Elebrato Ellipta

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, please 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
PAM – H /	This study was submitted in accordance with	25/04/2025	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).

EMA/PAM/0000248973	article 46 of regulation (EC) No 1901/2006, as amended. The MAH's submission of the data within the scope of Article 46 is considered acceptable although only 2 paediatric patients out of 286 patients were listed as having been included in the study. The submitted study was conducted in patients with asthma in Japan where this indication is approved. Of note, Elebrato Ellipta is not approved for use in asthma in the EU. The use of Trelegy/Elebrato Ellipta in asthmatic patients has been previously assessed in the EU and was refused by CHMP following assessment of variation EMEA/H/C/004363/X/0012/G. In this context, while the overall conclusions of Study 214953 are noted, the data are not robust to support any changes to the currently approved indication. The previous CHMP conclusions refusing the use of Trelegy Ellipta in asthmatic patients in the EU still remain. Overall, no new safety concerns have been identified in this study and no updates to the product information have been proposed by the MAH. This is agreed.				

	It is recommended that the ongoing safety of Elebrato Ellipta continues to be routinely monitored.				