Holoclar

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 /	C.I.11 Introduction of, or change(s) to, the	07/07/2025		Annex II	To amend a misalignment of the Risk Management

[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/0000262697	obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.z Other RMP changes (e.g. agreed wording + template change) - Accepted C.I.11.z (Type IB) – To amend a misalignment of the Risk Management Plan Annex 6 related to the completion of the HOLOSIGHT clinical trial enrolment. RMP Annex 6 still included a reference to informing and encouraging about the registration in the safety study registry in the key elements. This reference is proposed now for deletion to ensure harmonisation with the RMP body (approved in the 2023 renewal procedure EMEA/H/C/002450/R/0058) and the Educational materials (updated via type IB variation EMEA/H/C/002450/IB/0067). The Product Information Annex II has been updated in accordance for all languages. In addition, the marketing authorization holder has taken the opportunity to correct a typographical error in Annex II of the SmPC.				Plan Annex 6 related to the completion of the HOLOSIGHT clinical trial enrolment. RMP Annex 6 still included a reference to informing and encouraging about the registration in the safety study registry in the key elements. This reference is proposed now for deletion to ensure harmonisation with the RMP body (approved in the 2023 renewal procedure EMEA/H/C/002450/R/0058) and the Educational materials (updated via type IB variation EMEA/H/C/002450/IB/0067). The Product Information Annex II has been updated in accordance for all languages.
Variation type IB / EMA/VR/0000265797	This was an application for a group of variations. B.II.c) Control of excipients - B.II.c.z Other variation - Accepted	15/05/2025	N/A		

	B.II.c) Control of excipients - B.II.c.z Other variation - Accepted				