EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Alisade

Procedural steps taken and scientific information after the authorisation

No	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
IG/0034/G	This was an application for a group of variations. 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.g - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the site undertaking pharmacovigilance activities, 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, C.I.9.e - Changes to an existing pharmacovigilance system as described in the DDPS - Changes in the major contractual arrangements with other	06/01/2011	n/a	Annex II	

[1] Notifications are issued for type I variations (unless part of a group or a worksharing application). Opinions are issued for all other procedures.
[2] No Commission Decision is issued for type IA and type IB variations or for type II variations and annual re-assessments that do not affect the annexes.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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No	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
	persons or organisations involved in the fulfilment of pharmacovigilance obligations and described in the DDPS				
IB/0007	IA_08_b_02_Change in BR/QC testing - repl./add. manuf. responsible for BR - incl. BC/testing, 07_c_Replacement/add. of manufacturing site: All other manufacturing operations ex. batch release, IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site, 07_b_03_Replacement/add. of manufacturing site: Primary packaging site - liquid ph. forms	17/02/2010	n/a	Annex II, PL	
IB/0006	To extent the re-test period for the active substance 17_a_Change in re-test period of the active substance	29/01/2010	n/a		
II/0005	Update of the Detailed Description of the Pharmacovigilance System (DDPS) including change of the Qualified Person for Pharmacovigilance (QPPV). Consequently, Annex II has been updated with the new version number. Changes to QPPV, Update of DDPS (Pharmacovigilance)	17/12/2009	25/01/2010	Annex II	The DDPS has been updated (version 7.2) to reflect the change of the QPPV as well as to notify other changes to the DDPS performed since the last approved version. Consequently, Annex II has been updated using the standard text including the new version number of the agreed DDPS. The CHMP considers that the Pharmacovigilance System as described by the MAH fulfils the requirements.
II/0004	Inclusion of 'hypersensitivity' in section 4.8 'Undesirable Effects' of the Summary of Product Characteristics (SPC) and section 4 'Possible Side Effects' of the Package Leaflet (PL) accordingly. Moreover, Annex II was updated with information regarding the PSUR cycle. In addition, the MAH took the opportunity to make minor changes in sections 5.1 of the SPC and sections 3, 4	19/11/2009	23/12/2009	SPC, PL	Reports consistent with hypersensitivity reactions to intranasal fluticasone furoate were received from the MAH's Safety Database. A review of the spontaneously received reports, clinical trial data and literature supported the possibility that these events could be due to fluticasone furoate nasal spray. 'Hypersensitivity' with a 'rare' incidence was therefore added to the fluticasone furoate nasal spray product information.

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	and 5 of the PL. Finally, the instructions on the use of Alisade in the PL were added. Update of Summary of Product Characteristics and Package Leaflet				
II/0001	Update the sections 4.2, 4.4 and 4.8 of the Summary of Product Characteristics (SPC) with safety information following the assessment of the first PSUR. Relevant sections of the Package Leaflet (PL) were amended in line with the SPC. The details of the Danish local representative were also amended in the PL. The Annex II was updated following the assessment of the RMP (version 05). Update of Summary of Product Characteristics and Package Leaflet	23/04/2009	02/06/2009	SPC, Annex II, PL	Following the assessment of the 1st PSUR of fluticasone furoate, an increased number of adverse drug reactions related to eye disorders was reported, particularly for cataracts and glaucoma. On this basis, the CHMP recommended an update of the product information and the information was subsequently included in the SPC.
II/0002	Update of Detailed Description of the Pharmacovigilance System (DDPS). Changes to QPPV, Update of DDPS (Pharmacovigilance)	19/02/2009	07/04/2009	Annex II	The DDPS has been updated (version 6.2) to reflect the change of the Qualified Person for Pharmacovigilance (QPPV) as well as to notify other changes to the DDPS performed since the last approved version. Consequently, Annex II has been updated using the standard text including the new version number of the agreed DDPS.
IB/0003	02_Change in the name of the medicinal product	25/03/2009	n/a	SPC, Labelling, PL	