DECTOVA

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/0020	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	28/11/2024	n/a		
PSUSA/10763 /202401	Periodic Safety Update EU Single assessment - zanamivir (centrally authorised products only)	03/10/2024	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).

S/0018	Annual re-assessment.	25/07/2024	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation of DECTOVA should be maintained.
R/0017	Renewal of the marketing authorisation.	09/11/2023	05/01/2024	SmPC, Annex II and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of DECTOVA in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
S/0016	Annual re-assessment.	20/07/2023	n/a		
IG/1576	A.7 - Administrative change - Deletion of manufacturing sites	02/02/2023	n/a		
S/0013	Annual re-assessment.	21/07/2022	n/a		
IB/0014	B.II.d.2.z - Change in test procedure for the finished product - Other variation	18/07/2022	n/a		
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/09/2021	18/03/2022	PL	
S/0011	Annual re-assessment.	16/09/2021	n/a		
PSUSA/10763 /202101	Periodic Safety Update EU Single assessment - zanamivir (centrally authorised products only)	02/09/2021	n/a		PRAC Recommendation - maintenance
PSUSA/10763 /202007	Periodic Safety Update EU Single assessment - zanamivir (centrally authorised products only)	11/03/2021	n/a		PRAC Recommendation - maintenance

IA/0009	A.7 - Administrative change - Deletion of manufacturing sites	03/03/2021	18/03/2022	Annex II and PL	
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/01/2021	18/03/2022	PL	
S/0006	1st annual re-assessment	17/09/2020	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation of Dectova should be maintained.
PSUSA/10763 /202001	Periodic Safety Update EU Single assessment - zanamivir (centrally authorised products only)	03/09/2020	n/a		PRAC Recommendation - maintenance
PSUSA/10763 /201907	Periodic Safety Update EU Single assessment - zanamivir (centrally authorised products only)	13/02/2020	n/a		PRAC Recommendation - maintenance
IAIN/0003	A.1 - Administrative change - Change in the name and/or address of the MAH	02/10/2019	23/07/2020	SmPC, Labelling and PL	
IAIN/0002	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	02/10/2019	n/a		
IAIN/0001/G	This was an application for a group of variations. B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP -	22/07/2019	23/07/2020	Annex II and PL	

	Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing				