

# Impact on Japanese Pharmaceutical Companies Unavoidable: TPP Negotiations

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Discussions are underway among nine countries, including the US and Australia, to hammer out the Trans-Pacific Partnership (TPP) (regional trade) initiative. Although the effects (of the TPP) on the agriculture sector tends to be a focal point in Japan, proposals made last month by the US have prompted discussions on promoting access for pharmaceutical products. Whether or not Japan takes part in the free trade initiative, its impact on the domestic pharmaceutical industry cannot be ignored.

Besides the US and Australia, the countries taking part in talks to join the TPP are New Zealand, Singapore, Malaysia, Brunei, Vietnam, Chile, and Peru. The accord is aimed at the elimination of tariffs on goods, expanded liberalization of trade in services, and the rule-making for non-tariff areas, targeting, in principle, complete liberalization. Members expect to reach an agreement on outlining a framework as early as November, at the Asia-Pacific Economic Cooperation summit.

In a negotiation round in September, the US announced its strategic initiative, Trade Enhancing Access to Medicines, or TEAM, to improve trade access for its pharmaceutical products, and proposed reaffirmation of the following: 1) promotion of (market) access for drug products, 2) the lowering of barriers for drug distribution, and 3) the World Trade Organization's TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement.

The US pharmaceutical industry supports TEAM, which calls for the protection of intellectual property, saying that it would boost competitiveness. The Pharmaceutical Research and Manufacturers of America (PhRMA), which advised the US government in drawing up TEAM, emphasizes the importance of TEAM and its proposal to include intellectual property rights in TPP talks. PhRMA Japan Representative Ira Wolf stresses that intellectual property is most important for the drug industry.

Kanto Gakuen University Faculty of Economics Associate Professor Akiko Kato turns her attention on a chapter calling for a review of TRIPS. WTO's TRIPS is the world's first international agreement that has made the protection

of intellectual property mandatory for its member states, and includes the protection of unreleased clinical trial data in addition to patents. While Ms Kato says US objectives are yet unclear at present, she speculates that proceedings to protect clinical data that is relevant to information for approval application could be aimed at streamlining the drug regulations of negotiating partners.

US President Barack Obama plans to cut the period of exclusive marketing of biopharmaceuticals from 12 years to seven, and is tightening control to cover increasing medical expenses. At the same time, his administration is looking to protect intellectual property through the TPP and tap into overseas markets, while securing profits that were not previously accessible due to violations by other parties, showing US strategy to reach a balance between domestic and international policy.

The impact of TPP on the Japanese pharmaceutical industry is varied. An official at a Japanese drugmaker that currently operates overseas remarked that the impact would be limited, as negotiating parties for the TPP are small countries. PhRMA's Ira Wolf says that considering the aspects of intellectual property protection, an adoption of TEAM would offer advantages to Japanese manufacturers of innovative drugs, even if Japan did not join the TPP.

Keiichi Umada, professor, Faculty of Social Sciences, Kyorin University, foresees the TPP impact on supply chains. "The TPP would remove tariffs, making transactions between (member countries) companies next to nothing. Expansions in supply chains would mean enhanced efficiency (in production and sales)." He does not rule out the possibility that it could trigger industry reorganization aimed at boosting international competitiveness.

In the future, India, among other countries, is expected to join the free trade accord. Whether Japan takes part or not, changes are inevitable in the economic environment of the Pacific Rim region. There are, of course, possibilities that overseas companies would make use of supply chains in the region and enter their low-priced generic drug products into the Japanese market. Changes in the environment brought about by the TPP will be a test of the international competitiveness of Japanese pharmaceutical companies, both at home and abroad. (Taro Fujimoto)

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