Cuprior

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/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)	25/03/2024		SmPC	
IB/0027	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	15/01/2024	n/a		

[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).

IB/0025/G	This was an application for a group of variations. 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.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer	16/08/2023	n/a		
IB/0024	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	16/06/2023	n/a		
IB/0022	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	05/05/2023	n/a		
IA/0023/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor	12/04/2023	n/a		

	changes to an approved test procedure				
IA/0021	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	17/02/2023	n/a		
IB/0020	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	31/01/2023	n/a		
R/0018	Renewal of the marketing authorisation.	23/06/2022	17/08/2022	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 Cuprior in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10637 /202109	Periodic Safety Update EU Single assessment - trientine	07/04/2022	n/a		PRAC Recommendation - maintenance
PSUSA/10637 /202009	Periodic Safety Update EU Single assessment - trientine	09/04/2021	n/a		PRAC Recommendation - maintenance
IB/0014/G	This was an application for a group of variations. B.I.z - Quality change - Active substance - Other variation 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 B.I.d.1.b.3 - Stability of AS - Change in the storage	15/10/2020	n/a		

	conditions - Change in storage conditions of the AS 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				
IAIN/0015	A.1 - Administrative change - Change in the name and/or address of the MAH	27/08/2020	09/10/2020	SmPC, Labelling and PL	
IAIN/0013/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH C.I.3.a - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Implementation of wording agreed by the competent authority	05/08/2020	09/10/2020	SmPC, Labelling and PL	
PSUSA/10637 /201909	Periodic Safety Update EU Single assessment - trientine	17/04/2020	n/a		PRAC Recommendation - maintenance
IB/0012/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.f.1.e - Stability of FP - Change to an approved stability protocol	16/01/2020	09/10/2020	SmPC	
IA/0010/G	This was an application for a group of variations.	28/11/2019	n/a		

	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 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)				
IB/0009	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	10/10/2019	09/10/2020	SmPC, Labelling and PL	
PSUSA/10637 /201903	Periodic Safety Update EU Single assessment - trientine	03/10/2019	n/a		PRAC Recommendation - maintenance
IB/0008	A.7 - Administrative change - Deletion of manufacturing sites	16/09/2019	n/a		
PSUSA/10637 /201809	Periodic Safety Update EU Single assessment - trientine	26/04/2019	25/06/2019	SmPC	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10637/201809.
PSUSA/10637 /201803	Periodic Safety Update EU Single assessment - trientine	04/10/2018	n/a		PRAC Recommendation - maintenance

IB/0004	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)	24/09/2018	25/06/2019	SmPC	
II/0001/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.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.a.1.g - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the AS that is not supported by an ASMF and requires significant update to the relevant AS section in the dossier B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method	13/09/2018	n/a		

	B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method 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				
IB/0003/G	This was an application for a group of variations. B.II.a.1.b - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in scoring/break lines intended to divide into equal doses B.II.a.4.z - Change in coating weight of oral dosage forms or change in weight of capsule shells - Other variation 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.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size 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 B.II.b.5.z - Change to in-process tests or limits	19/07/2018	25/06/2019	SmPC, Labelling and PL	

	applied during the manufacture of the finished product - Other variation B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation				