

December 26, 2025

Joint Statement on FY2026 National Health Insurance Drug Pricing and Cost-Effectiveness Assessment System Reform Frameworks

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 and cures they need.

Today, the Ministry of Health, Labor and Welfare (MHLW) finalized the FY2026 National Health Insurance (NHI) Drug Pricing System Reform Framework and the FY2026 Cost-Effectiveness Assessment (CEA) System Reform Framework at a meeting of the Central Social Insurance Medical Council. PhRMA and EFPIA are issuing this joint statement regarding the outcome and the continued need for the Japanese Government to make meaningful policy reforms to restore its innovation ecosystem.

We share the Japanese Government's goal of ensuring NHI sustainability, but the current policy framework, which depends on repeated price cuts to patented medicines, does not function well. The result has been a decrease in Japan's share of the world's early-stage pipeline, stagnant R&D investment and extensive drug loss in which innovative medicines available in other countries are not launched in Japan. To reverse this decline, we have regularly engaged with the government and proposed policy reforms to maintain drug prices during the patent period, improve how Japan sets initial prices for new medicines and address inefficiencies in NHI spending on non-patented medicines and other health care. Unfortunately, the FY2026 reform frameworks announced today largely ignore these opportunities and signal continued dependence on price cuts to patented medicines.

FY2026 NHI Drug Pricing System Reform Framework

While we welcome the abolishment of the spillover repricing rule, which for years irrationally cut the prices of medicines when competing products earned larger-than-expected sales revenue, we are disappointed that other systemic improvements have been postponed and that the overall outcome remains heavily skewed toward cost-containment. Instead of supporting innovation by reinvesting savings from reduced spending on long-listed products as originally envisioned, the announced framework will expand the frequency and criteria for Market Expansion Repricing and implement the FY2027 Off-Year Drug Price Revision. This continues a troubling pattern whereby price-cutting rules are created or amended to target specific breakthrough medicines for hepatitis C, cancer, Alzheimer's Disease, diabetes and obesity.

FY2026 Cost-Effectiveness Assessment System Reform Framework

We have raised concerns that Japan's CEA system is an elaborate price-cutting tool that should not be expanded, and the accumulated experience now supports our assertion. To date, 39 of 51 (76%) patented medicines that completed these flawed assessments had prices cut and none had prices increased. While we appreciate the planned "objective verification" of the CEA system before making future reform decisions, we have significant concerns regarding the assumption that the price-cut range will be expanded in FY2026. We expect that this objective verification process will be conducted transparently by independent experts based on scientific evidence and

that any future system does not continue to undermine the value of innovative medicines to Japan's patients and health care system.

In conclusion, restoring Japan's drug discovery capabilities and ensuring timely patient access to new medicines will require bold policy reforms instead of the status quo. A successful effort must overcome the current funding structure in which medicines account for less than 10% of social security spending but receive 70% of social security budget cuts. The reform imperative has never been more urgent given the need for all wealthy countries to pay their fair share for innovative medicines against the backdrop of U.S. Most-Favored-Nation policies that are reshaping global incentives for product development and launches in Japan. We look forward to participating actively in these reform discussions and working with the new Takaichi Administration to achieve a fairer outcome for all.