



European Federation of Pharmaceutical
Industries and Associations



November 29th, 2017

FOR IMMEDIATE RELEASE

PhRMA and EFPIA Shocked and Dismayed by Japanese Government's Proposed Plans to Abandon Pro-Innovation Policy Environment

- Proposal Threatens Patients' Early Access to Medicines -

Tokyo, Japan (November 30, 2017) — The following is a joint press release issued by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) after providing testimony at the November 29 Chuikyo hearing on the proposed drug pricing system reform package.

PhRMA and EFPIA are shocked and dismayed by the depth and breadth of cuts to innovative products contained in the proposal. At the same time, there are still significant opportunities for savings in the areas of LLPs and generic utilization.

The proposal is sending a clear message to both the domestic and foreign innovative pharmaceutical industry: that Japan is “closed for business” when it comes to providing sufficient reward for innovation to pharmaceutical companies. It will discourage these companies from investing in the next generation of treatments and cures for Japanese and global patients.

Since 2010, the Japanese government has enacted a comprehensive program of pro-innovation policies that have virtually eliminated delays for Japanese patients to access new therapies, significantly increased biopharmaceutical investments in Japan, especially in the area of clinical trials, and helped foster the biopharmaceutical sector as a continued growth engine for the Japanese economy. One key element of these pro-innovation policies was the establishment of the Price Maintenance Premium (PMP), which rewards innovation and allows for pricing stability throughout the patent life of a medicine. It also allows for a sharp drop in price and a shift to generics at the end of a medicine's patent period. The reform proposal released by the Japanese

government on November 22 significantly narrows the eligibility and reduces the benefits for this important program, threatening to reverse much of the progress Japan has made in recent years.

Some of the potential negative consequences to Japan's future as an innovator and to Japanese patients should the reform package be adopted in its current form include the following:

- A return of the drug lag, which means that Japanese patients will not get access to life-saving medicines until significantly after their U.S. and EU counterparts.
- R&D investment in the innovative pharmaceutical sector in Japan could plummet and inclusion of Japan in global product development efforts could be significantly eroded.
- Cultivation of new domestic pharmaceutical companies that can succeed in foreign markets will be stunted.
- The innovative pharmaceutical industry is not able to fulfill its potential as a growth engine for the Japanese economy.

PhRMA and EFPIA are also concerned that specific elements of the draft criteria for eligibility for the PMP call into question Japan's commitment to fair and non-discriminatory policies related to drug pricing and reimbursement.

PhRMA and EFPIA fully support Japan's efforts to ensure the long-term sustainability of its health care system and have put forward proactive policy solutions meant to address anomalies that have appeared over the last few years. However, data from a credible third party source (IQVIA, formerly Quintiles IMS) shows that spending on medicines is well-controlled in Japan. Further, Japan is predicted to be the lowest growing of all the major global pharmaceutical markets, and spending may even go into decline in the near future. If this proposal moves forward in its current form, it will be a strong disincentive to further invest in the Japanese market.

Patrik Jonsson, Chairman of the Japan-based Executive Committee (JBEC) of PhRMA Japan stated: ""We are strongly concerned and disappointed with Japan stepping away from its pro-innovation policies and dismayed by the huge potential impact on Japanese patients. With this move, Japan also risks an outflow of investment to countries that are now significantly outpacing Japan in the promulgation of meaningful pro-innovation policies."

Ole Molskov Bech, Chairman of EFPIA Japan stated: “It is very disturbing to see the many advances that have been made to give Japanese patients access to new drugs as early as in the other markets being rolled back to square one. The proposed policies are likely to make many fewer new drugs available for Japanese doctors to treat their patients in the best possible way. And knowing that many new drugs are actually helping to control overall health care costs, EFPIA believes that targeting innovation for savings in the health care budget will soon prove to be very expensive for Japan.”

About PhRMA

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country’s leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than \$600 billion in the search for new treatments and cures, including an estimated \$65.5 billion in 2016 alone.

About EFPIA

European Federation of Pharmaceutical Industries and Associations (EFPIA), headquartered in Brussels, the capital of Belgium, represents the pharmaceutical industry operating in Europe. Through its direct membership of 33 national associations and 42 leading pharmaceutical companies, EFPIA is the voice of 1,900 companies committed to developing and bringing new treatments to patients around the world that will improve the quality of life.

- PhRMA Tokyo Office Website <http://www.phrma-jp.org>
- PhRMA Website <http://www.phrma.org>
- PhRMA Facebook <https://www.facebook.com/phrmajapanoffice>

- EFPIA JAPAN Website <http://efpia.jp/index.html>
- EFPIA Website <http://www.efpia.eu/>

For any media inquiries,
Contact at PhRMA PR Office (at Japan Counselors Inc.)
Tel: +81-3-3291-0118 Fax: 81-3-3291-0223
E-mail: phrma_pr@jc-inc.co.jp