At a glance...

This note summarises some of the key changes set out in the New Pharma Decree and analyses whether Vietnam finally allows foreign-invested pharmaceutical companies to exercise their long-awaited import rights.
New Decree No. 54/2017/ND-CP dated 8 May 2017 ("Pharma Decree")

(implementing a number of provisions of the 2016 Pharmaceutical Law, which came into force on 1 January 2017)

The Vietnamese Government recently issued the new Pharma Decree, which will come into force on 1 July 2017 and will replace the former decrees No. 79/2006/ND-CP, 89/2012/ND-CP and 102/2016/ND-CP.

The Pharma Decree revises the following:

- Procedures and applications for various types of pharmaceutical business licences such as practicing certificates and certificates of satisfaction of pharmaceutical business conditions for manufacturers / importers / exporters / wholesalers / retailers (including pharmacies) / drug storage service providers / clinical testing service providers, etc.
- Conditions for trading of controlled drugs
- Procedures and applications for import/export of drugs
- Procedures for registration of drug information content and notices
- Drug advertising, and
- Measures for management of drug prices.

Following our previous NewsBrief published on 24 January 2017 in relation to the draft of the Pharma Decree, we have set out in this note some key points of the Pharma Decree.

**Foreign-invested enterprises (FIEs) with import rights**

The Pharma Decree appears to allow FIEs with import rights to directly import pharmaceutical products. The 2016 Pharmaceutical Law introduced for the first time the term "entities which have the right to import but are not allowed to exercise distribution rights of pharmaceutical products in Vietnam" without giving any further definition or explanation. While the Pharma Decree clarifies the rights of these importers, it fails to define who these importers are. By reference to Vietnam’s WTO commitments, it is understood that the importers here refer to foreign-invested companies licensed to carry out import rights (the right to import and sell to Vietnam-based wholesalers) but which are not allowed to distribute pharmaceutical products (the right to sell to wholesalers, retailers and patients).
Until now, these FIEs with import rights have not been able to get the relevant import licence (known as “certificate of satisfaction of pharmaceutical business conditions for importers”) from the Ministry of Health (“MoH”) because the latter claims there is not sufficient legal basis (in the form of implementing regulation) for it to do so.

What has changed under the Pharma Decree –and what can FIEs with import rights do now?

FIEs with import rights are allowed to sell the imported products to wholesalers only. To do so, they will have to register their wholesalers with the MoH before they can commence to sell (and also when they terminate their contracts with the wholesalers). The MoH will publish on its website the list of wholesalers which are eligible to purchase imported products from the relevant FIEs with import rights.

However, importantly the Pharma Decree explicitly prohibits FIEs with import rights from conducting any of the following activities, which are considered distribution activities:

- Selling drugs to, or accepting purchase orders of, drug retailers/pharmacies, hospitals and clinics, and other organisations or individuals which are not wholesalers
- Transportation of drugs and provision of drug storage services
- Determining or fixing the sale prices of drugs distributed by other companies
- Deciding the distribution strategy or business policy for drugs distributed by other companies
- Making drugs supply plans for hospitals and clinics in Vietnam
- Providing financial support to its purchasers in order to control or intervene in their distribution activities, and
- Conducting other activities related to drugs distribution.

The Pharma Decree is a positive regulatory step towards granting FIEs the right to legally import and sell to Vietnamese wholesalers, a decade after that was first allowed in principle upon Vietnam’s accession to WTO. It remains to be seen whether the Vietnamese authorities will rely on these relevant provisions of the Pharma Decree or will rather wait for the MoH to issue further “guidelines on import/export” of drugs. We understand that the MoH is preparing a draft circular on the subject, however it is still unclear if and when the MoH can enact it.
**No additional requirements for wholesalers purchasing from FIEs**

Unlike what was set out in its draft form, the Pharma Decree does not require wholesalers to meet technical conditions in relation to facilities (such as GSP warehouses, laboratories, etc.) in order to purchase imported products from FIEs with import rights. The Pharma Decree requires that wholesalers must have the capacity to directly organise the distribution of the products purchased from the foreign invested pharma companies “without being subject to any intervention from or control by” the seller. The foregoing is likely to have implications on the conduct of business by foreign-invested pharma companies in Vietnam (including existing arrangements they may have with their Vietnamese partners).

**Requirements for foreign-based pharma sellers**

Another key change under the Pharma Decree is in relation to foreign-based pharma sellers. At present, prior to selling products to Vietnamese distributors, foreign-based pharmaceutical companies must obtain an “operating licence” from the MoH and meet a number of conditions in relation to experience, minimum revenues, etc. Pursuant to the Pharma Decree, the operating licence requirement will no longer apply – instead, only eligible foreign exporters will be authorised to sell their pharmaceutical products to Vietnam-based distributors. These foreign exporters include:

- the manufacturers
- the product owners or the market authorisation (“MA”) holders as stipulated in the Certificate of Pharmaceutical Products of the imported drugs
- foreign companies which are MA holders of the imported drugs in Vietnam, or foreign companies which already obtained an operating licence from the MOH (before the effective date of the Pharma Decree, i.e. 1 July 2017) provided that they have an authorisation from the manufacturers, product owners or the MA holders for selling products to Vietnam (such authorisation is exempted in certain circumstances provided in the Pharma Decree).

The foregoing is likely to facilitate the export process to Vietnam for international pharmaceutical companies, but can affect intermediary exporters which are not manufacturers, product owners or MA holders.
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