Pylobactell

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
PSUSA/6/202301	Periodic Safety Update EU Single assessment - ^{13}C-urea, ^{14}C-urea	31/08/2023	n/a		PRAC Recommendation - maintenance
T/0020	Transfer of Marketing Authorisation	23/06/2023	28/07/2023	SmPC, Labelling and	

[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).

				PL	
IAIN/0017	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	16/01/2020	11/01/2021	Annex II and PL	
T/0016	Transfer of Marketing Authorisation	26/06/2019	06/09/2019	SmPC, Labelling and PL	
PSUSA/6/201801	Periodic Safety Update EU Single assessment - ^{13}C-urea, ^{14}C-urea	06/09/2018	n/a		PRAC Recommendation - maintenance
IAIN/0014	A.1 - Administrative change - Change in the name and/or address of the MAH	03/03/2017	09/07/2018	SmPC, Labelling and PL	
IAIN/0013/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.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing	16/03/2012	10/10/2012	Annex II and PL	
R/0012	Renewal of the marketing authorisation.	24/04/2008	29/07/2008	SmPC, Labelling and PL	Based on the CHMP review of the available information and on the basis of a re-evaluation of the benefit risk balance, the CHMP is of the opinion that the quality, safety and efficacy of this medicinal product continues to be adequately and sufficiently demonstrated and therefore

					considers that the benefit risk profile of Pylobactell continues to be favourable. The CHMP is of the opinion that the renewal can be granted with unlimited validity
IA/0010	IA_32_a_Change in batch size of the finished product - up to 10-fold	17/01/2005	n/a		
IB/0011	IB_42_a_01_Change in shelf-life of finished product - as packaged for sale	13/01/2005	n/a	SmPC	
R/0009	Renewal of the marketing authorisation.	19/03/2003	11/06/2003	SmPC, Annex II, Labelling and PL	
I/0008	03_Change in the name and/or address of the marketing authorisation holder	23/08/2002	03/10/2002	SmPC, Labelling and PL	
T/0007	Transfer of Marketing Authorisation	06/07/2001	17/09/2001	SmPC, Labelling and PL	
I/0006	01_Change in or addition of manufacturing site(s) for part or all of the manufacturing process	19/12/2000	05/03/2001	Annex II and PL	
I/0005	03_Change in the name and/or address of the marketing authorisation holder	19/12/2000	05/03/2001	SmPC, Labelling and PL	
I/0004	01_Change in or addition of manufacturing site(s) for part or all of the manufacturing process	27/10/2000	08/11/2000		

I/0003	01_Change in or addition of manufacturing site(s) for part or all of the manufacturing process	14/04/2000	12/05/2000		
I/0002	01_Change following modification(s) of the manufacturing authorisation(s)	28/10/1998	17/12/1998		
I/0001	01_Change following modification(s) of the manufacturing authorisation(s)	28/10/1998	17/12/1998	PL	