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Public statement

Prepandrix

Withdrawal of the marketing authorisation in the European Union

On 17 December 2020, the European Commission withdrew the marketing authorisation for Prepandrix (prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted)) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, GlaxoSmithkline Biologicals SA, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Prepandrix was granted marketing authorisation in the EU on 14 May 2008 for active immunisation against H5N1 subtype of influenza A virus. The marketing authorisation was initially valid for a 5-year period. It was subsequently renewed for an additional 5-year period in 2013. It was then granted unlimited validity in 2017. The product had not been manufactured since 2010.

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European Public Assessment Report (EPAR) for Prepandrix will be updated to indicate that the marketing authorisation is no longer valid.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union