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**EFPIA and PhRMA Regret the Continued Moves Away from a
Pro-innovation Policy Environment and Call for a Partnership with
Government to Restore Stability and Predictability in the Japanese
Pharmaceutical Market**

Carsten Brunn

Chairman, EFPIA Japan

Patrik Jonsson

Chairman, Japan Based Executive Committee, PhRMA

EFPIA and PhRMA regret the continued deterioration in the stability and predictability of the Japanese pharmaceutical pricing environment. The industry shares the goal of ensuring the long-term sustainability of the national healthcare system, but also believes stronger emphasis must be put on providing adequate reward for innovation to ensure that Japanese patients continue to have early access to cutting edge life-saving medicines, to attract further investment in Japan, and to allow this sector to reach its potential as a growth engine of the Japanese economy. In particular:

- The two associations regret the decision of the Japanese government to impose a large out-of-cycle price cut on one specific drug. This is another sudden policy change and has serious implications on future R&D and innovation in Japan. While recognizing the budget pressures that the Japanese government faces, changing the pricing rules at short notice to deal with a single product or a small number of products (as happened with the Special Repricing) undermines faith in the rules-based system. A better approach would be for government to form a partnership with the industry aimed at finding sustainable long-term joint solutions. In this partnership, government and industry should engage in comprehensive discussions aimed at restoring stability and predictability for all stakeholders.

- EFPIA and PhRMA are also both concerned about the practical introduction of a new optimal use guidelines system which may cause reimbursement to diverge from label just for cost reasons. The MHLW has been clear throughout that the introduction of such guidelines will not delay patient access to new medicines. Recent developments raise the risk that this may not be the case. The two associations therefore call on MHLW to confirm that the principle of no delay to patient access from these guidelines remains a key priority.
- Recent discussions at the Central Social Insurance Medical Council raise concerns that economic factors, rather than the good of Japanese patients, might drive future product approval decisions. The two associations therefore call on MHLW to confirm that clinical and scientific decisions will continue to be kept separate from economic decisions.

In recent years, the Japanese pro-innovation pharmaceutical pricing environment has worked efficiently to the benefit of patients/society, government and the industry. Exceptional cases have raised questions about reform of the pricing system, but it continues to function well. The government, the industry, and other stakeholders should work in partnership to find long-term solutions that will maintain a system that supports continued innovation for the benefit of patients in Japan. EFPIA and PhRMA are ready and willing to contribute to such a partnership.

- EFPIA JAPAN Website <http://efpia.jp/index.html>
- EFPIA Website <http://www.efpia.eu/>
- PhRMA Tokyo Office Website <http://www.phrma-jp.org>
- PhRMA Website <http://www.phrma.org>
- PhRMA Facebook <https://www.facebook.com/phrmajapanoffice>