IRISH MEDICINES BOARD

Comhairle na nDochtúirí Leighis
Medical Council

MEMORANDUM OF UNDERSTANDING

between

the Irish Medicines Board

and

the Medical Council

CONCERNING COOPERATION IN THE REGULATION OF PUBLIC HEALTH

1. BACKGROUND

The **Medical Council**, established by the Medical Practitioners Act 1978, which has been repealed and replaced by the Medical Practitioners Act 2007 ("2007 Act") and the **Irish Medicines Board ('IMB')**, established by the Irish Medicines Board Acts 1995 and 2006, as amended (hereinafter referred to as the "Participants") wish to establish a framework for cooperation in the area of the regulation of public health in Ireland.

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 areas of common interest;

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 the public.

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

a. that each Participant has jurisdiction over different areas of regulation. This MOU is intended to cover areas of common interest or where co-operation will lead to better informed regulation; and

b. each Participant may, in particular circumstances, limit the scope of disclosure of information to the other Participant particularly if the disclosure may be prejudicial to the commercial or other 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 law.

3. DEFINITIONS

In this MOU the following definitions shall apply:

a) "clinical trial" means any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption,

distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy;

b) "complaint" means a complaint about a registered medical practitioner to the Preliminary Proceedings Committee ("PPC");

c) "medical device" means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacture to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

d) "medicinal product" means (a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting or modifying pharmacological, immunological or metabolic action, or to making a medical diagnosis;

e) "registered medical practitioner" means a medical practitioner whose name is entered in the Register of Medical Practitioners;

f) "tissue establishment" means a tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissues and cells are undertaken. It may also be responsible for procurement or testing of tissues and cells.

4. AREA OF COOPERATION

The Participants having reached the above understanding will:

a) establish avenues of communication to facilitate the exchange of information in situations where either Participant comes across information which could be considered relevant to the other Participant's role, including but not limited to:
   i. information obtained by the IMB in relation to the behaviour, conduct, practise and/or professional competency of a medical practitioner registered with the Medical Council, and
   ii. information obtained by the Medical Council in relation to the improper use, supply, administration, advertisement of a medicinal and health care products where such information may indicate a breach of medicines and other legislation enforced by the IMB;

b) establish avenues of communication with each other to facilitate the exchange of information about their respective fields of regulation and operation of their organisations; and

c) undertake collaborative activities consistent with this MOU.

5. CONFIDENTIALITY

a) IMB

   i. Nothing in this MOU requires the IMB to release confidential information to the Medical Council, except in accordance with law.

   ii. Unless otherwise required by law, the IMB will not disclose any information received from the Medical Council under this MOU, except with the written consent of the Medical Council. If disclosure is required by law, the IMB will take all reasonable measures to ensure that the information received from the Medical Council will be disclosed in a manner that protects the information from any disclosure that is not required or authorised by law.

   iii. 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 regulatory activities.

b) Medical Council

i. Nothing in this MOU requires the Medical Council to release confidential information to the IMB, except in accordance with law.

ii. Unless otherwise required by law, the Medical Council will not disclose any information received from the IMB under this MOU, except with the written consent of the IMB. If disclosure is required by law, the Medical Council will take all reasonable measures to ensure that the information received from the IMB will be disclosed in a manner that protects the information from any disclosure that is not required or authorised by law.

iii. Unless otherwise required by law, the Medical Council will not use the information disclosed to it under this MOU for any other purpose than for the purposes of giving effect to the provisions of the 2007 Act.

6. FINANCIAL ARRANGEMENTS

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

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. The Participants will however observe and give due respect to the confidentiality undertakings which they have expressed in 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 IMB, the person holding the position of Director of Finance and Corporate Affairs; and

b) for the Medical Council, the person holding the position of Head of Corporate Services and Secretary to the Board.

11. TERMINATION

a. 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.

b. The termination of this MOU will not affect the confidentiality undertakings expressed by the Participants in this MOU and 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 this 16 day of June 2011

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

on this 16 day of June 2011

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by Caroline Spillane, Chief Executive, the Medical Council