AMOUNTS OF STATE DUTIES FOR THE REGISTRATION OF MEDICINES FOR HUMAN USE AND MEDICAL DEVICES AND THE PROCEDURES FOR PAYING SUCH DUTIES HAVE BEEN ESTABLISHED ACROSS THE EURASIAN ECONOMIC UNION.

For the attention of Russian and foreign manufacturers.

Pepeliaev Group advises that the amounts and payment procedures have been established with respect to state duties to be paid for the registration by authorised agencies of medicines for human use and medical devices across the Eurasian Economic Union (EAEU)[1].

The new regulation will come into force on 7 April 2017, and with respect to specific provisions of the Law on 7 April 2017 but not before the first day of the next successive reporting period for the relevant tax.

Key developments

The Law establishes the following state duties depending on the type of activities required from an authorised state registration body:

1. For medicinal products for human use:

Registration activity	Amount of the fee
• Expert examination of a medicine for human use during its registration • Assessment of the expert report on the safety, effectiveness and quality of the medicine for human use	RUB 325,000
• Confirmation of the registration of a medicine for human use	RUB 145,000
• The making of amendments requiring an expert examination of a medicine for human use to the documents contained in the registration dossier of the medicine for human use • Ensuring that the registration dossier of a medicine for human use complies with the EAEU's requirements	RUB 75,000
• Expert examination of a medicine with a well-established medicinal use during its registration • Assessment of the expert report on the safety, effectiveness and quality of a medicine with a well-established medicinal use upon its registration	RUB 45,000

[1] Federal Law No. 25-FZ *On amending Part Two of the Russian Tax Code* dated 7 March 2017 (the "Law").

• The issuing of the registration certificate for a medicine for human use	RUB 10,000
• The making of amendments not requiring an expert examination of a medicine for human use to documents from the registration dossier of the medicine for human use	RUB 5,000
• The re-issuing of the registration certificate for a medicine for human use	RUB 2,000

2. **For medical devices:**

Registration activity	Amount of the fee
For registration under Federal Law No. 323-FZ *On the fundamentals of health protection in Russia* dated 21 November 2011.	
• Expert examination, during registration, of the quality, effectiveness and safety of a medical device (rated according to its potential risk class)	Class 1 - RUB 45,000 Class 2a - RUB 65,000 Class 2b - RUB 85,000 Class 3 - RUB 115,000
• Expert examination of the quality, effectiveness and safety of a medical device (according to their potential risk class) for amending the registration dossier of the medical device	Class 1 - RUB 20,000 Class 2a - RUB 30,000 Class 2b - RUB 40,000 Class 3 - RUB 55,000
• The issuing of the registration certificate for a medical device	RUB 7,000.
• The re-issuing of the registration certificate for a medical device • The making of amendments not requiring an expert examination of the quality, effectiveness and safety of a medical device to documents from the registration dossier of the medical device	RUB 1,500.
For registration under the EAEU laws to allow circulation in the EAEU common market	
• An expert examination, during registration, of the quality, effectiveness and safety of a medical device (rated according to the potential risk class as per EAEU laws) • Approval, during registration, of the expert opinion on the quality, effectiveness and safety of a medical device (rated according to the potential risk class as per EAEU laws)	Class 1 - RUB 45,000 Class 2a - RUB 65,000 Class 2b - RUB 85,000 Class 3 - RUB 115,000
• Expert examination of the quality, effectiveness and safety of medical devices (rated according to the potential risk class as per EAEU law) when amendments are made to documents contained in the registration dossier of the medical device	Class 1 - RUB 20,000 Class 2a - RUB 30,000 Class 2b - RUB 40,000 Class 3 - RUB 55,000

• Approval of the expert opinion on the quality, effectiveness and safety of a medical device (rated according to the potential risk class as per EAEU law) for amending documents contained in the registration dossier of the medical device	Class 1 - RUB 20,000 Class 2a - RUB 30,000 Class 2b - RUB 40,000 Class 3 - RUB 55,000
• The issuing of a registration certificate for a medical device	RUB 7,000.
• The re-issuing of a registration certificate for a medical device • The making of amendments not requiring an expert examination of the safety, quality and effectiveness of the medical device to documents contained in the registration dossier of the medical device	RUB 1,500.

What to consider and act upon

It should be noted that the adoption of this document is in many ways an important step towards the practical application of the principles of the common EAEU market for medicines and medical devices.

We advise that all players on the market of the medicinal products for human use and medical devices should familiarize themselves with this new regulation. In future, when putting registrations in place, they should be aware of the amounts of state duties during the registration process.

Help from your adviser

Pepeliaev Group's lawyers provide advice on all matters related to legal support with respect to the circulation of medicines and medical devices to ensure compliance with the currently developing legal framework of the Eurasian Economic Union as well as the national laws of its member states.

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