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In Brief:

- The Board of the Eurasian Economic Commission has prepared guidelines on the evaluation of medical devices for the purposes of their registration in the Eurasian Economic Union
- Roszdravnadzor advises that supplying information to the medicine tracking system will be compulsory
- The Federal Anti-Monopoly Service has issued guidance on applying certain elements of the methodology for calculating prices for essential medicines
- The Federal Anti-Monopoly Service has issued guidance on the application of wholesale mark-ups on supplies of essential medicines under state/municipal contracts
- Roszdravnadzor has issued a further notice in connection with the launch of the updated pharmacovigilance database
- The regulations of the Health Ministry's planning department have been approved
- Roszdravnadzor has set out its main goals and objectives for 2019

In Detail:

The Board of the Eurasian Economic Commission (EEC) has prepared guidelines on evaluating the safety, quality and effectiveness of medical devices for the purposes of their registration in the EEU[1]

Guidelines have been developed for official experts tasked with evaluating medical devices for the purposes of their registration in the Eurasian Economic Union (EEU). The guidelines have two main aims: to establish uniform approaches to the evaluation of medical devices and to standardize experts' requirements for materials provided by manufacturers of medical devices for registration purposes.

The guidelines propose a risk-based approach to the evaluation of medical devices, whereby experts' requirements regarding the scope and detail of evidentiary materials (documents) in the registration file are proportional to the risk class of the medical device concerned.

Roszdravnadzor advises that supplying information to the medicine tracking system will be compulsory[2]

The Federal Service for Healthcare Supervision (Roszdravnadzor) has advised that, starting from 1 January 2020, companies and entrepreneurs engaged in the manufacture, storage, importation into Russia, supply, sale, transfer, use and destruction of medicinal products for medical use will be obliged to ensure that information on such products is entered in the system for monitoring the movement of medicinal products for medical use (the "medicine tracking system").

From that date, advises Roszdravnadzor, companies and entrepreneurs that have not signed up to the medicine tracking system will not be able to trade medicinal products marked with Data Matrix codes.

Companies found selling unmarked medicinal products are liable to an administrative fine of up to three hundred thousand roubles together with confiscation of the offending items[3].

The Federal Anti-Monopoly Service (FAS) has issued guidance on applying certain elements of the methodology for calculating prices for essential medicines[4]

In particular, the guidance addresses the calculation of the maximum manufacturer's selling price for a generic drug. The FAS makes the following points:

- where multiple maximum prices have been registered for a reference medicinal product with the same dosage strength and total quantity in secondary packaging (e.g. based on different primary packages, different barcodes, etc.), the lowest registered price is used, taking into account the last price re-registration (reduction)
- where multiple maximum prices have been registered for each consumer package of a reference medicinal product with a given INN and dosage form, the mean value of the reduction factor (RF) is calculated for each consumer package and the mean of the RF values obtained is then calculated (disregarding cases where RF is nil)
- given that maximum prices are registered in roubles and kopecks (to two decimal places), in order to ensure a uniform approach the FAS advises that figures be rounded to hundredths when calculating

[1] Recommendation No. 14 of the Board of the Eurasian Economic Commission of 21 May 2019 "On Methodological Recommendations for Conducting an Evaluation of the Safety, Quality and Effectiveness of Medical Products for the Purpose of Their Registration within the Eurasian Economic Union"
[2] Roszdravnadzor Letter No. 01i-1269/19 of 20 May 2019 "On Compliance with Current Legislation"
[3] Clause 2 of Article 15.12 of the Administrative Offences Code
[4] Federal Anti-Monopoly Service Letter No. ATs/39362 of 14 May 2019 "On the Application of Certain Provisions of the Methodology for the Calculation of Maximum Selling Prices Set by Manufacturers of Medicinal Products for Medicinal Products Included in the List of Vital and Essential Medicinal Products", as approved by Decree No. 979 of the Russian Government of 15 September 2015

the mean cost per dosage form and unit of active ingredient

- where there is no reference medicinal product (or no price has been registered for it), the FAS advises that the maximum price should be determined in accordance with clause 35 of the Methodology using an approach similar to that prescribed for determining the price for a reference medicinal product in accordance with clause 32 of the Methodology. The maximum price should be calculated using a medicinal product with the same INN, dosage form and strength and the same maximum cost per dosage form. If multiple maximum prices have been registered for the product in question, the RF is calculated for each consumer package (taking into account the last price re-registration (reduction)), and the RF values obtained are used to calculate a mean value of RF according to the requirements of clauses 36 and 33 of the Methodology

The FAS has issued guidance on the application of wholesale mark-ups for supplies of essential medicines under state/municipal contracts[5]

The FAS asserts that the price at which vital and essential medicines are supplied within the state procurement system may exceed the registered manufacturer's maximum selling price (by not more than the maximum wholesale mark-up established in a constituent region of Russia) if the supplier is not the manufacturer and at the same time:

- in the case of procurements for federal needs, the starting (maximum) contract price does not exceed 10 million roubles
- in the case of procurements for the needs of a constituent region, the starting (maximum) contract price does not exceed an amount set by the highest executive authority of that region

Where a supplier of medicinal products is not the manufacturer but the starting (maximum) contract price exceeds 10 million roubles in the case of federal procurements or, in the case of regional or municipal procurements, exceeds the level set by the relevant executive authority, the price at which essential medicines are supplied may not exceed the registered manufacturer's selling price inclusive of VAT.

Roszdravnadzor has issued a further notice in connection with the launch of the updated pharmacovigilance database[6]

Further to its letter regarding the launch of the updated pharmacovigilance database, on which we reported in a previous alert, Roszdravnadzor has additionally advised that the process of registering/re-registering users of the "Pharmacovigilance" resource is set out in the "Pharmacovigilance automated system" subsection under the "Online services" tab on Roszdravnadzor's official website (http://www.roszdravnadzor.ru/services/npr_ais).

The regulations of the Health Ministry's planning department have been approved[7]

The planning department is a division of the Health Ministry responsible for organizing the ministry's planning activities through coordination and communication with various divisions within the ministry and liaising with federal executive bodies and the Government's planning office on the implementation of national projects, federal projects forming part of national projects and Ministry-specific projects. The planning department provides support for national projects. It is headed by Melik Guseinov[8].

[5] Federal Anti-Monopoly Service Letter No. ATs/38800/19 of 13 May 2019 "On the Application of Wholesale Mark-Ups for Suppliers of Vital and Essential Medicines under State (Municipal) Contracts

[6] Roszdravnadzor Letter No. 01i-945/19 of 8 April 2019 "Further to Roszdravnadzor Letter No. 01i-841/19 of 29 March 2019"

[7] Ministry of Health Order No. 195 of 5 April 2019 "On Approval of the Regulations of the Planning Department of the Ministry of Health of the Russian Federation"

[8] *https://www.rosminzdrav.ru/ministry/61/29*

Roszdravnadzor has set out its main goals and objectives for 2019[9]

Roszdravnadzor has identified three priority objectives for 2019: (1) monitoring the fulfilment of the rights of Russian citizens and the achievement of the targets set out in the Presidential Edict "On National Goals and Strategic Objectives for the Development of the Russian Federation in the Period to 2024" in the area of healthcare, (2) improving the efficiency and effectiveness of control and supervision activities, and (3) reducing the risk of substandard medicinal products and medical devices entering into legal circulation.

Roszdravnadzor has set itself tasks corresponding to each of those goals. Most notably, these include devising and implementing a "dynamic model" for organizing control and supervision activities using a risk-based approach, introducing test purchasing procedures and strengthening the role of preventive measures in control and supervision activities. The service believes that accomplishing these tasks will help raise the efficiency and effectiveness of control and supervision activities.

To reduce the risk of substandard medicines and medical devices entering into legal circulation, Roszdravnadzor plans to improve regulatory mechanisms relating to the circulation of medical devices, develop pharmacovigilance and safety monitoring systems in line with international formats and work towards introducing automated systems for monitoring the movement of medicinal products and medical devices from manufacturer to end consumer.

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[9] "Public Declaration of the Goals and Objectives of the Federal Service for Healthcare Supervision for 2019" (approved by Roszdravnadzor)

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