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 IB /	Outcome:	24/06/2026			

[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/0000349501	C.9 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.9.b) Implementation of changes which require additional minor assessment (e.g. change to the due date of obligations and conditions of a marketing authorisation and required pharmacovigilance activities in the risk management plan, including changes to the due date of study milestones, and template updates) - Accepted C.9.b (Type IB) – To update the RMP by revising the specific adverse reaction follow-up questionnaires for hepatic events and muscle injury to include administrative elements, namely introductory text describing the purpose of the questionnaires and a data privacy statement.				
Variation type II / EMA/VR/0000339224	Outcome: C. Safety, efficacy, pharmacovigilance changes - C.4 Change(s) in the summary of product characteristics, labelling or package leaflet due to new quality, preclinical, clinical or pharmacovigilance data. - Accepted Update of sections 4.3, 4.4, 4.5, 4.6 and 5.2 of the SmPC in order to update drug-drug interaction information based on results from study CLIN-60190-468. This is an open-label,	11/06/2026		SmPC and PL	Based on clinical studies conducted, elafibranor may be a mild CYP3A4 inducer. A clinical interaction study demonstrated that co-administration of elafibranor 80 mg once daily at steady state and a single dose of combined oral contraceptive (0.02 mg ethinylestradiol and 0.15 mg levonorgestrel) produced a decrease of ethinylestradiol exposure (Cmax decreased by 20% and AUCinf decreased by 35%) which may lead to contraceptive failure and/or an increase in breakthrough bleeding, while levonorgestrel exposure remained unaffected. As a

	Phase 1 study to evaluate the effects of steady state levels of elafibranor on the pharmacokinetics of combined oral contraceptives in healthy female participants. Additionally, the MAH took the opportunity to implement editorial changes in the SmPC. The Package Leaflet is updated accordingly.				result, women of childbearing potential should use effective non-hormonal contraceptives or add a barrier method when using hormonal contraceptives. For more information, please refer to the Summary of Product Characteristics.
Variation type IA_IN / EMA/VR/0000285287	Outcome: B.II.e.5.a Change in the number of units (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	28/07/2025		SmPC, Labelling and PL	
Renewal - 1 year / EMA/R/0000257350	Outcome: - 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	Outcome: 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/0000296570	EURD: PSUSA/00011092/202506 Active	15/01/2026			Maintenance

	substance: elafibranor Outcome: Maintenance				
PSUR / EMA/PSUR/0000257878	EURD: PSUSA/00011092/202412 Active substance: elafibranor Outcome: Maintenance	10/07/2025			Maintenance
PSUR / EMA/PSUR/0000336148	EURD: PSUSA/00011092/202512 Active substance: elafibranor Outcome: Maintenance Maintenance	09/07/2026			