HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Agência Nacional de Vigilância Sanitária

MEMORANDUM OF UNDERSTANDING

between

The Brazilian Health Surveillance Agency (ANVISA)

And

Health Products Regulatory Authority (HPRA)

CONCERNING COOPERATION IN THE REGULATION OF THERAPEUTIC PRODUCTS

1. BACKGROUND

Agência Nacional de Vigilância Sanitária (ANVISA) of Brazil and **Health Products Regulatory Authority (HPRA)** of Ireland (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 the Participants and permit meaningful collaboration between them. This may include, but is not limited to, medicinal products and medical devices; 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, is contrary to the public interest or the interests of the Participant concerned, would be in breach or inconsistent with statutory obligations or requirements or other obligations and requirements imposed by the respective laws of Brazil or Ireland.

3. DEFINITIONS

In this MOU "therapeutic products" means:

(i) Medicinal products, herbal medicinal products, medical devices or other products or devices 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, advanced therapy medicinal products, medical devices or similar products or devices related to or connected with the functions of HPRA as described in Section 4 of the Health Products Regulatory Authority Act, 1995 as amended from time to time.

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-market assessment, post-market 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. HPRA

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

5.1.2. The HPRA 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 ANVISA to HPRA.

5.1.3. Unless otherwise required by law, the HPRA 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 HPRA 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 HPRA 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 HPRA, except in accordance with law.

5.2.2. ANVISA will make all reasonable efforts to inform the HPRA of any effort made by a judicial, legislative or other authority to obtain confidential information that has been provided by HPRA to ANVISA. If disclosure is required by law, ANVISA will consult with the HPRA in advance of releasing such information and will take all reasonable measures to ensure that the information received from the HPRA 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 HPRA under this MOU, except with the written consent of the HPRA.

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.

9. EFFECTIVE DATE

This MOU will come into effect upon the date of signature of both signatories and will continue in effect until terminated in accordance with clause 11.

10. AGENCY CONTACT

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

a. for the HPRA, the person holding the position of Director of Finance and Corporate Affairs; and

b. for the ANVISA, the person holding the position of Director Chairman.

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 six months after the date of receipt of the notice of termination.

11.2. The termination of this MOU will not affect any commitments given under or as a consequence of this MOU in respect of any arrangement or action taken during the period before the termination takes effect.

Signed in Mexico

on this 13 day of November 2015

.....

by the Representative of the Health Products Regulatory Authority (HPRA), Ireland.

on this day of 2015

.....

by the Representative of **ANVISA**