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FOR IMMEDIATE RELEASE

Consequences Expected from the Final Drug Pricing Reform Package
Industry concerned about Potential Impact for Japanese Patients and for the
Japanese Economy

Tokyo, Japan (December 20, 2017) — The following is a joint press statement issued by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

The innovative pharmaceutical industry is a significant contributor to Japan in the form of foreign direct investment in R&D, tens of thousands of jobs, and significant tax revenue. The industry has also contributed in a meaningful way to achieving Prime Minister Abe’s vision of a “vibrant Japan” by helping Japanese people to live longer, healthier lives.

In light of this, although we recognize that the Ministry of Health, Labour, and Welfare (MHLW) made some minor improvements, the innovative pharmaceutical industry is disappointed with and concerned by the final drug pricing reform package that was presented to the Chuikyo this morning by MHLW. Despite significant input and alternative proposals put forward by all industry associations, we observe that few meaningful changes were made to the draft package that was shared with the Chuikyo on November 22. In particular, we note that in the final reform package the pro-innovation incentives have been seriously eroded, sending the message to domestic and foreign players that Japan is backing away from its pro-innovation environment and risks not attracting early investment for next generation medicines. The industry is, in particular, concerned that the number of future innovative products to qualify for the Price Maintenance Premium (PMP) will be reduced dramatically and that, despite their efforts, fewer companies will qualify under the new company requirements for PMP. Further, specific elements of the PMP eligibility criteria could create discriminatory or unfair situations between companies, which is very troubling to our industry associations.

The expected consequences of the pricing reform are that:

- Incentives to develop new products in Japan will be so eroded that early patient access to new medicines will be seriously jeopardized.

- R&D investment will be encouraged to prioritize over Japan those countries that are providing a predictable environment and are actively promoting innovation.
- Potential growth in the Japanese economy that was expected to come from this sector is now unlikely to be realized.
- Japan will be perceived as and will become less competitive within the innovation arena.

PhRMA and EFPIA will continue to strive for fair and innovation-friendly policies to be enacted in Japan for the benefit of Japanese patients and the Japanese economy. In that vein, the organizations call for the Japanese government to urgently undertake a fair and transparent process to ensure that all elements of the healthcare sector are contributing their share of burden to ensure our common goal of long-term sustainability of the Japanese healthcare system.

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.

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