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Press Release

EFPIA Japan

**Welcoming the Publication of the Working Group Roadmap
under the Japan Growth Strategy**

**Announcing Policy Recommendations to Strengthen
the Drug Discovery Ecosystem
— Advancing discussions through public-private dialogue platforms and
deliberations at the Central Social Insurance Medical Council —**

The Japan Growth Strategy Council has recently published a public-private investment roadmap covering 17 strategic sectors.

EFPIA Japan welcomes the fact that this roadmap sets out policy directions for strengthening the drug discovery ecosystem—including “Drug Discovery and Advanced Medicine” and “Synthetic Biology and Biotechnology”—and that it positions the pharmaceutical industry as a “key industry” and a “cornerstone of national security” that underpins Japan’s growth, economy, and health and medical security. Furthermore, we endorse the policy direction aimed at improving patient access by fostering the growth of the branded-drug market to levels comparable to the rest of the world and realizing an attractive domestic market. We particularly welcome the clear commitment to achieve growth in the patented medicines market that is comparable to global levels, with reference to the 9.6% average growth rate observed across G7 markets excluding Japan.

At the same time, structural changes in drug pricing policies—including Most-Favored-Nation (MFN) treatment—are underway internationally. The fact that Japan’s drug price levels are lower than those in other countries could lead to risks of “drug lag” and “drug loss,” as well as affect the ability to secure the investment necessary for sustained innovation. Therefore, during the “implementation” phase of the roadmap, it is essential to ensure predictability of investment and the validity of market valuation.

EFPIA Japan presents two key recommendations as follows,

1) Initial pricing on par with advanced economy basket

In light of trends in international drug pricing reference systems, such as the U.S. MFN pricing policy, we must prevent drug lag and loss and establish an environment in which domestic and foreign pharmaceutical companies can make rational decisions regarding business continuity, the introduction of new drugs, and new investments in the Japanese market. To this end, pricing for new drugs at the time of market launch should be set at a level that is not inferior to that of other advanced economy countries. For example, as a practical step toward this goal, we request that measures be taken, such as abolishing the

rule that excludes the United States from the list of reference countries used in foreign average price adjustments.

2) Ensuring Predictability Through “Price Maintenance” During the Patent Term

To enhance predictability in drug discovery and ensure that innovation is appropriately valued throughout the patent period, thereby encouraging further investment, we call for a freeze on measures that reduce prices during the patent period—such as regular market price revisions, market expansion repricing (including special repricing), and cost-effectiveness assessments—and for the firm implementation of a de facto “price maintenance” approach.

Regarding the expansion of products subject to the cost-effectiveness evaluation system and the expansion of the scope of price adjustments—which conflicts with the drug pricing system—the consistency and validity of the system are being questioned. Given reports of opaque administrative practices and multiple technical challenges, we request that such expansions not be pursued until an objective review—extending beyond technical considerations—is conducted and the necessary revisions are fully completed.

To Ensure the Reliable Implementation of the Roadmap

EFPIA Japan hopes that the government and the industry will foster a shared understanding through forums such as the Public-Private Council, that deliberations will be conducted at the Central Social Insurance Medical Council (Chuikyo), and that discussions and implementation will proceed continuously in accordance with the roadmap.

In addition, we believe that the development of concrete measures and their steady implementation will be essential for realizing the roadmap going forward. EFPIA Japan stands ready to contribute to the development of practical solutions and will work in close collaboration with the government to support the effective implementation of this roadmap.

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About EFPIA Japan (<http://efpia.jp/>)

Established in April 2002, EFPIA Japan represents 24 R&D-based European pharmaceutical companies operating in Japan. In 2024, combined sales from the member companies accounted for approximately 29.4% of the pharmaceutical market in Japan. The mission of EFPIA Japan is to “Contribute to healthcare and patients in Japan through the early introduction of innovative medicines and vaccines.” EFPIA Japan aims to strengthen dialogue with decision-makers in order to improve Japanese healthcare for all.

About EFPIA (The European Federation of Pharmaceutical Industries and Associations) (<http://www.efpia.eu>)

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical industry operating in Europe. Through its direct membership of 36 national associations, 40 leading pharmaceutical companies, and growing number of small and medium sized enterprises (SMEs), EFPIA’s mission is to



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create a collaborative environment that enables our members to innovate, discover, develop, and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy.

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