Flucelvax 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/0041	B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability	14/12/2023	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).

IB/0043	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	11/12/2023	n/a		
R/0040	Renewal of the marketing authorisation.	12/10/2023	07/12/2023	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Flucelvax Tetra in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
II/0039	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol	09/11/2023	n/a		
IB/0042	B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	24/10/2023	n/a		
PSUSA/10737 /202303	Periodic Safety Update EU Single assessment - influenza vaccine (surface antigen, inactivated, prepared in cell cultures)	28/09/2023	n/a		PRAC Recommendation - maintenance
II/0037	B.I.a.5.a - Changes to the AS of a seasonal, prepandemic or pandemic vaccine against human influenza - Replacement of the strain(s) in a seasonal, prepandemic or a pandemic vaccine against human influenza	06/07/2023	24/07/2023	SmPC, Labelling and PL	

N/0036	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/05/2023	24/07/2023	PL	
IB/0034	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	10/05/2023	n/a		
IA/0035	A.7 - Administrative change - Deletion of manufacturing sites	14/04/2023	n/a		
IB/0033/G	This was an application for a group of variations. B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test	09/02/2023	n/a		
II/0030	Update of section 4.8 of the SmPC in order to add Guillain Barré syndrome (GBS) to the list of adverse drug reactions (ADRs) based on the assessment of the global safety database. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to carry out minor updates to the Package Leaflet to fully align it with the information in the SmPC.	09/02/2023	24/07/2023	SmPC and PL	As a possible relationship between GBS and Flucelvax Tetra cannot be excluded, and there is at least a reasonable possibility to consider a causal association between GBS and Flucelvax Tetra, Section 4.8 of the SmPC was updated to include Guillain Barré syndrome (GBS) to the list of adverse drug reactions (ADRs), with frequency 'not known'.

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
II/0031	B.II.d.2.c - Change in test procedure for the finished product - Substantial change to or replacement of a biol/immunol/immunochemical test method or a method using a biol. reagent or replacement of a biol. reference preparation not covered by an approved protocol	15/12/2022	n/a		
II/0029	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	01/12/2022	n/a		
PSUSA/10737 /202203	Periodic Safety Update EU Single assessment - influenza vaccine (surface antigen, inactivated, prepared in cell cultures)	29/09/2022	n/a		PRAC Recommendation - maintenance
II/0027	B.I.a.5.a - Changes to the AS of a seasonal, prepandemic or pandemic vaccine against human influenza - Replacement of the strain(s) in a seasonal, prepandemic or a pandemic vaccine against human influenza	07/07/2022	27/07/2022	SmPC, Labelling and PL	As a result of this variation, Section 2 of the SmPC (qualitative and quantitative composition) has been updated to reflect the changes in Influenza strains included in the NH 2022/2023 formulation. For NH 22/23 influenza season, the following influenza strains have been included: • A/Delaware/55/2019 CVR-45 (H1N1), an A/Wisconsin/588/2019 (H1N1) pdm09-like virus • A/Darwin/11/2021 (H3N2), an A/Darwin/6/2021 – like virus • B/Singapore/WUH4618/2021 (B-Victoria), a B/Austria/1359417/2021 - like virus

					• B/Singapore/INFTT-16-0610/2016 (B-Yamagata), a B/Phuket/3073/2013 – like virus The Labelling, Package leaflet and Annex A have been updated accordingly.
II/0025/G	This was an application for a group of variations. B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products 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.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	24/03/2022	n/a		
II/0024	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	17/02/2022	n/a		
IA/0026	A.7 - Administrative change - Deletion of manufacturing sites	14/02/2022	n/a		
II/0023	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance	13/01/2022	27/07/2022	SmPC and PL	

	data				
PSUSA/10737 /202103	Periodic Safety Update EU Single assessment - influenza vaccine (surface antigen, inactivated, prepared in cell cultures)	30/09/2021	n/a		PRAC Recommendation - maintenance
II/0021	B.I.a.5.a - Changes to the AS of a seasonal, prepandemic or pandemic vaccine against human influenza - Replacement of the strain(s) in a seasonal, prepandemic or a pandemic vaccine against human influenza	08/07/2021	23/07/2021	SmPC, Labelling and PL	As a result of this variation, Section 2 of the SmPC (qualitative and quantitative composition) has been updated to reflect the changes in Influenza strains included in the NH 2021/2022 formulation. The virus strains included in the vaccine for the season 2021-2022 are: • A/Washington/19/2020 (H1N1) (an A/Wisconsin/588/2019 (H1N1) pdm09-like strain), wild type • A/Tasmania/503/2020 (H3N2) (an A/Cambodia/e0826360/2020-like strain), wild type • B/Singapore/INFTT-16-0610/2016 (B-Yamagata) (a B/Phuket/3073/2013 - like strain), wild type • B/Darwin/7/2019 (B-Victoria) (a B/Washington/02/2019 - like strain), wild type Labelling and Package leaflet are updated accordingly.
IA/0020	A.7 - Administrative change - Deletion of manufacturing sites	03/03/2021	23/07/2021	Annex II and PL	
IB/0019	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	05/02/2021	n/a		

	material/intermediate				
IA/0018/G	This was an application for a group of variations. 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 B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	01/12/2020	n/a		
II/0017	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	12/11/2020	n/a		
II/0013	Extension of the indication of prophylaxis of influenza, from the currently approved age range "adults and children from 9 years of age" to "adults and children from 2 years of age" for Flucelvax Tetra; as a consequence, sections 4.1, 4.2, 4.8, 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.1 of the RMP has also been approved. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	17/09/2020	22/10/2020	SmPC and PL	Please refer to Scientific Discussion "Flucelvax Tetra EMEA/H/C/004814/II/0013"
PSUSA/10737	Periodic Safety Update EU Single assessment -	01/10/2020	n/a		PRAC Recommendation - maintenance

/202003	influenza vaccine (surface antigen, inactivated, prepared in cell cultures)				
II/0014	B.I.a.5.a - Changes to the AS of a seasonal, prepandemic or pandemic vaccine against human influenza - Replacement of the strain(s) in a seasonal, prepandemic or a pandemic vaccine against human influenza	10/07/2020	27/07/2020	SmPC, Labelling and PL	
IB/0016	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	24/06/2020	n/a		
IB/0011	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	03/04/2020	n/a		
IAIN/0012	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	06/03/2020	n/a		
IAIN/0009/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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	06/03/2020	27/07/2020	SmPC, Labelling and PL	

	the range of the currently approved pack sizes				
II/0008	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	28/11/2019	n/a		
PSUSA/10737 /201903	Periodic Safety Update EU Single assessment - influenza vaccine (surface antigen, inactivated, prepared in cell cultures)	03/10/2019	n/a		PRAC Recommendation - maintenance
II/0007	B.I.a.5.a - Changes to the AS of a seasonal, prepandemic or pandemic vaccine against human influenza - Replacement of the strain(s) in a seasonal, prepandemic or a pandemic vaccine against human influenza	09/08/2019	23/08/2019	SmPC, Labelling and PL	
II/0003	B.II.b.2.c.3 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing for a biol/immunol product and any of the test methods is a biol/immunol/immunochemical method	27/06/2019	23/08/2019	Annex II and PL	
II/0004/G	This was an application for a group of variations. 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.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	23/05/2019	n/a		

IAIN/0005	A.1 - Administrative change - Change in the name and/or address of the MAH	26/04/2019	23/08/2019	SmPC, Labelling and PL	
IB/0002	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	27/02/2019	23/08/2019	SmPC, Labelling and PL	
IB/0001	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	12/02/2019	n/a		