Ledaga

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/0036/G	This was an application for a group of variations. B.II.e.1.b.1 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms	07/09/2023		SmPC	

[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.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 B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site 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.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits				
IA/0034	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	09/09/2022	n/a		
IA/0033/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	09/09/2022	n/a		

	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 A.7 - Administrative change - Deletion of manufacturing sites				
IB/0032	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	11/04/2022	n/a		
PSUSA/10587 /202108	Periodic Safety Update EU Single assessment - chlormethine	10/03/2022	n/a		PRAC Recommendation - maintenance
R/0030	Renewal of the marketing authorisation.	11/11/2021	07/01/2022	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 LEDAGA in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0029	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)	12/05/2021	07/01/2022	SmPC	
IB/0028/G	This was an application for a group of variations. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP -	26/04/2021	n/a		

	Replacement/addition of a site where batch control/testing takes place				
PSUSA/10587 /202008	Periodic Safety Update EU Single assessment - chlormethine	11/03/2021	n/a		PRAC Recommendation - maintenance
IB/0026	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	25/02/2021	07/01/2022	SmPC, Labelling and PL	
IB/0025/G	This was an application for a group of variations. B.I.z - Quality change - Active substance - Other variation B.I.z - Quality change - Active substance - Other variation B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	11/12/2020	n/a		
PSUSA/10587 /202002	Periodic Safety Update EU Single assessment - chlormethine	01/10/2020	n/a		PRAC Recommendation - maintenance
IA/0023/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.II.d.2.f - Change in test procedure for the finished	06/08/2020	n/a		

	product - To reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number B.II.d.2.f - Change in test procedure for the finished product - To reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number B.II.d.2.f - Change in test procedure for the finished product - To reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number				
IB/0022	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	21/07/2020	n/a		
IB/0020/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	17/07/2020	n/a		
PSUSA/10587	Periodic Safety Update EU Single assessment -	12/03/2020	n/a		PRAC Recommendation - maintenance

/201908	chlormethine				
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/10/2019	28/02/2020	Labelling	
IAIN/0018	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	11/10/2019	n/a		
IB/0016	B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	17/09/2019	n/a		
PSUSA/10587 /201902	Periodic Safety Update EU Single assessment - chlormethine	05/09/2019	n/a		PRAC Recommendation - maintenance
IB/0015	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	23/08/2019	n/a		
IAIN/0012	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	10/05/2019	n/a		
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/04/2019	28/02/2020	PL	

IB/0009/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place 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.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure 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 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 B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement	03/04/2019	n/a		

	or addition) for the AS or a starting material/intermediate 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				
IAIN/0010/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites 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	15/03/2019	28/02/2020	Annex II, Labelling and PL	
PSUSA/10587 /201808	Periodic Safety Update EU Single assessment - chlormethine	14/03/2019	n/a		PRAC Recommendation - maintenance
T/0008	Transfer of Marketing Authorisation	22/11/2018	18/12/2018	SmPC, Labelling and PL	

PSUSA/10587 /201802	Periodic Safety Update EU Single assessment - chlormethine	06/09/2018	n/a		PRAC Recommendation - maintenance
PSUSA/10587 /201708	Periodic Safety Update EU Single assessment - chlormethine	08/03/2018	n/a		PRAC Recommendation - maintenance
IG/0839	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	20/11/2017	28/05/2018	SmPC, Annex II and PL	
IB/0003/G	This was an application for a group of variations. B.II.z - Quality change - Finished product - Other variation B.II.z - Quality change - Finished product - Other variation	15/09/2017	n/a		
IA/0001	B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	28/06/2017	28/05/2018	SmPC and PL	