Sixmo

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
R/0017	Renewal of the marketing authorisation.	25/01/2024	27/03/2024	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 Sixmo in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.

[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).

PSUSA/10778 /202305	Periodic Safety Update EU Single assessment - buprenorphine (implant)	11/01/2024	n/a		PRAC Recommendation - maintenance
PSUSA/10778 /202211	Periodic Safety Update EU Single assessment - buprenorphine (implant)	06/07/2023	n/a		PRAC Recommendation - maintenance
IAIN/0015	C.I.11.a - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of wording agreed by the competent authority	16/02/2023	06/02/2024	Annex II	
PSUSA/10778 /202205	Periodic Safety Update EU Single assessment - buprenorphine (implant)	12/01/2023	n/a		PRAC Recommendation - maintenance
PSUSA/10778 /202111	Periodic Safety Update EU Single assessment - buprenorphine (implant)	10/06/2022	n/a		PRAC Recommendation - maintenance
IA/0012	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	25/04/2022	n/a		
IB/0011	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	08/03/2022	n/a		
PSUSA/10778 /202105	Periodic Safety Update EU Single assessment - buprenorphine (implant)	13/01/2022	n/a		PRAC Recommendation - maintenance
IB/0009	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)	17/12/2021	28/11/2022	SmPC, Labelling and PL	

IA/0008	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	02/08/2021	n/a		
PSUSA/10778 /202011	Periodic Safety Update EU Single assessment - buprenorphine (implant)	10/06/2021	n/a		PRAC Recommendation - maintenance
IAIN/0006/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	17/03/2021	n/a		
PSUSA/10778 /202005	Periodic Safety Update EU Single assessment - buprenorphine (implant)	14/01/2021	n/a		PRAC Recommendation - maintenance
N/0004	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	27/11/2020	25/01/2022	PL	
IAIN/0003	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	07/09/2020	25/01/2022	SmPC and PL	
PSUSA/10778 /201911	Periodic Safety Update EU Single assessment - buprenorphine (implant)	11/06/2020	n/a		PRAC Recommendation - maintenance