EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Alpivab

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/0004	Transfer of Marketing Authorisation	24/04/2019	06/06/2019	SmPC, Labelling and PL	
IB/0002/G	This was an application for a group of variations. B.I.z - Quality change - Active substance - Other variation B.I.b.1.z - Change in the specification parameters	29/01/2019	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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	and/or limits of an AS, starting material/intermediate/reagent - Other variation				
PSUSA/10687 /201806	Periodic Safety Update EU Single assessment - peramivir	17/01/2019	n/a		PRAC Recommendation - maintenance