Agência Nacional de Vigilância Sanitária

Agenzia Italiana del Farmaco AIFA

MEMORANDUM OF UNDERSTANDING

between

The Brazilian Health Regulatory Agency (ANVISA)

And

the Italian Medicines Agency (AIFA)

CONCERNING COOPERATION IN THE REGULATION OF THERAPEUTIC PRODUCTS

1. BACKGROUND

Agência Nacional de Vigilância Sanitária (ANVISA) of Brazil and **Italian Medicines Agency (AIFA)** (hereinafter referred as the "Participants") wish to establish a framework for cooperation in the area of the regulation of therapeutic products.

2. OBJECTIVES

The objectives of this Memorandum of Understanding (MOU) are:

a. to promote an understanding between the Participants of each other's regulatory framework, requirements and processes;
b. to facilitate the exchange of information and documentation relating to the regulation of therapeutic products;
c. to encourage the development of collaborative activities between the Participants; and
d. to enhance the ability of the Participants in the provision of their services relating to or in connection with public health, to meet the needs of their respective population.

This MOU represents the understanding reached by the Participants, in particular

(i) that each Participant has jurisdiction over specific therapeutic products and may define those products differently. This MOU is intended to cover all types of therapeutic products regulated by, and common to, the Participants and permit meaningful collaboration between them. This may include, but is not limited to, medicinal products; and

(ii) each Participant may, in particular circumstances, limit the scope of disclosure of information particularly if the disclosure may be prejudicial to the commercial interests of a third party, breach the duty of confidence or privacy, disclose a trade secret, be contrary to the public interest or the interests of the Participant concerned, be in breach or inconsistent with statutory obligations or requirements or other obligations and requirements imposed by the respective laws of Brazil or Italy.

3. DEFINITIONS

In this MOU "therapeutic products" means:

(i) Medicinal products, herbal medicinal products, related to the regulatory functions of ANVISA, according to Federal Laws 6.360/1976 and 9.782/1999 and Decree 79.094/1977 as amended from time to time; and

(ii) medicinal products, herbal medicinal products, related to or connected with the functions of AIFA according to the rules set out in the Legislative Decree 219/2006.

4. AREA OF COOPERATION

The Participants having reached the above understanding will:

(i) establish avenues of communication to facilitate the exchange of information about the regulation of therapeutic products by each Participant, including: policies, practices, standards, laboratory testing, pre-marketing assessment, post-marketing vigilance, market compliance, regulation of manufacturers, regulation of clinical trials and requirements for the regulation of therapeutic products; and

(ii) undertake collaborative activities, including, where practical, the exchange of personnel.

5. CONFIDENTIALITY

5.1. AIFA

5.1.1. Nothing in this MOU requires AIFA to release confidential information to ANVISA, except in accordance with law.

5.1.2. The AIFA will make all reasonable efforts to inform ANVISA of any effort made by a judicial, legislative or other authority to obtain confidential information that has been provided by one Participant to the other Participant..

5.1.3. Unless otherwise required by law, the AIFA will not disclose any information received from the ANVISA under this MOU, except with the written consent of ANVISA. If disclosure is required by law, the AIFA will consult with ANVISA in advance of releasing such information and will take all reasonable measures to ensure that the information received from ANVISA will be disclosed in a manner that protects the information from any disclosure that is not required or authorised by law.

5.1.4. Unless otherwise required by law, the AIFA will not use the information disclosed to it under this MOU for any other purpose than the performance of its therapeutic products regulatory activities.

5.2. ANVISA

5.2.1. Nothing in this MOU requires ANVISA to release confidential information to the AIFA, except in accordance with law.

5.2.2. ANVISA will make all reasonable efforts to inform the AIFA of any effort made by a judicial, legislative or other authority to obtain confidential information that has been provided by one Participant to the other Participant. If disclosure is required by law, the ANVISA will consult with the AIFA in advance of releasing such information and will take all reasonable measures to ensure that the information received from the AIFA will be disclosed in a manner that protects the information from any disclosure that is not required or authorised by law.

5.2.3. Unless otherwise required by law, ANVISA will not disclose any information received from the AIFA under this MOU, except with the written consent of the AIFA.

5.2.4. Unless otherwise required by law, ANVISA will not use the information disclosed to it under this MOU for any other purpose than the performance of its therapeutic products regulatory activities.

6. FINANCIAL ARRANGEMENTS

Each Participant will be solely responsible for the administration and expenditure of its own resources associated with activities conducted under the arrangement.

7. VARIATION

Any provision of this MOU may be amended at any time by the mutual consent in writing of the Participants via the respective signatories.

8. STATUS OF MEMORANDUM OF UNDERSTANDING

This MOU reflects the intentions of the Participants. Other than section 5 above, it is not intended to create legal obligations of any nature, either in domestic or international law. In respect of section 5 both parties agree to be bound by the obligation of confidentiality outlined in section 5 in respect of any documents that are released to either party under this MOU.

In case of differences derived from the application or interpretation of this Instrument between the Participants, the English version of this MoU is the only one to be regarded as binding.

9. EFFECTIVE DATE

This MOU will come into effect upon the date of signature of both signatories and its effects continue until termination, according with clause 11.

10. AGENCY CONTACT

The liaison officers responsible for the administration of this MOU are:

a. for the AIFA, the person holding the position of head of the International Affairs Office; and

b. for the ANVISA, the person holding the position of head of the International Affairs Office.

11. TERMINATION

11.1. Either Participant may, at any time, give written notice of termination to the other Participant. This MOU (excepting clause 5) will terminate 30 days after the date of receipt of the notice of termination.

11.2. The termination of this MOU will not affect any commitment undertaken under or as a consequence of this MOU, in accordance with all arrangements or actions taken during the period before the termination .

Signed in

on this 06 day of DEC 2013

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by the Representative of the AIFA.

on this 6th day of dec 2013

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by the Representative of **ANVISA**