Ketoconazole Esteve

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
IAIN/0025/G	This was an application for a group of variations. A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs A.1 - Administrative change - Change in the name and/or address of the MAH	13/01/2025		SmPC, Labelling and PL	

[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).

IA/0024	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	13/06/2024	n/a		
IA/0023	B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	02/04/2024	n/a		
IA/0022	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	16/01/2023	n/a		
PSUSA/10316 /202111	Periodic Safety Update EU Single assessment - ketoconazole (centrally authorised product only)	10/06/2022	n/a		PRAC Recommendation - maintenance
IA/0019/G	This was an application for a group of variations. B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate	30/09/2021	n/a		

	from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer				
PSUSA/10316 /202011	Periodic Safety Update EU Single assessment - ketoconazole (centrally authorised product only)	10/06/2021	n/a		PRAC Recommendation - maintenance
IA/0018	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	20/04/2021	02/06/2022	SmPC, Labelling and PL	
PSUSA/10316 /201911	Periodic Safety Update EU Single assessment - ketoconazole (centrally authorised product only)	11/06/2020	n/a		PRAC Recommendation - maintenance
T/0015	Transfer of Marketing Authorisation	11/09/2019	07/11/2019	SmPC, Labelling and PL	
R/0014	Renewal of the marketing authorisation.	29/05/2019	31/07/2019	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Ketoconazole HRA in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10316 /201811	Periodic Safety Update EU Single assessment - ketoconazole (centrally authorised product only)	14/06/2019	n/a		PRAC Recommendation - maintenance

IAIN/0012	A.1 - Administrative change - Change in the name and/or address of the MAH	16/01/2019	31/07/2019	SmPC, Labelling and PL	
PSUSA/10316 /201805	Periodic Safety Update EU Single assessment - ketoconazole (centrally authorised product only)	29/11/2018	n/a		PRAC Recommendation - maintenance
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/08/2018	31/07/2019	Labelling	
PSUSA/10316 /201711	Periodic Safety Update EU Single assessment - ketoconazole (centrally authorised product only)	14/06/2018	n/a		PRAC Recommendation - maintenance
PSUSA/10316 /201705	Periodic Safety Update EU Single assessment - ketoconazole (centrally authorised product only)	30/11/2017	n/a		PRAC Recommendation - maintenance
PSUSA/10316 /201611	Periodic Safety Update EU Single assessment - ketoconazole (centrally authorised product only)	22/06/2017	22/08/2017	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10316/201611.
PSUSA/10316 /201605	Periodic Safety Update EU Single assessment - ketoconazole (centrally authorised product only)	15/12/2016	23/02/2017	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10316/201605.
II/0005	Update of section 4.5 to include information related to interactions with CYP 2A6, 2C19, and 2E1, CYP2B6, 2C9/C8 and 2D6 and antidiabetics (tolbutamide).The Package Leaflet is updated in accordance. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	15/09/2016	23/02/2017	SmPC and PL	Update of the section 4.5 of the SmPC to reflect that in vitro data indicate that ketoconazole is an inhibitor of CYP1A2 and does not significantly inhibit CYP 2A6, 2C19, and 2E1. At clinically relevant concentrations inhibition of CYP2B6, 2C9/C8, and 2D6 by ketoconazole cannot be excluded. In addition, table 1 (interactions and recommendations for co-administration) is updated regarding co-administration with tolbutamide, to recommend careful monitoring and possible need for dose

					adjustment, due to an expected increase in tolbutamide exposure (1.7 fold).
PSUSA/10316 /201511	Periodic Safety Update EU Single assessment - ketoconazole (centrally authorised product only)	23/06/2016	31/08/2016	SmPC and PL	Please refer to ketoconazole HRA-PSUSA 010316-201511 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation.
PSUSA/10316 /201505	Periodic Safety Update EU Single assessment - ketoconazole (centrally authorised product only)	17/12/2015	22/02/2016	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10316/201505.
IAIN/0002/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	13/03/2015	22/02/2016	Annex II and PL	
IAIN/0001	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	08/01/2015	n/a		