Deltyba

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
R/0076	Renewal of the marketing authorisation.	30/01/2025	25/04/2025	SmPC, Annex II and PL	The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the

[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).

					renewal of the conditional MA for Deltyba, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion. SOB 002 has been revised, to specify that the use of delamanid should be investigated in different combination treatment regimens as per approved indication. Because the MAH has not been able to agree on terms that would allow for data sharing of the individual patient data (IPD) of the endTB study, the delamanid-specific analysis based on the CHMP agreed statistical analysis plan will not be possible as this was based on the availability of the IPD. Publicly available data will have to be used instead, both from the publication of the endTB study results and from the planned 2025 WHO update of the tuberculosis treatment guidelines. A critical discussion of the publicly available data is also required, including as possible an analysis based on the agreed delamanid-specific analysis plan and with an additional discussion when deviating from it. Finally, publicly available results from the BEAT-TB South-Africa clinical study conducted by Wits Health Consortium should be submitted and discussed. In this study the 6-month BDLLfxC regimen was investigated in place of 9-month or longer (> 18 months) regimens in patients with RR-TB. The due date of SOB 002 was also changed from Q2 2025 to Q3 2026, and it was specified that the MAH should investigate the use of delamanid in different combination treatment regimens 'as per approved indication'.
PSUSA/10213 /202404	Periodic Safety Update EU Single assessment - delamanid	28/11/2024	n/a		PRAC Recommendation - maintenance

IA/0077	A.7 - Administrative change - Deletion of manufacturing sites	02/10/2024	n/a		
IB/0075	B.II.f.z - Stability of FP - Other variation	16/08/2024	n/a		
IB/0073	B.II.c.z - Change in control of excipients in the Finished Product - Other variation	24/06/2024	n/a		
PSUSA/10213 /202310	Periodic Safety Update EU Single assessment - delamanid	16/05/2024	n/a		PRAC Recommendation - maintenance
R/0070	Renewal of the marketing authorisation.	14/12/2023	26/02/2024	Annex II	The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Deltyba, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion. The due date for the specific obligation (SOB 002) related to the submission of the results of the Evaluating Newly approved Drugs for multidrug-resistant TB (endTB) study has been postponed, from Q3 2024 to Q2 2025.
PSUSA/10213 /202304	Periodic Safety Update EU Single assessment - delamanid	14/12/2023	22/02/2024	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10213/202304.
IA/0071	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)	12/12/2023	n/a		

II/0061	Update of sections 4.2 and 4.4 of the SmPC in order to update the treatment duration based on final results from EU PASS (protocol no. 242-12-402), listed as a category 3 study in the RMP. This is a "A Multicentre, EU-wide, Non-Interventional Post-Authorisation Study to Assess the Safety and Usage of Delamanid in Routine Medical Practice in Multidrug-Resistant Tuberculosis (MDR-TB) Patients". This treatment registry was for monitoring and documenting Deltyba use in routine medical practice and aimed to assess compliance with the recommendations in the authorised product information when prescribed as part of an appropriate combination regimen (ACR) for the treatment of MDR-TB. The Package Leaflet is updated accordingly. Update of Annex II and the RMP to version 5.0 to remove the additional Risk Minimisation Measures (aRMMs). C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	06/07/2023	22/02/2024	SmPC, Annex II and PL	SmPC new text Section 4.2 Treatment duration The total duration of treatment with delamanid is 24 weeks. Data on longer treatment duration is very limited. When treatment with delamanid is considered necessary beyond 24 weeks to obtain a curative treatment, a longer duration of therapy may be considered. Section 4.4 Deletion of the sentence: There are no data on treatment with delamanid for mor than 24 consecutive weeks (see section 4.2). For more information, please refer to the Summary of Product Characteristics.
IA/0068/G	This was an application for a group of variations. A.8 - Administrative change - Changes to date of the audit to verify GMP compliance of the manufacturer of AS A.8 - Administrative change - Changes to date of the audit to verify GMP compliance of the manufacturer	04/07/2023	n/a		

	of AS				
IB/0067	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)	15/06/2023	22/02/2024	SmPC	
PSUSA/10213 /202210	Periodic Safety Update EU Single assessment - delamanid	12/05/2023	n/a		PRAC Recommendation - maintenance
R/0062	Renewal of the marketing authorisation.	26/01/2023	24/03/2023	Annex II	The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Deltyba, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
IA/0066	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	08/03/2023	n/a		
PSUSA/10213 /202204	Periodic Safety Update EU Single assessment - delamanid	01/12/2022	n/a		PRAC Recommendation - maintenance
IA/0064/G	This was an application for a group of variations. 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 B.II.b.3.a - Change in the manufacturing process of	22/11/2022	n/a		

	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.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation				
IA/0063/G	This was an application for a group of variations. 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.z - Change in the manufacturing process of the finished or intermediate product - Other variation	03/11/2022	n/a		
IB/0060	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)	07/09/2022	24/03/2023	SmPC	
II/0053	Update of section 4.8 of the SmPC in order to update the list of adverse drug reactions (ADRs table) following the development of an improved methodology to identify relevant ADRs likely attributable to delamanid. The section 4 of the Package Leaflet is updated accordingly. The RMP version 4.1 has also been submitted. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	01/09/2022	24/03/2023	SmPC and PL	The MAH has proposed an update of section 4.8 of the SmPC, based on a statistical and medical judgement of ADRs seen in the two clinical trials 204 (phase 2) and 213 (phase 3) as well from all post-marketing sources. Some ADRs were removed due to insufficient supporting evidence to retain them, in addition there was an update of some of the ADR frequencies, grouping of terms and addition of hypothyroidism with a frequency "common". For more information, please refer to the Summary of Product Characteristics.

IB/0058	B.II.z - Quality change - Finished product - Other variation	18/07/2022	n/a		
IA/0057/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.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	07/06/2022	n/a		
R/0052	Renewal of the marketing authorisation.	27/01/2022	22/03/2022	SmPC, Annex II and PL	The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Deltyba, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
PSUSA/10213 /202104	Periodic Safety Update EU Single assessment - delamanid	16/12/2021	16/02/2022	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10213/202104.
IAIN/0056	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	01/02/2022	n/a		

IA/0055	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	04/01/2022	n/a		
IB/0054/G	This was an application for a group of variations. B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing 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)	12/11/2021	16/02/2022	SmPC, Annex II and PL	
X/0046/G	This was an application for a group of variations. Annex I_2.(d) Change or addition of a new pharmaceutical form C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	22/07/2021	16/09/2021	SmPC, Annex II, Labelling and PL	
PSUSA/10213 /202010	Periodic Safety Update EU Single assessment - delamanid	10/06/2021	n/a		PRAC Recommendation - maintenance
II/0048	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	29/04/2021	16/09/2021	SmPC and Annex II	
R/0047	Renewal of the marketing authorisation.	25/02/2021	13/04/2021	Annex II	The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and

					having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Deltyba, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion. The due date of SOB 002 in Annex II of the PI has been changed to Q1 2023.
II/0045	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	09/04/2021	16/09/2021	Annex II	
IA/0050	A.7 - Administrative change - Deletion of manufacturing sites	01/03/2021	16/09/2021	Annex II and PL	
II/0040	Extension of indication to include adolescents and children with a body weight of at least 30 kg. As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.2 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.1 and the Marketing Authorisation Holder (MAH) took the opportunity to make minor editorial changes. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or	17/09/2020	27/10/2020	SmPC, Annex II, Labelling and PL	Please refer to Scientific Discussion 'Deltyba-H-C-002552-II-0040'

	modification of an approved one				
IAIN/0044	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	25/06/2020	n/a		
PSUSA/10213 /201910	Periodic Safety Update EU Single assessment - delamanid	14/05/2020	n/a		PRAC Recommendation - maintenance
R/0041	Renewal of the marketing authorisation.	27/02/2020	23/04/2020	Annex II	The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Deltyba, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion. No changes to the Product Information (PI) are introduced with this renewal procedure.
IA/0042	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)	03/12/2019	n/a		
II/0037	C.I.13 MIC report as amendment to CSR 242-09-213. C.I.13 - Other variations not specifically covered	24/10/2019	n/a		

	elsewhere in this Annex which involve the submission of studies to the competent authority				
IB/0038	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	05/08/2019	n/a		
PSUSA/10213 /201810	Periodic Safety Update EU Single assessment - delamanid	29/05/2019	25/07/2019	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10213/201810.
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 A.7 - Administrative change - Deletion of manufacturing sites	12/06/2019	n/a		
R/0033	Renewal of the marketing authorisation.	31/01/2019	02/04/2019	SmPC, Annex II and PL	The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Deltyba, subject to the modified Specific Obligations and Conditions as laid down in Annex II to the opinion. Minor amendments to the product information are introduced, pertaining the correct denotation for tenofovir disoproxil", (245 mg daily) (SmPC section 4.5) and adding

					of antimalarials with QT-prolonging potential, to be listed in "special considerations – cardiac risk factors" (SmPC section 4.4. and PL).
IAIN/0035/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.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site 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	13/02/2019	n/a		
PSUSA/10213 /201804	Periodic Safety Update EU Single assessment - delamanid	29/11/2018	n/a		PRAC Recommendation - maintenance
II/0030	Update of the RMP (finally approved version 2.11), as requested by PRAC following the assessment of the Annual renewal to revise the risk re-categorisation justifications and lay language wording, as well as to add clarifications to the described additional pharmacovigilance activities to assess the effectiveness of risk minimisation measures and the set up date of an EU network of	06/09/2018	n/a		

	laboratories. 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				
IAIN/0031	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	11/06/2018	02/04/2019	Annex II and PL	
PSUSA/10213 /201710	Periodic Safety Update EU Single assessment - delamanid	17/05/2018	n/a		PRAC Recommendation - maintenance
II/0021	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	17/05/2018	02/04/2019	SmPC, Annex II and PL	
R/0027	Renewal of the marketing authorisation.	22/02/2018	19/04/2018	Annex II	The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Deltyba, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.

N/0029	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/04/2018	02/04/2019	PL	
PSUSA/10213 /201704	Periodic Safety Update EU Single assessment - delamanid	30/11/2017	n/a		PRAC Recommendation - maintenance
IB/0026	B.II.f.1.e - Stability of FP - Change to an approved stability protocol	09/10/2017	n/a		
IA/0025/G	This was an application for a group of variations. B.II.e.1.b.3 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Deletion of an immediate packaging container without a complete deletion of a strength or pharmaceutical form B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)	26/09/2017	19/04/2018	SmPC, Labelling and PL	
II/0020/G	This was an application for a group of variations. B.I.a.2.b - Changes in the manufacturing process of the AS - Substantial change to the manufacturing process of the AS which may have a significant impact on the quality, safety or efficacy of the medicinal product 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.d - Change in the specification parameters	14/09/2017	n/a		

	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.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				
IB/0023	B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	26/07/2017	n/a		
IB/0022	B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure	26/07/2017	n/a		
PSUSA/10213 /201610	Periodic Safety Update EU Single assessment - delamanid	05/05/2017	n/a		PRAC Recommendation - maintenance
N/0019	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	04/05/2017	19/04/2018	PL	
R/0017	Renewal of the marketing authorisation.	26/01/2017	03/03/2017	Annex II	The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Deltyba, subject to the Specific Obligations and Conditions as laid down in Annex II

					to the Opinion.
PSUSA/10213 /201604	Periodic Safety Update EU Single assessment - delamanid	01/12/2016	n/a		PRAC Recommendation - maintenance
II/0014	Update of section 5.1 of the SmPC further to the submission of final clinical study report for trial 242-12-244 "Determination of Delamanid MIC Values and Sub-species Analysis of Mycobacterium tuberculosis Complex Isolates". Moreover the MAH has taken the occasion to implement version 10.0 of the QRD template. The date of the latest renewal has been included as well. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	06/10/2016	03/03/2017	SmPC and Labelling	The statement that a clinical breakpoint for delamanid has not been determined has been removed from the SmPC.
IAIN/0016	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	05/10/2016	n/a		
IB/0013/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.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF	07/06/2016	n/a		
PSUSA/10213	Periodic Safety Update EU Single assessment -	13/05/2016	n/a		PRAC Recommendation - maintenance

/201510	delamanid				
R/0010	Renewal of the marketing authorisation.	28/01/2016	11/03/2016		The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Deltyba, subject to the Specific Obligations and Conditions as laid down in Annex II of the Marketing Authorisation.
N/0012	Inclusion of the list of the local representatives at the end of the package leaflet. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	04/03/2016	03/03/2017	PL	
PSUSA/10213 /201504	Periodic Safety Update EU Single assessment - delamanid	06/11/2015	n/a		PRAC Recommendation - maintenance
IA/0009	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)	16/09/2015	n/a		
IB/0007/G	This was an application for a group of variations. 1) B.I.d.1 a.4 (Type IB) – to increase the retest period of the active substance from 48 months to 60 months when stored below 30°C. 2) B.II.f.1 b.1 (Type IB) – to increase the shelf-life of	03/06/2015	11/03/2016	SmPC and PL	

	the finished product packaged in glass bottles and aluminum/aluminum foil blisters from 4 years to 5 years (section 6.3 of the SmPC is updated). In addition the MAH took the opportunity to add the date of the latest renewal in the SmPC, to correct a typographical error in the SmPC (for all languages), and to correct a typographical error in the Latvian version of the package leaflet. Moreover, a typographical error has been corrected in Modules 2.3.P.2, 2.3.P.3, 3.2.P.2.3, 3.2.P.3.3, 3.2.P.3.4. B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data 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)				
II/0006	Submission of final study report for Trial 242-13-246 "A Phase 1 Trial to Assess the Mass Balance and Pharmacokinetics of 14C-OPC-67683 Following Oral Administration in Healthy Subjects" C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	21/05/2015	n/a		
PSUSA/10213 /201410	Periodic Safety Update EU Single assessment - delamanid	07/05/2015	n/a		PRAC Recommendation - maintenance

R/0004	Renewal of the marketing authorisation.	26/02/2015	24/04/2015		The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Deltyba, subject to the Specific Obligations and Conditions as laid down in Annex II to the Opinion.
IB/0002/G	This was an application for a group of variations. B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes 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) B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation	06/08/2014	24/04/2015	SmPC, Labelling and PL	
IAIN/0003	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	17/07/2014	n/a		
IAIN/0001/G	This was an application for a group of variations. A.5.a - To change the name of the site responsible for primary packaging, secondary packaging, import	12/06/2014	24/04/2015	Annex II and PL	

	and batch release of the finished product. The address remains unchanged. B.II.b.2.c.1 - To add an alternative site responsible for importation and batch release of the finished product. In addition, the applicant took the opportunity to amend product information and labelling with editorial changes. A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release 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				