No. 45744

Switzerland
and
Singapore

Memorandum of Understanding between the Health Sciences Authority of Singapore and the Federal Department of Home Affairs acting in the name of the Federal Council of the Swiss Confederation regarding therapeutic products. Singapore, 12 May 2008

Entry into force: *12 May 2008 by signature, in accordance with section X*

Authentic text: *English*

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Suisse
et
Singapour

Protocole d'entente entre le Département fédéral de l'intérieur agissant au nom du Conseil fédéral de la Confédération suisse et l'Autorité sanitaire de Singapour relatif aux produits thérapeutiques. Singapour, 12 mai 2008

Entrée en vigueur : *12 mai 2008 par signature, conformément à la section X*

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Enregistrement auprès du Secrétariat des Nations Unies : *Suisse, 10 février 2009*

[ENGLISH TEXT – TEXTE ANGLAIS]

MEMORANDUM OF UNDERSTANDING

BETWEEN THE

HEALTH SCIENCES AUTHORITY OF SINGAPORE

AND

THE FEDERAL DEPARTMENT OF HOME AFFAIRS ACTING IN THE NAME OF THE FEDERAL COUNCIL OF THE SWISS CONFEDERATION

REGARDING THERAPEUTIC PRODUCTS

I. BACKGROUND

1. The Health Sciences Authority of Singapore (HSA), and the Federal Department of Home Affairs, Switzerland (FDHA), share the common goal of protecting the health and safety of their respective populations by ensuring the safety, quality and efficacy of Therapeutic Products, manufactured in, imported into, and exported from, their respective countries.

2. The HSA and FDHA share a high regard for each other's regulatory practices and systems.

II. PURPOSE

1. On the basis of this Memorandum of Understanding (MOU) the HSA and Swissmedic, Swiss Agency for Therapeutic Products (Swissmedic), acting in the name of FDHA, hereafter referred to as "the Participants", will:

a. facilitate the exchange of information and sharing of documentation relating to the regulation of Therapeutic Products, to advance and improve policy and operational regulatory affairs from the pre-market to the post-market lifecycle of Therapeutic Products and to enable the Participants to acquire reciprocal knowledge and understanding of each other's regulatory requirements and processes and to improve the safety, quality and efficacy of Therapeutic Products marketed in each country.

b. encourage the development of collaborative activities relating to the regulation of Therapeutic Products.

2. Information and documentation that may be exchanged under this MOU may only be used for the purposes of this MOU.

3. The circumstances under which information and documentation may be exchanged include:

a. where either Participant has already completed a particular regulatory activity, and the other Participant requires insight into issues that arose during that activity, and how those issues were dealt with during the final decision-making process, or

b. where the Participants are carrying out a particular regulatory activity synchronously, and would like to share information about their process(es) and/or issues that have been identified.

4. This MOU does not modify existing cooperative activities nor does it preclude entering into separate arrangements for specific activities that can be handled more efficiently by special arrangements.

5. Nothing in this MOU is intended to diminish or otherwise affect the authority of either Participant in carrying out its regulatory responsibilities.

III. DEFINITIONS

1. In this MOU:

"Concerned Person" in relation to Non-public Information, means any individual or other legal person to whom the Non-public Information relates.

"Non-public Information" means any information not in the public domain that is held by a Participant and is treated as confidential by that Participant in accordance with laws applicable to the Participant.

"Therapeutic Products" means:

a. medicinal products and medical devices as defined in Article 4.1 (a) and (b) of the Swiss *Federal Law on Medicinal Products and Medical Devices 2000* as amended from time to time (Law on Therapeutic Products); and

b. Therapeutic goods as defined in Section 2(1) of the Health Products Act 2007 and its First Schedule, and in Section 3 of the Medicines Act (Chapter 176), as amended from time to time.

"Vigilance Information" means information relating to the monitoring and study of the effects and other safety-related aspects of Therapeutic Products that have been approved and/or are marketed to the public, e.g., product safety assessments, individual adverse event reports, adverse event trend information, health hazard evaluations and alert system notifications as appropriate.

IV. SCOPE

1. The types of information and documentation that may be exchanged include:

a. Guidance documents, policies, procedures, and other technical documents for which the Participants have responsibility.

b. Information related to the categorization of Therapeutic Products pre-market applications, e.g., priority review status, orphan drug designation, etc.

c. Information contained in, and about, clinical trial or investigational applications for Therapeutic Products, including adverse event reports or evaluation reports from the various discipline reviews, e.g., chemistry and manufacturing, clinical, etc.

d. Information about ongoing clinical trials for Therapeutic Products, including information related to clinical trial site inspections directed at determining compliance with good clinical practice.

e. Information contained in, or about, Therapeutic Products marketing applications, including evaluation reports from the various discipline reviews, e.g., chemistry and manufacturing, clinical, etc., and results from any on-site evaluations.

f. Information that supports the conformity of Therapeutic Products with applicable regulatory requirements, including the results from pre-approval consistency testing, post-approval lot release testing and information on testing methodologies or algorithms for biological pharmaceuticals, or product sample test results for chemical pharmaceuticals.

g. Information related to compliance and completed enforcement activities, e.g., product or establishment investigations.

h. Information regarding the suppliers of Therapeutic Products that are the subject of specific shortage situations in either jurisdiction.

i. Inspection reports, or other information, that supports the compliance of facilities that manufacture, wholesale, test or import Therapeutic

Products, with applicable regulatory requirements.

j. Information on facilities licensed, registered or authorized in each Participant's country that then market Therapeutic Products in the other Participant's country.

k. Information related to import refusals for reasons related to the safety, quality, or integrity of a shipment.

l. Post-market surveillance information having potential impact on public health, including Vigilance Information, and information about impending regulatory actions, e.g., proposed market withdrawals and product recalls.

m. Information on safety and quality defects reported for, and product recalls effected for, Therapeutic Products manufactured and/or supplied in Singapore or Switzerland.

n. Information on practices and procedures relating to the development of policy, regulation or legislation, including strategies designed to ensure that regulatory processes are transparent and open. Information regarding risk management, risk communication, or public involvement strategies, and consideration for ethical or other socio-economic issues in the development of new regulatory frameworks.

o. Information on technology, e.g., information management systems, database systems, and other related computer applications that support the evaluation, testing and investigation of Therapeutic Products, the tracking of Therapeutic Products applications, or the inspection of facilities in which Therapeutic Products are manufactured.

p. Any other information technology or systems that may be mutually agreed upon from time to time.

2. Collaborative activities may include the exchange, training and development of professional competence in the evaluation, assessment or regulation of specific Therapeutic Products, collaborative research relating to the quality, safety or efficacy of Therapeutic Products, and the planning of joint workshops, conferences, seminars or meetings for the mutual benefit of each other.

   The Participating Parties will collaborate, where appropriate, (and where necessary, establish joint working groups) to assess new and emerging technologies and the risk management strategies associated with such innovations. This may include, but will not be limited to :

   - Laboratory testing and validation methodologies
   - Laboratory proficiency testing programs
   - Information collection and sharing; and