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
T/0006	Transfer of Marketing Authorisation	23/05/2018	15/06/2018	SmPC, Labelling and PL	
PSUSA/1751/ 201710	Periodic Safety Update EU Single assessment - insulin glargine	17/05/2018	n/a		PRAC Recommendation - maintenance
IB/0005	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a	12/03/2018	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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	re-test period/storage period supported by real time data				
IB/0004	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	02/03/2018	15/06/2018	SmPC and PL	
PSUSA/1751/ 201704	Periodic Safety Update EU Single assessment - insulin glargine	30/11/2017	n/a		PRAC Recommendation - maintenance
IB/0001	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	23/06/2017	n/a		