EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Zontivity

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/0009	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	16/08/2016	n/a		
II/0005	Extension of Indication to include	23/06/2016	29/07/2016	SmPC,	Refer to the Scientific Discussion Zontivity- H-C-2814-II-05

[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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	treatment of patients with symptomatic Peripheral Arterial Disease (PAD) and as a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the contact details of local representative in Luxembourg in the Package Leaflet. Furthermore, the PI is brought in line with the QRD template version 9.1. Moreover, revised RMP version 2.4 has been agreed. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one			Annex II and PL	
PSUSA/10357 /201507	Periodic Safety Update EU Single assessment - VORAPAXAR	11/02/2016	n/a		

N/0006	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/09/2015		PL	
IA/0004	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	16/09/2015		SmPC and PL	
IA/0003/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.f - Change in the manufacturer of	08/05/2015	n/a		

	AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place				
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	26/03/2015	n/a		