Prevenar 20

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 / EMA/VR/0000291245	This was an application for a group of variations.	23/10/2025		SmPC and Annex II	The SmPC Sections 4, 5, 10 and Annex IIA have been updated as follows: SmPC - minor editorial changes Annex IIA – update of company name to

[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).

	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 manufacturer (including where relevant quality control testing sites); or an ASMF				state Wyeth Holdings LLC

	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 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				
Variation type IB / EMA/VR/0000301381	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	03/10/2025	N/A		

	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 components or devices (when mentioned in the dossier) - B.II.e.7.b Replacement or addition of a supplier - Accepted B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.f The scale for a biological/immunological medicinal product is increased / decreased without process change (e.g. duplication of line) - Accepted				

Variation type IB / EMA/VR/0000282487	This was an application for a group of variations. B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.a Tightening of specification limits - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.d Other changes to a test procedure (including replacement or addition) - Accepted	21/07/2025	N/A		
Variation type IB / EMA/VR/0000273537	This was an application for a group of variations. B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - Accepted B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted	05/06/2025	N/A		
Variation type IB / EMA/VR/0000264020	This was an application for a group of variations. B.I ACTIVE SUBSTANCE - B.I.z Other variation - Accepted B.I ACTIVE SUBSTANCE - B.I.z Other	30/04/2025	N/A		

	variation - Accepted B.I ACTIVE SUBSTANCE - B.I.z Other variation - Accepted				
Variation type IB / EMA/VR/0000254575	This was an application for a group of variations. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - 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.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	24/04/2025	01/10/2025	SmPC, Annex II and PL	

	· Type IB (C.I.z) - Update of Product Information to include updated wording for Polysorbate 80 in Prevenar 20 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.				
PSUR / EMA/PSUR/0000257867	- -				Based on the PRAC Rapporteur review of data on safety and efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing 20vPnC remains unchanged and therefore recommends the maintenance of the marketing authorisation.