| In accordance with Art. 58 of the ACT of March 9, 2023 on clinical trials on medicinal products for human use (Journal of Laws of 2023, item 605) subject to a fee in the scope of implementation of provisions of Regulation 536/2014 is an application submission for a permit of: | | | | |
|---|---|---|---|---|
| **No.** | **CLINICAL TRIAL** | | **FEE AMOUNT* to the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products accounts** | **REQUIRED TRANSFER TITLE**** |
| **1** | phase I–III commercial clinical trial | The Republic of Poland acts as rapporteur | 15 000 PLN | **111, EU trial number: …** |
| **2** | | The Republic of Poland does not act as rapporteur | 10 000 PLN | |
| **3** | | based on Article. 14 of Regulation 536/2014 | 10 000 PLN | |
| **4** | phase IV clinical trial | The Republic of Poland acts as rapporteur | 10 000 PLN | |
| **5** | | The Republic of Poland does not act as rapporteur | 6 000 PLN | |
| **6** | | based on Article. 14 of Regulation 536/2014 | 6 000 PLN | |
| **7** | non-commercial clinical trial | The Republic of Poland acts as rapporteur | 4 000 PLN | |
| **8** | | The Republic of Poland does not act as rapporteur | 2 000 PLN | |
| **9** | | based on Article. 14 of Regulation 536/2014 | 2 000 PLN | |
| **No.** | **SUBSTANTIAL MODIFICATION** | | **FEE AMOUNT * to the URPL, WM and PB accounts** | **REQUIRED TRANSFER TITLE**** |
| **1** | substantial modification to the clinical trial in the aspect covered by Part I of the clinical trial ethical assessment report | The Republic of Poland acts as rapporteur | 2 000 PLN | **112, EU trial number: …** |
| **2** | | The Republic of Poland does not act as rapporteur | 1 500 PLN | |
| **3** | substantial modification to the clinical trial in the aspect covered by Part II of the clinical trial ethical assessment report | | 1 500 PLN | |
| **4** | substantial modification to the clinical trial in the aspect covered by Part I of the clinical trial ethical assessment report and the substantial modification to the clinical trial in the aspect covered by Part II of the clinical trial ethical | The Republic of Poland acts as rapporteur | 2 500 PLN | |
| **5** | | The Republic of Poland does not act as rapporteur | 1 500 PLN | |
| **6** | the same substantial modification to more than one clinical trial protocol in the aspect covered by Part I of the clinical trial evaluation report (in accordance with Article 17 of Regulation 536/2014) | modification in the first clinical trial | 100% amendment fee | |
| **7** | | modification in each subsequent study | 50% of the amount of the fee for the modification **in the first clinical trial** | |

**The amount of the fees referred to in paragraph. 1 Art. 58 of the ACT of March 9, 2023 on clinical trials on medicinal products for human use, is subject to indexation every 5 years to the extent corresponding to the consumer goods and services price index total for the previous 5 years, calculated on the basis of average annual consumer goods and services price index, announced by the President of Statistics Poland on the basis of the regulations on retirement and disability pensions from the Social Insurance Fund, rounded up to whole zlotys.*

*** In accordance with Art. 58 of the ACT of March 9, 2023 on clinical trials on medicinal products for human use Fees due for submission of different applications are paid separately*

**The above fees apply from April 14, 2023 and concern payments to the to the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products accounts only.**