Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

IRISH MEDICINES BOARD

MEMORANDUM OF UNDERSTANDING
between
the Therapeutic Goods Administration of Australia
and
the Irish Medicines Board of Ireland

CONCERNING COOPERATION IN THE REGULATION OF THERAPEUTIC PRODUCTS

1. BACKGROUND

The Therapeutic Goods Administration (TGA) of Australia and **The Irish Medicines Board (IMB)** 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 Australia or Ireland.

3. DEFINITIONS

In this MOU "therapeutic products" means:

a. therapeutic goods as defined in Section 3 of the Australian *Therapeutic Goods Act 1989*, as amended from time to time; and

b. medicinal products, herbal medicinal products, 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 will:

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

5.1 IMB

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

5.1.2 Unless otherwise required by law, the IMB will not disclose any information received from the TGA under this MOU, except with the written consent of the TGA.

5.2.3 Unless otherwise required by law, the IMB 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 TGA

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

5.2.2 Unless otherwise required by law, the TGA will not disclose any information received from the IMB under this MOU, except with the written consent of the IMB.

5.2.3 Unless otherwise required by law, the TGA 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. It is not intended to create legal obligations of any nature, either in domestic or international law.

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

b. for the TGA, the person holding the position of Head, Executive Support Unit of the TGA.

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 Dublin

on the 8th day of June 2010

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

on the 8th day of June 2010

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by Rohan Hammett, National Manager, Therapeutic Goods Administration (TGA), Australia