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Foreign invested enterprises' pharmaceutical trading right on the move!

Eight years after the lapse of the phase-in schedule for its relevant WTO commitment, Vietnam for the first time is setting forth a legal framework for foreign invested enterprises ("FIEs") to trade in drugs and drug ingredients to fulfill its WTO Commitments. With the long-awaited new Pharmaceutical Law taking effect this January 2017 and the draft of the decree implementing the Pharmaceutical Law ("Draft Decree") being finalized for issuance, pharmaceutical FIEs appear to be able to exercise their trading right in a very near future.

In this briefing, the "Pharmaceutical Law" refers to the new Pharmaceutical Law and the "2005 Pharmaceutical Law" refers to the old Pharmaceutical Law, which has been in effect since 2005 and which was superseded by the new Pharmaceutical Law in January 2017.

I. VIETNAM'S INTERNATIONAL COMMITMENTS

When acceding to the WTO in 2007, Vietnam made different commitments for the "import right" and the "distribution right" of FIEs with respect to pharmaceuticals, summarized below:

Import right

Import right refers to the right to import goods to resell to distributors or wholesalers in Vietnam. An FIE with the import right and without the distribution right cannot sell its imported goods to retailers and/or consumers.

Under its WTO Commitments, Vietnam commits to grant FIEs the import right for pharmaceuticals as of 1 January 2009.

Regardless, to date, FIEs have not been able to exercise their import right for pharmaceuticals due to procedural barriers under local laws.

Under recently concluded Vietnam-Europe Free Trade Agreement, which is expected to take effect in 2018, Vietnam undertakes to "adopt and maintain in force appropriate legal instruments" to allow FIEs "to sell pharmaceuticals legally imported by them to distributors or wholesalers."

Distribution right

Distribution right refers to the right to conduct wholesale, retail and similar commercial activities. An FIE with the distribution right may resell goods to any buyer, including wholesaler, retailer and consumer.
Vietnam's WTO Commitments exclude the distribution right for pharmaceuticals.

II. TRADING RIGHTS UNDER PHARMACEUTICAL LAW

To fulfill its WTO Commitments, Vietnam has finally concluded a legal framework for pharmaceutical FIEs' trading rights, which is implied in the Pharmaceutical Law and further elaborated in the Draft Decree, expected to be issued in a near future.

The Pharmaceutical Law implies the import right of FIEs by a reference to "pharmaceutical importers not having the distribution right for drugs," which this briefing will refer to as "FIE pharmaceutical importers."

For reference, a "pharmaceutical importer" has the following major rights, amongst others, under Article 44 of the Pharmaceutical Law:

1. Drugs and drug ingredients introduction (via pharmaceutical introduction representatives, circulation of drug information and organization of drug introduction seminars) and advertising (for drugs for which advertising is permitted);

2. Importing drugs and drug ingredients [for resale];

3. Registering drugs and transferring drug registrations; and

4. Reselling imported drugs and drug ingredients, provided that, if the pharmaceutical importer does not have the distribution right for drugs, its resale rights are subject to regulations issued by the Ministry of Health ("MOH"). This scope of the resale right is further discussed in Section III below.

III. DRAFT DECREE: SCOPE OF THE IMPORT RIGHT

Under the Draft Decree, a FIE pharmaceutical importer may sell its imported pharmaceuticals only to pharmaceuticals wholesalers who has been certified by the MOH as satisfying the conditions to buy pharmaceuticals from a FIE pharmaceutical importer.

Among conditions imposed by the Draft Decree for a pharmaceuticals wholesaler to be eligible to buy pharmaceuticals from FIE pharmaceutical importers is the unusual condition of having a testing laboratory meeting the standards of Good Laboratory Practice ("GLP"), with capacity to check and control no less than 70% of the imports purchased from the FIE pharmaceutical importer and 100% of imports subject to special storage/preservation conditions.

The Draft Decree explicitly restricts a FIE pharmaceutical importer from conducting any of the following activities, which are considered as activities of a distributor or wholesaler:

1. Delivering drugs to drugs retailers, health clinics except those wholesalers satisfying the statutory conditions to purchase from FIE pharmaceutical importers;

2. Accepting purchase orders or accepting payments under purchase orders of drugs distributed by other enterprises;

3. Determining or fixing the sale prices of drugs distributed by other enterprises;

4. Participating in developing and/or making decisions on the distribution strategy and/or business policy for drugs distributed by other enterprises;

5. Intervening in drugs supply plans of health clinics in Vietnam; or

6. Conducting other activities related to drugs distribution.

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IV. ELIGIBILITY CERTIFICATES UNDER PHARMACEUTICAL LAW

Under Article 33 of the Pharmaceutical Law, a pharmaceutical enterprise must obtain a certificate of eligibility for conducting pharmaceutical business ("Eligibility Certificate") for the relevant pharmaceutical business categories it wishes to conduct, such as manufacturer, importer, wholesaler, retailer, laboratory, clinical testing, etc.

To be granted an Eligibility Certificate as a pharmaceutical importer, an enterprise must have a business location, a drug warehouse, storage equipment, transport facilities, quality control system, technical materials, and personnel satisfying the Good Storage Practice ("GSP"). An Eligibility Certificate no longer has any term or expiry date.

The application dossier for an Eligibility Certificate as a pharmaceutical importer consists of the following and must be filed with the MOH:

- An application in the statutory form;
- Technical documents evidencing satisfaction of the statutory conditions described above;
- A certified true copy of the enterprise registration certificate or equivalent forms of corporate licenses; and
- A certified true copy of the practice certificate of the person-in-charge of the professional activities of the importer.

V. REPRESENTATIVE OFFICES ("ROs")

ROs in Vietnam of the offshore pharmaceutical enterprises still have the right to register drugs and drug ingredients for marketing authorization under the Pharmaceutical Law.

It appears that the Pharmaceutical Law and the Draft Decree does not intend to grant those ROs the right to conduct drug introduction via RO's drug introducers or advertise OTC drugs though this issue is subject to further guidance by the MOH.

FOR MORE INFORMATION PLEASE CONTACT:

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