EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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
IB/0011	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	09/07/2018		SmPC and PL	
IB/0010/G	This was an application for a group of variations.	12/01/2018	19/07/2018	SmPC and PL	

[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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N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/11/2017	19/07/2018	PL	
IB/0008	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	01/08/2017	19/07/2018	SmPC and PL	
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/02/2017	19/07/2018	Labelling and PL	
N/0006	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/06/2016	11/11/2016	PL	
IG/0693	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	02/06/2016	n/a		

II/0003	B.II.e.5.c - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products	17/03/2016	11/11/2016	SmPC, Labelling and PL	
IB/0004	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	28/01/2016	11/11/2016	SmPC, Labelling and PL	
IG/0645	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	17/12/2015	n/a		
IAIN/0001/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs 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	13/11/2015	11/11/2016	SmPC, Annex II, Labelling and PL	