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< News Release >

(English translation)

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

EFPIA and PhRMA Companies Step Up Their Investment in Clinical Research in Japan: Results Benefitting Patients

PhRMA and EFPIA are pleased to announce that a new report shows that their member companies are making a greater than ever contribution to clinical research in Japan. US and European companies have not only increased their investment in Japan's drug development infrastructure, but more importantly the primary beneficiaries are Japanese patients, who as a result are now getting more rapid access to the latest treatments.

The two industry associations first produced the "Research in Your Backyard" report and database in 2014. This has now been updated, and is available on their websites :

PhRMA: http://www.phrma-jp.org/library/riby/

EFPIA: http://efpia.jp/link/201608_RIYB_EN_w_QR_code_v1.1.pdf

The key conclusions of the 2016 report are:

- EFPIA and PhRMA member companies conducted 825 clinical trials across Japan in 2015, showing an increase of 21% in comparison to 2013.
- An even greater increase was seen in the number of trial sites involved in the studies, to 18,095 sites. This was a 55% increase over the previous period.
- Trials were conducted for new products covering more than 16 disease areas, ranging from common ailments to serious rare diseases.

As a result of the increased clinical trial activity, the 34 EFPIA and PhRMA member companies have racked up an increasing number of new drug approvals. Between 2010 and 2015, a total of 123 new medicines from our companies were approved: almost 50 percent of approvals granted by the Ministry of Health Labor and Welfare (MHLW). A similar trend can be seen in the number of new indications approved. Over that same time period, EFPIA and PhRMA companies received 266 new indications; again, almost half of the total number. This shows our great commitment to the interests of Japanese patients, through making innovative medicines rapidly available in the Japanese market.

One of the ways in which foreign-based pharmaceutical companies have made a significant effort to eliminate the “drug lag” has been by including Japan in global and regional development programs, and thereby accelerating the development process. According to the 2016 report of the NDA submissions based on on-going development programs, 79 percent are considered to be made simultaneously with other major countries.

In terms of the total monetary investment in clinical trials, JPMA member companies reported that their investment in 2014 was 204 billion, including 79 billion yen by EFPIA and PhRMA companies. This figure represents only the direct costs related to the trials and does not include the positive economic effects of creating employment opportunities and other associated spending.

Government policy has been important in supporting an innovation-friendly environment in Japan, and the Japanese government should be congratulated for its success. In recent years, the pharmaceutical industry has been positively influenced by two policy developments. First, the “Price Maintenance Innovation Premium System” was launched as part of the pharmaceutical pricing system on a trial basis in 2010 by the MHLW. This system has since been extended several times, and the Abe Cabinet has expressed its clear support for innovation in pharmaceutical research. The Price Maintenance Innovation Premium System has encouraged foreign-based companies to invest in bringing their innovative medicines more quickly to the Japanese market and ultimately to Japanese patients. Secondly, this effort has been greatly supported by the regulatory agency, PMDA, which has increased its staff numbers and improved its processes so that it has reduced times for regulatory approval to the levels seen in the US and the EU. As a result of these two changes, Japan has made significant progress toward eliminating the “drug lag”. The US and European pharmaceutical industry is proud to have played its part in contributing to that success.

PhRMA and EFPIA aim to continue their commitment to bringing the latest medical innovations to Japanese patients as fast as possible. For this commitment to be realized, the Japanese government and the industry will need to work in partnership to maintain an environment which is predictable and favorable to innovation. The updated “Research in Your Backyard” report shows that Japan was a pro-innovation market for pharmaceuticals up until 2015. The challenge for the future is to keep it that way.

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