Bemfola

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/0043	B.IV.1.a.1 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking	09/01/2024		PL	

[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).

IAIN/0042/G	This was an application for a group of variations. B.II.g.3 - Deletion of an approved change management protocol related to the finished product A.7 - Administrative change - Deletion of manufacturing sites	08/11/2023	n/a		
IB/0041/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 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 A.7 - Administrative change - Deletion of manufacturing sites	26/04/2023	n/a		
IB/0040	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	16/12/2022		SmPC and PL	
IB/0039	C.I.11.z - Introduction of, or change(s) to, the	13/10/2022	n/a		

	obligations and conditions of a marketing authorisation, including the RMP - Other variation				
IB/0038/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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	12/07/2022	n/a		
IB/0037	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	15/06/2022	n/a		
PSUSA/1463/ 202110	Periodic Safety Update EU Single assessment - follitropin alfa	10/06/2022	n/a		PRAC Recommendation - maintenance
N/0036	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/05/2022		PL	
IB/0034/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.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch	21/12/2021	n/a		

	control/testing takes place				
IB/0032	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	13/12/2021	n/a		
IB/0033	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	28/10/2021	n/a		
IA/0031/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.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 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 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	30/09/2021	n/a		

	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure 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				
II/0029	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	28/05/2021	n/a		
IA/0030	A.7 - Administrative change - Deletion of manufacturing sites	17/03/2021	n/a		
II/0027	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	15/10/2020	n/a		
IA/0026	A.7 - Administrative change - Deletion of manufacturing sites	08/07/2020	n/a		
II/0025/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	25/06/2020	n/a		

	control/testing takes place and any of the test method at the site is a biol/immunol method 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				
IA/0024	B.II.c.3.z - Change in source of an excipient or reagent with TSE risk - Other variation	13/03/2020	n/a		
IB/0023/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 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)	05/02/2020	n/a		
II/0022	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	30/01/2020	n/a		
PSUSA/1463/201810	Periodic Safety Update EU Single assessment - follitropin alfa	14/06/2019	n/a		PRAC Recommendation - maintenance
II/0021/G	This was an application for a group of variations. B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP -	07/03/2019	n/a		

	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.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				
R/0019	Renewal of the marketing authorisation.	20/09/2018	12/11/2018	SmPC, Annex II, Labelling and PL	
II/0016	Update of the RMP version 2 based on the phase-3 multicentre study conducted to compare the efficacy and safety of two r-hFSH formulations in normal ovulatory women 35 to 42 years of age undergoing in vitro fertilisation (IVF) (CSR FIN3002). 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	14/06/2018	n/a		
IA/0018	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	13/06/2018	n/a		

N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/05/2018	23/07/2018	Labelling and PL	
IB/0015	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	04/12/2017	n/a		
IA/0014	A.7 - Administrative change - Deletion of manufacturing sites	20/10/2017	23/07/2018	Annex II and PL	
IB/0013	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	09/08/2017	23/07/2018	SmPC and PL	
IAIN/0012/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.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	23/06/2017	23/07/2018	Annex II, Labelling and PL	
II/0011	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	23/02/2017	n/a		

	release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes				
T/0010	Transfer of Marketing Authorisation	25/10/2016	21/11/2016	SmPC, Labelling and PL	
IA/0009	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	14/09/2016	n/a		
PSUSA/1463/ 201510	Periodic Safety Update EU Single assessment - follitropin alfa	09/06/2016	n/a		PRAC Recommendation - maintenance
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	04/11/2015	21/11/2016	PL	
IAIN/0006/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.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	02/06/2015	n/a		
IA/0005	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	07/04/2015	n/a		

	the product information				
IA/0004	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	17/03/2015	n/a		
IAIN/0003	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	23/12/2014	n/a		
IB/0001/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	12/08/2014	03/07/2015	SmPC, Annex II, Labelling and PL	