



REPORT

- the requirement for an export permit for medicinal products -

National Council for Economy and Investments

Prepared by the Secretariat of the National Council for Economy and Investments

Prishtina, Kosovo

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1. INTRODUCTION

This report, prepared by the Secretariat of the National Council for Economy and Investments, is a comprehensive and independent report, which addresses the issue of whether the requirement for a permit for exporting medicinal products is necessary. The report is compiled for use by the National Council for Economy and Investments (the "**Council**").

The Council is an independent entity, which, through constructive dialogue between the business community and public institutions, aims to improve the business climate in Kosovo.

This report is based on the current factual situation and should be understood as an instrument for providing recommendations that contribute to the development of the business climate in Kosovo.

2. Background of the issue

In the Sectoral Forums held within the public-private dialogue platform, one of the few medicinal products producers in Kosovo, simultaneously one of the few exporters of medicinal products, has initiated discussion on the request for an export permit in the field of medicinal products (permit L-04).

Although it is not a complicated process technically, to obtain this permit from the Kosovo Medicines Agency (KMA), the export company is obliged to apply, namely,

to upload the necessary documents in the "Barnatari" electronic system. According to the issue's initiator, obtaining this permit takes up to one (1) week. As a result, one of the main services this company offers - the export of medicinal products - is facing obstacles. This is despite an import permit being required by the receiving country for the product.

To address this challenge, the exporting company proposed a simple solution. Since the export permit (except for controlled substances and products) is not required by the law in force, this company proposed that the KMA notify Kosovo Customs through a decision or letter that the export permit is no longer needed, and this request will then be removed from the "Barnatari" electronic system.

If this burden were avoided, this manufacturer would be able to deliver products to its customers faster, which would lead to an increase in the export level because of the increase in customer satisfaction regarding the time of product delivery. Moreover, this requirement negatively affects the perception of the business climate in Kosovo. For potential investors who are not familiar with other conditions of doing business in Kosovo, such requirements are a discouraging signal to invest further.

For additional context, this issue's initiator indicated that he was also part of the working group for amending and

supplementing the Law in force on Medicinal Products and Medical Devices, but he faced resistance from the public institutions' representatives when he brought up addressing this issue.

3. LEGAL ANALYSIS

Legal regulation

There are several laws and by-laws, which, directly or indirectly, regulate this issue. Therefore, the legal analysis of this issue inevitably requires the examination of the relevant provisions from different segments of the legislation in force in Kosovo.

The primary law to be analyzed for this matter is the Law on Medicinal Products and Medical Devices, dated April 25, 2014.

Law on Medicinal Products and Medical Devices¹

Law No. 04/L-190 for Medicinal Products and Medical Devices (LMPMP) has been in force since 2014 and has not undergone changes since then. This law contains only two provisions which briefly address the issue of the export of medicinal products.

Accordingly, in Article 12, paragraph 14, it stipulates that KMA can directly export medicinal products if it meets the special conditions for equipment with an export license.

¹ Law No. 04/L-190 for Medical Products and Equipment - <https://gzk.rks-gov.net/ActDocumentDetail.aspx?ActID=9437>

Regarding these special export conditions, the provision refers to a by-law that sets the conditions for equipment with an export license. According to this provision, these conditions must be met to control the quality of medicinal products placed on the market outside the Republic of Kosovo. However, such a by-law has not been drafted yet, thus leaving the export permit/license issue unregulated adequately.

Further, paragraph 8 of article 13 of the LMPMP provides that the export of medicinal products, whether manufactured in Kosovo or imported, can be exported freely, with the only condition that the KMA **is notified** in advance by the exporter regarding the product being exported and its quantity. Therefore, this provision does not require the equipment with a special permit or license for export, but only notifying the KMA.

Law on Permit and License System²

The "notification" term is recognized by the Law on Permit and License System, as one of the four forms of *permits* issued by the competent public authorities. According to Article 6 of this law, notification is required when a given activity is developed as a single instance and will present a low risk to public health, public safety or the environment.

² Law No. 04/L-202 for the System of Permits and Licenses - <https://gzk.rks-gov.net/ActDetail.aspx?ActID=8967>

This law, in its article 32, determines that "1. All types of permits and licenses that are not part of the Central Registry of Permits and Licenses have no legal effect."

Further, in paragraph 2, this article foresees the responsibility of the heads of the relevant institutions for sending and updating data with the Central Registry of Permits and Licenses.

This is also clarified through the Regulation on the Central Register of Types of Permits and Licenses ³, which serves as secondary legislation on this matter. This Regulation establishes in its article 9 that the condition for the entry into force of new permits from central institutions or independent institutions is that they be published in the Central Register of Permits and Licenses. In the present case, since the export permit L-04 is not found in the register, this condition is not met.

Furthermore, article 17 of the Law on the Permit and License System stipulates that permits and licenses can only be defined by law. As such, the criteria, requirements, rules and procedures related to the issuance, administration and revocation, if applicable, of a permit must be defined by a law or a bylaw. This does not reflect the current

situation regarding the export of medicinal products according to the LMPMP in force.

*The Integrated Tariff of Kosovo (TARIK)*⁴

For the export of medicinal products, Kosovo Customs requires the L-04 permit, however, on a different legal basis. Annex 8 of TARIK provides the form for the export license issued by KMA, which is based on Article 32 of Law 03/L-188 on Medicinal Products and Medical Devices of 2010. This law has been abolished by the current law in force. TARIK explains that the request for the L-04 license originates from UNMIK Regulation, No. 2004/23, dated 07.07.2004, by which this law was promulgated.

Article 32 of the above-mentioned law, now repealed, in its paragraph 1, provides that legal entities or natural persons must be authorized in a special way for the export of medical devices. However, in its entirety, this article does not regulate the export of medicinal products. Consequently, this law does not clarify whether the export of medicinal products is regulated in the same way. Despite this, Kosovo Customs through TARIK, requests the L-04 permit on this legal basis.

³ Regulation (QRK) No. 06/2015 for the Central Register of Types of Permits and Licenses, approved at the 23rd meeting of the Government of the Republic of Kosovo, with decision number No. 03/23 dated 15.04.2015 - <https://kryeministri.rks-gov.net/wp-content/uploads/2022/08/Regular-No.-062015-for->

[the-central-register-of-types-of-permits-and-licenses.pdf](#) .

⁴ Integrated Tariff of Kosovo (TARIK), version dated 01.01.2024 - https://dogana.rks-gov.net/sharedfolder/ProductFiles/2024_d7f030b5-058f-4eee-801b-f49573877bb3.pdf ;

Law on Foreign Trade⁵

Finally, this issue is also regulated through Law No. 08/L-021 on Foreign Trade, which puts emphasis on promoting the export of goods and services as a priority. While the law does not go into detail on the different types of permits and licenses for the purpose of export, it provides in its article 22 that the procedures for applying, examining, granting, refusing and revoking permits must be in accordance with the Law on Permit and License System and the Law on General Administrative Procedure.

Possibilities for regulating this issue in the legal framework

The amendment of the LMPMP in force is in the legislative program for 2024, scheduled to be approved on 28.06.2024. Therefore, now that we have limited time before this law undergoes public consultation, we deem it necessary to discuss the possibility of clearly addressing this issue in the law, in order for the request for export permits for medicinal products ultimately be removed.

Finally, although the waiting period for this permit does not pose too much of a large burden on the business, to analyze the level of burden this requirement imposes, the following analysis should be followed.

a) Program for the prevention and reduction of the administrative burden

Administrative burden is the cost imposed on businesses (but also individuals or NGOs), when they fulfill the *mandatory information* derived from legal acts of the central or local government⁶.

The Government of Kosovo has drafted and approved a Program for the prevention and reduction of the administrative burden, the main goal of which is to adopt legislation that does not impose unnecessary administrative burdens on businesses. According to the Program, for each new legal act, the administrative burden is required to be reviewed through the Standard Cost Model (SCM). This model aims to create a more optimal and efficient environment for businesses, but without jeopardizing the general objectives that the given legal act aims to achieve.

According to the general methodology for prevention and reduction of the administrative burden, it is foreseen that the procedures are redesigned, so that they contribute to the administrative simplification. Among the first priorities of the Government at the starting phase of this program includes the simplification of mandatory information at the central level, which includes permits, licenses,

⁵ Law No. 08/L-021 for Foreign Trade - <https://gzk.rks-gov.net/ActDetail.aspx?ActID=55136>

⁶ Prevention and Reduction Program Administrative Burden 2022-2027, ZPS-ZKM - [https://kryeministri.rks-gov.net/wp-](https://kryeministri.rks-gov.net/wp-content/uploads/2022/09/ZPS-shtator2022-PPZBA-2022-2027-dhe-PV-2022-2027-Appendix-1-6-FINAL-ALB.pdf)

[content/uploads/2022/09/ZPS-shtator2022-PPZBA-2022-2027-dhe-PV-2022-2027-Appendix-1-6-FINAL-ALB.pdf](https://kryeministri.rks-gov.net/wp-content/uploads/2022/09/ZPS-shtator2022-PPZBA-2022-2027-dhe-PV-2022-2027-Appendix-1-6-FINAL-ALB.pdf).

registrations, certifications, consents, authentications, authorizations, recognitions, etc.

To decide whether the simplification of a certain procedure serves the public interest, it must go through some guiding questions, so that the proposed changes are in harmony with the principles of the LGAP.

In this regard, when thinking about simplification in terms of removing mandatory information in its entirety (such as the permit for the export of medicinal products), the guiding questions that must be asked are:

- Is this mandatory information 1) necessary and 2) appropriate to ensure the protection of the general interest intended?
- Can the protection of the general interest be achieved with other, less restrictive information?
- Can mandatory information be replaced/removed?

In supplementing and amending the LMPMP, these questions should be considered so that the export notification issue is clarified as much as possible.

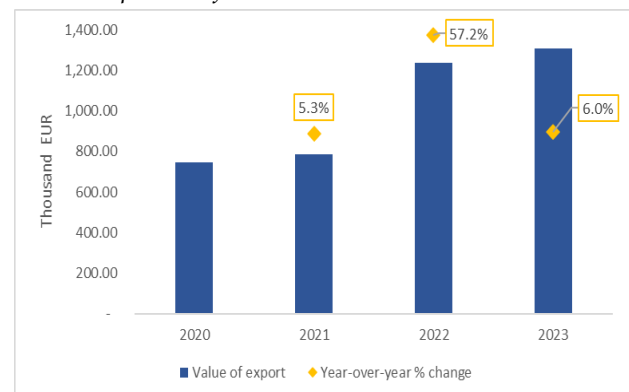
4. ECONOMIC IMPLICATIONS

Export as a component of the Gross Domestic Product (GDP) plays an important role in promoting economic growth. In a country like Kosovo, with a negative trade

balance, export promotion is vital for sustainable development. Eliminating barriers to exporting products is consistent with this goal, as it facilitates the trade process, encourages investment and increases competition in the global market. By improving export procedures and reducing bureaucratic obstacles, Kosovo can use its export potential, attract foreign investments and, as a result, stimulate the creation of job positions, influencing the growth of economic prosperity.

As for the permit for export of medicinal products L-04, it also represents a barrier for manufacturers of medicinal products who want to export. Regardless that the value of medicinal products exported (chapter 30 of TARIK) has a modest participation in the total export, there has been an upward trend of this value over the years. Figure 1 shows the value and annual change for the export of medicinal products under chapter 30, for which the L-04 permit is needed.

Figure 1. Export of medicinal products in thousands '000 (Chapter 30 of TARIK)



Data source: Kosovo Customs

According to the practices in Western countries, for a significant part of the exports, usually there is no need to be equipped with a permit or license from the exporting country. Even in cases where a permit or license is required, businesses are often not required to obtain such authorization for each export transaction - as is the situation with permits for the export of medicinal products in Kosovo.

Barriers such as export permits for products not related to national security negatively impact the climate of doing business. First, companies that need to be licensed often face bureaucratic procedures as well as unnecessary delays that limit their access to international markets. Secondly, the existence of such permits negatively affects the perception of potential investors when they consider Kosovo as a place to invest.

5. COORDINATION OF KMA WITH KOSOVO CUSTOMS

During a joint meeting, while giving context to the goal of easing burdens for export companies, KMA informed that, during the last years, they have undertaken measures to the benefit of export companies of medicinal products. Among these measures, he mentioned the removal of the tariff for export permits and the removal of the tariff for the import of raw materials to produce medicinal products.

However, KMA expressed its willingness to remove business barriers even further to the extent allowed by the legislation.

Kosovo Customs, on the other hand, expressed its willingness to remove the requirement for the L-04 permit, given that the exported medicinal products must also be equipped with an import permit for the receiving state's purposes. For the countries that receive these products, the documents issued by the institutions of Kosovo do not suffice⁰ and they need to conduct checks for their own purposes.

Kosovo Customs explained that the procedures in place do not leave room for possible misuse by companies.

Even in the absence of the export permit as currently required, the Customs would still need the Unique Customs Document, the products would still be subject to control during exit, the corresponding invoice would still be filled out, and all of this would appear in the digital system of Kosovo Customs. An important benefit for companies in removing the export permit will be that this procedure can be carried out at any time, that is, even during weekends and official holidays. This makes the export process faster.

The digital Kosovo Customs system will record the history of all products exported by each company. At the same time, this system will also reflect how much these companies abided by the customs procedures. In line with this, Kosovo Customs also expressed its willingness to provide access to the KMA in their digital system, so that KMA can be informed for the

complete history of the export of medicinal products from Kosovo.

supplementing and amending the current law.

6. CONCLUSION

Considering the above-mentioned, as well as the fact that the law in force does not expressly require obtaining a permit for the export of these products, KMA and Kosovo Customs agreed to change the practice of requesting a permit export from companies exporting medicinal products.

In this way, the representatives of these institutions agreed that sending an official notification (such as via an official email) to the KMA at their official email address, while copying Kosovo Customs, would be sufficient for export notification purposes, as required by law.

With the entry into force of the decision of the KMA, through which these changes will be put into effect, the Customs will remove this request from its system within a very short period.

The institutions agreed that, although this request does not represent a great burden for the companies, nor does it have great budgetary implications for our country, it eases a burden for the exporting companies, and stimulates the business climate in Kosovo.

Finally, these findings, along with the changes to be implemented in practice, must be reflected during the process of