Helicobacter Test INFAI

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/0029	A.1 - Administrative change - Change in the name and/or address of the MAH	19/08/2024		SmPC, Labelling and PL	
PSUSA/6/202301	Periodic Safety Update EU Single assessment - ^{13}C-urea, ^{14}C-urea	31/08/2023	n/a		PRAC Recommendation - maintenance

[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).

N/0026	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/01/2023		PL	
N/0025	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/11/2022		PL	
N/0024	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/04/2021	05/07/2021	PL	
IAIN/0023	A.1 - Administrative change - Change in the name and/or address of the MAH	07/08/2020	05/07/2021	SmPC, Labelling and PL	
N/0022	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/01/2019	05/07/2021	Labelling	
PSUSA/6/201801	Periodic Safety Update EU Single assessment - ^{13}C-urea, ^{14}C-urea	06/09/2018	n/a		PRAC Recommendation - maintenance
IB/0020/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-	07/03/2018	08/02/2019	SmPC, Annex II, Labelling and PL	

	release, batch control, primary and secondary packaging, for non-sterile medicinal products B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing				
IB/0018	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	22/04/2015	21/04/2016	SmPC, Annex II, Labelling and PL	
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/10/2013	21/04/2016	PL	
N/0016	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/12/2012	21/04/2016	PL	
IA/0015	B.IV.1.b - Change of a measuring or administration device - Deletion of a device	22/03/2011	23/03/2011	SmPC, Labelling and PL	
N/0013	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/04/2010	n/a	PL	
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/06/2009	n/a	PL	
R/0011	Renewal of the marketing authorisation.	20/09/2007	11/03/2008	SmPC, Annex II, 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 considered that the benefit risk profile of Helicobacter Test INFAI continues to be favourable.

					The CHMP is also of the opinion that the renewal can be granted with unlimited validity.
IB/0010	IB_41_a_02_Change in pack size - change in no. of units outside range of appr. pack size	27/02/2004	27/02/2004	SmPC, Labelling and PL	
R/0009	Renewal of the marketing authorisation.	27/06/2002	29/10/2002	SmPC, Annex II, Labelling and PL	
X/0008	X-3-iii_Addition of new strength	27/06/2002	10/10/2002	SmPC, Labelling and PL	
II/0007	New presentation(s)	17/01/2002	02/05/2002	SmPC, Labelling and PL	
II/0006	Extension of Indication	18/10/2001	23/04/2002	SmPC, Labelling and PL	
N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	05/06/2000	11/07/2000	Labelling and PL	
I/0004	11_Change in or addition of manufacturer(s) of active substance	18/02/2000	14/05/2000		
N/0003	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	06/03/2000	24/05/2000	PL	
N/0002	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/03/1999	11/06/1999	PL	

N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	05/05/1998	07/07/1998	Labelling	