09 January 2025
EMA/586339/2024
EMEA/H/C/005466

Public statement

PreHevbri (hepatitis B surface antigen)

Withdrawal of the marketing authorisation in the European Union

On 25 November 2024, the European Commission withdrew the marketing authorisation for PreHevbri (hepatitis B surface antigen) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, VBI Vaccines B.V., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

PreHevbri was granted marketing authorisation in the EU on 25 April 2022 for active immunisation against infection caused by all known subtypes of the hepatitis B virus in adults. The marketing authorisation was initially valid for a 5-year period.

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European Public Assessment Report (EPAR) for PreHevbri will be updated to indicate that the marketing authorisation is no longer valid.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