MEMORANDUM OF UNDERSTANDING

Concluded between

Medicines and Medical Devices Agency of Serbia, hereinafter: ALIMS (Republic of Serbia), with registered office in Belgrade, Vojvode Stepe 458, 11221, Belgrade, Republic of Serbia, represented by Acting Director Saša Jaćović, M.D.Sp., as one Party.

and

State Institute for Drug Control, hereinafter: SIDC (Slovak Republic), with registered office in Bratislava, Kvetná 11, 825 08 Bratislava, Slovak Republic, represented by Director PharmDr. Peter Potúček, PhD., MSc. as the other Party,

- Since the agreements signed between the European Agency for Reconstruction and the Republic of Serbia Government in October 2004 led to the development of the Medicines and Medical Devices Agency of Serbia within the EU integration of Serbia, which also presupposed cooperation with some developed regulatory authorities in the European Union Member States and other countries acceding towards EU;

- Since the mission of ALIMS is to contribute to the realization of the basic human right to access quality, effective, and safe medicinal products and medical devices, as well as to promote and improve public and animal health through the following: issuing marketing authorizations for solely quality, safe and effective medicinal products and medical devices; providing adequate information in order to ensure safe and rational use of such medicinal products and medical devices and quality control of medicinal products and medical devices which is in full compliance with all the national and international laws and standards;

- Since the mission of SIDC is to control the quality, efficacy, and safety of medicinal products and medical devices, to issue decisions of the registration of human medicines and to issue licenses for activities with specified substances, to perform the state supervision in the field of pharmacy, to execute state administration in the matters of drug antecedents, to control the manufacture and wholesale distribution of medicinal products and medical devices, and to cooperate with EU organizations;

- Since this cooperation is a vital step in the development of the Medicines and Medical Devices Agency of Serbia, their functioning, and the adoption of European and WHO standards in the field of health safety and management.

- Finally, having in mind that the already established relationship between ALIMS and SIDC should be strengthened through cooperation within this frame and through bilateral collaboration.

Parties have agreed upon the following:

Article 1

SIDC (Slovak Republic) and ALIMS (Republic of Serbia), hereinafter jointly referred to as "Parties", have adopted the decision to, based on the mutual reciprocity and partnership, establish a cooperation in the field of quality, safety, and efficacy of medicines and medical devices for human use, as well as in the field of institutional development, and for purpose of more successful realization of operations and tasks entrusted to them.

Article 2

The Parties also undertake to use the network of correspondents that has been established between the two institutions during the current informal cooperation and that the exchange of scientific and technical information, will be performed in accordance with current European and national legislation, provided the confidentiality of data shall be respected and no such information shall be disclosed to third parties. The Parties also agreed that the correspondents shall inform each other about holding seminars and other scientific and expert meetings that may be important for the other Party.

Article 3

ALIMS believes that, in order to improve its operations, it is necessary to give priority to the development of the following fields: Harmonization with EU aquis and its implementation, and integration in the European regulatory network; Marketing authorizations for the medicinal products for human and veterinary use and entering of medical devices for human use in the Register of Medical Devices; operations regarding the activities of the National center for information on medicinal products and medical devices, namely interchangeability of medicinal products, trade and consumption of medicinal products and advertising; Pharmacovigilance and medicinal devices vigilance; Clinical trials for medicines and medicinal products and medical devices; Electronic submission and digitalization; Communications; International cooperation and projects, and Quality management (Benchmarking), as well as other fields that may prove necessary in the course of future cooperation.

The Parties noted that the improvement in these fields is necessary for further development of ALIMS achieved in previous years and can also be beneficial for SIDC in establishing standard operative procedures, comparison of best practices, and benchmarking.

Article 4

Financial costs connected with the implementation of this Memorandum shall be agreed upon in a separate agreement.

Article 5

The Parties have agreed to annually conduct assessment of implementation of this Agreement.

Article 6

All provisions listed here are subject to and shall be conducted in accordance with, all applicable laws, regulations, and other legal requirements of the Slovak Republic and the Republic of Serbia.

The exact terms and conditions of any future cooperation between the Parties shall be negotiated in due course and shall be set out in a separate agreement if circumstances allow so.

This Memorandum does not in any way limit any Party to participate in any activities with other public or private agencies, organizations, or individuals.

Article 7

This Memorandum shall enter into force on the day following its signature by both parties and is concluded for three years, i.e. for the period 2023-2025. The Memorandum can be renewed by written agreement for a new three-year period.

Article 8

Each of the Parties may terminate this Memorandum by providing written notice to the other Party sixty (60) days in advance. In the event of termination of this Memorandum, all necessary measures shall be taken in a timely manner to ensure the completion of initiated projects.

Article 9

This Memorandum was concluded in Bratislava on 29th of May 2023 in six identical copies (two in Slovak, two in Serbian and two in English language).

For

PharmDr. Peter Potucek, PhD., MSc.

Director

For
Medicines and Medical Devices

Acting Director