Summary of the Japanese healthcare and HTA systems.

HTA System in Japan: Progress and Issues
ISPOR RWS 2025

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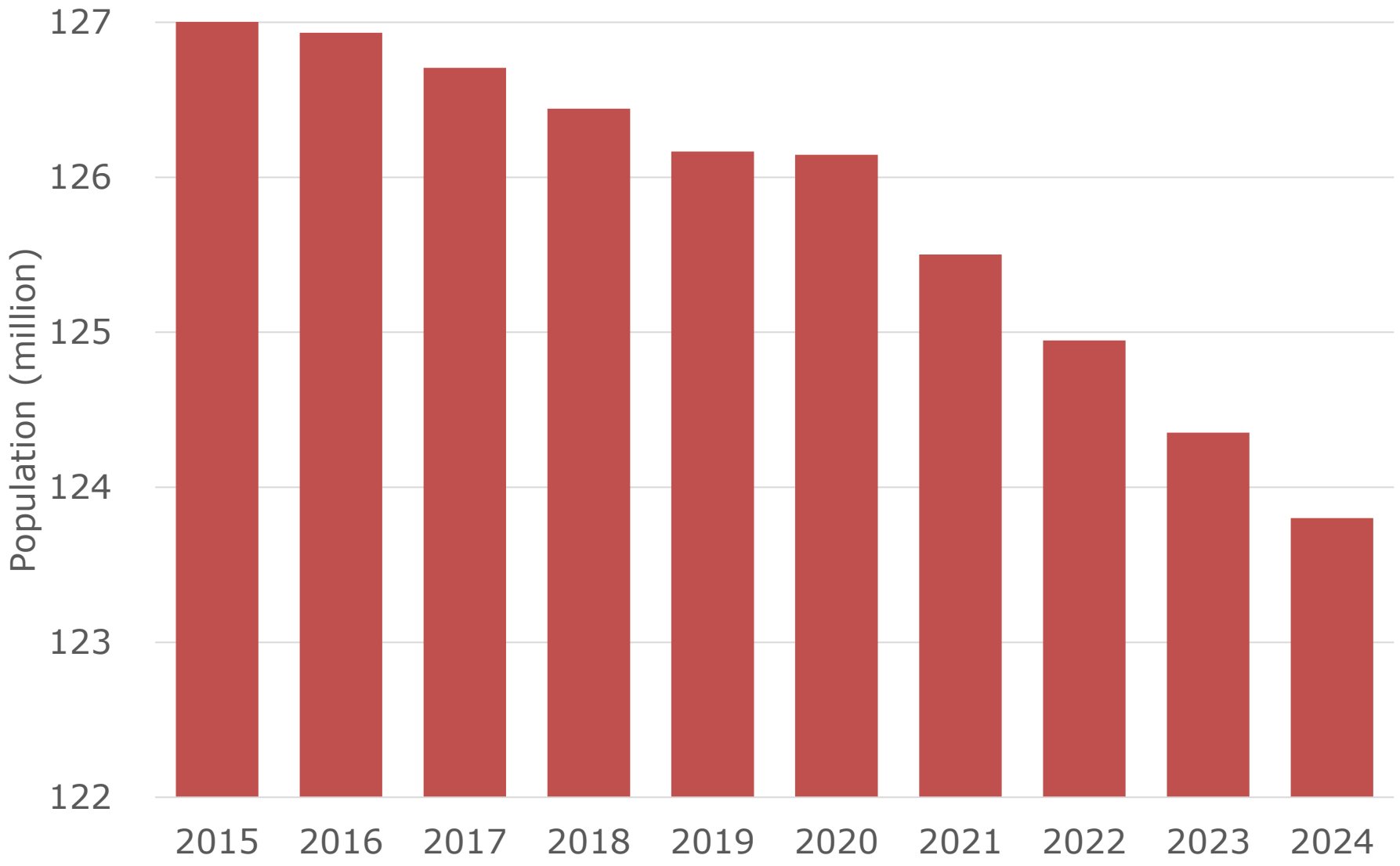
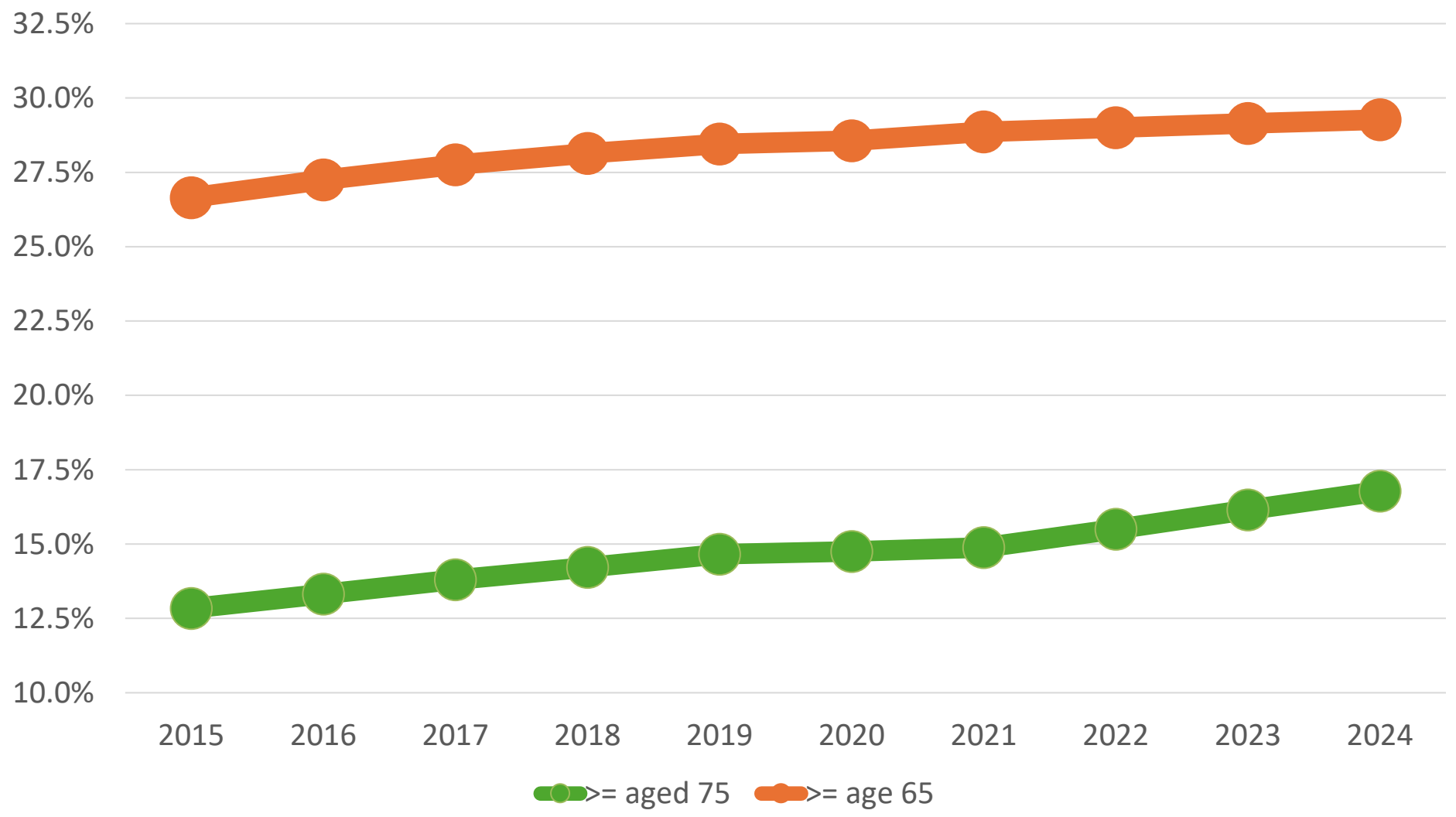
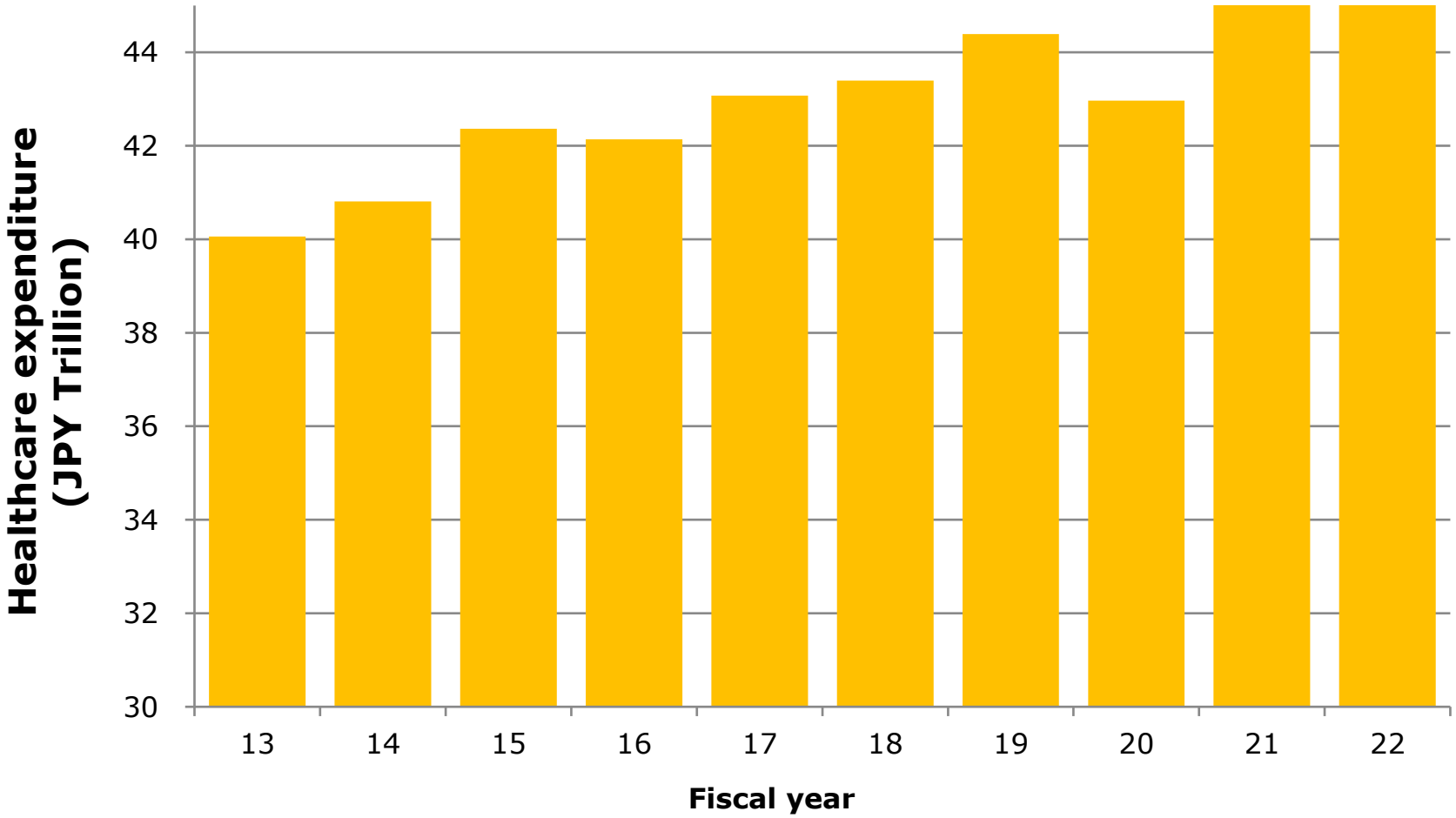
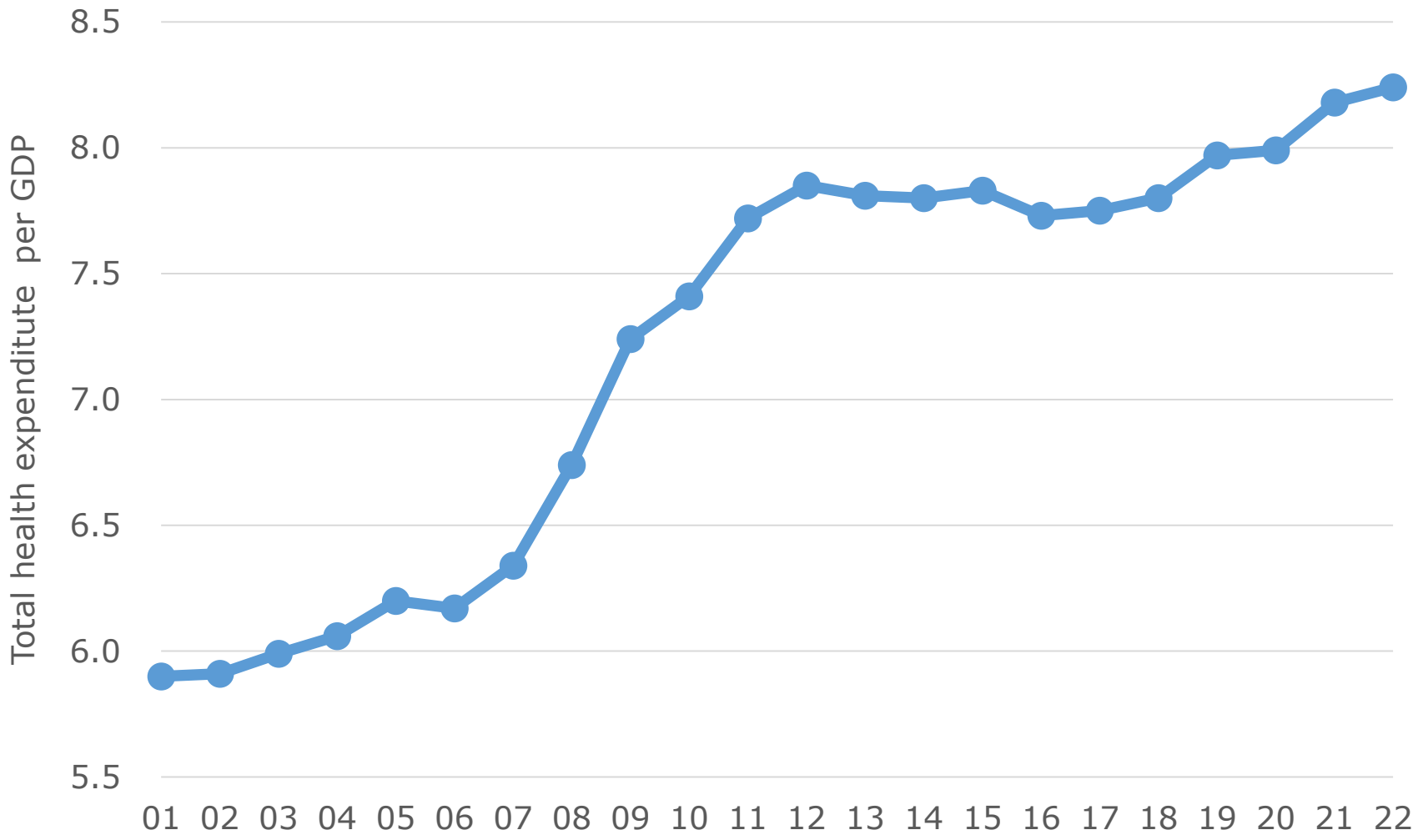
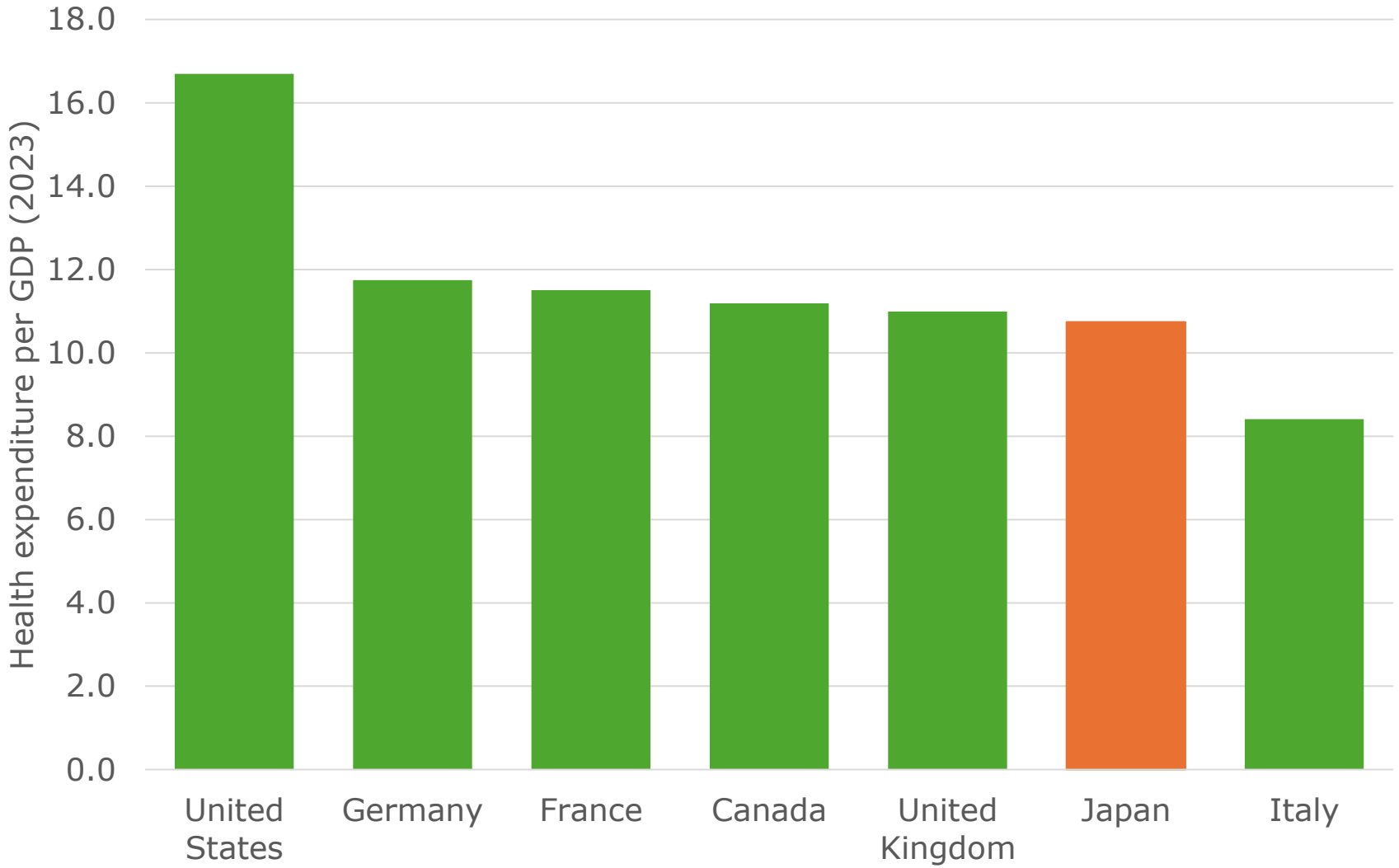

Population (million)
127
126
125
124
123
122
2015
2016
2017
2018
2019
2020
2021
2022
2023
2024

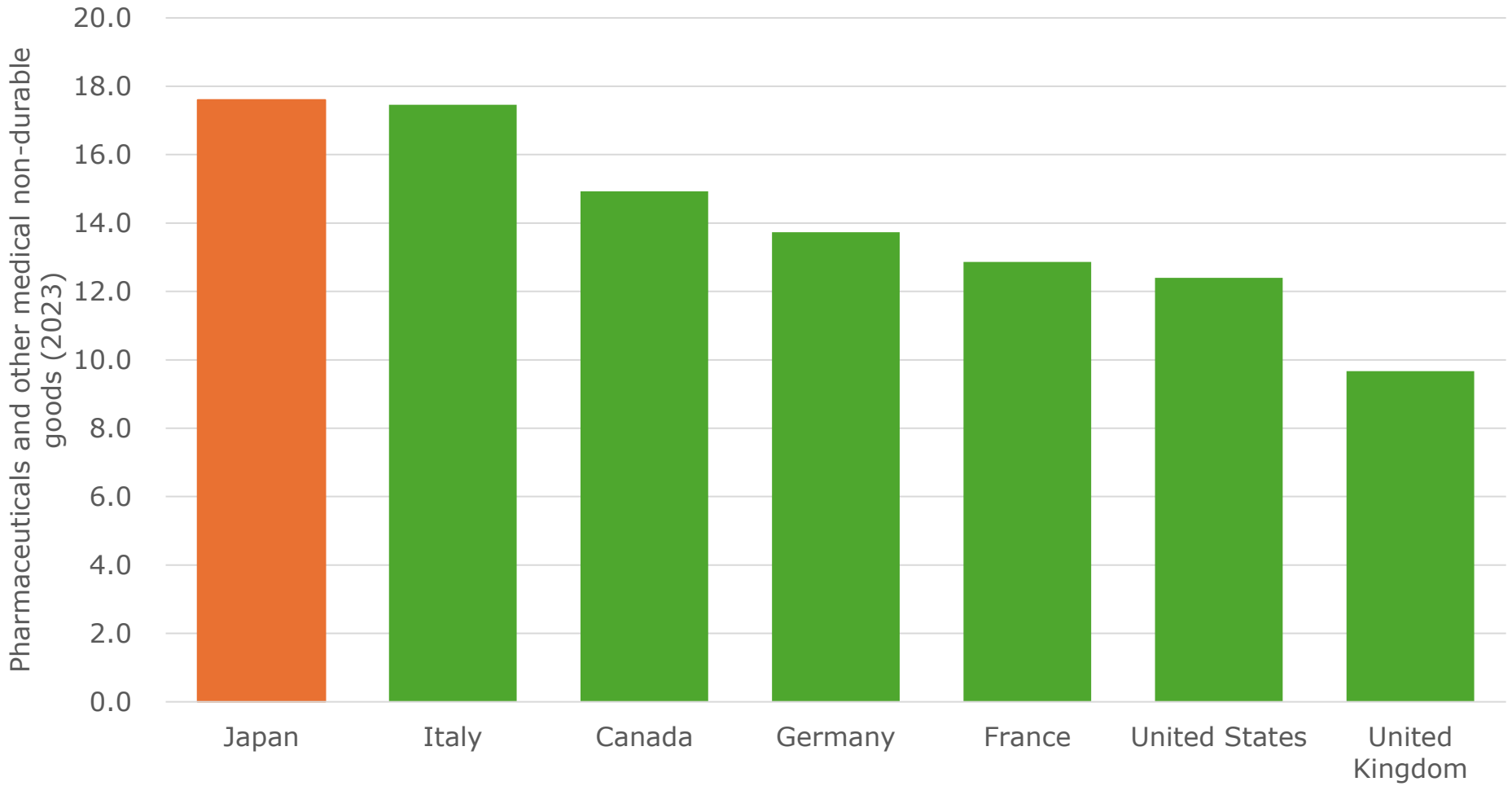

32.5%
30.0%
27.5%
25.0%
22.5%
20.0%
17.5%
15.0%
12.5%
10.0%
2015
2016
2017
2018
2019
2020
2021
2022
2023
2024
>= aged 75
>= age 65

- USD 1= JPY 150
- EUR 1 = JPY 170
- JPY 1 trillion = USF 6.6 million = EUR 5.9 billion

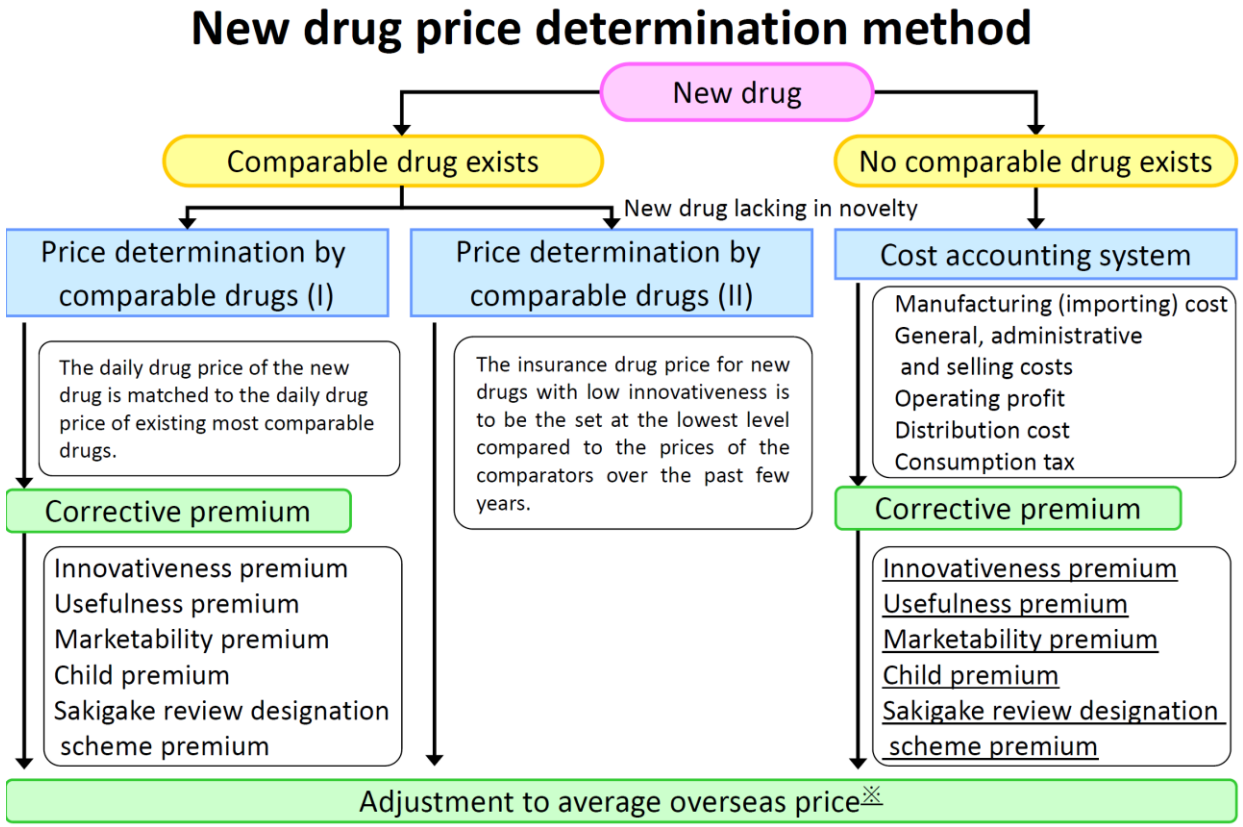



Total health expenditute per GDP
8.5
8.0
7.5
7.0
6.5
6.0
5.5
01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22


Health expenditure per GDP (2023)
18.0
16.0
14.0
12.0
10.0
8.0
6.0
4.0
2.0
0.0
United States
Germany
France
Canada
United Kingdom
Japan
Italy


Pharmaceuticals and other medical non-durable goods (2023)
20.0
18.0
16.0
14.0
12.0
10.0
8.0
6.0
4.0
2.0
0.0
Japan
Italy
Canada
Germany
France
United States
United Kingdom

Drug pricing system in Japan



More detailed information: https://www.pmda.go.jp/files/000236926.pdf

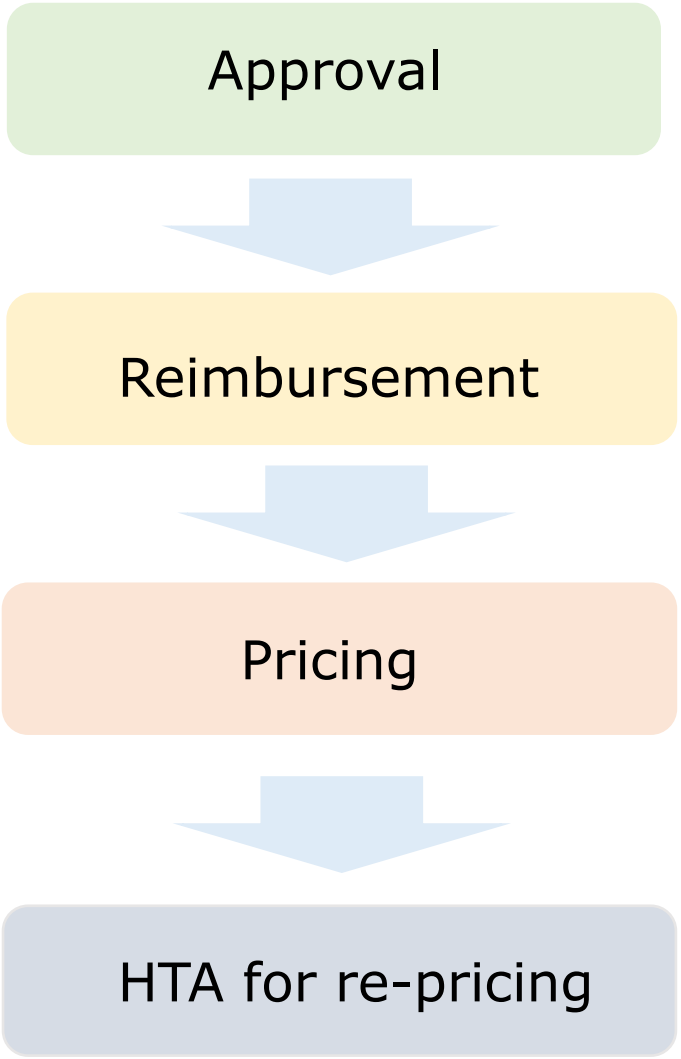
- **Cost-comparison method (類似薬効比較方式)**

  New drug price = Existing drug price + Premium (5-120%, if it is accepted)

- **Cost-calculation method (原価計算方式)**

  New drug price = Manufacturing costs + Profit + Premium

(*)Japanese drug price is reimbursement price, not ex-factory price. No official margin of wholesalers.



Pharmaceuticals and Medical Devices Agency (PMDA) [Japanese FDA]

・Health economic bureau of Ministry of Health, Labour and Welfare (MHLW)

Drug prices were determined at the same time as reimbursement.

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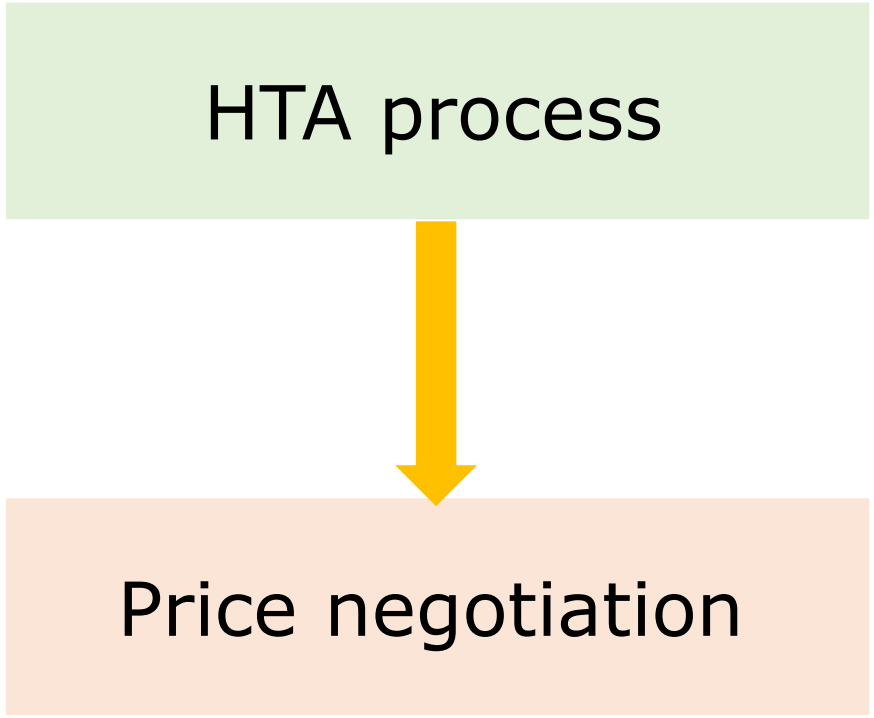
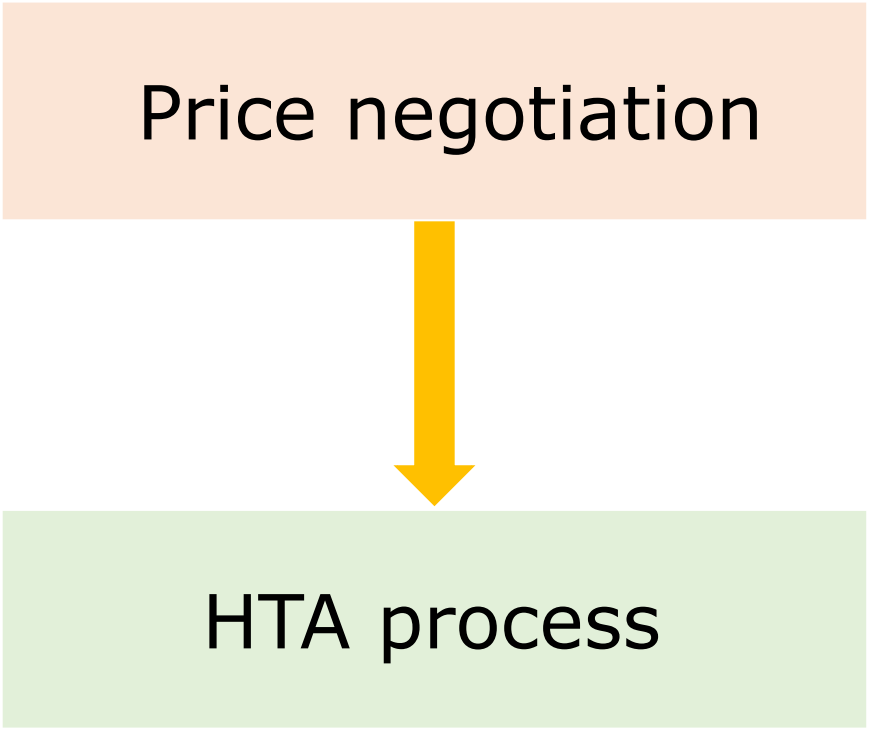
(a) Many countries



(b) Japan



- Negative listing: Almost all approved products were reimbursed
- Reimbursement continues even if a drug is not cost-effective.
- Pharmaceutical companies can not offer confidential discounts.

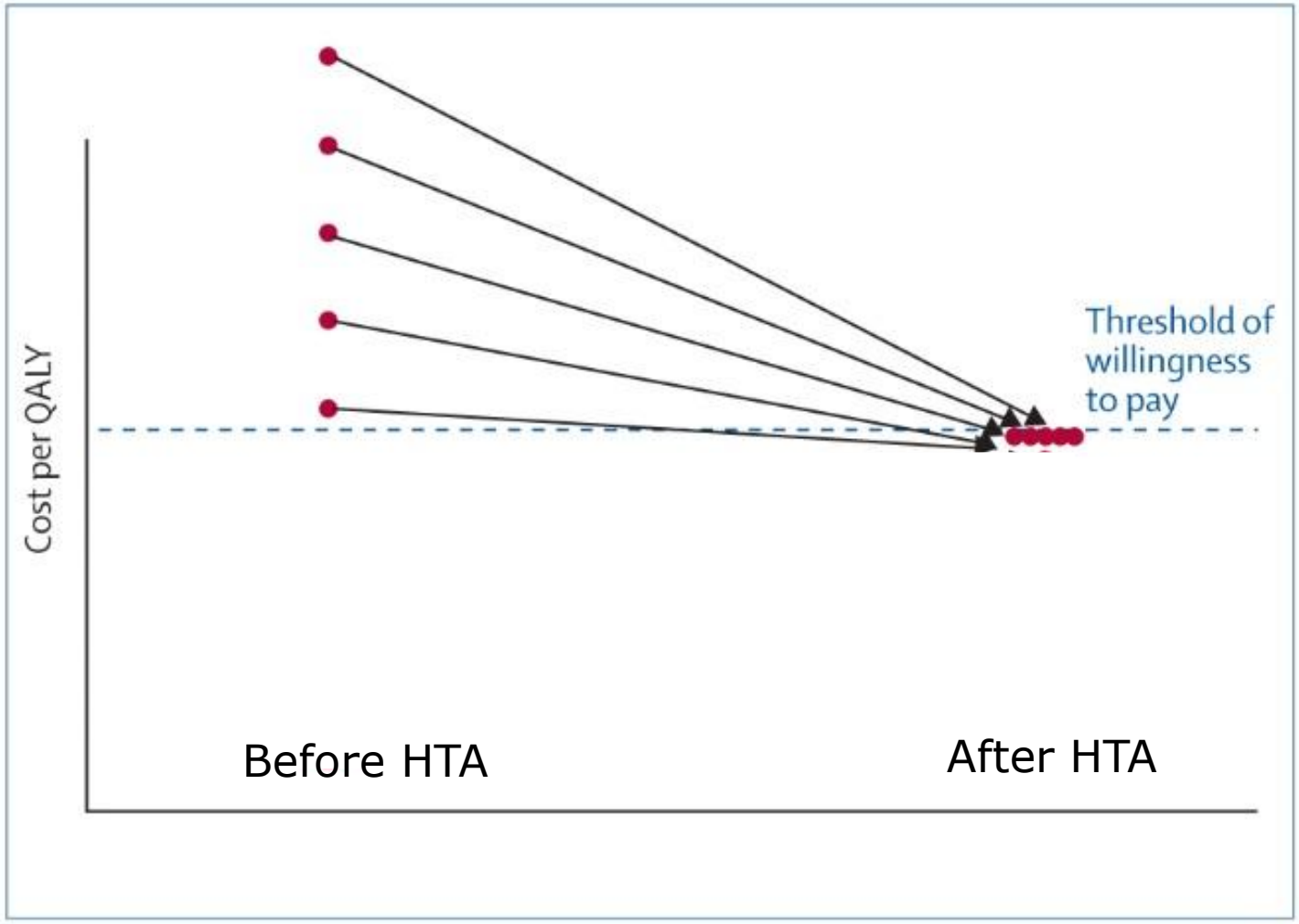
Selection criteria of products for cost-effectiveness evaluation

- **Cost-comparison method (類似薬効比較方式)** -> Only Products with premium

  New drug price = Existing drug price + Premium (5-120%, if it is accepted)

- **Cost-calculation method (原価計算方式)** -> All products

  New drug price = Manufacturing costs + Profit + Premium


Cost per QALY
Threshold of willingness to pay
Before HTA
After HTA

New prices after cost-effectiveness evaluation

- **Cost-comparison method (類似薬効比較方式)**

  New drug price = Existing drug price + Premium

  Reduction rate by cost-effectiveness evaluation: ~90%

- **Cost-calculation method (原価計算方式)**

  New drug price = Manufacturing costs + Profit + Premium

  Reduction rate: ~50%

Maximum Discount rate : 15% of new drug price

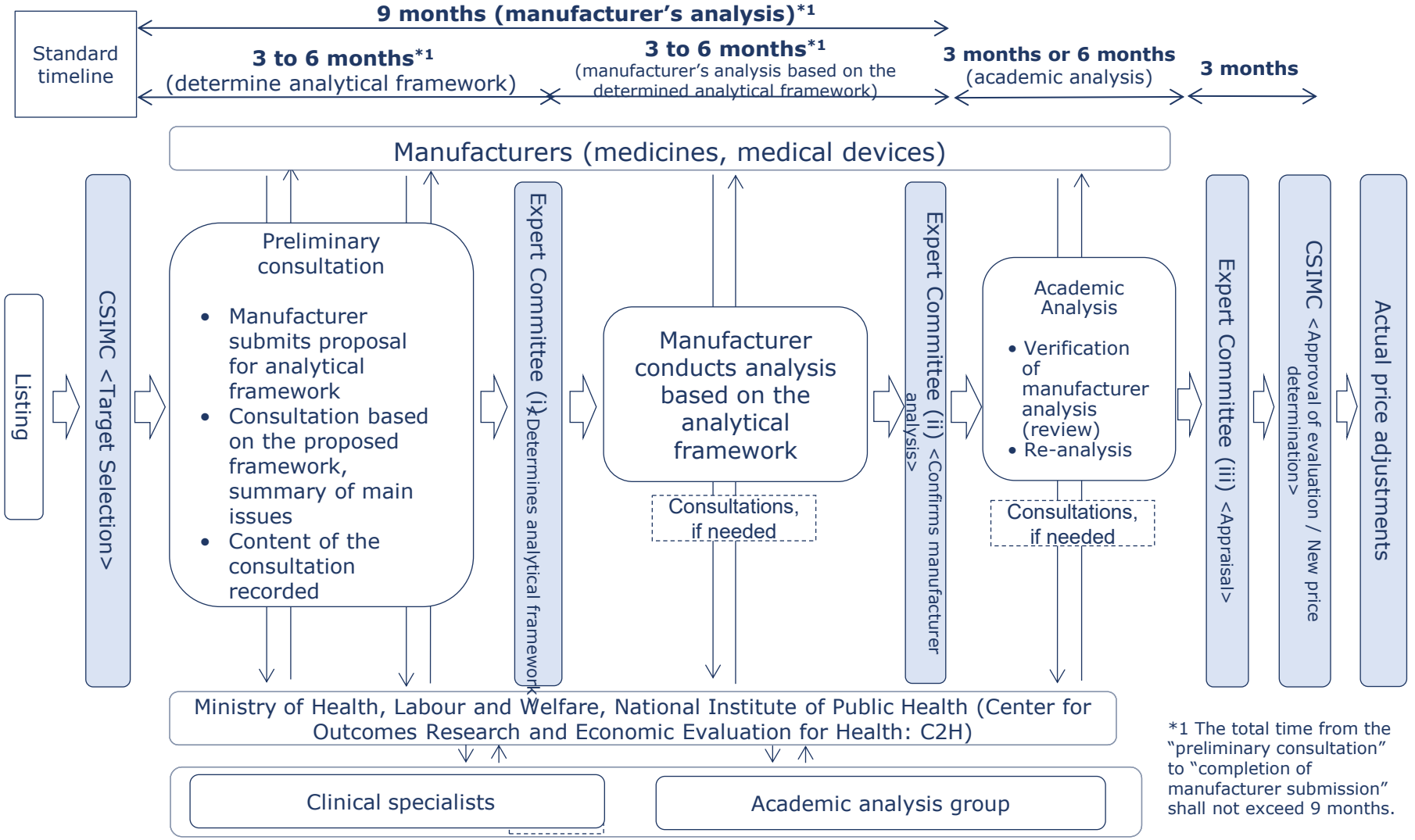
- Basic threshold:

  JPY 5 million (about EUR 30,000) per QALY
  ≈ 1x GDP capita in Japan

- Threshold for special products
(anti-cancer drugs, pediatric drugs etc.)

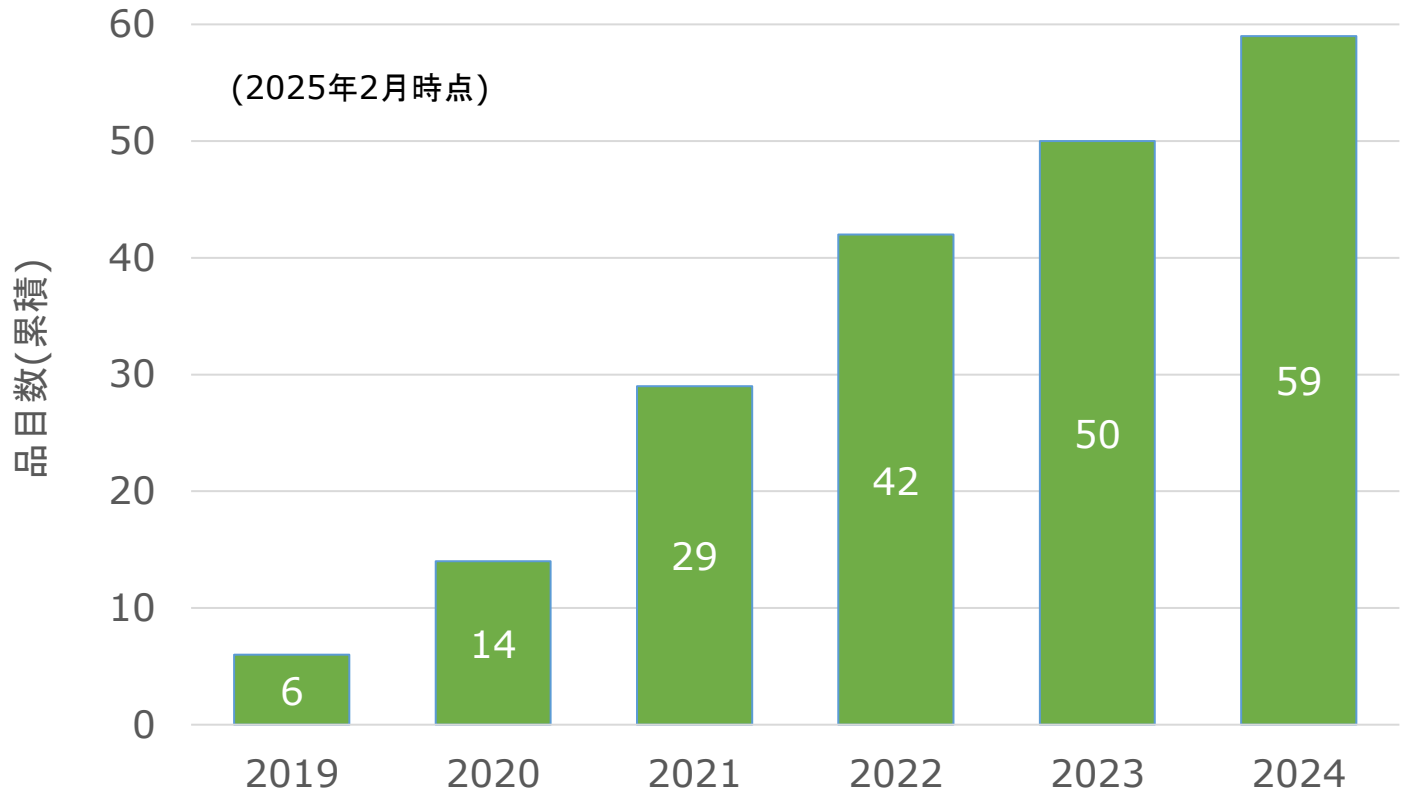
  :JPY 7.5 million (about EUR 45,000) per QALY

(3) [1]-[5] Process for cost-effectiveness evaluations

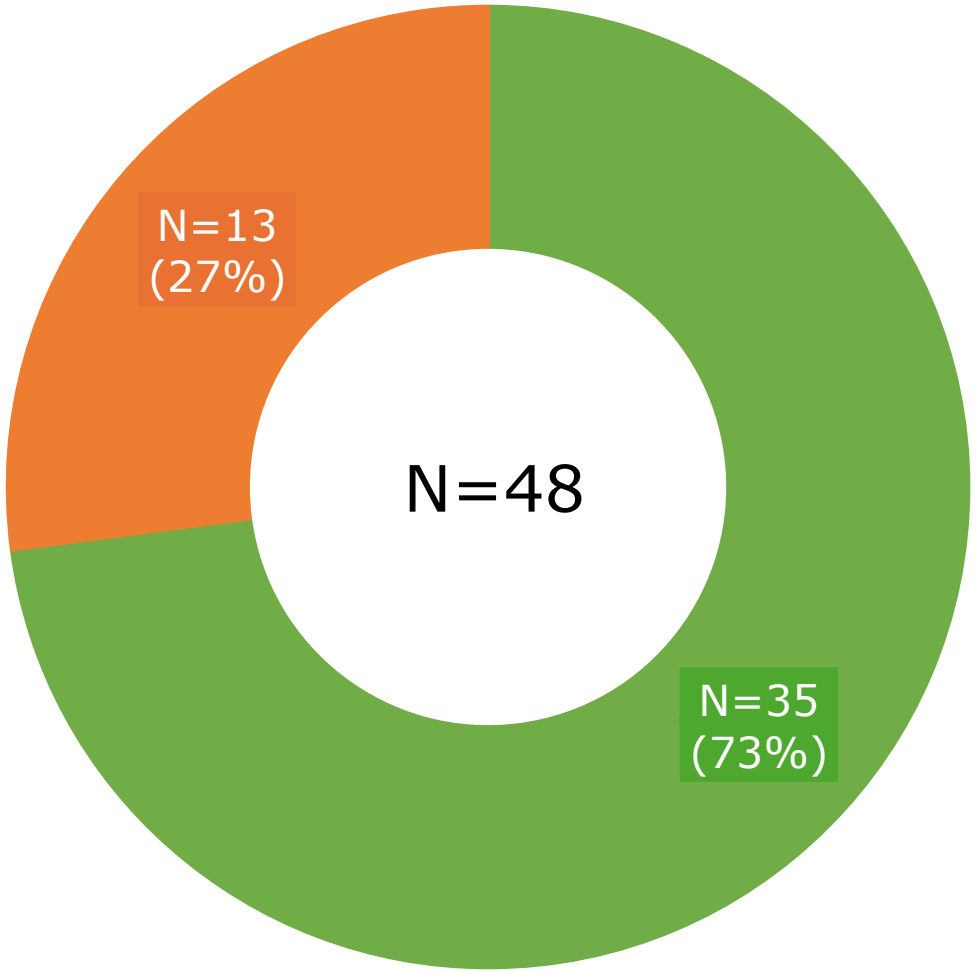


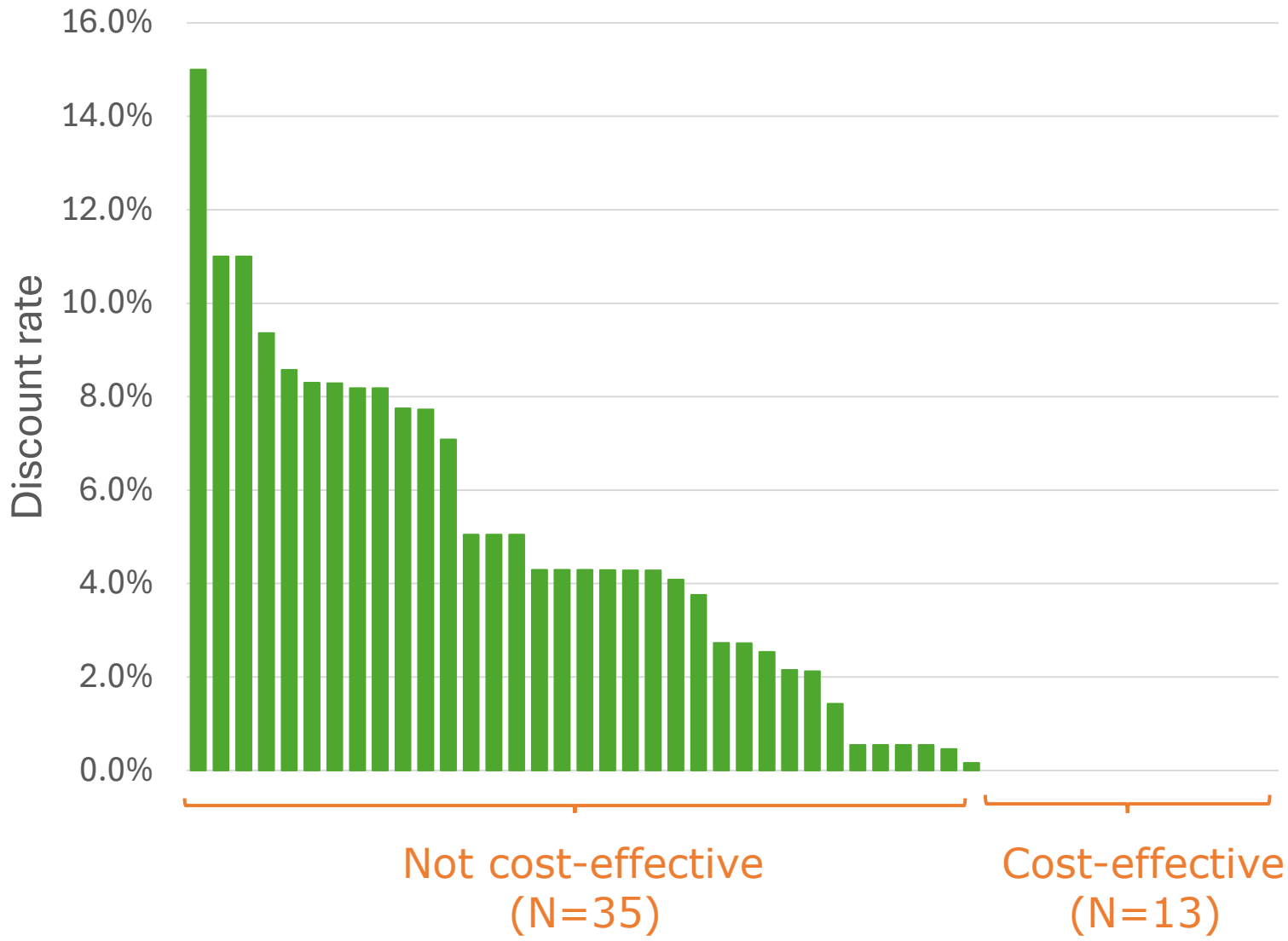
*1 The total time from the "preliminary consultation" to "completion of manufacturer submission" shall not exceed 9 months.

The accumulated number of drugs for cost-effective evaluation

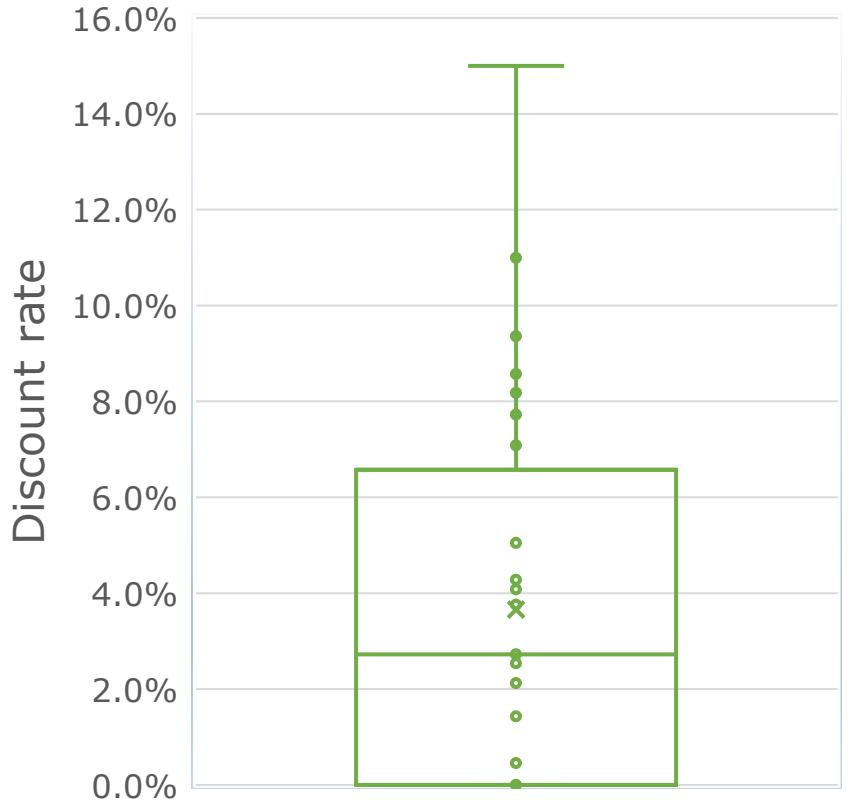


Results:

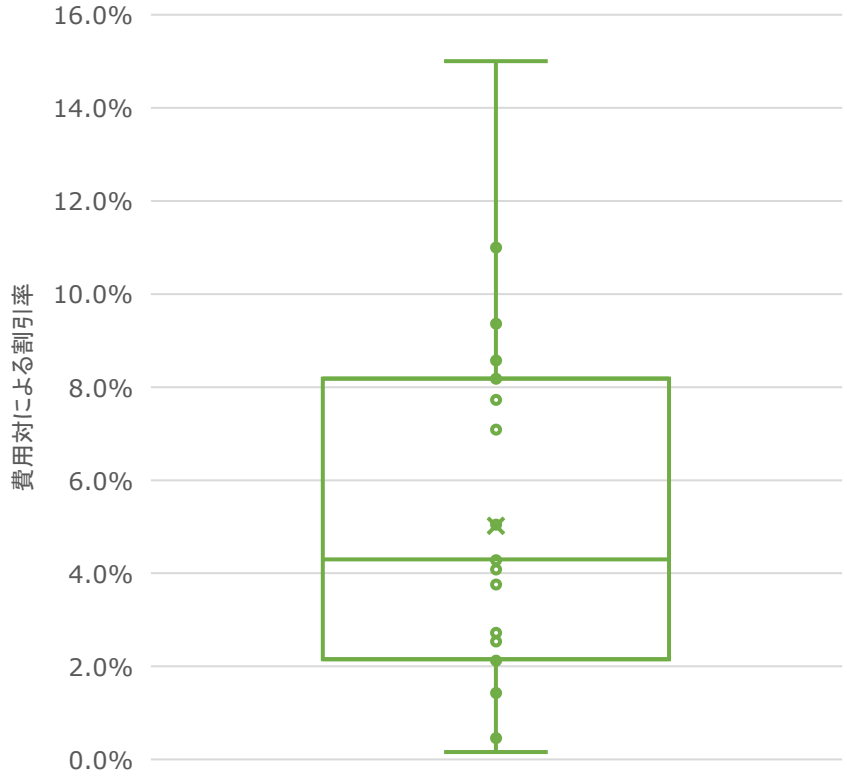

N=13
(27%)
N=48
N=35
(73%)
Not cost-effective
Cost-effective
(as of Aug 2025)


16.0%
14.0%
12.0%
10.0%
8.0%
6.0%
4.0%
2.0%
0.0%
Discount rate
Not cost-effective
(N=35)
Cost-effective
(N=13)

(1) All the products



(2) Only not cost-effective products



Basic Policy on Economic and Fiscal Management and Reform

経済財政運営と改革の基本方針2025について

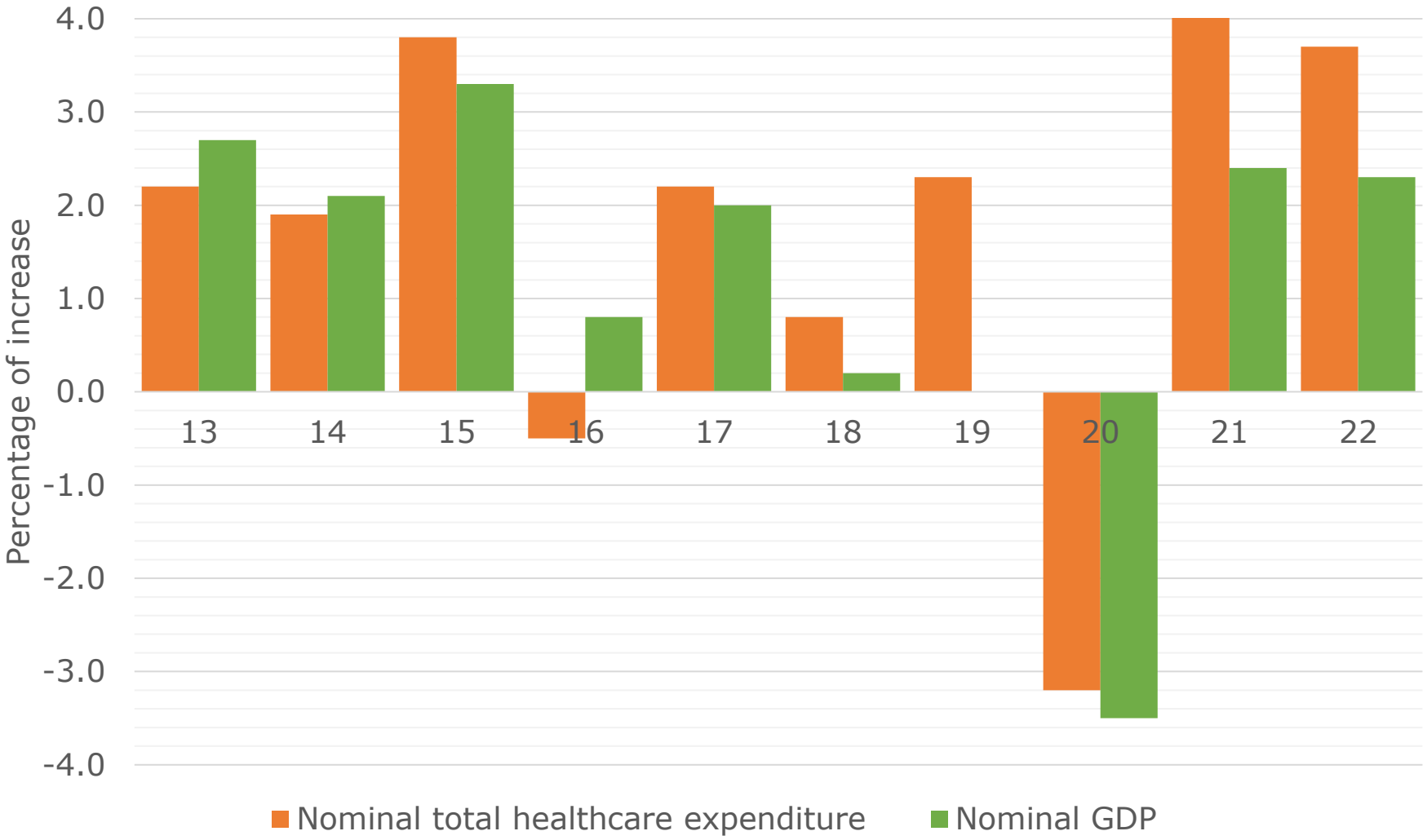
令和７年６月１３日
閣議決定

経済財政運営と改革の基本方針2025を別紙のとおり定める。

費用対効果評価制度について、客観的な検証を踏まえつつ、更なる活用に向け、適切な評価手法、対象範囲や実施体制の検討と併せ、薬価制度上の活用や診療上の活用等の方策を検討する。


healthwatch
NICE
National Institute for
Health and Care Excellence

Back up


4.0
3.0
2.0
1.0
0.0
-1.0
-2.0
-3.0
-4.0
Percentage of increase
13
14
15
16
17
18
19
20
21
22
Nominal total healthcare expenditure
Nominal GDP

- Mandatory coverage for anyone who permanently resides in Japan for three months or more. This includes both Japanese citizens and non-Japanese citizens.

- Enrollees have no choice of health insurance programs. Plans are designated according to the enrollee's employment status, age, and residence

- There are no restrictions on access. Regardless of the plan, enrollees can receive care from any medical provider as frequently as they would like.

- Benefit packages are essentially the same.

- Copayments are the same across all plans. Cost-sharing varies according to age. Normally 30%. Children under 3 have a 20% copayment and persons over 70 with low incomes have a 10% copayment.3

https://japanhpn.org/en/hs1/