THE PROCEDURE FOR CREATING THE REGISTRATION DOSSIER FOR A BIOMEDICAL CELL PRODUCT AND FEES FOR THE STATE REGISTRATION OF SUCH PRODUCTS HAVE BEEN OFFICIALLY APPROVED

For the attention of Russian and foreign developers and manufacturers

Pepeliaev Group advises that new legal regulation has been approved of the state registration of biomedical cell products ("BMCPs").

Russian Healthcare Ministry's Order No. 32n "On approving the Procedure for submitting documents that comprise the registration dossier for a biomedical cell product and the form for an application for the state registration of a biomedical cell product" dated 31 January 2017 ("Order No. 32n" (was the first practical step in creating the system of regulation.

Federal Law No. 25-FZ "On amending part two of the Tax Code of the Russian Federation") the "Federal Law"(which the Russian President signed on 7 March 2017 and which is to come into effect on 7 April 2017, has become the logical end of this process.

Key developments

Order No. 32n establishes the list of the documents that comprise the registration dossier for a BMCP and the procedure for submitting them. It also approves the form of an application for the state registration of a BMCP.

Special procedures for filing documents have been established for different types of clinical trials:

- if no clinical trials have been performed for the BMCP within Russia, the registration dossier is created and the documents are submitted in stages;

- if international multicentre clinical trials have been performed for the BMCP, including within Russia, the registration dossier is created and the documents are submitted on a one-time basis.

For the state registration of a BMCP (in order to receive the registration certificate) an applicant pays a state fee, the amount of which is now established by the Federal Law.

The following fees have been established for different types of registration activities regarding a BMCP:

Registration activity	Amount of the fee
• expert examination of the quality of a BMCP; • expert examination of documents required to obtain permission to conduct a clinical trial of a BMCP and an ethical examination of whether a clinical trial of a BMCP is possible when an application is filed for the state registration of the BMCP; • expert examination of the efficacy of a BMCP and of the ratio of the expected benefit to the possible risk of using a BMCP for which international multicentre clinical trials have been performed, including within Russia, when an application is filed for the state registration of the BMCP	RUB 200,000

• introducing into documents in the registration dossier for a registered BMCP amendments that require a biomedical expert examination of the BMCP;	RUB 75,000
• expert examination of the efficacy of a BMCP; • expert examination of the ratio of the expected benefit to the possible risk of using a BMCP during the state registration of the BMCP; • confirming the state registration of a BMCP;	RUB 50,000
• granting permission to perform a clinical trial of a BMCP; • granting a registration certificate for a BMCP; • granting a duplicate registration certificate for a BMCP; • introducing into documents in the registration dossier for a registered BMCP amendments that do not require a biomedical expert examination of the BMCP.	RUB 5,000

What to think about and what to do

We recommend that all players in the medicines market familiarise themselves with the new regulation. They should take into account the statutory procedure for the creation of the registration dossier and the statutory fees when they perform registration activities regarding BMCPs.

Help from your adviser

Pepeliaev Group's lawyers provide comprehensive legal support with respect to registration activities regarding BMCPs and other matters connected with the regulation of the circulation of BMCPs.

Contact details

Sergey Klimenko

Head of Practice
Tel.: +7 (495) 967-00-07
S.Klimenko@pgplaw.ru