



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Elaprase

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency's update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
Variation type IB /	Outcome:	15/10/2026		SmPC, Annex	

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).



EMA/VR/0000373474	This was an application for a group of variations. E. Administrative Changes - E.5 Deletion of manufacturing sites for an active substance, intermediate or finished product, storage of master and/or working cell bank, primary and/or secondary packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the dossier) - Accepted C. Safety, efficacy, pharmacovigilance changes - C.z Other variation - Accepted E.5 (Type IA) – To delete Shire Pharmaceuticals Ireland Limited (Block 2-3 Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, Ireland) as a site responsible for batch release of the finished product Elaprase. C.z (Type IB) – To update sections 2, 4.4, and 6.1 of the SmPC, section 3 of the labelling, and sections 2 and 6 of the PL with information on the excipient polysorbate 20, based on the Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'. In addition, the MAH took the opportunity to implement editorial changes across the			II, Labelling and PL	
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	product information to (1) update the wording on the excipient sodium in section 4.4 of the SmPC in line with the above-mentioned EC excipients guideline, (2) implement changes in line with the latest QRD-template, (3) update the contact details of the local representatives in the PL, and (4) correct typographical errors.				
Variation type IB / EMA/VR/0000357282	Outcome: This was an application for a group of variations. Q.I.a.1 Change in the manufacturing site of a starting material/intermediate used in the manufacturing process of the active substance or change in the manufacturing site (including where relevant quality control testing sites) of the active substance - Q.I.a.1.k) Addition or replacement of a storage site of the Master Cell Bank and/or Working Cell Banks - Accepted Q.I.a.1 Change in the manufacturing site of a starting material/intermediate used in the manufacturing process of the active substance or change in the manufacturing site (including where relevant quality control testing sites) of the active substance - Q.I.a.1.k) Addition or replacement of a storage site of the Master Cell Bank and/or Working Cell Banks - Accepted Q.II.h.1.b) Replacement of obsolete studies	17/09/2026			

	related to manufacturing steps and adventitious agents already reported in the dossier - Q.II.h.1.b.2 without modification of risk assessment - Accepted Q.I.a.1 Change in the manufacturing site of a starting material/intermediate used in the manufacturing process of the active substance or change in the manufacturing site (including where relevant quality control testing sites) of the active substance - Q.I.a.1.i) Addition or replacement of a batch control/testing site of the active substance or starting material/intermediate used in the manufacturing of a biological active substance, applying a biological/immunological/immunochemical analytical procedure - Accepted Q.I.a.1 Change in the manufacturing site of a starting material/intermediate used in the manufacturing process of the active substance or change in the manufacturing site (including where relevant quality control testing sites) of the active substance - Q.I.a.1.i) Addition or replacement of a batch control/testing site of the active substance or starting material/intermediate used in the manufacturing of a biological active substance, applying a biological/immunological/immunochemical analytical procedure - Accepted				
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Annual reassessment - H / EMA/S/0000339599	Outcome: - Annual Reassessment - Accepted 19th annual re-assessment	23/07/2026			The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation of Elaprase should be maintained.
Variation type IB / EMA/VR/0000309404	Outcome: B.II.g.5 Implementation of changes foreseen in an approved change management protocol - B.II.g.5.c Implementation of a change for a biological/immunological medicinal product - Accepted	09/01/2026			
Variation type IA / EMA/VR/0000314076	Outcome: This was an application for a group of variations. A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted A. ADMINISTRATIVE CHANGES - A.7	28/11/2025			

	Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted				
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Variation type II / EMA/VR/0000279282	Outcome: C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.b Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required* - Accepted Update of an RMP to version 5.2 to reflect the completion of the Hunter Outcome Survey (HOS) study and removal from Pharmacovigilance plan following procedure EMEA/H/C/PSUSA/00001722/202407; update the exposure data with information from the ongoing study SHP-ELA-401; include template updates; remove all safety concerns, including missing information, in alignment with GVP Module V, Revision 2.	04/09/2025			
Annual reassessment - H / EMA/S/0000263922	Outcome: - Annual Reassessment - Accepted 18th annual re-assessment	24/07/2025			The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation of Elaprase should be maintained.
Variation type IB / EMA/VR/0000264647	Outcome: B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used	13/05/2025			

	in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.f Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place - Accepted				
Variation type IA_IN / EMA/VR/0000263366	Outcome: C.I.3 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - C.I.3.a Implementation of wording agreed by the competent authority - Accepted	16/04/2025	11/06/2026	SmPC	To update section 4.4 of the SmPC to implement the wording agreed by the CHMP following the assessment done by the competent authority under Article 46 of Regulation 1901/2006, after completion of the pediatric study TAK-665-4001 for Elaprase: A Prospective, Multicenter, Single-arm, Open-label, Interventional Phase IV Study to Evaluate the Safety and Efficacy of Idursulfase (r-DNA origin) (Elaprase™) in Indian Pediatric and Adult Population.
Variation type IA / EMA/VR/0000256375	Outcome: A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted	14/03/2025			

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