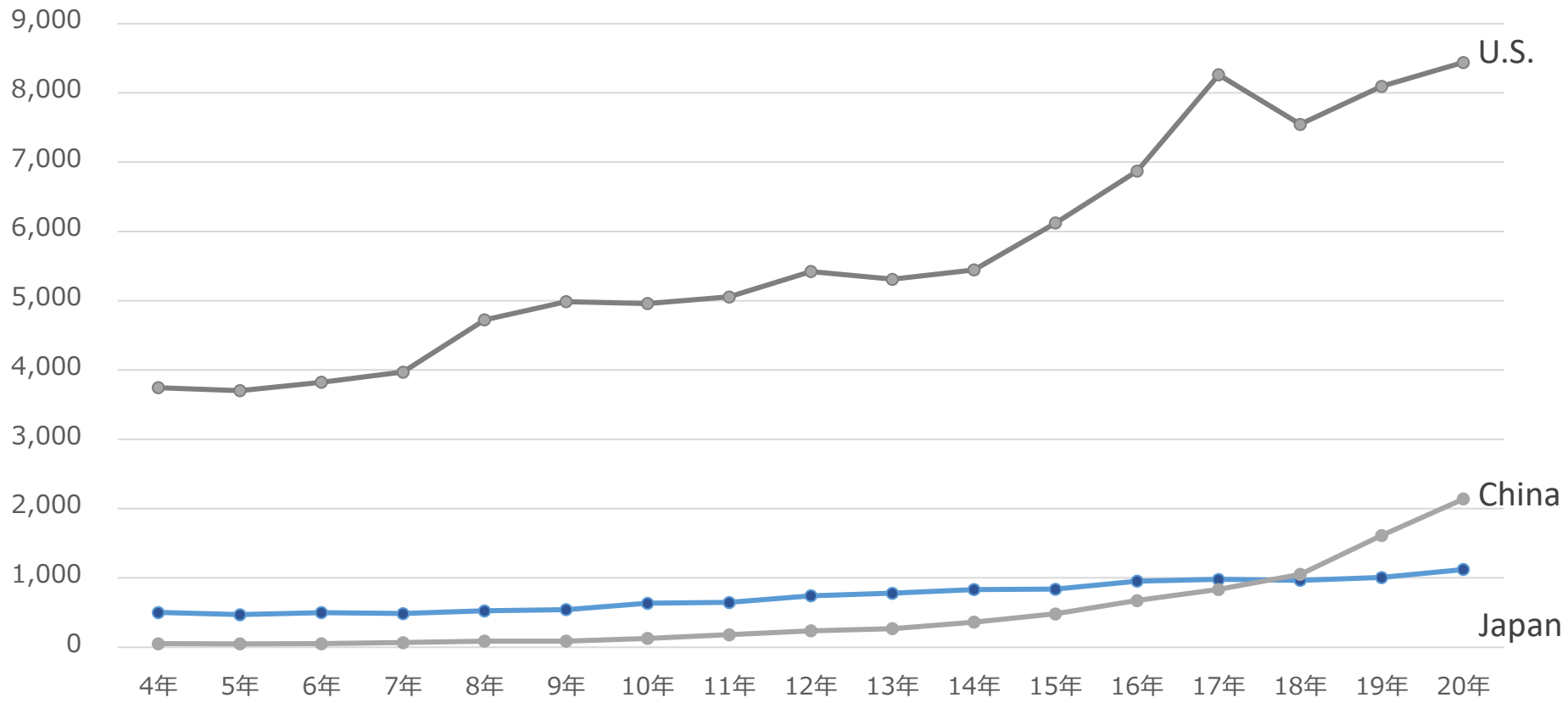


Source: MOF material

Fundamental issues③ : Stagnation of new drug development in Japan

While the U.S. and China are increasing clinical trials…

Number of drugs under development at clinical trial stages*



*includes pipeline drugs at preclinical stage

Source: Pharmaprojects

Position of the drug pricing system and the direction of its reform

Exploring system reform which enables the balancing of fiscal and industry policies without expanding the pie

Drug pricing system tying the two

Fiscal policies (Insurance)

- Fiscal health
- Reduce risk for citizens

Industry policies (Economy)

- Promote innovation
- Promote pharmaceuticals as a growth industry

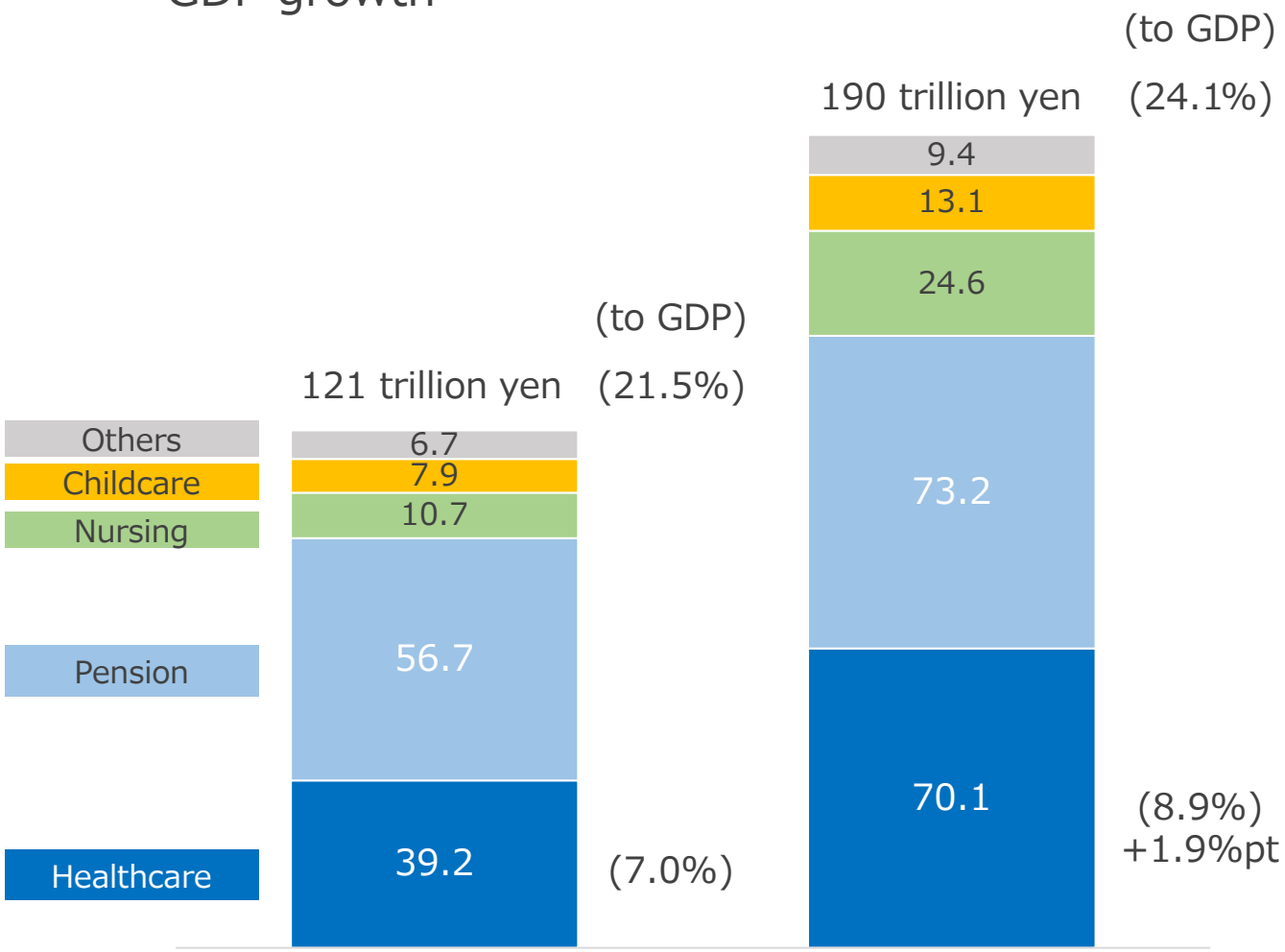
Balancing the two while no expansion of the total budget

Harmonization with macroeconomic growth

Securement of funding and reallocation to innovation through prioritization

Growth rate of drug expenditures based on government projections of social security benefits

If the ratio of drug exp. remains constant, drug exp. will grow at 0.021% more than nominal GDP growth



Increase of social security benefits by 2040 (Percentage of GDP)

- Social security : +2.6%pt
- Healthcare : +1.9%pt

Assumptions

- Nominal GDP growth by 2040 : Z%
- Drugs as % of HC exp. : 22% (Constant)

Increase of drug expenditures by 2040 (Percentage of GDP)

- HC exp. increase (+1.9%pt)×22%=+0.42%pt
- 0.42%pt ÷ 20yrs = +0.021%／yr

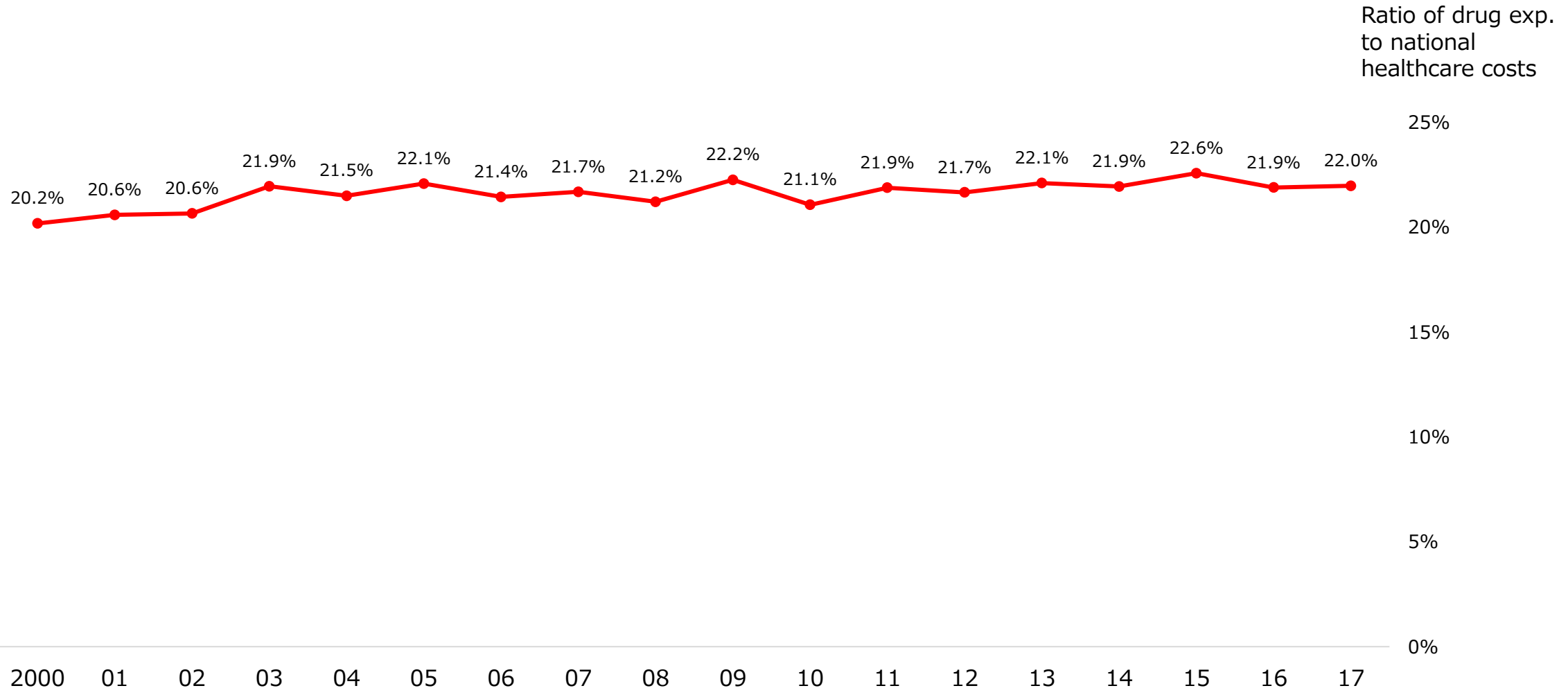
Average annual growth of drug expenditures

- **Growth of nominal GDP (Z%) +0.021%**

Source: Future prospect of social security toward 2040 (By the government on May 21, 2018)

(Reference) Drug expenditures as a percentage of healthcare costs

Constant at around 22% for several years



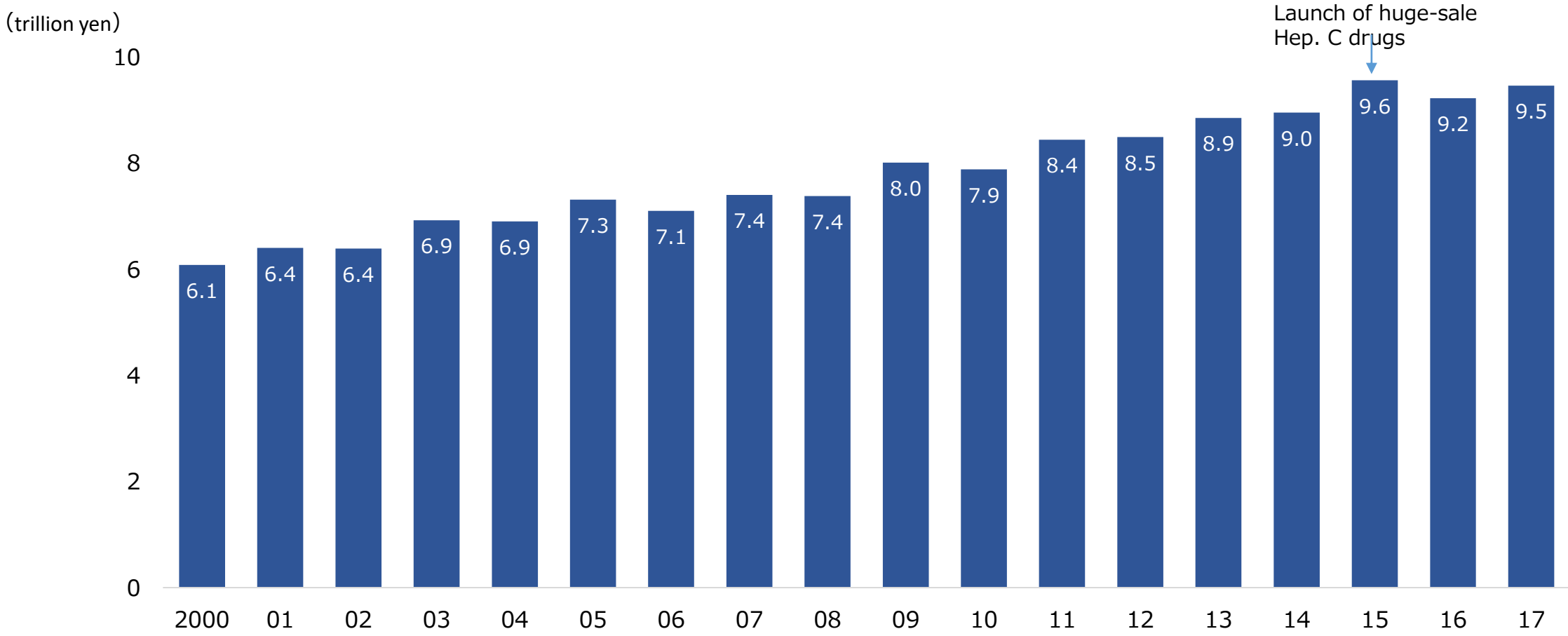
Source: Chuikyo materials

Note: The cases of drug exp. included in the hospitalization expenses such as DPC are not included.

Drug expenditures (government statistics)

Growth slowing down in the past several years

Growth rate of drug exp.	2000～'07: average of +2.5%/year	'08～'14: average of +2.8%/year	'15～'17: average of ▲0.3%/year



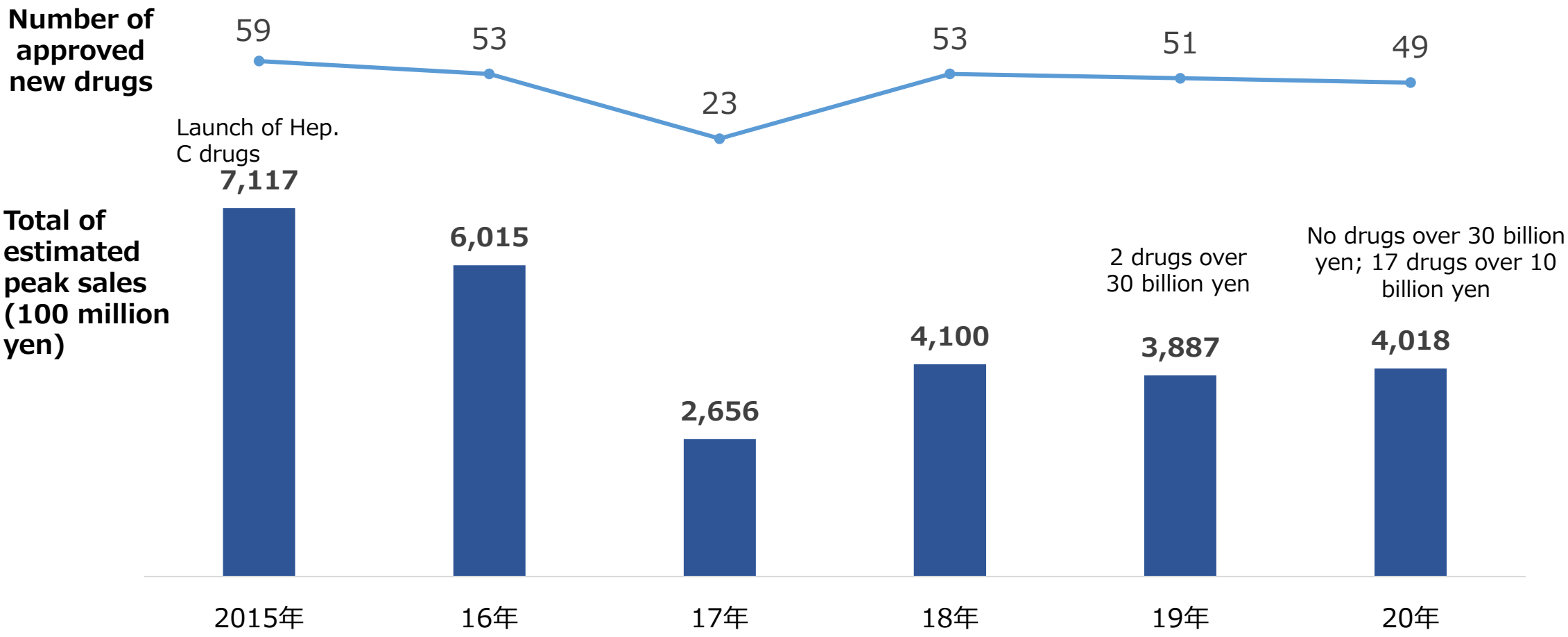
Source: Chuikyo materials

Note: The cases of drug exp. included in the hospitalization expenses such as DPC are not included.

Fiscal impact of innovation

Sales of new drugs since 2015 are declining. If uncertainty regarding innovation can be controlled, balancing with fiscal health becomes easier

Number of new drug listings and estimated peak sales

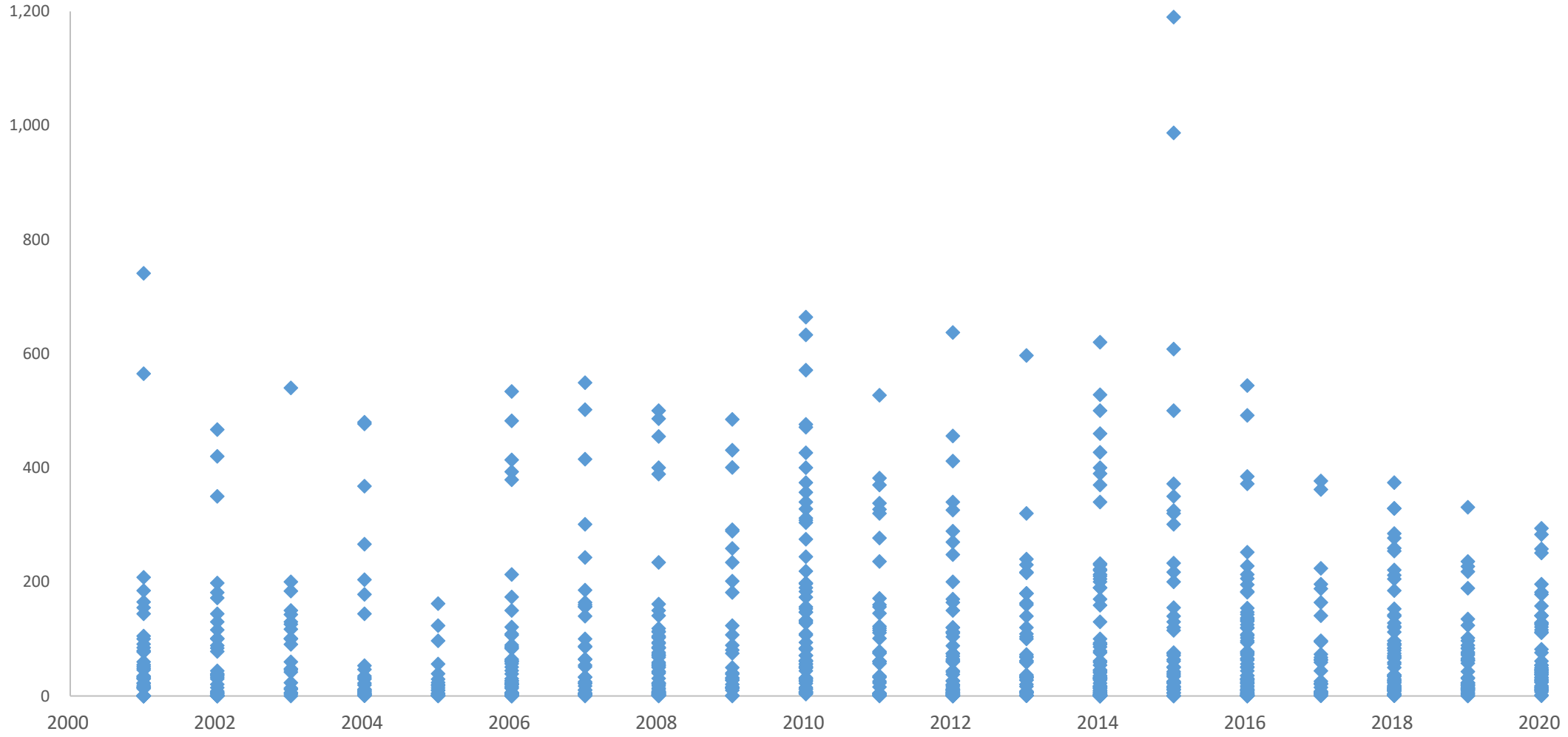


Sources: Approved drugs by Nikkan Yakugyo, estimated peak sales by Chuikyo materials

Estimated peak sales of newly listed drugs by fiscal year

Sales of new drugs after 2016 are smaller. No huge-sale drug which could impact governmental budget has been listed recently

(100 million yen)



Source: Chuikyo materials

Challenges of the drug pricing system

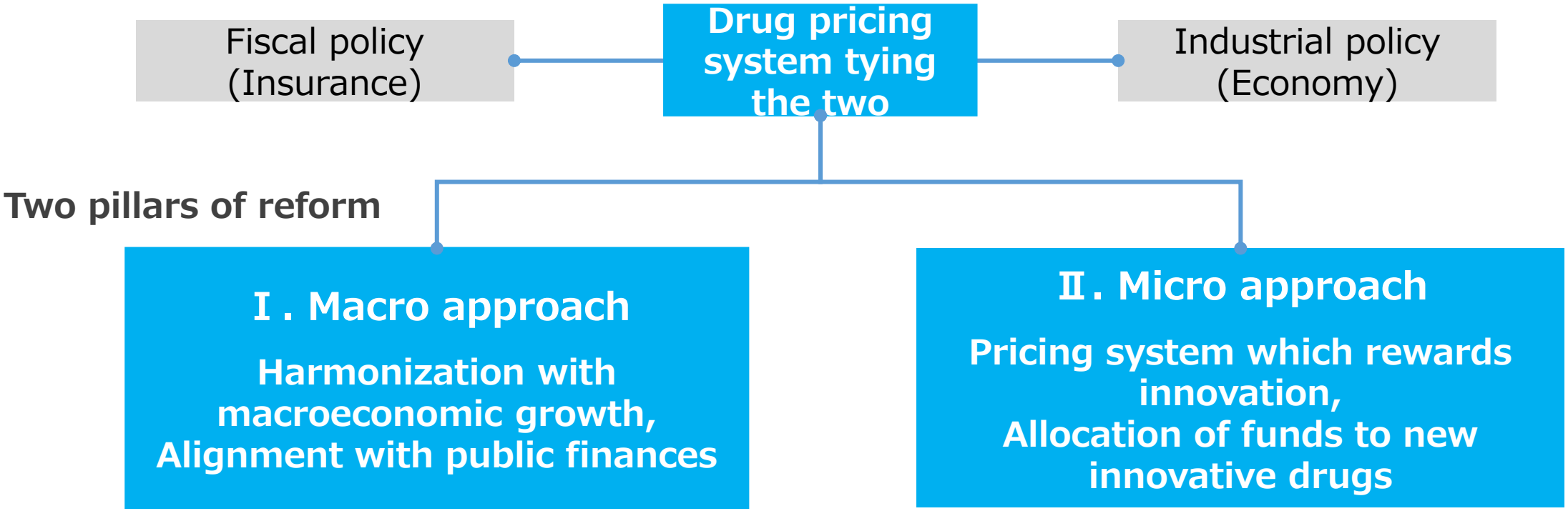
Conventional drug pricing system reform has reached its limit

Point of view	Challenges
System design/ alignment with public finances	■ Despite there being a range of detailed policies to address individual issues, the patchwork of policies makes it difficult to see a clear relationship between them and future health insurance finances.
Promotion of innovation	■ Within the same innovative new drug category, there is a coexistence of carrot policies (e.g., Price Maintenance Premium) and stick policies (e.g., Repricing for Market Expansion), and the framework is not designed to focus financial resources on innovation. ■ Concerns about fiscal volatility due to the introduction of large-scale breakthrough drugs have prevented the setting of drug prices that fully reflect their clinical value.
Global competitiveness of Japan	■ There is a great deal of uncertainty about policy changes, and with no positive outlook for the pharmaceutical market, it is questionable whether we can maintain parity and superiority against other developed countries. ■ The current situation is damaging economic opportunities for R&D investment/investment in Japan.

Proposal for drug pricing system reform

Through both macro and micro approaches, we aim to realize a drug pricing system that promotes innovation and is consistent with public finances

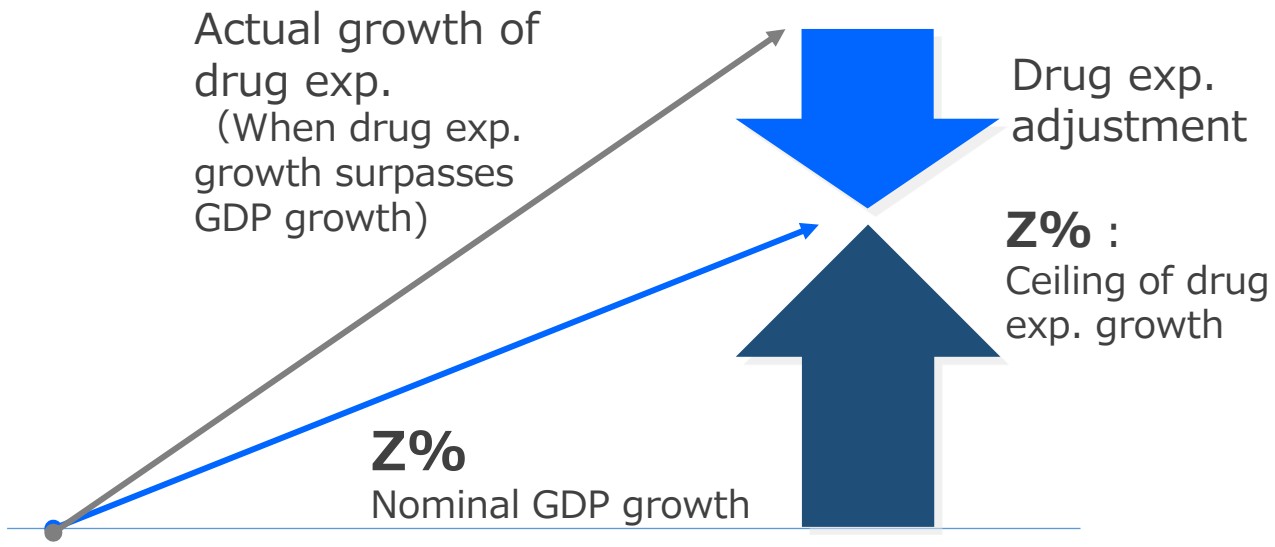
Proposal of drug pricing system reform by INES New Drug Innovation Study Group



Ⅰ. Macro approach : Harmonize with macroeconomic growth and secure alignment with public finances

Controlling the growth of drug exp. to be within the range of mid-/long-term economic growth

Drug exp. macroeconomic slide [indexing] (provisional name)



Manage drug exp. commensurate with the level of economic growth in the med-/long-term

- Upper limit of drug exp. growth rate for X years: nominal GDP growth rate (Z%)
- If the growth rate of drug exp. exceeds the level of economic growth due to the introduction of a breakthrough new drug, drug exp. will be adjusted within the GDP growth rate through drug price revisions.

=>Minimize fiscal volatility without stifling innovation.

Impact on drug exp. growth rate

- Drug exp. growth based on government forecast: GDP+ 0.021%

=>Theoretically restrain the growth of drug costs by more than 0.021% points

Upper limit growth rate used for macroeconomic indexing of drug costs (Z%)

Assuming the GDP growth rate used in the Cabinet Office's "Medium- to Long-term Estimates”

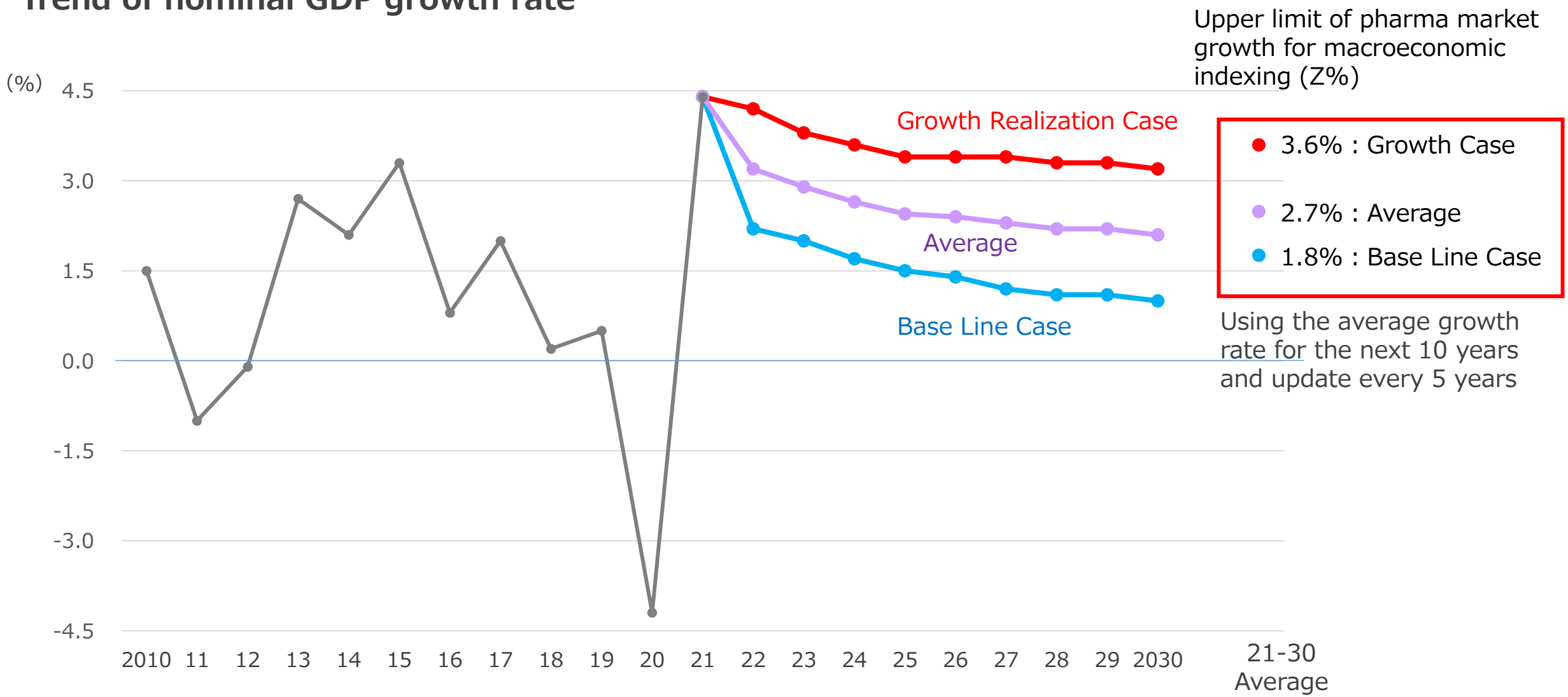
(1) Growth realization case

(2) Either the baseline case or the average of (1) and (2)

The average growth rate for the next 10 years will be calculated and updated every 5 years.

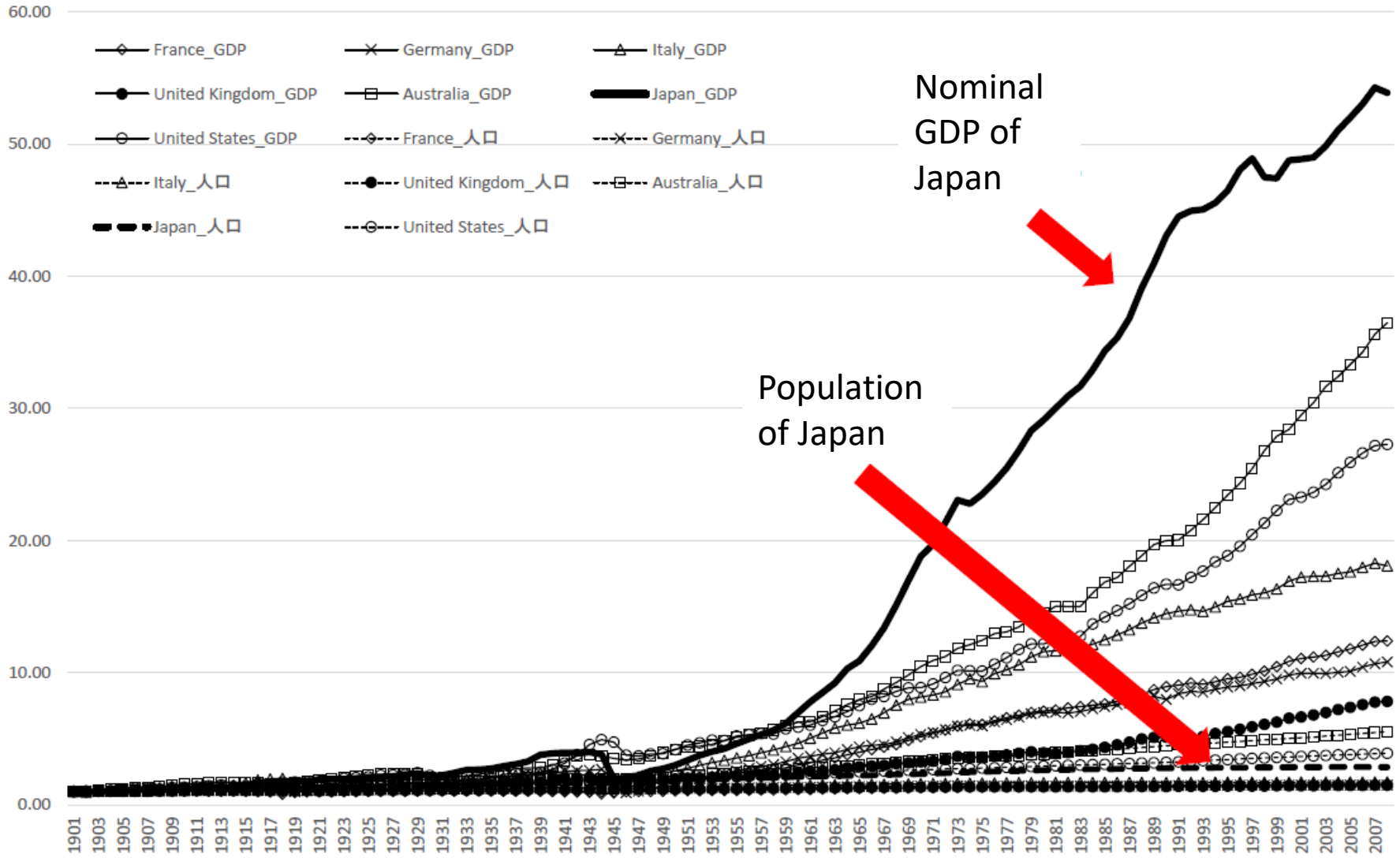
(Reference) GDP growth rate indexed for macroeconomic indexing of drug costs

Trend of nominal GDP growth rate



Source: Cabinet Office “Medium- to Long-term Estimates”

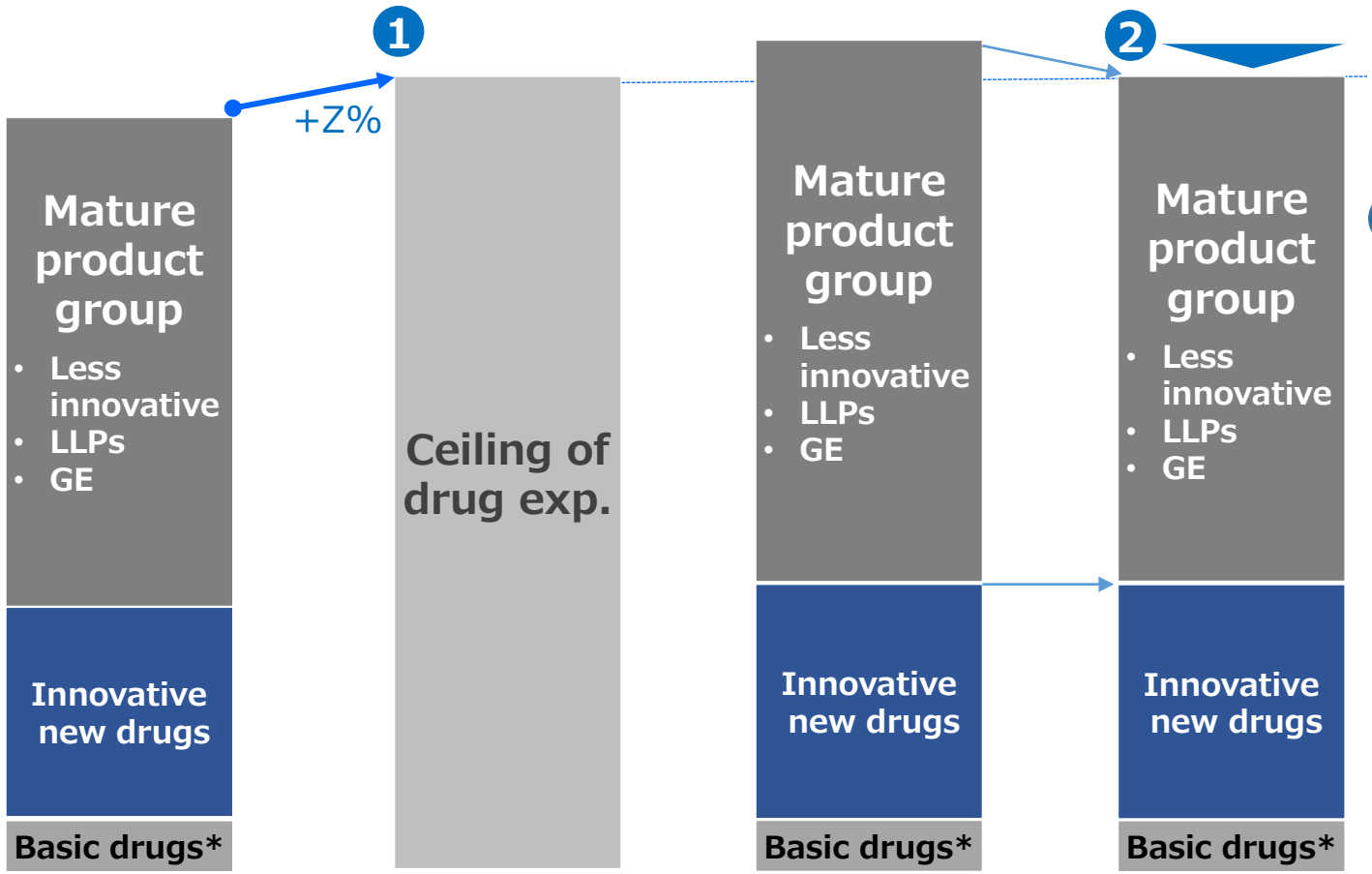
(Reference) GDP and population（1901＝1）



Source: http://www.ggdc.net/Maddison/oriindex.htm

Ⅰ. Macro approach: Management of drug exp. through macroeconomic indexing of drug costs

If the indexed economic growth rate is exceeded, drug exp. will be adjusted through broad and thin drug price revisions targeting mature product group



*Blood derivatives, narcotics, etc.

1 Set the upper limit of drug exp. growth

- Set upper limit of total drug exp. for the current year based on the growth rate ceiling of drug exp. (+Z%)

2 Adjustment through macroeconomic indexing of drug exp.

- Reduce prices of mature products in line with the upper limit of growth (if actual exp. is within upper limit, macroeconomic indexing adjustment will not be implemented)

- Set the adjustment rate based on the upper limit.

Adj. drug price＝prevailing market price＋pre-revision price × slide adjustment rate

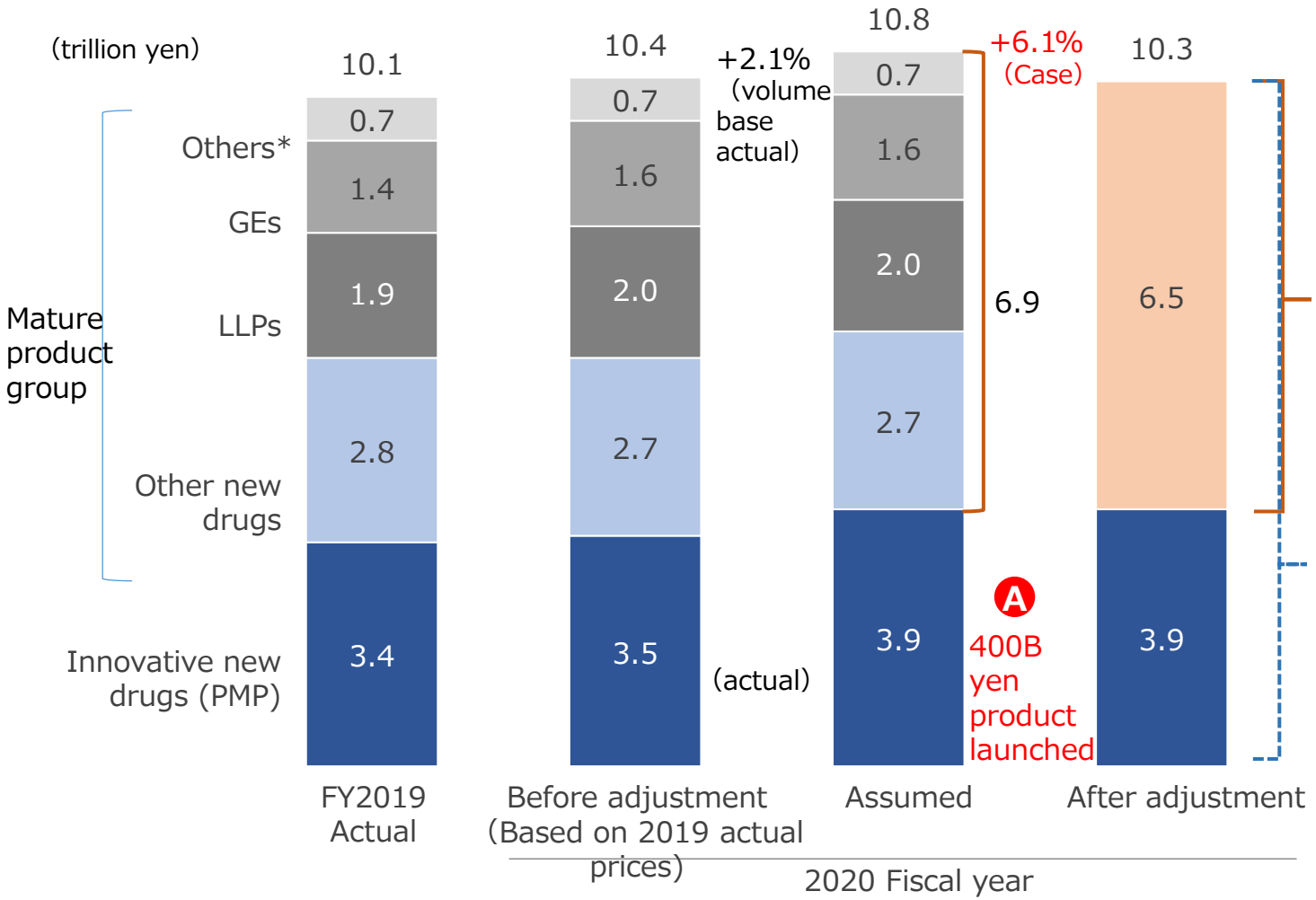
- Expand the current revision method, which adds an adjustment range (currently 2%) to the prevailing market price and introduce a new adjustment method commensurate with the upper limit of growth.

- **Basic drugs** such as blood products and narcotics **will be excluded from the macro indexing system.**

Simulation of macroeconomic indexing of drug exp.

Case assuming new product records explosive sales from 1st year (similar size to Hep C in 2015)

〈Hypothetical case〉 Upper limit of market growth (Z%): +1.8%, assuming launch of blockbuster (400B yen) in addition to the actual market, assuming innovative drug group = current PMP products



+1.8% (Upper growth limit)

Ⓑ ▲6.3% : Average price revision of mature product group

Ⓒ ▲4.0% : Average price revision of total market

Simulation of macro-slide adjudt.
(Case for Z=+1.8%)

Ⓐ Increased Sales	Ⓑ Mature: revision	Ⓒ Market: revision
+100B	▲1.9%	▲1.3%
+200B	▲3.4%	▲2.2%
+400B	▲6.3%	▲4.0%

＊1） Blood products and narcotics included in Others as no detailed data available.

2） Vaccines and others not listed are excluded from the market figures.

Analyzed by INES based on the data from IQVIA

Implementation of macroeconomic indexing : Setting of adjustment rate （When Z=+1.8%）

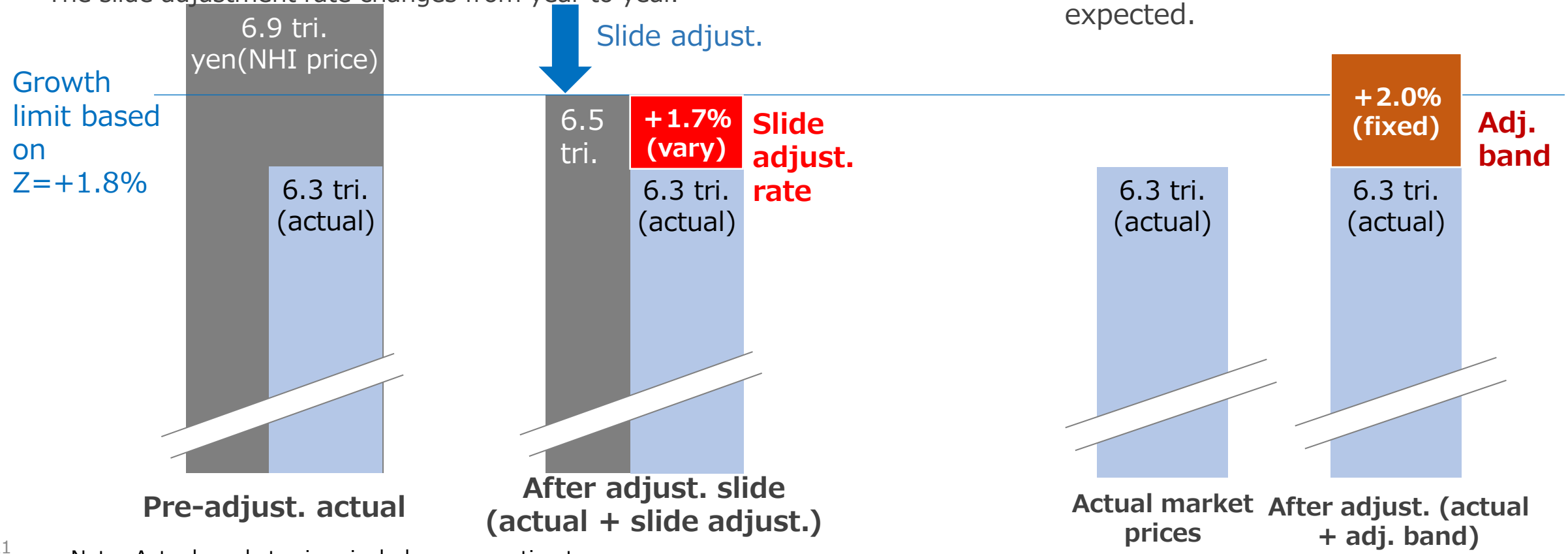
The current method of making revisions based on prevailing market prices will be revised and a sliding scale adjustment method will be introduced to match the upper limit of growth.

Macro-indexing with mature product group

- The deviation between the upper limit of growth and the actual price level is set as the slide adjustment rate.
- The upper limit is set, and the drug expenditure for the relevant fiscal year can be predicted.
- The slide adjustment rate changes from year to year.

[Current]Revision based on actual prices

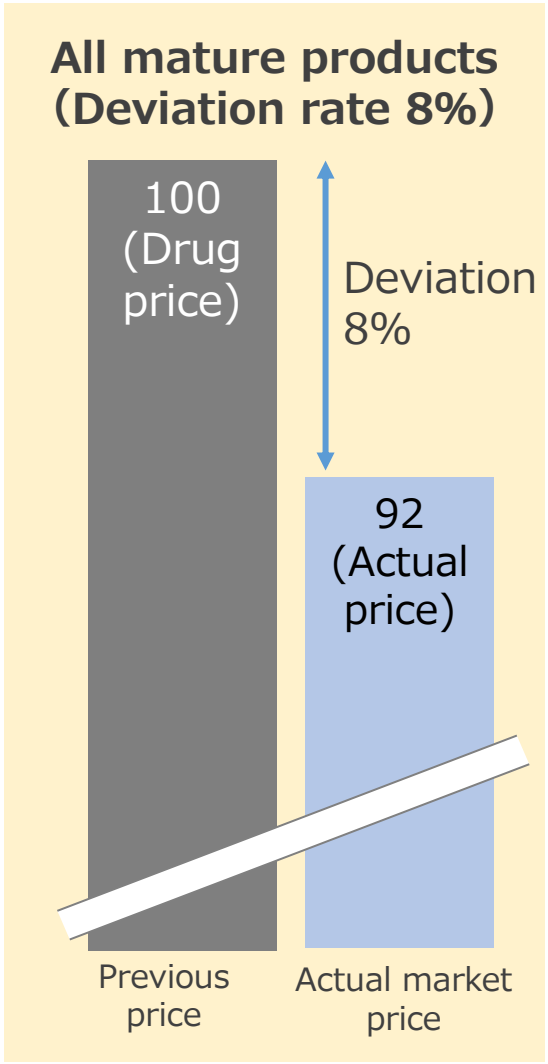
- 2% adjustment added to actual market price.
- Unexpected market expansion could increase drug exp. more than expected.

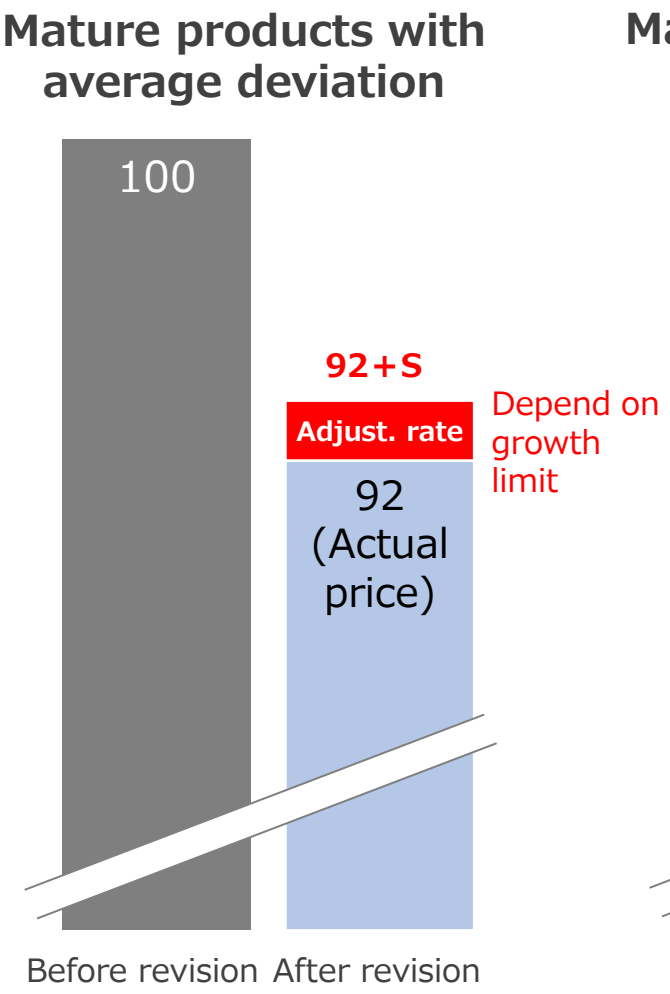


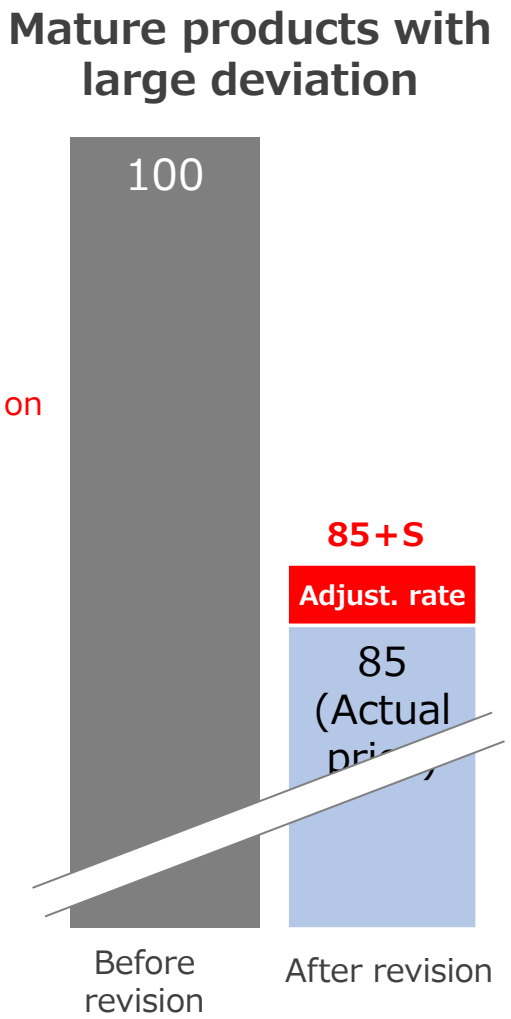
Note: Actual market prices include consumption tax.

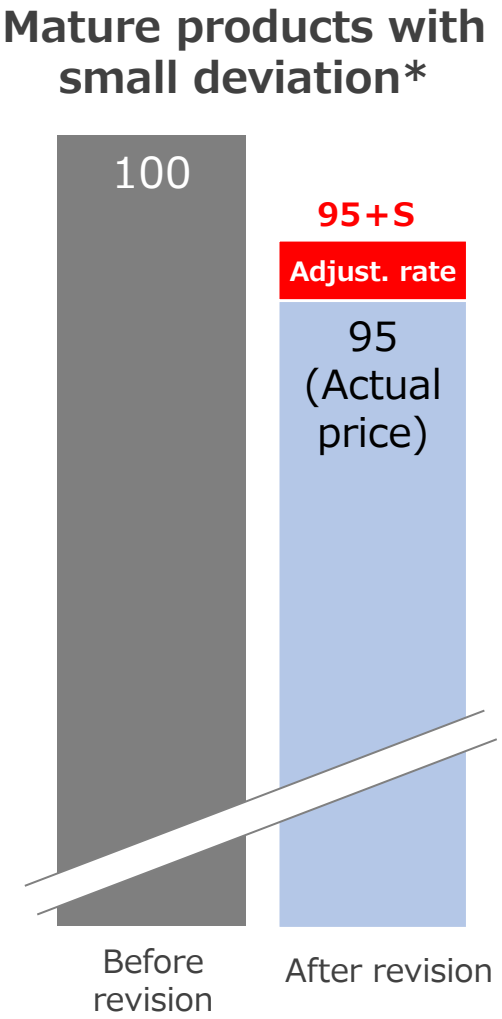
(Reference) Example of price revision of mature product group with macroeconomic indexing (Previous drug price＝100)

Revised price＝actual market price＋previous price × slide adjustment rate (S)









*This slide shows price revision for all products regardless of the level of deviation. Another idea is to exclude mature products with the deviation below a certain level from the macroeconomic indexing.

Proposal for drug pricing system reform

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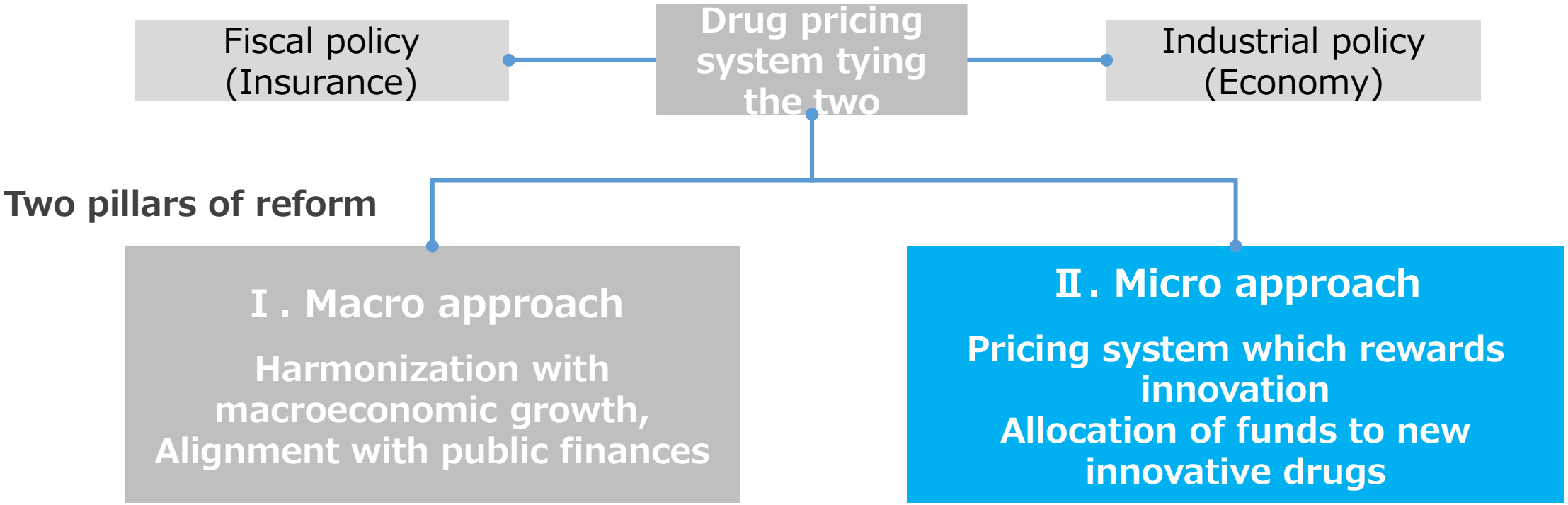


Ⅱ. Micro approach: Drug pricing system reform which rewards innovation

Aiming for a drug pricing system which properly evaluates the value of innovation

Drug pricing system reform to properly reward innovative new drugs

【Concerns】

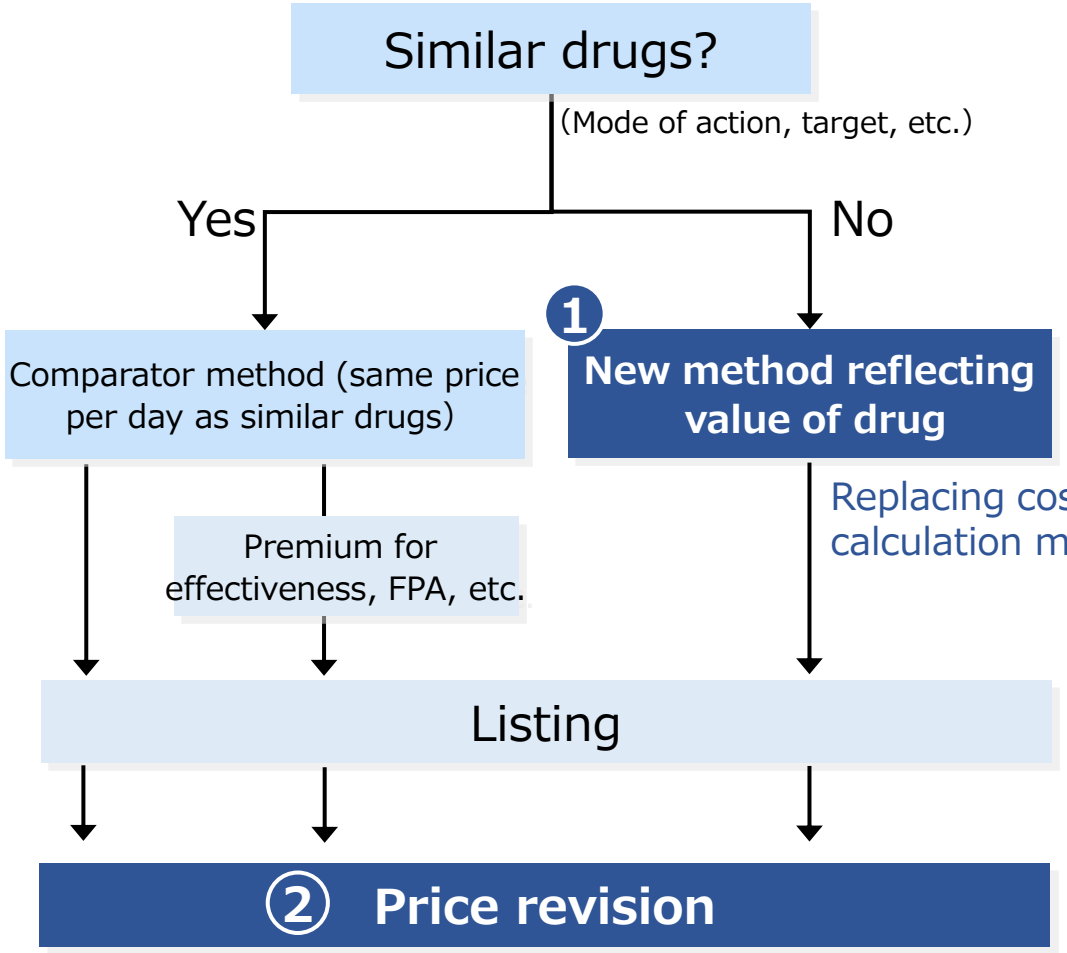
- Characteristics of expected upcoming innovative new drugs: may be for smaller number of patients, may take time to evaluate their value, and their value may not be sufficiently rewarded under the current pricing system, especially under the inflexible **cost calculation method** in Japan.
- Value of large-scale new drugs are damaged by the **repricing for market expansion** rule.

【Proposals】

- Introduce a drug pricing system which properly reflects the value of innovative new drugs.
  - **Drug price setting:** Introduce **a method which reflects the value of drugs and replace the existing cost calculation method with the new method.**
  - **Drug price revision :**
    - Only maintain the indication-change repricing and dosage-change repricing rules and **do not apply (i.e. abolish) the market expansion repricing** rule.
- In principle, innovative new drugs should be excluded from the adjustment of total drug expenditures with macroeconomic indexing.
  - Accordingly, through **macroeconomic indexing innovative new drugs will, in relative terms, be favorably rewarded**.

Ⅱ. Micro approach: Drug pricing system reform which rewards innovation

Drug price setting and revision based on the value of drug innovation



Not a repricing for market expansion which targets specific drugs but adjust total drug expenditures with macroeconomic indexing

1 Introduce a pricing method which is not a simple stacking up of costs, but based on the drug's value

- If scientifically and objectively similar drugs do not exist, the price is set based on value comparison with existing treatment. **The new system replaces the existing cost calculation method.** Design the system referencing other countries which have value-based pricing system.
- Pharmaceutical companies provide data to prove value based on reasonable methods.
- DPO evaluates whether to apply **PMP**.
- **Set upper limit of price referencing foreign prices.**

2 Price revision reflecting the drug's value

- **No repricing based on sales size only**
  - Do not implement: Repricing for market expansion, including special repricing
  - Implement: Indication-change repricing, and dosage-change repricing

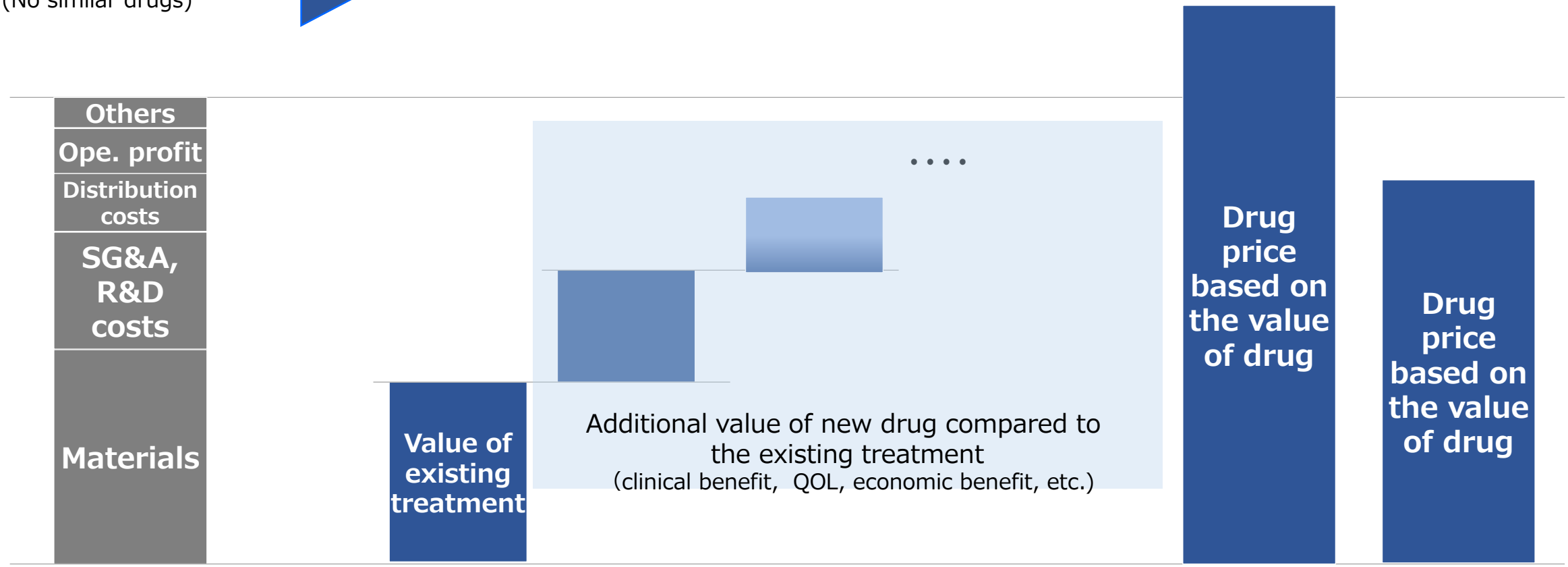
⇨ If total drug expenditures expand more than expected, macroeconomic indexing is applied. (Not on specific products, but wider and thinner adjustment with focus on mature products)

Ⅱ. Micro approach: Example of drug pricing based on the value of innovative new drugs

New pricing system replaces cost calculation method and reflects the value of an innovative new drug to the drug price

Current: Cost calculation method
(No similar drugs)

Proposal: New method reflecting value of drug



Two drugs with similar costs

Two drugs with similar costs

Stance toward repricing in this proposal

Repricing for market expansion and special repricing for expansion will not be applied (abolished)

Type of repricing	Direction	Number of ingredients/products since 2014	Examples (ingredients/products)
For market expansion	Not applicable (Abolish)	54 ingredients/ 126 products	• Pregabalin/ Lyrica • Tolvaptan/ Samsca, etc.
Special repricing for expansion	Not applicable (Abolish)	8 ingredients/ 17 products	• Pembrolizumab/ Keytruda • Sofosbuvir/ Sovaldi • Edoxaban tosilate hydrate/ Lixiana • Esomeprazole magnesium hydrate/ Nexium, etc.
For change of indication	Maintain as it is	2 ingredients/ 7 products	• Omalizumab/ Xolair • Edoxaban tosilate hydrate/ Lixiana
For change of dosage and administration	Maintain as it is	4 ingredients/ 7 products	• Nivolumab/ Opdivo • Pembrolizumab/ Keytruda • Avelumab/ Bavencio • Omalizumab/ Xolair

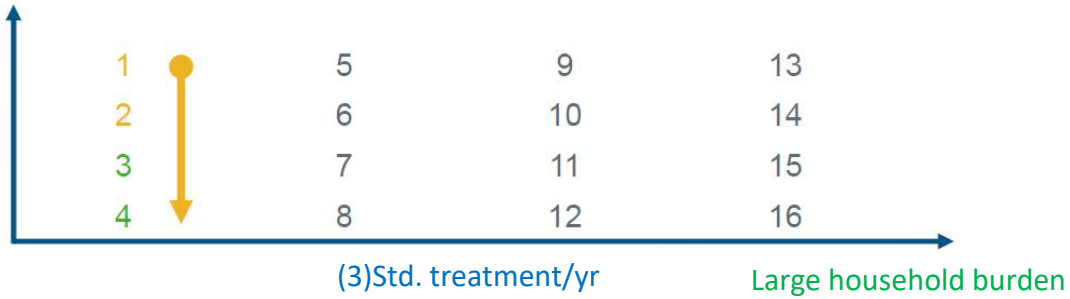
Analysis by INES based on the Chuikyo materials

Challenges for the future（1）Prioritization to secure funding

Prioritization based on a philosophy of social insurance benefits and sustainability of public finances

Priorities for drug pricing system reform (on a single-year basis*)

Three variables	
(1) Drug price	Not important as it is a variable only in appearance
(2) Market size (PxQ)	Impact on public finances for insurance, balance between the sustainability of insurance system and industry competitiveness
(3) Std. treatment/yr	Impact to citizens (patients) Protecting against fiscal risk
Priority of reform	Protecting against fiscal risk



Priorities for reform to secure funding

① Standard expenses are small, but the market size is large. (e.g., patches)

↓

② Standard expenses are small, and the market size is also small.

↓

③ Standard expenses are large, and the market size is also large.

↓

④ Standard expenses are large, but the market size is small. (e.g., Zolgensma, Kymriah)

*Some drugs are used for multiple years and the consideration should be for multiple years, but single-year basis was applied here to simplify the discussion.

Challenges for the future（1）Measures to secure funding

Measures focused on drugs with small personal burden

Product category	Issues
Drugs with large impact on insurance but small financial risk to individuals	■ **Introduction of partial copayment of drug costs and its specific measures** • Introduce the "French method" of changing the copay rate for each drug or the "Swedish method" of requiring a certain fixed amount of copay. ⇨ Need to revise Health Insurance Law (Supplementary provision to the 2002 amendment to the Health Insurance Law: the benefit rate shall be maintained at 70% in the future)
Generics, Biosimilars **LLPs**	■ **Promote use of generic drugs and biosimilars** • Promote further uptake to achieve healthier public finances ■ **Speed up withdrawal of LLPs and accelerate new drug development** • Rules to promote withdrawal of LLPs that have been replaced by a certain level of generics. • Ask generics manufacturers to share the responsibility of stable supply, information gathering/sharing, and quality control and speed up the pace of LLPs to generics replacement.
OTC drugs, OTC equivalents	■ **Exclude OTC equivalents from insurance listing** • Exclusion of OTC equivalents and other drugs with low economic evaluation should be through existing systems such as the “system for medical treatment combining insurance-covered and non-covered services” to avoid mixed medical treatment. ⇨ However, the fiscal impact of excluding OTC equivalents may be only temporary. ■ **OTC equivalents, OTC drugs, and switch OTC** • Large distribution costs are added to OTC drug prices, making OTC equivalents much cheaper. Excluding OTC equivalents from insurance may not increase OTC drug usage/self-medication. • If OTC equivalents are excluded from insurance when switch OTC is introduced, manufacturers may not want to promote switch OTC.

Challenges for the future（2）Securing budget for development of low-profit drugs: use of special quota

Setting a threshold value based on P×Q×T, and maintaining the drug price until the threshold is met to ensure profitability.

Special quota:

- Special quotas will be set for drugs that have a high medical need but low profitability, making it difficult for companies to invest in R&D. The quotas will provide flexibility in setting drug prices within a threshold based on P x Q x T, thereby enhancing predictability and promoting return on investment.

Target items:

- Drugs for which profitability is low despite high necessity, such as drugs for AMR (drug-resistant bacteria)
- The MHLW will designate the target items based on the opinions of external experts.

Scheme:

- A threshold of cumulative annual sales (P x Q x T) is set in advance for each drug covered by the special quota.
- The drugs subject to the special quota shall not be subject to macroeconomic indexing. However, if the threshold value of P x Q x T is exceeded, the adjustment mechanism will be applied.
- The system will be operated as a separate system from PMP.

Drug price calculation:

- The price will be negotiated with the manufacturer. The price and the P x Q x T threshold will be renegotiated in advance when changes in dosage and administration or additional indications are expected.

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