

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

Swissmedic understands that some of the information it receives from Pharmaceutical and Food Safety Bureau, Ministry of Health Labour and Welfare, Japan (PFSB) may include non-public information on pharmaceuticals and medical devices¹ / medicinal products and medical devices² (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 PFSB 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 PFSB and Swissmedic. PFSB 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 PFSB from public disclosure.

Swissmedic should not publicly disclose the PFSB-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

¹ As defined in Article 2 of the Pharmaceutical Affairs Law (Law No. 145 dated August 10, 1960) as amended from time to time

² 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 PFSB that the information no longer has non-public status.

Swissmedic should inform PFSB of any effort made to obtain PFSB -provided non-public information from Swissmedic by judicial or legislative mandate. If such judicial or legislative mandate orders disclosure of PFSB-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 PFSB of any changes to Swiss laws, Swissmedic 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

Date

Mr Jürg H. Schnetzer

Executive Director

Swissmedic, Swiss Agency for Therapeutic Products,

In the name of the Federal Council of the Swiss Confederation

Address: Hallerstrasse 7, 3000 Bern 9, Switzerland

Contact point:

Cordula Landgraf; Head of Networking, Swissmedic

Telephone: +41 31 322 0478; Facsimile: + 41 31 322 0406

CONFIDENTIALITY ARRANGEMENT
STATEMENT
FROM THE PHARMACEUTICAL AND FOOD SAFETY BUREAU,
MINISTRY OF HEALTH, LABOUR AND WELFARE OF JAPAN (PFSB),
NOT TO PUBLICLY DISCLOSE NON PUBLIC INFORMATION
SHARED BY
THE FEDERAL DEPARTMENT OF HOME AFFAIRS,
ACTING IN THE NAME OF THE FEDERAL COUNCIL,
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EXECUTING AUTHORITY: SWISSMEDIC, SWISS AGENCY FOR THERAPEUTIC
PRODUCTS

The PFSB understands that some of the information it receives from Swissmedic may include non-public information on medicinal products and medical devices³ / pharmaceuticals and medical devices⁴ (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 PFSB understands that this non-public information is shared in confidence, and that Swissmedic considers it critical that the PFSB maintain the confidentiality of the information. Public disclosure of this information by the PFSB could seriously jeopardize any further scientific and regulatory interactions between Swissmedic and PFSB. Swissmedic should advise the PFSB of the non-public status of the information at the time that the information is shared.

The PFSB states that it has the authority to protect the non-public information provided to the PFSB in confidence by Swissmedic from public disclosure. PFSB should not publicly disclose Swissmedic-provided non-public information without the written authorization of the owner of the information, the written

³ 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)

⁴ As defined in Article 2 of the Pharmaceutical Affairs Law (Law No. 145 dated August 10, 1960) as amended from time to time

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.

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

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

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Signature of foreign government official

Date

Print or Type foreign government official

Director General of Pharmaceutical and Food Safety Bureau

Title of foreign government agency official

Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare

Name of foreign government agency.

Address: 2-2, Kasumigaseki 1-chome, Chiyoda-ku, Tokyo 100-8916

Contact point:

Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau

Telephone: +81 3-3595-2431, Facsimile: + 81-3-3597-9535

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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 devices ⁶ (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, Swissmedic 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

Date

Mr Jürg H. Schnetzer

Executive Director

Swissmedic, Swiss Agency for Therapeutic Products,

In the name of the Federal Council of the Swiss Confederation

Address: Hallerstrasse 7, 3000 Bern 9, Switzerland

Contact point:

Cordula Landgraf; Head of Networking, Swissmedic

Telephone: +41 31 322 0478; Facsimile: + 41 31 322 0406

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STATEMENT
FROM THE PHARMACEUTICALS AND MEDICAL DEVICES AGENCY
(PMDA),
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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 devices⁷ / pharmaceuticals and medical devices⁸ (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 without the written authorization of the owner of the information, the written authorization from the individual who is the subject of the personal privacy

⁷ 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)

⁸ As defined in Article 2 of the Pharmaceutical Affairs Law (Law No. 145 dated August 10, 1960) as amended from time to time

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.

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Signature of foreign government official

Date

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