

Investing in Vietnam's Healthcare Sector: Emerging Opportunities and Entry Strategies

Filippo Bortoletti

Senior Manager – International Business Advisory





# **Table of Contents**

- 1. Vietnam's Healthcare Industry Overview
- 2. Emerging Opportunities in Healthcare Industry
- 3. Market Barriers & Entry Strategies



Part 1 Vietnam's Healthcare Industry Overview

# **Snapshot of Vietnam's Healthcare Industry**



Cons Counterfeit drugs

Rising income per capita

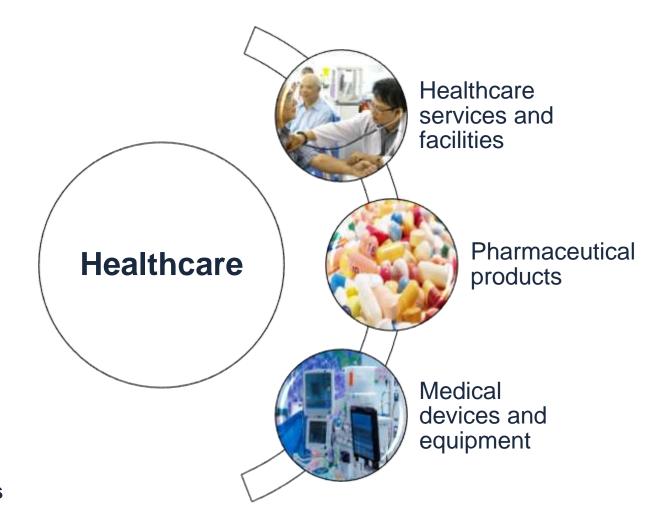
Complex regulations

Increasing urban population

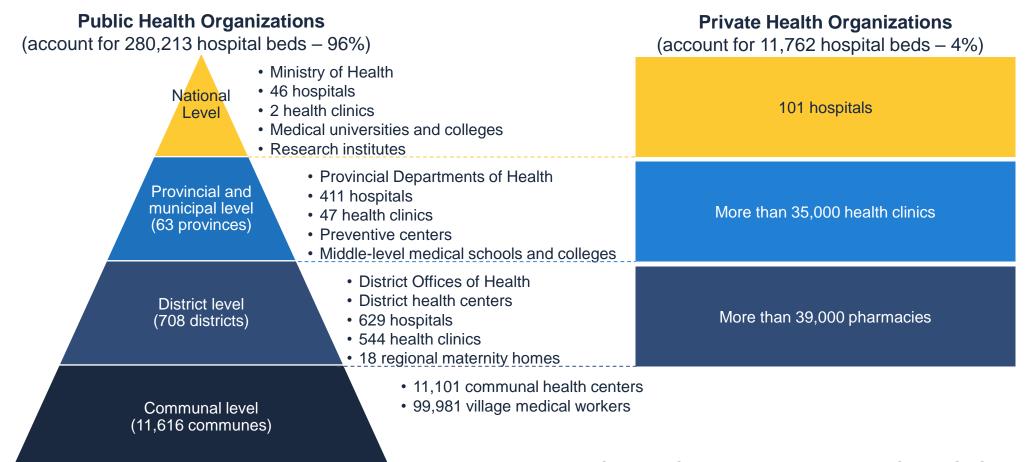


Estimated turnover US\$17,4 billion in 2018

Double digit growth across the market segments



# **Healthcare System**



#### VIETNAM'S PUBLIC AND PRIVATE HEALTHCARE SYSTEM

Ministry of Health (2017)

# **Pharmaceuticals Industry Overview**



**180** drug producers

**GMP-standard domestic** pharmaceutical factories



employed

**44,000** people



accounted for

**2.2%** of GDP

## **Vietnam**

can manufacture certain types of generics but are

Level 2: Countries that

still dependent on drug

imports.

Level 3: Countries that have domestic pharmaceutical industry and manufacture generics as well as export some pharmaceutical products to other countries.

Level 4: Countries that are self-sufficient in medicinal raw materials and invent new drugs.

Level 1: Countries whose medicine are entirely imported

DEVELOPMENT PATH OF PHARMACEUTICAL INDUSTRY

World Health Organization (WHO) and United Nations Conference on Trade and Development (UNCTAD)

# **Pharmaceuticals Industry Overview**

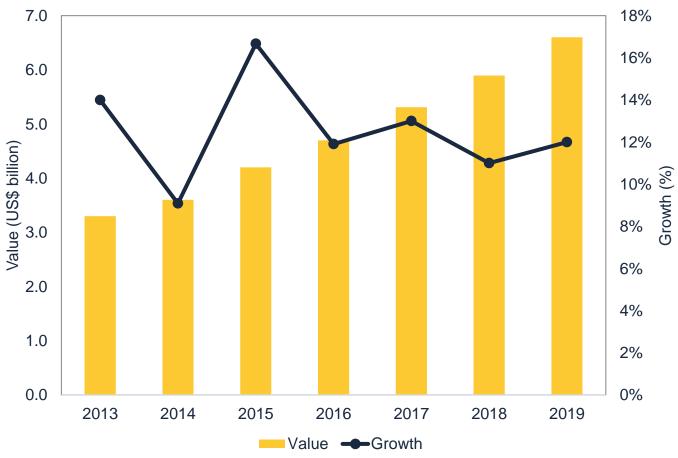
#### **Feature**

- Domestic firms mainly produce simple dosage medications, functional foods, and generic drugs.
- Domestic firms are lack of research and development capability and the ability to invest in new compounds.
- Vietnam depends on imported materials and finished products.

## **Drivers of growth**

- Ageing population
- Growing middle-class
- > Rising health concerns





Source: VIRAC, DAV

# **Import - Export of Pharmaceuticals**

Despite higher growth rate of exports, Vietnam remains a net importer of pharmaceutical products

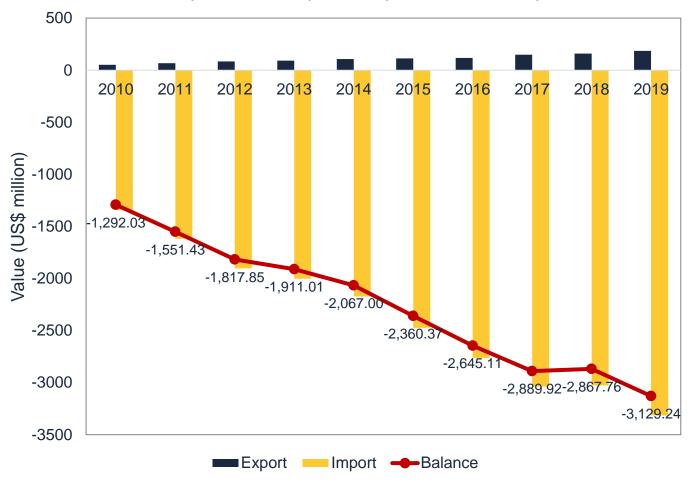
13.59% CAGR of exports

**9.45%** CAGR of imports

9.25% CAGR of trade deficits

Over a decade from 2010 to 2019

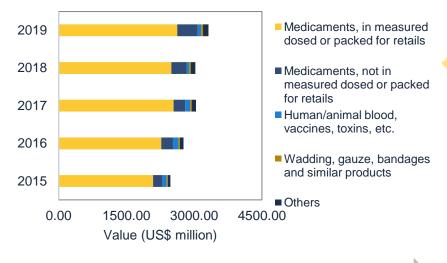
#### Vietnam's imports and exports of pharmaceutical products



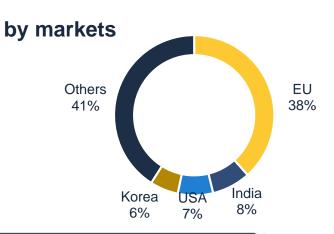
Source: UN Comtrade

# **Import – Export of Pharmaceuticals**

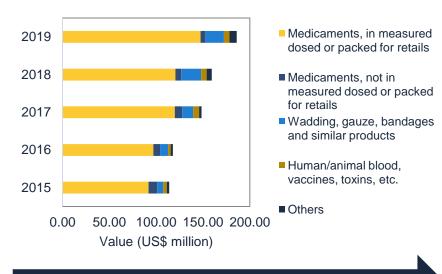
## by products



#### **IMPORT**

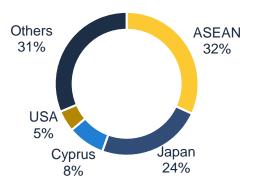


## by products



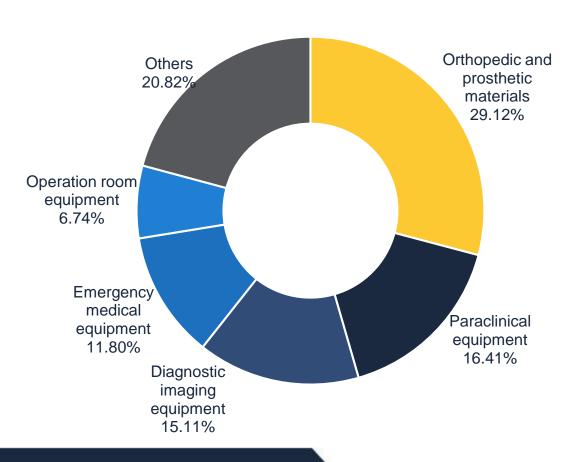
#### **EXPORT**

## by markets

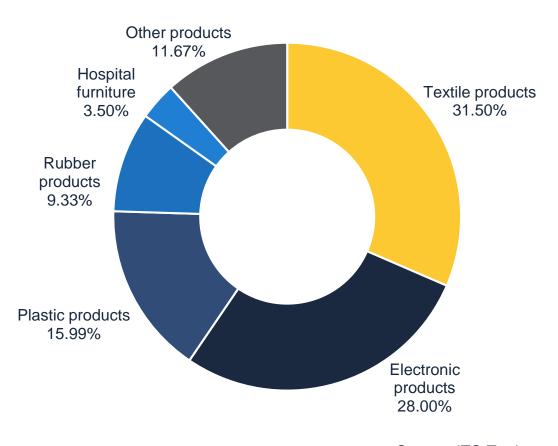


# **Medical Devices Industry Overview**

# Market share of medical equipment sorted by applications



# Market share of medical equipment sorted by materials



Source: ITC Trademap

# **Import – Export of Medical Devices**

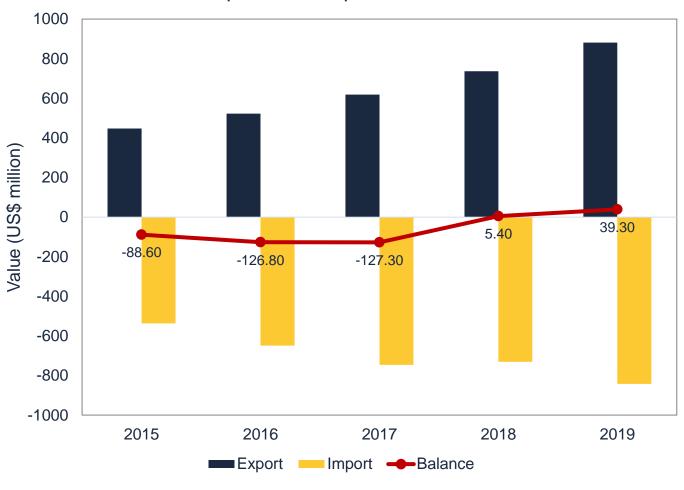
Higher exports growth rate in the last few years made Vietnam's trade balance of medical devices positive in 2018 and 2019. Still, in certain segments – such as x-rays and radiations instruments, ultrasonic scanning, magnetic resonance – Vietnam remains heavily reliant on imports.

**18.46%** CAGR of exports

12.29% CAGR of imports

From 2015 to 2019

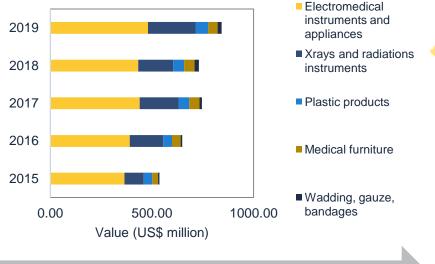
## Vietnam's imports and exports of medical devices



Source: ITC Trademap

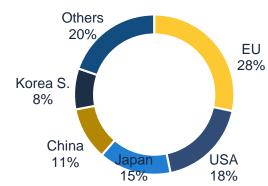
# **Import – Export of Medical Devices**

## by products



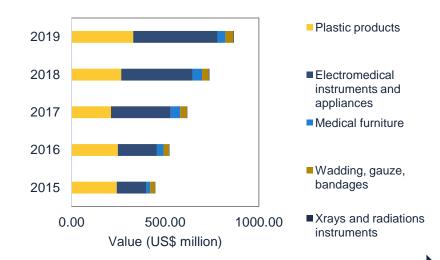
## **IMPORT**

### by markets



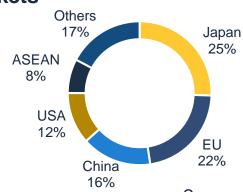
#### Source: Custom Office

## by products



#### **EXPORT**

### by markets



Source: ITC Trademap



# **Major Trends**

High economic growth, rising income per capita, increasing urban population, aging population Local production of pharmaceuticals and medical equipment not been able to meet local demand Digitalization

## **Local Macroeconomic Trends**

## Economic growth

- Vietnam is one of the fastest growing countries in Asia, with an estimated growth of 8.1% in 2021 notwithstanding Covid-19
  according to HSBC
- Overall the last 2 decades, Vietnam population expanded from 72 million people in 1995 to over 95 million people in 2019
- Rising income per capita from US\$277 in 1995 to US\$2,715 in 2019 according to the world bank

## Urbanization

- Urban areas have developed at 2.8% per year according to World Bank, being among the fastest growth rates in the Asian region
- New urban middle-class can influence community behaviors and consumption patterns with positive effects the demand for healthcare

## Aging population

- Vietnam population officially entered an 'aging phase' in 2017 and is among the most rapidly aging countries in the world
- Public, provincial-level hospitals funded by the governments are undergoing upgrades of their facilities and opening new departments for specialty treatment
- Government aims to bring insurance coverage to 100% of the population by 2030 with additional initiatives also being developed to further enhance health care delivery

## **Local Market Trends**

## Medical devices

- Local producers have only been able to supply basic medical supplies such as scissors, rubber health products, scalpels, hospital beds and other disposable supplies
- According to the Ministry of Health, 90% of medical devices in Vietnam need to be imported

# Pharmaceutical products

- Domestic drug firms focus mostly on producing generic products and other simple areas of drug production, as they lack research and development capabilities as well as the ability to invest in new compounds
- Much of Vietnam's spending on pharmaceuticals is on imports

## Healthcare

- According to medical experts, 10 percent of Vietnamese people under 40 suffer the Parkinson disease i.e. about 85,000 people statistically
- According to the Vietnam Society of Hepato Biliary Pancreatic Surgery, liver cancer is the leading cause of cancer death in Vietnam
  presently killing up to 25,000 patients yearly, tripling traffic accident-related victims
- Additionally, hepatitis, cirrhosis, disorders of the pancreas are challenges of the country's health sector

# **Digitalization**

## Smart hospitals

- Ministry of Health has a roadmap for digitizing patients' records at hospitals and setting up smart hospitals to improve the quality of healthcare to achieve customer
- Application of new techniques and technologies such as AI, expert systems, the internet of things, and big data to create information management systems and powerful applications
- Many hospitals in the country have adopted health information technology systems such as electronic medical records, eHealth and telemedicine

## Health ID

• Each Vietnamese citizen will be issued with a unique health ID card, which they will be able to use throughout their lives. ID cards will be able to create and connect health reports for patients nationwide

## **E-prescriptions**

- About 95 percent of medical facilities in Vietnam have prescription management software, but many still sell medicines without prescription
- All prescriptions sent from healthcare facilities nationwide would be saved on the software and shared with patients and medicine suppliers. The e-prescriptions would be connected with e-medical records → the system is being piloted in Ha Tinh and Hung Yen and has been assessed as operating smoothly so far

# **EVFTA** | Emerging Opportunities from Tariff Reduction

HS Code	Products	Number of Tariff Lines	Vietnam's Average Tariff	Tariff reduction schedule under the EVFTA (number of tariff lines)			
				Schedule A	Schedule B5	Schedule B7	Schedule B10
30	Pharmaceutical products	99	2.26	51	1	33	2
3001	Glands, organs for organo-therapeutic uses	2	0.00	2	0	0	0
3002	Human and animal blood, antisera, vaccines and toxins	9	0.00	9	0	0	0
3003	Medicaments, not in measured dose or packed for retails	8	2.20	6	0	2	0
3004	Medicaments, in measured dose or packed for retails	60	2.22	34	1	25	0
3005	Wadding, gauges, bandages and similar products	5	7.00	0	0	5	0
3006	Other pharmaceutical goods	15	2.67	0	0	1	2

#### Note:

- Schedule A: Customs duties on originating goods shall be removed **immediately** upon the EVFTA's entry into force.
- Schedule B5: Customs duties on originating goods shall be removed in **six** equal annual stages and thereafter be free of any customs duty.
- Schedule B7: Customs duties on originating goods shall be removed in **eight** equal annual stages and thereafter be free of any customs duty.
- Schedule B10: Customs duties on originating goods shall be removed in **eleven** equal annual stages and thereafter be free of any customs duty.

# **EVFTA** | Emerging Opportunities from Tariff Reduction

HS Code	Products	Number of Tariff Lines	Vietnam's Average Tariff	Tariff reduction schedule under the EVFTA (number of tariff lines)			
				Schedule A	Schedule B5	Schedule B7	Schedule B10
90	Optical [] measuring, checking, precision medical or surgical instruments and apparatus	49	0.16	49	0	0	0
9018	Instruments and appliances used in medical, surgical, dental or veterinary science	25	0.00	25	0	0	0
9019	Mechano-therapy appliances; massage apparatus; psychological aptitude-testing apparatus; ozone, oxygen, aerosol therapy; artificial respiration or others	3	0.00	3	0	0	0
9020	Other breathing appliances and gas masks, excluding protective masks	1	1.70	1	0	0	0
9021	Orthopedic appliances	12	0.00	12	0	0	0
9022	Apparatus based on the use of x-rays or of alpha, beta or gamma radiations	8	0.79	8	0	0	0

#### Note:

- Schedule A: Customs duties on originating goods shall be removed **immediately** upon the EVFTA's entry into force.
- Schedule B5: Customs duties on originating goods shall be removed in **six** equal annual stages and thereafter be free of any customs duty.
- Schedule B7: Customs duties on originating goods shall be removed in **eight** equal annual stages and thereafter be free of any customs duty.
- Schedule B10: Customs duties on originating goods shall be removed in **eleven** equal annual stages and thereafter be free of any customs duty.

# **EVFTA** | Rule of Origin for Pharmaceuticals

Products must be wholly obtained or undergo sufficient working or processing in Vietnam or EU members to acquire origin status and preferential tariff

Listed rule of origin under the EVFTA

Heading (1)	Description of the good (2)	Required Working or Processing (3)		
ex Chapter 30	Pharmaceutical products	Manufacture from materials of any heading.		
	Medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured	Manufacture from materials of any heading, except that of the product; or		
3004	doses (including those in the form of transderma administration systems) or in forms or in forms o packing for retail sale.	manufacture in which the value of all the materials used does not exceed 70 % of the ex-works price of the product.		

Exporters must possess a proof of origin, which shall be valid for <u>12 months</u> from the date of issuance in the exporting country, and shall be submitted to the customs authorities of the importing country within that period

# **EVFTA** | Rule of Origin for Medical Devices

Products must be wholly obtained or undergo sufficient working or processing in Vietnam or EU members to acquire origin status and preferential tariff

Listed rule of origin under the EVFTA

Heading (1)	Description of the good (2)	Required Working or Processing (3)
ex Chapter 90	Optical, photographic, cinematographic, measuring, checking, precision, medical or surgical instruments and apparatus	Manufacture from materials of any heading, except that of the product; or
Chapter 94	Furniture; bedding, mattresses, mattress supports, cushions and similar stuffed furnishings []	manufacture in which the value of all the materials used does not exceed 70% of the ex-works price of the product

Exporters must possess a proof of origin, which shall be valid for <u>12 months</u> from the date of issuance in the exporting country, and shall be submitted to the customs authorities of the importing country within that period

# **EVFTA** | Emerging Opportunities from Non-Tariff Barriers



## Intellectual Property Rights (IPR)

Intellectual Property Rights will be intensified, which make difficulties for patent-protected pharmaceuticals to become generic drugs, and thus have their prices reduced.

The opportunity is available for all foreign investors, not limits to EU-based ones.



# Direct pharmaceuticals imports

EU-based investors are allowed to establish a company to import pharmaceutical products that have been authorized to be in Vietnam to local distributors wholesalers. or They will be also permitted to build warehouses to preserve imported drugs, carry out clinical research and trials, and information about introduce imported drugs to healthcare staff in line with local rules.



## Simplified procedures

Vietnam will align with international standards on both pharmaceutical products and medical devices, which means products already certified in the EU will not require additional testing and certification in Vietnam, thus reducing costs and time to market.



Bidding

Vietnam commits to open pharmaceutical-related bidding packages in a number of central and local state agencies.

- Vietnam Social Insurance
- Ministry of Health
- Hanoi and HCMC Department of Health
- 33 hospitals

The EVFTA specifies minimum values of bidding packages for each agencies, which are gradually reduced within 16 years.



# **Market Entry Strategies**

Invest in Vietnam as form of representative office for promotion, marketing and brand awareness

- Invest to Vietnam as form of trading company and enjoy preferential tariff under the EVFTA or other FTAs
  - 3 Operate a manufacturing company in Vietnam
- Provide healthcare services in Vietnam

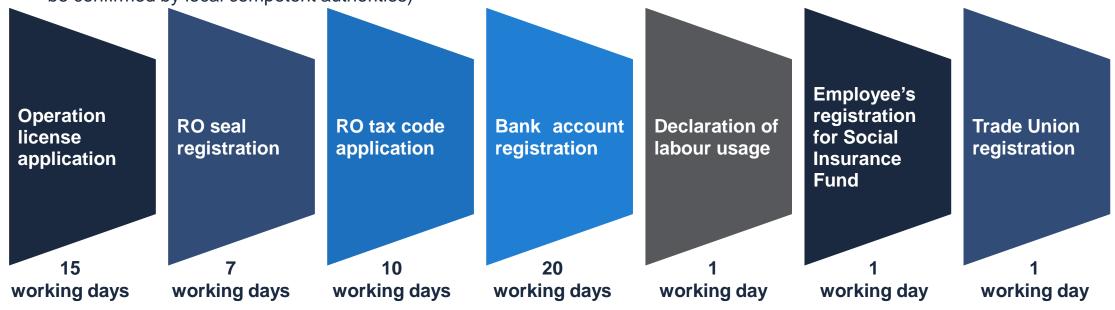
Participate bidding for medical devices in public health establishments

# **Strategy 1** | Establish a Representative Office in Vietnam

The purpose is having a non-separate legal entity for market research and promotion purposes, acting in liaison on behalf of the parent company. Commitment to the market is really appreciated by local entrepreneurs, and RO is a low-cost solution which can be preliminary to more relevant investment

- Cannot conduct revenue-generating activities
- Parent company bears liability

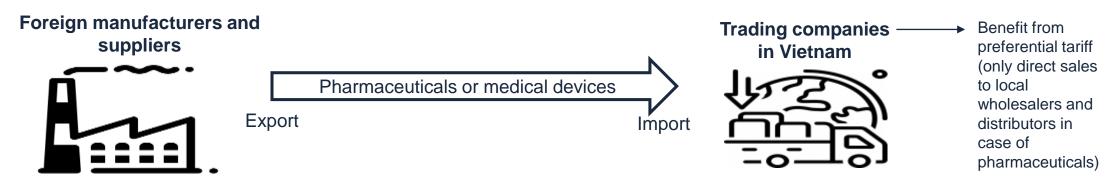
• RO is <u>not allowed to conduct direct advertising and marketing for pharmaceutical products</u>. Only allowed to provide information about drugs to doctors and sales representatives of licensed pharmaceutical distributors (information about the products must be confirmed by local competent authorities)



# **Strategy 2** | Establish a trading company in Vietnam



For the purpose of enjoying preferential tariffs under EVFTA or the benefits from other FTAs, investors can register a local trading company and obtain the relevant import license instead of relying on a local importer.



Step 1: Establish a trading company in Vietnam

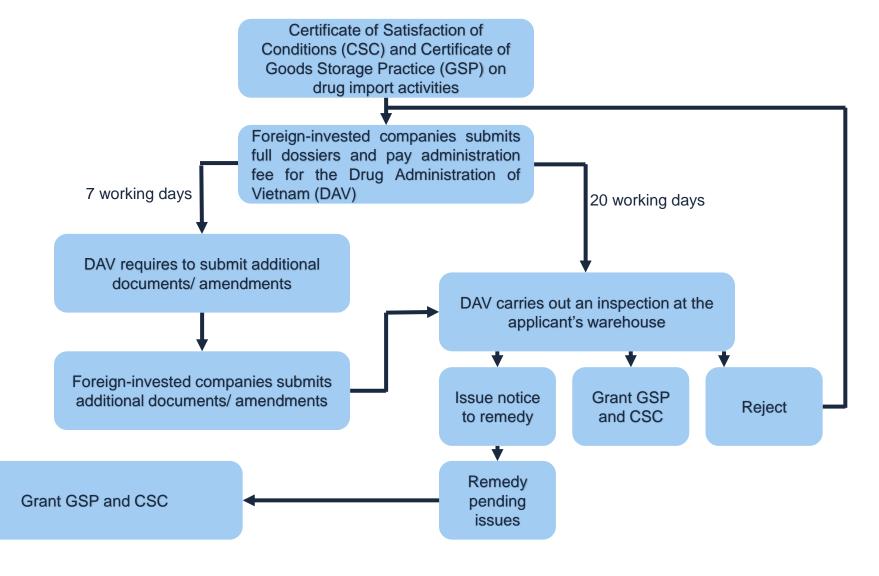
**Step 2:** Obtain import license, along with other certificates

# **Strategy 2** | Application for drug importation in Vietnam

#### Note:

The timeline and procedures in the chart were based on provisions of the law.

In practice, the timeline may extend longer.



Product registration at the DAV if imported products have not been certified for sales in Vietnam.

(60 – 90 days)

# **Strategy 2** Application for medical devices importation in Vietnam

### **Step 1. Classification of medical devices**

- Application shall be lodged to Ministry of Health
- MoH issues a Certification of Eligibility Declaration and post it on its website in 3 working days
- Implemented to obtain the medical device classification certificate

## **Step 2. Registration of medical devices**

- If Group A devices: declaration of applied standards to the local Dept. of Health, which will be certified if satisfactory and published on the MoH web portal within 3 working days
- If Group B, C or D devices: application for the registration number to MoH and if satisfactory:
- 1. If no applicable National technical regulation: MoH conducts inspection within 60 days
- 2. If applicable National technical regulation: MoH conducts inspection within 15 days

## **Step 3. Import license**

- After receiving the application, MoH shall issue the applicant with the certification of declaration;
- If the application is not required to be amended, the Ministry of Health shall conduct inspection serving the issuance of the license for importing medical devices within 15 working days
- If the application is unsatisfactory, within 5 working days from the date written on the certification of declaration, the Ministry of Health shall send a written response to the applicant for completion



# **Strategy 3** | Manufacture in Vietnam



#### **Pharmaceuticals**

Foreign-invested enterprises registered in Vietnam can manufacture pharmaceutical products but are prohibited from distributing drugs in Vietnam.

Pharmaceutical companies with foreign ownership over 49% cannot distribute drugs, and they are only permitted to do conduct wholesale and retail activities with non-pharmaceutical supplements in the form of tablets, capsules and powder.

#### Entry strategies:

- M&A
- JV with local partner

More and more foreign pharmaceutical companies are cooperating with local manufacturers to take advantage of cheap production costs and distribution systems



#### **Medical Devices**

Foreign-invested enterprises registered in Vietnam and possessing an import license can manufacture and distribute medical devices.

No restriction on foreign ownership.

#### Entry strategies:

- WFOE
- M&A
- JV with local partner

Typically, foreign manufacturers choose to sell through local distributors since they offer immediate access to the customer network and knowledge. Still, investors can choose to invest in local manufacturing facilities to leverage low labor costs and exploit tax incentives

# **Strategy 3** | Manufacture in Vietnam

# M&A

- (+) Less time-consuming
- (+) Local partner has better ability to form connections with distributors
- (+) Eliminate some of barriers faced with brand awareness due to the restrictions on advertising pharmaceuticals in Vietnam

(-) Cannot fully control decisionmaking









# Strategy 4 | Provide healthcare services in Vietnam



#### Restrictions



No restriction on foreign ownership.



- WFOE
- M&A
- JV with local partner



## Requirements

Minimum investment capital\*:

- US\$20 million for a hospital;
- US\$2 million for a polyclinic unit;
- US\$200,000 for a specialty unit.

\*: restrictions do not apply for ASEAN investors

Obtain operation license from MoH → must satisfy certain conditions on equipment and personnel

# Strategy 5 | Bidding

## Minimum value of bidding package

# Central State Agencies

- 16 departments of Vietnam Social Insurance
- 20 departments of the Ministry of Health

2020-2024 2025-2029 2030-2034 2035 onwards

US\$2 US\$1.33 US\$665,2

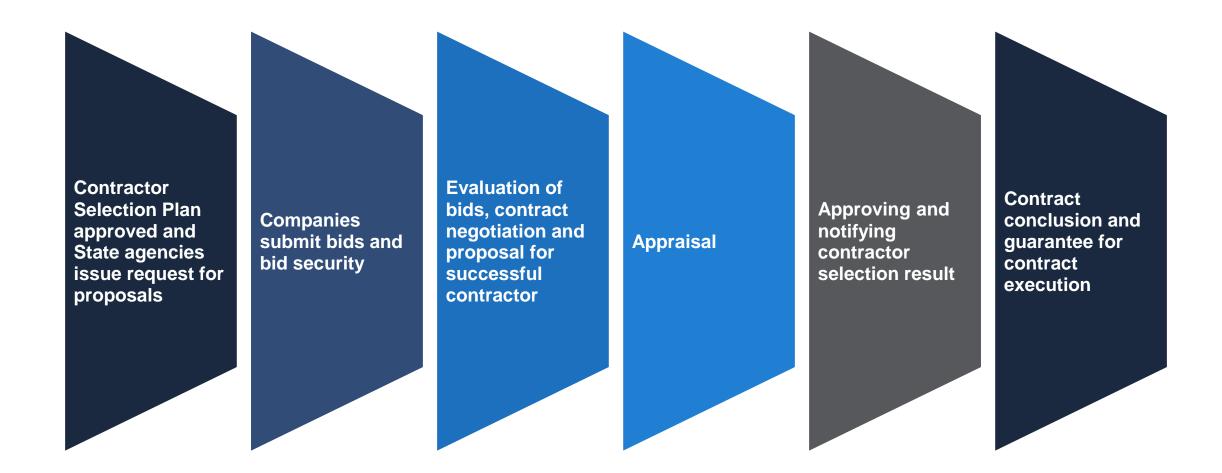
US\$665,200 US\$173,900

# Local State Agencies

- Hanoi & HCMC Health Department
- 33 hospitals

US\$4 US\$2.67 US\$2 US\$1.33 million million million

# **Strategy 5** | Bidding process





Vietnam regulatory updates @ www.vietnam-briefing.com



#### Scan this QR code

Visit our mobile page and get the latest updates investors news and resources with us

Contact Filippo Bortoletti at: filippo.bortoletti@dezshira.com www.dezshira.com