MEDSAFE
NEW ZEALAND MEDICINES
AND MEDICAL DEVICES
SAFETY AUTHORITY
A BUSINESS UNIT OF
THE MINISTRY OF HEALTH
www.medsafe.govt.nz

IRISH MEDICINES BOARD

ARRANGEMENT
between
the New Zealand Ministry of Health
and
the Irish Medicines Board of Ireland

CONCERNING COOPERATION IN THE REGULATION OF THERAPEUTIC PRODUCTS

1. BACKGROUND

The New Zealand Ministry of Health, acting for and on behalf of the New Zealand Medicines and Medical Device Safety Authority (Medsafe) of New Zealand 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 Arrangement 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 Arrangement 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 Arrangement 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 New Zealand or Ireland.

3. DEFINITIONS

In this Arrangement "therapeutic products" means:

a. Medicines and medical devices as defined in sections 3 and 4 of the Medicines Act 1981 of New Zealand 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 voluntary collaborative activities, including, where practical, the exchange of personnel.

5. CONFIDENTIALITY

5.1 IMB

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

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

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

5.2 Medsafe

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

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

5.2.3 Unless otherwise required by law, the Medsafe will not use the information disclosed to it under this Arrangement 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 Arrangement may be amended at any time by the mutual consent in writing of the Participants via the respective signatories.

8. STATUS OF ARRANGEMENT

This Arrangement reflects the intentions of the Participants and the basis on which they intend to voluntarily co-operate..

9. EFFECTIVE DATE

This Arrangement 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 Arrangement are:

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

b. for Medsafe, the person holding the position of Principal Advisor Regulation, or any person designated by the Group Manager of Medsafe;.

11. TERMINATION

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

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

Signed in London

on this 14th day of OCTOBER 2010

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by the Representative of the Irish Medicines Board (IMB), Ireland.

on this 14th day of OCTOBER 2010

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by the Representative of the Medsafe, New Zealand