

Recommendations of the SEC (Reproductive) made in its 05th/24 meeting held on 04.06.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT21/FF/2023/3 8351 Trinbelimab Injection 300mcg/150mcg vial and PFS (Additional indication)	M/s. BSV	<p>In light of earlier SEC recommendations dated 19.10.2023, the firm presented the data from the RhYTHM study (Real World observational study on Rh-negative pregnant women in India) generated by BSV, PSUR data and market survey results of Trinbelimab Recombinant Anti RhoD Immunoglobulin Injection 300mcg/150mcg vial and PFS for proving the safety of patients in proposed indication.</p> <p>The committee noted the results of the RhYTHM study and observed that 8 neonates were delivered with complications to mothers who have received antenatal administration for which detailed casualty analysis was not presented.</p> <p>After detailed deliberation, the committee recommended the firm to submit the detailed casualty analysis of 8 neonatal complications observed in the study including still born analysis for further evaluation by the committee.</p>