Sialanar

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/0026	Submission of an updated RMP version 3.1 in order to remove a Drug Utilisation Study (DUS). In addition, the safety concerns, pharmacovigilance activities and risk minimisation measures in the RMP of Sialanar are revised to be in line with the Guideline on good pharmacovigilance practices (GVP)	08/06/2023		Annex II	Based on results of the safety data generated from the Drug Utilisation Study (DUS) and Pharmacovigilance database that did not point to outstanding safety or risk minimisation issues regarding the identified risks Off label treatment of children with mild to moderate sialorrhoea, and Off label use in patients below the age of 3 years due

[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).

	Module V – Risk management systems (Rev 2). Furthermore, Annex II D "Conditions or restrictions with regard to the safe and effective use of the medicinal product" was revised to delete information about the utilisation study from the key elements of the physician educational material. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				to the higher susceptibility to adverse effects, and missing information Safety in long-term use, beyond 24 weeks the PRAC agreed to remove the DUS from the RMP.
PSUSA/10529 /202209	Periodic Safety Update EU Single assessment - glycopyrronium (indicated for the treatment of severe sialorhoea)	14/04/2023	n/a		PRAC Recommendation - maintenance
II/0025/G	This was an application for a group of variations. 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) B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	01/09/2022	31/03/2023	SmPC	The SmPC section 6.3 has been updated as follows: Shelf life is extended from 2 to 3 years.
IAIN/0024	A.1 - Administrative change - Change in the name and/or address of the MAH	13/04/2022	31/03/2023	SmPC, Labelling and PL	

PSUSA/10529 /202109	Periodic Safety Update EU Single assessment - glycopyrronium (indicated for the treatment of severe sialorhoea)	07/04/2022	n/a		PRAC Recommendation - maintenance
IAIN/0022/G	This was an application for a group of variations. 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 B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	28/09/2021	n/a		
IB/0021/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) 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-release, batch control, primary and secondary packaging, for non-sterile medicinal products	18/06/2021	n/a		
R/0018	Renewal of the marketing authorisation.	22/04/2021	17/06/2021	SmPC, Annex	Based on the review of data on quality, safety and efficacy,

				II, Labelling and PL	the CHMP considered that the benefit-risk balance of Sialanar in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10529 /202009	Periodic Safety Update EU Single assessment - glycopyrronium (indicated for the treatment of severe sialorhoea)	09/04/2021	n/a		PRAC Recommendation - maintenance
IA/0020	A.7 - Administrative change - Deletion of manufacturing sites	09/03/2021	17/06/2021	Annex II and PL	
IAIN/0019	B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	02/12/2020	17/06/2021	Annex II and PL	
IAIN/0016/G	This was an application for a group of variations. B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing A.7 - Administrative change - Deletion of manufacturing sites	02/12/2020	17/06/2021	Annex II and PL	
PSUSA/10529 /202003	Periodic Safety Update EU Single assessment - glycopyrronium (indicated for the treatment of severe sialorhoea)	01/10/2020	n/a		PRAC Recommendation - maintenance
IB/0014	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	30/04/2020	n/a		

PSUSA/10529 /201909	Periodic Safety Update EU Single assessment - glycopyrronium (indicated for the treatment of severe sialorhoea)	17/04/2020	n/a		PRAC Recommendation - maintenance
IB/0012	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	03/10/2019	09/10/2020	SmPC, Labelling and PL	
PSUSA/10529 /201903	Periodic Safety Update EU Single assessment - glycopyrronium (indicated for the treatment of severe sialorhoea)	03/10/2019	n/a		PRAC Recommendation - maintenance
IAIN/0010/G	This was an application for a group of variations. 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 B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	24/05/2019	n/a		
PSUSA/10529 /201809	Periodic Safety Update EU Single assessment - glycopyrronium (indicated for the treatment of severe sialorhoea)	11/04/2019	n/a		PRAC Recommendation - maintenance
T/0009	Transfer of Marketing Authorisation	15/03/2019	28/03/2019	SmPC, Labelling and PL	

IB/0008	B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products	04/01/2019	28/03/2019	SmPC, Labelling and PL	
PSUSA/10529 /201803	Periodic Safety Update EU Single assessment - glycopyrronium (indicated for the treatment of severe sialorhoea)	04/10/2018	n/a		PRAC Recommendation - maintenance
PSUSA/10529 /201709	Periodic Safety Update EU Single assessment - glycopyrronium (indicated for the treatment of severe sialorhoea)	12/04/2018	n/a		PRAC Recommendation - maintenance
PSUSA/10529 /201703	Periodic Safety Update EU Single assessment - glycopyrronium (indicated for the treatment of severe sialorhoea)	28/09/2017	n/a		PRAC Recommendation - maintenance
IAIN/0003	A.1 - Administrative change - Change in the name and/or address of the MAH	11/05/2017	13/04/2018	SmPC, Labelling and PL	
IB/0002	B.II.f.1.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening (supported by real time data)	22/03/2017	13/04/2018	SmPC, Labelling and PL	
IB/0001	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	05/01/2017	n/a		