Marixino

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
N/0015	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	06/12/2021		PL	
IB/0014	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	06/11/2020	18/11/2021	SmPC, Annex II, Labelling	

[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).

				and PL	
T/0013	Transfer of Marketing Authorisation	16/03/2018	04/04/2018	SmPC, Labelling and PL	
R/0012	Renewal of the marketing authorisation.	12/10/2017	18/01/2018	SmPC, Labelling and PL	
IA/0011/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.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.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	29/06/2017	n/a		
IB/0010	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)	05/04/2017	18/01/2018	SmPC and PL	
IB/0009	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	03/03/2017	n/a		

IB/0008	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	11/05/2016	16/06/2017	SmPC, Annex II, Labelling and PL	
IAIN/0007	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	11/08/2015	n/a		
IAIN/0006	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	02/02/2015	n/a		
N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/01/2015	16/06/2017	PL	
IA/0004	B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size	24/10/2013	n/a		
IAIN/0003	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	09/08/2013	26/08/2014	SmPC, Labelling and PL	
T/0002	Transfer of MA from Krka d.d. Novo mesto to Consilient Health Ltd Transfer of Marketing Authorisation	08/07/2013	05/08/2013	SmPC, Labelling and PL	