Incurin

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
IA/0008	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		The Agency accepted the variation to change the name of the manufacturer of the finished product not responsible for batch release.
IA/0007	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	30/10/2014	n/a		The Agency accepted the variation to submit an updated certificate of suitability for the active substance following the name change of the supplier.
IA/0006/G	This was an application for a group of variations. 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 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)	30/08/2014		SPC, Annex II, Labelling and PL	The Agency accepted the variation to change the name of the manufacturer of the biological active substance and the name of the manufacturer of the finished product.

[1] Notifications are issued for type I variations (unless part of a group including a type II variation or higher procedure or a worksharing application). Opinions are issued for all other procedures.
[2] A CD is issued for procedures that affect the terms of the marketing authorisation (e.g. SPC, Annex II, Labelling, PL). The CD is issued within 2 months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within 1 year for other procedures.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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R/0005	Renewal of the marketing authorisation.	09/12/2009	15/03/2010	SPC, Annex II, Labelling and PL	The European Commission renewed indefinitely the marketing authorisation for Incurin.
IA/0004	1A-04 Change in name and/or address of a manufacturer of the active substance	01/10/2007	01/10/2007		The Agency accepted the variation to change the name of the active ingredient supplier.
R/0003	Renewal of the marketing authorisation.	09/02/2005	11/04/2005	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Incurin.
N/0002	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	10/03/2004	07/04/2004	PL	The Agency accepted a change in the package insert (deletion of the list of local representatives).
N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/08/2000	09/10/2000	PL	The European Medicines Agency accepted a change in the package insert (change of the list of local representatives).