



Joint Statement on FY2025 Off-Year Drug Price Revision Outcome, Cost-Effectiveness Evaluations and Mandatory Drug Discovery Support Fund

The Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) represent the world's leading biopharmaceutical research companies operating in Japan. We support an innovation ecosystem that encourages the discovery of medicines that transform lives, and where we work as trusted partners with the Japanese government so that patients can access the treatments they need.

Today, the Ministry of Health, Labor and Welfare (MHLW) finalized the FY2025 National Health Insurance off-year drug price revision at a meeting of the Central Social Insurance Medical Council. MHLW also announced plans to consider expanding cost-effectiveness evaluations in FY2026 and implementing market expansion re-pricing in the FY2027 off-year drug price revision, as well as to develop legislation that would require biopharmaceutical research companies to pay for a startup fund. PhRMA and EFPIA are issuing this joint statement opposing these policies.

We have repeatedly raised concerns about the declining state of Japan's ecosystem following nearly a decade of unpredictable changes to drug pricing rules and the introduction of annual price cuts to patented medicines. The result has been a decrease in Japan's share of the early-stage pipeline, stagnant R&D investment, and a drug loss in which innovative medicines available in other countries are not launched in Japan.

The Kishida Administration took important first steps to restore Japan's ecosystem and reduce drug loss, including the FY2024 drug pricing reform implemented in April, goals proposed at the Gate Opening Summit for Innovative Drug Discovery in July, and plans for a Public-Private Council next year. We embraced this positive change and began developing policy proposals, a bioventure fund and other investment initiatives. Many of our member companies re-examined and even accelerated their drug development programs in Japan.

Yet only months later, we are surprised and deeply disappointed that the new Ishiba Administration has reversed course and expanded the scope of price cuts to innovative medicines in the FY2025 off-year drug price revision. In doing so, the government will apply price cuts to 43% of patented medicines and implement rules, such as Price Maintenance Premium (PMP) return, that are not based on actual market prices and that have never been applied in an off-year drug price revision. For some companies, this unexpected decision disrupts over a decade of careful planning and costs tens of billions of yen.

We are also discouraged by the lack of transparency that has led to this point. While the industry communicated the initial positive impact of the FY2024 drug pricing reform in good faith, the government pursued anti-innovation policies with no stakeholder consultation that will only further harm Japan's patients, health care system and economy.

In addition, MHLW will proceed with considering an expansion of cost effectiveness evaluations in the FY2026 system reform, which may include increasing the number of innovative medicines subject to price cuts and the magnitude of these price cuts. As has been the experience in other countries, expanding these anti-innovation policies in Japan will only worsen drug loss and decrease R&D investment.

We also learned recently that the government intends to mandate a “Drug Discovery Support Fund” for early-stage startups by taxing company revenues from medicines that qualify for the PMP – products that MHLW recognizes as the most clinically innovative in Japan. We welcome voluntary funding initiatives to help translate promising science into clinically successful products if they are coupled with policy reforms to restore Japan’s ecosystem. We oppose mandating companies to invest in this government fund, which will further decrease market attractiveness. Creating a vibrant investment environment cannot be achieved by fiat.

This decision takes Japan back down the path that led to declining drug discovery and drug loss in the first place. Earlier this year, we presented MHLW with a joint association survey in which 28 of 30 member companies identified off-year price revisions as the most significant policy decreasing the willingness of companies to develop new medicines and invest in Japan. Without a predictable and supportive reimbursement environment for cutting-edge treatments, the goals proposed at the Gate Opening Summit for Innovative Drug Discovery are unachievable and the plans for the Public-Private Council will be futile. As a result, we will suspend our participation in these efforts until MHLW chooses to retract this misguided policy.

Our industry remains committed to fighting so that Japanese patients have early access to the latest innovations. We are confident that Japan can prevent drug loss, restore its global leadership in drug discovery and attract global biopharmaceutical industry investment with the right policy environment and trust between partners.