

Recommendations of the SEC (Reproductive) made in its 04th/26 meeting held on 21.04.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/151/25 Online Submission (52585) Corifollitropin Alfa	M/s. Bharat Serums and Vaccines Limited	<p>The firm presented phase III clinical study Protocol no. BSV_CFA_150_2025_02, version 2.0 dated 30Jan 2026.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition.</p> <ol style="list-style-type: none"> 1. Follow up of mother and fetus during pregnancy and delivery for adverse events and complications. 2. Following delivery, the neonate shall be monitored for a minimum period of 28 days, with continued follow-up up to three months, to assess neonatal outcomes and to rule out any congenital malformations or deformities.
Biological Division			
2.	BIO/CT04/FF/2026/5 4259 Trinbelimab Injection 300 mcg/mL	M/s. Intas Pharmaceuticals Limited	<p>The firm presented the proposal to conduct Phase I/III clinical trial titled "A Prospective, Multicentre, Randomized, Assessor-Blind, 2-Arm, Parallel Study to Investigate Efficacy, Safety, Immunogenicity and Pharmacokinetics of Recombinant Anti-Rh(D) Antibody of Intas Pharmaceutical Limited with Trinbelimab (Recombinant Anti Rho-D Immunoglobulin) in RhD-negative Pregnant Women for the Prevention of Maternal - Foetal Rh(D)-Alloimmunization" vide Protocol No.: 0185-25, Version No.: 1.0, Dated 02 September 2025.</p>

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			<p>After detailed deliberation, the committee did not consider the subject Phase-I/III study protocol in its current form.</p> <p>The committee recommended that the firm should instead conduct the PK/PD study in healthy post-menopausal women or in women who have completed their family and do not intend further child bearing.</p> <p>Accordingly, the said protocol shall be revised to conduct the Phase I (PK/PD) study and revised protocol shall be submitted to CDSCO for further evaluation by the committee.</p>