



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

12 February 2010  
EMA/84828/2010  
Directorate

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

Following the request dated 28<sup>th</sup> 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 Executive Director of the European Medicines Agency is pleased to acknowledge receipt of the letter dated 4<sup>th</sup> February 2010 of the Swiss Agency for Therapeutic Products, Swissmedic, on behalf of the Federal Department of Home Affairs acting in the name of the Federal Council, as follows:

1. 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 and which 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. The European Medicines Agency understands that, in relation to any information it receives from Swissmedic 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 the Federal Act of December 15, 2000, on Therapeutic Products, as amended from time to time and within the framework of the Swiss legislation on data protection, including (but not limited to) confidential commercial information, trade secret information, personal privacy information, law enforcement information or internal operational information. The European Medicines Agency understands that this non-public information is shared in confidence, and that Swissmedic considers it critical that the European Medicines Agency maintain the confidentiality of the information. For the purpose of this arrangement, sharing of information between the European Medicines Agency, the European Commission and its experts is not deemed as public disclosure. Public disclosure of this information by the European Medicines Agency could seriously jeopardise any further scientific and regulatory interactions between Swissmedic and the European Medicines Agency. Swissmedic will advise the European Medicines Agency of the confidential or non-public status of the information at the time that the information is shared.
3. Therefore, the European Medicines Agency, affirming that it has the authority and has procedures in place to protect from public disclosure the non-public information Swissmedic provides in confidence to the European Medicines Agency,
  - 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 the 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 Swissmedic;
- 3.2. should not publicly disclose Swissmedic-provided confidential or non-public information without the prior written consent of Swissmedic or a written statement from Swissmedic that the information is now in the public domain;
  - 3.3. should inform Swissmedic within two working days of any effort made to obtain Swissmedic-provided confidential or non-public information from the European Medicines Agency under European Union or national law. If such law permits disclosure of Swissmedic-provided confidential or non-public information, the European Medicines Agency should take all reasonable measures to ensure that the information will be disclosed in a manner that is in accordance with the law that protects the information from public disclosure
  - 3.4. should promptly inform Swissmedic of any changes to European Union or national laws, regulations, directives, policies or procedures that would affect the European Medicines Agency's ability to honour the provisions in this document;
  - 3.5. should not charge Swissmedic for information or assistance provided under this arrangement.
4. Upon completion of the aforesaid Purpose, the European Medicines Agency should cease all use and make no further use of the information disclosed to the European Medicines Agency hereunder. Upon written request from Swissmedic, the European Medicines Agency should promptly return to Swissmedic 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;
    - 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 co-operation envisaged under this arrangement and that information should not be published.
  7. The European Medicines Agency accepts the terms of cooperation proposed in Swissmedic's letter of 4<sup>th</sup> February 2010. Consequently, the letter at hand establishes a mutual arrangement between the European Medicines Agency and Swissmedic which commences on the date of the signature of this letter and will terminate one year after this date.

Signature on file

Mr Thomas Lönngren

Executive Director  
European Medicines Agency

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12/2 2010  
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Date