Kirsty

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 IA /	This was an application for a group of variations.	26/01/2026	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/VR/0000323082	B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted				
Variation type II / EMA/VR/0000285173	This was an application for a group of variations. B.IV.1.a Addition or replacement of a device which is not an integrated part of the primary packaging - B.IV.1.a.1 Device with CE marking - Accepted B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.2 Change outside the range of the currently approved pack sizes - Accepted B.II.e.1.b Change in type of container or addition of a new container - B.II.e.1.b.2 Sterile medicinal products and biological/ immunological medicinal products - Accepted	30/10/2025		SmPC, Labelling and PL	The SmPC Annex I and Annex II have been updated to add reference to the new presentation Kirsty 100 units/ml solution for injection in cartridge. The new presentation is available in pack sizes of 5 and 10 cartridges (EU/1/20/1506/008 and EU/1/20/1506/009). The new presentation is to be used only with the reusable EZPen. The Labelling, Package Leaflet and Annex A have been updated accordingly.
Renewal - 5 year /	- Renewal -	18/09/2025			

EMA/R/0000276245	Renewal of marketing authorisation				
Variation type II / EMA/VR/0000256842	B.I.e) Design Space and post-approval change management protocols - B.I.e.2 Introduction of a post approval change management protocol related to the active substance - Accepted	03/07/2025	N/A		
Variation type IB / EMA/VR/0000262357	This was an application for a group of variations. B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.a Tightening of specification limits - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification	19/05/2025	N/A		

	parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.z Other changes - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted				
Variation type IA / EMA/VR/0000269546	This was an application for a group of variations. B.I.c.2 Change in the specification parameters and/or limits of the immediate packaging of the active substance - B.I.c.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.I.c.2 Change in the specification parameters and/or limits of the immediate packaging of the active substance - B.I.c.2.c Deletion of a	07/05/2025	N/A		

	non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted B.I.c.2 Change in the specification parameters and/or limits of the immediate packaging of the active substance - B.I.c.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted B.I.c.2 Change in the specification parameters and/or limits of the immediate packaging of the active substance - B.I.c.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted B.I.c.2 Change in the specification parameters and/or limits of the immediate packaging of the active substance - B.I.c.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted B.I.c.2 Change in the specification parameters and/or limits of the immediate packaging of the active substance - B.I.c.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted B.I.c.2 Change in the specification parameters and/or limits of the immediate packaging of the active substance - B.I.c.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted				

	B.I.c.2 Change in the specification parameters and/or limits of the immediate packaging of the active substance - B.I.c.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted				
Variation type IA / EMA/VR/0000248762	B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.c Addition of a new specification parameter to the specification with its corresponding test method - Accepted	07/02/2025	N/A		