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Regulatory Update
for medicines and MDs manufacturers
14 April 2020

Advocate Bureau of the City of Moscow

Zero-import customs duties

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Decision of the EEC Counsel dated 3 April 2020 No. 33 "On Amendments to Certain Decisions of the Customs Union Commission and Approval of the List of Critical Import Products"

Effective since 18 April 2020

Applicable to legal arrangements arising from 1 April 2020

Exemption from payment of import duties is applicable:

- if product declaration (under the customs clearance procedure of release for domestic consumption) is registered until 30 June 2020;
- if medicines have the following customs codes: 3004 10 000 4, 3004 10 000 5, 3004 10 000 7, 3004 10 000 8, 3004 20 000 1, 3004 20 000 2, 3004 20 000 9, 3004 39 000 1, 3004 39 000 9, 3004 50 000 1, 3004 50 000 2, 3004 60 000 0, 3004 90 000 2, 3004 90 000 9

Decision of the EEC Counsel dated 16 March 2020 No. 21 "On Amendments to Certain Decisions of the Customs Union Commission and on Approval of the List of Goods Imported to the EAEU Customs Territory in Order to Implement Measures Aimed at Preventing the Spread of Coronavirus Infection 2019-nCoV"

Effective since 3 April 2020 / Amendments introduced by EEC Counsel Decision dated 3 April 2020 No. 34 → effective since 18 April 2020

Applicable to legal arrangements arising from 16 March 2020

Exemption from payment of import duties is applicable:

- if product declaration (under the customs clearance procedure of release for domestic consumption) is registered until 30 September 2020;
- if documents, issued by the authorized body of EAEU member state, confirming the purpose of import (to implement measures against 2019-nCoV), are presented to the customs authorities;
- if a product is included (by its name&customs code) on the list, approved by the EEC Counsel Decision No. 21, as amended by the EEC Counsel Decision No. 34 (the list includes: products used for medicines' production; and certain medical devices - MDs)

Potential influence on EDL pricing requires further analysis and clarifications from authorized bodies

On-line sales of Rx medicines

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Federal Law dated 3 April 2020 No. 105-FZ "On Amendments to Article 15.1 of the Federal Law "On Information, Information Technologies and Information Protection" and the Federal Law "On Circulation of Medicines" (effective since 3 April 2020)

On-line sales of RX medicines may be allowed until 31 December 2020 if due to emergency situation or threat of outbreak of a disease that constitutes a danger to the public, the Russian Government:

(i) Approves a temporary procedure governing on-line retail sales of Rx medicines

(ii) Approves specific procedure for obtaining a regulatory permit for on-line sales of Rx medicines

(iii) Approves specific regulatory requirements, applicable to pharmacies that are allowed to sell Rx medicines on-line

(iv) Approves temporary requirements for the delivery of Rx medicines to patients

Accelerated registration and other temporary flexibilities

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Resolution of the Russian Government dated 3 April 2020 No. 441 "On the Specifics of Circulation of Medicines for Human Use that are Intended for Use in Case of Threat, Occurrence and Liquidation of Emergency Situation and for the Provision of Medical Care to Persons Injured as a Result of Emergency Situation, Prevention of Emergency Situations, Prevention and Treatment of Diseases that Constitute a Danger to the Public, Diseases and Injuries Sustained as a Result of Exposure of Adverse Chemical, Biological, Radiation Factors"

Effective since 14 April 2020 → Expires on 1 January 2021

The Resolution No. 441 approves the following regulatory regimes:

- medicines' registration on conditions (registration certificate effective until 1 January 2021);
- accelerated registration of medicines registered in the EU-member states, US, Canada (or other countries included on the specific list by the MoH) without quality evaluation and risk/benefit expertise, but with subsequent serial selective quality control and obligatory post-registration clinical studies;
- authorization for temporary circulation until 1 January 2021 of a series (batch) of a medicine that is not registered in Russia, but is permitted for use by the authorized body of a foreign state (provided that certain preconditions are met);
- off-label use of medicines;
- registration of a specific price of an EDL medicine (applicable during the period of emergency / similar circumstances), if such a medicine is not in the circulation due to the pending pricing requirements

The categories of medicines, for which these regulatory regimes are available → medicines, which are intended for human use in case of threat, occurrence and liquidation of emergency situation and for the provision of medical care to persons injured as a result of emergency situation, for prevention of emergency situations, prevention and treatment of diseases that constitute a danger to the public, diseases and injuries sustained as a result of exposure of adverse chemical, biological, radiation factors

Many regulatory provisions of this document remain unclear and require further clarifications

Side effects of sole supplier mechanisms

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Resolution of the Russian Government dated 3 April 2020 No. 431 "On Specifics of Circulation of Medical Devices and Restrictions on the Wholesales and Retail Sales of Medical Devices and the List of such Medical Devices" (enters into force on 13 April 2020)

The document, *inter alia*:

- prohibited the free turnover of such MDs as medical masks, medical gloves, respirators, protective medical clothing etc.
- strongly restricted wholesalers' and pharmacies' pricing mark ups for such MDs
- appointed one of Rostech subsidiaries as an exclusive federal operator over supplies of the relevant MDs to Russian regions

The pharmacies reacted immediately and warned the Government that the document application may result in severe deficit of the necessary MDs / The Russian regions guaranteed the due level of control over the relevant MDs turnover*

Resolution of the Russian Government dated 14 April 2020 No. 500 "On Suspension of the Resolution of the Russian Government dated 3 April 2020 No. 431" (enters into force on 22 April 2020)

NB: the application of the Resolution No. 431 is suspended, but the document is not formally abolished

See at: https://pharmvestnik.ru/content/news/V-Minpromtorge-obyasnili-snyatie-ogranichenii-na-torgovlu-medizdeliyami.html (in Russian).

Thank you for your attention!

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