EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Panretin

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
IAIN/0045	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	24/01/2019		Annex II and PL	
IAIN/0044	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	24/01/2019	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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	responsible for importation and/or batch release - Not including batch control/testing				
T/0043	Transfer of Marketing Authorisation	19/11/2018	20/12/2018	SmPC, Labelling and PL	
IAIN/0042	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	04/07/2018	n/a		
A31/0037	Pursuant to Article 31 of Directive 2001/83/EC, the United Kingdom triggered on 7 July 2016 a referral resulting from pharmacovigilance data, and requested the PRAC to review the routine risk minimisation in place for the oral and topical retinoids to ensure the available data and the risks associated with the adverse teratogenic effects and neuropsychiatric disorders are accurately and consistently addressed within the product information where appropriate and justified by data. Furthermore, the PRAC was requested to review any additional risk minimisation measures to ensure that these are optimal in terms of provision of information and delivery of effective risk management that is subject to appropriate monitoring. The PRAC was called upon to assess the impact of the above concerns on the benefit-risk balance of retinoid-containing medicinal products and issue a recommendation on whether the products should be maintained, varied, suspended or revoked.	22/03/2018	21/06/2018	SmPC, Annex II and PL	Please refer to the assessment report: Panretin EMEA/H/A-31/1446/C/000279/0037

	As the request resulted from the evaluation of data resulting from pharmacovigilance activities, the PRAC issued a recommendation to the Committee for Medicinal Products for Human Use (CHMP).				
N/0040	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/11/2017	21/06/2018	PL	
PSUSA/90/20 1701	Periodic Safety Update EU Single assessment - alitretinoin	01/09/2017	n/a		PRAC Recommendation - maintenance
IA/0039	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	03/08/2017	n/a		
PSUSA/90/20 1601	Periodic Safety Update EU Single assessment - alitretinoin	02/09/2016	n/a		PRAC Recommendation - maintenance
IA/0035	A.7 - Administrative change - Deletion of manufacturing sites	16/09/2015	08/09/2016	Annex II and PL	
IAIN/0034	B.II.d.1.h - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur. for the finished product	17/11/2014	n/a		

N/0033	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	04/11/2014	08/09/2016	PL	
IB/0032/G	This was an application for a group of variations. B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation B.II.f.1.e - Stability of FP - Change to an approved stability protocol 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.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site	25/10/2013	n/a		
IB/0031	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)	07/10/2013	19/08/2014	SmPC	
IG/0345	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	03/09/2013	n/a		
N/0028	The MAH applied to change the details of the local representative for France. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/07/2013	19/08/2014	PL	

IAIN/0029	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	20/05/2013	n/a		
N/0027	Update of the local representatives contact details. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/08/2012	19/08/2014	PL	
IAIN/0026	A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release	20/01/2012	23/08/2012	Annex II and PL	
IAIN/0025/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release 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 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 B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	16/12/2011	n/a		

R/0024	Renewal of the marketing authorisation.	22/07/2010	27/09/2010	SmPC, Annex II, Labelling and PL	Based on the CHMP review of the available information and on the basis of a re-evaluation of the benefit risk balance, the CHMP is of the opinion that the quality, safety and efficacy of this medicinal product continues to be adequately and sufficiently demonstrated and therefore considered that the benefit risk profile of Panretin continues to be favourable. The CHMP recommends the renewal of the Marketing Authorisation for Panretin, subject to the conditions as laid down in Annex II to the Opinion as well as the commitments of the Marketing Authorisation Holder as laid down in his Letter of Undertaking (see Attachment 4 of this Assessment Report). The CHMP is also of the opinion that the renewal can be granted with unlimited validity.
N/0023	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/05/2010	n/a	PL	
IA/0022	To add Eisai B.V as a new manufacturing site for QP batch release activities regarding Panretin finished product. IA_08_b_01_Change in BR/QC testing - repl./add. manuf. responsible for BR - not incl. BC/testing	21/12/2009	n/a	PL	
IA/0021	IA_01_Change in the name and/or address of the marketing authorisation holder	06/04/2009	n/a	SmPC, Labelling and PL	
IB/0020	IB_29_a_Change in qual./quant. composition of immediate packaging - semi-solid/liquid ph. forms	27/03/2009	n/a		

IA/0019	IA_08_b_01_Change in BR/QC testing - repl./add. manuf. responsible for BR - not incl. BC/testing	05/02/2009	n/a	Annex II and PL	
N/0018	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/10/2008	n/a	PL	
T/0017	Transfer of Marketing Authorisation Transfer of Marketing Authorisation	16/03/2007	11/04/2007	SmPC, Labelling and PL	The MAH applied for a transfer of the Marketing Authorisation from 'Ligand Pharmaceuticals UK Ltd' to 'Eisai Ltd'. The MAH also took the opportunity to update the Annexes in compliance with the latest QRD template 7.2.
IA/0016	IA_05_Change in the name and/or address of a manufacturer of the finished product	19/01/2007	n/a	Annex II and PL	
IB/0015	IB_14_b_Change in manuf. of active substance without Ph. Eur. certificate - new manufacturer	04/01/2007	n/a		
N/0014	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	23/01/2006	n/a	PL	
IA/0013	IA_05_Change in the name and/or address of a manufacturer of the finished product	16/12/2005	n/a		
R/0012	Renewal of the marketing authorisation.	15/09/2005	17/11/2005	SmPC, Annex II, Labelling and PL	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 Panretin continues to be favourable.
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	23/05/2005	n/a	PL	

IA/0009	IA_05_Change in the name and/or address of a manufacturer of the finished product	23/03/2004	n/a	Annex II and PL	
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/05/2003	11/06/2003	PL	
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/02/2003	10/04/2003	PL	
I/0006	15_Minor changes in manufacture of the medicinal product	04/02/2003	07/02/2003		
I/0005	16_Change in the batch size of finished product	04/02/2003	07/02/2003		
I/0004	01_Change in or addition of manufacturing site(s) for part or all of the manufacturing process	04/02/2003	07/02/2003		
I/0002	03_Change in the name and/or address of the marketing authorisation holder	11/06/2002	10/07/2002	SmPC, Labelling and PL	
N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/07/2001	n/a	Labelling and PL	