Aqumeldi

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
X/0001/G	This was an application for a group of variations. Annex I_2.(c) Change or addition of a new strength/potency C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	27/02/2025	23/04/2025	SmPC, Labelling and PL	
PSUSA/201/202403	Periodic Safety Update EU Single assessment - enalapril maleate (centrally authorised product for use in children below the age of 18)	31/10/2024	n/a		PRAC Recommendation - maintenance

[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).