



CONFIDENTIALITY ARRANGEMENT
STATEMENT

From

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

EXECUTING AUTHORITY: SWISSMEDIC, SWISS AGENCY FOR THERAPEUTIC
PRODUCTS

NOT TO PUBLICLY DISCLOSE NON PUBLIC INFORMATION
SHARED BY PHARMACEUTICALS AND MEDICAL DEVICES AGENCY.

Swissmedic understands that some of the information it receives from Pharmaceuticals and Medical Devices Agency (PMDA) may include non public information on pharmaceuticals and medical devices⁵ / medicinal products and medical devices⁶ (hereinafter referred to as “non public information”) exempt from public disclosure under the laws and regulations of Japan, such as confidential commercial information; trade secret information; personal privacy information; law enforcement information; or internal, pre-decisional information. Swissmedic understands that this non public information is shared in confidence, and that PMDA considers it critical that Swissmedic maintain the confidentiality of the information. Public disclosure of this information by Swissmedic could seriously jeopardize any further scientific and regulatory interactions between PMDA and Swissmedic. PMDA should advise Swissmedic of the non public status of the information at the time that the information is shared.

Swissmedic states that it has the authority to protect the non public information provided to Swissmedic in confidence by PMDA from public disclosure.

Swissmedic should not publicly disclose the PMDA provided non public information without the written authorization of the owner of the information, the written authorization from the individual who is the subject of the personal privacy

⁵ As defined in Article 2 of the Pharmaceutical Affairs Law (Law No. 145 dated August 10, 1960) as amended from time to time

⁶ As defined in Article 4 (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)



information, or a written statement from PMDA that the information no longer has non public status.

Swissmedic should inform PMDA of any effort made to obtain PMDA provided non public information from Swissmedic by judicial or legislative mandate. If such judicial or legislative mandate orders disclosure of PMDA-provided non-public information, Swissmedic should take all measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure.

Swissmedic should promptly inform PMDA of any changes to Swiss laws, Smwissedic policies, or procedures that would affect Swissmedic's ability to carry out the contents in this document.

This Confidentiality Arrangement does not impose any legal obligations.

Signature

3. Nov. 2010
Date

Mr Jürg H. Schnetzer
Executive Director

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In the name of the Federal Council of the Swiss Confederation

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