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TIPLO Spot News

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Brief Introduction

Taiwan Pharmaceutical Affairs Act Amendment

(amended on December 29, 2017)

Amendment to Taiwan Pharmaceutical Affairs Act passed its third reading at the Taiwan Legislative Yuan on December 29, 2017 to be in response to the negotiation for the Trade and Investment Framework Agreement (TIFA) and for joining The Trans-Pacific Partnership (TPP). Two key points of this amendment are (1) incorporation of data exclusivity for new drug with new indications and (2) introduction of the system of linkage between drug patent and market approval (hereinafter referred to as "patent linkage"). With relevant provisions pertaining to the key points amended and added, the Taiwan Pharmaceutical Affairs Act will keep pace with relevant international treaties and pharmaceutical systems of other countries. Please see the attached document for English translation of the text of this amendment. A brief introduction of the amended provisions of the Pharmaceutical Affairs Act is provided below.

1. Data Exclusivity

With respect to data exclusivity, "data" refers to the scientific and technological data/information submitted to the health authority along with a new drug registration application for seeking grant of market approval, and such data/information includes the ingredients, preparations, control, animal experimentations, human trials of the new drug. Under the protection of data exclusivity, data exclusivity for a certain duration is conferred on new drug applicants. During the duration, a generic drug applicant shall not cite such the data/information submitted in a new drug application to prove the therapeutic effects and safety of his/her product (generic drug) to seek grant of market approval from the health authority, unless the generic drug applicant has obtained the authorization of the data/information holder (namely, the new drug applicant). On the other hand, the health authority shall not, based on its knowledge acquired from such data/information previously submitted, grant approval of the generic drug application by allowing the generic drug applicant to simply submit bioequivalence data without submitting the complete required scientific and technological data/information.

Under this amendment, **within three (3)** years after the issuance of approval for a new drug of new chemical entity, any other pharmaceutical firm **shall not apply for registration of**

the same by citing the data/information previously submitted by the holder of the approval for the new drug without such holder's consent, which forms a period of "absolute data exclusivity". Upon expiration of the three-year duration of "absolute data exclusivity", other pharmaceutical firms will not be precluded from filing a drug registration by citing the previously submitted data/information, but the health authority will not grant a drug approval until the date following expiration of five (5) years after the drug approval was issued for the new drug of new chemical entity. That is to say, data exclusivity for new drug of new chemical entity shall last for five (5) years.

The data exclusivity protection also covers new drugs with new indications and the duration thereof will be three (3) years, but the duration of "absolute data exclusivity" for new drugs with new indications is only two (2) years (in which two-year duration of "absolute data exclusivity", any other pharmaceutical firm shall not apply for registration of the same drugs with new indications by citing the data/information previously submitted by the holder of the approval for the new drug without such holder's consent). For encouraging new drug manufacturers to conduct clinical trials in Taiwan, the exceptional five-year duration of data exclusivity (which includes the two-year duration of "absolute data exclusivity") will be conferred on the new drugs with new indications if and only if the clinical trials for the new or changed indications are conducted in Taiwan.

2. New Chapter of Patent Linkage

"Patent linkage" system is established to make potential patent infringement a mandatory consideration and an examination basis during the process of generic drug approval and market approval examination. The patent linkage system will clear potential patent infringement dispute before the marketing of generic drugs. The operation of patent linkage system will not only enhance a pharmaceutical patentee's right exercise and economic interests but also avoid launch of infringing generic drugs on market and ultimately decrease any adverse influence on public health. A table is compiled below for easy understanding.

	Taiwan (Patent Linkage)
Patent listing	Relevant patent information has to be submitted.
Generic drug applicant's written notice to the central health authority, the patentee(s), and new drug approval holder	The written notice should be issued within twenty (20) days beginning from the date following the applicant's receipt of notification from the central health authority that the application for drug marketing approval has been completed for review.
Time limit for the patentee(s)'s initiation of a patent infringement action against the generic drug applicant	A patent infringement action should be initiated within 45 days upon receipt of the notice.
Suspension of issuing of market approval to generic drug applicant	Suspension of issuing of market approval should be for a maximum period of 12 months beginning from the new drug approval holder's receipt of the generic drug approval applicant's notice.
Marketing exclusivity for generic drugs	Marketing exclusivity for generic drugs should be 12 months.
Report to the competent authority of anti-trust laws	Relevant report shall be filed first to the central health authority. If any possible violation of the Taiwan Fair Trade Act is involved, the central health authority shall report the same to the Fair Trade Commission.

- The notice indicated in the above refers to the notice regarding the generic drug approval applicant's certification that the listed patent is invalid or is not infringed by the generic drug.

To boost generic drug manufacturers' research and development and patent circumventing design, this amendment also introduces a mechanism of marketing exclusivity for generic drugs. Under this mechanism, the first applicant of generic drug approval application to have produced complete in full the materials required of its application filed under subparagraph 4 of Article 48-9 (with the certification that the listed patent(s) is invalid or is not infringed by the generic drug for which the application is submitted) for approval of the generic drug will be granted an exclusive marketing period of 12 months, and the health authority shall issue no other drug approval of the same generic drug until the said period duly expires.

3. Enforcement

The amended provisions with respect to data exclusivity for new drugs shall come into force after promulgation by the presidential order (promulgated on January 31, 2018). The date of enforcement for the added provisions in regard to patent linkage and report to the authority of anti-trust laws shall be separately decided by the Executive Yuan.

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