



Ryeqo

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/0009	Update of sections 5.3 and 6.6 of the SmPC based on final results from MVT-601-9030_Relugolix_ZEOGRT_Study (Rec); this is a fish, full life cycle test performed in the context of the Environmental Risk Assessment of relugolix. The Package Leaflet is updated accordingly.	30/06/2022		SmPC and PL	Please refer to Scientific Discussion 'Ryeqo-H-C-5267-II-09'.

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).



	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IB/0010	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	20/06/2022		SmPC	
PSUSA/10942 /202111	Periodic Safety Update EU Single assessment - relugolix / estradiol / norethisterone acetate	10/06/2022	n/a		PRAC Recommendation - maintenance
IB/0008	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	11/05/2022	n/a		
II/0006	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	05/05/2022	n/a		
IB/0005	B.I.b.z - Change in control of the AS - Other variation	22/12/2021	n/a		
IA/0004/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	11/10/2021		Annex II and PL	

IB/0002/G	<p>This was an application for a group of variations.</p> <p>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation</p> <p>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation</p>	02/09/2021	n/a		
IB/0001	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	27/08/2021		SmPC, Labelling and PL	
IA/0003/G	<p>This was an application for a group of variations.</p> <p>A.7 - Administrative change - Deletion of manufacturing sites</p> <p>B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place</p>	05/08/2021	n/a		