NEWSLETTER

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Healthcare Group

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Pharmaceutical Affairs Act Amended to Limit 'Joint Use of Bioequivalence Test'

The amendment to the Pharmaceutical Affairs Act (**PAA**) passed the National Assembly on June 29, 2021, and is expected to be promulgated sometime in July.

The key points of the amendment include: (i) **limiting the number of items that may be approved by using previously submitted bioequivalence (BE) test or clinical trial data to three (joint BE/clinical trial 1+3 system)**, (ii) expanding the **prohibition on economic benefits provision by** drug suppliers to also include **those contracted to promote the sale of drugs (CSO), while requiring CSOs to also prepare an expenditure reports**, and strengthening penalties for violations, all for purpose of strengthening restrictions on drug rebates, and (iii) **reinforcing sanctions against drugs that have obtained market approval or lot release approval via false or fraudulent means.**

The amendment will generally come into effect six months after its promulgation. However, because restrictions on the number of items that may be approved by using previously submitted BE test or clinical trial data will be effective immediately upon promulgation and transitional regulations exist for different provisions, the industry should pay particular attention to such differing timelines.

1. Key Points of the PAA Amendment

- **Restrictions on use of previously submitted BE test and clinical trial data (effective immediately upon promulgation)**

  The PAA at present does not restrict the number of market approvals obtainable using previously submitted BE test or clinical trial data. This has led to the issue of excessive numbers of identical generic drugs flooding the market. The amendment restricts the number of items that may be approved by using previously submitted BE test or clinical trial data to three in order to solve the issues of disorder in drug distribution and weakening of product development capabilities, whiles strengthening the competitiveness of the pharmaceutical

industry (PAA Article 31, Paragraphs 10-16).

This amendment will apply to products which submit market authorization on or after the enforcement of the amendment. However, the pre-amended statute will apply in situations where multiple drug manufacturers in a joint development arrangement for a particular product and have received approval for their clinical trial plan at the time the amendment is enforced. In such instances, those that have received approval of their clinical trial plan must file documented proof of the existence of a joint development arrangement to the Minister of Food and Drug Safety within one month after the amendment comes into force. In addition, it should be noted that the consent given for the use of the BE test or clinical trial data by its sponsor before the enforcement of the amendment is not tallied towards the three consent limit in the amendment.

- **New provisions prohibiting provision of economic benefits by to those consigned to promote sale of drugs (effective six months after promulgation)**

  The PAA currently prohibits drug suppliers (market approval holders, importers, wholesalers) from providing economic benefits such as money, goods, and advantages, for purposes of promoting sales. The PAA also currently imposes an obligation to prepare and store an expense report on any such economic benefits provided. However, the current PAA had limitations in that there were no regulatory legal basis for the restricting those contracted to promote the sale of drugs (CSOs) from providing economic benefits to pharmacists, health care providers, and founders of medical institutions.

  In order to strengthen drug distribution management, the amendment expands the rebate restrictions applicable to drug suppliers to also cover CSOs. The amendment also requires CSOs to prepare and maintain expense reports, and applies an increased penalty for related violations (PAA Articles 47, 47-2, 69-4, 95).

  The requirement for preparing expense reports will apply from the fiscal year following the year of enforcement, and the requirement for disclosure of expense reports will apply two years after promulgation.

- **Reinforcement of sanctions for cases where market approval or lot release approval is obtained via unlawful means (effective six months after promulgation)**

  The PAA currently stipulates that re-application is possible one year after market approval revocation, regardless of the reason of revocation. There have been increasing criticisms that this waiting period is too short, particularly after a case was recently revealed where fraudulent data was used to obtain a lot release approval.

  Accordingly, in order to strengthen sanctions against drugs that have obtained market approval or lot release approval via false or fraudulent means, the amendment extends the time limit for re-approval to: (i) five years in cases where market approval was revoked for using false or fraudulent means, and (ii) three years where lot release approval was revoked for using false or fraudulent means (PAA Article 31, Paragraph 17).

  In addition, legal grounds for imposing administrative dispositions and penalties have been specified in cases where lot release approval was obtained via false or fraudulent means. In cases where lot release approval regulations have been

violated (including cases where lot release approval was not obtained, or obtained via false or other fraudulent means), a provision was added imposing a penalty surcharge of up to two times the sale proceeds of the product (PAA Articles 76, 81-2, 93).

- **Mandatory labelling of drugs for the visually and hearing impaired (effective three years after promulgation)**

  In order to reduce the occurrence of health issues attributed to misuse by individuals with disabilities, the amendment includes a mandatory labelling of safety information in braille, and audio and sign language convertible code on the container, packaging or attachments of readily available first-aid drugs [designated by the designated by the Minister of Health and Welfare], along with other drugs and quasi-drugs designated by the Minister of Food and Drug Safety (PAA Articles 59-2, 65-5, 65-6).

  The relevant industry should note that this requirement will come into force three years after the date of promulgation. In addition, the Minister of Food and Drug Safety may additionally require necessary preparations before implementation.

- **Obligation to register overseas manufacturing sites when importing drug substances (effective one year after promulgation)**

  At present, overseas manufacturing sites are required to be registered in the case of drugs that have received market approval or been registered. The amendment additionally will require that overseas manufacturing sites be registered even when importing drug substances. However, drug substances may be imported without registration for up to six months from the date the amendment is enforced (PAA Article 42, Paragraph 7).

- **Penalties for illegal purchasers of prescription drugs (effective one year after promulgation)**

  The PAA currently only punishes the sellers of illegally distributed prescription drugs. It was difficult to investigate and control consumer purchase of these products because there was no legal basis for punishing them, making investigation difficult. Accordingly, the amendment establishes legal grounds for punishing consumers who illegally purchase prescription drugs that are of serious concern to public health, such as steroidal and ephedrine injections, while also paying a reward to those who report such violations (PAA Article 47-4; Article 90; Article 98, Paragraph 1).

- **Conditional approval and priority review regulations in subordinate statutes have been elevated to the statute level (effective six months after promulgation)**

  Currently, there are conditional approval and priority review regulations in place to expand treatment opportunities for patients with severe conditions. However, the basis for operating the system has been elevated to statutory level in order to secure procedural legitimacy of the system, while strengthening its management and operation (PAA Article 35-2; Article 35-4).

2. Implications

This amendment is an integration and adjustment of 18 amendments to the PAA

that have been submitted to the Health and Welfare Committee. It should be noted that the amendment contains a vast amount of information on various issues, with differing implementation periods for different articles. In particular, regarding the restriction in the joint use of the same BE test and clinical trial data (joint BE/Clinical Trial 1+3 System), which is expected to have a major impact on the relevant industry, because the deadline to report a joint development agreement in order to have the previous statute apply is only one month from the enforcement date of the amendment, prompt preparation for this is necessary.

Lee & Ko will continue to promptly provide you with useful information by regularly monitoring the progress of amendments to the PAA and its subordinate statutes, as well as the overall progress of the PAA, its subordinate statutes and relevant administrative guidelines. If you require any further guidance regarding this matter, please contact the Lee & Ko Healthcare Group at any time.

For more information pertaining to this newsletter, please contact the attorneys identified on the left.

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