The Ministry of Food and Drug Safety Submitted the Bill for Partial Amendment of the Pharmaceutical Affairs Act relating to the Drug Patent-Approval Linkage System

On October 22, 2014, the Ministry of Food and Drug Safety (the "**MFDS**") submitted to the National Assembly the bill for partial amendment of the Pharmaceutical Affairs Act (the "**PAA**") relating to the drug patent-approval linkage system (the "**Bill**"). This is the third legislative announcement following the announcements of March 21, 2014 and July 25, 2014. It shows that interests among the related parties are very difficult to coordinate.

Major differences of the Bill compared to the bill dated July 25, 2014 are as follows.

(1) Marketing Prevention

A registered patent right holder (i.e., patent holder or exclusive license holder) may apply for marketing prevention of the notified drug to the MFDS within 45 days from the date of reception of notification by a generic company regarding its application for drug-approval (Article 50-5(1) of the Bill). In case an application for marketing prevention is filed for the notified drug, the Minister of Food and Drug Safety (the "**Minister**") shall limit the marketing of the notified drug for a period of 12 months from the date of notification, unless one of the exceptions to marketing prevention applies (Article 50-6 of the Bill).

The Bill introduces the regulations on (i) prohibition of dual application for marketing prevention and (ii) Prohibition of partial application for marketing prevention which have not been included in the bill dated July 25, 2014.

Regulations	Bill Dated July 25, 2014	The Bill
Prohibition of dual application for marketing prevention	Not applicable	Additional application for marketing prevention cannot be made for the same drug which had been subject to marketing prevention (Article 50-5(3) of the Bill)
Prohibition of partial application for marketing prevention	Not applicable	If application for marketing prevention is filed only as to a portion of the 2 or more drugs notified (i.e., identical drugs), then marketing prevention is prohibited (Article 50-6(1)(e) of the Bill)

(Continued)

(2) Exclusive Marketing Right of the First Generic Drug Applicant

The Minister shall approve the application for exclusive marketing right of the first generic drug if all of the requirements for such application are met upon receipt of the application (Article 50-8 of the Bill). Upon approval, the Minister may limit marketing of any drug, which files an application for the approval by relying on the safety and efficacy information of the listed drug, and is identical to the drug with the exclusive marketing right, for 12 months (up to 14 months for the drug subject to national health insurance program) from the approval date (Article 50-9 of the Bill).

Outlook

Meanwhile, on June 20, 2014, the Ministry of Health and Welfare preannounced the legislation of the bill for partial amendment of the National Health Insurance Act in preparation for the drug patent-approval linkage system to be implemented on March 15, 2015. Under the bill, the National Health Insurance Service, by the notice of the Minister, will collect all or a portion of the loss to the national health insurance in case it determines that the reimbursements have been excessively made. This provision allows recovery of the unjust profits obtained by the original drug company as a result of the delay in the marketing of the generic drug. PAA amendments in connection with the patent-approval linkage system, including the amendment to incorporate the recovery of excessive profit, are expected to be continuously made until the implementation of the drug patent-approval linkage system.

Yoon & Yang's Health Care Practice Group provides advice to pharmaceutical companies in connection with drug approvals and related patent disputes such as those relating to drug patent-approval linkage system. Please feel free to contact Yoon & Yang's Health Care Practice Group if you have any inquiries or issues to discuss in connection with the Bill.

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