Memorandum on information exchange

BETWEEN
THE HEALTH SCIENCES AUTHORITY OF the Republic of SINGAPORE
AND
PHARMACEUTICAL AND FOOD SAFETY BUREAU OF THE MINISTRY OF HEALTH, LABOUR AND WELFARE
TOGETHER WITH THE
PHARMACEUTICALS AND MEDICAL DEVICES AGENCY OF JAPAN

1. BACKGROUND

1.1 The Health Sciences Authority (HSA) of the Republic of Singapore and the Pharmaceutical and Food Safety Bureau of the Ministry of Health, Labour and Welfare (MHLW) together with the Pharmaceuticals and Medical Devices Agency of Japan (PMDA) (hereinafter referred to as "the Participants"), have recognized the need to exchange information in the field of the regulations of medicines, medical devices, and cosmetics (including Japanese quasi-drugs).

1.2 The Participants intend to cooperate through exchanging more regulatory information including advance drafts of legislation and/or regulatory guidance documents as well as information related to authorization and supervision of medical products for human use in accordance with their respective national laws and regulations, since this type of information may include information of a non-public nature, Participants assure that they will keep the information exchanged confidential.

2. PURPOSE

2.1 This cooperation is intended to advance and improve policy and operational regulatory issues from pre-market to post-market stages in the lifecycle of medicines, medical devices and cosmetics, enable the Participants to acquire reciprocal knowledge and understanding of each other's regulatory requirements and processes, and to ensure the quality, safety, and efficacy of medicines, medical devices and cosmetics marketed in each country.

2.2 On the basis of this Memorandum, the Participants will facilitate the exchange of relevant information relates to the regulations of medicines, medical devices and cosmetics.

3 DEFINITIONS

3.1 In this Memorandum:

"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.

"Medicines and medical devices and cosmetics (including Japanese quasi-drug)" will be construed in accordance with the respective laws and regulations governing each Participant.

"Vigilance Information" means information relating to the monitoring for, and study, of the effects and other safety-related aspects of medicines, medical devices and cosmetics 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.

4. CONFIDENTIALITY

4.1 <u>The MHLW and the PMDA</u>

The MHLW and the PMDA have responsibility to protect the non-public information provided to the MHLW and the PMDA by the HSA from public disclosure.

The MHLW or the PMDA will inform the HSA within five working days of any request made by judicial or legislative mandate to the MHLW or the PMDA to submit the non-public information provided by the HSA. Even if such judicial or legislative mandate orders disclosure of the non-public information provided by the HSA, the MHLW or the PMDA will take all possible measures in an effort to ensure that the information will not be disclosed to the public.

The MHLW or the PMDA will promptly inform the HSA of any changes to laws, policies or procedures that would affect the MHLW and the PMDA's ability to honor the cooperation under this memorandum.

- Before releasing any non-public information to the HSA regarding medicines, medical devices and cosmetics, the MHLW or the PMDA will obtain the consent of any Concerned Person, where appropriate, to provide such information to the HSA in accordance in a manner stated in this Memorandum. When seeking such consent, the MHLW or the PMDA will inform any Concerned Person of the purposes for which the HSA might use the information, and that the HSA has consented to treat the information as confidential.

- The MHLW or the PMDA will inform the HSA of the response from any Concerned Person to a request for consent under this section.

- The MHLW and the PMDA will protect the confidentiality of any information they receive from the HSA from disclosure to any third entities, and will not release it to any persons other than the MHLW or the PMDA staff or contractors who need to know the information for work purposes, except when there is a written consent from the HSA or written confirmation from the HSA that the information has been made public in Singapore.

4.2 HSA

The HSA has responsibility to protect the non-public information provided to the HSA by the MHLW and the PMDA from public disclosure.

The HSA will inform the MHLW and the PMDA within five working days of any request made by judicial or legislative mandate to the HSA to submit the non-public information provided by the MHLW and the PMDA.

The HSA will promptly inform the MHLW and the PMDA of any changes to laws, policies or procedures that would affect the HSA's ability to honor the cooperation under this memorandum.

- Before releasing any non-public information to the MHLW and the PMDA regarding medicines, medical devices and cosmetics, the HSA will obtain the consent of any Concerned Person, where appropriate, to provide of such information to the MHLW and the PMDA in a manner stated in this Memorandum. When seeking such consent, the HSA will inform any Concerned Person of the purposes for which the MHLW or the PMDA might use the information and that the MHLW or the PMDA has consented to treat the information as confidential.

- The HSA will inform the MHLW and the PMDA of the response from any Concerned Person to a request for consent under this section.

- The HSA will protect the confidentiality of any information it receives from the MHLW or the PMDA from disclosure to any third entities, and will not release it to any persons other than HSA staff or contractors who need to know the information for work purposes, except when there is a written consent or a written confirmation from the MHLW or the PMDA that the information has been made public in Japan.

4.3 The Participants accept that there may be occasions when it is necessary to limit the scope of the information outlined in section 2, particularly if its dissemination or exchange may

- Harm the commercial interests of a third party;
- Breach a duty of confidence or privacy attaching to the information;
- Disclose a trade secret;
- Be contrary to the public interest or the interests of the authority concerned; or
- Be inconsistent with other statutory obligations or requirements or other obligations or requirements imposed by the respective laws of Singapore or Japan

4.4 Refusal of a Concerned Person to share information as outlined in this Memorandum will not affect the regulatory processes for which purposes it was originally prepared.

5. ADMINISTRATION

5.1 All activities of the HSA and the MHLW or the PMDA carried out pursuant to this Memorandum are to be conducted in accordance with the laws and regulations of Singapore and Japan respectively. These activities are also subject to the availability of personnel, resources and funds.

5.2 This cooperation will commence on 15 May, 2010 and will be in operation until otherwise advised by any of the Participants.

The content and operation of this Memorandum will be reviewed by the Participants after one year and at such intervals after that as decided by the Participants.

Signed in duplicate at ***Singapore***, on this 13 May, 2010 in English.

FOR THE
HEALTH SCIENCES AUTHORITY OF
SINGAPORE

Dr. John C. W. Lim
Chief Executive Officer

Signed in duplicate at ***Tokyo***, on this 28. Apr. , 2010 in English.

FOR THE
PHARMACEUTICAL AND FOOD SAFETY BUREAU OF THE MINISTRY OF HEALTH, LABOUR AND WELFARE OF JAPAN

Mr. Yasuyuki Takai
Director-General
Pharmaceutical and Food Safety Bureau

FOR THE
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Dr. Tatsuya Kondo
Chief Executive