Zarzio

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
IA/0044	A.7 - Administrative change - Deletion of manufacturing sites	31/05/2018	n/a		
IB/0043	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	24/05/2018		SmPC, Annex II, Labelling and 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).

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IAIN/0042	C.I.3.a - 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 - Implementation of wording agreed by the competent authority	24/04/2018		SmPC and PL	
IA/0041	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	16/04/2018	n/a		
IB/0040	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	02/03/2018	n/a		
WS/1275/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation	22/02/2018	n/a		
WS/0935/G	This was an application for a group of variations following a worksharing procedure according to Article	14/09/2017	n/a		

	20 of Commission Regulation (EC) No 1234/2008. 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.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation				
IAIN/0037	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	15/08/2017		Annex II and PL	
WS/0954	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.e.2 - Introduction of a post approval change management protocol related to the AS	23/02/2017	n/a		
N/0035	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	04/01/2017		PL	
IB/0033	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	10/10/2016	n/a		

PSUSA/1391/ 201509	Periodic Safety Update EU Single assessment - filgrastim	13/05/2016	n/a		PRAC Recommendation - maintenance
WS/0917	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	25/02/2016	30/06/2016	SmPC, Annex II, Labelling and PL	
WS/0779/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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 C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	24/09/2015	n/a		
WS/0744/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	02/07/2015	30/06/2016	SmPC and PL	

	Update of the SmPC section 4.4 in order to revise the warning related to use of product in latex sensitive individuals; consequently section 6.5 has also been revised. Update of SmPC sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.7, 4.8, 5.1, 5.3, and 6.4 in order to align the PI with the reference product Neupogen. The Package Leaflet is updated accordingly. 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 C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IG/0550	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	29/04/2015	n/a		
WS/0711/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.3.c - Change in batch size (including batch size ranges) of AS or intermediate - The change requires assessment of the comparability of a biological/immunological AS B.I.c.1.c - Change in immediate packaging of the AS -	23/04/2015	n/a		

	Liquid ASs (non sterile) B.I.a.2.z - Changes in the manufacturing process 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 B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation A.7 - Administrative change - Deletion of manufacturing sites B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation				
IB/0024/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 control/testing takes place	08/10/2014	n/a		
WS/0583	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following	26/06/2014	06/02/2015	SmPC and PL	

	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				
IA/0022/G	This was an application for a group of variations. B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	20/01/2014	n/a		
IB/0020	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	07/01/2014	n/a		
IA/0021	B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	06/01/2014	n/a		
IA/0018	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	13/12/2013	n/a		

	manufacturer of a novel excipient				
IA/0019	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	11/12/2013	n/a		
IB/0017	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	15/11/2013	06/02/2015	SmPC and PL	
R/0015	Renewal of the marketing authorisation.	19/09/2013	13/11/2013	SmPC, Annex II, Labelling and PL	
IB/0016	B.I.a.3.e - Change in batch size (including batch size ranges) of AS or intermediate - The scale for a biological/immunological AS is increased/decreased without process change (e.g. duplication of line)	03/07/2013	n/a		
WS/0323/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. to add a manufacturing and control testing site for Zarzio and Filgrastim Hexal drug products. As a consequence, changes are implemented to some IPCs and the batch size.	21/02/2013	n/a		

	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, batch control, and secondary packaging, for biological/immunological medicinal products. B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the currently approved batch size B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new tests and limits				
IB/0014	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	10/12/2012	13/11/2013	SmPC	
WS/0183	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Change in the immediate packaging of the finished product. B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products	17/11/2011	17/11/2011		

N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/10/2011	n/a	PL	
WS/0136/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of section 4.8 of the SmPC to include the terms Graft versus Host Disease (GvHD) and pseudogout as undesirable effects and update of section 4.4 to include a statement on traceability. The inclusion of GvHD was requested by the CHMP following the assessment of PSUR 3 and the additional changes were proposed by the MAH to bring the product information in line with the reference medicinal product. The Package Leaflet has been updated accordingly. In addition the local representatives have been updated in the PL. This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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 are submitted by the MAH C.I.3.a - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under A 45/46, or amendments to reflect a Core SPC - Changes with	23/06/2011	10/08/2011	SmPC and PL	The MAH has submitted two type IB variations as part of a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008, in order to align the product information of Zarzio and Filgrastim Hexal to the latest version available for the reference medicinal product Neupogen. The changes proposed were an update of section 4.8 of the SmPC to include the terms Graft versus Host Disease (GvHD) and pseudogout as undesirable effects and an update of section 4.4 to include a statement on traceability. The inclusion of GvHD was requested by the CHMP following the assessment of PSUR 3 and the additional changes were proposed by the MAH to bring the product information in line with the reference medicinal product. The Package Leaflet has been updated accordingly.

	NO new additional data are submitted by the MAH				
IG/0056/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV C.I.9.e - Changes to an existing pharmacovigilance system as described in the DDPS - Changes in the major contractual arrangements with other persons or organisations involved in the fulfilment of pharmacovigilance obligations and described in the DD C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system A.4 - Administrative change - Change in the name and/or address of a manufacturer or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV	23/03/2011	n/a		
WS/0059	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Additional down stream purification plant. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The	17/02/2011	17/02/2011		

	change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product				
IB/0004	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	17/02/2011	n/a	SmPC, Annex II, Labelling and PL	
WS/0023	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Registration of new storage location of the active substance B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer	23/09/2010	23/09/2010		
IG/0018/G	This was an application for a group of variations. C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV C.I.9.e - Changes to an existing pharmacovigilance system as described in the DDPS - Changes in the major contractual arrangements with other persons or organisations involved in the fulfilment of pharmacovigilance obligations and described in the DD	09/09/2010	n/a	Annex II	

N/0003	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/05/2010	n/a	Labelling and PL	
IG/0001/G	This was an application for a group of variations. 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 the range of the currently approved pack sizes 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 the range of the currently approved pack sizes 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 the range of the currently approved pack sizes 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 the range of the currently approved pack sizes 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 the range of the currently approved pack sizes 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 the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets,	26/03/2010	26/03/2010	SmPC and Labelling	

	ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes 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 the range of the currently approved pack sizes				
II/0002	Update of Summary of Product Characteristics section 4.4 following CHMP request during FUM 003 assessment. The Labelling and Package Leaflet are also updated. Update of Summary of Product Characteristics and Labelling	24/09/2009	21/10/2009	SmPC and Labelling	As per CHMP request following the conclusions of FUM 003, the MAH submitted an update of the SPC section 4.4 to bring the information in line with the one contained in the reference medicinal Product (Neupogen). The SPC is updated to amend recommendation of a systematic record and tracking of the stem cell donors for a duration of at least 10 years.
II/0001	Change(s) to the manufacturing process for the active substance Change(s) to the manufacturing process for the active substance	24/09/2009	30/09/2009		