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Public statement

Vepacel

Withdrawal of the marketing authorisation in the European Union

On 24th September 2020, the European Commission withdrew the marketing authorisation for Vepacel (prepandemic influenza vaccine H5N1 (whole virion, vero cell derived, inactivated)) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Ology Bioservices Ireland Limited, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Vepacel was granted marketing authorisation in the EU on 17 February 2012 for prophylaxis of H5N1 subtype of influenza A. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2017. The product had not been marketed in the EU.

The European Public Assessment Report (EPAR) for Vepacel will be updated to indicate that the marketing authorisation is no longer valid.

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