Pergoveris

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/0085	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	26/05/2023		SmPC	

[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/0084	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	09/05/2023	n/a		
IA/0083/G	This was an application for a group of variations. 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 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.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits 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.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	03/03/2023	n/a		

	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.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				
IB/0082	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	23/11/2022	n/a		
WS/2275/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.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 B.I.e.2 - Introduction of a post approval change management protocol related to the AS	27/10/2022	n/a		
N/0081	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/08/2022	14/10/2022	PL	

IB/0080	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	11/07/2022	n/a		
PSUSA/1464/ 202110	Periodic Safety Update EU Single assessment - follitropin alfa / lutropin alfa	10/06/2022	n/a		PRAC Recommendation - maintenance
IA/0079	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	25/05/2022	n/a		
II/0075	Update of sections 4.1, 4.2, 4.4, 5.1, 5.2, 6.6 of the SmPC in order to revise the definition of severe LH and FSH deficiency and to clarify the treatment target and the pharmacokinetic and pharmacodynamic properties of the two gonadotropins included in the medicinal product, as well as disposal precautions, based on current medical guidelines, clinical practice and literature; the Package Leaflet and Labelling are updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.2 and to align with the guideline on the Excipients in the labelling and package leaflet of the medicinal products for human use. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	14/10/2021	14/10/2022	SmPC, Annex II, Labelling and PL	Provision of context and alignment regarding the definition of severe LH and FSH deficiency based on current medical guidelines and standards of clinical care in section 4.1. of the SmPC, as well as description of the physiologic action of Pergoveris and its use in relevant clinical settings associated with Medically Assisted Reproduction in section 4.2 of the SmPC. Clarification and reorganisation of information in section 5.1 of the SmPC. For more information, please refer to the Summary of Product Characteristics.

IA/0076/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.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits 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	16/07/2021	n/a		
IB/0073	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	26/05/2021	n/a		
II/0072	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	29/04/2021	n/a		
IA/0074	B.II.f.1.e - Stability of FP - Change to an approved stability protocol	13/04/2021	n/a		

II/0068	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	10/09/2020	n/a		
II/0071	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	04/09/2020	n/a		Not applicable
II/0069	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	23/07/2020	n/a		
IB/0070/G	This was an application for a group of variations. B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products 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	24/06/2020	n/a		

	control/testing takes place B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process 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 originally approved batch size				
WS/1799/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.4.d - Change to in-process tests or limits applied during the manufacture of the AS - Widening of the approved in-process test limits, which may have a significant effect on the overall quality of the AS B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer	18/06/2020	n/a		
II/0066	Submission of an updated RMP version 5.3 (updated to version 6.0) in order to adapt to the RMP template as per Good Pharmacovigilance Practice (GVP) Module V, rev 2, with consequential removal of important identified risks and important potential risks.	12/03/2020	n/a		

	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				
IB/0064/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)	13/11/2019	n/a		
IA/0065	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	30/10/2019	n/a		
IB/0063	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	20/08/2019	n/a		
IB/0062	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)	08/07/2019	n/a		

PSUSA/1464/201810	Periodic Safety Update EU Single assessment - follitropin alfa / lutropin alfa	14/06/2019	n/a		PRAC Recommendation - maintenance
IA/0060	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	12/12/2018	n/a		
T/0059	Transfer of Marketing Authorisation	30/07/2018	20/08/2018	SmPC, Labelling and PL	
IB/0058	B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site	28/06/2018	n/a		
II/0055	Update of the Pergoveris Risk Management Plan to version 5.2 in order to: · Align the RMP template with Good Pharmacovigilance Practice (GVP) Module V, revision 1. · Add the reference to Pergoveris solution for injection in pre-filled pen (300IU/150IU, 450IU/225IU and 900IU/450IU) following the approval in the European Union (EU) on the 8th of May 2017. Additionally, minor updates have been introduced to the safety specification sections based on the data reviewed until the most recent data lock point. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing	14/06/2018	n/a		

	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/0057	B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products	08/05/2018	n/a		
IB/0056	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	11/04/2018	n/a		
II/0054/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.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	22/02/2018	n/a		
IB/0053/G	This was an application for a group of variations. B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a	21/09/2017	n/a		

	new or an already approved manufacturer B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material)				
II/0052/G	This was an application for a group of variations. 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 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	14/09/2017	n/a		
IB/0051	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	27/07/2017	n/a		
R/0050	Renewal of the marketing authorisation.	23/02/2017	08/05/2017	Annex II, Labelling and PL	
X/0047	Extension application to introduce a new pharmaceutical form (solution for injection) associated with 3 new presentations of (300 IU, 150 IU)/ 0.48 ml, (450 IU, 225 IU)/ 0.72 ml and (900 IU,	23/02/2017	08/05/2017	SmPC, Annex II, Labelling and PL	

	450 IU)/ 1.44 ml. Annex I_2.(d) Change or addition of a new pharmaceutical form				
IB/0049	B.I.a.4.f - Change to in-process tests or limits applied during the manufacture of the AS - Addition or replacement of an in-process test as a result of a safety or quality issue	02/09/2016	n/a		
IA/0048/G	This was an application for a group of variations. 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 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 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	01/09/2016	n/a		
PSUSA/1464/ 201510	Periodic Safety Update EU Single assessment - follitropin alfa / lutropin alfa	09/06/2016	n/a		PRAC Recommendation - maintenance

IB/0046	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	23/03/2016	n/a		
IA/0045	B.II.e.3.b - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition)	25/02/2016	n/a		
WS/0655	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Change in test procedure for AS and FP 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	20/11/2014	n/a		Change in test procedure for AS and FP
IG/0500	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	17/11/2014	n/a		
IA/0042	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	21/10/2014	n/a		

WS/0579/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.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure 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.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 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) B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation 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.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other	24/07/2014	n/a		

	variation 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.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation				
IG/0461	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	22/07/2014	n/a		
WS/0506	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Change to the manufacturing process of the active substance. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	20/03/2014	n/a		
IA/0038/G	This was an application for a group of variations.	24/01/2014	n/a		

	B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier				
IB/0037	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	20/01/2014	03/02/2015	SmPC, Annex II, Labelling and PL	
IG/0395	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	20/12/2013	n/a		
WS/0457	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Change to the control of 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 or addition) for the AS or a starting material/intermediate	18/12/2013	n/a		
IB/0034	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other	31/10/2013	n/a		

	changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate				
IB/0033/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.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	18/10/2013	n/a		
IG/0361	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	04/10/2013	n/a		
N/0029	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	02/10/2013	03/02/2015	PL	
IG/0358	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	25/09/2013	n/a		
WS/0380	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Change to the control of the active substance B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition	30/05/2013	n/a		

	of a new in-process test and limits				
N/0027	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/12/2012	03/02/2015	PL	
IB/0025	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	05/12/2012	n/a		
IG/0224	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	11/10/2012	n/a		
WS/0294	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Change to the control of the drug substance and drug product 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	20/09/2012	n/a		
WS/0275	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Change to the control of the finished product	19/07/2012	n/a		

	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation				
R/0021	Renewal of the marketing authorisation.	15/03/2012	22/05/2012	SmPC, Annex II, Labelling and PL	Based upon the data that have become available since the granting of the initial Marketing Authorisation, the CHMP considers that the benefit-risk balance of Pergoveris remains positive, but considers that its safety profile has to be closely monitored since there are grounds for suspecting significant off-label use of Pergoveris in Assisted Reproductive Technology (ART) for women who do not have severe LH and FSH deficiency, and a number of issues are still required monitoring in the risk management plan, including potential side effects with long latency. Therefore, based upon the safety profile of Pergoveris, which requires submission of three yearly PSURs, the CHMP concluded that the MAH should submit one additional renewal application in 5 years time.
IB/0022	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	06/01/2012	n/a		
WS/0174	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Change to the manufacturing process of lutropin alfa active substance B.I.a.2.c - Changes in the manufacturing process of	20/10/2011	20/10/2011		

	the AS - The change refers to a [-] substance in the manufacture of a biological/immunological medicinal product and is not related to a protocol				
WS/0148	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. New TSE certificate for a raw material used in the manufacture of the active substance. B.III.1.b.2 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer	21/07/2011	21/07/2011		
IG/0087	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	18/07/2011	n/a		
IG/0076/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.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the contact details of the QPPV C.I.9.h - Changes to an existing pharmacovigilance	01/07/2011	n/a	Annex II and PL	

	system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system				
IB/0015/G	This was an application for a group of variations. B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method	06/01/2011	n/a		
II/0014	Change to the purification process of the active substance 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	16/12/2010	04/01/2011		
WS/0016	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Change of reference standard B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement	24/06/2010	24/06/2010		

	or addition) for the AS or a starting material/intermediate				
II/0013	Update of the Detailed Description of the Pharmacovigilance system (DDPS). In addtion mistakes in the PI have been corrected. Update of DDPS (Pharmacovigilance)	22/04/2010	10/06/2010	Annex II and PL	With this variation the MAH submitted a new version of the DDPS (core version 9.0) in accordance with the current Pharmacovigilance guideline. After assessing the documentation the CHMP concluded that the submitted DDPS contained all required elements. Consequently, Annex II has been updated with the new version number of the agreed DDPS. In addition the MAH took the opportunity to amend the following: - Correct mistakes in the "Possible side effects" section of the Patient Leaflet which applies to all EU languages - Update the list of representatives in the Patient Leaflet (Bulgaria, Denmark, Germany, Estonia, Latvia, Lithuania, Sweden) which applies to all EU languages - Correct grammatical/linguistic errors in some national translations of the Product Information
II/0012	Change to the shelf life of the drug substance Change(s) to shelf-life or storage conditions	21/01/2010	02/02/2010		
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/01/2010	n/a	PL	
IA/0010	IA_04_Change in name and/or address of a manuf. of the active substance (no Ph. Eur. cert. avail.)	09/07/2009	n/a	Annex II	

IA/0009	IA_01_Change in the name and/or address of the marketing authorisation holder	09/07/2009	n/a	SmPC, Labelling and PL	
II/0008	Change of reference standard Change(s) to the test method(s) and/or specifications for the active substance	25/06/2009	25/06/2009		
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	26/05/2009	n/a	Labelling and PL	
IA/0006	IA_04_Change in name and/or address of a manuf. of the active substance (no Ph. Eur. cert. avail.) IA_05_Change in the name and/or address of a manufacturer of the finished product	24/03/2009	n/a	Annex II	
IA/0005	IA_05_Change in the name and/or address of a manufacturer of the finished product	14/11/2008	n/a	Annex II and PL	
IA/0004	IA_04_Change in name and/or address of a manuf. of the active substance (no Ph. Eur. cert. avail.) IA_05_Change in the name and/or address of a manufacturer of the finished product	14/11/2008	n/a		
II/0003	Change(s) to the manufacturing process for the active substance	30/05/2008	26/06/2008		
II/0002	Change(s) to the manufacturing process for the active substance	21/02/2008	04/04/2008	Annex II	

II/0001	Change(s) to the manufacturing process for the active substance	21/02/2008	26/02/2008		