Supemtek Tetra

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/0021/G	This was an application for a group of variations. Grouped application comprising two type II variations as follows: C.I.6.a – Extension of indication to include the active immunisation of children 9 years of age and older for Supemtek Tetra, based on final results from study	27/02/2025	28/03/2025	SmPC, Annex II and PL	Please refer to Scientific Discussion 'Supemtek Tetra-H-C-005159-II-0021-G'

[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).

	VAP00027; this is a Phase III, non-randomised, open-label, uncontrolled study to demonstrate the non-inferior HAI immune response of Supemtek Tetra in participants aged 9 to 17 years compared to participants aged 18 to 49 years; as a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been approved. C.I.4 - Update of sections 4.2 and 5.1 of the SmPC in order to update paediatric information of children between 3 to 8 years of age based on final results from study VAP00026; this is a Phase III, randomised, modified double-blind, active-controlled 2-arm to demonstrate the non-inferior HAI immune response of Supemtek Tetra compared to an authorised inactivated tetravalent influenza vaccine. The MAH also took the opportunity to include editorial updates in the SmPC and Annex II. The group of variations leads to amendments to the Summary of Product Characteristics and Package Leaflet and to the Risk Management Plan (RMP). C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
IB/0025	A.7 - Administrative change - Deletion of manufacturing sites	07/01/2025	n/a		

II/0015/G	This was an application for a group of variations. B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation	19/12/2024	n/a		
IB/0024	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	18/12/2024	n/a		
T/0023	Transfer of Marketing Authorisation	30/10/2024	25/11/2024	SmPC, Labelling and PL	
IA/0022/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	12/09/2024	n/a		

PSUSA/10886 /202401	Periodic Safety Update EU Single assessment - quadrivalent influenza vaccine (recombinant, prepared in cell culture)	05/09/2024	n/a		PRAC Recommendation - maintenance
IA/0019	A.7 - Administrative change - Deletion of manufacturing sites	24/06/2024	25/11/2024	Annex II	
IB/0017/G	This was an application for a group of variations. B.II.z - Quality change - Finished product - Other variation A.7 - Administrative change - Deletion of manufacturing sites B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits	28/03/2024	n/a		
II/0013/G	This was an application for a group of variations. B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method B.I.a.2.z - Changes in the manufacturing process of the AS - 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.a.1.k - Change in the manufacturer of AS or of a	14/03/2024	n/a		

	starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB				
IB/0014/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS A.7 - Administrative change - Deletion of manufacturing sites B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation 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	26/01/2024	n/a		
N/0016	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/12/2023	28/06/2024	PL	
PSUSA/10886 /202301	Periodic Safety Update EU Single assessment - quadrivalent influenza vaccine (recombinant, prepared in cell culture)	31/08/2023	n/a		PRAC Recommendation - maintenance
II/0011/G	This was an application for a group of variations. B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling down to 10-fold	20/07/2023	28/06/2024	Annex II	The Annex II has been updated to include the name and address of the new biological active substance manufacturing site: Protein Sciences Corp. 401 North Middletown Road

	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.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.4.d - Change to in-process tests or limits applied during the manufacture of the AS - Widening of the approved in-process test limits, which may have a significant effect on the overall quality of the AS B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS B.I.c.1.b - Change in immediate packaging of the AS - Qualitative and/or quantitative composition for sterile and non-frozen biological/immunological ASs				Pearl River, NY 10965-1298 United States
II/0010/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.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change	16/03/2023	n/a		

	to an approved stability protocol				
PSUSA/10886 /202201	Periodic Safety Update EU Single assessment - quadrivalent influenza vaccine (recombinant, prepared in cell culture)	01/09/2022	n/a		PRAC Recommendation - maintenance
II/0007/G	This was an application for a group of variations. B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	21/07/2022	n/a		

	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.f.1.e - Stability of FP - Change to an approved stability protocol B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products				
II/0005/G	This was an application for a group of variations. B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method	10/02/2022	n/a		
N/0006	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	10/11/2021	28/06/2024	PL	
PSUSA/10886 /202101	Periodic Safety Update EU Single assessment - quadrivalent influenza vaccine (recombinant, prepared in cell culture)	02/09/2021	n/a		PRAC Recommendation - maintenance
IB/0004/G	This was an application for a group of variations.	16/07/2021	n/a		

	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits				
IB/0001/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.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	09/03/2021	n/a		
IB/0002/G	This was an application for a group of variations. B.II.b.z - Change in manufacture of the Finished Product - Other variation 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	14/01/2021	n/a		