**Second part of the Tax Code of the Russian Federation

Abstracts**

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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 came into force from January 01, 2022)**

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 135,000;

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 420,000;

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 135,000;

5) ceased to be in force as of January 01, 2022 (Federal Law of November 29, 2021 No. 382-FZ);

6) ceased to be in force as of January 01, 2022 (Federal Law of November 29, 2021 No. 382-FZ);

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 172,000;

14) for confirmation of the state registration of a medicinal product for veterinary use – RUB 70,000;

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 – RUB 490,000;

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, - RUB 5,000;

17) for entering of a pharmaceutical substance produced to be sold into the state register of medicines – RUB 253,000;

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 – RUB 253,000;

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 – RUB 5,000;

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 – RUB 70,000;

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 – RUB 2,600;

22) for issue of a duplicate of the registration certificate for the medicinal product – RUB 2,000.

**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, - RUB 5000;

(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) – RUB 350;

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