IRISH MEDICINES BOARD

swissmedic

MEMORANDUM OF UNDERSTANDING

Between

The Federal Department of Home Affairs acting in the name of the Federal Council of the Swiss Confederation

and

the Irish Medicines Board of Ireland

CONCERNING COOPERATION IN THE REGULATION OF THERAPEUTIC PRODUCTS

1. BACKGROUND

The Federal Department of Home Affairs, Switzerland acting for and on behalf of Swissmedic, Swiss Agency for Therapeutic Products (Swissmedic), and **The Irish Medicines Board (IMB)** of Ireland wish to establish a framework for cooperation between Swissmedic and the IMB (hereinafter referred as the "Participants") 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 the Participants. This may include, but is not limited to, medicinal products and medical devices; and

(ii) that some information may be classified as non-public / confidential information exempt from public disclosure under the laws and regulations of Switzerland and Ireland, such as confidential commercial information, trade secret information, personal privacy information, law enforcement information, or internal pre-decisional information.

3. DEFINITIONS

In this MOU "therapeutic products" means:

a. medicinal products and medical devices as defined in Article 4 (a) and (b) of the Swiss Federal Act on Medicinal Products and Medical Devices 2000 as amended from time to time (Act on Therapeutic Products, ATP); and

b. medicinal products, herbal medicinal products, homeopathic, advanced therapy medicinal products, medical devices or similar products or devices related to or connected with the functions of the IMB as described in Section 4 of the Irish Medicines Board Act, 1995 as amended from time to time.

4. AREA OF COOPERATION

The Participants having reached the above understanding declare their intention to:

a. establish avenues of communication to facilitate the exchange of information about the regulation of therapeutic products by each Partcipant, 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

b. undertake collaborative activities, including, where practical, the exchange of personnel.

5. CONFIDENTIALITY

Each Participant may release information, either public or non public information, to the other Participant based on each Participants' own laws and policies.
The release of information is subject to each Participants' own procedures described in the respective laws and policy guidelines.

Any information the Participants receive under the terms of this MOU is protected from disclosure to any third party and persons other than IMB/Swissmedic staff and is subject to the applicable national laws of each country.

The Participants understand that some information they receive from each other may include confidential information protected from public disclosure under the Irish/Swiss laws and regulations.

The Participants understand that this non-public information is shared in confidence, and that each Participant considers it critical that the other Participant maintains the confidentiality of the information. Public disclosure of this information by one of the Participants could seriously jeopardize any further scientific and regulatory interactions between the Participants. Swissmedic should advise the IMB of the non-public status of the information at the time that the information is shared and vice-versa.
Both Agencies state that they have the authority to protect the non-public information provided to each other in confidence from public disclosure.

6. FINANCIAL ARRANGEMENTS

Each Participant is responsible for the administration and expenditure of its own resources associated with activities conducted under the MOU.

7. STATUS

7.1 Nothing in this MOU will impose an obligation on either Participant to release information, either public or non public information to the other Participant. It will be a matter for either Participant to determine if they will release information based on its own applicable laws and policies.

7.2 The MOU will enter into effect on the day on which it is signed by the last Participant.

7.2 The Participants may evaluate this MOU at any time and propose amendments to it. Any proposed amendments will be subject to consultations between the Participants. Amendments may be made to the MOU with the mutual written consent of the Participants.

7.3 The Participants may withdraw at any time from the MOU . Information about the intention to withdraw should be given to the other Participant at least one month in advance. Point 5 "Confidentiality" shall continue to apply to any information shared prior to the withdrawal.

8. AGENCY CONTACT

The liaison officers for the administration of this MOU are:

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

b. for Swissmedic, the person holding the position of Head of Networking

Signed in Sydney, Australia

on this 27 day of October 2011

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by Pat O'Mahony, ~~Chief~~ Executive Irish Medicines Board (IMB), Ireland.

on this 27 day of october 2011

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by Jürg H. Schnetzer, Director, Swissmedic, Swiss Agency for Therapeutic Products, Switzerland