



December 20, 2023

**Joint Statement on FY2024 NHI Drug Pricing System Reform Framework
and FY2024 Cost-Effectiveness Analysis System Reform Framework**

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

Today, the Central Social Insurance Medical Council (“Chuikyo”) finalized the FY2024 NHI Drug Pricing System Reform Framework (“Drug Pricing System Reform Framework”) and the FY2024 Cost Effectiveness Analysis System Reform Framework (“Cost Effectiveness Analysis 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 innovative medicines, we express the following opinions.

JPMA, PhRMA and EFPIA have fundamentally sought to achieve the promotion of innovation and patient access to new medicines, and the sustainability of universal health coverage. To this end, we have advocated to ensure that the value of innovative medicines is appropriately reflected in pricing decisions and that prices are maintained during the patented period as in other developed countries.

The Drug Pricing System Reform Framework includes a new price premium to incentivize the early introduction of new drugs to Japan, positive changes to how pediatric drugs are evaluated, and expansion of the product eligibility criteria for the Price Maintenance Premium (PMP). In addition, other measures will be taken to more appropriately value innovative medicines, such as the abolishment of the PMP company criteria and reform to the spillover re-pricing rule.

We recognize that these changes are based on some of our recommendations regarding the evaluation and promotion of innovation and view this as an important first step to eliminate drug lag and loss. These changes are positioned as the beginning of Japan’s transformation toward an innovation-oriented economy that can improve patient access to new medicines. We would like to express our respect to all who have contributed their efforts and perspectives.

On the other hand, the Cost-Effectiveness Analysis System Reform Framework indicates that discussions will continue on expanding price cuts beyond the current price adjustment range for new medicines that have a large market size due to their breakthrough status. We believe that continued engagement on this issue with all stakeholders is necessary to ensure that any future policies do not hinder innovation and access.

Many issues and recommendations raised by the Expert Panel on Comprehensive Measures to Achieve a Rapid and Stable Supply of Pharmaceuticals remain to be resolved. We hope to build a drug pricing system that is transparent and compelling to all stakeholders, appropriately values innovations that patients need, and maintains prices during the patented period to ensure the continued early introduction of new medicines to Japan. To this end, we will participate actively in future discussions regarding reform of the NHI drug pricing system and cost-effectiveness analysis system, as well as the FY2024 reform review analysis.