Second part of the Tax Code of the Russian Federation

Abstracts

Article 333.32.1. Amount of the state duty for activities of the authorized federal executive body when carrying out state registration of medicinal products
(Version came into force from January 01, 2015)

In accordance with the Federal Law On Circulation of Medicines the state duty for activities of the authorized federal executive body related to carrying out state registration of medicinal products shall be payable as follows (depending on the type of activity):

1) for expert review of the documents required to get approval for conducting clinical trials of a medicinal product for medical use and ethical expert examination when applying for state registration of the medicinal product – RUB 110,000;
(as worded in Federal Law No. 221-FZ dated July 21, 2014)

2) for expert quality examination of a medicinal product and expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product for medical use when carrying out state registration thereof – RUB 325,000;
(as worded in Federal Law No. 221-FZ dated July 21, 2014)

3) for expert quality examination of a medicinal product and expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product permitted for medical use in the Russian Federation for over twenty years when carrying out state registration thereof - RUB45,000;
(as worded in Federal Law No. 221-FZ dated July 21, 2014)

4) for expert quality examination of a medicinal product and expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product for medical use for which international multicentre clinical trials have been conducted, partially in the territory of the Russian Federation when carrying out state registration thereof – RUB 325,000;
(as worded in Federal Law No. 221-FZ dated July 21, 2014)

5) for expert quality examination of a medicinal product and expert examination of a correlation between the anticipated benefit and possible risk from the use of a medicine for veterinary use when carrying out state registration thereof – RUB 215,000;
(as worded in Federal Law No. 221-FZ dated July 21, 2014)

6) for confirmation of the state registration of a medicinal product for medical use – RUB 145,000;
(as worded in Federal Law No. 221-FZ dated July 21, 2014)

7) for confirmation of the state registration of a medicinal product for veterinary use – RUB 70,000;
(as worded in Federal Law No. 221-FZ dated July 21, 2014)

8) for alteration of Package Leaflet of a medicinal product for medical use – RUB 70,000;
(as worded in Federal Law No. 221-FZ dated July 21, 2014)

9) for entering amendments to the documents contained in the registration dossier for a registered medicinal product for veterinary use requiring expert examination of the medicinal products for veterinary use – RUB 70,000;
(sub-clause 9 as worded in Federal Law No. 312-FZ dated October 22, 2014)

9.1) for entering amendments to the documents contained in the registration dossier for a registered medicinal product for veterinary use not requiring expert examination of the medicinal products for veterinary use – RUB 2,600;
(sub-clause 9.1 brought into force by Federal Law No. 312-FZ dated October 22, 2014)

10) for alteration of formula of a medicinal product for medical use – RUB 145,000;
(as worded in Federal Law No. 221-FZ dated July 21, 2014)

11) for entering of a pharmaceutical substance not used in production of medicinal products into the state register of medicines – RUB 145,000;
(as worded in Federal Law No. 221-FZ dated July 21, 2014)

12) for issue of an approval for conducting international multicentre clinical trial of a medicinal product for medical use – RUB 290,000;
(as worded in Federal Law No. 221-FZ dated July 21, 2014)

13) for issue of an approval for conducting post-registration clinical trial of a medicinal product for medical use – RUB 70,000.

(as worded in Federal Law No. 221-FZ dated July 21, 2014)

Article 333.33. Amount of the state duty for state accreditation as well as for other legally significant activities

1. The state duty shall be payable as follows:

…

73) for issue of a document on accreditation (national accreditation) of organizations, except as specified in paragraphs 74, 75, 127 - 131 of this paragraph, - 5000 rubles;
(as worded in Federal Law No. 221-FZ dated July 21, 2014)

…

77) for issue of a duplicate of the document confirming accreditation (state accreditation) - RUB350;
(as worded in Federal Law No. 221-FZ dated July 21, 2014)

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Article 333.32.1. Amount of the state duty for activities of the authorized federal executive body when carrying out state registration of medicinal products
(version comes into force from July 01, 2015)

In accordance with the Federal Law On Circulation of Medicines the state duty for activities of the authorized federal executive body related to carrying out state registration of medicinal products shall be payable as follows (depending on the type of activity):

1) for ethical expert examination, expert review of the documents required to get approval for conducting clinical trial of a medicinal product for medical use – RUB 110,000;

2) for expert review of the documents submitted for determination of possibility to consider a medicinal product for medical use as an orphan medicine when carrying out state registration thereof – RUB 25,000;

3) for expert review of a medicinal product documents required to get approval for conducting an international multicentre clinical trial of a medicinal product for medical use – RUB 210,000;

4) for ethical expert examination, expert review of the documents required to get approval for conducting post-registration trial of a medicinal product for medical use – RUB 60,000;

5) for expert quality examination of a medicinal product and expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product for medical use after state registration thereof – RUB 325,000;

6) for expert quality examination of a medicinal product and expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product permitted for medical use in the Russian Federation for over twenty years when carrying out state registration thereof – RUB 45,000;

7) for expert quality examination of a medicinal product and expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product for medical use for which international multicentre clinical trials have been conducted, partially in the territory of the Russian Federation when carrying out state registration thereof – RUB 325,000;

8) for expert quality examination of a medicinal product and expert examination of a correlation between the anticipated benefit and possible risk from the use of a medicine for veterinary use when carrying out state registration thereof – RUB 215,000;

9) for issue of an approval for conducting clinical trial of a medicinal product for medical use – RUB 5,000;

10) for issue of an approval for conducting international multicentre clinical trial of a medicinal product for medical use – RUB 5,000;

11) for issue of an approval for conducting post-registration clinical trial of a medicinal product for medical use – RUB 5,000;

12) for issue of registration certificate for the medicinal product – RUB 10,000;

13) for confirmation of the state registration of a medicinal product for medical use – RUB 145,000;

14) for confirmation of the state registration of a medicinal product for veterinary use - RUB70,000;

15) for entering amendments to the documents contained in the registration dossier for a registered medicinal product for medical use requiring expert examination of the medicinal products to the extent of quality examination and (or) expert examination of a correlation between the anticipated benefit and possible risk from the use of the medicinal product for medical use - RUB75,000;

16) for entering amendments to the documents contained in the registration dossier for a registered medicinal product for medical use not requiring expert examination of the medicinal products for medical use, - RUB5,000;

17) for entering of a pharmaceutical substance produced to be sold into the state register of medicines - RUB145,000;

18) for entering amendments to the documents of a pharmaceutical substance produced to be sold and included into the state register of medicines requiring expert examination of the medicinal products - RUB75,000;

19) for entering amendments to the documents of a pharmaceutical substance produced to be sold and included into the state register of medicines not requiring expert examination of the medicinal products - RUB5,000;

20) for entering amendments to the documents contained in the registration dossier for a registered medicinal product for veterinary use requiring expert examination of the medicinal products for veterinary use - RUB70,000;

21) for entering amendments to the documents contained in the registration dossier for a registered medicinal product for veterinary use not requiring expert examination of the medicinal products for veterinary use - RUB2,600;

22) for issue of a duplicate of the registration certificate for the medicinal product - RUB2,000.