Atosiban SUN

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
IB/0021	The marketing authorisation holder took the opportunity to align the PI to the latest QRD template (version 10.2). C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	02/02/2022		Labelling and PL	The marketing authorisation holder took the opportunity to align the PI to the latest QRD template (version 10.2).

[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).

IA/0020/G	This was an application for a group of variations. B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	10/12/2021	n/a		
N/0019	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/10/2020		PL	
IB/0017	B.II.z - Quality change - Finished product - Other variation	08/04/2020	n/a		
N/0018	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	31/03/2020		PL	
N/0016	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/08/2019		PL	
IA/0015	B.II.e.3.b - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition)	30/08/2019	n/a		
N/0014	Minor change in labelling or package leaflet not	16/08/2018		Labelling and	

	connected with the SPC (Art. 61.3 Notification)			PL	
N/0013	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/07/2018		PL	
R/0012	Renewal of the marketing authorisation.	22/03/2018	28/05/2018	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 Atosiban SUN in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IAIN/0011	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	10/08/2017	n/a		
N/0010	Update of the package leaflet with revised contact details of the local representatives for Germany, Italy, Spain and the United Kingdom. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/08/2016	28/05/2018	PL	
IA/0009	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	22/01/2016	n/a		
IAIN/0008	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	28/09/2015	n/a		

IB/0007/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size	26/06/2015	n/a		
IB/0006	B.II.d.1.g - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter wit its corresponding test method as a result of a safety or quality issue	10/06/2015	n/a		
IB/0005/G	This was an application for a group of variations. B.I.b.1.h - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition or replacement (excl. Biol. or immunol. substance) of a specification parameter as a result of a safety or quality issue B.I.d.1.b.1 - Stability of AS - Change in the storage conditions - Change to more restrictive storage conditions of the AS B.I.a.4.f - Change to in-process tests or limits applied during the manufacture of the AS - Addition	18/02/2015	n/a		

	or replacement of an in-process test as a result of a safety or quality issue				
IA/0004	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	04/02/2015	n/a		
IB/0003/G	This was an application for a group of variations. B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	13/10/2014	n/a		
IAIN/0002	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the	21/11/2013	n/a		

	PSMF location				
IB/0001	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)	24/10/2013	15/10/2014	SmPC	