Izba

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
IA/0015	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	21/09/2021		SmPC, Annex II, Labelling and PL	
WS/1944	This was an application for a variation following a worksharing procedure according to Article 20 of	26/11/2020	n/a		

[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).

	Commission Regulation (EC) No 1234/2008. C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation				
IAIN/0013/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	31/03/2020	n/a		
PSUSA/3011/ 201902	Periodic Safety Update EU Single assessment - travoprost	31/10/2019	n/a		PRAC Recommendation - maintenance
R/0011	Renewal of the marketing authorisation.	20/09/2018	14/11/2018	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Izba in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
WS/1385	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	26/07/2018	14/11/2018	SmPC	

T/0010	Transfer of Marketing Authorisation	16/04/2018	08/05/2018	SmPC, Labelling and PL	
II/0008	Update of sections 4.4 and 4.8 of the SmPC in order to update the safety information in line with Travoprost 40 µg/mL Eye Drops PI, based on the review of clinical trial and post-marketing data along with literature references. The package leaflet section 4 is updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	15/02/2018	08/05/2018	SmPC and PL	Section 4.4 of SmPC has been updated to include information that IZBA should be used with caution in patients with active intraocular inflammation and that macular oedema has been reported during treatment with prostaglandin F2a analogues. The updates have been done in line with the Travoprost 40 µg/mL SmPC. Izba SmPC contains in section 4.8 two different tables of adverse reactions: Table 1 contains the tabulated list for Travoprost 30 µg/mL eye drops and a second table, table 2, contains the tabulated list of adverse reactions assessed to be related with Travoprost 40 µg/mL eye drops, solution. Table 2 that includes ADR for Travoprost 40 µg/mL eye drops, solution have been updated in line with Travatan SmPC: Four new adverse events based on post-marketing data: insomnia, arrhythmia, epistaxis and vomiting with frequency unknown have been added. In addition, table 2 has been updated following review of clinical trials data as follows: cough frequency has been upgraded from rare to uncommon and arthralgia frequency has been upgraded from not known to rare; dizziness, asthenopia, dyspnoea, asthma, visual field defect have been downgraded to frequency rare; and four adverse reactions were included: trichiasis, eyelash hyperpigmentation (recoded from eyelash discoloration, frequency downgraded), rhinitis allergic, nasal dryness (based on several nasal disorders already listed) and ophthalmic herpes simplex (recoded from the combination with herpes simplex and keratitis

					herpetic). For further details see the Annexes. The Patient Information Leaflet has been updated accordingly.
II/0005	Extension of Indication to include treatment of paediatric patients aged 3 years to < 18 years with ocular hypertension or paediatric glaucoma in order to decrease of elevated intraocular pressure. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	18/05/2017	23/06/2017	SmPC and PL	Please refer to Scientific Discussion Izba-H-2738-II-005
T/0007	Transfer of Marketing Authorisation	06/04/2017	20/04/2017	SmPC, Labelling and PL	
IB/0006/G	This was an application for a group of variations. B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	03/03/2017	n/a		
PSUSA/3011/ 201602	Periodic Safety Update EU Single assessment - travoprost	29/09/2016	n/a		PRAC Recommendation - maintenance
PSUSA/3011/	Periodic Safety Update EU Single assessment -	08/10/2015	n/a		PRAC Recommendation - maintenance

201502	travoprost				
PSUSA/3011/ 201402	Periodic Safety Update EU Single assessment - travoprost	09/10/2014	n/a		PRAC Recommendation - maintenance
IG/0452	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	28/07/2014	n/a		