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Public statement

Celvapan

Withdrawal of the marketing authorisation in the European Union

On 21 November 2016, the European Commission withdrew the marketing authorisation for Celvapan (pandemic influenza vaccine (H1N1) (whole virion, inactivated, prepared in cell culture)) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Nanotherapeutics Bohumil sro, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Celvapan was granted marketing authorisation in the EU on 6 October 2009 for prophylaxis of influenza caused by A/H1N1v 2009 virus. The marketing authorisation was initially valid for a 5-year period and was then renewed with unlimited validity on 26 February 2015. The product has not been marketed in the EU since 2010.

Nanotherapeutics Bohumil sro is the marketing authorisation holder for another pandemic vaccine, Pandemic Influenza Vaccine H5N1 Baxter AG, which is authorised in the EU for pandemic preparedness. Nanotherapeutics Bohumil sro will maintain the marketing authorisation for Pandemic Influenza Vaccine H5N1 Baxter AG.

The European Public Assessment Report (EPAR) for Celvapan will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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