Iqirvo

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
Variation type IA_IN /	B.II.e.5.a Change in the number of units	28/07/2025		SmPC,	

[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).

EMA/VR/0000285287	(e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.1 Change within the range of the currently approved pack sizes - Accepted			Labelling and PL	
Renewal - 1 year / EMA/R/0000257350	- Renewal - Accepted Renewal of marketing authorisation	22/05/2025	30/07/2025		The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Iqirvo, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
Variation type IA_IN / EMA/VR/0000263255	A. ADMINISTRATIVE CHANGES - A.1 Change in the name and/or address of the marketing authorisation holder - Accepted	15/04/2025	30/07/2025	SmPC, Labelling and PL	
PSUR / EMA/PSUR/0000257878	- -				Maintenance