European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency adopts first positive opinion for mock-up pandemic influenza vaccine

The European Medicines Agency (EMEA) has adopted the first positive opinion recommending the granting of a Community authorisation for a mock-up pandemic influenza vaccine. The objective behind a mock-up vaccine is to have a marketing authorisation in place that can be changed quickly in the event of a pandemic to include the virus strain responsible, once it has been identified.

The vaccine concerned, Daronrix from GlaxoSmithKline Biologicals S.A., is intended for the prevention of influenza during an officially declared pandemic situation, once the pandemic viral strain has been included. The mock-up pandemic influenza vaccine is not expected to be used or stockpiled in its current form.

The availability of vaccines in the event of an outbreak of pandemic influenza is essential for protecting the public from the disease. However, it is impossible to prepare an appropriate vaccine in advance of an outbreak, because the strain of the virus responsible for it is unknown until after the outbreak has started. To facilitate the approval of pandemic vaccines, the European Commission and the EMEA developed a novel approach for the European Union that allows the authorisation of a mock-up vaccine in advance of a potential pandemic.

A mock-up pandemic influenza vaccine is a vaccine that mimics the future pandemic influenza vaccine in terms of its composition and manufacturing method. Instead of the pandemic influenza virus strain, which is as yet unknown, the mock-up contains an influenza virus strain that has been specifically chosen because the population is immunologically naïve to it (i.e. a strain to which the population has never been exposed). In the event of an influenza pandemic, the marketing authorisation holder will submit additional data as a variation to the marketing authorisation to include the actual pandemic virus strain in the vaccine.

The strain chosen for Daronrix is derived from a strain that has been involved in recent outbreaks of influenza in birds (H5N1). This strain is not circulating in humans.

The EMEA positive opinion on Daronrix will now be forwarded to the European Commission, which takes the final decision on the granting of a marketing authorisation.

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Notes
1. A question and answer document on mock-up vaccines can be found here.
2. The summary of opinion for Daronrix with more detailed information on the medicinal product is available here.
3. The EMEA pandemic influenza crisis management plan can be found here.
4. Guidelines for the preparation of pandemic influenza vaccines can be found here and here.
5. A core summary of product characteristics for pandemic influenza vaccines was adopted in 2005 and can be found here.
6. This press release together with other information about the European Medicines Agency can be found on the EMEA website: www.emea.europa.eu

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