"Competition and Research and Development Incentives in the Pharmaceutical Market - Through Examinations of the Impact of the Entry of Generic Drugs on the Market -" (Summary)

This report pointed out that, with regard to generic drugs (drugs that have the same active ingredients and the same effects and efficacy as original drugs and are sold after the patents of the original drugs have expired), in the EU and the U.S., there were activities for deterring competition (reverse payment) whereby the manufacturers of original drugs make payments to the manufacturers of generic drugs to delay the timing of the sales of such products. In this environment, the report proposes that, because incentives of the manufacturers of original drugs to deter competition are expected to increase in Japan in the same manner as in the EU and the U.S. as a result of a rise in the share of generic drugs in the market in the future, it is necessary for the Japan Fair Trade Commission (JFTC) to strengthen its monitoring.

1. The situation of generic drugs in Japan

(1) The share of generic drugs in Japan

The share of generic drugs in the ethical drug market in Japan has been rising as a result of a number of policies to promote the use of generic drugs. Compared with Western countries, however, the share remains at a lower level (for example, 49% in Japan, 92% in the U.S. and 83% in Germany between October 2013 and September 2014).

(2) Systems characteristic of the ethical drug market in Japan

a. Price regulation system

The retail prices of drugs are determined by the state. Under the price regulation system, the public prices of generic drugs when they are newly introduced to the market are, in principle, of 60% of the public prices of original drugs. The prices then will be changed on a regular basis in light of the prevailing market prices (wholesale prices set freely by manufacturers to medical institutions and other organizations) (unlike in the EU or the U.S., direct price competition in the consumer (patient) market does not seem to be active).

b. Patent linkage and ex-ante coordination

As for issues related to patent infringements by generic drugs, it is regarded as a precondition in the EU and the U.S. to resolve the issues through patent infringement suits that are filed by the manufacturers of original drugs against the manufacturers of generic drugs. In Japan, on the other hand, if the patent for the active ingredients of original drugs remains valid, approval for the manufacture and sale of generic drugs will not be granted (which is termed as "patent linkage"). In addition, the manufacturers of original drugs and the manufacturers of generic drugs examine possible patent issues

between the original drugs and the generic drugs, and then they report its results to the government (the Ministry of Health, Labour and Welfare) (ex-ante coordination).

(3) Economic analysis related to the market structure

Unlike in the U.S., in Japan, price competition between original drugs and generic drugs is limited even after the market entry of generic drugs, compared with price competition among generic drugs. However, if the share of generic drugs exceeds a certain level, it is possible in the future that the prices of original drugs will also fall to a similar extent to the fall in the prices of generic drugs as a result of pressure from the competition.

2. Situation in the EU and the U.S.

(1) Trends of prices

In general, after the entry of generic drugs, in line with their prices, the prices of original drugs also fall significantly.

(2) Existence of activities that may have any competition law concerns (reverse payments)

In the EU and the U.S., the manufacturers of original drugs sometimes file patent infringement suits against the manufacturers of generic drugs, even after the expiry of key patents related to original drugs, such as the active ingredients, on the grounds of the continued existence of other related patents and other factors. In such suits, there are cases where, at the point of the settlement, the manufacturers of original drugs make large payments for the manufacturers of generic drugs (which is termed as “reverse payments”). These cases are considered to be anti-competitive practices to delay the market entry of generic drugs.

The main case is FTC v. Actavis, Inc., 133 S.Ct. 2223 (June 17, 2013). A manufacturer of the original drugs, Solvay, had filed a patent infringement suit related to percutaneous absorption-type testosterone (a kind of male hormone) products against three manufacturers of generic drugs (Actavis, Par and Paddock). The suit was settled in 2006 with the agreement that the generic drugs would not be sold until the end of August 2015, 65 months prior to the expiry of the valid period of the patent, and payments would be made to the three companies (between USD19 million and USD30 million per year for nine years for Actavis). The court admitted that the settlement that enabled the related parties to avoid costs and the complexity involved in patent suits had its own merits, but it ruled that while it did not rule out the possibility of the settlement being judged to be an infringement of antitrust laws, payments of unexplainable large payments have high risks of bringing about anticompetitive effects.

3. Implication for Japan

Under the current system and market structure in Japan, it is considered that Japan is in an environment in which reverse payments, which potentially become a competition issue as in the EU and the U.S., are less likely to take place. However, if the share of generic drugs

continues to grow and the pressure of the competition from generic drugs increases, incentives for engaging in reverse payments may increase in the same manner as in the EU and the U.S. in the future. For this reason, it is necessary for the JFTC to carry out monitoring as needed and consider to ensure that the Anti-Monopoly Act is actively applied to such cases.