Tel. direct +41 31 322 02 01
Fax +41 31 322 04 30

Arrangement for shared non-public information regarding Influenza A (H1N1) pandemic

1. Following the request dated 28th January 2010 from the Mission of Switzerland to the European Union to the European Commission, Directorate General for Health and Consumers, to increase cooperation between the European Medicines Agency and Swissmedic, and the response of the European Commission to this request, the Swiss Agency for Therapeutic Products, Swissmedic, on behalf of the Federal Department of Home Affairs acting in the name of the Federal Council on the one side and the European Medicines Agency on the other side (collectively "the Participants") have recognised a specific and urgent need for an interim co-operative arrangement to enable the exchange of specific scientific and technical information and documents related to ensuring the safety, quality, efficacy and post-authorisation follow-up of medicinal products and vaccines that may be used in the context of the Influenza A (H1N1) pandemic, which for the European Medicines Agency means those subject to evaluation or authorised under the centralised procedure in the European Union (EU), as well as medicinal products authorised at national level by the EU Member States that are subject to official European Union arbitration and referrals and for Swissmedic means those approved or under evaluation in accordance with the Federal Act of December 15, 2000, on Therapeutic Products (CC 812.21).

2. Swissmedic understands that, in relation to any information it receives from the European Medicines Agency, this may include information communicated in confidence and non-public information that may reasonably be expected or considered to be exempt from public disclosure under European law, including (but not limited to) confidential commercial information, trade secret information, personal privacy information, law enforcement information or internal operational information. Swissmedic understands that this non-public information is shared in confidence, and that the European Medicines Agency considers it critical that Swissmedic maintain the confidentiality of the information. For the purpose of this arrangement, sharing of information between the Swissmedic and its experts is not deemed as public disclosure. Public disclosure of this information by Swissmedic could seriously jeopardise any further scientific and regulatory interactions between the European Medicines Agency and Swissmedic. The European Medicines Agency will advise Swissmedic of the confidential or non-public status of the information at the time that the information is shared.

3. Therefore, Swissmedic, affirming that it has the authority and has procedures in place to protect from public disclosure the non-public information the European Medicines Agency provides in confidence to Swissmedic,
   3.1. should use the information only for the purpose of evaluating and discussing it in the context of ensuring the safety, quality, efficacy and post-authorisation follow-up of medicinal products and vaccines concerned (hereinafter referred to as "the Purpose"), and should make no other use thereof whatsoever without the prior written consent of the European Medicines Agency;

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3.2. should not publicly disclose the European Medicines Agency-provided confidential or non-public information without the prior written consent of the European Medicines Agency, or a written statement from the European Medicines Agency that the information is now in the public domain;
3.3. should inform the European Medicines Agency within two working days of any effort made to obtain the European Medicines Agency-provided confidential or non-public information from Swissmedic under the Swiss Act on Transparency of December 17, 2004 as amended from time to time. If such law permits disclosure of the European Medicines Agency-provided confidential or non-public information, Swissmedic should take all reasonable measures to ensure that the information will be disclosed in a manner that is in accordance with the law and that protects the information from public disclosure
3.4. should promptly inform the European Medicines Agency of any changes to Specific country laws, regulations, directives, policies or procedures that would affect Swissmedic's ability to honour the provisions in this document;
3.5. should not charge European Medicines Agency for information or assistance provided under this arrangement.

4. Upon completion of the aforesaid Purpose, Swissmedic should cease all use and make no further use of the information disclosed to Swissmedic hereunder. Upon written request from the European Medicines Agency, Swissmedic should promptly return to the European Medicines Agency or destroy all of the information received including any copies thereof and notes or other materials incorporating such information.

5. The Participants note that this arrangement to exchange confidential information:
5.1. does not affect the authority of either Participant to carry out its regulatory responsibilities (as they exist from time to time) in accordance with its laws and administrative policies (as they exist from time to time);
5.2. does not prevent either Participant from declining to provide information to the other participant where that information includes or consists of confidential or non-public information. For Swissmedic, especially Article 64 of the Federal Act of December 15, 2000, on Therapeutic Products needs to be considered; and
5.3. is not intended to create legal obligations of any nature, either in domestic or international law and the Participants acknowledge that this instrument (setting out these arrangements) is not governed by international law and does not constitute or create, and will not be deemed to constitute or create any legally binding or enforceable obligations or declaration, (express or implied) on the part of any of the Participants and is not intended to give rise to legal process.

6. Any information exchanged which is confidential or non-public should be protected by the Participants and should not be released to any government officials who are not required to know that information for the purposes of the protection of public health and order in the context of the co-operation envisaged under this arrangement and that information should not be published.

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7. If the terms above are acceptable to the European Medicines Agency then a letter from the European Medicines Agency, accepting the proposed terms of cooperation mutatis mutandis, will establish a mutual arrangement between the European Medicines Agency and Swissmedic which commences on the date of the signature of the letter from the European Medicines Agency and will terminate one year after this date.

Signature on file

..... 4 February 2010

Jürg H. Schnetzer
Executive Director

Date

The Swiss Agency for Therapeutic Products, Swissmedic
On Behalf of the Federal Department of Home Affairs
Acting in the name of the Federal Council

Hallerstrasse 7
CH-3000 Berne 9
Switzerland