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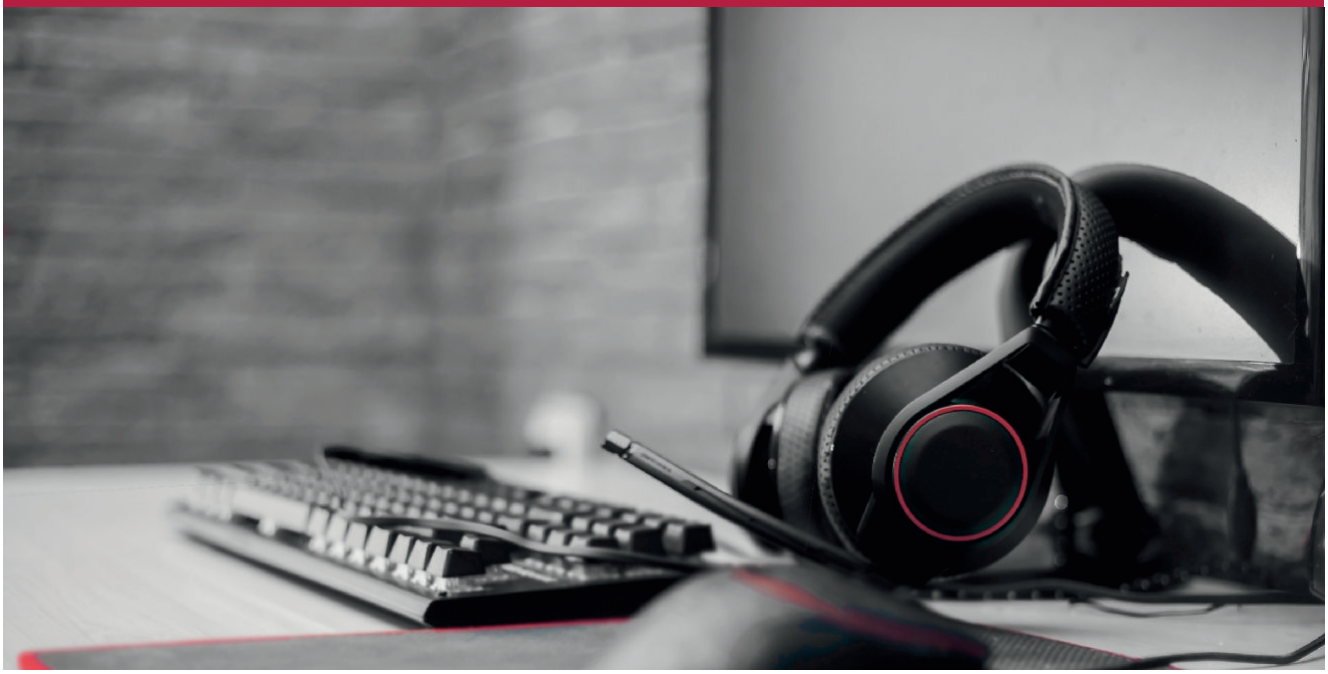
Suspension and Cessation of the Manufacture and Import of Medical Devices in Russia: Clarifications from Roszdravnadzor



Federal Law No. 323-FZ dated 21 November 2011 "On the Fundamentals of Public Health Protection in the Russian Federation" (the "**Law**") was amended in 2022 to include a new regulation establishing the specifics of the suspension and cessation of the manufacture and import of medical devices in Russia.

A similar regulation has been in force for medicinal products since 2018.

In practice, however, these provisions raise many questions in the professional community, as the legislators have not defined a specific procedure for these processes.

At the request of ADVANT Beiten, Roszdravnadzor (Federal Service for Surveillance in Healthcare) has clarified a number of ambiguous provisions.[1]

The essence of the restrictions

According to the new restrictions, manufacturers and importers of medical devices must notify Roszdravnadzor at least six months in advance of any planned suspension or cessation of the manufacture or import of medical devices.

This restriction was imposed in order to reduce the risk of inventory shortages in medical devices and the threat to the life and health of citizens.[2]

Is the importer obliged to notify of the suspension or cessation of import of each medical device?

The aforementioned notification obligation arises for each medical device that has undergone state registration in accordance with the procedure established by the Government of the Russian Federation and each medical device that has undergone registration in accordance with the international treaties and acts constituting the law of the Eurasian Economic Union.

What period of time is considered to be a suspension?

The product range of medical devices imported to Russia by large foreign manufacturers may consist of a large number of goods. Imports of any particular medical device may be carried out irregularly, depending on the demand on the Russian market and the stocks remaining in the importer's Russian warehouses. In this regard, the term "suspension of import of medical devices" is a matter for evaluation.

Roszdravnadzor also points out that the concept of a "period of suspension of manufacture of medical devices" has not been established by law. This leaves room for interpretation, depending on the circumstances of each specific situation.

However, given the rather long advance period for notification (six months), we believe it is not intended to notify the state in the event of short-term suspension of shipments related to the search for new logistic routes, delays at the border, or other circumstances that do not potentially result in a shortage of the medical device.

How should Roszdravnadzor be notified of the suspension or cessation of import of medical devices into Russia?

The law also does not define the scope or form for notifying Roszdravnadzor of a planned suspension or cessation of the manufacture of medical devices or their import into the territory of the Russian Federation.

Roszdravnadzor points out, however, that such notification must be made by manufacturers of medical devices or entities importing medical devices into the Russian Federation in accordance with the laws of the Russian Federation.

This means that, firstly, the notification must be made by an authorised person of the manufacturer or importer of the medical device.

Secondly, the notification must contain sufficient registration data for the agency to properly identify the medical device.

Thirdly, as the new regulation is aimed at preventing shortages of medical devices, it is recommended that the notification specify a timeframe for the anticipated suspension of import or manufacture (the Law does not explicitly make such a requirement).

Liability

The Law does not provide for special liability for or any other consequences of a failure to notify Roszdravnadzor of the suspension or cessation of import or manufacture of medical devices.

At the same time, the Code of Administrative Offences of the Russian Federation (the "**Administrative Offences Code**") contains Article 19.7.8 "Failure to submit information or submission of deliberately false information to the federal executive body responsible for control and supervision in the field of healthcare".

According to this regulation, the following liability is established for a failure to submit, late submission, or submission of false information to Roszdravnadzor:

- an administrative fine of RUB 10,000 to 15,000 for officials;
- an administrative fine of RUB 30,000 to 70,000 for legal entities.

In each case, based on the general provisions of the Administrative Offences Code, it must definitely be taken into account whether, for example, an importer who failed to notify Roszdravnadzor of the suspension of import of medical devices into Russia in a timely manner was aware of this suspension, or whether the manufacturer notified it less than six months before the date of the proposed suspension of shipments, etc.

Should you have any further questions, we would be delighted to answer them.

[1] Letter No. 10-8363/23 dated 16 February 2023 of the Federal Service for Surveillance in Healthcare (Roszdravnadzor) "On the Provision of Information" is available at ADVANT Beiten.

[2] Explanatory note to Draft Federal Law No. 84920-8 "On Amendments to Certain Legislative Acts of the Russian Federation".

Kind regards,

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