



Recent Direction of Management for Drug Pricing in Japan Including Oral Hypoglycemic Agents (OHAs)

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Abstract

The authors have researched primary care medicine with drug pricing in actual practice, and reported oral hypoglycemic agents (OHAs) annually in 2023-2025. The drug price revision in April 2025 aimed to promote pharmaceutical innovation, ensure a stable supply, and reduce the burden on the public. It has decided by the Ministry of Health, Labor and Welfare (MHLW), Japan. In consideration of current rising prices and ensuring stable supply of medicines, the minimum drug price was elevated by about 3%, and it was applied to 680 ingredients and 3,231 items. MHLW considers establishing a "Drug Discovery Support Fund" in the future.

Keywords: Ministry of Health, Labor and Welfare (MHLW); Drug pricing; Oral hypoglycemic agent (OHA); Drug Discovery Support Fund; Japan Pharmaceutical Manufacturers Association (JPMA)

Commentary Article

The authors have traditionally practiced and researched primary care medicine, focusing on diabetes and life style-related diseases. Understanding drug prices is also important during our daily practice, and we reported on oral hypoglycemic agents (OHAs) for diabetes in spring 2023 and spring 2024 [1,2]. In Japan, detailed adjustments are made every year in response to trends in the medical region. In this article, some important topics for pharmaceutical issues, as well as drug pricing trends and changes in spring 2025 will be described.

In November 2024, "Joint Statement on Proposals for the FY2025 Off-year Drug Price Revision and National Biopharmaceutical Strategy" was announced from three groups [3]. They included Japan Pharmaceutical Manufacturers Association (JPMA), Pharmaceutical Research and Manufacturers of America (PhRMA) and European Federation of Pharmaceutical Industries and Associations (EFPIA Japan) [4]. Among them, two proposals were included: They are i) Abolish the FY2025 Off-year Drug Price Revision and Oppose Backsliding Policies. By the FY2024 drug pricing reform, the eligibility criteria for the Price Maintenance Premium (PMP) was improved. Consequently, it increased the

probability that prices of future medicines will be maintained during the patent period. In addition, ii) Create a New National Biopharmaceutical Strategy Under Cross-ministerial Body. With the right policies and plans, Japan can prevent drug loss, restore its global leadership in drug discovery and attract global biopharmaceutical industry investment that drives economic growth. To realize these, Japanese strong leadership and collaboration with the private sector would be necessary. In the next year's Public-Private Council, the platform will be required for regular dialogue with the global biopharmaceutical industry.

The drug price revision implemented in April 2025 aimed to promote pharmaceutical innovation, ensure a stable supply, and reduce the burden on the public. Then, it developed a major shift from the previous uniform price reduction method to more tailored responses according to the characteristics of each pharmaceutical. The new fiscal year 2025 started on April 1, 2025 [5]. After making the necessary announcements on March 7, adjustments were made to the original drugs for which generic versions exist. As a result, the prices for many medicines have been decided by the Ministry of Health, Labor and Welfare (MHLW), with minor adjustments to April 1, April 16, and May 21, and are also published online.

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Instead of previous uniform standard of "more than 0.625 times the average deviation rate," different standards were set for each drug category in the 2025 revision [6].

- New drugs eligible for the new drug creation premium: Items with a deviation rate exceeding the average deviation rate (5.2%) are subject to the revision.
- New drugs not eligible for the new drug creation premium: Items with a deviation rate exceeding 0.75 times the average deviation rate (approximately 3.9%) are subject to the revision.
- Long-listed products: Items with a deviation rate exceeding 0.5 times the average deviation rate (approximately 2.6%) are subject to the revision.
- Generic drugs: Items with a deviation rate exceeding the average deviation rate are subject to the revision.

From these review, the number of items subject to revision has been reduced from 69% to 53% of the total.

Table 1: Changes in drug prices for OHA.

Meds	Dosis	2023	2024	2025
Metformin	250mg	10.10	10.10	10.40
Metformin	500mg	10.30	10.10	10.40
Equa	50mg	65.30	60.60	42.70
EquMet LD	50mg/250mg	55.70	51.00	47.20
EquMet HD	50mg/500mg	55.00	50.20	46.50

a) Prices are described by Japanese Yen (JY).
 b) One dollar equals to 142-143 JY on June 3, 2025.
 c) Latest information is in the reference #5 and #6.

MHLW raised the minimum drug price and repricing unprofitable products. In consideration of current rising prices and ensuring stable supply of medicines, the minimum drug price was elevated by about 3%, and it was applied to 680 ingredients and 3,231 items. Furthermore, repricing of the unprofitable products was applied to 182 ingredients and 429 items, and antipyretics and also analgesics (ibuprofen, acetaminophen, and loxoprofen sodium) and hemostatic agents (tranexamic acid) were added in response to the influenza epidemic. For OHAs, drug prices of Metgluco (metformin), Equa (vildagliptin) and EquMet (vildagliptin/metformin) are summarized in Table 1. For an impressive determinant, the prices of combined agents are lower than single agent.

The Central Social Insurance Medical Council held a general meeting on January, 2025 and approved a proposal to revise drug price calculation standards in conjunction with the 2025 drug price revision. For the 2025 revision, the scope of revisions will be set in detail according to the characteristics and role of each item. In response to the sudden rise in raw material costs and to ensure a stable supply of pharmaceuticals, unprofitable products will be also

revalued. Initially, the items to be subject to the revaluation were planned to be i) items with the same composition and dosage form as those designated as essential pharmaceuticals, ii) items in categories A and B of stable pharmaceuticals, and iii) items for which the MHLW requested increased production (antitussives and expectorants). However, the current influenza epidemic was given great importance.

In March 2025, the MHLW announced the drug price revision for fiscal year 2025 [6] (MHLW). This is the third midyear revision, and the scope of revision was set for each drug category based on the average deviation rate (5.2%). Among them, rules such as the price range of generic drugs, recalculation of unprofitable products, basic drugs, minimum drug prices, new drug creation surcharge, revision surcharge, and foreign average price adjustment were applied. This midyear revision was the first to deduct the accumulated amount of new drug creation surcharge. Among them, 21 ingredients and 46 products, including the anticoagulant "Xarelto (Rivaroxaban)" and the DPP4-inhibitor "Januvia (sitagliptin phosphate hydrate)", returned the surcharge one year earlier than scheduled. The minimum drug price increase, which was the first to be raised except in response to the consumption tax increase, was applied to 680 ingredients and 3,231 products for the first time. Following the previous midyear revision, unprofitable product recalculation was carried out and applied to 182 ingredients and 429 products.

The MHLW is considering establishing a "Drug Discovery Support Fund (tentative name)" with the aim of promoting innovation in drug discovery. This fund is designed to support start-up companies based on contributions from companies that have new drug development premium items. With the right policies and plans, Japan can prevent drug waste and regain global leadership in drug discovery. The direction could attract research and development (R&D) investment from the innovative pharmaceutical industry, both domestic and international, which would boost economic growth. To achieve this, strong leadership from the Japanese government and cooperation with industry are necessary. We recommend that next year's Public-Private Council establish a permanent inter-ministerial organization to formulate national strategies and Key Performance Indicators (KPIs). Furthermore, we expect the establishment of a forum for regular and fruitful discussions with innovative pharmaceutical companies, both domestic and international.

In summary, latest trends for drug pricing in Japan has been introduced associated with situation for three years [1,2]. Among them, the changes in OHA were summarized. Various influences seem to be found by the judgement of MHLW for adequate management in the future, where pharmacological management will bring well-being of all people.



Conflict of Interest

The authors declare no conflict of interest.

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