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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 2024 Drug Pricing Reform

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 support a biopharmaceutical innovation ecosystem that encourages the discovery of important, new medicines for patients. The ecosystem we envision begins with research and development to address unmet medical needs and includes an internationally harmonized regulatory review that promptly approves safe and effective medicines, as well as a reimbursement system that appropriately values innovation. Every part of the ecosystem must function well to ensure that patients receive timely access to a stable supply of new medicines and that companies can reinvest in the next generation of treatments and vaccines.

Japan has long been a global leader in life sciences and is a critically important partner in developing new medicines for patients around the world. Over the past several years, however, numerous changes to pricing rules and annual price cuts to patented medicines have put Japan's biopharmaceutical innovation ecosystem at a competitive disadvantage. Japan is now viewed as a negative growth market and life sciences investment continues to decline in contrast to the positive global trend. The result has been a decrease in Japan's share of the early-stage pipeline, stagnation in new clinical trials and a return of the drug lag in which innovative medicines to treat unmet medical needs are increasingly not launched in Japan in a timely manner – or even are not launched at all. The upcoming reform year represents an important opportunity to reverse these negative trends.

We believe that strengthening Japan's biopharmaceutical innovation ecosystem – including drug pricing reform – is urgently needed to restore sustainable growth to the market and ensure that Japan is not left behind in developing and accessing the world's latest treatments and vaccines. Below are three policy proposals that we believe should be prioritized for consideration by the Ministry of Health, Labour and Welfare Expert Panel on Comprehensive Measures to Achieve a Rapid and Stable Supply of Pharmaceuticals for the 2024 National Health Insurance (NHI) Drug Pricing Reform.

Proposal 1: Maintain Drug Prices During the Patent Period

Following drastic changes to the eligibility criteria for the Price Maintenance Premium (PMP) and the introduction of annual price revisions, approximately half of innovative medicines now receive annual price cuts. In addition, the price of an innovative medicine can be reduced significantly and repeatedly by market expansion repricing even if the product is eligible for the PMP. As a result, most innovative medicines in Japan face commercial uncertainty with frequent price cuts, in contrast to the practice of other leading countries. To address these challenges, we propose excluding innovative medicines from the actual market price-based revisions during the patent period and continuing discussions on transitioning



to a system that does not cause excessive and unevenly distributed *yakka-sa*, as well as improving the market expansion and spillover repricing rules based on the current issues raised by the MHLW Expert Panel.

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 reflect the value of innovation. Two-thirds of innovative medicines fail to receive a price premium at NHI listing, and most new products with a premium only receive the minimum amount. The situation is particularly challenging for highly innovative medicines with new treatment modalities, which lack appropriate comparators under the current pricing criteria and deliver considerable value to patients, the health care system and society that is not appropriately recognized. As a result, the launch prices of new medicines in Japan, especially first-in-class products, increasingly diverge from other leading countries, which decreases the incentives for early product launches in Japan. To improve initial NHI price-setting, we propose expanding the assessment criteria to allow for a more holistic evaluation of product value that is difficult to capture under the current requirements, as well as expanding the scope of comparators allowed.

Proposal 3: Reduce Inefficient Spending on Non-Innovative Medicines

We support the sustainable growth of Japan's biopharmaceutical market and believe there are many opportunities across the health care system to create budget headroom for the above proposals. Our companies want to play their part with cost-savings policies proposed by various stakeholders, including reducing duplicate prescriptions and polypharmacy, increasing clinically appropriate uptake of generics and biosimilars, and promoting prompt price reductions for long-listed products while ensuring stable supply.

Need for Enhanced Public-Private Dialogue to Develop and Implement Reforms

We appreciate that these kinds of policy change are not simple, but we believe the best policies are made when all stakeholders come together and work as partners towards common goals. To successfully develop and implement these needed reforms, we support more routine and substantive opportunities for dialogue between the Japanese government and multinational and domestic biopharmaceutical research companies.

Our industry is on the cusp of some of the greatest medical breakthroughs in decades, discoveries that were unimaginable only a few years ago and that have the potential to transform lives. We are committed to working with Japan to find policy solutions for a thriving biopharmaceutical innovation ecosystem that fosters science, economic growth and timely access to new medicines for Japanese patients. Working together, we are confident that we can achieve these shared goals.