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# Modern technologies in import substitution policy on pharmaceutical market

Nowoczesne technologie w polityce substytucji importu na rynku farmaceutycznym

**Keywords:** pharmaceutical manufacturing, import substitution policies, e-commerce, e-government, information technology, B2G, G2C, G2B, G2G

**Słowa kluczowe:** produkcja farmaceutyczna, polityki substytucji importu, e-commerce, e-administracja, informatyka, B2G, G2C, G2B, G2G

# Introduction

The key task of economic policy is to create favorable conditions for the supply of domestic producers in the domestic market as the main source of growth in the domestic economy is domestic demand.

An important element of public administration is the management of the pharmaceutical industry, which figures prominently in both the health care system and the economy as a whole. Due to the emergence of dangerous trends that lead to an increase in imports against a background of slow economic growth there is a need for measures to intensify the policy of import substitution on pharmaceutical market.

Each government should develop a domestic pharmaceutical industry and manufacture of medical devices, which would provide public with accessible, high-quality medicines and be competitive on the world market.

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# 1. Import substitution policy of pharmaceutical market

The main goal of the pharmaceutical market is to provide the population with quality medicines produced domestically. Import substitution is the process of reducing or stopping the import of certain goods by their replacement from domestic commodity market of the country with similar domestic adequate and with higher consumer characteristics of cost that is not higher than imported ones [Prychod'ko O., 2011]. Thus, import substitution strategy conforms to the goal of development of the pharmaceutical market.

In the policy of import substitution almost all protectionist measures can be used to make it difficult to make an access of imported goods and services to the internal market regulations of foreign trade: the tariff – different kinds of import duties, anti-dumping and non-tariff restrictions – licensing, quotas, certification, conscious complexity of customs procedures [Žalilo Ja.A., Hac'ko V.M., 2006].

According to Eurostat, the pharmaceutical industry is the undisputed leader among the other high-tech industries in the world in terms of creation of gross value added per occupied person. In addition, pharmaceutical production accounts for about 19% of total R & D expenditure in the world [Eurostat].

The main drawback of import substitution policy is to provide for local businesses extremely favorable conditions, protecting against competition. Import substitution strategy is also known as "surface industrialization", because of the absence of competition the motivation to innovate reduces. As a result, protected by the state area does not create a demand for qualified personnel, so investments in science lead to an increase in the outflow of intelligence abroad [Petrušenko Ju.M., 2013].

It is noteworthy that it is possible to follow the trend, according to which countries are adopting a strategy of import substitution in economic recovery and reject it when faced with financial difficulties. Import substitution should be a transitional stage in the process of economic restructuring and must be used for accelerated modernization and development of new trends of the industry, and then gradual transition to export-oriented development model should take place, due to the limited domestic market and the need to ensure new markets [Enej Ja.I., 2012].

# 2. The world experience of import substitution policy implementation in pharmaceutical market

Saving the demand of domestic consumers of the goods, the importation of which is restricted, creates favorable conditions for the development of the national production of its counterparts. Therefore, the policy of import substitution in different time periods in more or less obvious form was adopted by the vast majority of the world [Žalilo Ja.A., Hac'ko V.M., 2006].

Positive experience in solving the problems of import substitution in the pharmaceutical field was shown in India. Even 50 years ago, a private pharmaceutical

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industry in this country was almost absent, the Indian market was full of multinational companies that have accumulated 85% of the pharmaceutical market in money equivalent. In 1970, India has taken patent law, there was established a state control over the prices on drugs, the program of preferences was implemented in public procurement for national producers if they produce medicines of the same quality as imported. This led to the rapid growth of the Indian pharmaceutical industries – drugs of local production were significantly profitable than imported drugs [Gerster R., 2002]. In 2006, the amount of Indian pharmaceutical products in the world was more than \$ 13 billion, while in 2013 this figure reached \$ 22 billion, and by the end of the decade analysts predict that it will reach \$ 75 billion. According to experts, India is the third largest global manufacturer of medical products with an annual growth of 15–20%. India is the fifth of all of the world's generics. According to the experts, if the rate of development of Indian pharmaceutical industry will remain at this year's level, then in 2020 it will occupy a dominant position in the global pharmaceutical market [Paškov V., 2013].

Japan also faced the introduction of the policy of import substitution, and although it does not take a leading position in the global pharmaceutical market, with a high level of sales, its experience in implementing a policy of import substitution undoubtedly deserves attention. Products of Japanese pharmaceutical manufacturers come mainly for the domestic market and the export does not exceed 6% of total production. It should be noted that local producers offer their products on the domestic market at prices that are 10% lower than prices of western analogues but the purchase of imported medicinal products is carried out in strict accordance with the needs of the population, despite the presence of similar drugs on the market in Japan. This approach encourages improving the quality of Japanese medicines and development of competitive principles of pharmaceutical production products [Klunko N., 2012, p. 28].

Earlier in Russia they built mostly enterprises of "packaging", which only packaged and marked tablets and solutions, that were imported into the country. However, this did not contribute to the development of innovative pharmaceutical business, technology transfer and training. Thus, the main priorities have changed for companies in Russia. For example, to establish production "from scratch". Import substitution strategy is realized through localization of production facilities of large foreign companies. Also, international companies can count on a variety of preferences in public procurement of [Baranovyč M., 2011].

In Russia, foreign pharmaceutical companies are choosing different strategies of localization in terms of public policy of import substitution, such as:

- the creation of a strategic alliance for the purpose of production;
- acquisition of existing plants with a view to update them according to the rules of GMP, with the transfer of its advanced technology and training;
- · transfer of intellectual property rights;
- construction of own factories first of all for packaging of medicines, and eventually a full cycle of production, except the main active ingredient;

• transfer to the full cycle technology.

The Ukrainian pharmaceutical market depends on import. In monetary terms, the share of domestic products is 30%, and the foreign ones – 70%, and in natural – the share of domestic production – 65%, and foreign – 35%, respectively. Ukraine has experienced a significant loss of market positions of pharmaceutical production – the share of consumption of domestic production in terms of money fell from 50% in 2002 to 29% in 2013, with almost stable consumption in physical terms [Deržavna prohrama]. Fig. 1 presents dynamics of export and import of pharmaceutical products of Ukraine during 2005–2013.

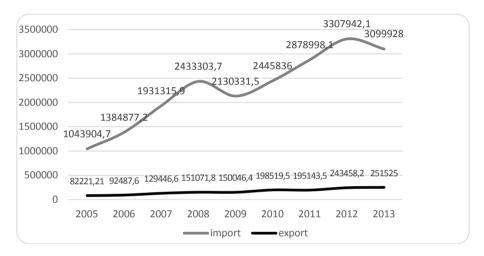


Fig. 1. Dynamics of export and import of pharmaceutical products of Ukraine during 2005-2013.

Source: Author's own study, based on [www.ukrstat.gov.ua ]

As shown in Fig. 1, in Ukraine the volume of imports of pharmaceutical products increased in 2005 and 2008 and in 2009–2012, and decreases in 2009 compared to 2008 to 14.2% and in 2013 compared to the year 2012 to 6.71%. As for exports, its volume, with the exception of minor changes (in 2009 it decreased by 0.68% compared with 2008, in 2011 – decreased by 1.73% compared to 2010) has steadily increased. Overall, Fig. 1. demonstrates a significant excess of total imports of pharmaceutical products in Ukraine over exports.

Numerous problems prevent the development of pharmaceutical industry in Ukraine, including: the lack of funding of state development programs of the pharmaceutical market, the lack of cooperation between government, business and science in the creation of complete production cycle of pharmaceutical products, the lack of funding for modernization measures in the pharmaceutical industry [Žalilo Ja.A., 2012, pp. 16-19] and high level of corruption, especially in the area of public procurement, which creates significant obstacles to the implementation of any governmental action, including implementation of import substitution policy.

# 3. Modern technologies in import substitution policy on pharmaceutical market

In the project Concept of the State Target Program "Development of import-substituting industries in Ukraine and substitution of imported medicines by domestic ones, including biotech drugs and vaccines" in 2011–2021 years procurement of medicines was one of the most important areas of public policy. The first priority of state action in this area is the elimination of corruption during the tender procedures. According to independent experts, from 30% to 60% of the budget is "washed out" because of application of corruption schemes (based on an annual assessment of the level of transparency in 2013 Ukraine ranked 144 place – gaining 25 points out of 100 and has once again confirmed its country rating as one with the highest levels of corruption [Indeks Spryjnjattja Korupciï 2013]). As a result – there is a total problem of underfunding of treatment programs that leads to inefficient use of budget funds on the one hand and on the other – to increased morbidity, disability and increased mortality of the population.

In our view, this issue is crucial to the policy of import substitution in the pharmaceutical industry, it touches directly as public spending and the quality, timeliness and availability of public with provision of medicines and requires priority attention.

Summarizing worldwide organization practice and public procurement, including the pharmaceutical industry, it can be stated that there are two basic models. The first model is based on the principles of electronic commerce (e-commerce) and is implemented in import substitution policies in such countries as USA, Mexico, Chile, Peru, Poland, the EU, the second – is based on the implementation of the concept of "e-government" (i.e. continuous optimization of the delivery of administrative social services, political participation of citizens in the state development by changing internal and external relationships through technical means, the Internet and modern media) and is used in such countries as Australia, Canada, Saudi Arabia. Characteristic features of these two models are shown in Table 1.

Taking into account fundamental differences between these models, we believe that a critical factor to consider justifying the choice of one of them as the base are:

- the level of commerce, and e-commerce in particular;
- the structure of the economy (the amount of the public sector in the economy);
- the level of development of internet technology, IKI, telecommunications systems;
- the readiness of society to innovations (use of public e-services);
- state funds;
- the time required for modernization.

Analyzing these critical factors it can be argued that, unfortunately, at this stage of development, Ukraine is not ready to implement the second model in practice, because of technological, financial and conceptual backwardness of government. At the same time, it can achieve success in the thoughtful application of the first model, in particular, using modern information technology and tools of marketing and logistics.

Table 1. Characteristic features of organization models and public procurement

Characteristic features of organization models and public procurement		
1) based on e-trade	2) based on the implementation of the «e-government» concept	
• need to introduce a set of technical, technological, legal support measures	• the need in substantial restructuring of existing IT infrastructure (IKI), almost its construction from «0»	
no significant financial investment compared to the second model	• significant financial investment into the construction of IKI and full modernization of processes of interaction with other state entities	
independent of the level informatization of society and business	the dependence from the critical set of «electronic citizens» (e-citizens) and «Electronic Enterprises» (e-business) to obtain a sustainable impact on internal efficiency and transparency of public administration	
• short-term implementation	long-term implementation process	
extensive use of marketing, information technology	• wide use of «cloud» technologies (cloud computing)	
problem of transparency and safety of data		

Source: Author's own study

In particular, the application of advanced information technologies and modern marketing (as part of the concept of macro marketing) in the above-mentioned Concept of the State program of development of import substitution industries in Ukraine systemic measures in public procurement of medicines is given in Table 2.

However, we believe that the outlined list of systematic measures is not complete, because it is based only on the use of one-way interaction model "business-state" (B2G – business-to-government), in which the state acts as a recipient of goods and services from businesses and does not consider other models of interaction, in which the state acts as the service provider, "state – consumer» (G2C – government-to-citizen), "state – business" (G2B – government-to-business), and model of interaction of bodies of state administration between themselves (G2G – Engl. government-to-government). In the pharmaceutical industry it is of particular relevance, because the main objective of public procurement is to meet the needs of the population with respect to quality, safe and affordable medicines.

Integration in the public procurement system of all models of interaction, in which the state acts as the provider and the recipient and the products / services using updated logistics technologies in the organization of public procurement and drug delivery to end-users (as part of macro logistics). Using logistic concept in the public procurement system will help significantly improve the efficiency of the competitive procurement for state needs on the basis of "consistency, integrity, optimizing of total

expenses," that is, through the consideration of processes in the complex from systematic positions, providing: economy; efficiency of procurement; liquidation of abuse.

Table 2. Scope of application of advanced information technologies and modern marketing technologies in the public procurement system of medicines

	Scope of application:	
Systematic actions in the field of public procurement of medicines according to the draft Concept	of advanced information technologies	of modern marketing technologies
Development of a system of monitoring and analyzing of the needs of the population of Ukraine in important medicines	+	+
Development of transparent procedure of amendments to the list of medicines for public procurement	+	-
Creation of a unique electronic database of public procurement of medicines	+	+
Giving preferences to national companies		-
Improving the regulatory basis for the tender procurement mechanism		-
Recovery of the mechanism of state orders during procurement of drugs for budget funds recognizing the rational use of effective, safe, quality and affordable medicines within the state target programs in health state needs		+
Making changes in the list of remedies of domestic and foreign production, which can be purchased by schools and health care institutions, fully or partially funded from state and local governments	-	+
Making amendments to the National List of Essential Medicines and Medical Products, to provide the substitution of imported medicines with national ones under the benchmark analysis	-	+

Source: Author's own study

Relevant examples of the application of logistics technologies are: development of evaluation system of competitive proposals aimed at minimizing the risk of the state customer when concluding a contract for the supply of goods and services of inadequate quality (justification of the choice of suppliers for multiobjective approach); decision on the compromise – eliminating of conflict objectives of the institution and its customers); decisions about the optimal parties of orders concerning the optimization of processes of transportation, warehousing, storage of goods purchased and their subsequent delivery to end users and so on.

In turn, the use of information technology should envisage: the creation of a single integrated information infrastructure, electronic data interchange, electronic databases, introduction of electronic document circulation (within the Ministry of Health, Ministry of Health between subordinate and medical institutions, between the Ministry of Health, universities and other authorities), the use of modern types of software, selection of which is carried out according to such criteria as: simplicity, transparency and openness. And the use of marketing techniques, we believe, requires the creation of information and marketing center (IMC), which would be entrusted with the following functions: 1. Organizer of electronic trading and competition for clients (public institutions); 2. Development of monitoring and analysis of requirements of the population of Ukraine of important medicines and the formation of requests for purchase of goods / services of specified level of quality, safety, availability and prices in accordance with existing financial opportunities; 3. Providing support bidding procedure (calculation of obligations of participants, financial calculations, transaction support, interaction with insurance companies, transportation infrastructure); 4. Providing clients with integrated marketing services to promote their products; 5. Consulting clients on legal issues and the most effective use of tools and infrastructure of IMC to solve their problems.

Overall, the design of a process of public procurement of medicines, which is built on the integration of all models of interaction in which the state acts as a provider and a recipient of goods / services can be presented in Fig. 2.

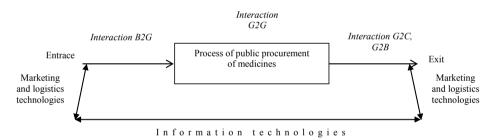


Fig. 2. The integrated process of public procurement of medicines and place in this process of information, marketing and logistics technologies

Source: Author's own study

Therefore, a public procurement system is a complex process of interaction between authorities and businesses and consumers through various legislatively defined procedures for the most efficient use of budget funds in the process. An important role in this process belongs to the use of information, marketing and logistics technologies that make opening prospects of modernization of the existing system of public procurement of medicines on the principles of transparency, openness, competitiveness, efficiency and accountability.

# **Conclusions**

Problem of import substitution is actualized due to the high level of foreign trade deficit and slowing their countries in dynamics of exports. The development of the pharmaceutical industry, support for domestic producers have a great importance for the health system in the world, their independence from imported goods and supporting of the economy. This process should be based on an objective analysis of the possibilities of modern enterprises and scientific base, accompanied by a thorough financial and economic analysis and must not be contrary to the international recommendations on providing citizens with quality drugs with proven effectiveness and safety for an affordable price.

International experience in the policy of import substitution shows, that it can be effective when the national pharmaceutical industry based on its own resources, scientific and production potential will be able to meet the needs of the population in imported medicines. The process of import substitution should be made carefully, with minimization of possible negative consequences for consumers of drugs.

A key problem in implementing the policy of import substitution in the pharmaceutical industry, which directly affects as public spending as the quality, timeliness and availability of drugs to ensure people are overcoming corruption in the sphere of public procurement of medicines. By implementing the model of e-commerce Ukraine can achieve significant progress in solving this problem through the use of modern information technology and marketing and logistics tools.

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### Modern technologies in import substitution policy on pharmaceutical market

The article deals with the nature and characteristics of import substitution policy in the pharmaceutical market. It displays advantages and disadvantages of implementation of import substitution. The foreign experience of state regulation of the pharmaceutical industry is analyzed in the application of the policy of import substitution. It shows integration process of public procurement of medicines on the basis of all models of interaction, in which the state acts as the provider and the recipient of products / services. The application of advanced information and advanced marketing and logistics technologies in supporting this process is identified.

### Nowoczesne technologie w polityce substytucji importu na rynku farmaceutycznym

W artykule poruszono problematykę charakteru i cech polityki substytucji importu na rynku farmaceutycznym. Wskazano zalety i wady wdrożenia tego rozwiązania. Przeanalizowano zagraniczne doświadczenia w tym zakresie. Artykuł pokazuje proces integracji zamówień publicznych leków na podstawie wszystkich modeli interakcji, w których państwo występuje jako dostawca i odbiorca produktów/usług. Zidentyfikowano także zastosowanie skomplikowanych technologii informacyjnych zaawansowanego marketingu i technologii logistycznych wspierających ten proces.