04 March 2025
EMA/CHMP/81378/20255 Rev. 2

Vitrolife IVF media

Procedural steps and scientific information after initial consultation

Application number	Scope	Opinion/ Notification [1] issued on	Summary
IB/0006/G	This was an application for a group of variations. Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	04/02/2025	To change the name of the site responsible for manufacturing and release testing of the ancillary active substance Recombinant Human Albumin. To increase an in-process limit applied during the manufacture of the ancillary active substance Recombinant Human Albumin. To remove product presentations.
II/0005	Major changes to an ancillary medicinal substance -	30/05/2024	

[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.

	Post consultation procedure equivalent to II		
IA/0003	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	08/03/2023	
IA/0002	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	06/12/2021	
IA/0001	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	18/02/2021	Deletion of a site responsible for batch testing and product release of the ancillary medicinal substance. In consequence, minor changes to the test procedure and assay have been introduced for the remaining site.