



Special Alert

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Vietnam's Policy for Importation of Covid-19 Vaccines in Emergency Use

Amid the growing Covid-19 cases from the fourth outbreak in the country, the Government of Vietnam is taking measures to speed up the vaccine rollout for its population. The Government has approved the establishment of a Covid-19 vaccine fund, which will receive, manage, and use voluntary financial and vaccine donations and assistance from domestic and foreign organisations and individuals, for COVID-19 vaccine procurement and import, research and production in Vietnam, and distribution of vaccines for the people. One of Vietnam's goals for prevention of the spread of Covid-19 is to have 75 per cent of its population vaccinated by the end of this year, which would require about 150 million doses of vaccines, as told by Health Minister Nguyen Thanh Long. This would cost more than US\$1 billion, and the fund is in place to mobilize the resources for that goal.

Towards that goal, the Government encourages all localities and businesses to seek proper vaccine resources and negotiate with vaccine manufacturers for the purpose of importation into Vietnam. This article will look at the rules and policies for importation and distribution of Covid-19 vaccines in Vietnam.

Under the Law on Pharmacy No. 105/2016/QH13 dated 6 April 2016 as amended by Law No. 28/2018/QH14 dated 15 June 2018 (the "Pharmacy Law") and its guiding regulations, only certain companies that are duly licensed with the business lines of pharmacy importation and/or trading, and have valid certificates of eligibility for pharmacy business can import vaccines into Vietnam. To obtain a certificate of eligibility for pharmacy business, a company must have the premises, drug storage, storage equipment, transportation means, quality control system, technical documents and qualified personnel that meet the GSP requirements as specified in Article 33.1(b) of the Pharmacy Law, Decree No. 54/2017/ND-CP dated 8 May 2017 (as amended by Decree No. 155/2018/ND-CP dated 12 November 2018) ("Decree 54"), and Circular No. 36/2018/TT-BYT dated 22 November 2018 regulating good storage practices (GSP) of drugs and drug materials.

As published by the Ministry of Health (MOH) recently, 36 companies have been licensed and are eligible to import and trade vaccines in Vietnam. Localities and businesses who have been approached with supply resources must cooperate with the MOH or one of these licensed companies for the purpose of importation of vaccines. Those foreign invested enterprises (FIEs) which have been granted the importation rights in their IRCs (Investment Registration Certificate) can act as the importers of the vaccines for wholesale to authorized Vietnamese companies, but such FIEs shall not be permitted to distribute vaccines as regulated in Circular No. 34/2013/TT-BCT dated 24 December 2013 of the Ministry of Industry and Trade publicizing roadmaps for goods trading and goods trading directly related activities of foreign invested enterprises in Vietnam.

Per Article 60 of the Pharmacy Law, vaccine with a valid marketing authorization granted by the MOH can be imported with a volume to satisfy the demand by eligible companies without an importation permit. Commonly, it takes from six to twelve months to obtain a marketing authorization for a vaccine. However, the MOH has announced that according to warnings from the World Health Organization (WHO), a clinical trial which is one of the requirements for imported vaccines, will not be required, but will be based only on an application dossier which process may take about 48 hours. That means the entire time for the procedure for granting a marketing authorization for Covid-19 vaccines will be drastically shortened. In addition, the MOH is considering on an urgent basis the issuance of a new circular on registration of Covid-19 vaccines under summary procedure for response to the emergency pandemic situation, which will facilitate localities and businesses in importation of vaccines into Vietnam.

Also in accordance with Article 60 of the Pharmacy Law, in certain cases, including the existing emergency demand for prevention and elimination of epidemics, vaccines which have not yet been granted marketing authorization by the MOH can be imported into Vietnam with relevant importation permits granted on a case by case basis by the MOH. These permits have the duration of one year from the issuance date and are limited to stated volumes of vaccines to be imported.

In response to the current situation of Covid-19 pandemic, the MOH will base on Article 60 of the Pharmacy Law and Article 67 of Decree 54 to consider and grant conditional approvals of certain vaccines for the emergency use. Accordingly, the ministry will examine and grant importation permits within about five (5) working days for those vaccines already approved by the WHO, or within about ten (10) working days for those vaccines which have not yet been approved by the WHO but have been approved in other countries, upon receipt of all valid application dossiers. Till date, the MOH has approved for importation of three Covid-19 vaccines for the emergency use: AstraZeneca, Sputnik V and COVID-19 (Vero Cell), Inactivated.

With the expedite approval process and the active support the Government, along with the mobilization of resources and donations from the business community and the public for the Covid-19 vaccine fund, it is hoped that the target of importing 150 million doses of vaccines into Vietnam this year will be possible.

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