WAYLIVRA

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/10762 /202011	Periodic Safety Update EU Single assessment - volanesorsen	10/06/2021	n/a		PRAC Recommendation - maintenance
IB/0011/G	This was an application for a group of variations. A.6 - Administrative change - Change in ATC Code/ATC Vet Code	25/05/2021		SmPC, Labelling and PL	The Product Information includes the following updates: - To include the ATC Code in Section 5.1 of the Summary of Product Characteristics (SmPC). - To change the shelf-life from '4 years' to '5 years' in

[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).

	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)				section 6.3 of the SmPC. - To introduce editorial changes throughout the product information.
R/0009	Renewal of the marketing authorisation.	10/12/2020	04/02/2021		The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for WAYLIVRA, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
PSUSA/10762 /202005	Periodic Safety Update EU Single assessment - volanesorsen	26/11/2020	n/a		PRAC Recommendation - maintenance
IA/0008/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol	12/10/2020	n/a		

	B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol				
IB/0006	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	12/06/2020	n/a		
PSUSA/10762 /201911	Periodic Safety Update EU Single assessment - volanesorsen	11/06/2020	n/a		PRAC Recommendation - maintenance
IB/0005	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	24/04/2020	04/02/2021	SmPC and PL	
R/0003	Renewal of the marketing authorisation.	30/01/2020	16/03/2020		The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for WAYLIVRA, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
IB/0002	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	18/07/2019	n/a		
IB/0001	B.II.f.1.b.1 - Stability of FP - Extension of the shelf	18/07/2019	16/03/2020	SmPC	

	life of the finished product - As packaged for sale (supported by real time data)				