



CONFIDENTIALITY ARRANGEMENT
STATEMENT
FROM THE PHARMACEUTICALS AND MEDICAL DEVICES AGENCY
(PMDA),
NOT TO PUBLICLY DISCLOSE NON PUBLIC INFORMATION
SHARED BY
• 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

The PMDA understands that some of the information it receives from Swissmedic may include non public information on medicinal products and medical devices¹ / pharmaceuticals and medical devices² (hereinafter referred to as “non public information”) exempt from public disclosure under the laws and regulations of Switzerland, such as confidential commercial information; trade secret information; personal privacy information; law enforcement information; or internal, pre-decisional information. The PMDA understands that this non public information is shared in confidence, and that Swissmedic considers it critical that the PMDA maintain the confidentiality of the information. Public disclosure of this information by the PMDA could seriously jeopardize any further scientific and regulatory interactions between Swissmedic and PMDA. Swissmedic should advise the PMDA of the non-public status of the information at the time that the information is shared.

The PMDA states that it has the authority to protect the non public information provided to the PMDA in confidence by Swissmedic from public disclosure. PMDA should not publicly disclose Swissmedic provided non public information

¹ 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)

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

without the written authorization of the owner of the information, the written authorization from the individual who is the subject of the personal privacy information, or a written statement from Swissmedic that the information no longer has non-public status.

PMDA should inform Swissmedic of any effort made to obtain Swissmedic provided non public information from the PMDA by judicial or legislative mandate. If such judicial or legislative mandate orders disclosure of Swissmedic provided non public information, the PMDA 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.

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

This Confidentiality Arrangement does not impose any legal obligations.

Signature of foreign government official

Nov. 7, '10

Date

Tatsuya Kondo

Print or Type foreign government official

Chief Executive

Title of foreign government agency official

Pharmaceuticals and Medical Devices Agency

Name of foreign government agency.

Address: Shin-kasumigaseki Bldg., 3-3-2, Kasumigaseki, Chiyoda-ku, Tokyo 100-0013

Contact point:

Division of Regulatory Cooperation, Office of International Programs

Telephone: +81-3-3506-9456, Facsimile: + 81-3-3506-9572