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# ĐỀ XUẤT ĐỐI VỚI NHẬP KHẨU DƯỢC PHẨM CỦA DOANH NGHIỆP VIỆT NAM TỪ LIÊN MINH CHÂU ÂU TRONG BỐI CẢNH THỰC THI EVFTA

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# Tóm tắt

Thị trường dược phẩm Việt Nam được nhận định là một khu vực tiềm năng. Mức độ sẵn sàng chi trả cho các dịch vụ y tế có xu hướng tăng lên do thu nhập bình quân đầu người cao hơn, trong khi môi trường sống đang có nguy cơ ô nhiễm cao làm gia tăng nhiều loại bệnh tật... là yếu tố chính dẫn đến sự phát triển của ngành dược. Do đó thị trường Việt Nam đang thu hút các doanh nghiệp dược phẩm ở nhiều quốc gia từ khối Liên minh châu Âu (EU). Kể từ khi Hiệp định Thương mại tự do Liên minh châu Âu-Việt Nam (EVFTA) có hiệu lực vào năm 2020, con đường nhập khẩu dược phẩm từ thị trường Liên minh châu Âu càng mở rộng. Vì vậy, nhóm nghiên cứu mong muốn tìm hiểu về EVFTA trong nhập khẩu dược phẩm từ các nước trong Liên minh châu Âu nhằm mục tiêu: Thứ nhất, tìm hiểu chung về các nội dung chính của hiệp định EVFTA cũng như cam kết đến từ hai phía. Thứ hai, phân tích về thực trạng, cơ hội và thách thức mà EVFTA đem lại cho thị trường nhập khẩu dược phẩm của Việt Nam. Thứ ba, đề xuất phương hướng cho doanh nghiệp Việt Nam trong bối cảnh thực thi hiệp định EVFTA.

**Từ khóa:** Hiệp định Thương mại tự do Liên minh châu Âu-Việt Nam (EVFTA), được phẩm, nhập khẩu, Việt Nam.

# RECOMMENDATIONS FOR PHARMACEUTICAL IMPORTS OF VIETNAMESE ENTERPRISES FROM THE EU IN THE CONTEXT OF EVFTA IMPLEMENTATION

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# Abstract

Vietnam's pharmaceutical market is considered a potential area. Consequently, the Vietnamese market is attractive to large pharmaceutical corporations and enterprises from many countries, including the European Union (EU). Since the EU-Vietnam Free Trade Agreement (EVFTA) officially took effect in 2020, the path to import pharmaceuticals from the EU market area is even wider. This research has been done for three main reasons. Firstly, to study the main contents of the EVFTA as well as commitments from both sides. Secondly, to analyze the condition, opportunities and challenges that EVFTA brings to Vietnam's pharmaceutical import market. Lastly, to show recommendations for Vietnamese enterprises in the context of EVFTA implementation.

#### Keywords: EU-Vietnam Free Trade Agreement (EVFTA), pharmaceutical, imports, Vietnam.

### 1. Introduction

The EU-Vietnam Free Trade Agreement (EVFTA) is a new generation Free Trade Agreement between Vietnam and 27 European Union member states (Nhan dan News, 2019). It is a comprehensive and high-quality agreement which ensures balanced benefits for both Vietnam and the EU, with consideration for the differences in development levels between the two sides. The EVFTA is projected to give Vietnam's exports a big boost, benefiting by diversifying markets and exports, especially agricultural and aquatic products, as well as Vietnamese products with competitive advantages.

Pharmaceutical import expenses from the EU into Vietnam's market have continuously increased in recent years. With more than 97 million people, the level of payment for healthcare is increasing, the Vietnamese market is attractive to large pharmaceutical corporations and enterprises from many countries, including the European Union (EU). Since the EU-Vietnam Free Trade Agreement (EVFTA) came into effect, more and more Vietnamese enterprises have taken advantage of the Priority from the EVFTA. The appearance of the EVFTA also made it easier to import pharmaceutical products from the EU with less cost.

Since EVFTA was signed on June 30, 2019, a great number of researchers have expressed concern about the potential of EVFTA for EU pharmaceutical enterprises. The research of Do (2020) has pointed out the potential of EVFTA, the emerging opportunity for the EU importers, and the challenges for the Vietnam domestic pharmaceutical corporation. The result of Vu's research (2016) showed that the EVFTA will have enormous impacts on Vietnam's pharmaceutical imports from the EU. Generally, these researchers proved that the EVFTA will deeply affect Vietnam pharmaceutical imports. Researches in Vietnam had been made to assess the potential of EVFTA in Vietnam's pharmaceuticals import from the EU.

The EVFTA will bring huge benefits for EU importers and multinational pharmaceutical corporations thanks to non-tariff barriers. Nevertheless, the EVFTA will make domestic

pharmaceutical enterprises hard to compete with other multinational pharmaceutical corporations. Therefore, this research had been conducted with an aim to propose some recommendations for Vietnam's pharmaceutical enterprises in the context of EVFTA implementation to optimize the opportunities and overcome the challenges.

# 2. Overview of EVFTA

#### 2.1. The main contents of EVFTA

The EVFTA is a win-win trade agreement that benefits both Vietnam and the EU equally and complies with World Trade Organization (WTO) rules (Nhan dan News, 2019). The agreement consists of 17 chapters, two protocols, and several attached memorandums, with the following main contents:

*Trade in goods:* The elimination of tariff barriers will be at the highest level, which will benefit exports of both sides. Other contents related to trade in goods: Vietnam and the EU also agreed on contents related to customs procedures, Sanitary and Phytosanitary (SPS), technical barriers to trade (TBT), trade remedies, etc., creating a legal framework for the two sides to cooperate, creating favorable conditions for export and import of enterprises.

Services, Investment liberalisation and E-commerce: The goal of Vietnam and the EU's commitment on investment services trade is to create an open and advantageous investment environment for both sides' firms. In e-commerce, in order to promote the development of this field between Vietnam and the EU, the two sides commit not to impose import tax on electronic transactions. The two sides also committed to cooperate through maintaining dialogue on management issues raised in e-commerce. Both sides will also work together to share information on domestic legal restrictions and enforcement difficulties.

*Government procurement:* Vietnam and the EU have agreed on contents equivalent to the Government Procurement Agreement (GPA) of the WTO. With some obligations such as online bidding, setting up an electronic portal to publish bidding information, etc., Vietnam has a roadmap for implementation. The EU is also committed to providing technical assistance to Vietnam to fulfill these obligations.

Intellectual property rights: Commitments of both sides on intellectual property include commitments on copyrights, inventions, patents, commitments related to pharmaceuticals and geographical indications, etc.

Beside the main contents, the EVFTA also covers other aspects including rules of origin, customs and trade facilitation, sanitary and phytosanitary measures, technical barriers to trade, sustainable development, cooperation and capacity building, and legal-institutional issues.

3. The commitments of Vietnam and EU to EVFTA

# 3.1. Reduction of tariffs

#### Trade in goods

When products with origins in the other party are imported into each other's territory, both Vietnam and the EU use a shared tariff schedule. Import tariff reductions under the EVFTA are separated into four categories: eliminating import tariffs immediately, eliminating import tariffs under the specific schedule, applying tariff rate quota (TRQ), and uncommitted goods. According to the agreement, the EU would remove import tariffs on 85.6% of tariff lines, approximately 70.3% of Vietnam's exports to the EU, as soon as the agreement takes effect. The EU will then cut import taxes on 99.2 percent of tariff lines, or 99.7% of our exports, after seven years. The EU offers TRQ for the remaining 0.3 percent of Vietnam's exports, with zero import tariffs. As a result, 100% of Vietnam's exports to the EU will be removed within a short period. So far, among signed FTAs, this is the greatest level of commitment a partner has given us. This perk is especially significant given that the EU has long been one of our two major export markets. Vietnam committed to remove import taxes on 48.5 percent of tariff lines, equivalent to 64.5 percent of EU exports. After that, Vietnam would abolish import taxes on 91.8% of tariff lines, representing 97.1% of EU exports, after seven years. After 10 years, the corresponding elimination rate is 98.3% of EU tariff lines and 99.8% of EU exports.

Following the implementation of the agreement, about 71% of pharmaceutical items from the EU will bear no import duty. The remaining 29% will be excluded from import tariffs after a five-to seven-year period. Vietnam also implements the TRQ in accordance with WTO commitment or the schedule of reducing import duties in more than 10 years to 1.7 % of the remaining EU tariff lines.

#### Tariffs quotas

A small number of goods originating from the opposite Party are susceptible to TRQ in addition to import taxes. Part B – Tariff Rate Quotas, Annex 2-A of the EVFTA specifies the content of this commitment, which includes the fundamental principles, detailed commitments for each item, as well as the related regulations and conditions for the grant of a TRQ. The Tariff Quotas shall be managed by the EU in accordance with EU legislation, with the goal of promoting trade among the Parties and maximizing the TRQ. Vietnam continues to apply tariff quotas in line with its WTO commitments regarding the quantity of quotas, the mode of administration, and other terms and conditions relating to tariff quota allocation. Within 11 years of the EVFTA's coming into effect, the TRQ for goods imported from the EU will be gradually eliminated. *Non-tariffs barrier* 

The two parties agree to improve the application of the WTO's TBT rules, in which Vietnam commits to enhancing the use of international standards in issuing TBT regulation. The Agreement uses a separate Annex on non-tariff barriers to the automotive sector, in which Vietnam agrees to recognize all technical conformity certification for EU automobiles issued in accordance with the principles of the 1958 UNECE Agreement five years after the EVFTA takes effect. Vietnam also agrees to accept the label "Made in EU" for non-agricultural products, with the exception of pharmaceuticals, while continuing to accept specific labels of origin from EU countries. Furthermore, Vietnam and the EU have agreed on a number of SPS's principles to promote trade in animal and plant items. The Agreement also includes commitments towards reducing: commitments on export/import licensing, customs procedures, etc.

### Appendix on pharmaceutical

A separate Annex on pharmaceuticals is included in the agreement, with EU export goods accounting for 9% of total imports from the EU and Vietnam. The two parties willingly take a series of steps to make pharmaceutical trade between the EU and Vietnam more efficient. Foreign-invested businesses will be allowed to import medicines but will not be allowed to participate in wholesale or retail sales, and will only be allowed to resell Vietnam's pharmaceutical products to certified distributors. Vietnam allow EU contractors to participate in pharmaceutical bidding packages, with some separate reservations.

#### 3.2. Services, Investment liberalisation and E-commerce

Vietnam and EU's commitments on trade in services and investment with an attempt to develop an open and favorable investment environment for firms of both sides. In service sectors, Vietnam's commitment goes further than that of the WTO. The EU's commitment is higher than the WTO's and is comparable to the EU's most recent agreements' highest level of commitment. Professional services, financial services, telecommunications services, transportation services, distribution services, and other industries are among those in which Vietnam has committed to assisting EU investment. A new Vietnam-EU e-commerce trading platform has been established to increase trading between small and medium-sized businesses, as well as home businesses, while also taking use of the EVFTA's potential. Vietnam has also made a number of commitments in terms of recycling.

#### 3.3. General obligations in Trade in Services and Investment Market access

Unless the Schedule of Specific Commitments specifies otherwise, both Parties agree not to impose restrictions on: the number of enterprises allowed to participate in the market, the value of transactions, the number of operations, the participation of foreign capital, the types of legal entity, and the number of natural persons employed.

#### National treatment

According to the Schedule of Specific Commitments, both Parties commit to accord to services, service suppliers and investors of the other Party treatment no less favourable than that accorded to its like services, service suppliers and investors, unless prescribed otherwise in the Schedule. Both Parties agree to treat enterprises of a Party's investors operating on the territory of the other Party in the same way as enterprises of their own investors are treated, with the exceptions specified in the Schedule and other specific exceptions.

# Most-favoured nation

Both Sides agree to handle the investments of licensed investors from the other Party in the same way as investments from third-country investors are treated. Communication, recreational, cultural, and sports services, air transport and commercial aviation rights, fisheries and aquaculture, forestry and hunting, and oil and gas mining are excluded from these requirements. *Performance requirements* 

As listed in the Schedule of Specific Commitments, both Parties agree not to impose or enforce performance requirements such as: regulation on a given level or percentage of goods or services exported, regulation on a given level or percentage of domestic content, binding the volume or value of imports to the volume or value of exports or to the amount of foreign exchange inflows associated, etc.

#### 3.4. Government procurement

In the EVFTA, the principle of government procurement (public tendering) is the same as in the WTO GPA. The EU-Vietnam Government Procurement Agreement focuses on improving the transparency and effectiveness of government procurement while also maintaining the efficiency of government spending. Vietnam's responsibility is to handle online bidding by creating a site where bidding information may be posted. In exchange, the EU offers to give technical support to Vietnam in order for it to meet its responsibilities. Vietnam also reserves the right to set aside a percentage of the value of bidding packages for domestic contractors, goods, services, and employees under certain conditions. As a result, the EVFTA's Government Procurement Chapter is divided into two sections: general rules and contractor selection procedures; and market access commitments in Government Procurement between Vietnam and the EU, which includes one annex on Vietnam's commitments to open the market to EU suppliers and another on EU commitments to open the market to Viet Nam suppliers.

According to the Government procurement chapter, European firms will be able to access the Vietnamese public procurement markets after 2 years of the EVFTA's implementation. This will reduce the share of public contracts reserved for local companies to 50%. The Ministry of Health

and the 34 public hospitals listed in the chapter will be able to centralize their purchases of pharmaceutical products due to this opening. Furthermore, this approach will save these businesses time and money, as well as provide a new window of opportunity for European companies.

#### Intellectual property rights

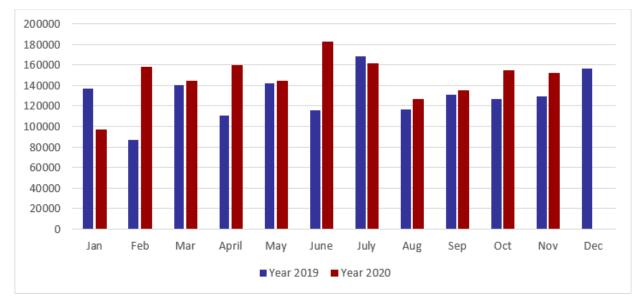
In general, Viet Nam's Intellectual Property commitments are in line with the country's present laws and regulations. Copyright, trademarks, patent rights linked to healthcare, geographical indications, and other intellectual property commitments are among them.

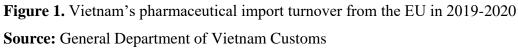
In the case of pharmaceuticals, foreign firms were prohibited from directly distributing medications on Vietnamese premises under Vietnamese legislation. To get access to the Vietnamese market, European firms were compelled to employ native enterprises, primarily through mergers and acquisitions. However, as part of the EVFTA, Vietnam has agreed to allow international pharmaceutical businesses, notably those from Europe, to open on its territory. As a result, these businesses will be allowed to import pharmaceutical items legitimately, store and sell them to local distributors and wholesalers. Vietnam also agrees to extend exclusive data protection for EU pharmaceutical items, and the patent protection period may be extended for no more than two years if the government delays the issue of pharmaceutical product licenses.

#### 4. EVFTA and Vietnam's pharmaceutical imports from the EU

#### 4.1. An overview of Vietnam's pharmaceutical imports from the EU before EVFTA

The EU, India, the United States, and South Korea are Vietnam's top pharmaceutical import markets, while the ASEAN area, Japan, Cyprus, and the United States are its top export markets. It's worth noting that most EU investors buy raw materials within the EU, transport them to Vietnam, and then manufacture or process the product before re-importing it. Due to the aging of medical equipment in public hospitals, Vietnam has implemented reduced tariffs and no restrictions for certain items under the EVFTA. The same may be said about pharmaceuticals. Customs taxes on pharmaceutical items varied from 0% to 14%. Most domestic companies lack research and development capabilities and do not meet the European Union Good Manufacturing Practice (EU-GMP) or Pharmaceutical Inspection Co-operation Scheme Good Manufacturing Practice (PIC/S-GMP) standards required to manufacture high-quality generic drugs, which is one of the reasons for Vietnam's reliance on imports. With many Chinese manufacturers closing owing to environmental concerns, the market is seeking for exporters from other nations. Vietnam imports more than 90% of its medication supplies from China. Currently, 70% of medicines are sold through hospitals in Vietnam, with the remaining 30% coming through pharmacies. Yet, it is crucial to highlight that recent domestic legislation has made it more difficult to enter the market. The major legislative framework controlling the pharmaceutical sector in Vietnam, including registration, sale, and distribution of medicines, is the 2016 Law on Pharmacy, which went into effect on January 1, 2017. In addition, the MOH has issued Circular No. 07/2018/TT-BYT, which states that medical representatives who give medication information to doctors and hospital managers can no longer be housed in Representative Offices. Many pharmaceutical companies have expressed concern that the Law raises questions about Representative Offices' rights and responsibilities, particularly whether such offices can provide drug information to health care providers directly or indirectly (through third parties) and employ representatives to do so.





The EU (EU27) continues to be Vietnam's largest pharmaceutical supplier in 2020. According to figure 1, pharmaceutical import turnover from the EU market reached 1.58 billion USD on May 11, 2020, up by 15.4% over the same period in 2019, and accounting for approximately 53% of Vietnam's total import turnover. However, the activity of importing goods from scratch within 2020 has been proven to be very challenging so far due to the Covid-19 epidemic. In the first eleven months of 2020, the import of these items has only decreased in January and July, while they increased for all of the remaining months. Vietnam's pharmaceutical imports from the EU in June saw the highest level of increase since the start of 2020, with 183.6 million USD (Figure 1). The major reason for the increase in EU pharmaceutical imports is to satisfy the requirements of individuals and medical facilities during the quarantine period. The Covid-19 outbreak is causing fear that pharmaceutical supply from Europe will continue to be affected.

# 4.2. An overview of Vietnam's pharmaceutical imports from the EU after EVFTA

Vietnam's pharmaceutical market remains attractive to EU investors. Over the past few years, EU27 has been the largest pharmaceutical supply market area in Vietnam. Pharmaceutical imports

from the EU have accounted for approximately 53% of the total import turnover of this commodity into Vietnam (Ministry of Industry and Trade 2021). From an overall perspective, according to the calculation from the General Department of Vietnam Customs, the total import turnover of pharmaceuticals from the EU market to Vietnam in the first 11 months of 2020 reached 1,583 billion USD and increased to 15.4% compared to the same period in 2019. Furthermore, within 4 months after the EVFTA officially took effect (from August 2020 to November 2020), 71% of EU pharmaceutical imports will be duty-free immediately with the rest exempted from duty from five to seven years, Vietnam's pharmaceutical import turnover from the EU rose to 19.1% over the same period last year (Table 1).

To be specific, according to table 1, in the first 11 months of the year 2020, Vietnam's pharmaceutical imports witnessed an increase in most EU market compared to the same period in 2019, with only 02 markets which were Denmark and Belgium declined to 42.5% and 1.8% respectively. From August 2020 to November 2020, there were also only 03 markets: Denmark, Austria, and Italy that saw a decrease of 71.9%, 6.6%, and 1.9% respectively over the same period last year. Meanwhile, France is still firmly in the top position of drug supply market in Vietnam with an import turnover far ahead of the following market. Accordingly, in the 4 months after the EVFTA took effect, the import turnover of pharmaceuticals from France attained the highest number (158.2 million USD) among the EU market. In the first 11 months of 2020, this figure reached 465.8 million USD, increased approximately 27% compared to the same period last year, and accounted for 29.4% of the total pharmaceutical import turnover of Vietnam from the EU market. Germany is the second largest pharmaceutical supply market with import turnover reaching 128.4 million USD after the EVFTA came into effect and reaching 356.7 million USD in 11 months of 2020. Germany witnessed a rise of 23.4% over the same period in 2019 and accounted for 22.5% of total pharmaceutical imports from the EU. In addition, there are also a few markets with import turnover increasing by more than 15% in the first 11 months of 2020 including: Ireland (19%), Sweden (27.3%), and the Netherlands (15.3%) (Table 1). 
**Table 1.** Vietnam's pharmaceutical imports from the EU market

Goods	August 2020 to November 2020	Compared to the same period in 2019	First eleven months in 2020	Compared to the same period in 2019	Proportion	
	Thousand USD	%	Thousand USD	%	%	
Total	562,759	19.1	1,583,327	15.4	100.0	
France	158,209	22.0	465,811	26.9	29.4	
Germany	128,480	27.8	356,691	23.4	22.5	
Italia	57,387	-1.9	170,358	9.7	10.8	
Belgium	50,041	31.7	134,801	-1.8	8.5	
Ireland	33,220	28.9	103,202	19.0	6.5	
Sweden	28,425	85.4	69,794	27.3	4.4	
Spanish	21,957	0.2	68,764	2.5	4.3	
Austria	23,144	-6.6	68,405	5.3	4.3	
Poland	23,892	26.2	49,340	0.7	3.1	
Netherlands	21,245	33.4	46,673	15.3	2.9	
Hungary	13,078	27.8	30,478	14.4	1.9	
Denmark	3,680	-71.9	19,010	-42.5	1.2	

Source: General Department of Vietnam Customs

It can be clearly seen from table 2 that pharmaceutical import turnover from the EU after the EVFTA officially took effect (last 5 months of the year 2020) reached 726 million USD and rose to 17.3% over the same period in 2019. However, compared to the last 5 months of 2020 and the whole of 2020, pharmaceutical import growth in the first quarter of 2021 had slowed down. Pharmaceutical import turnover from the EU market in the first quarter of 2021 reached 354 million USD which fell to 6.7% over the same quarter in 2020 (Table 2).

Goods	Last 5 months of 2020	Compared to the same period in 2019	2020	Compared to 2019	The first quarter of 2021	Compared to the same period in 2020
	Thousand USD	%	Thousand USD	%	Thousand USD	%
Pharma- ceuticals	726.600	17,3	1.747.167	15,1	354.065	-6,7

Table 2. Vietnam's pharmaceutical imports from the EU in the first quarter of 2021

# Source: General Department of Vietnam Customs

#### **Opportunities for Vietnam's pharmaceutical market**

The recent settlement of the EVFTA has stimulated a succession of opportunities aimed at evaluating the impact of trade openness and tariff reductions on the performance of domestic pharmaceutical enterprises and measuring the country's potential benefits in terms of pharmaceutical imports.

#### The expansion of pharmaceutical businesses on e-commerce platform

Thanks to the EVFTA, Vietnam can alter its regulatory framework for digital transformation so as to promote the development of electronic commerce between the EU and Vietnam. The EVFTA offers a secure foundation for such platforms by facilitating e-commerce between Vietnam and the EU. An e-commerce website to promote trade between Vietnam and the European Union will be established soon to enable corporation to exploit opportunities offered by the EVFTA. The site is part of a cooperation program of the Vietnam Institute of Digital Economy and Management Science (VIDEM), the Vietnam E-Commerce and Digital Economy Agency (IDEA) under the Ministry of Industry and Trade, and the Kim Nam Group. The site's goal is to create a national database of capacity profiles and to provide essential information about agreements and policies related to international trade activities as well as the origin of Vietnamese firms' products and services (Phi, n.d.)

# The growth of multinational pharmaceutical corporations in Vietnam

Haissam Chraiteh, Managing Director of General Medicine in Asia and General Director of Sanofi Indochina (2020) stated that the implementation of EVFTA is a great opportunity for multinational pharmaceutical companies to enter and develop in Vietnam's market. The new FTA will bring fair and equal access to the market enabling EU investors to further expand their business and thus allowing foreign investors to meet the strong growth of the pharmaceutical sector. Vietnam is considered a potential and attractive market for multinational pharmaceutical corporations to set up a manufacturing base, from which to export to other countries.

Many large-scale projects have been launched such as the construction project of a factory to manufacture pharmaceutical products in Saigon Hi-Tech Park (HCMC) between the Vinapharm and the Sanofi - a French multinational pharmaceutical company with a total investment of 80 million USD. Recently, Vietnam's pharmaceutical market has officially welcomed a prominent international manufacturer, AstraZeneca Vietnam, which belongs to AstraZeneca Group (UK). This group commits to invest about 5,000 billion VND (about 220 million USD) in Vietnam between 2020 and 2024 (Hoang, 2020).

# Challenges for Vietnam's pharmaceutical market

Along with opportunities, the implementation of EVFTA also poses many threats which are currently deterring the development of Vietnam's pharmaceutical market. The agreement is likely to trigger aggressive competition from foreign rivals on local businesses and affect the country's economy as a whole.

# Higher levels of protection and enforcement of intellectual property rights for pharmaceutical products

It can be noted that high levels of intellectual property protection may create obstacles for Vietnam's pharmaceutical enterprises as they have to undergo numerous difficulties in order to launch new products.

About the commitment to the compensation for delay in marketing authorization procedures, the actual exclusivity period of pharmaceutical products may be longer than the maximum legal protection period. This may lead to drug prices may be kept high because of royalty fees for longer than usual, and enterprises manufacturing generic drugs (drugs whose protection has expired) will have to wait longer to be able to freely produce these drugs (Ministry of Industry and Trade, 2017).

About the commitment to the protection of undisclosed/exclusive data, it may limit the capability of pharmaceutical firms who desire to register for marketing authorization for their products in the domestic market, even if those products have already received marketing authorization for a certain entity, for the reason that other entities cannot rely on the results of the previous review of the competent authority to apply for marketing authorization for the same drug (Ministry of Industry and Trade, 2017).

Besides, Vietnam's pharmaceutical products with trademarks, patents, and exclusive industrial designs must register for exclusive protection in the EU at a high cost and go through complicated registration procedures under strict terms and conditions.

The competitive pressure on Vietnam's pharmaceutical firms

With the EVFTA in effect, importing pharmaceutical products from the EU into Vietnam will be more convenient, easier, and more direct, especially for drugs that Vietnam has not been able to produce yet (Ministry of Industry and Trade, 2017). The rapid growth in pharmaceutical imports from the has created competitive pressure on domestic pharmaceutical enterprises, especially small and medium-sized companies (SMEs), not to mention that the EU is currently one of the largest pharmaceutical manufacturers in the world and their pharmaceutical products are always preferred and praised for their quality and effectiveness. In that situation, Vietnam's pharmaceutical firms are worried as pharmaceuticals are one of the EU's main export products (Duc, 2020).

Moreover, the EU pharmaceutical enterprises may have far-reaching impacts when being deeply involved in the supply chain, production, circulation, and distribution in the Vietnamese market, whereas the competitiveness of Vietnamese enterprises are quite weak. Vietnamese enterprises are forced to accept fair competition with the EU enterprises in the domestic market (Hoang, 2020). It can be said that EVFTA will create fierce competition in bidding packages supplying pharmaceuticals to Vietnamese hospitals (in the group which has committed to open doors to EU contractors). This effect is more pronounced with brand-name drugs and specialized drugs (the group of drugs with exclusive protection, which Vietnam has not yet produced) (Ministry of Industry and Trade, 2017).

# 5. Recommendations for Vietnamese pharmaceutical enterprises

#### 5.1. Optimizing the opportunities

# 5.1.1. Digital transformation in the pharmaceutical industry

Telemedicine, Artificial Intelligence medical assistive devices, electronic medical records are some significant proofs of how technology can help in health care, optimize the sales pipeline and administer the commodity distribution system. Before, to administer the marketing channel distribution, enterprises were usually being managed by handwork through books, papers, etc. This will cause several insufficient conditions such as: Order processing procedure extended, difficulties in monitoring and updating the effectiveness at sale points, ineffective connection between the producer and the sale points. This will waste both time and resources due to the slow and ineffective reports which leads to the difficulties in declaring new and timely business strategies (Trong, 2020).

Besides, people think that only large pharmaceutical enterprises need to apply electronic solutions in managing distribution channels. As small pharmaceutical enterprises have uncomplicated commodity distribution systems, they should apply digital transformation soon to encourage the selling procedure, create a premise to improve, manage and widen distribution channels afterwards.

# 5.1.2. Cooperation with foreign enterprises

Domestic pharmaceutical companies mainly produce functional foods, while modern drugs are more inclined to generic drugs - pharmaceuticals that have expired intellectual property rights protection (accounting for over 50%), while brand-name drugs are the "playground" of FDI pharmaceutical enterprises.

By cooperating with foreign companies, both enterprises can learn and utilize each other's strength. The cooperation with foreign enterprises will bring more capital, technology and high-quality human resources to domestic pharmaceutical manufacturers, towards high standard product lines. These are some companies which cooperate and share funds with other foreign enterprises (Huong, 2021) (Table 3).

Company	CK Code	Foreign ownership rate (%)	Maximum ownership limit (%)	Available rate left to buy (%)
Hau Giang Pharmaceutical	DHG	54,72	100	45,28
Corporation				
Domesco Medical Clearance Corporation	DMC	57,99	100	42,01
Traphaco Corporation	TRA	43,00	49	6,00
Binh Dinh Pharmaceutical-Medical Equipment Corporation	DBD	0,06	100	99,40
Imexpharm Pharmaceutical Corporation	IMP	49,00	49	0
Pymepharco Corporation	PME	88,30	100	11,70

Table 3. Foreign ownership rate in some pharmaceutical enterprises

Company	CK Code	Foreign ownership rate (%)	Maximum ownership limit (%)	Available rate left to buy (%)
OPC Pharmaceutical Corporation	OPC	5,10	49	43,90

# Source: Tinnhanhchungkhoan.vn

# 5.2. Overcoming the challenges

# 5.2.1. Complying with the EVFTA's regulations

As the EU's pharmaceutical industry owns multiple intellectual property rights, therefore Vietnamese enterprises will have difficulties in introducing new products. In order to solve the problems, Vietnamese enterprises should understand clearly about the EVFTA's intellectual property rights articles. Enterprises should also study about pharmaceutical imports into Vietnam to avoid being sued by the EU enterprises.

# 5.2.2. Improving the quality of Vietnamese enterprises

One solution to improve the quality of Vietnamese enterprises is to invest in GMP-EUqualified production technology. The GMP standard forced the enterprises to follow the safety

procedure. This will prevent factors affecting the product's quality. Besides, GMP standard is also the criterion many pharmaceutical manufacturing bases aim for. In addition, a qualified production procedure also helps enterprises to gain customers' trust. GMP-qualified production lines must follow all the procedures correctly, because this is a health-related industry (Duc Anh, 2020).

Product organization structure, customer organization structure, pricing policy, review national shopping and maximizing taxes and working capital can be a solution. Enterprises should also focus on strategic repositioning, including business model reform, growth model rethinking, supply chain diversification, and feedback reform. Another solution is to promote studying, analyzing, proving the effectiveness of non-drug diagnosis and treatment methods, traditional medicine, remedies and herbs. Companies can also focus on support discovery, registration, recognition of intellectual property and commercialization of traditional medicine, honor and protect the rights of the doctors. A key solution to the improvement of the pharmaceutical industry of Vietnam is to utilize the natural available medicine in Vietnam to serve the pharmacy industry and improve drug production from herbal medication (PV, 2018).

#### 6. Conclusion

Vietnam's pharmaceutical market has enormous potential. As the EVFTA finally took effect in 2020 and brought many opportunities, the potential of the industry became even bigger. After several research about the EVFTA and Vietnam's pharmaceutical market, we have detected and pointed out several opportunities to the Vietnamese pharmaceutical industry such as being able to access the e-commerce platform, and the growth of multinational corporations. However, alongside the opportunities, it also brings lots of challenges to the market. Vietnamese enterprises must face higher levels of protection and enforcement of intellectual property rights for pharmaceutical products and compete head-to-head with the EU's pharmaceutical industry. Therefore, we have come up with some solutions in order to support the enterprises in overcoming the challenges and optimizing their advantages. Due to limited personal qualifications and initial application of theory to practice, this paper inevitably contains shortcomings and limitations in the writing process.

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