The Protocol of Intent on Cooperation in the Field of Control of Medical Products Between the Brazilian Health Regulatory Agency (the Federative Republic of Brazil) and the Federal Service for Surveillance in Healthcare (the Russian Federation)

The Brazilian Health Regulatory Agency (the Federative Republic of Brazil) and the Federal Service for Surveillance in Healthcare (Russian Federation), hereinafter referred to as "the Parties",

expressing firm commitment to strengthen dialogue and cooperation in the field of public health,

noting that the States of the Parties face similar challenges in public health, with the global character,

recognizing that the circulation of falsified, counterfeit and substandard medical products is a global problem that poses an immediate threat to health and life, destroys the reputation of health systems and undermines the public trust in the health authorities and health care institutions has a negative impact on the security, cohesion and prosperity of society, causing significant socio-economic damage,

realizing the need for close cooperation in the field of control of medical products, coordination of positions in international forums on regulation of medicines and medical devices, including ICH, IPRF, ICMRA, IMDRF, the activities carried out by WHO, , etc.,

following shared objectives of ensuring access to affordable, high-quality, effective and safe medicines and medical devices, improving efficiency and rising capacity and capabilities of the Parties, strengthening public health systems and strengthening global cooperation in the field of public health,

came to the following mutual understanding:

Principles of cooperation: the Parties actively contribute to the development of cooperation in the field of control over medicines and medical devices on the basis of equality, reciprocity and mutual benefit.

Specific areas of cooperation between the Parties will include, but are not limited to, the following:

1. The parties will exchange experience in the organization of work of state authorities that control the circulation of medicines and medical devices, as well as

promote exchange and mutual visits between the representatives of these authorities and technical experts in these areas.

2. The parties will promote cooperation and exchange of experience in the areas of joint research, advanced developments and best practices in the field of quality, efficacy and safety of medicinal products and medical devices, of control over their circulation, will facilitate exchange of experience and contacts between specialists and expert organizations in these areas.

3. The parties shall encourage the exchange of information on issues of legal regulation of turnover of medical products, on a regular basis to exchange information on quality, efficacy and safety of medicinal products, pharmaceutical substances and medical devices; exchange of information about serious unexpected adverse reactions at application of medical products and adverse reactions related to quality defects and counterfeiting of medical products; exchange of experience in the field of GLP, GCP, GMP and QMS inspections, organization of laboratory control, expert and analytical work in the territory of states Parties; and the exchange of data within the framework of post-marketing monitoring of medical products (NCAR Exchange Program).

4. The parties understand that the exchange of information on quality, efficacy and safety of medical products and other matters, may include information considered to be confidential in the state Party providing the information. At the time of transmission of information, the Party shall notify about the confidentiality of this information. In this case, each other Party will treat the information in accordance with laws and regulations, and policies of their state and make every reasonable effort to prevent public disclosure of confidential information or any other dissemination of this information for purposes not stipulated in this Protocol of Intent.

The parties will consult with each other on each occasion when public disclosure of the information received from one of the Parties is required.

Each Party will make reasonable efforts to inform other Parties of any changes to laws and regulations, and policies of their States or procedures that may affect the treatment of confidential information received from other Parties.

The parties agree that the information within the information exchange will be sent from a designated employee of one of the Parties specifically assigned to the employees of other Parties responsible for the exchange of information.

The parties will exchange contact information of designated officers within a period not exceeding 30 (thirty) days from the date of signing of this Protocol of Intent.

5. The parties will carry out contacts for daily activities and emergency situations. The parties will exchange contact information of employees responsible for contacts on the day-to-day activities and emergency situations in a period not exceeding 30 (thirty) days from the date of signing of this Protocol of Intent.

6. The parties will make efforts to coordinate positions in international forums on regulation of medicines and medical devices, including ICH, IPRF, ICMRA, IMDRF, the activities carried out by WHO and other international organizations.

7. The parties will establish a mechanism of regular meetings of heads of the Supervisory authorities, will work together to develop plans for cooperation, to conduct negotiations on the implementation of this Protocol of Intent and other matters.

Each of the Parties will bear the costs of cooperation under this Protocol of Intent, except when the Parties will agree otherwise.

This Protocol of Intent is not an international Treaty and does not create any legal obligations and responsibilities.

Issues arising in the implementation of this Protocol of Intent are to be resolved through direct consultations and negotiations between the Parties.

This Protocol of Intent shall apply from the date of its signing by the Parties. Either party may withdraw from this Protocol by notifying in writing all other Parties of its intention to discontinue its use at least 30 (thirty) days before the termination of the application.

This Protocol of Intent may be amended by the Parties with agreed changes and additions.

This Protocol of Intent is signed in Brasilia, Brazil on March 10th, 2016 in English, Portuguese and Russian language, each in two copies.

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Jarbas Barbosa
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