VIETNAM

By Dang Dinh Truong

Indochine Counsel
Business Law Practitioners

Ho Chi Minh City Office – Unit 305, 3rd Floor, Centec Tower
72-74 Nguyen Thi Minh Khai, Ward 6, District 3, Ho Chi Minh City, Vietnam
Tel: (84) 8 3823 9640 / Fax: (84) 8 3823 9641
E: info@indochinecounsel.com
Hanoi Office – Unit 705, 7th Floor, CMC Tower, Duy Tan Street, Cau Giay District, Hanoi, Vietnam
Tel: (84) 4 3795 5261 / Fax: (84) 4 3795 5262 / Mobile: (84) 906 242 513
E: truong.dang@indochinecounsel.com W: www.indochinecounsel.com

Pharmacy Activities

More than 10 years since its implementation, Vietnam has revised and supplemented the regulatory framework for the pharmaceutical industry to reflect the realities of practice and to catch up with state policy.

The National Assembly passed Law on Pharmacy No. 105/2016/QH13, dated April 6, 2016 (the Law on Pharmacy 2016), which will supersede the Law on Pharmacy No. 34/2005/QH11, dated June 14, 2005 (the Law on Pharmacy 2005) on January 1, 2017.

In comparison with the current Law on Pharmacy 2005, the Law on Pharmacy 2016 adds four chapters on state policies on pharmacy and pharmaceutical industry development, pharmacy practice, clinical pharmacy and management of drug prices.

State policies

The Law on Pharmacy 2016 provides that investment in the fields of, among others, manufacturing drugs, drug materials, essential drugs, vaccines, drugs for preventing social deceases and traditional drugs shall enjoy certain incentives. Meanwhile, for drugs bought by public medical establishments, using: the state budget, medical insurance funds, income from health services, and other legal financial resources the priority shall be reserved to domestic drugs in the list of National Products, and generic drugs, similar bio-preparations manufactured for the first time in Vietnam, drugs from materia medica, traditional drugs manufactured from domestic materials, drugs with active ingredients, excipients, drug capsules and drug packaging manufactured by domestic Good Manufacturing Practice establishments.

Pharmacy practice certificate

According to the Law on Pharmacy 2016, persons who are responsible for quality assurance of the pharmaceutical manufacturing establishments, pharmaceutical raw material manufacturing establishments and persons who are responsible for works of clinical pharmacy in the deceased examination and treatment establishments are subject to the pharmacy practice certificate requirement. It is worth noting that a pharmacy practice certificate does not have a validity duration. Compared to the current regulation, the time limit for grant of a certificate is shorter.

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A backward looking provision of the Law on Pharmacy 2016 is the time limit for examination of the application dossier for obtaining a marketing authorisation licence for a new drug. This period is now increased from six months as regulated in the Law on Pharmacy 2005 to no longer than 12 months from the submission date of the proper application dossier. This is because, as explained by the competent authority, they need more time for examining the clinical trial results and bioequivalent study results, and this prolonged time limit conforms with international customs of about 18 months in some other countries.

Management of drug prices

The management of drug prices must comply with the market mechanism and respect the rights of drug manufacturers and traders to pricing and price competition. The State will apply measures to stabilise drug prices and other measures to manage drug prices suitable to socio-economic development conditions in each period. The State will take measures to stabilise the prices of drugs on the list of essential drugs in accordance with the Price Law only when there are abnormal price fluctuations or price fluctuations affecting socio-economic stability.

The Law on Pharmacy 2016 no longer requires announcement of ceiling prices of medicines which are paid with the state budget and health insurance. The comparison between the drug prices at home and those in countries which have healthcare and commercial conditions similar to Vietnam's is not prescribed in the Law on Pharmacy 2016.

It is hoped that the Law on Pharmacy 2016 will encourage the development of the domestic pharmaceutical industry, and help state authorities manage pharmacy activities more effectively to ensure the quality of drugs delivered to end users.