October 7, 2026
Japan Pharmaceutical Manufacturers Association (JPMA)
Pharmaceutical Research and Manufacturers of America (PhRMA)
European Federation of Pharmaceutical Industries and Associations (EFPIA Japan)

Joint Statement on Proposed Expansion of the Cost-Effectiveness Assessment System

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 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.

On September 30, the Ministry of Health, Labour and Welfare (MHLW) proposed at the Central Social Insurance Medical Council (Chuikyo) to expand price cuts under the Cost-Effectiveness Assessment (CEA) system, and Chuikyo supported this direction. JPMA, PhRMA and EFPIA are issuing this joint statement to share our concerns and to urge the Japanese government to reconsider.

In July, we welcomed the Takaichi Administration's Basic Policy for Economic and Fiscal Management and Reform (*Honebuto*) and Japan Growth Strategy. These policies position the innovative biopharmaceutical industry as a strategic sector. They set a goal of restoring Japan's patented medicines market to 9.6% annual growth, comparable with leading markets, and commit to further recognition of innovation in prices at initial National Health Insurance listing and during the patent period.

To help realize these goals, we proposed concrete measures at the Chuikyo hearing on August 26. Japan should reform its initial price-setting rules to align with U.S. price levels after adjusting for purchasing power parity. Japan should also freeze the rules that prevent the maintenance of prices during the patent period, including market price revisions, market expansion re-pricing and the CEA system. In practice, the CEA system has operated as a means to cut prices. Of the 57 patented medicines that have completed mandatory assessments, 45 (79%) had their prices cut, while none had their prices increased.

In parallel, we participated in good faith in an "objective verification" process regarding the CEA system from May to August and identified unresolved systematic and technical issues. Nevertheless, the report summary presented to Chuikyo on September 9 concluded that the assessments have "a certain degree of validity." We respectfully disagree and question the objectivity of the verification that led to this conclusion.

At the Chuikyo hearing on September 16, we highlighted that the basis and scope of this conclusion had not been made clear. Given that institutional discussions remain incomplete, we requested to freeze price cuts under the CEA system for the time being. However, MHLW treated the conclusion as settled and proposed to proceed with discussions premised on expanding the price cut range. A decision of this significance deserves more careful and transparent deliberation.

We are therefore deeply disappointed by the MHLW proposal and Chuikyo support for it. Expanding the CEA system would further reduce prices during the patent period, which is difficult to reconcile with the government's goal of growing the patented medicines market. We are also

concerned that the proposal is moving forward without any substantive discussion evaluating its consistency with the positive direction set by the *Honebuto* and the Japan Growth Strategy.

To achieve the goals of the Takaichi Administration, Japan needs to strengthen incentives for innovation and contribute its fair share for innovative medicines. This has become even more important as U.S. Most-Favored-Nation policies reshape global incentives for developing and launching new medicines in Japan. Further price reductions during the patent period risk worsening drug loss and weakening Japan's attractiveness for investment, running directly counter to the development of the biopharmaceutical industry as a strategic sector for economic growth. We urge MHLW not to implement this expansion and to pursue thorough discussions consistent with the government's policy direction.

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