

**Memorandum of Understanding on cooperation between the  
National Health Surveillance Agency – ANVISA, of the  
Federative Republic of Brazil, and the State Administration of  
Ukraine on Medicinal Products – SAUMP, of the Republic of  
Ukraine**

The National Health Surveillance Agency – ANVISA, of the Federative Republic of Brazil, and the State Administration of Ukraine on Medicinal Products – SAUMP, of the Republic of Ukraine, here after referred to as “Parties”;

**RECOGNIZING that the ANVISA** is the National Medicines Regulatory Agency responsible for the protection and promotion of public health by intervening in the risks caused by the production and use of products and services regulated by health surveillance;

**RECOGNIZING that the SAUMP** is the Ukrainian Central Executive Authority responsible for ensuring the implementation of the national policy in the areas of quality control and safety of medicinal products, including medicinal immunobiological preparations, medical equipment and medical devices that are out in circulation and/or applied in health care, that are approved for marketing in pharmacy institutions and their structural subdivisions, as well as for the licensing of pharmaceutical manufacturing, wholesale and retail sale of medicines.

**CONSIDERING**

The interest shown by both Parties to strengthen the regulatory dialogue between them;

The mutual interest for contributing effectively to the health development of both countries and its impact to the improvement of health conditions of the population through the surveillance and control of the quality, safety and access of medicinal products;

The benefits that would be derived from the exchange of information on relevant themes for both institutions;

The legal and the technical competence of both institutions;

**RECALLING THAT**

The laws and regulations of both Parties contain certain restrictions on international co-operation, including information disclosure, and that nothing

in this Memorandum requires Parties to provide assistance or information if such is prohibited by their respective laws and regulations, national policies or for other important reasons, both sides have reached mutual understanding as follows:

### **General principles**

The National Health Surveillance Agency – ANVISA, of the Federative Republic of Brazil, and the State Administration of Ukraine on Medicinal Products – SAUMP, of the Republic of Ukraine, agree to establish a consultation and cooperation mechanism with a view to deepen the dialogue on Good Manufacturing Practices (GMP), pharmaceutical standards and technologies.

### **Objectives**

Parties realized that enhancing cooperation in the area mentioned above will promote mutual understanding, trust and bilateral cooperation.

The main objectives of bilateral cooperation are as follows:

To establish cooperation mechanisms in the field of health surveillance, to support the process of transfer of technology and the joint development of projects and technical-scientific research between Brazil and Ukraine;

To promote mutual knowledge and cooperation between the Parties in order to enhance the future elaboration of specific technical projects, including training of experts and personnel, exchange of regulatory framework, in identified areas, that can lead to the establishment of a larger and more effective cooperation between the two institutions;

To establish communication channels in regards to pharmaceutical standards and legislation;

Timely notification and exchange of information on the latest developments and legislative updates;

To establish a cooperation framework in regards to GMP standards and GMP inspection results;

other mutually agreed issues.

## **Work procedures**

Any and all activities under this MoU will be subject to the needs of both Parties based on mutual agreement. The activities will be at each moment of time agreed between both Parties based on scientific, technical, regulatory or other needs.

Both Parties agree to hold regular meetings according to the current needs of cooperation in order to consult on the main issues of concern to each side and to agree on procedures and a work program for their further discussion with a view to resolve these issues.

The meetings will be held alternately in Brazil and in Ukraine or will take place by video or audio conference. The level of representation should be equivalent on both sides, taking into account differences in the organizational structure of both parties.

Other Brazilian and Ukrainian Authorities, Ministries and relevant stakeholders such as businesses, public and consumer associations can also be involved if agreed by both sides. There should be written mutually agreed meeting records in English, Portuguese and Ukrainian for all relevant meetings.

Parties agreed to establish contact points for each area of co-operation.

## **Working groups**

At the regular meetings Parties may decide when necessary to establish technical working groups to collaborate in the resolution of issues identified. The technical working groups will agree on a suitable work program and a time schedule.

Both sides will adequately support the working groups so that they can implement their work program.

Representatives of other Authorities, organizations and independent experts can be involved as appropriate.

## **Costs**

Both Parties understand that any and all activities under this MoU will be subject to the availability of funds and resources and the laws governing the respective Institution.

Both Parties agree to bear expenses relating to co-operation in accordance with the following: unless agreed otherwise, Parties will be responsible for bearing their own costs, including international and domestic travel and accommodation costs.

The respective host country should offer appropriate support and assistance to the visiting delegation.

### **Revision of terms of cooperation**

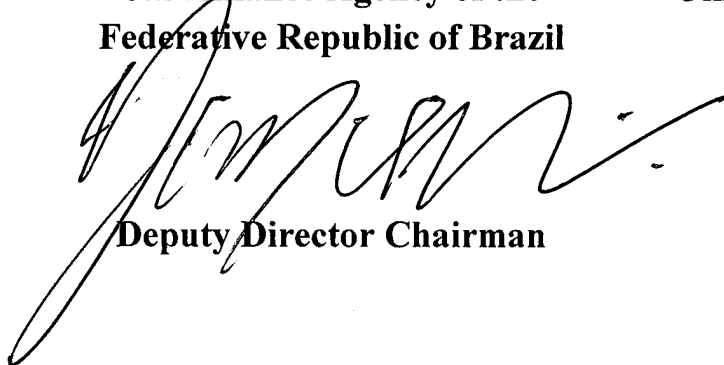
This MoU may be modified at any time with the approval in writing of both Parties.

This MoU is to become effective on the date of signature and continue in effect for a period of one year from such date, unless one side notifies the other of its intention to terminate this MoU before.

Such notification should be given to the other side no later than 30 days before termination. This MoU continues to be extended for another year unless otherwise stated by one of the sides.

Signed in the city of Brasilia, DF, Brazil, on November 8, 2013, in three copies, English, Portuguese and Ukrainian, each language being of equal validity.

**For the National Health  
Surveillance Agency of the  
Federative Republic of Brazil**



**Deputy Director Chairman**

**For the State Administration of  
Ukraine on Medicinal Products**



**Deputy Head**