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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 Proposals for the FY2025 Off-year Drug Price Revision and National Biopharmaceutical Strategy**

The Japan Pharmaceutical Manufacturers Association (JPMA), Pharmaceutical Research and Manufacturers of America (PhRMA) and European Federation of Pharmaceutical Industries and Associations (EFPIA) collectively represent the world's leading biopharmaceutical research companies operating in Japan. We congratulate Prime Minister Shigeru Ishiba on his new administration and offer the following statement with the aim of realizing a society of health and longevity through the research, development and stable supply of innovative medicines.

We have previously raised concerns about the state of Japan's biopharmaceutical innovation ecosystem, which is at a competitive disadvantage following nearly a decade of changes to drug pricing rules and annual price cuts to patented medicines. Japan now faces a resurgence of drug loss as life sciences investment continues to decline. We welcomed the FY2024 National Health Insurance (NHI) drug pricing reform in December 2023 as an important first step to reverse these negative trends.

However, to restore a globally competitive biopharmaceutical innovation ecosystem, Japan must stay the course and not backslide on policy reforms. With this goal in mind, we propose that the following policies should be prioritized in government decisions later this year.

### ***Proposal 1: Abolish the FY2025 Off-year Drug Price Revision and Oppose Backsliding Policies***

The FY2024 drug pricing reform improved the eligibility criteria for the Price Maintenance Premium (PMP), increasing the likelihood that medicines launched in the future can maintain their prices during the patent period. However, approximately half of innovative medicines still receive annual price cuts.

Despite this, government discussions are underway to expand the rules applied in off-year drug price revisions (e.g., early return of the PMP and market expansion repricing) and to expand the role of cost-effectiveness analysis. These anti-innovation policies would reverse the positive momentum of the FY2024 drug pricing reform and must be abandoned. Instead, Japan should reaffirm the need for an NHI drug pricing system that incentivizes innovation and patient access.

### ***Proposal 2: 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. A bold new national biopharmaceutical strategy and pro-innovation reforms are required so that all parts of the biopharmaceutical innovation ecosystem function fully.

To realize this, Japan needs strong government leadership and collaboration with the private sector. Next year's Public-Private Council should develop a new national biopharmaceutical strategy and KPIs under a permanent cross-ministerial body and include a platform for regular dialogue with the global biopharmaceutical industry. We look forward to working with Japan as partners to achieve these shared goals.