Vietnam Investment Review

CPTPP signals pharma breakthrough

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Amid enforcement of landmark free trade agreements, Vietnam's Ministry of Health has made significant legislative changes. Vu Thi Thu Hien and Le Huu Hong Chuyen of Tilleke & Gibbins, Southeast Asia's leading full service regional law firm, give an inside view into how these agreements and legislative changes can make an impact on the local pharmaceutical market in the future.

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The market for pharmaceuticals in Vietnam is developing rapidly, in step with the country's growing and aging population, rising per capita income, and increasing awareness of foreign brand-name drugs, which many Vietnamese consumers consider to be more reliable than generics and local brands. Naturally, Vietnam has become an attractive investment - destination for foreign pharmaceutical companies eager to target new customers.

The government is doing its part to encourage this investment, as seen by its participation in international free trade agreements and ongoing legislative reform. A revised Law on Pharmacy was issued in 2016 followed by subsequent guiding legislation, but obstacles to overseas investment remain. One thing is certain: the business environment in the pharmaceutical sector is constantly changing.

The Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), a multilateral trade agreement signed by 11 countries on both sides of the Pacific, officially came into force in Vietnam in January. Among its provisions, the CPTPP requires each of its members to have a system of pharmaceutical patent linkage. Prior to granting marketing approval to any generic drug, Vietnam must notify the original drug's patent holder of the generic drug's application for approval.

By virtue of such notice, the patent holder would then have adequate time and opportunity to seek judicial or administrative proceedings and expeditious remedies, such as preliminary injunctions, for the timely resolution of disputes concerning the validity or infringement of an applicable patent.

Instead of the above-mentioned system, Vietnam may alternatively adopt a non-judicial regime to preclude the issuance of marketing approval to generic drugs based on the available patent-related information. This may come from co-operation between Vietnam's intellectual property office and the Drug Administration of Vietnam, the marketing applicant, or the - concerned patent holder.

Within the framework of the CPTPP, Vietnam also reached agreements on marketing approval with some other members such as Japan, New Zealand, and Canada. By means of such agreements, Vietnam has the right to establish conditions, limitations, or exceptions when implementing the obligations set forth under Article 18.53 of the deal.

Foreign firms are being encouraged to seek legal assistance when doing business in Vietnam's pharmaceutical market, Photo: Le Toan

Changes in the legislative framework

The government's Decree No.54/2017/ND-CP of May 2017, the primary legislation guiding the implementation of the Law on Pharmacy, took effect in July 2017. Subsequently, last year two noteworthy guidance documents were issued for the pharmaceutical sector.

The first was Circular No.07/2018/TT-BYT of the Ministry of Health (MoH), effective from June 2018, on guidelines for some articles on pharmacy business of the Law on Pharmacy and Decree 54. The other was the government's Decree No.155/2018/ND-CP of the government, effective in November 2018, amending some regulations related to investment and business conditions under the management of the MoH.

Circular 07 confirms that only drug business establishments are allowed to hire medical representatives, also known as drug introducers, to introduce drugs to healthcare professionals. After Decree 54 took effect, a representative office cannot hire new medical representatives, as the definition of drug business establishments excludes representative offices.

However, Circular 07 allows the representative offices to continue employing medical representatives who have valid drug introduction cards until the cards expire. Accordingly, several foreign pharmaceutical companies who are operating through representative offices in Vietnam are restructuring their operations to comply with the new regulations. Only drug business establishments can issue drug introduction cards to their medical representatives. The local department of health is no longer the entity that will issue these cards to the medical representatives.

Though Decree 155 does not create any substantial changes to the rights and obligations of a drug business establishment, including drug importers, it creates less regulated, more pro-business conditions by shortening the time or lessening documents required for the issuance of the Certificate of Eligibility for Pharmaceutical Business (CEPB).

For example, technical documents and human resources according to the principles of Good Distribution Practice for drugs and drug raw materials are not required in the application dossier, as the requested scope for CEPB does not cover the right to sell drugs and drug raw materials to retailers or medical service establishments.

Furthermore, the statutory timeline for the authority to issue the CEPB is 20 days, instead of 30 days under Decree 54, from the date recorded in the application receipt in cases where physical and technical facilities and human resources have been verified and assessed as conforming to the respective good practice of the business operating area, and onsite assessment at the applicant establishment facility is not required.

Import licences for drugs

Decree 155 makes the import licence procedure clearer and simpler. For example, to obtain an import licence for a new drug without a marketing authorisation in Vietnam, Decree 155 no longer requires such drug to have full clinical documents on efficacy and safety as mentioned in Decree 54. This change may give foreign manufacturers quicker access to the Vietnamese market.

Additionally, if such new drugs were previously granted an import licence, there is no need to submit clinical documents when requesting a new import licence, unless the drug has undergone major changes. Regarding the quantity of the drug to be imported, Decree 155 uses the business needs of the local importer as a basis, rather than the progress and scope of the targeted disease as in Decree 54.

Decree 155 abrogates previously strict conditions on drugs for special treatment and allows such drugs to be imported more liberally based on the country's needs. Also, for import licence dossiers in all scenarios, Decree 155 relieves the burdens on trading entities by reducing the documentary requirements.

The import registration dossier must include the drug's label and package insert which are used in the manufacturing or exporting countries, instead of in the certificate of pharmaceutical product (CPP)-granting country as required in Decree 54. Furthermore, it is required to submit a legalised original label and package insert for parallel import licences only; for other import licences, a copy of the label and package insert can be submitted, provided they are stamped by the manufacturer, the product owner, the marketing authorisation holder named on the CPP, or the local importer.

Decree 155 abrogates regulations on amendment and re-issuance of Certification of Drug Information and Certification of Drug Advertisement Contents. The administrative procedures for amending and re-issuing these certifications no longer exist.

The procedure for new issuance of such certifications under Decree 54 is unchanged. However, Decree 155 removes the requirement to submit the marketing authorisation or import licence in the applications for the certifications. Furthermore, the CEPB issued by the Ministry of Health is no longer required in the application if the applicant is the pharmaceutical business establishment who owns such CEPB.

Slowly but surely, the Vietnamese pharmaceutical sector appears to be falling in line with international standards and practices. The reduced bureaucratic requirements and improved intellectual property protection are certainly positive signs and may encourage further market entry. However, international pharmaceutical companies looking to do business in Vietnam may still encounter regulations and restrictions that do not exist in other jurisdictions, and would be well advised to seek professional assistance from a legal perspective to ensure strict compliance with the law.

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