Prevenar 13

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 II /	This was an application for a group of	15/01/2026		Annex II	Annex II.A has been updated to reflect the correct

[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/0000309455	variations. 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.j Changes to quality control testing arrangements for a biological active substance: replacement or addition of a site where batch control/testing including a biological / immunological / immunochemical method takes place - Accepted A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a				names of the biological active substance manufacturers sites.

	manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted				
Variation type IB / EMA/VR/0000317316	This was an application for a group of variations. B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.f Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products - Accepted 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 or a novel excipient - Accepted	14/01/2026	N/A		

	B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted				
Variation type IB / EMA/VR/0000300819	This was an application for a group of variations. B.II.e.4 Change in shape or dimensions of the container or closure (immediate packaging) - B.II.e.4.c Sterile medicinal products - Accepted B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.z Change in supplier of sterilised primary container components, which are to be used in the aseptic manufacture of medicinal products - Accepted B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.z Change in supplier of sterilised primary container components, which are to be used in the aseptic manufacture of medicinal products - Accepted B.II.e.7 Change in supplier of packaging	16/10/2025	N/A		

	components or devices (when mentioned in the dossier) - B.II.e.7.b Replacement or addition of a supplier - Accepted				
Variation type IB / EMA/VR/0000254585	This was an application for a group of variations. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted 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 A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted	24/04/2025		SmPC, Annex II and PL	

	· Type IB (C.I.z) - Update of Product Information to include updated wording for Polysorbate 80 in Prevenar 13 SmPC and Package Leaflet. · Type IA (A.4) - Change in the legal entity name and address of the currently registered manufacturer of active substance and the currently registered master cell bank storage site Pfizer Ireland Pharmaceuticals, Grange Castle. · Type IA (A.5(b)) - Change in the legal entity name and address of the currently registered manufacturer of finished product, Pfizer Ireland Pharmaceuticals, Grange Castle. In addition, the MAH took the opportunity to align the PI to the latest QRD template 10.4 and to update the contact details of the Irish local representative.				
Variation type IB / EMA/VR/0000254759	This was an application for a group of variations. B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted	25/03/2025	N/A		

	B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted				