Kyiv National University of Trade and Economics

Department of commodity science and customs affairs

FINAL QUALIFYING PAPER

On the topic:

« Tariff and non-tariff regulation of medicines import from WTO countries »

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АНОТАЦІЯ

Дичко К. Тарифне та нетарифне регулювання імпорту лікарських засобів з країн СОТ.

Випускна кваліфікаційна робота присвячена аналізу тарифного та нетарифного регулювання імпорту лікарських засобів з країн СОТ. Проаналізовано стан міжнародного фармацевтичного ринку та найбільші міжнародні фармацевтичні компанії. Висвітлені тарифні та нетарифні заходи регулювання імпорту лікарських засобів походженням з країн СОТ. Проаналізовано асортимент лікарських засобів, що імпортуються в Україну. Представлені результати ідентифікаційної експертизи лікарських засобів, що ввозяться в Україну. Проаналізовано визначення митної вартості, нарахування митних платежів та митне оформлення лікарських засобів, що імпортуються в Україну з Індії згідно з митною декларацією.

Ключові слова: лікарські засоби, тарифне та нетарифне регулювання, митне оформлення, митна вартість, митні платежі, імпорт, код УКТЗЕД.

ANNOTATION

Dychko K. Tariff and non-tariff regulation of medicines import from WTO countries.

The final qualifying paper is devoted to the analysis of tariff and non-tariff regulation of medicines import from WTO countries. The state of the international pharmaceutical market and the largest international pharmaceutical companies in have been analyzed. Tariff and non-tariff measures to regulate the import of medicines originating from WTO countries were highlighted. The assortment of medicines imported to Ukraine was analyzed. The paper contain the results of identification examination of medicines imported to Ukraine. The customs value, calculation of customs duties and customs clearance of medicines imported to Ukraine from India according to the customs declaration have been analyzed.

Keywords: medicines, tariff and non-tariff regulation, customs clearance, customs value, customs payments, import, UCGFEA code.

ABBREVIATIONS

CCU – Customs Code of Ukraine

MD-2 – customs declaration of form MD-2

MD-6 – addition to customs declaration of form MD-6

SCS – State Customs Service

UCGFEA – Ukrainian Classification of Goods for Foreign Economic Activity

VAT – value added tax

WTO – World Trade Organization

OTC – non-prescription medicines

Rx – prescription medicines

MHU - Ministry of Health of Ukraine

WHO – World Health Organization

CONTENT

INTRODUCTION

Topic actuality. Today, the pharmaceutical industry is one of the most important industries in the international market. This is due to the high level of diseases of the population, which needs innovative medicines for the treatment of serious diseases every year. Since this industry is one of the most profitable, different countries are trying to develop this industry, which leads to great competition. In recent years, the pharmaceutical market has tended to grow. This is due to the saturation of pharmaceutical products, increasing the cost of research, increasing the efficiency of medicines production, the consolidation of pharmaceutical companies, the conclusion of agreements between firms on the joint creation of medicines.

Ukraine is no exception, where the pharmaceutical industry is one of the most popular. Our country has good domestic pharmaceutical companies-manufacturers, which are quite noticeable in the Ukrainian pharmaceutical market. Every year, new medicines appear on the Ukrainian pharmaceutical market that require their own customs clearance procedure. Despite the sufficient supply of medicines, the Ukrainian population is not able to receive all the necessary medicines. In conditions of economic instability, low incomes, the Ukrainian pharmaceutical market has problems but high potential for development.

The relevance of the pharmaceutical industry grows rapidly every year. Today, we can see it in a pandemic caused by COVID-19. The situation in the modern world has shown how important to be provided with medicines for every country that will help in the fight against the disease. A significant increase in imports of relevant medicines has attracted the attention of customs authorities. Due to the high demand of the population for medicines, the rules of customs and tariff regulation were changed. Measures of customs and tariff regulation of the movement of medicines across the customs border of Ukraine are the collection of taxes on medicines imported into Ukraine, which helps protect the national domestic market by adjusting

domestic prices for Ukrainian medicines by domestic producers with additional income.

Tariff regulation consists in charging VAT in the amount 20% of the custom value. The rate of duties on medicines is 0%, but this product is under the strict control of customs authorities. Non-tariff regulation measures are understood as a set of restrictive and prohibitive measures that prevent the penetration of foreign goods into domestic markets. Non-tariff regulation measures include registration of medicines, licensing of medicines and phytosanitary control. Quality control during the import of medicines is carried out by the State Medical Service of Ukraine. Quality control of medicines is an integral part of import control. All these measures protect the health of the Ukrainian population from low-quality, counterfeit medicines and the national market from irresponsible manufacturers and suppliers.

Research object – medicines imported from WTO countries to Ukraine.

Research subject – criteria, methods and means of identification, customs clearance of medicines.

The final qualifying paper purpose - to conduct an expert examination and analyze the customs clearance of medicines import.

To achieve this goal, the following tasks were defined:

- To analyze world market of medicines.
- To study legislation documents regulated medicines import from WTO countries.
- To analyze assortment of medicines imported from WTO countries.
- To conduct identification expert examination of medicines for customs purposes.
- To analyze customs valuation and customs taxation of medicines import.
- To analyze customs clearance of medicines import.

Research methods: analytical, organoleptic and instrumental.

The final qualifying paper scientific originality. Analysis of medicines world market and analysis of requirements to medicines in Ukraine and in the world was

conducted; identification expert examination of medicines moving across the customs border of Ukraine was carried out;

Obtained results practical value. Result of identification expert examination of medicines, developed identification methods of medicines and analysis of requirement of medicines can be used by State Customs Service of Ukraine when carrying out customs clearance of medicines.

Research results approbation. The research results were presented and discussed at the III International Student Scientific and Practical Conference in a report on “Identification expert examination of medicines at import" (Kyiv, KNUTE, June 18, 2020). According to the results of the research, an article was published in the collection of scientific articles of students: Dychko K. Development of the identification criteria of medicines for customs purposes // Митна справа: практичний аспект: зб. наук. ст. студ. — К. : Київ. нац. торг.-екон. ун-т, 2020. – С. 82-86.

The final qualifying paper structure and volume. The paper consists of an introduction, three charters, conclusions and recommendations, references, annexes. The main text of the paper includes 47 pages. The paper contains 9 tables, 11 figures. The list of references includes 50 items. 6 annexes are added to the paper and placed on 13 pages.

CHAPTER 1
THEORETICAL BASES OF TARIFF AND NON-TARIFF REGULATION OF IMPORT OF MEDICINES FROM WTO COUNTRIES

1.1. World market of medicines.

The world pharmaceutical market is the difficult, multilevel, polyfunctional entity with a high growth rate of production, sales and profitability indicator. It is proved by specifics of medicines that have high demand independently of economic and political factors.

The development of pharmaceuticals industry in direct of launch the most effective and safety medicines is the priority trending for the most world's major economies and famous pharmaceutical companies. This is due to the social significance of the industry's products, changes in the demographic situation in all countries of the world, which are associated with an aging population, increasing diseases among the world's human, especially the elderly.

The global pharmaceutical market has experienced significant growth in recent years. In 2019, the total global pharmaceutical market was valued at about 1.25 trillion U.S. dollars. This is a significant increase from 2009 when the market was valued at just 830,6 billion U.S. dollars. The pharmaceutical market plays a key role in how people get medications and what people pay for medication. However, some markets are better for pharmaceutical companies than others (Figure 1.1) [1].

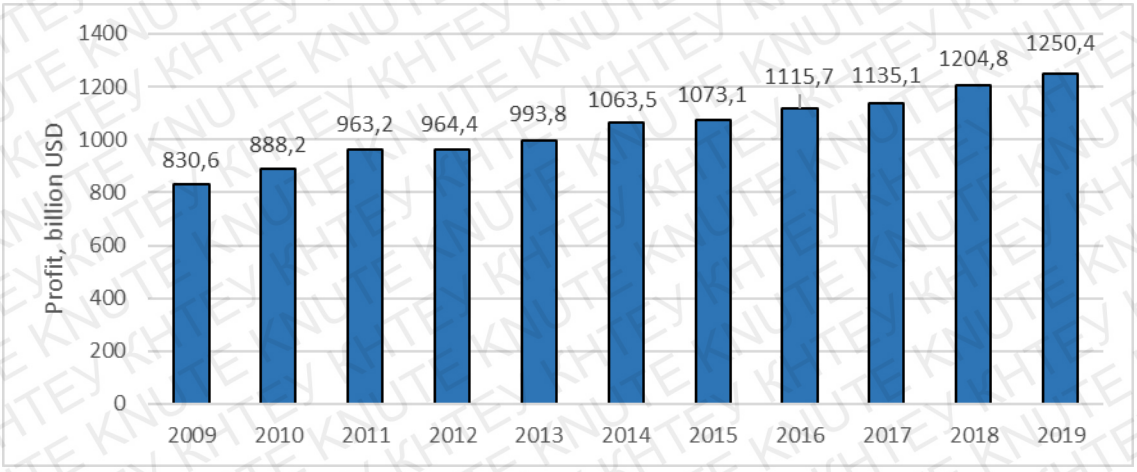


Figure 1.1 Profit of the worldwide pharmaceutical market 2009-2019, billion USD[1]

The factors that influence on the pharmaceutical market size include disease prevalence, medicines affordability, consumer attitudes, government policies and some supply-side factors [2,3]:

- Disease prevalence is related to population size, age, genetic inheritance and behavior (infectious disease incidence is lower where sanitation practices are better; sedentary lifestyles also encourage chronic disease).
- Affordability is related to income but also to medicines prices.
- Consumer attitudes include willingness to use alternative therapies or distrust of taking medicines.
- Government (and insurance company) policies affect reimbursement and who the payer is. Other government policies determine regulation, which can be a significant barrier to the launch of new treatments.
- A major supply-side factor is availability of an appropriate treatment, which may be a matter of quantity, as in an epidemic, or of medicines discovery and development.

During of analyzing of Ukrainian pharmaceutical market there is determined the volume of manufacturing medicines in the last 5 years. Since 2015 we have seen upward trend. From 2015 to 2017 Ukrainian companies increased manufacturing from 42,1 thousand ton to 48 thousand ton. In 2018 the volume dropped to 44,7 thousand ton and in the 2019 becoming 46,9 thousand ton [4].

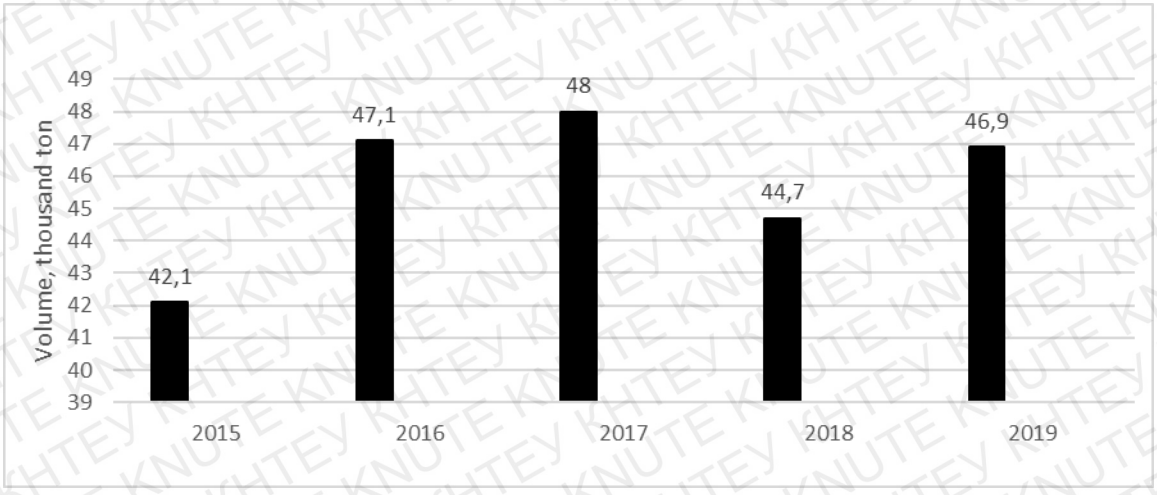


Figure 1.2 Volume of manufacturing medicines by Ukrainian pharmaceutical companies from 2015 to 2019, thousand ton [4]

Pharmaceutical sphere is very popular in international business, because it has one of the biggest profit in the world. There are 10 the most popular and profitable companies in the international pharmaceutical market (Figure. 1.3). The leading company-manufactory is China Resources National (75,8 billion dollars US), Johnson & Johnson (71,9 billion USD) [5].

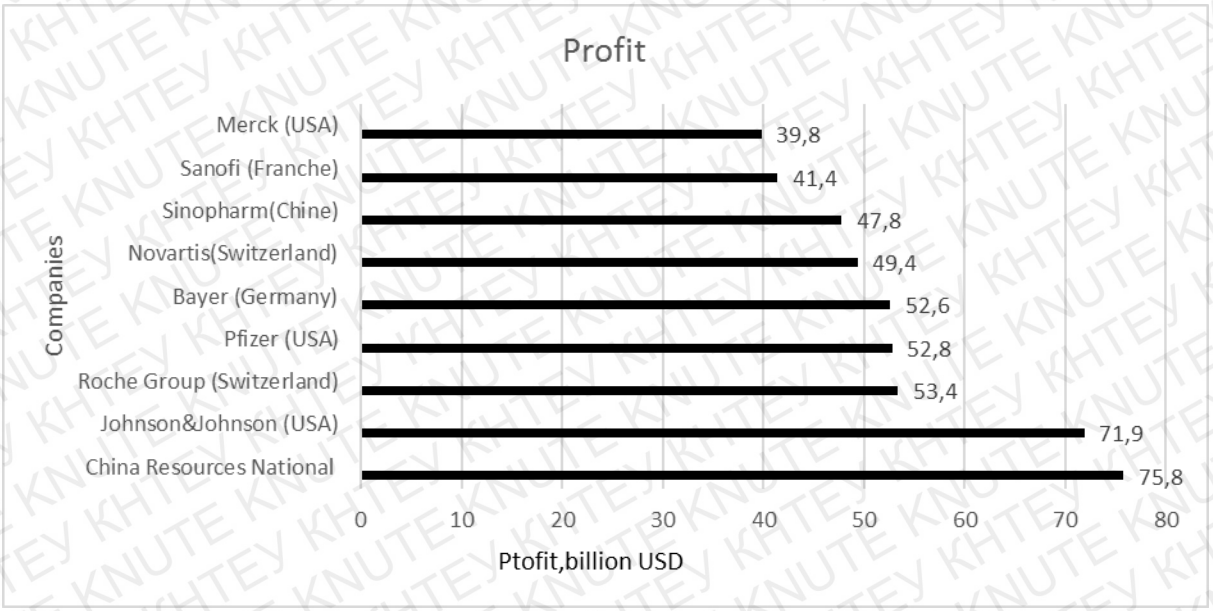
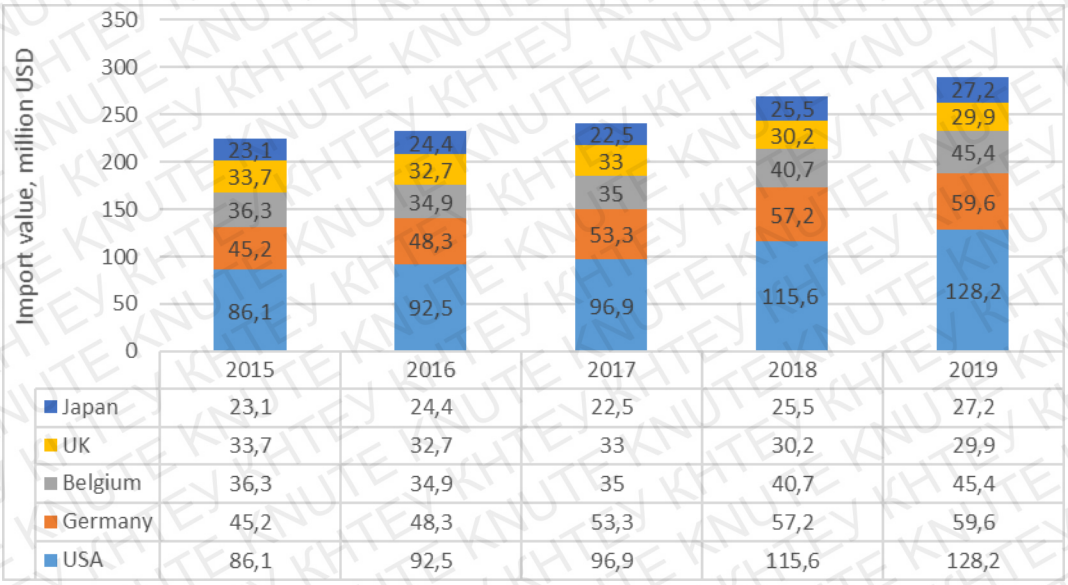


Figure 1.3 Annual profit of the largest pharmaceutical companies in 2019, billion USD [5]

The main part of medicines launching in the international market are made by USA, Japan, Germany, France, Great Britain, Switzerland, Italy and Belgium. These countries are producers of original, most effective and high-quality medicines. The dynamics of the global pharmaceutical market shows that medicines will remain in the future one of the most promising industries over the past 10 years (Figure 1.4).

Also, this countries are the biggest importers of pharmaceuticals products. The United States of America is the first country in the import of medicines. The value of import has grew up on 42,1 million USD in the last 5 years. Germany is on the second level and it has plus 14,4 million USD in 2019 (Figure 1.4)[6].



	2015	2016	2017	2018	2019
Japan	23,1	24,4	22,5	25,5	27,2
UK	33,7	32,7	33	30,2	29,9
Belgium	36,3	34,9	35	40,7	45,4
Germany	45,2	48,3	53,3	57,2	59,6
USA	86,1	92,5	96,9	115,6	128,2

Figure 1.4 Volume of medicines imported to Ukraine in 2015-2019, million USD [6]

Besides international pharmaceutical market, there is Ukrainian pharmaceutical market that includes famous and successfully medicines. Domestic pharmaceutical manufacturers are gaining market share. In some segments, they even displace imported medicines. However, recent events with the spread of COVID-19 have shown that the pharmaceutical market faces new challenges that did not exist before. A research of Ukrainian pharmaceutical companies was conducted, during which we determined that the leaders are: JSC "Pharmak", Corporation "Arterium" , CJSC "Darnytsia", Corporation "Yuria-Pharm", LLC "Pharmaceutical company Zdorovya" and other [7].

International trade of medicines becomes more significant every year. Ukrainian market includes many types of medicines. Every year our country import the large volume of medicines that is why foreign manufacturers have a big part in our market. Since 2015 we have seen upward trend. In 2015 our country imported 1,09 billion USD (17,4 billion tons), in 2016 the value was 1,29 billion USD (22,9 billion tons), in 2017 – 1,42 billion USD (25,5 billion tons), in 2018 – 1,53 billion USD (24,9 billion tons). But in 2019 we have less marker - value is 1,51 billion USD (22,4 billion tons). We can see it in the figure 1.5 [8].

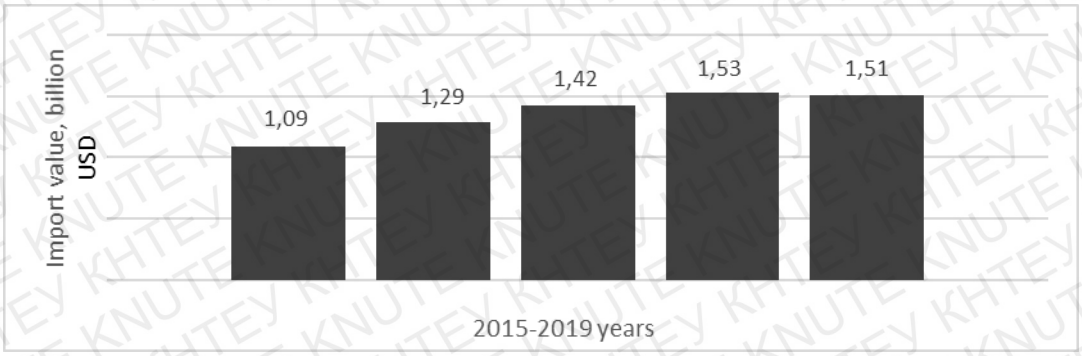


Figure 1.5 Dynamics of medicines import into Ukraine in 2015-2019, billion USD [8]

Ukraine has many companies of product medicines like JSC "Pharmak", Corporation "Arterium" , CJSC "Darnytsia" and export it to other countries. We have wide pharmaceutical market and have possibility to sell it in international market. In the last 5 years, volume of export has increased on 75 million USD. Since 2015 we have seen upward trend. In 2015 Ukraine exported 0,14 billion USD (10 billion tons), in 2016 the value was 0,16 billion USD (11,3 billion tons), in 2017 – 0,17 billion USD (13,3 billion tons), in 2018 - 0,18 billion USD (12,8 billion tons). In 2019 we have the biggest value - 0,21 billion USD (14,9 billion tons). We can see it in the figure 1.6 [7,8].

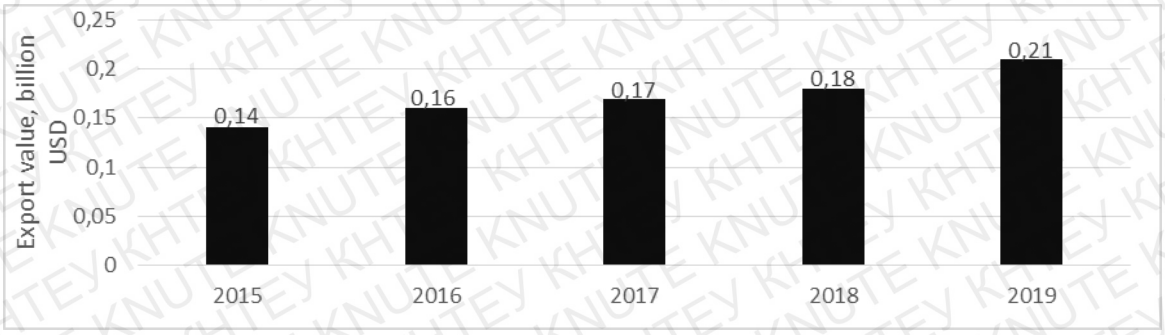


Figure 1.6 Dynamics of medicines export in 2015 - 2019, billion USD [8]

The volume of the Ukrainian pharmaceutical market is growing every year. This is due to the large number of pharmaceutical companies in the international market and the high demand of the population for medicines. Ukrainian pharmaceutical companies can not have such a rapid development, as it is impossible in the economic conditions of our country. But despite this, our manufacturers have quality and popular medicines.

1.2. Analysis of WTO countries and Ukrainian legislation on medicines safety and quality regulation.

The rapid development of modern medicines requires restorative legal regulation. According to international standards, the laws carry out international trade in medicines, which requires control by the relevant national authorities. Each of the WTO countries has its own laws and rules for the import of medicines into the country. But there is also international law that is common to the regulatory quality of medicines for WTO countries.

Medicines are a special category of goods. The legislative definition of the concept of medicines is contained in the Law of Ukraine “On medicines”. There is the definition of medicines according to article 2 of this Law [9]:

- medicines are substances or their mixtures, of natural, synthetic, or biotechnological nature used for prevention of pregnancy, for prophylaxis, diagnosis, and treatment of human diseases, or intended to change the physiological state and functions of the organism;
- medicines shall include: active agents (substances); finished medicines (medicinal preparations, medicines, medicaments); homoeopathic agents; agents used to detect and eliminate pathogenic organisms or parasites; cosmetic products and medicinal supplements to food products;

Legal relations related to the making, registration, production, quality control and sale of medicines means, rights and responsibilities of enterprises, institutions, organizations and citizens, as well as the powers in this area of executive authorities and officials are defined and regulated by the Law of Ukraine "On medicines". The legislation on medicines consists of the Law and other acts of legislation adopted in accordance with it. In accordance with the Regulation on the State Service of Ukraine for Medicines and Drug Control, approved by the Resolution of the Cabinet of Ministers of Ukraine dated August 15, 2015 №647 (with changes), the central executive body that implements the state policy in the areas of quality control and safety of medicines is the State Service of Ukraine for Medicines and Drug Control[10].

Legislation governing the quality of medicines has scheme in figure 1.7. All normative documents used by WTO countries and Ukrainian subjects of quality regulation of medicines are closely related to each other. Thus, there is a single document for determining the quality of medicines - Pharmacopoeia (United States Pharmacopeia, European Pharmacopoeia) [11]. According to this document, there are two main documents according to which the quality of medicines is regulated – Specification for medicine (table with elements that are part of the medicines) and Production Analytics (step-by-step testing methods) [12,13]. Quality Control Methods (QMS) are formed on the basis of these two documents. After the medicines passes all stages of examination, the last document is formed - the Certificate of quality of the medicine [15].

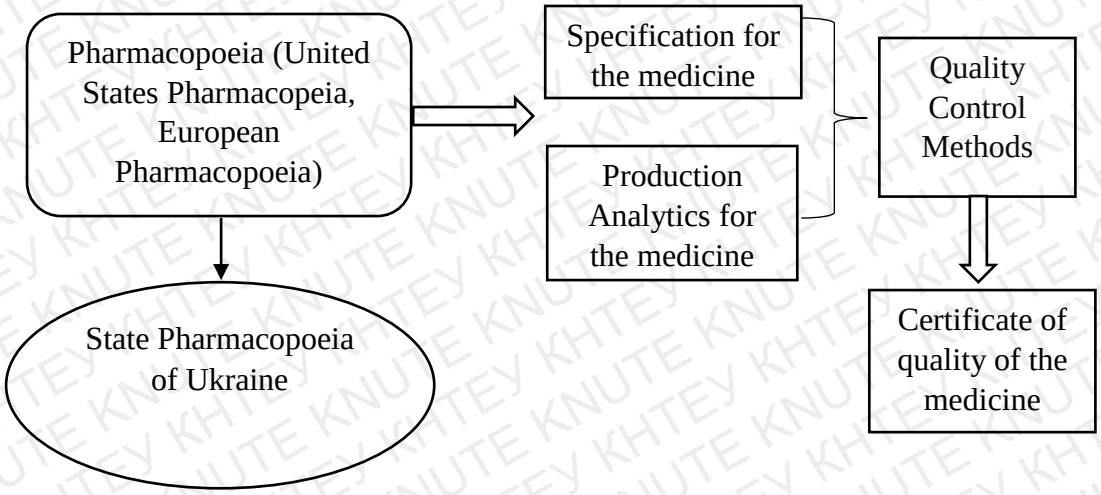


Figure 1.7 Scheme determination of quality methods control of medicines

The Cabinet of Ministers of Ukraine noted that the import of medicines to Ukraine is limited. It can be carried out only with a license for such imports. However, only medicines registered in Ukraine can be imported and it must be certified by the manufacturer. Customer need to have three documents that are permissible in order to overcome the restriction [14]:

- license;
- registration certificate;
- certificate of quality;

But there is unregistered medicines can be imported into the customs territory of Ukraine without the right to sell for [14]:

- conducting preclinical research and clinical trials;
- registration of medicines in Ukraine;
- exhibiting at exhibitions, fairs, conferences, etc .;
- individual use by citizens;

etc. by a separate decision of the Ukrainian Ministry of Health in the presence of documents confirming.

The procedure for importing medicines across the customs border of Ukraine is determined by the Law of Ukraine "On Medicines"

1. Medicines registered in Ukraine

Customs authorities can complete the procedure of customs clearance of medicines imports only in the presence of:

- the license
- registration certificate (Ukrainian Ministry of Health)
- the certificate of quality of the manufacturer or issued by the State Service of Ukraine on Drugs Control

2. Medicines not registered in Ukraine

Can be imported into the customs territory of Ukraine for:

- conducting preclinical research and clinical trials
- registration of medicines in Ukraine (samples of medicines in dosage forms)
- exhibiting at exhibitions, fairs, conferences, etc. without the right to sell
- individual use by citizens

3.Humanitarian aid or certain circumstances (natural disaster, catastrophe, etc.)

medical equipment and medical devices that are not registered in Ukraine may be imported into the customs territory of Ukraine for use in medical practice only after a state examination of their quality and safety (the State Service of Ukraine on Drugs Control)

Figure 1.8 The procedure of import of medicines in Ukraine [14]

The quality of medicines is compliance with all conditions of registration and production (technology, production areas, staff).The main indicators that determine the quality of medicines are [15]:

- safety - is the most important quality property that all consumer goods should have. If the permissible safety levels exceed the permissible value, medicines are classified as dangerous and destroyed;
- functional properties - the suitability of products to perform their functions as intended in the specified conditions of operation or consumption;
- eliability - the ability of goods to retain a functional purpose in the process of storage and consumption for a predetermined period;
- environmental friendliness - the degree of harmful effects of medicines on the safety of the environment during their production, storage and consumption;

High quality of medicines is provided by quality control of raw materials, metrological control of equipment, qualification of workers and quality control of finished products, development of requirements to conditions of storage and realization.

The market for medicines is divided into two major groups: original medicines (innovative, hereinafter - original medicines) and their copies (reproduced medicines, better known as generic medicines or non-proprietary, hereinafter - generic medicines or generics) [16].

The Pharmaceutical Encyclopedia of Ukraine states that medicenes (generic) is a copy that, in terms of therapeutic efficacy and safety, must correspond to an innovative (original) preparation produced by pharmaceutical companies after the expiration of the patent protection. Patent protection in accordance with the Law of Ukraine "On Protection of Rights to Inventions and Utility Models" lasts 20 years, and after the expiration of this period, patent protection of medicines can be extended for another 5 years. After all the time of protection, this tool goes into the status of "unpatented" and becomes free for further use by others, in particular for the creation

of generic medicines. In this case, patent protection may be granted on the dosage form of the generic, and not on its active substance [17,18].

Clinical trials are performed to determine the quality of medicines. The term "clinical trial of a medicies" means research work, purpose which is any study involving humans as a subject of study designed to identify or confirm clinical, pharmacokinetic, pharmacodynamic and / or other effects, in particular to study the absorption, distribution, metabolism and excretion of one or more drugs means and / or detection of adverse reactions to one or more of the studied medicines in order to assess its (their) safety and / or efficiency in accordance with the Procedure clinical trials of medicines and examination of clinical trial materials, approved by the Order of the Ministry of Health of Ukraine dated 23.09.2009 № 690 [19].

According to Article 7 Law of Ukraine "On Medicines" clinical trials of medicines are produced for the purpose of identification or confirmation efficacy and safety of the medicines. Clinical trials of medicines in Ukraine are carried out in accordance with the Guidelines "Good Clinical Practice" according to the Order of the Ministry of Health of Ukraine dated 16.02.2009 № 95 as last amended. The adopted Guidelines operate in accordance with the above-mentioned GCP International Standard on Planning Quality and conducting clinical trials of medicines in their use with human participation, as well as documentation and presentation of their results. In addition, it is applied to generic medicines. Analyzing the international legislation in the field of medical research with human participation, we can mention the Convention for the Protection of Human Rights and Dignity with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine dated of 4 April 1997 [20,21].

GMP is a system of rules and guidelines for the production of medicines and medical supplies. It regulates and evaluates the parameters of production and quality control of medicines, which is mandatory for further registration of the medicines and its release for sale [22]. The main purpose of GMP is not to harm the consumer with the products and to ensure the quality of such a product by certifying that it is safe to use. Subsequently, the standard adopted in the United States was regulated in many

countries around the world. For example, GMP is accepted in all countries participating in the System of National Pharmaceutical Inspectors Europe (PIC/S), which is an international system of control over the production and circulation of medicines [23]. Based on the US GMP, the EU Directive was created and adopted with its own amendments «EU Guideline Good Manufacturing Practice Medicines for Human and Veterinary Use» from 91/356 / EEU as amended by Directive 2014/94 / EU and 91/412 / EEU respectively. Directive 2014/94 sets out the principles and basic principles of good manufacturing practice for treatment and sale of medicines for humans [24].

The EU GMP Guideline replaces the "Medicines. Good Manufacturing Practice" from 2015, as appropriate changes have been made. This Guideline aims to introduce modern quality standards that the EU has to develop, manufacture and control of medicines. It states that the effectiveness of good manufacturing practices in the EU depends on the trade licensing system. Therefore, a license is a mandatory document for pharmaceutical manufacturers in the EU, regardless of where will be the sale of medecines - in the EU, or outside them [25].

1.3. Peculiarities of tariff and non-tariff regulation of medicines import from WTO countries.

Import of goods into the customs territory of Ukraine under the import regime involves the payment of taxes and fees specified by the laws of our country according to the Custom Code of Ukraine. When moving goods (including medicines) and vehicles across the customs border of Ukraine, the following taxes are levied in accordance with the current laws of Ukraine [26]:

- import duty;
- value added tax (VAT) during import operations;
- payment for customs clearance of goods outside the location of customs authorities or out the working time;

Import duty shall be imposed on the goods imported into the customs territory of Ukraine. Establishment of new and change the current rates of import duty defined in the Customs tariff of Ukraine and it carried out by the Verkhovna Rada of Ukraine through the adoption of laws of Ukraine [26].

If medicines that belong to commodity position – 3004 imported from WTO country, there is import duty – 0%. And according to the the Tax Code Value added tax is 7 %. The example of taxes for medicines (UCGFEA – 3004490000) that imported from WTO country has [27, 28]:

- import duty - 0%;
- value added tax (VAT) - 7%;

There is import duty in the amount of 0% for medicines in accordance with the Customs Code of Ukraine. It includes pharmaceutical products, compounds used for its manufacture, which are not produced in Ukraine and are classified by product groups 28, 29, 30 of UCGFEA the list of which is approved by the Cabinet of Ministers of Ukraine [28].

Importantly, with the accession to the WTO, Ukraine has undertaken additional international obligations to exempt from duty the components used for the production of finished medicines. Therefore, in order to provide the Ukrainian population with imported medicines, operations on importing medicines by legal entities are exempt from customs duties [29].

The issue of VAT taxation are important during the import of medicines and the grounds for exemption from payment of this tax. VAT is a consumption tax placed on a product whenever value is added at each stage of the supply chain, from production to the point of sale.

In accordance with the Tax Code sets the VAT rate at 7% of the tax base for:

- supply in the customs territory of Ukraine and import into the customs territory of Ukraine of medicines authorized for production and use in Ukraine and entered in the State Register of medicines according to the list approved by the Cabinet of Ministers of Ukraine;

- supply in the customs territory of Ukraine and import into its customs territory of medicines for use in clinical trials, authorized to be issued by the central executive body, which ensures the formation of state policy in the field of health care;

The presence in the Database of the specified medicines and confirmation of its inclusion in the State Register of medicines is the basis for exemption of medicines from VAT during their importation into the customs territory of Ukraine. [30].

The State Customs Service defines such a condition for exemption from VAT on a medicines as mandatory. Mandatory conditions for granting VAT benefits on imported medicines are [27]:

- submission by legal entities during customs clearance of the original or notarized copy of the registration certificate for the medicines and production license;
- the presence of the specified medicines in the State Register of medicines and in the Database;
- during customs clearance, the VAT preference code “02” must be entered in the cargo customs declaration;

If the medicine does not match one of the conditions, the VAT will be 20 %.

Measures of non-tariff regulation of foreign economic activity - not related to the application of customs duties on goods that move across the customs border of Ukraine, established in accordance with the law prohibitions and restrictions aimed at protecting the internal market, public order and safety, public morals, health and life of people and animals, protection of the natural environment, protection of the rights of consumers of goods imported into Ukraine, Non-tariff regulation of medicines import from WTO countries includes such measures:

- registration of medicines and inclusion it in the State Register of Medicines;
- licensing of medicines;
- official control measures - veterinary and sanitary control of medicines;

Registration of a medicine is one of the measures of non-tariff regulation. This procedure includes assigned a registration number for medicine and it is entered in the State Register of Medicinal Products. State registration of medicines in Ukraine gives the right to use and sell them only on the territory of Ukraine. If procedure finishes successfully, Registration Certificate can be issues by the Ukrainian Ministry of Health. There is the basis for the issuance of a licensee for the import of medicines: availability of appropriate material and technical base, qualified personnel, aconditions for quality control of imported medicines. The license for import of medicines is issued together with the Annexes, which indicates the place of business of the licensee. The license for the import of medicines is an integral part of it and is issued in the appropriate form. Information about all stages of the technological process is indicated in the registration dossier [31].

According to the Resolution of the Cabinet Ministers of Ukraine "Some issues of official control of goods imported into the customs territory of Ukraine" October 24, 2018 №960 (with changes), medicines are subject to phytosanitary control. The medicines must have a phytosanitary certificate in the original, issued by the state body for quarantine and plant protection of the exporting country, certifying the phytosanitary status of the product. This document is subject to verification during the preliminary documentary control [32].

CHAPTER 2
ASSORTMENT ANALYSIS AND IDENTIFICATION EXPERT EXAMINATION OF MEDICINES

2.1. Organization, object and research methods

During of the work, the research of medicines quality was conducted at the State Expert Center. The object of research is medicines, named Flucold-N. It is intended for symptomatic treatment of acute respiratory viral infections and influenza, accompanied by fever, chills, headache, runny nose and nasal congestion, sneezing, aches and pain in the body. There is the scheme according to which the work was executed and the analysis of the medicine was implemented on the Figure 2.1.

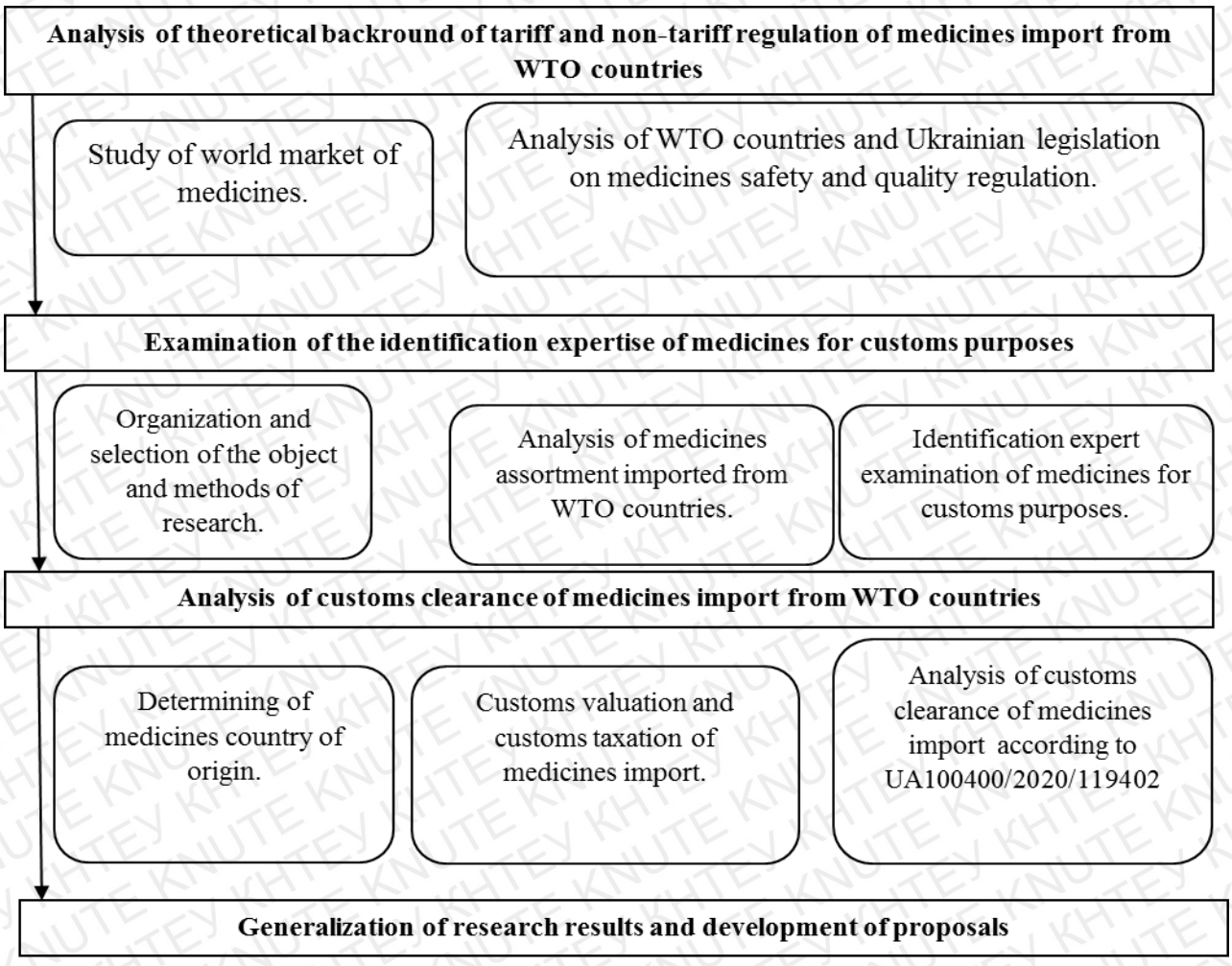


Figure 2.1 Scheme of analysis of medicines

In order to analyze and identificate of medicines, samples of goods are taken in the minimum quantity, which provides an opportunity to examine them (analysis, examination) according to the standards approved by the specially authorized central executive body in the field of customs [33,34].

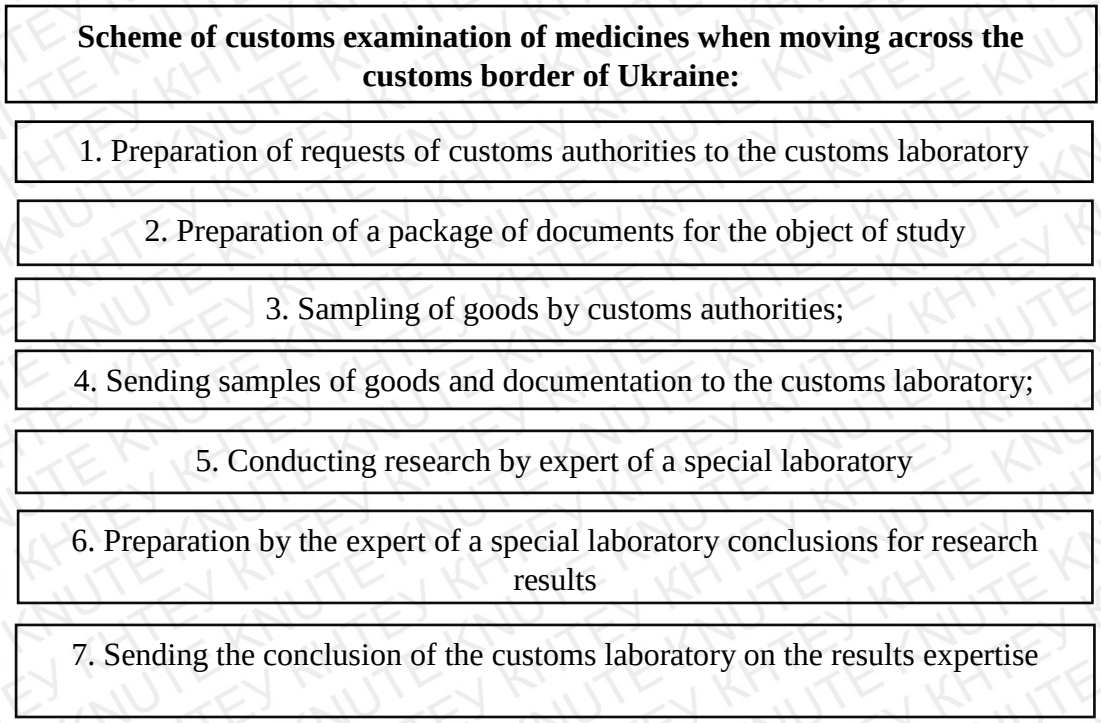


Figure 2.2 Scheme of customs examination of medicine

Identification of a medicines is a very important part of customs control, as it will determine the quality of medicines that will be on the Ukrainian market. Therefore, customs authorities pay special attention to correctness identification of indicators such as country of origin and customs value, including medicines not included in the State Register of Medicines and measures are taken to accelerate customs control [35].

The purpose of identification is establishing the content of the main constituent substances of the medicines, establishing the absence of substances that are prohibited for movement on the Ukrainian territory and definition the quality of medicines. It include such criteria, means and methods. There is two types of criteria: general and specific [36]. Identification expert examination of medicines for customs purposes is done by analytical method, organoleptic method and instrumental method (Table 2.4).

2.2 Analysis of medicines assortment imported from WTO countries.

The pharmaceutical market of Ukraine includes many foreign medicines. Most of these medicines are imported from WTO countries. The range of medicines is divided into prescription and non-prescription medicines (OTC). Since most of our medicines are available without a prescription, we can analyze this group of medicines. There are the most popular medicines, that imported from WTO countries.

There is shows the leader of medicines that are in the pharmaceutical market of Ukraine in the Table 2.1. European country like Germany, UK, Italy, France have the most popular medicines in our pharmaceutical market.

Table 2.1

The range of leaders of medicines imported from WTO countries

Medicines	Active substance	Manufacturer
Actovegin	deproteinized calf blood haemoderivative	Takeda Pharmaceutical Company Limited (Germany)
Nurofen	Ibuprofen	Reckitt Benckiser Healthcare International Ltd (United Kingdom)
Nimesil	Nimesulide	LLC"E Pharma Trento" (Italy)
No-shpa	Drotaverine	Representative organization "Sanofi-Aventis Group JSC" (France)
Essentiale® forte N	Phospholipides	A. Nattermann & Cie. GmbH (Germany)
Spasmalgon®	metamizole sodium, pitofenone, fenpiverinium bromide)	LLC "Sopharma AD" (Bulgaria)
Sinupret®	sorrel herbs, verbena herbs, gentian root, elder flowers, primrose flowers	Dragenopharm Apotheker Puschl GmbH (Germany)

Indian medicines are widely represented on the Ukrainian pharmaceutical market. India is a member of the WTO and we can analyze in detail the range of Indian medicines that are presented on the Ukrainian market. The main exporters of

medicines from India to Ukraine are the following manufacturers: LLC “Cipla”, LLC “Nabros Pharma”, LLC “Natco Pharma ”, LLC “Dr. Reddy’s Laboratories Ltd”.

Our world has very diverse pharmaceutical market and it increases every year. One of the leader is Dr. Reddy’s Laboratories – Indian pharmaceutical company that has noticeable position on the Ukrainian market. This company is a representative of the medicines of the above-mentioned Indian companies and also imports medicines from Europe countries.

The company has over 190 medications, 60 active pharmaceutical ingredients (APIs) for medicines manufacture, diagnostic kits, critical care, and biotechnology products. Dr. Reddy’s Laboratories works with other famous pharmaceutical companies that supply it medicines to Ukrainian pharmaceutical market:

LLC “Dr. Reddy’s Laboratorie”s includes 3 types of pharmaceuticals products: medicines, food supplement and cosmetics. Also, this pharmaceuticals products are divided to prescription (Rx) and non-prescription medicines (OTC). There is the most popular medicines that are imported by LLC “Dr. Reddy’s Laboratories”. Prescription medicines (Rx) are a group of medicines that require a prescription. Non-prescription (OTC) are a large group of medicines that a patient can buy for self-medication in a pharmacy without a prescription.

Prescription medicines (Rx) include such medicines like: “Omez”, “Cetrine”, “Nise”, “Flucold”. “Omez”, “Cetrine”, “Nise” medicines are made by Dr. Reddy’s Laboratories and have different purpose, active substance, release form and dosage. Flucold is produced by Nabros Pharma pvt Ltd and also have different characteristics of medicine. “Omez” tablets used when person has problem with stomach. It has two realese forms – capsules and injection. “Cetrine” medicine can help against allergies. It has only one release form – tablets. “Nise” and “Flucold” are very good analgesics and “Flucold” tablets can help against flue. This medicines has similar release form – tablets.

Table 2.2

Characteristics of the assortment of Rx medicines

Name	Purpose	Active substance	Release form	Dosage	Manufacturer
Omez D caps. N30	antiulcer	omeprazole	capsules	30 capsules	Dr. Reddy's Laboratories
Omez caps. 10 mg	antiulcer	omeprazole	capsules	10,20,30 mg	Dr. Reddy's Laboratories
Omez DSR caps.	antiulcer	omeprazole	capsules	30 capsules	Dr. Reddy's Laboratories
Omez injections 40 mg N1	antiulcer	omeprazole	injection	40 mg	Dr. Reddy's Laboratories
Cetrine tab 10 mg N20	against allergies	cetirizine	Tablets	10 mg	Dr. Reddy's Laboratories
Cetrine tab 10 mg N30	against allergies	cetirizine	Tablets	10 mg	Dr. Reddy's Laboratories
Nise tab 100 mg N20	acute pain	Nimesulide	Tablets	100 mg	Dr. Reddy's Laboratories
Flucold Lozenges lemon N18	analgesics	paracetamol	Tablets	18 tablets	Nabros
Flucold Lozenges orange N18	analgesics	paracetamol	Tablets	18 tablets	Nabros
Flucold-N tab N12, N200	analgesics	paracetamol	Tablets	18 tablets	Nabros

Non-prescription medicines (OTC) include three types of medicines. "Vicks" and "Nasivin" medicinesares widely used against fight coughs, colds and flu. It has different release form like balsam, spray nasal, powder and drops. They are produced by Germany company "Proctor&Gamble". Medicines named "Ketorol" are produced by Dr. Reddy's Laboratories and are good analgesics in Ukrainian pharmaceutical market. This medicines are popular in Ukrainian pharmaceutical market because people need Rx medicines every day. And it has comfortable dosage form for every person. The assortment of Rx medicines showed in the Table 2.3.

Table 2.3

Characteristics of the assortment of OTC medicines

Name	Purpose	Active substance	Release form	Dosage	Manufacturer
Vicks Active Balsam, 25 g, N1	fight coughs, colds and flu	oxymetazoline hydrochloride	Balsam	25 g, 50 g	Proctor&Gamble
Vicks Active Sinex, spray nasal 0,5 mg/ml, 15 ml N1	fight coughs, colds and flu	oxymetazoline hydrochloride	spray nasal	15 ml	Proctor&Gamble
Vicks AntiGrip Complex, N10 (P&G)	fight coughs, colds and flu	paracetamol	Powder	5,00 g	Proctor&Gamble
Vicks AntiGrip Max, lemon flavor, N10 (P&G)	fight coughs, colds and flu	paracetamol	Powder	5,00 g	Proctor&Gamble
Ketorol amp 30 mg/ml (1 ml) N10	analgesics	ketorolac	Injection	30 mg/m	Dr. Reddy's Laboratories
Ketorol Gel 2% 30 g N1 (Fto-6)	analgesics	ketorolac	Gel	30 g	Dr. Reddy's Laboratories
Ketorol tab 10 mg N20 (FTO-2)	analgesics	ketorolac	tablets	10 mg	Dr. Reddy's Laboratories
Nasivin drops nasal 0,01% 5 ml N1	fight coughs, colds and flu	oxymetazoline	drops	5 ml, 10 ml	Proctor&Gamble
Nasivin spray nasal 0,05% 10 ml N1	fight coughs, colds and flu	oxymetazoline	spray	10 ml	Proctor&Gamble

In this work we analize the medicine "Flucold-N tablets N200" and it has own assortment of the medicine. This medicine has 4 types, which are taken in different dosage forms. The first is - Flucold Lozenges, that has 2 types of smell: lemon and orange. Also, there are Flucold-N that has tablets dosage. This medicines is manufactured by the Indian company Nabros Pharma pvt Ltd, which is a prominent manufacturer of medicines in the global pharmaceutical market. Despite the fact that this medicine is produced by Nabros Pharma pvt Ltd, we can describe this medicine as belonging to the assortment of medicines of Dr. Reddy's Laboratories, because Dr.

Reddy's Laboratories is the representative of this medicine. Flucold is a generic and contains the active substance - Paracetamol.

There is the sales structure of medicines that are in the pharmaceutical market of Ukraine. We can analyze the most popular medicines on the our pharmaceutical market on the example of medicines that imported by LLC "Dr. Reddy's Laboratories".

The leader is – Omez. This medicine is for person who has problem with stomach. It has 13,3 % from imported medicines. It has 3 form of realese: capsules, injection and powder. Another medicine – Cetrine tablets. It helps people who have allergic reactions in the body. It has 12,5 % from imported medicines. It has only 1 form of reales – tablets. Vicks is not less popular medicines, that is imported from Germany - The Procter &Gamble Company. This medicine helps fight coughs, colds and flu. It has 12,5 % from imported medicines. Nise is a medicine for the treatment of acute pain. It has 9,2 % from imported medicines. This medicine has one form of release:

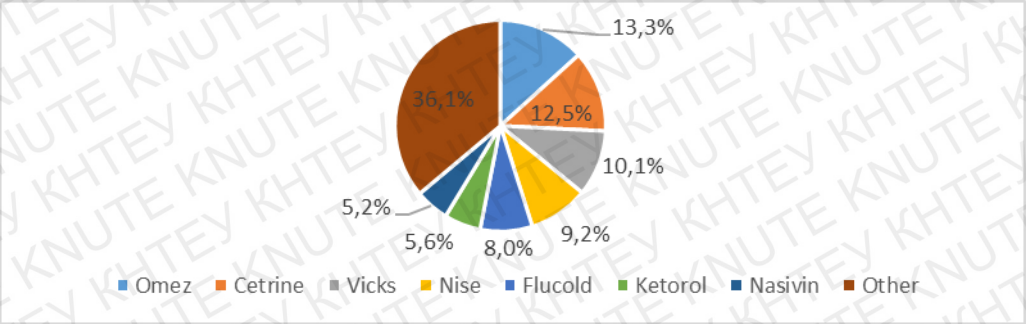


Figure 2.3 Sales structure of medicines produced by Dr. Reddy's Laboratories, %

The market for medicines will expand every year. The range of medicines will expand accordingly. Distribution of medicines manufacturers of foreign companies is the main goal of this manufacturers. Ukraine works closely with WTO pharmaceutical companies. Therefore, the range of medicines will be expanded by importing them from these countries.

2.3. Identification expert examination of medicines for customs purposes.

Ukrainian authority of quality control implements measures in order to prevent the circulation of falsified and unregistered products. Medicines can be imported in Ukraine if company have Certificate of Quality on particular medicines or batch of medicines. The control are provided by State Medical Service. Company send an application to the Public oversight authorities about conclusion of the quality of imported medicines in order to realize this product in the Ukrainian market. The application includes such documents (the copy of) [36, 37]:

- Certificate of Quality which issued by the manufactory for every batch of medicines;
- custom declaration with stamp of custom sign off leader of company;
- invoice;
- marketing authorization for imported medicines;
- the document which issued by State Medical Service about accordance of conditions of production for the all requirements;

Laboratory analysis is done in the laboratories of quality control and safety of medicines. At time of state inspection committee company places the cargo with medicines separately from other products in a specially designated area. State inspection committee includes such action:

- inspection of the documents which file by company;
- checking of medicines according to the custom declaration and achievement of sight control for every batch;

In the context of medicines “Flucold” which is produced by LLC “Dr. Reddy’s Laboratories”, there was achievement of identification of this tablets. As the medicines was registration in Ukraine in April 27, 2017 and this import operation was not the first, the company must give Certificates of Quality of every batch and the cargo with medicines was subject of sight control. Also, the company has the Certificate of GMP which proves that this medicine is quality and safety.

There are showed result of laboratory test of identification of "Flucold" that was achievement by company of producing. In process of import, there was 8 Batch of "Flucold" and in this table is showed identification of 1 batch. Other 7 batch are similar. Certificates of quality are compliant with: specification of the approved methods of control quality, conformity certificate producing of medicines GMP, requirement of Ukrainian legislation (table 2.4).

Table 2.4

Criteria, means and methods of identification of medicines

Criteria / indicators	Means	Method
General:		
Type of product	Regulatory document, goods, marking	Analytical
Name of product	Marking, accompanying documents, goods	Analytical
Classification Group	The explanation to the UCGFEA	Analytical
Country of origin	Marking, accompanying Documents	Analytical
Marking completeness	Regulatory document, marking, goods	Analytical
Product destination	Marking, accompanying documents, goods	Analytical
Specific:		
Pharmaceutical group	The Law of Ukraine #460 dated Augusts 23, 2015 [38]	Analytical
Pharmaceuticals form	Marking, accompanying documents, goods	Organoleptic
Active substance	European Pharmacopoeia 2.9.29 [39]	Instrumental
Caffeine content	European Pharmacopoeia 2.9.29 [39]	Instrumental
Abrasion	European Pharmacopoeia 2.9.7 [39]	Instrumental
Resistance to crushing	European Pharmacopoeia 2.9.7 [39]	Instrumental
Thickness of tablet	The State Pharmacopoeia of Ukraine (the 1st edition) [40]	Instrumental

The purpose of identification is establishing the content of the main constituent substances of the medicines, establishing the absence of substances that are

prohibited for movement on the Ukrainian territory and definition the quality of medicines. There are describes all methods and technology for determining the substances that are part of the medicine.

As analytical method we determined such criteria like: product name, type of product, classification group, country of origin, marking completeness, product destination, pharmaceutical group.

Organoleptic method - a generalized assessment of its quality, carried out only with the help of human senses. In this case, are evaluated as external characteristics such as pharmaceuticals form.

By instrumental method determine the content of:

1. Active substance (Paracetamol) and Caffeine. This analysis is performed by liquid chromatography in accordance with the European Pharmacopoeia [39].

The exact portion of the crushed tablets of the medicines, equivalent to the average weight of 1 tablet, is made in a volumetric flask with a capacity of 100 ml. Then add 50 ml of mobile phase and shake with an ultrasonic bath for 25 minutes and mix.

The test and standard solutions are alternately chromatographed under the specified conditions, obtaining at least 5 chromatograms for each. The ratio of the components of the mobile phase can be adjusted depending on the characteristics of the chromatographic system.

The results of the analysis are considered reliable if the requirements for the suitability of the chromographic system are met.

The content of paracetamol and caffeine in the preparation, in mg/tabl., is calculated by the formula (formula 2.1):

$$X = \frac{A_{pa} \times M_{st} \times 2 \times P \times M_{am}}{A_{st} \times M_{ts} \times 100} \quad (2.1)$$

A_{pa}, A_{st} - peak areas of the determined component on the chromatographs and standard samples;

M_{st} - sample of standard sample, mg;

M_{ts}- sample weight of the test sample, mg;

M_{am} - average tablet weight, mg;

P - the content of the basic substance in the suspension,%;

The content of paracetamol in one tablet (450-550) mg, (90-110)%.

The caffeine content in one tablet (27-33) mg, (90-110)%.

2. Abrasion.

The determination is performed on 10 tablets in accordance with the requirements of the European Pharmacopoeia [39].

3. Resistance to crushing.

The determination is performed on 10 tablets in accordance with the requirements of the European Pharmacopoeia [39].

The result of identification expert examination of medicine "Flucold" by the general criteria are shown in the Table 2.5.

Table 2.5

The result of expert examination of medicine "Flucold" by general criteria

Criteria	**Result**
Type of product	Medicines
Product Name	Flucold
Classification Group	3004490000
Country of origin	India
Marking completeness	Full (Country of manufactory, Number of batches, name, content)

There are the results of general criteria in the Table 2.6. Medicines is the type of product of this sample. Product Name is Flucold. This medicines has particular Classification Group – 3004490000. All products have each other country of origin. This medicine is made in India. Also, marking of product must be full and it includes all needful information.

The result of identification expert examination of medicine "Flucold" by the general criteria are shown in the Table 2.6.

Table 2.6

The result of expert examination of medicine "Flucold" by specific criteria

Criteria	Result
Pharmaceutical group	Generics
Pharmaceuticals form	Tablets
Active substance	Paracetamol
Caffeine content	70%
Average weight of tablets	646,49 mg
Abrasion	0,31 %
Resistance to crushing	7,06 kg/cm^2
Thickness of tablet	5,20 mm

Specific criteria of medicines are very important in the process of identification. Flucold belong to Generics pharmaceutical group. It's mean that generic medicines is a medication created to be the same as an existing approved brand-name medicine in dosage form, safety, strength, route of administration, quality, and performance characteristics.

Pharmaceuticals form of medicines – tablets. All medicines must have active substance. An active substance is the ingredient in a pharmaceutical medicines or pesticide that is biologically active. Flucold has Paracetamol. Also there is other substance: Caffeine content - 70%. Average weight of tablets is 646,49 mg.

The abrasion is - 0,31 % and it is a type of open wound that's caused by the skin rubbing against a rough surface. Resistance to crushing (hardness) - 7,06 kg/cm^2 . Tablet thickness is determine by the diameter of the tablet. Micrometer and vernier caliper are used for checking tablet thickness and Flucold has 5,20 mm.

One of the most important stage of identification expert examination of medicines is the determination of code according to the UCGFEA. The expert report shows that this medicine complies with this code and accordingly has its own customs duties determined by the Ukrainian legislation. Expert report that was done by Kiev Chamber of commerce and industry showed that the medical product has such code according to UCGFEA: 3004490000 Medicinal product [medicines] (to

the exclusion of goods that include to the commodity items 3002, 3005, or 3006), that consist of mixes or not mixes products for therapeutic abo prophylactic use, in dosage form or packaged for retail trade [41]: - that include alkaloid or their matching, but without hormone, other composites commodity item 2937 or antibiotic: - - prepacked for retail trade.

CHAPTER 3
CUSTOMS CLEARANCE OF MEDICINES IMPORT FROM WTO COUNTRIES

3.1. Determining of medicines country of origin.

According to Article 36 of the CCU [26], the origin of medicine is determined for the purpose of taxation of this product, the application of non-tariff regulations, prohibitions and restrictions, as well as ensuring the accounting of this product in foreign trade statistics. The country of origin is determined on the basis of the principles of international practice. Also, according to Art. 36 of the CCU, the country of origin of goods is considered to be the country in which the goods were fully manufactured or subjected to sufficient processing in accordance with the criteria established by this Code. The country of origin can be group of countries, customs unions of countries, region or part of a country, if it is necessary to separate them in order to determine the origin of goods.

The confirmation the country of origin of the medicines is the Registration Certificate [42]. Country of origin of the medicine - the country of the manufacturer and/or holder of the registration certificate for the medicines. If more than one manufacturer is indicated in the registration certificate for medicines, the country of origin shall be the country of the holder of the Registration Certificate [Annex F].

The Registration Certificate approved by the Ministry of Health of Ukraine for the medicine – tablets “Flucold – N”. This document is a guarantee that this medicine is included in the state register of medicines.

This document has the number – UA/6266/01/01 [Annex F].

According to Article 9 of the Law of Ukraine "On medicines " and the resolution of the Cabinet of Ministers of Ukraine of May 26, 2005 №376 "On approval of the procedure for state registration (re-registration) of medicines and fees for their state registration (re-registration)" – medicine (tablets Flucold – N) is re-registered in Ukraine indefinitely. The validity of the registration certificate on the territory of Ukraine is unlimited [9].

In the registration certificate country of origin of this medicines is – India, that is "Nabros Pharma Pvt. Ltd./Survey No. 110/A/2 Amit Farm, Jain Upasrya, Near Coca Cola Factory, N. H. No. 8/Kajipura – 387411, Kheda, India". This document is mentioned under the code "d9904" UA/6266/01/01 – 27.04.17 in the "Box №31" of the MD-6.

According to Order of Ministry Finance of Ukraine "About the statement of the Procedure for filling in customs declarations on the form administrative document" the letter code Alpha-2 of the country of origin is indicated according to the classification of the world countries in the Box №34 "Country of origin code" of the MD-2. In our case it is the letter code Alpha-2 of India "IN".

Also if the country of origin is unknown or a certificate of origin is issued for the product made by mixing with the definition of the origin of the components, but without determining the origin of the final product, the Box 34 "Country of origin code" includes - "00"

3.2. Determination of customs value and taxation of medicines import.

Determining the true customs value of goods, including medicines that are imported to Ukraine is a very important step in completing customs formalities for goods that are in import regime. Determining the customs value affects the completeness of customs payments and the filling of the state budget of Ukraine.

Customs clearance is the performance of customs formalities by customs officials of the State Fiscal Service of Ukraine, necessary for the release of goods, including medicines.

Medicines are imported to Ukraine in accordance with MD UA100400/2020/119402 in the import customs regime. So their customs value is determined in accordance with Chapter 9 of the CCU. The declaration of the customs value of food processors is carried out by the declarant LLC "Universal Logistic"in accordance with the procedure established by Section VIII of the CCU.

The declared customs value is confirmed by such documents [43]:

1) declaration of customs value submitted in the cases specified in parts five and six of Article 52 of the CCU, and documents confirming the numerical values of the components of customs value on the basis of which the customs value was calculated (Annex A);

2) Supply agreement and annexes to it in the case of their presence (in our case, Supply agreement №2020-06-01/NPPL dated 01.06.2020) (Annex G);

3) invoice or proforma invoice (if the product is not the object of sale) (in our case, the invoice №EXP/40/20-21 from 18.09.2020 - Annex B);

4) other documents that can be identified with imported medicines, and which contain information about the cost of the latter;

The customs value of medicines is determined imported into Ukraine in accordance with the customs regime of import was carried out according to the main method - the price of the agreement (contract) for imported goods (transaction cost). This corresponds to the code "1" in box 43 of MD UA100400/2020/119402.

Medicines for the value 214434, 00 USD were imported to Ukraine. This price mentioned in the Invoice № EXP/40/20-21 (Annex A). There were imported 19494 packs of tablets “Flucold-N tablets N200” for amounts 214434,00 USD.

Table 3.1

Calculation of the invoice value of medicines “Flucold-N tablets” №EXP/40/20-dated 18/09/2020

Description of goods	Batch №	Quantity, pack	Price per unit, USD	Amounts, USD
Flucold-N tablets N200	FB0451	2438	11,00	26818,00
	FB0452	2439	11,00	26829,00
	FB0453	2836	11,00	26796,00
	FB0454	2434	11,00	26774,00
	FB0455	2438	11,00	26818,00
	FB0456	2437	11,00	26807,00
	FB0457	2439	11,00	26829,00
	FB0458	2433	11,00	26763,00
		19494		214434,00

In our case, invoice value is 214434,0000 that mentioned in box 42 “The price of the goods” and in the box 22 “Currency and total amount on the account” of the MD UA100400/2020/119402.

The invoice states that the Terms of delivery of medicines is “CIP”. According to Incoterms 2010 the seller must pay the costs and freight required to deliver the goods to the place of destination. So in this case invoice value includes costs and freight.

As the custom clearance was done 22 October 2020, the exchange rate was 28, 27370000 according to the MD UA100400/2020/119402. This rate should be appropriate to the current dollar rate on the National Bank of Ukraine.

So, the basis of accrual will be the amount of 6062842,59 UAH (214434, 00 USD*28.2737UAH). According to Tax Code of Ukraine all registered medicines that belong to “3004” group of UCGFEA like Flucold-N has VAT – 7 % and import duty – 0%.

There is analyzing of the calculation import duty when medicines are imported. The first box "Type" of box 47 indicates the code of import duty - 020 according to the Classifier of types budget revenues controlled by customs authorities.

There is accrual of customs duties of importing medicines in box 47 MD UA100400/2020/119402 in the Table 3.2.

Table 3.2

Calculation of customs duties of importing medicines in box 47

MD UA100400/2020/119402

Type	Base of calculation	Rate	Amount	PM
020	6062842,59	0%	0,00	01
028	6062842,59	7%	424398,98	01

There is analyzing of the calculation import duty when medicines are imported. The first box "Type" of box 47 indicates the code of import duty - 020 according to the Classifier of types budget revenues controlled by customs authorities.

The second box "Base of calculation" indicates the customs value of medicines, as the accrual is carried out at the ad valorem rate. In our case, we indicate the amount of 6062842,59UAH, which is specified in box 45 of MD UA100400/2020/119402.

The third box "Rate" indicates the current rate of import duty in accordance with the customs tariff of Ukraine - 0%. The fourth box "Amount" indicates the accrued amount of duty - 0,00UAH. There is the code of the method calculation according to the Classifier of methods calculation. In our case we note 01 - non-cash payment. There is analyze of the VAT when medicines are imported to the Ukrainian territory. The first box "Type" of box 47 indicates the code of the type payment according to the Classifier of types of taxes and fees - 028 (VAT). The second box "Basis of accrual" indicates the customs value of medicines, specified in box 45 MD - 6062842,59 UAH. The third box "Rate" indicates the statutory rate of value added tax - 20%.

$$VAT = \frac{6062842{,}59 \times 7\%}{100\%} = 424398{,}98\,UAH \qquad (3.1)$$

The fourth box "Amount" indicates the accrued amount of VAT. The calculation of the amount of VAT on food processors imported into the customs territory of Ukraine is carried out according to the formula (3.1).

3.3. Analysis of customs clearance of medicines import.

In this work, the import of a medicine was described on the example of a sea supply from India. Customs clearance of cargo has a certain sequence, which is regulated by the legislation of Ukraine. At customs clearance the package of documents which then was fixed by the MD-2 was formed. The following documents are used for customs clearance (table 3.3):

Table 3.3

Documents submitted to the customs control of medicines

Document code	Document number	Date of the document	Document name
1	2	3	4
0271	w/n for inv. EXP/40/20-21	18.09.2020	Packing List
0380	EXP/40/20-21	18.09.2020	Commercial invoice
0705	MEDUMG247 734	21.09.2020	Bill of lading
4100	Supply agreement №2020-06-01/NPPL	01.06.2020	Foreign trade agreement (contract) of purchase and sale of goods (except for code 4104), the submission of which for customs clearance is not accompanied by the submission of related intermediary (foreign economic and / or domestic) agreements
0830	5327558	21.09.2020	Shipping bill summary
0003	UA/6266/01/01	03.05.2017	Registration certificate
0911	AE193581	03.12.2013	License for import medicines

MD-2 - a statement of the prescribed form, in which the person indicates the customs procedure and provided by law information about goods, conditions and methods of movement across the customs border of Ukraine and the calculation of customs duties required for this procedure. As MD-2 is the main document that confirms that the goods have passed customs clearance, there is the analysis of this document and other documents that used in custom clearance. Filling the MD-2 box in the import mode is filled according to Order “About the statement of the Procedure for filling in customs declarations on the form of the uniform administrative document” from May 30, 2012 №651 [45].

In our case, MD-2 has such number - UA100400/2020/119402. There are mentioned letter code of the direction of movement of good (IM) and customs regime codes, declaration type (40|ДЕ) according to Order of the Ministry of Finance of Ukraine from September, 20 2012 № 1011 [46] (Annex A).

- IM - import mode;
- 40 - customs regime code;
- ДЕ - additional declaration to the previous customs declaration;

Box 2 shows information about the sender with addition in MD-6. The goods are imported from pharmaceutical company “Nabros Pharma Privated Limited”. The recipient is LLC "Dr.Reddi's Laboratories". There is such information about the recipient in box 8 of MD UA100400/2020/119402 (Annex A).

As medicines are declared by the customs broker, the series and number of the license for customs brokerage and the date of its issuance are additionally indicated. This information is in box 14 “Declarant/Representative” of MD UA100400/2020/119402. The name of company is LLC "Universal Logistic". The series and number of the license is AA 000278 from 29.12.2015. Also there is EDRPOU code of this company - UA0033594538 (Annex A).

There is short name of the country from which the goods are sent to Ukraine in the box 15 according to the classification of the world countries [47]. In our case it is India.

In our case, we import medicines from India by sea to Odessa. After that, the goods are sent to customs by road. In the box 18 “Identification and country of registration of the vehicle at departure / arrival” there are mentioned information about car on which the goods are directly at the presentation of customs destination – “BH5967HE/BH2955XK”. This medicines are shipped in one container that is why in box 19 showed “1”. Box 21 indicates information about vehicle on which the customs border is crossed and it is ship – “MSC REGULUS”. Also, Bill of Lading is the obligate document when the goods are delivery by sea (Annex D).

There are the name of the customs and the nine-digit code of the checkpoint through which the goods are imported into Ukraine in box 29. The goods arrived at the Odessa customs, through the checkpoint “Odessa-central/ customs clearance department №4” - which has a code “UA500040” (Annex A).

According to the Supply agreement №2020-06-01/NPPL, the terms of delivery of this shipment – CIP (Carriage and Insurance Paid To). It means that seller pays freight and insurance to deliver medicines to a seller. Box 20 gives the abbreviated letter name of the terms of delivery and indicates the letter code alpha-2 and the name of this geographical point – “UA v. Velyka Oleksandrivka” (Annex G).

In box 31 is mentioned full product description. Number 1 indicates the name and the usual trade description, which allows to identify and classify the product – “Medicines for people containing alkaloids packaged for retail trade: Flucold-N №200, tablets”. Also here is all batches of this medicines and quantity of packages, brand – Flucold, country of manufacture – IN (India), manufacturer - Nabros Pharma Privated Limited. At number 2 information on the number of cargo spaces is indicated – “722 places”. Under number 3, as in box 19 of the MD-2 is "1", there is information about the containers – “1/SEGU9467572/233/1” (Annex A).

Customs clearance is done by officials of the customs authorities of the State Fiscal Service of Ukraine, necessary for the release of goods, including medicines.

At the same time, customs formalities are understood as a set of actions to be performed by the relevant officials and customs authorities in order to comply with the requirements of the Ukrainian legislation Ukraine on state customs matters.

There is the procedure import of medicines in accordance with the customs declaration MD UA100400/2020/119402, which was submitted for customs clearance by the declarant Mikhalchuk O. V.

The first stage of customs procedures is the customs control of medicines imported into the customs territory of Ukraine in the import regime according to the customs declaration MD UA100400/2020/119402 (Annex A).

There is the weight of the container №SEGU9467572/233/1 and medicines moving in it when medicines imported to the Ukrainian customs territory. The weight control was carried out once at the checkpoint through the state control of Ukraine (point of import into the customs territory of Ukraine) - customs post "Odessa-Central", checkpoint "Odessa Sea Commercial Port" of Odessa Customs of the State Fiscal Service of Ukraine. This corresponds to the customs entry code UA500040 in box 29 of the MD UA100400/2020/119402.

Further customs clearance and customs control of the batch of the medicines was carried out by an official of the customs clearance department №4 on the customs post "Kyiv-Skhidnyi" by checking the documents and information submitted for customs control and customs clearance - documentary control.

Registration begins after submission of all documents together with the customs declaration of MD UA100400/2020/119402. The accredit person of the customs clearance department №4 "Kyiv-Skhidnyi" performs the following customs formalities when carrying out customs clearance of the customs declaration:

1) checks compliance with the deadlines for filing a customs declaration;

2) checks the presence of marks on the completion of the movement of medicines across the customs border of Ukraine;

3) control the comparison of data contained in the electronic copy of the customs declaration and documents submitted for customs clearance;

The control of data comparison is carried out by comparing the details of the authorized bank specified in box 28 with the data contained in the list of authorized banks of Ukraine in the Unified Automated Information System (UAIS) of the customs authorities of Ukraine. The exchange rate is determined by filing a customs declaration MD UA100400 / 2020/119402. In this case, the exchange rate as of 22.10.2020 was 28 27370000, and the total amount on the account - 214434,00 USD.

The availability of information in the documents used in the calculation of the customs value of medicines in box 12, box 20, box 22, box 31 of the customs declaration MD UA100400 / 2020/119402 and invoice EXP / 40 / 20-21 from 18.09.2020 during the verification customs value (Annex B).

Then the official of the customs clearance department №4 "Kyiv-Skhidnyi" checks the correctness of the classification of medicines, which is carried out by checking the compliance of the description of this product in box 31 and 33 of the customs declaration MD UA100400/2020/119402 (Annex A).

Verification of the correctness of determining the customs value of medicines is carried out by checking the numerical value of the declared customs value of the goods in box 45 of the customs declaration MD UA100400/2020/119402. In this case, the customs value of medicines is 6062842,59 UAH. The official of customs clearance department №4 "Kyiv-Skhidnyi" completes customs registration as a result of performance of all customs procedures at import of medicines according to the customs declaration of MD UA100400/2020/119402

The official of customs clearance department №4 " Kyiv-Skhidnyi " completes customs registration as a result of all customs procedures at medicines import according to the customs declaration of MD UA100400/2020/119402.

Completion of medicines customs clearance is carried out by [48]:

1) affixing in the customs declaration of the MD UA100400/2020/119402 an imprint of the personal number seal. In this case, in the box D/J of the sheet of the form MD-2 the ONP 69/125 from 22.10.2020 is put down;

2) put of a sign on completion of customs clearance and personal seal number of the official customs clearance department division No 4, Customs Post "Kyiv-Skhidnyi", which has completed the customs clearance of medicines according to the customs declaration MD UA100400 / 2020/119402 by means of the Automated system of customs registration to the electronic customs declaration

Thus, customs clearance involves the completion of a set of customs formalities for goods and other items moving across the customs border of Ukraine. In our case, the customs clearance of medicines imported into Ukraine from India in accordance with MD UA100400/2020/119402 dated 22.10.2020, provided for the implementation of such basic customs formalities as the preparation of the declarant LLC "Universal Logistics" the necessary package of documents for customs clearance , declaration of goods on the form SAD form MD-2, determination and control of the correctness of the customs value, verification of the completeness of accrual of customs payments by the official of customs clearance division No 4, Customs Post "Kyiv-Skhidnyi" and other customs formalities, which were completed in full.

CONCLUSIONS AND RECOMMENDATIONS

In the final qualifying paper we have considered the state of world and Ukrainian pharmaceutical market. It was determined the biggest international pharmaceutical companies. In the process of analyze of international trade of medicines, there were the biggest companies in the pharmaceutical market such as Chine Resources National (75,8 billion USD), Johnson & Johnson (71,9 billion USD), Roche Group (52,4 billion USD). The pharmaceutical market is developing rapidly and every year it includes more and more competitors. Analyzing export-import operations, we determined that import overbalances export when we analyzed export-import operations. Thus Ukraine imported medicine on the value of 1,51 billion USD, and exported only on the value of 0,21 billion USD in 2019. The occasions are - rapid growth of the pharmaceutical industry in the world and the high demand of the population for medicines. If we talk about our pharmaceutical market, foreign manufacturer is the lead. But despite of unstable state Ukrainian economy, it has quite major pharmaceutical manufacturers. They provide the Ukrainian market with effective, quality medicines and are visible in the international pharmaceutical market. It is JSC “Pharmak“, Corporation “Arterium” , CJSC “Darnytsia”, Corporation “Yuria-Pharm”, LLC “Pharmaceutical company Zdorovya”.

There was analysed the legislation governing the import of medicines from WTO countries. It was determined that Ukraine uses international legislation (Pharmacopoeia) when it creates Ukrainian legislation and methods of medicines quality control. The Ukrainian Pharmacopoeia is created on the basis of the US Pharmacopoeia and the European Pharmacopoeia. The specification, analytics and methods of quality control for medicines are created according to these documents. The certificate of quality is a confirmation of medicines required quality.

There was done identification of the batch of the medicine “Flucold” imported by Indian pharmaceutical companies Dr. Reddy’s Laboratories. In process of analyze we saw that this product complies with the statutory requirements and is serviceable for continued treatment of people. We identify that Flucold rank to the particular

commodity group and have such code: 3004490000. Also, this paper includes the criteria and methods of identification of medicines that separate as general and specific. The results of medicines expert examination by main indicators include: product name – Flucold, type of product – medicines, classification Group – 3004490000, Pharmaceutical group – generics, pharmaceuticals form – tablets, active substance – paracetamol.

In the process of analyzing tariff regulation of medicines it showed that medicines have the duty rate – 0% and VAT rate – 7%. Such rate of duty shows that Ukrainian pharmaceutical market need medicines for our human. Analyzing non-tariff regulation showed that medicines are subject of strict control. The import of medicines takes time and some measures. Non-tariff measures include licensing, phytosanitary control. Also, the medicines must be entered in the State Register of Medicinal Products.

The assortment of medicines imported into Ukraine and sold on domestic market is analyzed. The most popular medicines are – Nurofen, Nimisil, Noshpa, Essentiale, Spasmalgon, Sinupret. The largest importers of medicines are Germany, Italy and France. But India, as a WTO country, also has a significant share of its medicines in the Ukrainian pharmaceutical market. The most famous Indian companies in Ukraine – LLC "Cipla ", LLC "Nabros Pharma", LLC "Natco Pharma", LLC "Dr. Reddy's Laboratories". LLC "Dr. Reddy's Laboratories" is an representative of medicines produced by this company in the Ukrainian pharmaceutical market. All this medicines that are imported from WTO countries are divided into prescription and non-prescription. Prescription medicines include Omez", "Cetrine", "Nise", "Flucold" and non-prescription – "Vicks" and "Nasivin", "Ketorol". Therefore, Ukraine has a wide range of medicines, which confirms this analysis.

Customs clearance of medicines was analyzed. The object of the reserch was medicines "Flucold-N tablets" which was imported by LLC "Dr. Reddy's Laboratories". Determine the country of origin of medicines an important stage of customs clearance. As customs clearance was in import regime, the country of origin

of medicines was not determined, the country of manufacturer (India) was specified in customs declaration UA100400/2020/119402. The determination of the customs value and calculation of all customs payments were analyzed. Documents were submitted for analysis: customs declaration, supply agreement, invoice and other documents for customs clearance. All batches of the medicines had the same price – 11, 00 USD in accordance with the supply agreement. The total quantity of medicines was 19494 packs. The facture value was - 214434,00 US dollars according to the invoice EXP / 40 / 20-21 from 18.09.2020. The customs value was calculated 6062842.59 UAH. As the duty rate was 0% so 0 UAH was charged as import duty. The VAT rate was 7% and the amount was 424398,98 UAH.

There was described the customs clearance of medicines “Flucold-N tablets”. After analyzing all the documents, customs clearance carried out correctly. There is the procedure import of medicines in accordance with the customs declaration MD UA100400/2020/119402 dated 22.10.2020, which was submitted for customs clearance by the declarant Mikhalchuk O. V. Customs clearance involves the completion of a set of customs formalities for goods and other items moving across the customs border of Ukraine. The customs clearance of medicines imported to Ukraine from India in accordance with MD UA100400/2020/119402 dated 22.10.2020, provided for the implementation of such basic customs formalities as the preparation of the declarant LLC "Universal Logistics" the necessary package of documents for customs clearance. The control is done by the official of customs clearance division No 4, Customs Post "Kyiv-Skhidnyi" were completed in full. Therefore, all the requirements were met when medicines “Flucold- N tablets” was imported. So, this product has the right to occupy the Ukrainian pharmaceutical market and can be in free circulation.

The conducted researches allow us to make the following recommendations:

– The Ukrainian government should fund our Ukrainian pharmaceutical manufacturers to develop and produce new effective medicines. It can prevent the emergence of poor quality medicines in the Ukrainian pharmaceutical market that can be imported from WTO countries;

– The customs authorities should pay more attention to imported medicines, because counterfeit medicines can be imported under the names of other products. Such medicines are not registered in Ukraine and can be imported even by individuals as hand luggage;

– Ministry of Health of Ukraine should strengthen control over the registration of medicines and minimize the risks of counterfeit medicines on the Ukrainian pharmaceutical market.

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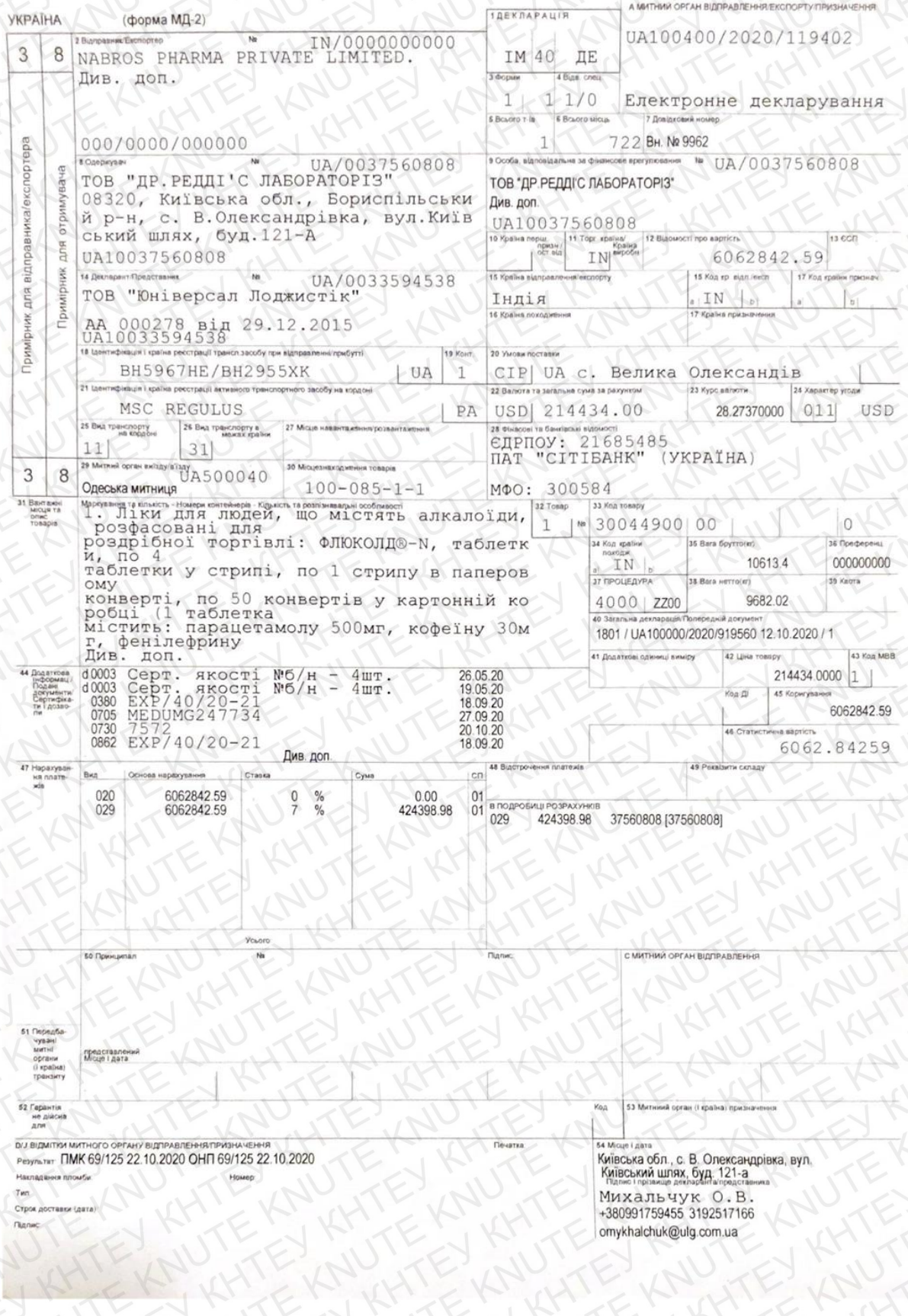
ANNEXES

ANNEX A

Customs declaration UA100400/2020/119402



УКРАЇНА (форма МД-2)

1 ДЕКЛАРАЦІЯ: IM 40 ДЕ

A МИТНИЙ ОРГАН ВІДПРАВЛЕННЯ/ЕКСПОРТУ/ПРИЗНАЧЕННЯ: UA100400/2020/119402

3 Форми: 1 1 1/0 — Електронне декларування

5 Всього т.ів: 1 — 6 Всього місць: 722 — 7 Довідковий номер: Вн. № 9962

Примірник для відправника/експортера / Примірник для отримувача

3 8

2 Відправник/Експортер № IN/0000000000
NABROS PHARMA PRIVATE LIMITED.
Див. доп.

000/0000/000000

8 Одержувач № UA/0037560808
ТОВ "ДР.РЕДДІ'С ЛАБОРАТОРІЗ"
08320, Київська обл., Бориспільський р-н, с. В.Олександрівка, вул.Київський шлях, буд.121-А
UA10037560808

9 Особа, відповідальна за фінансове врегулювання № UA/0037560808
ТОВ "ДР.РЕДДІ'С ЛАБОРАТОРІЗ"
Див. доп.
UA10037560808

14 Декларант/Представник № UA/0033594538
ТОВ "Юніверсал Лоджистік"
АА 000278 від 29.12.2015
UA10033594538

10 Країна перш. призн./ост. від: — 11 Торг. країна/Країна виробн.: IN — 12 Відомості про вартість: 6062842.59 — 13 ЄСП

15 Країна відправлення/експорту: Індія — 15 Код кр. відпр./експ.: a IN b — 17 Код країни призначення: a b

16 Країна походження — 17 Країна призначення

18 Ідентифікація і країна реєстрації транспортного засобу при відправленні/прибутті: BH5967HE/BH2955XK | UA — 19 Конт.: 1

20 Умови поставки: CIP | UA с. Велика Олександів

21 Ідентифікація і країна реєстрації активного транспортного засобу на кордоні: MSC REGULUS | PA

22 Валюта та загальна сума за рахунком: USD 214434.00 — 23 Курс валюти: 28.27370000 — 24 Характер угоди: 011 USD

25 Вид транспорту на кордоні: 11 — 26 Вид транспорту в межах країни: 31 — 27 Місце навантаження/розвантаження

28 Фінансові та банківські відомості:
ЄДРПОУ: 21685485
ПАТ "СІТІБАНК" (УКРАЇНА)
МФО: 300584

3 8

29 Митний орган виїзду/в'їзду: UA500040 Одеська митниця — 30 Місцезнаходження товарів: 100-085-1-1

31 Вантажні місця та опис товарів: Маркування та кількість - Номери контейнерів - Кількість та розпізнавальні особливості
1. Ліки для людей, що містять алкалоїди, розфасовані для роздрібної торгівлі: ФЛЮКОЛД®-N, таблетки, по 4 таблетки у стрипі, по 1 стрипу в паперовому конверті, по 50 конвертів у картонній коробці (1 таблетка містить: парацетамолу 500мг, кофеїну 30мг, фенілефрину
Див. доп.

32 Товар: 1 — 33 Код товару: № 30044900 00 0

34 Код країни походж.: a IN b — 35 Вага брутто(кг): 10613.4 — 36 Преференц.: 000000000

37 ПРОЦЕДУРА: 4000 ZZ00 — 38 Вага нетто(кг): 9682.02 — 39 Квота

40 Загальна декларація/Попередній документ: 1801 / UA100000/2020/919560 12.10.2020 / 1

41 Додаткові одиниці виміру — 42 Ціна товару: 214434.0000 | 1 — 43 Код МВВ

Код ДІ — 45 Коригування: 6062842.59

46 Статистична вартість: 6062.84259

44 Додаткова інформація / Подані документи / Сертифікати і дозволи

d.0003	Серт. якості №б/н - 4шт.	26.05.20
d.0003	Серт. якості №б/н - 4шт.	19.05.20
0380	EXP/40/20-21	18.09.20
0705	MEDUMG247734	27.09.20
0730	7572	20.10.20
0862	EXP/40/20-21	18.09.20

Див. доп.

47 Нарахування платежів

Вид	Основа нарахування	Ставка	Сума	СП
020	6062842.59	0 %	0.00	01
029	6062842.59	7 %	424398.98	01
Усього				

48 Відстрочення платежів — 49 Реквізити складу

В ПОДРОБИЦІ РОЗРАХУНКІВ
029 424398.98 37560808 [37560808]

50 Принципал № — Підпис — C МИТНИЙ ОРГАН ВІДПРАВЛЕННЯ

51 Передбачувані митні органи (і країна) транзиту

представлений
Місце і дата

52 Гарантія не дійсна для — Код — 53 Митний орган (і країна) призначення

D/J ВІДМІТКИ МИТНОГО ОРГАНУ ВІДПРАВЛЕННЯ/ПРИЗНАЧЕННЯ — Печатка

Результат: ПМК 69/125 22.10.2020 ОНП 69/125 22.10.2020

Накладання пломби — Номер

Тип

Строк доставки (дата)

Підпис

54 Місце і дата
Київська обл., с. В. Олександрівка, вул. Київський шлях, буд. 121-а
Підпис і прізвище декларанта/представника
Михальчук О.В.
+380991759455 3192517166
omykhalchuk@ulg.com.ua

Continuation of ANNEX A

1

до ВМД №

UA100400/2020/119402

До графи 2:
3RD FLOOR, ORIENTAL HOUSE II, OPPOSITE ART GALARY, BEHIND BRITISH LIBRARY,
LAW GARDEN, ELLIS BRIDGE, AHMEDABAD-380 006, Індія

До графи 9:
08320, Київська обл., Бориспільський р-н, с. В.Олександрівка, вул.Київський
шлях, буд.121-А

Товар № 1 до графи 31:
гідрохлориду 5мг, хлорфеніраміну малеату
2мг)
серія FB0451-2 438уп., серія FB0452-2 439уп.,
серія FB0453-2 436уп., серія FB0454-2 434уп.,
серія FB0455-2 438уп., серія FB0456-2 437уп.,
серія FB0457-2439уп., серія FB0458-2433уп.
Торгівельна марка: ФЛЮКОЛД
Країна виробництва: IN
Виробник: Наброс Фарма Пвт.Лтд
Див. "електронний інвойс"
2. Місць - 722 CT/722
3. 1/SEGU9467572/233/1

Товар № 1 до графи 44:

4103	Додаток II	01.06.20
4104	2020-06-01/NPPL	01.06.20 31.08.24
d4203	12	28.12.18 31.12.21
d4207	405	07.10.14
5069		
9610	5327558	21.09.20
d9904	UA/6266/01/01	27.04.17

ВІДМІТКИ МИТНОГО ОРГАНУ ВІДПРАВЛЕННЯ/ПРИЗНАЧЕННЯ

Печатка

Місце і дата

Київська обл., с. В. Олексан
івка, вул. Київський шлях, б

Підпис і прізвище декларанта/представника

Михальчук О.В.
+380991759455 3192517166
omykhalchuk@ulg.com.ua

ANNEX B

Invoice № EXP/40/20-21

INVOICE

EXPORTER :
M/S. NABROS PHARMA PVT. LTD.
3RD FLOOR, ORIENTAL HOUSE II,
OPP. ART GALARY,
B/H BRITISH LIBRARY, LAW GARDEN,
ELLISBRIDGE, AHMEDABAD - 380006, INDIA

Invoice No. & Date
EXP/40/20-21
DATED 18/09/2020

Exporter's Ref. :
IEC NO. 0891001859
PAN NO. AAACN7886N
GSTIN NO:24AAACN7886N1ZS

Buyer's Order No. & Date :
SUPPLY AGREEMENT NO. 2020-06-01/NPPL DATED 01.06.2020

Other Reference(s)
PURCHASE ORDER NO. 11 DATED 16.09.2020

CONSIGNEE :
LLC"DR.REDDY'S LABORATORIES"
121A,KYIVSKIY SHLYAKH STR,
VELYKA OLEXANDRIVKA VILLAGE ,
BORYSPIL DISTRICT,KIEV REGION
UKRAINE 08320

Buyer (if other than consignee)

TEMPERATURE NOT EXCEEDING 25°C. (BETWEEN 15°C TO 25°C)

Pre Carriage By	Place of Receipt by pre-carrier
By SEA	ICD,AHMEDABAD
Vessel/Flight NO.	**Port of Loading**
MSC REGULUS V.IS038R	MUNDRA, INDIA
Port of Discharge	**Place of Delivery**
ODESSA, UKRAINE	KIEV, UKRAINE

Country of Origin	Country of Final Destination
INDIA	UKRAINE

Terms of Delivery and Payment
D.A 120 DAYS FROM THE DATE OF CUSTOMS CLEARANCE
CIP SEA KIEV/UKRAINE

Marks & No. / Container No.	No. & Kind of Packages	Description of goods
LLC"DR.REDDY'S LABORATORIES" KIEV/UKRAINE	01-722 CARTONS	**Flucold®-N tablets N200** Each Tablet Contains: Paracetamol B.P..... 500 Mg Caffine B.P. .....30 Mg Phenylephrine HCL BP .....5mg Chlorpheniramine Maleate B.P..2 Mg Batch No.: FB0451 TO FB0458 Mfg. Dt. : 04/2020 Exp. Dt. : 03/2024 **H.S.CODE:30044920**
CTN No. : 1 - 722 CONTAINER NO:SEGU9467572		

Batch Nos.	Quantity	Rate CIP USD	Amounts CIP USD
FB0451	2438	11.00	26818.00
FB0452	2439	11.00	26829.00
FB0453	2436	11.00	26796.00
FB0454	2434	11.00	26774.00
FB0455	2438	11.00	26818.00
FB0456	2437	11.00	26807.00
FB0457	2439	11.00	26829.00
FB0458	2433	11.00	26763.00
	19494		

NET WEIGHT : 9682.020 KGS.
GROSS WEIGHT: 10613.400 KGS.
NET WEIGHT OF TABLETS: 2534.220 KGS.

AMOUNT CHARGEBLE: (in words) TOTAL CIP USD: TWO HUNDRED FOURTEEN THOUSAND FOUR HUNDRED THIRTY FOUR ONLY.

TOTAL CIP USD BY SEA **214434.00**

SDF NO:5327558 DATED 21.09.2020
S/B NO:5327558 DATED 21.09.2020
SEA WAYBILL NO:MEDUMG247734 DATED 27.09.2020

We declare that this Invoice shows the actual price of the goods described and that all the particulars are true and correct.

Signature & Date:
FOR, NABROS PHARMA PVT. LTD.
KAVIT SHAH
DIRECTOR

ANNEX C

Packing List EXP/40/20-21

PACKING LIST

EXPORTER :
M/S. NABROS PHARMA PVT. LTD.
3RD FLOOR, ORIENTAL HOUSE II,
OPP. ART GALARY,
B/H BRITISH LIBRARY, LAW GARDEN,
ELLISBRIDGE, AHMEDABAD - 380006, INDIA

Invoice No. & Date
EXP/40/20-21
DATED 18/09/2020

Exporter's Ref. :
IEC NO. 0891001859
PAN NO. AAACN7886N
GSTIN NO:24AAACN7886N1ZS

Buyer's Order No. & Date :
SUPPLY AGREEMENT NO. 2020-06-01/NPPL DATED 01.06.2020

Other Reference(s)
PURCHASE ORDER NO. 11 DATED 16.09.2020

CONSIGNEE :
LLC"DR.REDDY'S LABORATORIES"
121A,KYIVSKIY SHLYAKH STR,
VELYKA OLEXANDRIVKA VILLAGE ,
BORYSPIL DISTRICT,KIEV REGION
UKRAINE 08320

Buyer (if other than consignee)

Pre Carriage By	Place of Receipt by pre-carrier	Country of Origin	Country of Final Destination
By SEA	ICD, AHMEDABAD	INDIA	UKRAINE
Vessel/Flight NO. MSC REGULUS V.IS038R	**Port of Loading** MUNDRA, INDIA		
Port of Discharge ODESSA, UKRAINE	**Place of Delivery** KIEV, UKRAINE		

Marks & No. / Container No.	No. & Kind of Packages	Description of goods	Quantity
LLC"DR.REDDY'S LABORATORIES" KIEV/UKRAINE CTN No. : 1 - 722 CONTAINER NO:SEGU9467572	01-722 CARTONS	**Flucold®-N tablets N200** Each Tablet Contains: Paracetamol B.P..... 500 Mg Caffine B.P. .....30 Mg Phenylephrine HCL BP .....5mg Chlorpheniramine Maleate B.P..2 Mg Batch No.: FB0451 TO FB0458 Mfg. Dt. : 04/2020 Exp. Dt. : 03/2024 **H.S.CODE:30044920**	19494 X 50 X 4 TABS.

NET WEIGHT : 9682.020 KGS.
GROSS WEIGHT: 10613.400 KGS.
NET WEIGHT OF TABLETS: 2534.220 KGS.

PACKING DETAILS: FLUCOLD®-N TABLETS N200

BATCH NO.	CARTON NOS.	PACKING	QUANTITY
FB0451	01 TO 90	90 X 27 X 50 X 4	= 2430 X 50 X 4 TABS.
FB0452	91 TO 180	90 X 27 X 50 X 4	= 2430 X 50 X 4 TABS.
FB0453	181 TO 270	90 X 27 X 50 X 4	= 2430 X 50 X 4 TABS.
FB0454	271 TO 360	90 X 27 X 50 X 4	= 2430 X 50 X 4 TABS.
FB0455	361 TO 450	90 X 27 X 50 X 4	= 2430 X 50 X 4 TABS.
FB0456	451 TO 540	90 X 27 X 50 X 4	= 2430 X 50 X 4 TABS.
FB0457	541 TO 630	90 X 27 X 50 X 4	= 2430 X 50 X 4 TABS.
FB0458	631 TO 720	90 X 27 X 50 X 4	= 2430 X 50 X 4 TABS.
FB0451	721	01 X 27 X 50 X 4	= 08 X 50 X 4 TABS.
FB0452			= 09 X 50 X 4 TABS.
FB0453			= 06 X 50 X 4 TABS.
FB0454			= 04 X 50 X 4 TABS.
FB0455	722	01 X 27 X 50 X 4	= 08 X 50 X 4 TABS.
FB0456			= 07 X 50 X 4 TABS.
FB0457			= 09 X 50 X 4 TABS.
FB0458			= 03 X 50 X 4 TABS.
		TOTAL	**= 19494 X 50 X 4 TABS.**

NOTE: DATA LOGGER PLACED AT CORRUGATED BOX NO: 174/722

DATA LOGGER NO. 4611848219

FOR, NABROS PHARMA PVT. LTD.

VIJAY SHAH
DIRECTOR

ANNEX D

Sea Waybill №MEDUMG247734

See website for Large version of the reverse | Ver página Web para letra nos y condiciones | Смотрите веб-сайт для ознакомления с условиями и положениями | 提单的英文和条件请见网站 | www.msc.com

MEDITERRANEAN SHIPPING COMPANY S.A.
12-14, chemin Rieu, 1208 GENEVA, Switzerland
Website : www.msc.com
SCAC Code: MSCU

SEA WAYBILL No. MEDUMG247734
NOT-NEGOTIABLE
"Port-to-Port" or "Combined Transport" (see Clause 1)

NO. & SEQUENCE OF ORIGINAL B/L's	NO. OF RIDER PAGES
1/1	0

SHIPPER
M/S. NABROS PHARMA PVT. LTD.
3RD FLOOR,ORIENTAL HOUSE II
OPP,ART GALARY,
B/H.BRITISH LIBRARY,LAW GARDEN,
ELLISHBRIDGE, AHMEDABAD-380 006,(IN

CONSIGNEE This B/L is not negotiable unless marked "To Order" or "To Order of..." here.
LLC"DR.REDDY'S LABORATORIES"
121A,KYIVSKIY SHLYAKH STR,
VELYKA OLEXANDRIVKA VILLAGE,BORYSPIL
DISTRICT,KIEV REGION,UKRAINE 08320

NOTIFY PARTIES (No responsibility shall attach to the Carrier or to his Agent for failure to notify - see Clause 20)
LLC"DR.REDDY'S LABORATORIES"
121A,KYIVSKIY SHLYAKH STR,
VELYKA OLEXANDRIVKA VILLAGE,BORYSPIL
DISTRICT,KIEV REGION,UKRAINE 08320

CARRIER'S AGENTS ENDORSEMENTS (Include Agent(s) at POD)
PORT OF DISCHARGE AGENT ADDRESS
MSC ODESSA
MSC Ukraine Limited Liability Company 5, Lidersovskiy blvd,
Tel:+380 48 784 7272,Fax:+380 48 784 7274
EMAIL:UA539-odessa@msc.com
FCL/FCL
Lloyds / IMO Number = 9465291
DEMURRAGE / DETENTION IF ANY AS PER LINE TARIFF
FREE IN FREE OUT

VESSEL & VOYAGE NO. (see Clauses 8 & 9)	PORT OF LOADING	PLACE OF RECEIPT (Combined Transport ONLY - see Clauses 1 & 5.2)
MSC REGULUS V. IS038R	MUNDRA, INDIA	AHMEDABAD
BOOKING REF. (or) **SHIPPER'S REF**	**PORT OF DISCHARGE**	**PLACE OF DELIVERY** (Combined Transport ONLY - see Clauses 1 & 5.2)
363IN2042680920 XXXXX	ODESSA, UKRAINE	KIEV

PARTICULARS FURNISHED BY THE SHIPPER - NOT CHECKED BY CARRIER - CARRIER NOT RESPONSIBLE (see Clause 14)

Container Numbers, Seal Numbers and Marks	Description of Packages and Goods (Continued on attached Bill of Lading Rider page(s), if applicable)	Gross Cargo Weight KGS	Measurement CBM
	1X40' CNTR(S) S.T.C		
	SHIPPER'S LOAD STOW COUNT		
SEGU9467572/40HR	722 Carton	10613.400	49.1800
CARRIER SEAL/FX13199199	PHARMACEUTICALS PRODUCT		
CUSTOMS SEAL/180167	FLUCOLD-N TABLET - 19494X50X4 TABS.		
Tare Wt :4540	AS PER SUPPLY AGREEMENT NO.2020-06-01/NPPL DATED		
LLC"DR.REDDY'S	01.06.2020		
LABORATORIES"	S/B NO:5327558 DATED 21.09.2020		
KIEV,UKRAINE	NET WEIGHT: 9682.020 KGS.		
	V/S-7214203		
	"THE TEMPERATURE TO BE SET AT 22 DEGREE CELCIUS		
	IN ACCORDANCE WITH SHIPPER'S INSTRUCTION"		
	TEMPERATURE SET POINT: +22C		
	Temperature Set Point : +22C		
Total Tare wgt. 4540 KGS	Total No.of Items 722 Total Gross wgt. 10613.400 KGS Total Volume. 49.1800 CBM		

FREIGHT & CHARGES Cargo shall not be delivered unless Freight & Charges are paid (see Clause 16)

FREIGHT PREPAID

RECEIVED by the Carrier in apparent good order and condition (unless otherwise stated herein) the total number or quantity of Containers or other packages or units indicated in the box entitled Carrier's Receipt for carriage subject to all the terms and conditions hereof from the Place of Receipt or Port of Loading to the Port of Discharge or Place of Delivery, whichever is applicable. IN ACCEPTING THIS BILL OF LADING THE MERCHANT EXPRESSLY ACCEPTS AND AGREES TO ALL THE TERMS AND CONDITIONS, WHETHER PRINTED, STAMPED OR OTHERWISE INCORPORATED ON THIS SIDE AND ON THE REVERSE SIDE OF THIS BILL OF LADING AND THE TERMS AND CONDITIONS OF THE CARRIER'S APPLICABLE TARIFF AS IF THEY WERE ALL SIGNED BY THE MERCHANT.

If this is a negotiable (To Order / of) Bill of Lading, one original Bill of Lading, duly endorsed must be surrendered by the Merchant to the Carrier (together with outstanding Freight and charges) in exchange for the Goods or a Delivery Order. If this is a non-negotiable (straight) Bill of Lading, the Carrier shall deliver the Goods or issue a Delivery Order (after payment of outstanding Freight and charges) against the surrender of one original Bill of Lading or in accordance with the national law at the Port of Discharge or Place of Delivery whichever is applicable.

IN WITNESS WHEREOF the Carrier or their Agent has signed the number of Bills of Lading stated at the top, all of this tenor and date, and wherever one original Bill of Lading has been surrendered all other Bills of Lading shall be void.

DECLARED VALUE (only applicable if Ad Valorem Charges paid - see Clause 7.3)	CARRIER'S RECEIPT (No. of Cntrs or Pkgs rcvd by Carrier - see Clause 14.1)	SIGNED on behalf of the Carrier MSC Mediterranean Shipping Company S.A.
XXXXX	1 CNTR	For MSC AGENCY (INDIA) PVT. LTD.
PLACE AND DATE OF ISSUE	**SHIPPED ON BOARD DATE**	As AGENTS
AHMEDABAD, INDIA 27-SEP-2020	27-SEP-2020	For CARRIER MSC MEDITERRANEAN SHIPPING CO.S.A

Standard Edition - 02/2015

TERMS CONTINUED ON REVERSE

363

A 329046418

ANNEX F

Certificate of registration №UA/6266/01/01

МІНІСТЕРСТВО ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ

м. Київ

РЕЄСТРАЦІЙНЕ ПОСВІДЧЕННЯ
НА ЛІКАРСЬКИЙ ЗАСІБ

№UA/6266/01/01

Рішення про державну ***перереєстрацію*** лікарського засобу затверджене наказом МОЗ України від **27.04.2017 № 476.**

Згідно зі статтею 9 Закону України "Про лікарські засоби" та постановою Кабінету Міністрів України від 26 травня 2005 року № 376 "Про затвердження Порядку державної реєстрації (перереєстрації) лікарських засобів і розмірів збору за їх державну реєстрацію (перереєстрацію)"

лікарський засіб

ФЛЮКОЛД®-N,

таблетки

перереєстрований в Україні **безстроково.**

Термін дії реєстраційного посвідчення на території України **необмежений.**

Зобов'язання при видачі реєстраційного посвідчення існують – надання детального опису системи управління ризиками у вигляді плану управління ризиками до 30.10.2017 відповідно до підпункту 1.13 пункту 1 додатку 15 до Порядку проведення експертизи реєстраційних матеріалів на лікарські засоби, що подаються на державну реєстрацію (перереєстрацію), а також експертизи матеріалів про внесення змін до реєстраційних матеріалів протягом дії реєстраційного посвідчення, затвердженого наказом МОЗ від 26.08.2005 № 426 (у редакції наказу МОЗ із 23.07.2015 № 460).

Періодичність подання регулярно оновлюваного звіту з безпеки відповідно до Порядку здійснення нагляду за побічними реакціями лікарських засобів, дозволених до медичного застосування, затвердженого наказом МОЗ від 27 грудня 2006 року №898, зареєстрованого в Міністерстві юстиції України 29 січня 2007 року за №73/13340, становить: відповідно до періодичності складання регулярно оновлюваного звіту з безпеки лікарського засобу, дозволеного до медичного застосування, на центральному рівні.

Заявник та його місцезнаходження

Наброс Фарма Пвт. Лтд.
Наброс Хаус, 3-й поверх, позаду Брітіш Лайбрері, навпроти Арт Галері, Лоу Гарден, Еллісбрідж, Ахмедабад - 380006, Гуджарат, Індія
Nabros Pharma Pvt. Ltd.
Nabros House, 3rd Floor, Behind British Library, Opp, Art Galary, Law Garden, Ellisbridge, Ahmedabad - 380006, Gujarat, India

Реєстраційне посвідчення оформлене 03.05.2017.

РП 021342

Continuation of ANNEX F

ІНФОРМАЦІЯ ПРО ЛІКАРСЬКИЙ ЗАСІБ

Назва лікарського засобу: **ФЛЮКОЛД®-N**

Лікарська форма, дозування:

таблетки

Шлях введення: *пероральний*

Код АТХ: *N02B E51*

Показання:

симптоматичне лікування застуди та грипу, що супроводжуються підвищеною температурою тіла, ознобом, головним болем, нежитем та закладеністю носа, чханням, ломотою та болем у тілі

Вид, розмір та комплектність упаковки:

по 4 таблетки у стрипі; по 1 стрипу в паперовому конверті з маркуванням українською та англійською мовами;
по 4 таблетки у стрипі; по 3 стрипи у картонній коробці з маркуванням українською та англійською мовами;
по 4 таблетки у стрипі; по 1 стрипу в паперовому конверті; по 50 конвертів у картонній коробці з маркуванням українською та англійською мовами

Термін придатності: *4 роки*

Виробник(и) лікарського засобу:

Наброс Фарма Пвт. Лтд.
Сьорвей № 110/А/2 Амітт Фарм, Джейн Упасря, поблизу заводу Кока Кола, Н.Х. № 8, Каджіпура -387411, Кхеда, Індія
Nabros Pharma Pvt. Ltd.
Survey No. 110/A/2 Amit Farm, Jain Upasrya, Near Coca Cola Factory, N.H. No. 8, Kajipura - 387411, Kheda, India

Continuation of ANNEX F

ВИСНОВКИ
ПРО ЯКІСНИЙ ТА КІЛЬКІСНИЙ СКЛАД
ЛІКАРСЬКОГО ЗАСОБУ

1. Назва лікарського засобу, лікарська форма, дозування:

ФЛЮКОЛД®-N,

таблетки

2. Якісний та кількісний склад лікарського засобу:

Діючі речовини:

1 таблетка містить: парацетамолу 500 мг, кофеїну 30 мг, фенілефрину гідрохлориду 5 мг, хлорфенірамінy малеату 2 мг

Допоміжні речовини:

крохмаль кукурудзяний, натрію крохмальгліколят (тип А), тальк, желатин, магнію стеарат, сорбіту розчин (Е 420), Повідон К-30, натрію бензоат (Е 211), барвник Понсеау 4R (Е 124), вода очищена

Начальник Управління
фармацевтичної діяльності та
якості фармацевтичної продукції Т.М. Лясковський

ANNEX G

Supply Agreement 2020-06-01/NPPL

ДоговірПоставки №2020-06-01/NPPL	Supply Agreement 2020-06-01/NPPL
Цей договір поставки ("Договір Поставки") вступає в дію 1 Червня 2020 року м**іж:** **ТОВ «Др. Редді'с Лабораторіз»**, компанія, що зареєстрована та діє згідно із законодавством України, у подальшому іменується «**ПОКУПЕЦЬ»**, в особі Генерального директора Аруна Прсада М.С., що діє на підставі Статуту з однієї сторони, та **Наброс Фарма Прайват Лімітед**,компанія, що зареєстрована та діє згідно із законодавством Індії, у подальшому іменується «**ПОСТАЧАЛЬНИК»**в особі Директора Кавіт Шах, що діє на підставі статуту,в подальшому разом іменовані «Сторони», уклали цей Договір Поставки про наступне:	This supply agreement ("Supply Agreement") is executed on 1 June 2020 by and between: **LLC Dr. Reddy's Laboratories**, a company duly registered and acting under the laws of Ukraine, hereinafter referred to as "**the PURCHASER**" represented by the General Director Arun Prasad M.S., acting on the basis of Statute on the one hand, and **Nabros Pharma Private Limited**,a company duly registered and acting under the laws of India, further referred to as "**the SUPPLIER**" represented by the Director Kavit Shah acting on the basis of the charter, hereinafter jointly referred to as "Parties",has entered into this Supply Agreement regarding the following:
ВИЗНАЧЕННЯ У цьому Договорі Поставки наступні слова вирази використовуються у наступних значеннях (слова, що стосуються однини означають і множину і навпаки, якщо контекст не вимагає іншого): **Готовий Продукт** - означає готову Продукцію, марковану та упаковану в пакувальні матеріали згідно чинного законодавства на Території для дистрибуції та продажу. **Дистрибуційні права** - означає права на маркетинг, продаж, просування і дистрибуцію Продуктів на Території. **Продукти або Продукція –** означає лікарські засоби, дієтичні добавки та косметичні засоби, зазначені у Прайс-листі, що є Додатком І до цього Договору Поставки. Якщо у цьому Договорі Поставки визначено вимоги до Продукції, то ці вимоги стосуються виключно лікарських засобів, окрім випадків коли такі ж самі вимоги або аналогічні можуть стосуватись біологічних добавок та косметичних засобів. **Належна Виробнича Практика (GMP)** - частина системи забезпечення якості, яка	**DEFINITIONS** In this Supply Agreement the following words and expressions shall have the following meaning (it being understood that words denoting the singular include the plural and vice versa, all of it unless the context otherwise requires): **Finished Product** - means the finished Product labelled and packaged in the Packaging Materials according to effective legislation in the Territory for distribution and sale. **Distribution rights** - means rights for marketing, sale, promotion and distribution of the Products in the Territory. **Products**– means the medicines, dietary supplements and cosmetics specified in Price-list in Annexure I to this Supply Agreement. In case this Supply Agreement contains requirements to Products, such requirements are applicable to medicines only, unless where such requirements or similar requirements may be applicable to food supplements and cosmetics. **Good Manufacturing Practices (GMP)** - a part of quality assurance system which ensures that medicinal products are persistently

вузлах. ПОСТАЧАЛЬНИК має гарантувати, що транспортні засоби та обладнання, використовувані для поставки, відповідають своєму призначенню та були належним чином обладнаними для запобігання впливу на Продукцію умов, що могли б завдати шкоди її якості та цілості пакування." 2.11. Маркетинг: Сторони домовились, що ПОСТАЧАЛЬНИК, під час дії цього Договору поставки, інвестує кошти в маркетингові кампанії з просування певних товарів, як це визначено в Додатках до цього Договору на поставку. 2.12. Безкоштовні зразки. Сторони домовилися, що ПОСТАЧАЛЬНИК надаватиме щорічні безкоштовні зразки для конкретних Продуктів, як це передбачено в Додатках.	their mission and are properly equipped for preventing impact on production conditions, which could harm the quality and integrity of the packaging." 2.11. Marketing: The Parties agreed that the SUPPLIER, during term of this Supply agreement,shall invest costs into marketing campaigns to promote certain Products as it is defined in the Annexures to this Supply Agreement. 2.12. Free samples. The Parties agreed that SUPPLIER shall provide on an annual basis free samples for specific Products,as stipulated in the Annexures.
3. ЦІНА ПРОДУКЦІЇ, ТЕРМІНИ ОПЛАТИ ТА ЗАГАЛЬНА ВАРТІСТЬ ЗА ДОГОВОРОМ ПОСТАВКИ 3.1. Ціна Продукції встановлена у доларах США та зафіксована у Додатку II до Договору Поставки. 3.2. Ціна Продукції включає в себе захищену від негоди упаковку, маркування, доставку Продукції до місця призначення, страхування, використання Торгових марок для цілей промоції та дистрибуції Продукції та всі витрати, які несе ПОСТАЧАЛЬНИК на своїй території і під час транспортування Продукції до місця призначення. ПОКУПЕЦЬ сплачує мито, інші збори та всі формальності на території Україні, пов'язані з отриманням Продукції. 3.3. Загальна вартість Договору Поставки складає загальну вартість усієї поставленої Продукції згідно цього Договору Поставки. 3.4. Банківські витрати в банку ПОКУПЦЯ несе ПОКУПЕЦЬ. Банківські витрати в банку ПОСТАЧАЛЬНИКА несе ПОСТАЧАЛЬНИК. 3.5. Платіж за поставлену Продукцію здійснюється прямим банківським переказом у доларах США на рахунок ПОСТАЧАЛЬНИКА відповідно до реквізитів, наведених у цьому Договорі Поставки.	**3.PRICE OF PRODUCTS, TERMS OF PAYMENT AND THE TOTAL VALUE OF THE SUPPLY AGREEMENT** 3.1. Theprice of the Products is set forth inUS Dollars in Annexure II hereto and may be changed by the mutual consent of the Parties. 3.2. The Products' price includes the cost of weatherproof packing, marking, delivery to a place of destination, insurance, use of Trade Marks for the purposes of promotion and distribution of Products and any other expenses borne by the SUPPLIER in its country and during the transportation of Products to the place of destination. The PURCHASER shall pay customs and other duties and all formalities in Ukraine connected with acceptance of the Products. 3.3. The total value of the Supply Agreement is the overall value of all Products supplied hereunder. 3.4. Banking expenses at the PURCHASER's bank are for the account of the PURCHASER. Banking expenses at the SUPPLIER's bank are for the account of the SUPPLIER. 3.5. Payment for the supplied Products shall be affected through a direct bank transfer in USD to the SUPPLIER's account mentioned in this Supply Agreement. Payment shall be effected within 120 (one hundred twenty) days from the date of

Цільові показники, визначені у Додатку II до Договору Поставки щодо цієї Продукції не враховуються у річному обсязі закупівлі Продукції для даного року.	for the purchase plan of Products for that particular year.
2.6.**Умови поставки:** ПОСТАЧАЛЬНИК постачає Продукцію на умовах: **CIP Морем Велика Олександрівка, Київська обл. або CIP АВІА Бориспільський аеропорт** Україна згідно Інкотермс 2010. Доставка та страхування Продукції під час поставки проводиться ПОСТАЧАЛЬНИКОМ.	2.6.**Delivery conditions:** the SUPPLIER shall deliver Products on the one terms **CIP SEA Velyka Oleksandrivka Kyiv region or CIP AIR Boryspil Airport** Ukraine, Incoterms 2010. Delivery and insurance of Products during delivery is carried out by the SUPPLIER.
Право власності на Продукцію та ризики випадкової втрати або шкоди Продукції переходять до ПОКУПЦЯ з моменту митного очищення Товару. Датою поставки Товару вважається дата проставлення штампа «випуск дозволено у вільний обіг» українською митницею на митній декларації.	The title to the Products and risks of accidental loss or damage to the Products shall pass to the PURCHASERfrom the moment of the Products customs clearance. The delivery date of the Products s is considered the date of "delivery is permitted freely" stamp of the Ukrainian customs house on the customs declaration.
Разом із Продукцією, ПОСТАЧАЛЬНИК надає документи, які підтверджують якість Продукції, та інші документи: (a) оригінал рахунку-фактури (2) примірники; (b) оригінал пакувального листа (2) примірники; (c) сертифікати якостіна кожну партію (1)оригінал та (1) копію; (d) оригінал сертифікату походження (із зазначенням країни походження) 1 оригінал; (e) оригінал авіа накладної 3 оригінали або коносамента 1 оригінал; (f) страховий поліс (1) оригінал Якщо для митного оформлення Продукції митні органи України запросять додаткові документи, передбачені законодавством, ПОСТАЧАЛЬНИК зобов'язаний надати такі документи у найкоротший строк, що запитується ПОКУПЦЕМ.	Along with the Products the SUPPLIER shall provide the quality confirming documents and other documents: (a) Invoice (2) originals (b) Packing List (2) originals (c) Certificate of quality for each batch one (1) original and one (1) photocopy (d)Certificate of origin of goods (1) original (e)Bill of Lading (3) originals/ AWB (1) original (f)Insurance Policy (1) original If custom authorities of Ukraine request for additional documents, which are foreseen by legislation, the SUPPLIER is obliged to provide such documents as soon as practically possible in the requested term by the PURCHASER.
2.7.**Повідомлення про відправку:** До кожної поставки додається повідомлення про відправку, де вказано: (a) номер Замовлення ПОКУПЦЯ; (b) кількість Продукції; (c) сертифікат якості англійською та російською або українською мовами, як зазначить ПОКУПЕЦЬ; (d) Умови зберігання Продукції згідно вимог виробника;	2.7. **Advice note:** Each delivery shall be accompanied by an advice note that specifies: (a) the PURCHASER's Order number; (b) quantity of the Product; (c) certificate of quality in English & Russian or Ukrainian as informed by the PURCHASER; (d) Product storage specifications according to requirements of the producer; (e) invoice as provided by the PURCHASER;

Continuation of ANNEX G

DocuSign Envelope ID: 78F308A7-FA86-494C-AB2A-98E0E6A905B5

ДР.РЕДДІ'С ЛАБОРАТОРІЗ ТОВ Тел: +380444923173, Факс: +380444923174 Генеральний Директор Арун Прасад М.С.	DR. REDDY'S LABORATORIES, LLC Tel: +380444923173, Fax: +380444923174 General Director Arun Prasad M.S.
ПОСТАЧАЛЬНИК	**SUPPLIER**
Наброс Фарма Прайвет Лімітед Юридична адреса: **НАБРОС ФАРМА ПРАЙВАТ ЛІМІТЕД.** 3-й поверх, Орієнтал Хауз II, Напроти Арт Галереї, позаду Британської бібліотеки, Ло Гарден, Елліс Брідж, Ахмадабад – 390 006. Індія. Адреса листування: 3-й поверх, Орієнтал Хауз II, Напроти Арт Галереї, позаду Британської бібліотеки, Ло Гарден, Елліс Брідж, Ахмадабад – 380 006. Індія. **Банківські реквізити:** Банк бенефіціарій: КАНАРА БАНК, БХАДРА БРАНЧ. Адреса банку: Бхадра Бранч, Реліф Роуд, Ахмадабад – 380 001 Рахунок №: 0317 257 00 3303 Свіфт: CNRBINBBADB Банк кореспондент: ДжейПиМорган Чейз Банк, Нью Йорк Рахунок №: 011395969 Свіфт: CHASUS33 Директор Кавіт Шах	**NabrosPharma Private Limited.** Legal Address: 3rd Floor, Oriental House II, Opposite Art Galary, Behind British Library, Law Garden, Ellis Bridge, Ahmedabad – 380 006. India. Address for correspondence: 3rd Floor, Oriental House II, Opposite Art Galary, Behind British Library, Law Garden, Ellis Bridge, Ahmedabad – 380 006. India. **Bank Details:** Beneficiary Bank Name: CANARA BANK, BHADRA BRANCH. Bank Address: Bhadra Branch, Relief Road, Ahmedabad – 380 001 Account No: 0317 257 00 3303 Swift: CNRBINBBADB Correspondent bank: JPMorgan Chase Bank, New York Account No: 011395969 Swift: CHASUS33 Director Kavit Shah

DocuSigned by: Olena Vinnyk 959E58854AD5401

DocuSigned by: Rajeev Shrirang Nayak BFC6C639292C4AB

DocuSigned by: Krasnova Hanna 81AD2560BE6A44F

DocuSigned by: Pavlo Zubrytskyi 57DA3F37CFF34EC...

DocuSigned by: Svitlana Matiukha 86A51369D94F49D...

DocuSigned by: 0EA44B4202A4414...

DocuSigned by: 52290BCC86DC4A7...

DocuSigned by: Tsvietkova Viktoriia 136062872B9B4E7...

ANNEXURE II to the Supply Agreement No. 2020-06-01/NPPLdated1June, 2020 / ДОДАТОК II До Договору поставки №2020-06-01 / NPPL від 1 червня 2020 року

Annual Purchase Targets (Sales from Nabros Pharma Private Limited to Dr. Reddy's Laboratories LLC) Ukraine: / Щорічні цілі закупівлі (продаж від Наброс Фарма Прайват Лімітед для ТОВ «Др. Редді'с Лабораторіз») Україна:

				April 20-March 21 / Квітень 20 – Березень 21	April 21-March 22 / Квітень 21 – Березень 22	April 22-March 23 / Квітень 22 – Березень 23	April 23-March 24 / Квітень 23 – Березень 24
S.No. / №п/п	Brand/ Торгова назва препарату	SKU / одиниця складського обліку	TP in USD, CIP/CIF VelykaOlexandrivka or Kyiv / TP у доларах США, CIP / CIF Велика Олександрівка або Київ	Units / Одиниць	Units / Одиниць	Units / Одиниць	Units / Одиниць
		Пастилки №18					
8	Flucold-N / Флюколд - N	Tablets N 200 (50*4) / Таблетки № 200 (50*4)	11.0	178,200	197,200	216,200	235,200
9		Tablets N 12 (3*4) / Таблетки № 12 (3*4)	0.70	243,946	175,000	220,000	230,000