Ratiograstim

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/0082/G	This was an application for a group of variations. C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation C.I.2.a - Change in the SPC, Labelling or PL of a	26/05/2023		SmPC, 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).

	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				
N/0081	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/01/2023		PL	
IB/0080	B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB	04/01/2023	n/a		
IB/0079/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.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	16/11/2022	n/a		
IAIN/0078	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	11/10/2022	n/a		
PSUSA/1391/ 202109	Periodic Safety Update EU Single assessment - filgrastim	05/05/2022	n/a		PRAC Recommendation - maintenance

N/0076	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	03/12/2021	04/04/2022	PL	
IB/0075	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	17/11/2021	n/a		
IA/0074/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 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	10/09/2021	n/a		
IB/0073	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	04/08/2021	n/a		
IA/0072/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	04/05/2021	n/a		

	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation 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 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				
IB/0071/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	13/04/2021	n/a		
WS/1974	This was an application for a variation following a	25/03/2021	04/04/2022	SmPC, Annex	The PI is updated to reflect the change in the finished

	worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. To update section 6.4 of the SmPC in order to add finished product in-use storage conditions at room temperature not above 25 °C for a single period of up to 4 days. The package leaflet is updated accordingly. The MAH took also the opportunity to update the results for all filgrastim finished product long-term stability studies, which were presented in the dossier as `on-going', with results from the completed studies. The obtained results support the approved filgrastim drug product shelf-life of 30 months. The MAH also took the opportunity to correct some typos and formatting in line with the latest QRD template 10.1 and to update the list of local reps in the PL. B.II.f.1.c - Stability of FP - Change in storage conditions for biological medicinal products, when the stability studies have not been performed in accordance with an approved stability protocol			II, Labelling and PL	product in-use storage conditions at room temperature not above 25 °C for a single period of up to 4 days. The SmPC section 6.4 has been updated as follows: Within its shelf-life and for ambulatory use, the product may be removed from the refrigerator (2 °C – 8 °C) and stored at a temperature up to 25 °C for one single period of up to 4 days. If not used within 4 days, the product may be returned to the refrigerator (2 °C – 8 °C) up to the expiry date. Dispose of syringes if stored above 8 °C for more than 4 days. The PL has been updated accordingly.
II/0069	Submission of an updated RMP version 10.0 in order to remove the additional pharmacovigilance activity "Cooperation with SCNIR (Severe Chronic Neutropenia International Registry) and analysis of corresponding Ratiograstim/Tevagrastim-SCNIR data". C.I.11.b - Introduction of, or change(s) to, the	01/10/2020	n/a		Not applicable

	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				
IB/0068	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	17/07/2020	n/a		
IA/0067	A.7 - Administrative change - Deletion of manufacturing sites	26/06/2020	n/a		
IA/0066/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	17/04/2020	n/a		
IB/0065	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	07/01/2020	n/a		
IA/0064/G	This was an application for a group of variations.	18/12/2019	17/06/2020	Annex II	

	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 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)				
IA/0063/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 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	13/08/2019	n/a		

	intermediate used in the manufacture of the AS or manufacturer of a novel excipient 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 B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation 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/0060	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	21/06/2019	17/06/2020	SmPC and PL	
IB/0062	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	06/06/2019	n/a		

PSUSA/1391/201809	Periodic Safety Update EU Single assessment - filgrastim	16/05/2019	n/a		PRAC Recommendation - maintenance
IB/0059/G	This was an application for a group of variations. B.II.e.1.z - Change in immediate packaging of the finished product - Other variation B.II.e.2.a - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier	29/03/2019	n/a		
IAIN/0057	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	12/12/2018	13/05/2019	Annex II and PL	
IAIN/0056	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	31/05/2018	13/05/2019	SmPC, Labelling and PL	
IB/0055	B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished	23/05/2018	n/a		

	product - Deletion of a non-significant in-process test				
II/0054	B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS	28/09/2017	n/a		
II/0053/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.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation 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	06/07/2017	n/a		
II/0052	B.II.b.4.c - Change in the batch size (including batch size ranges) of the finished product - The change requires assessment of the comparability of a biological/immunological medicinal product or a new bioequivalence study	10/11/2016	n/a		

IB/0051	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	26/09/2016	n/a		
IAIN/0050	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	12/07/2016	18/05/2017	Annex II and PL	
IB/0049/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	08/06/2016	n/a		
PSUSA/1391/ 201509	Periodic Safety Update EU Single assessment - filgrastim	13/05/2016	n/a		PRAC Recommendation - maintenance
II/0046/G	This was an application for a group of variations. 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.f.1.e - Stability of FP - Change to an approved stability protocol	07/04/2016	n/a		
IB/0048	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other	18/03/2016	n/a		

	variation				
N/0047	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	03/02/2016	18/05/2017	PL	
II/0044	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	05/11/2015	n/a		
IB/0043	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	07/04/2015	n/a		
IB/0042/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 B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	30/01/2015	n/a		

	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.f.1.e - Stability of FP - Change to an approved stability protocol				
IA/0041	A.7 - Administrative change - Deletion of manufacturing sites	03/10/2014	n/a		
IB/0040	B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB	29/08/2014	n/a		
IA/0039/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	15/08/2014	n/a		
IB/0038	B.I.c.1.z - Change in immediate packaging of the AS - Other variation	22/07/2014	n/a		
IB/0037	B.I.c.z - Container closure system of the AS - Other variation	28/05/2014	n/a		
IB/0036	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	20/05/2014	n/a		
IA/0035/G	This was an application for a group of variations.	12/03/2014	n/a		

	B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material				
IB/0034	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	24/01/2014	n/a		
IB/0033/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.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	17/12/2013	n/a		
IA/0032/G	This was an application for a group of variations. B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material	22/11/2013	n/a		

	B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material				
IB/0030	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.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	30/10/2013	04/12/2014	SmPC and PL	Update of sections 4.4 and 4.8 of the SmPC to include a new adverse reaction, capillary leak syndrome, and a related warning following the same update for the originator. The PL is updated accordingly.

IA/0031	B.II.e.2.a - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits	15/10/2013	n/a		
R/0027	Renewal of the marketing authorisation.	30/05/2013	19/07/2013	SmPC, Annex II, Labelling and PL	
IA/0029/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test	11/07/2013	n/a		
IA/0028	B.II.e.2.a - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits	11/04/2013	n/a		
IB/0026/G	This was an application for a group of variations. B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation 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	18/01/2013	n/a		
II/0024/G	This was an application for a group of variations. To introduce a new site for WCB manufacture.	15/11/2012	n/a		

	To introduce a new WCB lot and some modifications to the manufacturing process of the WCB (change in scale, harvesting time and freezing volume). 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.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological medicinal product and is not related to a protocol				
IB/0025	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 NO new additional data are submitted by the MAH	24/10/2012	31/10/2012	SmPC, Annex II, Labelling and PL	
IB/0022/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	21/09/2012	n/a		
IA/0023	A.5.b - Administrative change - Change in the name	12/09/2012	n/a		

	and/or address of a manufacturer of the finished product, including quality control sites (excluding manufacturer for batch release)				
II/0021	Replacement of the peptide mapping method. B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Change (replacement) to a biological/immunological/ immunochemical test method or a method using a biological reagent for a biological AS	19/07/2012	n/a		
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 material/intermediate	10/05/2012	n/a		
IA/0018/G	This was an application for a group of variations. B.I.c.2.b - Change in the specification parameters and/or limits of the immediate packaging of the AS - Addition of a new specification parameter to the specification with its corresponding test method B.I.c.2.c - Change in the specification parameters and/or limits of the immediate packaging of the AS - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	14/03/2012	n/a		
IB/0017	B.I.a.3.e - Change in batch size (including batch size ranges) of AS or intermediate - The scale for a	08/12/2011	n/a		

	biological/immunological AS is increased/decreased without process change (e.g. duplication of line)				
IA/0016/G	This was an application for a group of variations. B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.I.d.1.a.1 - Stability of AS - Change in the re-test period/storage period - Reduction	25/10/2011	n/a		
II/0015/G	This was an application for a group of variations. Introduction of additional sterile filtration steps in the manufacturing process for the active substance. In addition, new in-process tests and limits are introduced. 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 medicinal product and is not related to a protocol 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	20/10/2011	n/a		
II/0013	Introduction of a new Pharmacovigilance System	23/06/2011	20/07/2011	Annex II	The MAH has introduced a new pharmacovigilance system

	(TEVA DDPS Version 10), including a new Qualified person for Pharmacovigilance. Annex II.B has also been updated with the latest wording as per October 2010 CHMP procedural announcement. C.I.8.a - Introduction of a new Pharmacovigilance system - which has not been assessed by the relevant NCA/EMA for another product of the same MAH				used by TEVA Pharmaceutical Industries Ltd., which will be applied for the product Ratiograstim. The detailed description of this pharmacovigilance system includes information pertaining to the qualified person responsible for pharmacovigilance, the global structure of the pharmacovigilance organisation, company procedures relating to pharmacovigilance activities, global safety databases, links with other organisations, training and the quality management system. The MAH has also taken the opportunity to update Annex II.B with the latest wording as per October 2010 CHMP procedural announcement.
IB/0014/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.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	20/07/2011	n/a		
IB/0012/G	This was an application for a group of variations. 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 NO new additional data are submitted by the MAH 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	21/02/2011	n/a	SmPC and PL	To implement changes requested in the PSUR 3 Assessment Report (dated 06 August 2010), as well as to bring the Product Information in line with the SmPC of the reference product (Neupogen). Minor linguistic amendments are introduced in the Package Leaflet for the following languages: CS, DA, ET, ES, FI, FR, HU, IT, NL, PL . In addition, the MAH amended the European Medicines Agency web address in section 10 of the SmPC.

	product - Implementation of change(s) for which NO new additional data are submitted by the MAH				
IA/0011	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	22/09/2010	n/a		
IB/0010	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	27/08/2010	n/a		
II/0007	Addition of an alternative site for manufacture (formulation, filling) of drug product. 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.	24/06/2010	01/07/2010		
IB/0009	To change a test procedure for the finished product B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	20/05/2010	n/a		
IB/0008	To change a test procedure for the active substance B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement	20/05/2010	n/a		

	or addition) for the AS or a starting material/intermediate				
IA/0006	B.II.e.6.a - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that affects the product information	05/03/2010	n/a	PL	
II/0001	Extension of the finished product shelf-life from 24 to 30 months. Change(s) to shelf-life or storage conditions	19/11/2009	08/01/2010	SmPC, Labelling and PL	
IA/0005	IA_28_Change in any part of primary packaging material not in contact with finished product	06/10/2009	06/10/2009	SmPC, Labelling and PL	
IA/0004	IA_28_Change in any part of primary packaging material not in contact with finished product	06/10/2009	06/10/2009	SmPC, Labelling and PL	
IA/0003	IA_28_Change in any part of primary packaging material not in contact with finished product	06/10/2009	06/10/2009	SmPC, Labelling and PL	
IA/0002	IA_28_Change in any part of primary packaging material not in contact with finished product	06/10/2009	06/10/2009	SmPC, Labelling and PL	