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Pharmaceuticals in EVFTA: How foreign investors can qualify for the preferential tariffs

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Part 1
Vietnam’s Pharmaceutical Industry Overview

Industry Overview

180 drug producers

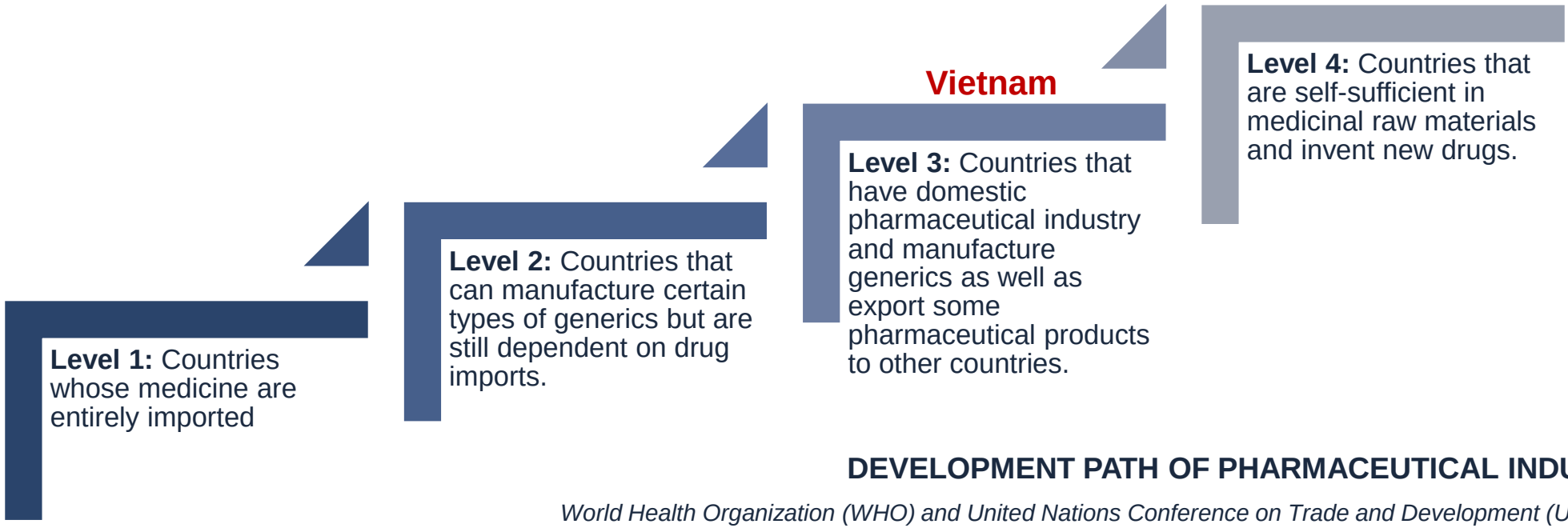
224 GMP-standard domestic pharmaceutical factories

employed

44,000 people

accounted for

2.2% of GDP



DEVELOPMENT PATH OF PHARMACEUTICAL INDUSTRY

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

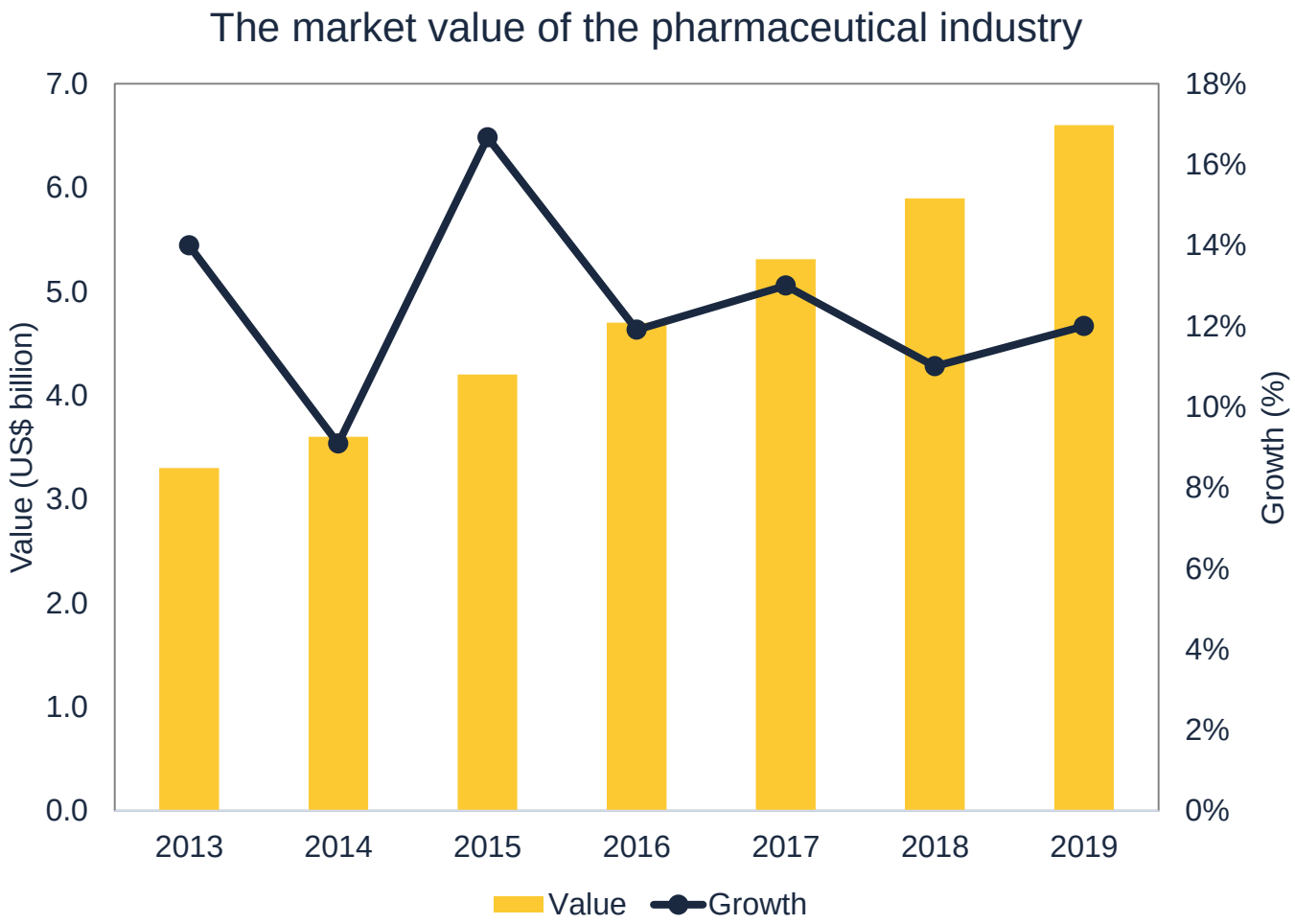
Industry Overview

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

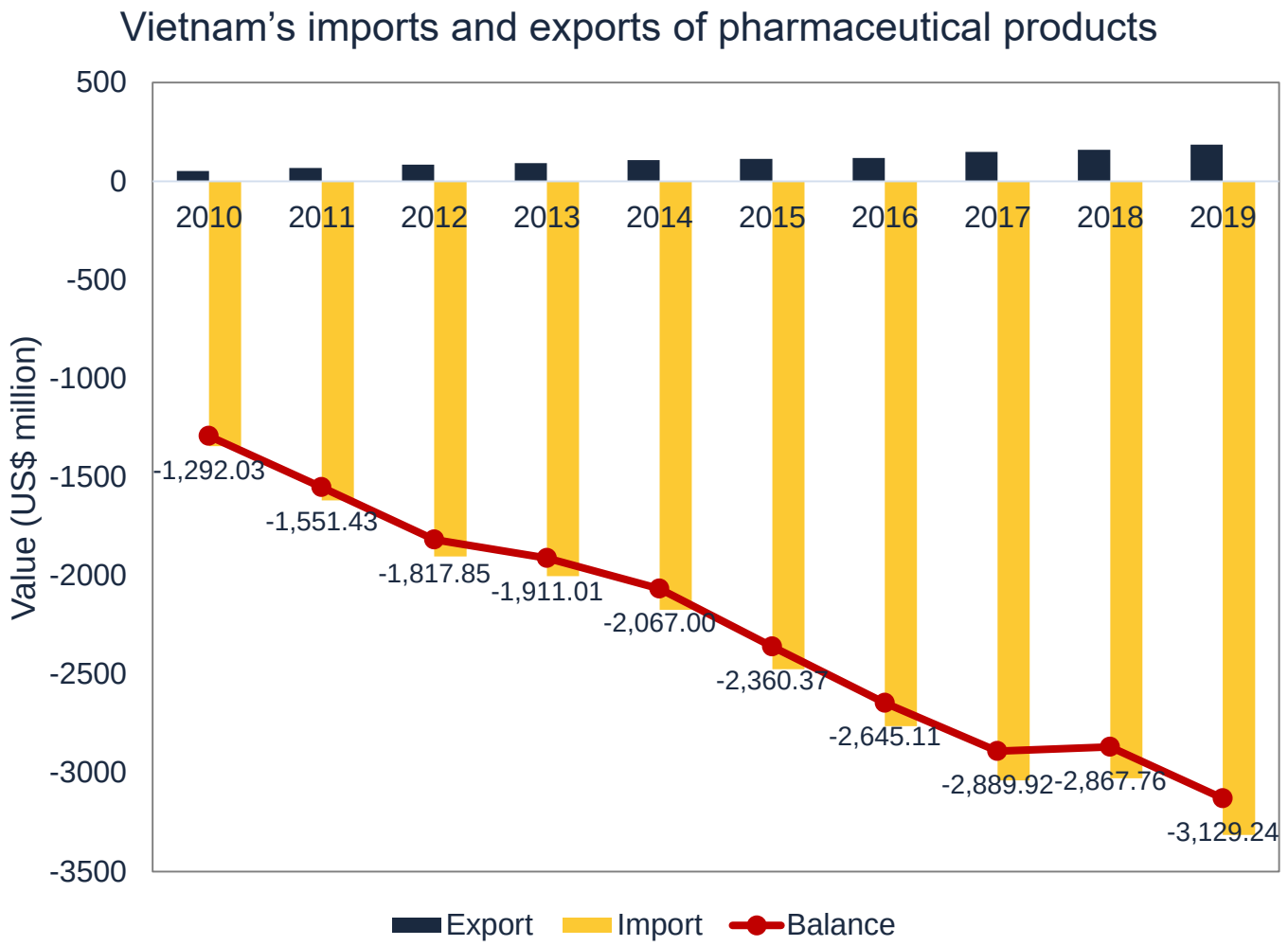
Despite higher growth rate of exports, Vietnam remains a net importer of pharmaceutical products

13.59% CAGR of exports

9.45% CAGR of imports

9.25% CAGR of trade deficits

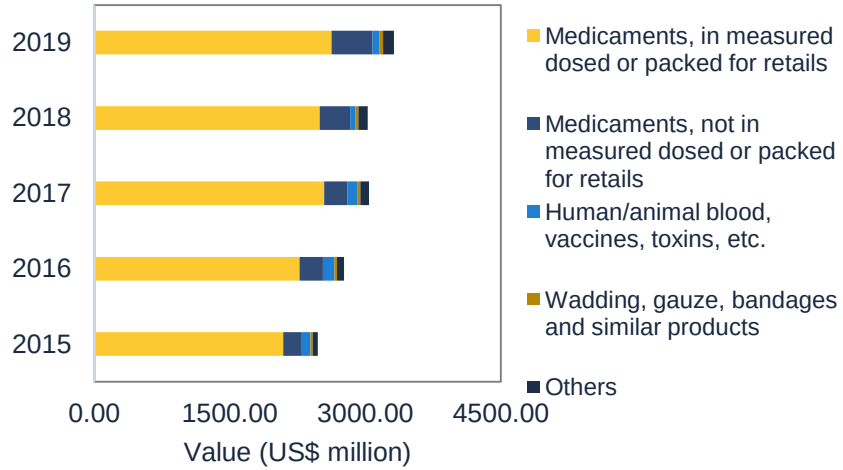
Over a decade from 2010 to 2019



Source: UN Comtrade

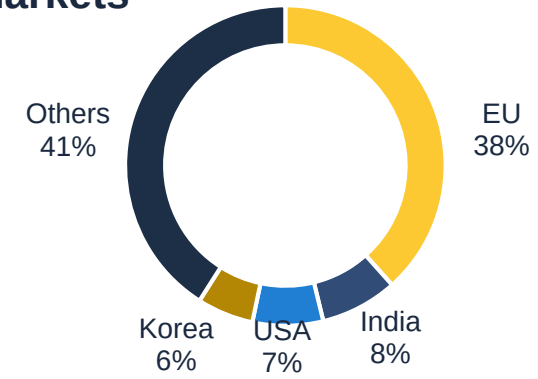
Import - Export

by products



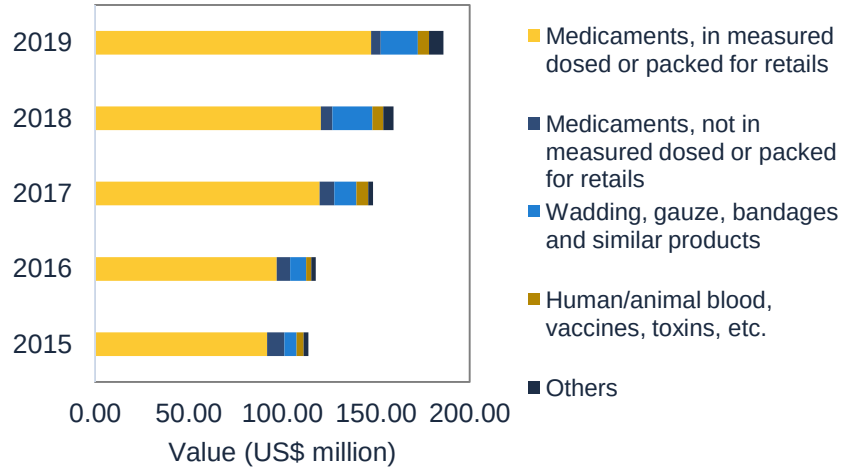
IMPORT

by markets



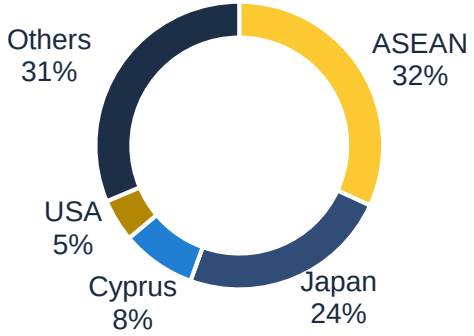
Source: Custom Office

by products

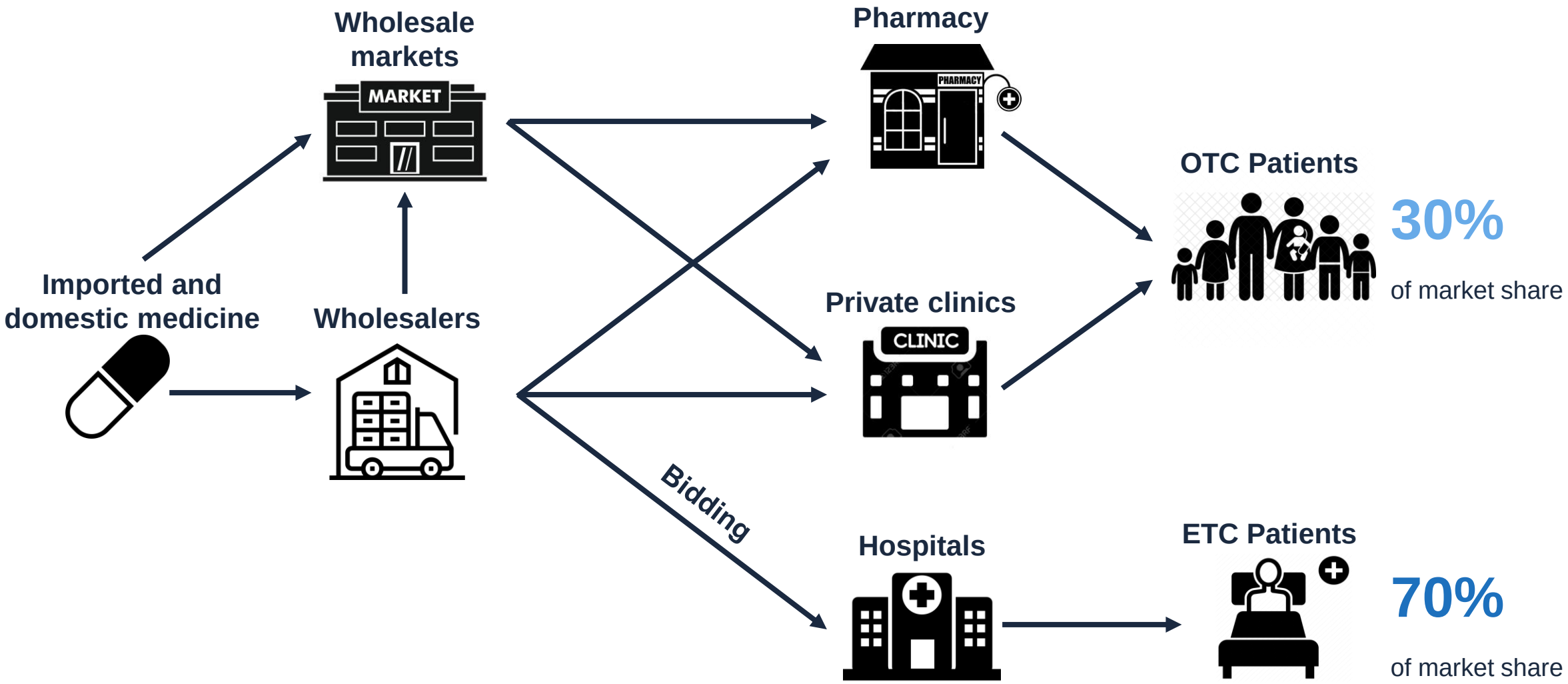


EXPORT

by markets

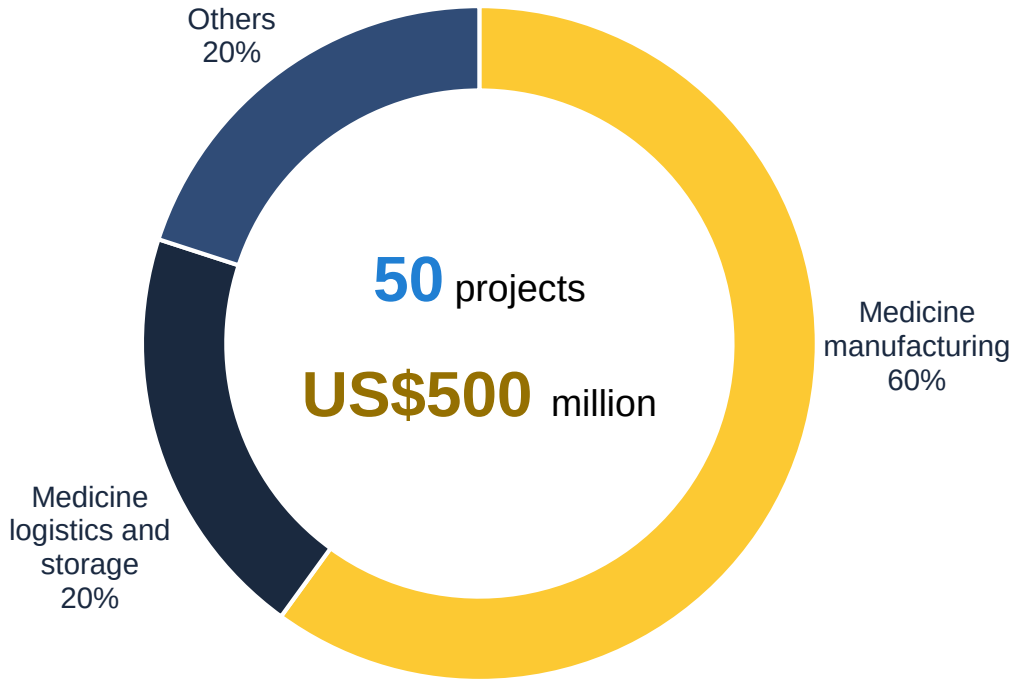


Domestic Supply Chain



Foreign Direct Investment (FDI)

FDI in Pharmaceutical Industry



Source: KPMG

M&As of pharmaceutical manufacturing group 2016 - 2019

Acquired business	Target acquisition	Plan	Time
Taisho Pharmaceutical	Hau Giang Pharmacy	Increase expected ownership rate 56.69%	April 2019
Stada Service Holding B.V.	Pymepharco (PME)	Proportion of ownership 62%	December 2018
Abbott Laboratories (Chile) Holdco SpA	Domesco	Proportion of ownership 51%	December 2017
Adamed Group	Dat Vi Phu Pharmacy	Proportion of ownership 70%	November 2017
Abbott Group	Glomed Pharmacy	Repurchase	August 2016

Source: VIRAC

Part 2
Emerging Opportunities and Remaining Barriers under 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.*

Originating goods

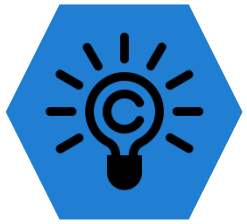
Products must be wholly obtained or undergo sufficient working or processing in Vietnam or EU members to acquire origin status and preferential tariff

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.
3004	Medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or in forms of packing for retail sale.	Manufacture from materials of any heading, except that of the product; or 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 12 months from the date of issuance in the exporting country, and shall be submitted to the customs authorities of the importing country within that period

Emerging Opportunities from Non-Tariff Barriers



Intellectual Property Rights (IPR)

Intellectual Property Rights for pharmaceuticals 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 sold in Vietnam to local distributors or wholesalers. They will be also permitted to build warehouses to preserve imported drugs, carry out clinical research and trials, and introduce information about imported drugs to healthcare staff in line with local rules.

Simplified procedures

Vietnam will align with international standards on pharmaceuticals, which means pharmaceutical 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.

Remaining Barriers

Distribution

Foreign-invested companies are prohibited from distributing drugs in Vietnam.

They are only permitted to do conduct wholesale and retail activities with non-pharmaceutical supplements in the form of tablets, capsules and powder.

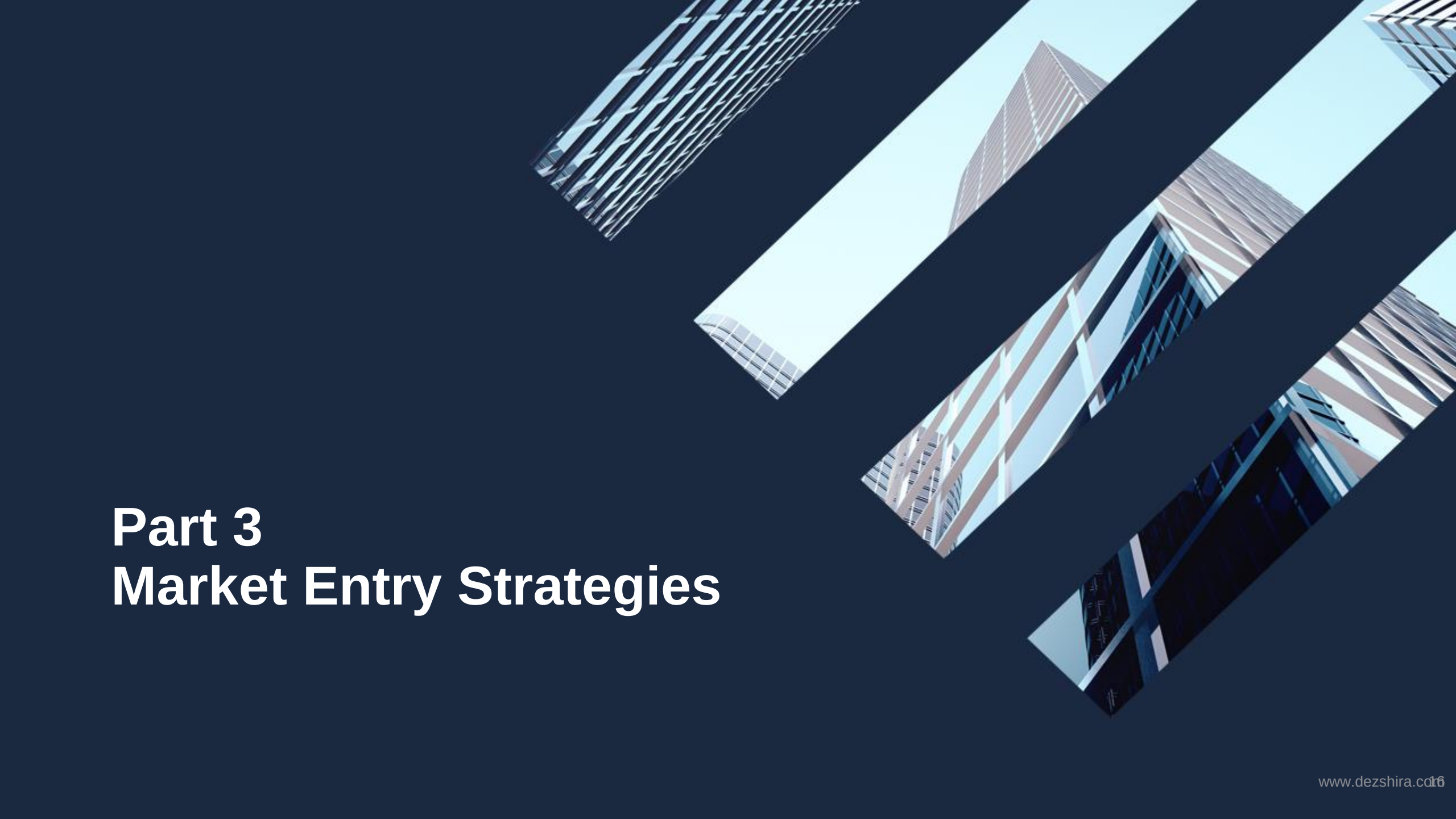
Marketing

For the promotion of drugs, it is prohibited to promote any drugs used for human treatment (such as giving free samples), except for promotion among drug traders/distributors. The promotion of drugs to end users or health professionals is strictly prohibited.

Only over-the-counter drugs granted Marketing Authorization numbers by the Ministry of Health can be advertised to the public.

Prescription drugs are prohibited from advertising but can be introduced to healthcare professionals via drug introducers, drug information materials for healthcare professionals, and drug introduction seminars.

Member of Pharma Group (EuroCham Vietnam) are required to adhere to the association's Code of Pharmaceutical Marketing Practices, which includes provisions related to the marketing of drugs in Vietnam.



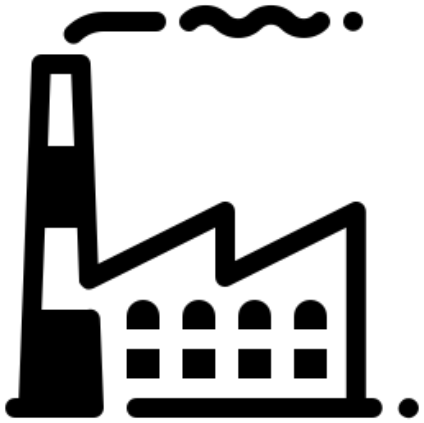
Part 3
Market Entry Strategies

Market Entry Strategies

1. Invest to Vietnam as form of drug importer and enjoy preferential tariff under the EVFTA
2. Operate a manufacturing company in Vietnam through M&A
3. Participate in pharmaceutical-related bidding packages of certain central and local state agencies

Strategy 1 | To enjoy preferential tariff

EU-based pharmaceutical manufacturers and suppliers



Pharmaceutical products

Export

Import

Trading companies in Vietnam

Beneficial from preferential tariff and direct sales to local wholesalers and distributors

Step 1: Establish a trading company in Vietnam and obtain import license, along with other certificates

Step 2: Obtain proof of origin for EU pharmaceutical products and export to Vietnam

Strategy 1 | Establish a trading company in Vietnam

To be obtained at the Departments of Planning and Investment

(normally in 1 month).

In general, the Department of Planning and Investment will issue the business registration certificate in 1 week.

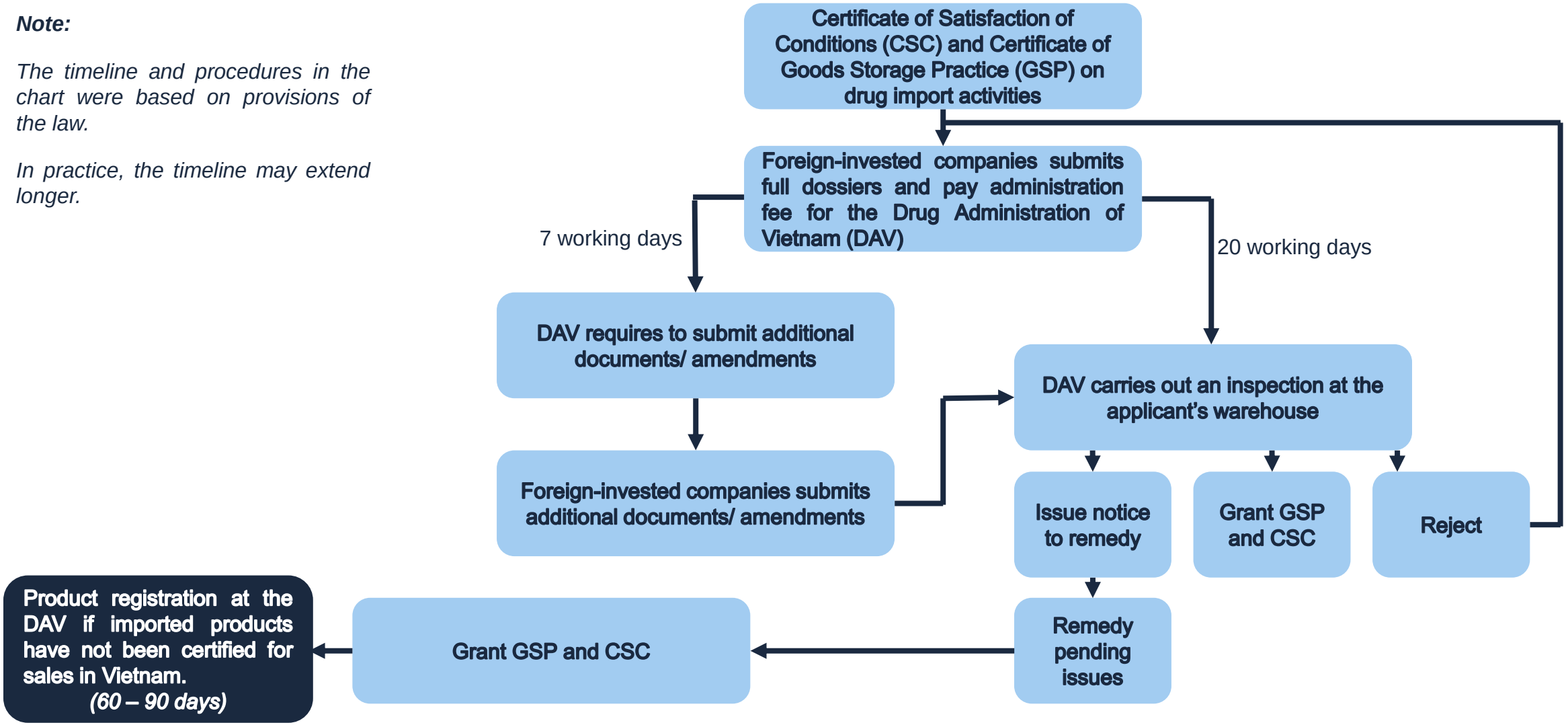
Upon granted the certificate, initial capital contribution must be made within *90 days.*

Strategy 1 | 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.



Strategy 1 | Exports from EU to Vietnam

EU exporters shall use only **the Registered Exporter system (the REX system)** as proof of origin under the EVFTA for shipments with total value exceeding EUR 6,000

Definition

The REX system simplifies export formalities by allowing the registered exporter to certify the preferential origin himself by including a specific declaration (so-called statements on origin) on the invoice or another commercial document identifying the exported products. Thus, the registered exporter does not need to apply upon each export for issue of a certificate of origin.

Procedure

Applicants need to provide the following information:

- Exporters' name, full address, country, Economic Operator Registration Number and Trader Identification Number
- Contact information
- Main activity (producing/ trading)
- Description of goods
- Signature of the exporter, for the undertakings and for the consent of publication of the data

Strategy 2 | Manufacture in Vietnam

M&A

(+) Less time-consuming

(+) Local partner has better ability to form connections with pharmaceutical distributors

(+) Eliminate some of barriers faced with brand awareness due to the restrictions on advertising in Vietnam

(-) Cannot fully control decision-making

STADA

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ADAMED GROUP

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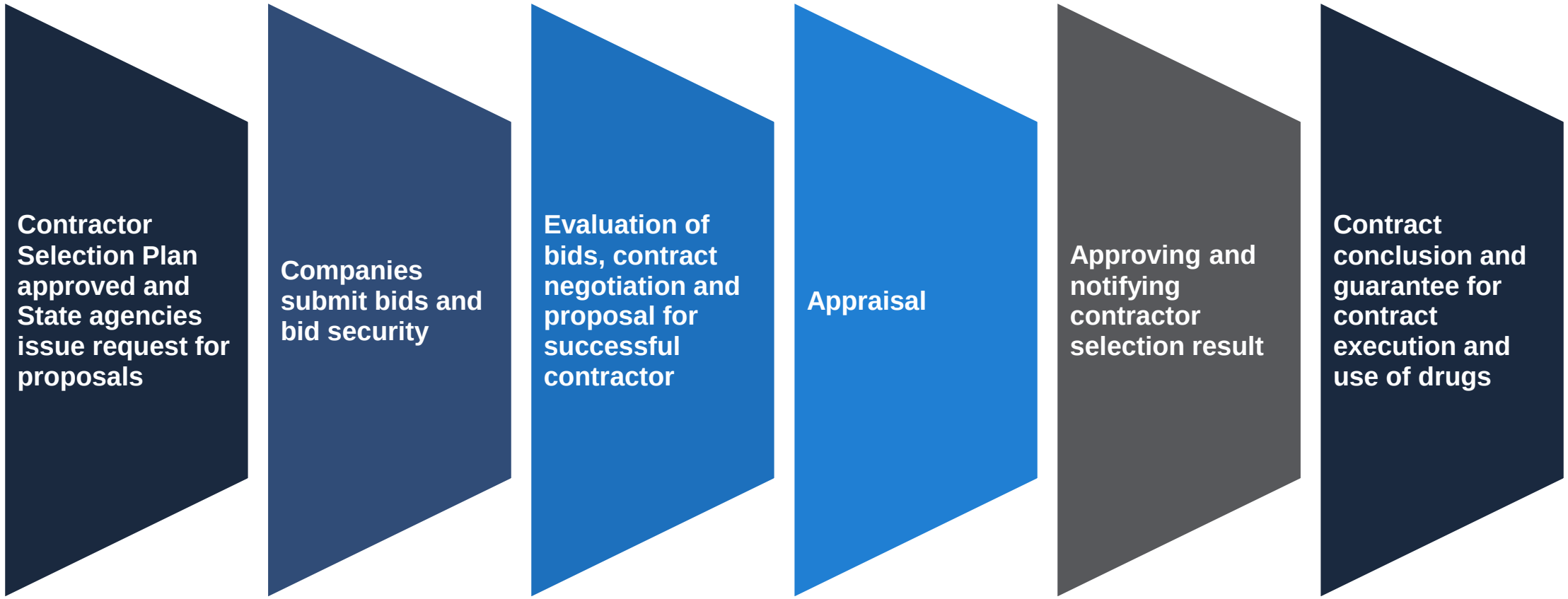
Strategy 3 | Bidding

Minimum value of bidding package

	2020-2024	2025-2029	2030-2034	2035 onwards
Central State Agencies • 16 departments of Vietnam Social Insurance • 20 departments of the Ministry of Health	**US$2 million**	**US$1.33 million**	**US$665,200**	**US$173,900**
Local State Agencies • Hanoi & HCMC Health Department • 33 hospitals	**US$4 million**	**US$2.67 million**	**US$2 million**	**US$1.33 million**

Strategy 3 | Bidding process for supply of medicines for public health facilities



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