AQUIPTA

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/0008	Update of section 4.6 and 5.2 of the SmPC in order to amend information on pregnancy and lactation based on data from study M22-394; this is a phase 1 lactation study to evaluate the pharmacokinetics and safety of ubrogepant and atogepant in healthy adult lactating female subjects one to six months post-	08/05/2025		SmPC and PL	Update of section 4.6 and 5.2 of the SmPC in order to amend information on pregnancy and lactation. For more information, please refer to the Summary of Product Characteristics.

[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).

	partum. The Package Leaflet is updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
PSUSA/100/202409	Periodic Safety Update EU Single assessment - atogepant	08/05/2025	n/a		PRAC Recommendation - maintenance
II/0005	Update of sections 4.3, 4.4 and 4.8 of the SmPC in order to update the contraindication and warning on hypersensitivity reactions to include anaphylaxis and dyspnoea and to add them to the list of adverse drug reactions (ADRs) with frequency not known, based on a comprehensive safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce minor editorial changes to the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	14/11/2024		SmPC and PL	Update of the SmPC in order to clarify the contraindication and warning on hypersensitivity reactions to include anaphylaxis and dyspnoea. For more information, please refer to the Summary of Product Characteristics.
PSUSA/100/202403	Periodic Safety Update EU Single assessment - atogepant	31/10/2024	n/a		PRAC Recommendation - maintenance
II/0006	Update of section 5.1 of the SmPC based on final results from study ELEVATE (3101-304-002). This is a phase 3, 12 weeks, randomized, double-blind, placebo-controlled, parallel-group study that evaluated the efficacy, safety, and tolerability of	10/10/2024		SmPC	Update of section 5.1 of the SmPC based on final results from study ELEVATE (3101-304-002). For more information, please refer to the Summary of Product Characteristics.

	atogepant 60 mg once daily (QD) for the prophylaxis of migraine in participants with episodic migraine who had previously failed 2 to 4 classes of oral prophylactic treatments. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IB/0004/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	13/08/2024	n/a		
II/0001/G	This was an application for a group of variations.	06/06/2024	n/a		

	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition B.I.a.1.g - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the AS that is not supported by an ASMF and requires significant update to the relevant AS section in the dossier B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation				
IB/0002	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	17/04/2024	n/a		