The Draft of Regulation for Patent Linkage of Drug

To protect the pharmaceutical intellectual property, the Pharmaceutical Affairs Act was amended. For implementing the patent linkage, the Regulation for Patent Linkage of Drugs was drafted by Ministry of Health and Welfare Food and Drug Administration.

The framework of the draft of Regulation for Patent Linkage of Drugs consists of the following:

1. The method and content of submission of the pharmaceutical patent information, the amendment and deletion thereof, the listing and publication of the pharmaceutical patent information.
2. The declaration made by the applicant for a generic drug and biosimilar drug permit. And the method and content of the written notification made by the applicant for the generic drug permit.
3. The patentee or the exclusive licensee obtains a final and binding judgment confirming infringement of the listed patent(s) within the 12-month period.
4. The commencement and termination of the marketing exclusivity period.
5. The application for a generic drug permit shall apply mutatis mutandis to the new drugs not having a new ingredient.
6. The exclusion of indication, declaration, and other matters shall be abided.