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Public statement

Pandemic Influenza Vaccine H5N1 Baxter (pandemic influenza vaccine H5N1 (whole virion, inactivated, prepared in cell culture))

Withdrawal of the marketing authorisation in the European Union

On 11 September 2023 the European Commission withdrew the marketing authorisation for Pandemic Influenza Vaccine H5N1 Baxter (pandemic influenza vaccine H5N1 (whole virion, inactivated, prepared in cell culture)) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Resilience Biomanufacturing Ireland Limited, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Pandemic Influenza Vaccine H5N1 Baxter was granted marketing authorisation in the EU on 16 October 2009 for prophylaxis of pandemic influenza. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2014.

The European Public Assessment Report (EPAR) for Pandemic Influenza Vaccine H5N1 Baxter will be updated to indicate that the marketing authorisation is no longer valid.

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