Fluad 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
IB/0058	B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation	06/01/2025	n/a		
R/0055	Renewal of the marketing authorisation.	17/10/2024	19/12/2024	SmPC, Labelling and	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Fluad

[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).

				PL	Tetra in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0057/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	18/11/2024	n/a		
PSUSA/10300 /202403	Periodic Safety Update EU Single assessment - influenza vaccine (surface antigen, inactivated, adjuvanted)	03/10/2024	n/a		PRAC Recommendation - maintenance
II/0053	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	11/07/2024	24/07/2024	SmPC, Labelling and PL	The SmPC section 2 has been updated as follows: - A/Victoria/4897/2022 (H1N1)pdm09-like strain (A/Victoria/4897/2022 IVR-238); - A/Thailand/8/2022 (H3N2)-like strain (A/Thailand/8/2022 IVR-237); - B/Austria/1359417/2021 (B/Victoria lineage)-like strain (B/Austria/1359417/2021 BVR-26); - B/Phuket/3073/2013 (B/Yamagata lineage)-like strain (B/Phuket/3073/2013 BVR-1B). The Labelling, PL and Annex A have been updated accordingly.
IB/0052	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	18/04/2024	n/a		

IB/0051	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	16/01/2024	n/a		
II/0043	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	09/11/2023	07/12/2023	SmPC, Labelling and PL	Please refer to Scientific Discussion Fluad Tetra EMEA/H/C/004993/II/0043.
IA/0050	B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	04/12/2023	n/a		
IB/0048	B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line)	23/11/2023	n/a		
IA/0049	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	17/11/2023	n/a		
IB/0047/G	This was an application for a group of variations. B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	17/11/2023	n/a		

	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS				
PSUSA/10300 /202303	Periodic Safety Update EU Single assessment - influenza vaccine (surface antigen, inactivated, adjuvanted)	28/09/2023	n/a		PRAC Recommendation - maintenance
II/0045	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	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 2023/2024 formulation. The SmPC section 2 has been updated as follows: • A/Victoria/4897/2022 (H1N1)pdm09-like virus (A/Victoria/4897/2022 IVR-238) • A/Darwin/9/2021 (H3N2)-like virus (A/Darwin/6/2021 IVR-227) • B/Austria/1359417/2021 (B/Victoria Lineage)-like virus (B/Austria/1359417/2021 BVR-26) • B/Phuket/3073/2013 (B/Yamagata Lineage)-like virus (B/Phuket/3073/2013 BVR-1B) The Labelling, package leaflet and Annex A have been updated accordingly.
N/0044	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/05/2023	24/07/2023	PL	
IB/0042/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	27/04/2023	n/a		

	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS				
IB/0040/G	This was an application for a group of variations. B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line) B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	28/03/2023	n/a		
IB/0041/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	10/03/2023	n/a		
IB/0037/G	This was an application for a group of variations. B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	21/02/2023	n/a		

	B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products				
IB/0039	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	03/02/2023	n/a		
II/0036	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	02/02/2023	n/a		
IB/0038/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place 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.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 B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished	01/02/2023	n/a		

	product - Minor changes to an approved test procedure 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 B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)				
IB/0034	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	13/01/2023	24/07/2023	SmPC and PL	
IB/0035	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	07/12/2022	n/a		
IB/0033	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	14/11/2022	n/a		
IA/0032	B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	03/10/2022	n/a		
PSUSA/10300 /202203	Periodic Safety Update EU Single assessment - influenza vaccine (surface antigen, inactivated, adjuvanted)	29/09/2022	n/a		PRAC Recommendation - maintenance

II/0030	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	23/06/2022	22/07/2022	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. The virus strains included in the vaccine for the season 2022-2023 are: A/Victoria/2570/2019 (H1N1)pdm09-like virus (A/Victoria/2570/2019 IVR-215); A/Darwin/9/2021 (H3N2)-like virus (A/Darwin/6/2021 IVR-227); B/Austria/1359417/2021 (B/Victoria lineage)-like virus (B/Austria/1359417/2021 BVR-26); B/Phuket/3073/2013 (B/Yamagata lineage)-like virus (B/Phuket/3073/2013 BVR-1B). Labelling, Package leaflet and Annex A are updated accordingly.
IA/0029	A.7 - Administrative change - Deletion of manufacturing sites	23/03/2022	n/a		
IB/0027	B.II.z - Quality change - Finished product - Other variation	25/02/2022	n/a		
II/0021	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	24/02/2022	n/a		
IA/0028	B.I.b.2.a - Change in test procedure for AS or	04/02/2022	n/a		

	starting material/reagent/intermediate - Minor changes to an approved test procedure				
IB/0026/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.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.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	22/12/2021	n/a		
IB/0025	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	20/12/2021	n/a		
IB/0024	B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol	15/12/2021	n/a		

IB/0023	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	15/12/2021	n/a		
IB/0022	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	06/12/2021	n/a		
IB/0020/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 B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	30/11/2021	n/a		
IA/0019/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	06/10/2021	n/a		
PSUSA/10300 /202103	Periodic Safety Update EU Single assessment - influenza vaccine (surface antigen, inactivated, adjuvanted)	30/09/2021	n/a		PRAC Recommendation - maintenance

II/0017	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/Victoria/2570/2019 (H1N1)pdm09-like virus (A/Victoria/2570/2019 IVR-215) A/Cambodia/e0826360/2020 (H3N2)-like virus (A/Cambodia/e0826360/2020 IVR-224 B/Washington/02/2019 (B/Victoria lineage)-like virus (B/Victoria/705/2018 BVR-11) B/Phuket/3073/2013 (B/Yamagata lineage)-like virus (B/Phuket/3073/2013 BVR-1B) Labelling and Package leaflet are updated accordingly.
IAIN/0016	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	19/04/2021	n/a		
IB/0015/G	This was an application for a group of variations. 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 B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS -	14/04/2021	n/a		

	Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place				
IA/0014	B.II.f.1.e - Stability of FP - Change to an approved stability protocol	17/03/2021	n/a		
IB/0012	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	08/03/2021	n/a		
IA/0013	A.7 - Administrative change - Deletion of manufacturing sites	01/03/2021	23/07/2021	Annex II and PL	
IB/0010	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	08/02/2021	n/a		
IB/0007/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply	02/02/2021	n/a		

	with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material				
IB/0011	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	18/01/2021	n/a		
II/0008	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	14/01/2021	n/a		
IAIN/0009/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites	20/11/2020	n/a		

	(excluding manufacturer for batch release) B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site				
IB/0006	B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	05/11/2020	n/a		
IB/0005/G	This was an application for a group of variations. B.II.d.1.h - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur. for the finished product B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	28/10/2020	n/a		
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.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	17/09/2020	n/a		

	material/intermediate B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range				
II/0002	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	17/09/2020	n/a		
IB/0001	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	02/09/2020	n/a		