Xromi

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
PSUSA/1692/ 202406	Periodic Safety Update EU Single assessment - hydroxycarbamide (for centrally authorised product only)	30/01/2025	24/03/2025	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/1692/202406.
IB/0024	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing	16/09/2024	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).

	authorisation, including the RMP - Other variation				
R/0023	Renewal of the marketing authorisation.	21/03/2024	16/05/2024	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Xromi in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. In section 4.6 of the SmPC it is clarified that "The recommended duration of contraception in male and female patients following the end of treatment with hydroxycarbamide, should be 3 and 6 months, respectively". The SmPC and the PL are brought in line with the latest QRD template and the PL section on Warnings and precautions is brought in line with the content of the SmPC.
II/0019	Extension of indication to include the prevention of vaso-occlusive complications of sickle cell disease in children from 9 months to 2 years of age for Xromi, based on final results from the paediatric study INV543, listed as a category 3 study in the RMP; this is a single-arm, open-label, multi-center study in children with sickle cell anaemia over 9 months of age. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 4.4 of the RMP has also been submitted. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	22/02/2024	19/03/2024	SmPC and PL	Please refer to Scientific Discussion: Xromi-H-C-4837-II-19.

PSUSA/1692/202306	Periodic Safety Update EU Single assessment - hydroxycarbamide (for centrally authorised product only)	11/01/2024	n/a		PRAC Recommendation - maintenance
IB/0021	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	15/05/2023	n/a		
IB/0020/G	This was an application for a group of variations. B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	03/03/2023	n/a		
PSUSA/1692/202206	Periodic Safety Update EU Single assessment - hydroxycarbamide (for centrally authorised product only)	12/01/2023	n/a		PRAC Recommendation - maintenance
IAIN/0018/G	This was an application for a group of variations. B.IV.1.a.1 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking B.IV.1.a.1 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking B.IV.1.a.1 - Change of a measuring or administration	09/01/2023	06/02/2023	SmPC, Labelling and PL	

	device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking				
IA/0017	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	22/11/2022	n/a		
IAIN/0016	B.IV.1.a.1 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking	10/10/2022	n/a		
IA/0014	A.7 - Administrative change - Deletion of manufacturing sites	01/06/2022	06/02/2023	Annex II and PL	
IA/0013/G	This was an application for a group of variations. B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	02/05/2022	n/a		
IB/0012	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	02/05/2022	n/a		
IB/0011	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	24/03/2022	n/a		To provide an updated study of ready biodegradability

					according to OECD 301
IB/0010	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	28/02/2022	06/02/2023	Annex II	To provide an updated RMP to implement the changes required as a result of the Assessment of the 1st PSUR, EMEA/H/C/PSUSA/00001692/202006 for the Risk Management Plan of Xromi 100 mg/ml oral solution.
PSUSA/1692/ 202106	Periodic Safety Update EU Single assessment - hydroxycarbamide (for centrally authorised product only)	13/01/2022	n/a		PRAC Recommendation - maintenance
IB/0008	C.I.3.z - 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 - Other variation	22/11/2021	14/02/2022	SmPC	
PSUSA/1692/ 202006	Periodic Safety Update EU Single assessment - hydroxycarbamide (for centrally authorised product only)	28/01/2021	15/04/2021	SmPC	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/1692/202006.
IB/0005	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	01/04/2021	n/a		
IA/0007	A.7 - Administrative change - Deletion of manufacturing sites	03/03/2021	14/02/2022	Annex II and PL	
IAIN/0006	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	02/02/2021	14/02/2022	Annex II and PL	

IA/0004	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	16/12/2020	n/a		
IAIN/0003	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	04/11/2020	n/a		
IA/0001	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	31/01/2020	n/a		