

**SERVICE CONTRACT**

Štátny ústav pre kontrolu liečiv (hereafter referred to as "ŠÚKL") (Rapporteur), whose registered address is Kvetná 11, 825 08 Bratislava, Slovakia, which is represented for the purposes of the signature of this contract by PharmDr. Zuzana Baťová, PhD., of the one part,

and

Bundesamt für Sicherheit im Gesundheitswesen (BASG) (Contractor), whose registered address is Traisengasse 5, 1200 Wien, Austria, represented for the purposes of the signature of this contract by DI Dr. Christa Wirthumer-Hoche, a duly authorized officer of the Contractor, of the other part,

**HAVE AGREED**

the Conditions below and the Annex I, which forms an integral part of this contract (hereinafter referred to as "the Contract").

1. The subject of the Contract is the assessment by the Contractor of the quality data submitted to support the centralized marketing authorization application of the medicinal product Teriflunomide Mylan (teriflunomide) for which ŠÚKL acts as a Rapporteur, drafting the respective part of the Assessment Report in accordance with EMA template and participation in any written or oral discussions relating to the respective data during the marketing authorization procedure (the "Services"). Rapporteur also has the administration responsibility, which includes coordination of the assessment by the contractor. ŠÚKL (Rapp) accepts to submit all relevant information, templates and documents to the relevant contact persons at BASG (Contractor).
2. The Contractor shall provide the Services assigned to it in accordance with the timetable set by CHMP for the assessment of Teriflunomide Mylan (teriflunomide) under procedure EMEA/H/C/005604.
3. The Contract shall become effective on the date on which it is signed by the last contracting party and published in the Slovak central contract register. Provision of the Services shall start from the 1st July, 2020.
4. The Contractor acknowledges and agrees that the Services shall be provided in accordance with European union pharmaceutical legislation and with all the relevant European Union and EMA published guidance documents and according to the timetable adopted by the CHMP. Upon completion of the assessment, the Contractor shall provide Rapporteur Agency with the respective parts of the draft assessment report.
5. The Contractor agrees that it will apply the same quality control and assurance system to the assessment under this contract as it does for the centralized marketing authorization application assessments where it acts as a Rapporteur.
6. The Contractor shall not subcontract the performance of the Services at any circumstances.
7. The Contractor shall ensure and is responsible that any of the Contractor's Staff members performing the Contract have professional qualifications and experience required for the performance of the Services assigned to them.

8. The Contractor shall take all necessary measures and is responsible to prevent any situation that could compromise the impartial and objective performance of the Contract. Such conflicts of interest could arise in particular as a result of economic interest, political or national affinity, family or emotional ties, or any other relevant connection or shared interest. In the event of any such conflict, the Contractor shall immediately take all necessary steps to resolve it.
9. The Contractor undertakes and is responsible that secrecy is provided for by the secrecy laws and regulation applicable to the Contractor, to address and handle the Results and other information received or obtained within the framework of the Contract as confidential information and not reveal or disclose such confidential information to third parties.

The secrecy obligations set forth above shall survive the termination of this Contract.

10. In the event of any action brought by a third party against the Rapporteur Agency in connection with performance of the Contract, the Contractor shall assist the Rapporteur Agency. Expenditure incurred by the Contractor to this end will be reimbursed by the Rapporteur Agency under the basis of a mutual agreement between the parties.
11. The European Medicines Agency (EMA) will perform direct fee payment to ŠÚKL based on a letter sent to the EMA executive director by the host NCA on the fee division (Annex 1). The total amount to be paid to the Contractor by EMA shall be 50% of the total fee paid by EMA on this procedure covering all the Services provided ("the Charges"). It is agreed that the Charges include all other expenditure that may be incurred by the Contractor in performance of the Contract.
12. Any notice or other communication relating to the Contract shall be made in writing and shall bear the Contract number. Ordinary mail shall be deemed to have been received by Rapporteur's Agency on the date on which it is registered by the Rapporteur Agency secretariat. All notices or other communications shall be sent to the following addresses:  
  
Rapporteur Agency  
Štátny ústav pre kontrolu liečiv (ŠÚKL)  
PharmDr. Zuzana Baťová, PhD.  
Kvetná 11, 825 08 Bratislava, Slovakia  
  
Contractor Agency  
Bundesamt für Sicherheit im Gesundheitswesen (BASG)  
AGES Medizinmarktaufsicht  
DI Dr. Christa Wirthumer-Hoche  
Traisengasse 5, 1200 Wien, Austria
13. Notwithstanding any other term of this Contract, Rapporteur's Agency may terminate the Contract forthwith in the circumstances where the Contractor is in breach of any obligations under the Contract.
14. Should the Contractor fail to perform its obligations under the Contract in accordance with the provisions laid down therein, the Rapporteur Agency may – without prejudice to its right to terminate the Contract – reduce or recover payments in proportion to the scale of the failure.
15. In case of force majeure, notified in accordance with the Contract, either contracting party may terminate the Contract at any time, where performance thereof cannot be ensured following the event amounting to force majeure occurring.
16. Neither party shall be held in breach of its contractual obligations if it has been prevented from performing them by force majeure.

- 16.1. Where the Contractor is unable to perform its contractual obligations owing to force majeure, it shall have the right to remuneration only for the Services actually executed.
- 16.2. If either party is faced with force majeure, it shall notify the other party without delay by registered letter with acknowledgement of receipt or equivalent, stating the nature, likely duration and foreseeable effects.
- 16.3. Force majeure shall mean any unforeseeable and exceptional situation or event beyond the control of the contracting parties including acts of terrorism which prevents either of them from performing any of their obligations under the Contract, was not due to an error or negligence on their part or on the part of a subcontractor, and could not have been avoided by the exercise of due diligence.
- 16.4. Defects in equipment or material delays in making it available, labour disputes, strikes or financial problems cannot be invoked as force majeure unless they stem directly from a relevant case of force majeure.
17. The Contract shall be governed and construed in accordance with the laws of the Slovakia. Any dispute arising out of this contract shall be referred to arbitration at Bratislava District court II.
18. Both parties may make separate new contracts on assessments of any future follow-up variations.
19. This contract and all the documentation related to this contract are classified between the contract parties.

This Contract (together with Annex 1) constitutes the whole agreement between the parties hereto relating to its subject matter and no variations or amendments to the Contract shall be effective unless the subject of a written agreement concluded by the contracting parties.

#### SIGNATURES

For the Contractor (BASG)  
DI Dr. Christa Wirthner-Hoche

For the Rapporteur (ŠÚKL)  
PharmDr. Zuzana Baťová, PhD.

ŠÚKL (host NCA),