



02 March 2021
EMA/83725/2021 Rev.1
Human Medicines Evaluation Division

Gems Medium Suite

Procedural steps and scientific information after initial consultation

Application number	Scope	Opinion/ Notification ¹ issued on	Summary
IA/0004	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	09/10/2020	<p>To change the Notified Body from BSI Group (Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom) to BSI Group The Netherlands B.V. (Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands).</p> <p>To change the address of the manufacturer and supplier of the ancillary medicinal substance, Octapharma AB, from Elersvagen 40, SE-112 75 Stockholm, Sweden to Lars Forssells gata 23, SE-112 75 Stockholm, Sweden.</p>

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.



			<p>To change the EU representative from Genea Biomedex UK Ltd to Donawa Lifescience consulting SRL. The manufacturer of the medical device remains unchanged.</p> <p>To submit a 2nd step notification procedure.</p>
IB/0003	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	19/08/2016	To introduce an additional medium, Geri Medium.
IB/0002	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	02/02/2016	To introduce an additional medium, Gavi Medium Cartridge (GAVI-MED-20), and to remove the following media: Sperm Medium with pentoxifylline, Sperm Buffer with pentoxifylline, Cleavage Stage Freezing Set, Cleavage Stage Thawing Set, Blastocyst Stage Freezing Set and Blastocyst Stage Thawing Set.
IA/0001	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	02/07/2015	To change the name and address of the medical device manufacturer from Genea Biomedx UK LTD, 10-18 Union Street, London SE1 1SZ, United Kingdom, to Genea Biomedx PTY LTD, Level 2, 321 Kent Street, Sydney NSW 2000, Australia.