Prevenar 20

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
IB/0033	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	17/02/2025	n/a		
IB/0032	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	27/01/2025	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).

PSUSA/10981 /202406	Periodic Safety Update EU Single assessment - pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)	16/01/2025	n/a		PRAC Recommendation - maintenance
II/0026	Update of sections 4.2 and 5.1 of the SmPC, in order to introduce a vaccination schedule for children 12 months to 23 months of age transitioning from another pneumococcal conjugate vaccine and to update clinical information based on the final results from the paediatric study B7471027. Based on the assessment, the MAH withdrew the proposed change in SmPC section 4.2. The study is described in section 5.1, which is considered acceptable. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	17/10/2024		SmPC and PL	Study 1027 In a multicentre, randomised, partially double blinded trial, 356 participants 12 months to less than 24 months of age with 2 prior infant doses of Prevenar 13 were enrolled and randomised to receive either 1 or 2 toddler doses of Prevenar 20, or a single dose of Prevenar 13 (control). In the group receiving 2 doses of Prevenar 20, the second dose was given approximately 2 months after Dose 1. IgG immune responses to the 13 matched serotypes were observed after 1 or 2 doses of Prevenar 20 with the observed IgG GMCs numerically higher for most of the 13 matched serotypes after 1 dose of Prevenar 20 than after 2 doses of Prevenar 20. The observed IgG GMCs 1 month after last vaccination for the 13 matched serotypes were lower after 1 or 2 doses of Prevenar 20 than after 1 dose of Prevenar 13. IgG immune responses to all 7 additional serotypes were observed after 1 or 2 doses of Prevenar 20, with numerically higher IgG responses after 2 doses of Prevenar 20 than after a single dose. The observed IgG GMCs for all 7 additional serotypes (not covered by Prevenar 13) were low 1 month after a single toddler dose of Prevenar 13.
IB/0027/G	This was an application for a group of variations. B.II.z - Quality change - Finished product - Other variation	30/08/2024	n/a		

	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation				
IB/0029	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	14/08/2024	n/a		
PSUSA/10981 /202312	Periodic Safety Update EU Single assessment - pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)	11/07/2024	n/a		PRAC Recommendation - maintenance
IB/0028/G	This was an application for a group of variations. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.b.z - Change in control of the AS - Other variation	08/07/2024	n/a		
II/0023	Submission of the final current B7471015 study protocol, the Statistical Analysis Plan (SAP) and the final country feasibility assessment report for Prevenar 20 (Apexxnar). The RMP (version 5.0) is updated accordingly. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required	11/04/2024	n/a		

II/0012	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	25/01/2024	11/03/2024	SmPC and PL	Please refer to Scientific Discussion 'Prevenar 20-H-C-005451-II-12'
IAIN/0024/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	25/01/2024	11/03/2024	SmPC, Annex II, Labelling and PL	
PSUSA/10981 /202306	Periodic Safety Update EU Single assessment - pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)	11/01/2024	n/a		PRAC Recommendation - maintenance
IB/0022/G	This was an application for a group of variations. B.I.z - Quality change - Active substance - Other variation B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS	04/01/2024	n/a		

IB/0021/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	21/12/2023	n/a		
IB/0020	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	25/09/2023	n/a		
II/0016	C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required	14/09/2023	11/03/2024	Annex II	
PSUSA/10981 /202212	Periodic Safety Update EU Single assessment - pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)	06/07/2023	n/a		PRAC Recommendation - maintenance
IB/0017/G	This was an application for a group of variations. B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.z - Change in container closure system of the	06/06/2023	n/a		

	Finished Product - Other variation B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation				
II/0014/G	This was an application for a group of variations. B.II.b.3.e - Change in the manufacturing process of the finished or intermediate product - Introduction or increase in the overage that is used for the AS B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	01/06/2023	n/a		
IB/0015/G	This was an application for a group of variations. B.I.z - Quality change - Active substance - Other variation B.I.z - Quality change - Active substance - Other variation	08/05/2023	n/a		
PSUSA/10981 /202206	Periodic Safety Update EU Single assessment - pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)	12/01/2023	n/a		PRAC Recommendation - maintenance
II/0006	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	01/12/2022	04/10/2023	SmPC and PL	Update of the Product Informaton to include details regarding the concomitant administration of Apexxnar with COVID-19 mRNA vaccine (nucleoside modified). For more information, please refer to the Summary of Product

					Characteristics.
IB/0011/G	This was an application for a group of variations. B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	07/11/2022	n/a		

II/0007/G	This was an application for a group of variations. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.z - Quality change - Active substance - Other variation B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.b.1.a - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits for medicinal products subject to OCABR B.I.b.1.a - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits for medicinal products subject to OCABR	20/10/2022	n/a		
II/0002	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	13/10/2022	04/10/2023	SmPC and PL	The Marketing Authorisation holder proposes an update to the PI to include information regarding the concomitant administration of Apexxnar with a seasonal quadrivalent influenza vaccine, adjuvanted (QIV). Apexxnar may be administered concomitantly with seasonal influenza vaccine (QIV; surface antigen, inactivated,

					adjuvanted). In subjects with underlying conditions associated with a high risk of developing life-threatening pneumococcal disease, consideration may be given to separating administrations of QIV and Apexxnar (e.g. by approximately 4 weeks). For more information, please refer to the Summary of Product Characteristics.
IAIN/0010/G	This was an application for a group of variations. B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	23/09/2022	04/10/2023	Labelling and PL	
IA/0008/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	15/08/2022	n/a		
IB/0005/G	This was an application for a group of variations. B.I.z - Quality change - Active substance - Other variation	08/06/2022	n/a		

	B.I.z - Quality change - Active substance - Other variation				
IB/0004/G	This was an application for a group of variations. B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time	29/04/2022	n/a		

	data				
IB/0003/G	This was an application for a group of variations. B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.z - Quality change - Active substance - Other variation B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.z - Quality change - Active substance - Other variation	11/04/2022	n/a		
IB/0001	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	25/03/2022	n/a		