Oslif Breezhaler

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
IG/1428	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	10/08/2021	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).

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IG/1424/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.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	06/08/2021		Annex II and PL	
IG/1357	B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier	12/02/2021	n/a		
IG/1309	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	08/01/2021	n/a		
WS/1931	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	10/12/2020		SmPC, Annex II, Labelling and PL	
IG/1271/G	This was an application for a group of variations.	21/07/2020	n/a		

	B.II.c.3.z - Change in source of an excipient or reagent with TSE risk - Other variation 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 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 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 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 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 B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from 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)				
PSUSA/1730/201911	Periodic Safety Update EU Single assessment - indacaterol	09/07/2020	n/a		PRAC Recommendation - maintenance
IG/1229	A.7 - Administrative change - Deletion of manufacturing sites	13/03/2020	n/a		
IG/1192/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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	28/01/2020	21/04/2021	Annex II and PL	
WS/1708	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	12/12/2019	21/04/2021	SmPC, Labelling and PL	
IG/1073/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites	12/03/2019	n/a		

	A.7 - Administrative change - Deletion of manufacturing sites				
IB/0051/G	This was an application for a group of variations. 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 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	16/11/2018	n/a		
WS/1440/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.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	13/09/2018	n/a		

	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.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits				
IA/0050	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/08/2018	14/08/2019	SmPC, Annex II, Labelling and PL	
IB/0049/G	This was an application for a group of variations. B.II.a.3.b.6 - Changes in the composition (excipients) of the finished product - Other excipients - Replacement of a single excipient with a comparable excipient with the same functional characteristics and at a similar level 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	24/07/2018	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 B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure				
IG/0950	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)	18/06/2018	n/a		
T/0045	Transfer of Marketing Authorisation	26/03/2018	08/05/2018	SmPC, Labelling and PL	
IG/0927/G	This was an application for a group of variations. B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from 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	26/04/2018	n/a		

	exist per material)				
WS/1254/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. A.7 - Administrative change - Deletion of manufacturing sites 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 B.I.a.1.g - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the AS that is not supported by an ASMF and requires significant update to the relevant AS section in the dossier	14/12/2017	n/a		
IG/0879	A.7 - Administrative change - Deletion of manufacturing sites	11/12/2017	n/a		
N/0043	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	06/11/2017	08/05/2018	Labelling	
PSUSA/1730/201611	Periodic Safety Update EU Single assessment - indacaterol	20/07/2017	18/09/2017	Annex II	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/1730/201611.
IG/0784/G	This was an application for a group of variations.	31/03/2017	n/a		

	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.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits 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.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.c.2.a - Change in test procedure for an excipient - 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				
WS/1102	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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)	23/02/2017	18/09/2017	SmPC	
IG/0712	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the	03/08/2016	n/a		

	finished product, including quality control sites (excluding manufacturer for batch release)				
WS/0944	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. The MAH submitted the final study report of US PASS QAB149B2432 (CQAB149BS232861) along with RMP update to fulfil MEA017/MEA015/MEA015 for Onbrez Breezhaler (EMEA/H/C/1114) and duplicate authorizations Hirobriz Breezhaler (EMEA/H/C/1211) and Oslif Breezhaler (EMEA/H/C/1210). The revisions of the RMP were also accepted (version 9.0) reflecting the results from this study and its completion. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	23/06/2016	n/a		
WS/0777/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. Submission of the final study reports of 2 PASS studies (UK PASS study QAB149B2433/QAB149BS641859 and EU PASS study QAB149B2431/QAB149AS232863) included in the RMP to monitor off-label use of indacaterol in asthma	23/07/2015	n/a		

	patients and to monitor specified safety risks among initiators of indacaterol relative to initiators of other long-acting beta2-agonists (LABA) medications for the COPD indication; an updated RMP (version 8.1) has been submitted. Additionally, the MAH took the opportunity to amend the RMP in line with the conclusions of previous assessment of RMP measures. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation				
IB/0034/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.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	10/02/2015	n/a		
IG/0484/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of	12/11/2014	n/a		

	manufacturing sites B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site				
IG/0488	A.1 - Administrative change - Change in the name and/or address of the MAH	13/10/2014	30/09/2015	SmPC, Labelling and PL	
R/0029	Renewal of the marketing authorisation.	24/07/2014	18/09/2014	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy the CHMP considered that the risk-benefit balance of the product in the maintenance bronchodilator treatment of airflow obstruction in adult patients with COPD remains favourable and therefore recommended the renewal of the marketing authorisation. The CHMP recommended that the renewal be granted with unlimited validity.
IB/0031	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	29/07/2014	n/a		
PSUV/0030	Periodic Safety Update	13/06/2014	n/a		PRAC Recommendation - maintenance
IB/0028	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	12/03/2014	n/a		
IG/0389/G	This was an application for a group of variations. 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	20/12/2013	n/a		

	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 A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites 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)				
IG/0375/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.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)	25/11/2013	n/a		
WS/0455	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	21/11/2013	18/09/2014	SmPC	Following the assessment of indacaterol RMP 014 (version 7.0 of the RMP), the MAH was requested by the CHMP to insert “medication error” as an important identified risk in the RMP and to propose further risk minimization

	Update of section 4.2 of the SmPC in order to draw the prescriber's attention to the possibility of patients swallowing the capsules instead of inhaling the product as further risk minimisation for the risk of "medication error", following a request from the CHMP and in order to fulfil RMP 014. The format of the outer and immediate outer packaging was updated accordingly without affecting the labelling text. In addition section 4.5 of the SmPC has been updated to bring it in line with section 12 part V Risk minimisation measures of the RMP regarding the risk of less effect of "beta-adrenergic blockers". C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation				measures. The MAH was also requested to revise the outer package so that the information "Do not swallow capsules" and "For inhalation use only" is emphasized e.g. by including a red relatively broad box around the text and by perhaps changing the font size. This variation led to an update of section 4.2 of the SmPC and the outer and immediate packaging accordingly. In addition section 4.5 of the SmPC has been updated to bring it in line with section 12 part V Risk minimisation measures of the RMP regarding the risk of less effect of "beta-adrenergic blockers".
IG/0369/G	This was an application for a group of variations. B.II.a.4.a - Change in coating weight of oral dosage forms or change in weight of capsule shells - Solid oral pharmaceutical forms 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 B.II.d.2.a - Change in test procedure for the finished	20/11/2013	n/a		

	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				
PSUV/0022	Periodic Safety Update	27/06/2013	26/08/2013	SmPC, Annex II and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUV/0022.
IG/0336/G	This was an application for a group of variations. 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 batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place	15/08/2013	n/a		
IB/0019/G	This was an application for a group of variations. B.II.e.7.z. - Change in supplier of packaging components or devices (when mentioned in the dossier) - Other variation B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier 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.a - Change in supplier of packaging	17/07/2013	n/a		

	components or devices (when mentioned in the dossier) - Deletion of a supplier				
IB/0020	B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation	02/07/2013	n/a		
IG/0315/G	This was an application for a group of variations. 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 B.III.1.b.3 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - Updated certificate from an already approved manufacturer	24/06/2013	n/a		
IG/0248	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	17/12/2012	n/a		
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		
IG/0204	B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition	08/08/2012	n/a		

	of inks used for product marking - Changes in imprints, bossing or other markings				
II/0014	Upon request from the CHMP following the assessment of the PSUR, the list and frequencies of adverse reactions in the SmPC section 4.8 have been updated based on additional data obtained post-marketing. A warning about hypersensitivity reactions has been added to SmPC section 4.4. In addition, two pictures illustrating the use of the inhaler device have been updated in the SmPC and PL. Also the SmPC, Annex II, labelling and PL have been updated to the latest QRD template. C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	21/06/2012	23/07/2012	SmPC, Annex II, Labelling and PL	Based on review of pooled safety data from 11 phase III studies with treatment duration of 12 weeks or longer, including 4,746 patients exposed to indacaterol up to 600 microgram once-daily, the list and frequencies of adverse reactions in the SmPC has been revised. For the newly included hypersensitivity reactions, a corresponding warning has been included in the SmPC.
IG/0194/G	This was an application for a group of variations. 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.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.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor	12/07/2012	n/a		

	changes to an approved test procedure				
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		
IG/0139/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 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)	16/12/2011	n/a		
IG/0113/G	This was an application for a group of variations. B.III.1.b.3 - Submission of a new or updated Ph. Eur.	11/11/2011	n/a		

	TSE Certificate of suitability - Updated certificate from an already approved manufacturer B.III.1.b.3 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - Updated certificate from an already approved manufacturer				
IG/0088/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	11/07/2011	n/a		
N/0006	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	31/05/2011	n/a	PL	Update of the local representatives contact details in Cyprus, Poland and Romania.
IG/0032/G	This was an application for a group of variations. To update the Detailed Description of the Pharmacovigilance System (DDPS) to version 9.0, to include: - a change in the deputy of the Qualified Person for Pharmacovigilance (QPPV); - a change in the major contractual arrangements. - administrative changes not impacting the operation	21/12/2010	n/a		

	of the pharmacovigilance system. Annex II.B has also been updated with the latest wording as per October 2010 CHMP procedural announcement. C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV C.I.9.e - Changes to an existing pharmacovigilance system as described in the DDPS - Changes in the major contractual arrangements with other persons or organisations involved in the fulfilment of pharmacovigilance obligations and described in the DD 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				
IB/0005	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	16/12/2010	n/a	SmPC, Annex II and PL	
IG/0025/G	This was an application for a group of variations. 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	20/10/2010	n/a		

	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 B.III.1.b.3 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - Updated certificate from an already approved manufacturer				
WS/0024	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	23/09/2010	23/09/2010		
IA/0004	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	16/06/2010	n/a	SmPC	
II/0001	Update of the Detailed Description of the Pharmacovigilance system (DDPS). Changes to QPPV Update of DDPS (Pharmacovigilance)	18/02/2010	23/03/2010	Annex II	With this variation the MAH submitted a new version of the DDPS (core version 8.0 and product specific version 5.0) 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 numb er of the agreed DDPS.
IB/0003	To extend from 18 months to 24 months the shelf life of the product	26/01/2010	n/a	SmPC	

	IB_42_a_01_Change in shelf-life of finished product - as packaged for sale				
IA/0002	To add Konapharma AG, Im Wannenboden as an additionnal manufacturing site IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site IA_07_b_01_Replacement/add. of manufacturing site: Primary packaging site - Solid forms	21/12/2009	n/a		