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Press Office

**Press release**

# European Medicines Agency and Swissmedic agree sharing of information on H1N1 pandemic medicines

The European Medicines Agency and Swissmedic will from now on be able to exchange confidential information about the authorisation and safety of medicines used in the context of the H1N1 pandemic influenza.

The confidentiality arrangement was agreed between the European Medicines Agency on the one side and the Swiss Agency for Therapeutic Products, Swissmedic, on the other side, on 12 February 2010.

The partners will be able to exchange confidential scientific and technical information to ensure the safety, quality, efficacy and post-authorisation follow-up of medicines used in the context of the pandemic.

This closer co-operation will provide the two authorities earlier access to information on the basis for their respective recommendations on pandemic medicines and complete the overall view on their safety. It will also create the opportunity to exchange experience regarding 'lessons learned' during the H1N1 pandemic.

The new confidentiality arrangement will allow exchange of information between the parties as part of their regulatory and scientific processes, both before and after a medicine has been approved.

## Notes

1. The confidentiality arrangement is valid for one year and is established by an exchange of letters which can be found here: Letter from the European Medicines Agency; Letter from Swissmedic

2. The confidentiality arrangement covers human medicinal products used in the context of the H1N1 pandemic influenza and subject to the evaluation or authorised under the centralised

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authorisation procedure as well as medicinal products authorised at national level by the European Union Member States that are subject to official European arbitration and referrals.

3. The scope of products covered in Switzerland includes those used in the context of the H1N1 pandemic influenza and approved or under evaluation in accordance with the Federal Act of December 15, 2000, on Therapeutic Products (CC 812.21).

4. This arrangement complements ongoing activities in the area of quality and manufacturing under the Mutual Recognition Agreement between the European Union and Switzerland: see here http://www.ema.europa.eu/Inspections/MRACH.html

5. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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