Memorandum of Understanding between

Iran Food and Drug Administration (IFDA)

And

Brazilian Health Regulatory Agency (ANVISA)

on

Information exchange relating to the field of health products regulation.

Paragraph 1

Purpose of the MOU

With this Memorandum of Understanding (MOU), the Iran Food and Drug Administration (IFDA) and the Brazilian Health Regulatory Agency (ANVISA), hereinafter referred to as the Parties, wishes to encourage bilateral cooperation and facilitate the mutual exchange of information and expertise on regulatory matters pertaining to health products, including medicines, medical devices and complementary health products.

Both Parties shall encourage exchanges and cooperation on the basis of equality, mutual benefit and reciprocity.

Paragraph 2

Forms of Cooperation

Through the following activities, the Parties will conduct close cooperation in the field of health products regulation:

- Exchange of information, including information on best practices;
- Exchange visits of staff and professionals from both parties;

Other cooperation in the area of health products to be agreed upon by both Parties.

Paragraph 3

Sharing of information in relation to health products for human use

The Parties consider that from time to time, circumstances will arise where sharing of information held by one Party will assist the other Party in carrying out its regulatory functions in relation to health products, including medicines, medical devices and complementary health products;, to ensure the safety, quality and efficacy of these products for human use.

To the extent permitted by the laws in the Parties' respective countries and without a Party being obliged to exchange information, if that Party providing and exchanging the information deems such exchange is not in its national interest, different types of information that may be shared between the Parties includes, but is not limited to:

- Post-authorization vigilance data held by one Party which raises safety concern about a product manufactured or distributed in the territory of the other Party.
- Inspection reports done by one Party which are of significant public health i nterest to the other Party.
- Information on quality defect or product recalls held by one Party in relation to medicinal products and medical devices which are distributed or have been manufactured in the territory of the other Party.
- Information contained in marketing authorization applications and applications to vary a marketing authorization received by one Party which are of significant public health interest to the other Party.

Paragraph 4

Confidentiality Commitment

The Parties will protect the confidentiality of information in accordance with their respective laws as well as the policies and procedures permitted by those laws and will make all reasonable efforts to inform the other Party of any changes to their laws, policies or procedures that may affect the treatment of confidential information received under this MOU.

Both Parties agree that the information exchanged among them may be confidential and not of public domain on the territory of the Participant that originated the information. At the moment of exchanging the information, the participant will inform of the confidentiality of this information. In this case, each participant understands that confidential information will be shared under a secure basis and in accordance to the applicable laws as well as policies and procedures allowed on each country. Each participant will make the best efforts to avoid and always seek the prior written permission of the other participant in case there should be:

(a) Public disclosure of confidential information that has been exchanged under the present Agreement; and

(b) Any other disclosure of information for purposes that are not established by this Agreement.

Paragraph 5

Cost related to activities under the MOU

The cost related to activities under the MOU is borne by the parties individually.

Cooperation activities under the MOU are to be coordinated between the Parties on a regular basis, after mutual consultations and in accordance with the requirements of each Party.

Cooperation activities under the MOU will be subject to the availability of the appropriate funds and other resources, as well as to the applicable laws and legal provisions of the country of each Party.

Paragraph 6

Single Point of Contact

Each Party shall designate a Single Point of Contact (SPOC). The SPOC shall serve as the principal coordinator of information and activities between the Parties.

Paragraph 7

Disputes Settlement

Any divergence in interpretation or performance of this MOU will be settled through negotiations between the competent authorities of the Parties and through diplomatic channels.

Paragraph 8

Amendment.

This MOU may be amended only by written request of either Party, and by written mutual agreement of both Parties. The amendment will be done in writing and will enter into force on the date of its signature by the Parties

Paragraph 9

Entry into Force and Termination

1. This MOU will enter into force on the date of its signature.

2. This MOU will be valid for a period of four years and after the said period it will remain valid, unless one of the Parties informs in writing its willingness for termination to the other Party. Should such a case happen, the MOU will be considered terminated 1(one) month after the notification.

This MOU comprising of 9 Paragraphs was made in .....in duplicate in, English Portuguese and Persian languages, on ..... corresponding to ....., all of which being equally authentic. In case of any divergence in interpretation, the English text shall prevail.

Dr. Gholam Reza Asghari

Deputy Minister

And

Head of the Food And Drug

Administration

Dr Jarbas Barbosa da Silva Jr

Director President

Brazilian Health Regulatory

Agency – ANVISA