Bundesamt für Sicherheit
im Gesundheitswesen

BASG
AGES-MEA
Traisengasse 5, 1200 Vienna, AUSTRIA

SERVICE CONTRACT

Bundesamt für Sicherheit im Gesundheitswesen (hereafter referred to as "BASG") *(Rapporteur),* whose registered address is Traisengasse 5, 1200 Wien, AUSTRIA, which is represented for the purposes of the signature of this contract by DI Dr. Christa Wirthumer-Hoche, of the one part,

and

State Institute for Drug Control (Štátny ústav pre kontrolu liečiv) *(Contractor),* whose registered address is Kvetná 11, 825 08 Bratislava, Slovenská republika, represented for the purposes of the signature of this contract by PharmDr. Zuzana Baťová PhD, 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 *Non-clinical, Clinical, Pharmacovigilance & RMP* data submitted to support the centralized marketing authorization application of the medicinal product *Deferasirox Accord (DEFERASIROX)* for which *BASG* 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. *BASG (Rapporteur)* accepts to submit all relevant information, templates and documents to the relevant contact persons at *State Institute for Drug Control (SUKL) (Contractor).*

2. The Contractor shall provide the Services assigned to it in accordance with the timetable set by CHMP for the assessment of *Deferasirox Accord (DEFERASIROX) under procedure EMEA/H/C/005156*

3. The Contract shall become effective on the date on which it is signed by the last contracting party. Provision of the Services shall start from the *12th November,* 2018.

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 *BASG* 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 40 % 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
    Bundesamt für Sicherheit im Gesundheitswesen (BASG)
    AGES Medizinmarktaufsicht
    DI Dr. Christa Wirthumer-Hoche
    Traisengasse 5, 1200 Wien, AUSTRIA

    Contractor Agency
    State Institute for Drug Control (Štátny ústav pre kontrolu liečiv)
    PharmDr. Zuzana Baťová PhD
    Kvetná 11, 825 08 Bratislava, Slovenská republika

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. It 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 *country of the Rapporteur Agency.* Any dispute arising out of this contract shall be referred to arbitration at Vienna court.

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 (State Institute for Drug Control)
PharmDr. Zuzana Baťová PhD

Signature(s)

Done at 28. 11. 2018

For the Rapporteur (BASG)

DI Dr. Christa Wirthumer-Hoche

Signature_

Done at *Vienna, 8th November 2018*

In duplicate in English
Annex I: A letter sent to the EMA by BASG (host NCA), dated 08-11-2018.

Bundesamt für Sicherheit
im Gesundheitswesen

BASG
AGES-MEA
Traisengasse 5, 1200 Vienna, AUSTRIA

Professor Guido Rasi
Executive Director
European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU

08.11.2018
EMEA/H/C/005156

Dear Professor Rasi,

Subject: Payment of Rapporteur's remuneration

We refer to the appointment of our national delegation Austrian Federal Office for Safety in Health Care / Bundesamt für Sicherheit im Gesundheitswesen (BASG) ("NCA") as Rapporteur for the assessment of the medicinal product **Deferasirox Accord** (DEFERASIROX), under procedure H0005156. This assessment is governed by the Cooperation agreement dated 8th November, 2018 (the "Cooperation Agreement").

We wish to inform you that our assessment team will also include representatives of the following NCA(s):

Štátny ústav pre kontrolu liečiv / State Institute for Drug Control

Kvetná 11, 825 08 Bratislava, Slovenská republika

We have separately agreed with the above NCA(s) that the total remuneration set forth in the Cooperation Agreement for this assessment would be split as detailed below; provided however, that the total remuneration shall remain unaltered and equal to the one set forth in the Cooperation Agreement.

Therefore, we hereby request and authorise the Agency to make direct payments to the participating NCA(s) as follows:

a) Lead NCA: 60% of the Rapporteur remuneration supporting the quality part of the dossier

b) Participating NCA (State Institute for Drug Control): 40% of the allocated remuneration supporting the non-clinical/clinical and pharmacovigilance part of the dossier.

We would like to confirm that the Agency will not be responsible for any dispute or difference arising out or in connection with the distribution of the remuneration as requested in this letter. Such disputes will be resolved solely between the lead NCA and the participating NCA(s).

We can also confirm that our NCA, as lead NCA, retains all responsibility for the quality of the Rapporteur assessment report.

Yours sincerely

DI Dr. Christa Wirthumer-Hoche

Head of Austrian Federal Office for Safety in Health Care