HEPLISAV B

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
Variation type IB /	B.I.a.1 Change in the manufacturer of a	16/01/2026	N/A		

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

EMA/VR/0000314545	starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.k New storage site of Master Cell Bank and/or Working Cell Banks - Accepted				
Renewal - 5 year / EMA/R/0000271891	- Renewal - Accepted The renewal is recommended to be granted with unlimited validity.	18/09/2025	17/11/2025	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of HEPLISAV B in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
Variation type II / EMA/VR/0000278533	This was an application for a group of variations. B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.b Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method - Accepted	04/09/2025	N/A		
PSUR / EMA/PSUR/0000248489		05/06/2025			Based on the PRAC review of data on safety and

					efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing hepatitis B surface antigen, CpG 1018 adjuvant remains unchanged and therefore recommends the maintenance of the marketing authorisation(s).
Variation type IA / EMA/VR/0000273148	A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted	23/05/2025	N/A		
Variation type IB / EMA/VR/0000262654	B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.a The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer - Accepted	28/04/2025	N/A		
Variation type IB / EMA/VR/0000258909	B.II.c.4 Change in synthesis or recovery of a nonpharmacopoeial excipient (when described in the dossier) or a novel excipient - B.II.c.4.a Minor change in synthesis or recovery of a nonpharmacopoeial excipient	10/04/2025	N/A		

	or a novel excipient - Accepted				
Variation type IB / EMA/VR/0000246523	B.II.g.5 Implementation of changes foreseen in an approved change management protocol - B.II.g.5.c Implementation of a change for a biological/immunological medicinal product - Accepted	26/02/2025	N/A		