VidPrevtyn Beta

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
II/0007/G	This was an application for a group of variations. A grouped application consisting of: Type II (C.I.4): Update of section 4.8 of the SmPC in order to include additional safety data based on safety update reports from studies VAT00008	15/02/2024		SmPC	The update of Section 4.8 of the SmPC was based on the analysis of safety data that have been accrued with the monovalent B.1.351 vaccine booster formulation from the MAH's safety database with over 3000 participants with at least 6 weeks of follow-up. The ATC Code is also being updated as per WHO's latest

[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).

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

	booster extension and VAT00002 Cohort 2, in order to fulfill REC 20. Type IA (A.6): To change the ATC Code of the COVID-19 protein subunit vaccine from J07BX03 to J07BN04. A.6 - Administrative change - Change in ATC Code/ATC Vet Code C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				recommendations. For more information, please refer to the Summary of Product Characteristics.
PSUSA/11035 /202305	Periodic Safety Update EU Single assessment - SARS-CoV-2, B.1.351 variant, prefusion Spike delta TM protein, recombinant	14/12/2023	08/02/2024	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/11035/202305.
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/12/2023	08/02/2024	PL	
II/0006	Update of section 4.8 of the SmPC in order to add 'Hypersensitivity and anaphylactic reactions' to the list of adverse drug reactions (ADRs) with frequency 'Not known', based on post-marketing data; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor changes to the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	21/09/2023	08/02/2024	SmPC and PL	SmPC new text This variation concerns the update of the Product Information to reflect a safety signal of allergic including anaphylactic reactions raised by the MAH detected from post-marketing data, following a booster dose with VidPrevtyn Beta vaccine. For more information, please refer to the Summary of Product Characteristics.

IB/0004/G	This was an application for a group of variations. B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	20/07/2023	n/a		
IB/0002	B.I.z - Quality change - Active substance - Other variation	30/03/2023	n/a		