Ytracis

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/0016	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	29/05/2015		SmPC and PL	
IG/0557	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	21/05/2015	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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

IG/0015	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	06/08/2010	n/a	Annex II	
N/0014	Change in the Package Leaflet to the names of the local representatives in Austria, Czech Republic, Denmark, Estonia, Finland, Hungary, Ireland, Latvia, Lithuania, Malta, Norway, Poland, Slovenia, Slovakia, Spain and Sweden. The addresses for all local representatives have been deleted. Additionally, the local representatives have been modified in the following countries: Portugal, Iceland and Cyprus. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/02/2009	n/a	PL	
R/0012	Renewal of the marketing authorisation.	13/12/2007	07/02/2008	SmPC, Annex II, Labelling and PL	
IB/0013	IB_37_a_Change in the specification of the finished product - tightening of specification limits IB_38_c_Change in test procedure of finished product - other changes	05/02/2008	n/a		
II/0010	Quality changes	24/05/2007	30/05/2007		
N/0011	Minor change in labelling or package leaflet not	13/04/2007	n/a	PL	

	connected with the SPC (Art. 61.3 Notification)				
IA/0009	IA_38_a_Change in test procedure of finished product - minor change to approved test procedure	09/01/2007	n/a		
IB/0008	IB_33_Minor change in the manufacture of the finished product	19/09/2005	n/a		
IB/0007	IB_38_c_Change in test procedure of finished product - other changes	17/05/2005	n/a		
II/0006	Change(s) to the manufacturing process for the finished product	15/12/2004	20/12/2004		
IB/0005	IB_42_a_01_Change in shelf-life of finished product - as packaged for sale	28/06/2004	n/a		
IB/0004	IB_37_a_Change in the specification of the finished product - tightening of specification limits	28/06/2004	n/a		
N/0003	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/05/2004	n/a	PL	
II/0001	Change(s) to the test method(s) and/or specifications for the active substance	22/04/2004	26/04/2004		
IB/0002	IB_33_Minor change in the manufacture of the finished product	25/03/2004	n/a	SmPC and PL	