Akeega

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
II/0003	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	11/07/2024		SmPC, Annex II and PL	Please refer to Scientific Discussion 'Akeega EMEA/H/C/005932/II/0003 Based on results from study MAGNITUDE, summary of the safety profile in section 4.8 and overall survival data have been updated in section 5.1. With 35.9 months median

[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).

					follow-up the HR for BRCA population of the MAGNITUDE study is 0.788 (0.554, 1.120). For more information, please refer to the Summary of Product Characteristics.
IA/0004	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	19/06/2024	n/a		
PSUSA/11051 /202310	Periodic Safety Update EU Single assessment - niraparib / abiraterone acetate	16/05/2024	n/a		PRAC Recommendation - maintenance
IA/0002	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	27/02/2024	n/a		