NEWSLETTER

April 2020

Healthcare Group

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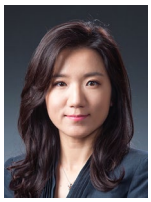

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Amendments to the Pharmaceutical Affairs Act to Strengthen Administrative & Criminal Sanctions for Data Manipulation Related to Applications for Regulatory Approvals

On April 7, 2020, an amendment to the Pharmaceutical Affairs Act (the '**PAA**') came into effect to provide a statutory basis for administrative and criminal sanctions to be enforced against companies that have obtained regulatory approval for a drug product through deceitful or otherwise improper means.

I. Amendment to the Pharmaceutical Affairs Act

Recently, multiple big pharmaceutical companies in Korea were found to have obtained regulatory approval for a drug product based on false or manipulated data. Yet, there was no statutory basis under the PAA to directly sanction such pharmaceutical companies for data manipulation. To address this legislative gap, the new PAA amendment established provisions based on which administrative sanctions and criminal penalties could be directly imposed on companies that obtained regulatory approval under the PAA through deceitful or otherwise improper means. The main details of the amendment are set out below:

Type of Action	Criminal Sanctions	Administrative Sanctions
■ If drug manufacturing approval or revised approval was obtained through deceitful or otherwise improper means ■ If marketing approval or revised approval was obtained through deceitful or otherwise improper means	Imprisonment of up to 5 years , fine of up to KRW 50 million (Article 93)	Cancellation of approval, registration, certification, suspension of business activities, or prohibition of manufacturing or importing a drug product (Article 76)

■ If DMF registration or revised registration of a drug product was obtained through deceitful or otherwise improper means		(Specific criteria not yet established)
■ If IND approval (including revised approval) was obtained based on false data or through an improper means	Imprisonment of up to 3 years , fine of up to KRW 30 million (Article 94)	

Based on the interpretation of 'deceitful' and 'improper' means that were at issue under a different law in a Supreme Court case precedent, this new amendment would not only be applicable to simple data manipulation, but is also expected to be more broadly applicable to "an action or inaction, which is deemed fraudulent or otherwise unfair by social norms, that can affect the decision-making of regulatory authorities granting regulatory approval when such approval otherwise could not have been granted."

II. Other efforts by MFDS to strengthen regulations on data manipulation

Further, based on the official press release by the Ministry of Food and Drug Safety (the '**MFDS**') on April 17, 2020, it appears that the MFDS is pursuing systemic and legal improvements with respect to data manipulation regulation through the following.

(1) Strengthen the MFDS' GMP compliance oversight by introducing a system that can track and verify the history of changes made, such as modification, deletion, and addition of data during the manufacturing and quality management of pharmaceutical products, for types of data that are more susceptible to manipulation (*e.g.*, handwritings and pictures); and

(2) Push for amendment of the PAA to enhance punitive fines and administrative sanctions against companies that have obtained economic benefits through data manipulation, and reject applications for marketing approval of such companies for a prescribed period of time.

III. Conclusion

The PAA amendment is expected to become an important stepping stone for Korean regulatory and investigative agencies to strictly evaluate and enforce pharmaceutical data integrity. In fact, in response to the recent pharma data manipulation case, not only have strong criminal measures been imposed, such as company search and seizure and the arrest of persons involved, but penalties which severely affect the business, such as cancellation of marketing approval for the relevant product item, have also been imposed.

Therefore, a thorough verification of data integrity with respect to its submitted materials would be needed for any company that wishes to obtain regulatory approvals for a drug product (i.e., marketing approval, IND, etc.) in Korea. In addition, it would be necessary to regularly conduct compliance due

diligence (i.e., mock inspections) of Korean offices and business sites in preparation for strengthened criminal investigations. A response manual should also be established for the company to rely on should the company be faced with a problematic situation. More importantly, in the event a problem occurs, it is crucial to engage competent legal counsel immediately to receive assistance during the investigation procedures and administration investigations.

Lee & Ko offers a full range of relevant legal services including establishing internal compliance policies described above and has also successfully represented clients in responding to criminal cases involving the PAA violations as well as obtaining suspension of execution. Its vast experience and in-depth expertise in these matters enable Lee & Ko to provide a one-stop legal solution service for clients in connection with investigation and enforcement activities by the MFDS or other authorities.

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

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