MEMORANDUM OF UNDERSTANDING

BETWEEN

THE MEDICINES EVALUATION BOARD OF THE NETHERLANDS

represented by the Executive Director of the Medicines Evaluation Board Agency

AND

THE STATE INSTITUTE FOR DRUG CONTROL OF SLOVAKIA

represented by the Director of the State Institute for Drug Control

PREAMBLE

The Medicines Evaluation Board of The Netherlands (hereinafter referred to as "The Netherlands") and the State Institute for Drug Control of Slovakia (hereinafter referred to as "Slovakia") hereinafter jointly referred to as the "Signatories" and in the singular "The Signatory",

- **Considering** that a balanced and strong European Union medicines regulatory network is of vital importance to European public health;
- **Taking into consideration** that the European Medicines Regulatory Network will benefit from efforts to increase the capacity and quality in scientific cooperation and the optimising of international collaboration;
- **Recognising** that the need for investment in capacity of the EU medicines regulatory network is reinforced by the potential consequences of the United Kingdom's withdrawal from the European Union and the planned relocation of the European Medicines Agency to Amsterdam;
- **Acknowledging** that the marketing authorisation and pharmacovigilance of medicinal products for human use has been centralised at EU level for certain categories of products, but continues to depend to a large extent on the scientific capacity and involvement of the national regulatory authorities in the field of human medicines;
- **Recognising** that medicinal products that are outside the scope of the centralised marketing authorisation procedure at EU level may be obtained through a decentralised procedure or mutual recognition procedure at Member State level;
- **Considering** that EU Member States can join forces and work more closely together by promoting joint packages, by entering in Mutual Recognition Procedures, by conducting joint assessments of pharmaceutical products and by sharing expertise, know-how and best-practices.

Have come to the following arrangements:

Paragraph 1

Scope and aims

The Signatories hereby declare their mutual willingness to engage into a long-term cooperation in the field of pharmaceutical policy and medicines regulatory affairs. With this Memorandum

Signatories intensify their collaboration in the field of medicines regulation, with the aim to support the State Institute for Drug Control of Slovakia to increase its scientific capacity and experience so that it can increase its contribution to the work sharing within the EU medicines regulatory network.

Paragraph 2

Activities

In order to facilitate such cooperation, the Government of the Netherlands will allocate the necessary funds to enter into subsequent bilateral cooperation arrangements with Slovakia for the period of 2018 to 2020. The Signatories hereby declare that they will enhance their bilateral cooperation in a choice of activities in one or more of the following areas:

a) Strengthening capacity and quality of the medicines regulatory work
b) Bilateral medicines regulatory cooperation

Paragraph 3

Strengthening capacity and quality of the medicines regulatory network

The Netherlands is willing to make investments in/fund bilateral regulatory medicines cooperation with Slovakia for a maximum period of 3 years. The MEB will provide specific expertise to the State Institute for Drug Control in accordance with a work program to be set up and agreed upon after this Memorandum has been signed . Bilateral cooperation may consist of but is not limited to a choice of:

1) training of (new) pharmaceutical regulatory professionals from Slovakia by the Dutch Medicines Evaluation Board (MEB) and covering the expenses connected to training periods of Slovakian staff members in The Netherlands or as part of training programs of the EU Network Training Center;

2) providing specific support and expertise to the State Institute for Drug Control focussing on areas of interest expressed which include but are not limited to preclinical and clinical assessment of medicinal products, pharmacovigilance and quality assessment of medicinal products;

3) exchange of expertise and best practices in the assessment of biological and biosimilar medicines, quality assessment of specific pharmaceutical forms and assessment of non-clinical data.

Bilateral cooperation can be initiated with regard to human medicinal products.

The activities covered by the Memorandum will be developed in close conjunction to existing training schemes and capacity building activities developed through the EU Network Training Center. The Medicines Regulatory Authorities of the Signatories will develop a sustainable working relationship with the aim of establishing bilateral and multilateral joint assessment teams.

The choice of priorities under the Memorandum will be laid down in more detailed agreements.

Paragraph 4

Bilateral medicines regulatory cooperation

The Government of the Netherlands is willing to operate as co-partner on decentralised marketing authorisation procedures with the perspective of supporting the supply of pharmaceutical products on the Slovakian market.

Notwithstanding further additions or amendments, the cooperation can include the following activities:

1) The government of The Netherlands can on request of the government of Slovakia ask marketing authorisation holders applying through decentralised procedures with NL=RMS to market their medicinal products not only in the Netherlands but also in Slovakia;
2) The government of The Netherlands can on request of the government of Slovakia ask marketing authorisation holders to provide adequate product instructions and labelling in both the Dutch and English/Slovakian language for products marketed through decentralised procedures wit NL=RMS;
3) The MEB will seriously look into possibilities for offering so-called "zero day MRP" facilities to marketing authorisation holders in the interest of the State Institute for Drug Control;
4) The MEB and the State Institute for Drug Control will engage in information sharing if needed and possible;
5) Slovakia is solely responsible for any decisions on reimbursement of medicinal products on its national market operating under a decentralised marketing authorisation in the Netherlands and that are allowed on the Slovakian market through a mutual recognition procedure.

Paragraph 5

Sustainability of the bilateral cooperation

In order to safeguard the sustainability of this bilateral cooperation, Slovakia will endeavour to continue and maintain the increased capacity and expertise also after the Memorandum expires.

Paragraph 6

Termination of this MoU

This Memorandum of Understanding will come into operation on the date of signature and will continue in operation until its aims and objectives have been fulfilled, unless terminated by either Signatory on three months written notice to the other Signatory.

The Signatories may make further arrangements which will be attached as annexes to this Memorandum of Understanding.

Paragraph 7

Legal status

This Memorandum of Understanding does not create any rights or obligations under International Law.

Signed in duplicate in the English language

Mr. H. R. Hurts

Executive Director
Medicines Evaluation Board
of the Netherlands

Date 15-03-2018

[redacted]

Ms. Zuzana Baťová

Executive Director
State Institute for Drug
Control of Slovakia

Date 15.3.2018