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Japan Pharmaceutical Manufacturers Association (JPMA)
Pharmaceutical Research and Manufacturers of America (PhRMA)
European Federation of Pharmaceutical Industries and Associations (EFPIA Japan)

Joint Statement on Need for FY2026 NHI Drug Pricing and Cost-Effectiveness Assessment System Reform

The Central Social Insurance Medical Council ("Chuikyo") is currently discussing the FY2026 NHI Drug Pricing System Reform and the FY2026 Cost-Effectiveness Assessment (CEA) System Reform. From the standpoint of the innovative biopharmaceutical industry, which aims to realize a society of health and longevity through the research, development, and stable supply of new medicines, we express the following opinions.

We have repeatedly raised concerns about the declining state of Japan's biopharmaceutical ecosystem following nearly a decade of unpredictable changes to drug pricing rules and the introduction of annual price cuts to patented medicines. We share the Japanese government's goal of ensuring National Health Insurance (NHI) sustainability and fiscal soundness, but the current ecosystem is not functioning well. The result has been a decrease in Japan's share of the world's early-stage pipeline, stagnant R&D investment, and an extensive drug loss in which innovative medicines available in other countries are not launched in Japan. For example, over the past decade, biopharmaceutical industry R&D investment doubled globally but grew minimally in Japan, with Japan's global share reducing by half.

Strengthening Japan's biopharmaceutical ecosystem is needed to ensure that Japan is not left behind in developing and accessing the world's latest treatments and vaccines. However, current drug pricing policies are undermining Japan's global competitiveness and preventing innovative biopharmaceutical companies operating in Japan from realizing their potential. There is increased urgency for reform given that the U.S. Most-Favored-Nation policy, which references Japan's prices, is reshaping global incentives and leading individual companies to change product development and launch strategies in Japan.

Given these serious challenges, reforms are essential to advance the new Takaichi Cabinet's investment agenda and reflect the findings of the Interim Report (Summary of Discussions) of the Public-Private Council for Enhancing Drug Discovery Working Group compiled on November 5. Furthermore, to ensure long-term fiscal soundness and attract investment, the budget framework that currently relies excessively on drug price cuts should be revisited. Less than 10% of the social security budget is spent on medicines but 70% of budget reductions are from drug price cuts. To reverse the current negative trajectory and secure Japan's future as a leader in innovation, two areas of reform should be prioritized for the FY2026 Drug Pricing System Reform and the FY2026 CEA System Reform.

Proposal 1: Maintain Drug Prices During the Patent Period

Under the current system, products that are ineligible for the Price Maintenance Premium (PMP), which account for half of all patented medicines, receive annual price reductions. Even medicines eligible for the PMP face price reductions through CEA and Market Expansion Repricing (MER). Moreover, the price gap between Japan and other leading developed markets continues to widen following NHI listing. To address these challenges, the following actions to maintain drug prices during the patent period are essential:

(1) Regarding the CEA system, we propose to conduct an objective verification by independent experts rather than expand the system prematurely.

(2) Regarding the drug pricing system, we propose to abolish huge-seller MER and spillover rules, as these significantly undermine innovation, and to improve the MER framework to accommodate new modalities (e.g., regenerative medicines). We also propose to abolish off-year price revisions of patented medicines.

Proposal 2: Improve Initial NHI Price-Setting

The current methods used to set the initial NHI prices of new medicines have restrictive criteria that do not appropriately recognize the value that these medicines bring to Japan's patients, health care system and society. The situation is particularly challenging for highly innovative medicines with new treatment modalities such as regenerative medicines, which lack appropriate comparators under the current pricing method criteria. To improve initial NHI price-setting for innovative medicines, we propose to expand the scope of comparators allowed, review the pricing methods applied to regenerative medicines, and reward additional product value demonstrated post-launch.