TOBI Podhaler

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
PSUSA/9315/ 202406	Periodic Safety Update EU Single assessment - tobramycin (inhalation powder, capsules)	27/02/2025	23/04/2025	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/9315/202406.
IB/0069	B.IV.z - Quality change - Change in Medical Devices - Other variation	05/02/2025	n/a		

[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).

IA/0068	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	17/12/2024	n/a		
IA/0067/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 B.II.d.2.a - Change in test procedure for the finished product - 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	09/12/2024	n/a		
IA/0066	A.7 - Administrative change - Deletion of manufacturing sites	05/11/2024	n/a		
IA/0064/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.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished	21/08/2024	n/a		

	product - Minor changes to an approved test procedure				
N/0063	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	05/08/2024	23/04/2025	PL	
IB/0062/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.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) 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.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 A.7 - Administrative change - Deletion of manufacturing sites B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its	18/06/2024	n/a		

	corresponding test method B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition) 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.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation 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.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products				

IB/0061/G	This was an application for a group of variations. 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.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) 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.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) 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.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) 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.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	13/12/2023	n/a		
IB/0060	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	12/09/2023	n/a		

	material/intermediate				
II/0057/G	This was an application for a group of variations. 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.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.I.z - Quality change - Active substance - Other variation 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.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.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.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-	31/08/2023	n/a		

	significant specification parameter (e.g. deletion of an obsolete parameter) 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)				
WS/2481	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	13/07/2023	20/06/2024	SmPC, Annex II and PL	
IA/0059/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - 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	28/06/2023	n/a		
II/0053	Submission of an updated RMP version 8.1 following the request by PRAC in the AR for PSUSA/00009315/202106 in order to update it based on the guidance provided in the GVP and to remove the safety concerns as well as to reflect the finalization of study CTBM100C2407 and the transfer of ownership.	14/04/2023	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				
T/0056	Transfer of Marketing Authorisation	08/03/2023	31/03/2023	SmPC, Labelling and PL	
IA/0055	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	13/02/2023	n/a		
IA/0054/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.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)	04/10/2022	n/a		
N/0052	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/05/2022	31/03/2023	PL	
PSUSA/9315/ 202106	Periodic Safety Update EU Single assessment - tobramycin (inhalation powder, capsules)	10/02/2022	n/a		PRAC Recommendation - maintenance

IA/0050/G	This was an application for a group of variations. B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.d.2.a - Change in test procedure for the finished product - 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	06/08/2021	n/a		
IB/0049	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)	22/07/2021	22/11/2021	SmPC and PL	To extend the shelf-life of the finished product as packaged for sale from 3 to 4 years.
IB/0048	B.II.z - Quality change - Finished product - Other variation	30/06/2021	n/a		
IA/0047/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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	01/03/2021	n/a		

	batch control/testing takes place				
IAIN/0046/G	This was an application for a group of variations. 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 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)	08/12/2020	22/11/2021	Annex II and PL	
IA/0045/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) 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.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 B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP -	12/10/2020	n/a		

	Replacement/addition of a site where batch control/testing takes place				
IB/0044/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.z - Quality change - Finished product - Other variation B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings	04/09/2020	22/11/2021	SmPC, Annex II and PL	
IB/0043/G	This was an application for a group of variations. B.II.z - Quality change - Finished product - Other variation B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.II.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)	13/07/2020	n/a		
IAIN/0042	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP -	16/08/2019	27/07/2020	Annex II and	

	Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing			PL	
T/0041	Transfer of Marketing Authorisation	31/05/2019	28/06/2019	SmPC, Labelling and PL	
IA/0040/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.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	29/05/2019	n/a		
IA/0039/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	15/03/2019	n/a		

	A.7 - Administrative change - Deletion of manufacturing sites				
PSUSA/9315/ 201806	Periodic Safety Update EU Single assessment - tobramycin (inhalation powder, capsules)	14/02/2019	n/a		PRAC Recommendation - maintenance
IA/0037	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/08/2018	28/06/2019	Labelling and PL	
T/0036	Transfer of Marketing Authorisation	20/03/2018	23/04/2018	SmPC, Labelling and PL	
IA/0035/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 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.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	16/05/2017	n/a		
R/0034	Renewal of the marketing authorisation.	17/12/2015	18/02/2016	SmPC and Annex II	Based on the review of the available information the CHMP is of the opinion that the quality, the safety and the efficacy

					of this medicinal product continues to be adequately and sufficiently demonstrated and therefore considers that the benefit/risk profile of TOBI Podhaler continues to be favourable. The CHMP is of the opinion that the renewal can be granted with unlimited validity.
PSUSA/9315/ 201506	Periodic Safety Update EU Single assessment - tobramycin (inhalation powder, capsules)	14/01/2016	n/a		PRAC Recommendation - maintenance
II/0030	Update of section 4.8 of the SmPC to add the new ADRs malaise and sputum discoloured based on reports from post-marketing experience. The PL is updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	29/10/2015	18/02/2016	SmPC and PL	
IB/0032/G	This was an application for a group of variations. B.II.z - Quality change - Finished product - Other variation 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	10/08/2015	n/a		
IA/0031	B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits	03/06/2015	n/a		
IA/0029	B.II.c.1.a - Change in the specification parameters	24/04/2015	n/a		

	and/or limits of an excipient - Tightening of specification limits				
PSUV/0026	Periodic Safety Update	09/01/2015	n/a		PRAC Recommendation - maintenance
II/0027/G	This was an application for a group of variations. Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to reflect data from study CTBM100C2401 (in fulfilment of MEA 10). Update of the RMP to reflect the study conclusion. In addition, update of the product information to reflect the change of address of the MAH. A.1 - Administrative change - Change in the name and/or address of the MAH C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	20/11/2014	11/02/2015	SmPC, Labelling and PL	In this variation application the MAH submitted the clinical study report from study CTBM100C2401, "A single arm, open label, multicentre, Phase IV trial to assess long-term safety of tobramycin inhalation powder (TIP) in patients with Cystic Fibrosis". Study CTBM100C2401 was conducted as a post-authorization measure (PAM) for TOBI Podhaler with the aim of addressing the need for long-term data. The CHMP concluded that the newly submitted data on safety provided by the MAH are consistent with the known safety profile of the product and are considered not to change the overall benefit/risk of TOBI Podhaler. The MAH proposal to remove the statement that long-term data are not available for TOBI Podhaler in sections 4.2, 4.4 and 4.8 of the SmPC and relevant section of the package leaflet was accepted.
IAIN/0028/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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)	30/10/2014	n/a		

	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 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				
IB/0025	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	26/09/2014	n/a		
II/0023	Minor change to the manufacturing process of the finished product; to add an alternative batch size of the finished product. B.II.b.4.d - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes	25/09/2014	n/a		
IAIN/0024	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	04/08/2014	11/02/2015	SmPC	
PSUV/0021	Periodic Safety Update	10/07/2014	n/a		PRAC Recommendation - maintenance
IA/0022	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	31/03/2014	n/a		

II/0020	Update of section 4.5 of the Tobi Podhaler SmPC to provide clarification on the concomitant use with intravenous mannitol. The PL was updated accordingly. The MAH took the opportunity to implement revisions in the PL previously agreed with the CHMP. Furthermore, the PI is being brought in line with the latest QRD template version 9.0. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	23/01/2014	11/02/2015	SmPC, Annex II, Labelling and PL	This variation was submitted to supplement the existing information in section 4.5 of the Tobi Podhaler SmPC regarding the concomitant use with mannitol by clarifying that it refers to intravenous mannitol and not to mannitol for inhalation. The PL was updated accordingly and was complemented by the implementation of a wording, previously agreed with the CHMP in the "Instructions for use" section, containing more clear instructions on the correct piercing orientation in order to improve the correct handling of the device during the piercing step.
PSUV/0017	Periodic Safety Update	09/01/2014	n/a		PRAC Recommendation - maintenance
II/0019	Update of section 4.8 of the SmPC in order to change the frequency of the adverse drug reaction "aphonia" from "not known" to "common", following a cumulative search of clinical data and post-marketing sources. The Package Leaflet is updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	18/12/2013	11/02/2015	SmPC and PL	Five completed clinical study reports have been examined with a focus on 'aphonia' adverse event reports. A cumulative search of clinical data and post-marketing sources was also conducted for the adverse drug reaction "aphonia". Based on the assessment of these data, the frequency of "aphonia" was updated to "common" in the Tobi Podhaler product information.
IA/0018/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - 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	24/10/2013	n/a		

	procedure B.II.d.2.a - Change in test procedure for the finished product - 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 B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure				
IB/0016	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	02/10/2013	n/a		
PSUV/0015	Periodic Safety Update	25/07/2013	24/09/2013	SmPC and PL	During the reviewed period, 1 new case of aphonia was reported. A total of three cases are available in Eudravigilance. The Marketing Authorisation Holder was requested to update the Product Information to include the adverse event "aphonia", because: • cases detailing the adverse event aphonia with a time to onset compatible with a causal relationship between aphonia and TOBI Podhaler have been reported, • aphonia might be a more severe form of dysphonia which is listed according to the currently approved SmPC and the adverse event might be related to the active substance and is listed for tobramycin nebuliser solution TOBI 300 mg/5 ml (UK/H/0361/001). Otherwise no new (potential) safety issue has been identified. In view of available data regarding aphonia the PRAC considered that changes to the product information were

					warranted. The CHMP agrees with the scientific conclusions made by the PRAC.
IB/0014	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	25/06/2013	n/a		
IB/0013	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	06/03/2013	n/a		
IAIN/0012	B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing	18/01/2013	24/09/2013	Annex II and PL	
IG/0248	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	17/12/2012	n/a		
IA/0009/G	This was an application for a group of variations. B.III.1.a.2 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	28/11/2012	n/a		
IA/0008/G	This was an application for a group of variations.	10/09/2012	n/a		

	B.III.1.a.2 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier				
IG/0209/G	This was an application for a group of variations. 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 system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system	17/08/2012	n/a		
IA/0006	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	10/08/2012	n/a		
IB/0004/G	This was an application for a group of variations. B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	20/06/2012	n/a		

	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation				
IB/0005	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	14/06/2012	n/a		
IG/0148/G	This was an application for a group of variations. 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	22/02/2012	n/a		
IA/0002/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 of the finished product, including quality control sites (excluding manufacturer for batch release) A.7 - Administrative change - Deletion of manufacturing sites	15/12/2011	n/a		

IG/0109	C.I.9.i - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH	30/09/2011	n/a	Annex II	