

December 21, 2022

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

### **Joint Statement on FY2023 NHI Price Revisions**

Today, the Central Social Insurance Medical Council finalized the Framework for FY2023 NHI Drug Price Revision (hereinafter referred to as the “Framework”).

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 consistently recommended that the FY2023 NHI price revision should not be implemented given that the negative impacts of five consecutive years of drug price cuts since 2018 have already emerged. In addition, given that maintaining drug prices during the patent period is the standard practice in major developed countries and that access to new innovative medicines may be further impaired by the declining attractiveness of the Japanese market, we have requested that patented medicines be excluded from the FY2023 revision.

However, based on the FY2021 NHI price revision, it has been decided that the FY2023 price revision will apply to products for which the percentage difference between the NHI price and the market price (yakka-sa) exceeds 0.625 times the 7% average yakka-sa obtained in the latest drug price survey (i.e., a yakka-sa exceeding 4.375%). It is deeply concerning that the government has decided to implement price cuts on such a wide range of products, despite the problems of access to and stable supply of innovative medicines that are directly impacting the lives of the Japanese people.

Regarding the addition of the special application of the Price Maintenance Premium, which will mitigate the FY2023 price cuts for a subset of innovative medicines, we recognize that the government has responded in part to our previous recommendations regarding the evaluation and promotion of innovation.

To ensure the continued early introduction of new innovative medicines to Japan, we request a fundamental review of the current approach to NHI price revisions based on prevailing market prices, as well as the establishment of a more appropriate framework for evaluating innovation and maintaining drug prices during the patent period. As indicated in the “Framework,” we request that the government actively considers these issues in the FY2024 NHI drug price reform, based on the discussions at the Expert Panel on Comprehensive Measures to Achieve a Prompt and Stable Supply of Pharmaceuticals.

We will continue to actively participate in discussions on the future reform of the NHI drug price system to help establish a system that ensures access to innovation in Japan and is transparent and convincing to all stakeholders, including the public.