IVF Media G5 Series

Procedural steps taken and scientific information after initial consultation*

*Due to the Agency's update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available under the title "Procedural steps and scientific information after initial consultation (archive)".

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
Variation type IB / EMA/VR/0000256711	This was an application for a group of variations.	03/06/2025	N/A		To update Plasma Master File certificates.

[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).

	- Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB - Accepted - Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA - Accepted				To add a new device / medium.