

Recommendations of the SEC (Cardiovascular & Renal) made in its 120th meeting held on 21.02.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2022/35084 Darbepoetin alfa	M/s. Dr. Reddy's Laboratories limited	<p>The firm presented the proposal for conduct of PK/PD clinical trial titled "A single dose, double-blind, two-period crossover, balanced sequences, comparative pharmacokinetic study with separate comparisons of three pairs of products of DRL- Darbepoetin (DRL_DA), US licensed reference Product (Aranesp®), and EU approved reference Medicinal Product (Aranesp®), administered by the subcutaneous route to male healthy volunteers vide Protocol number: DA-01-006; version 1.0 dated 04.08.2022".</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial subject to the following conditions:</p> <ol style="list-style-type: none"> 1. The range of hemoglobin during screening of the subjects should be 12-14 gm/dl. 2. The complete iron profile should be monitored including serum iron, TIBC, transferrin saturation and serum creatinine. <p>Accordingly, the firm should submit the revised protocol to CDSCO for approval.</p>
Medical Device Division			
2.	CI/MD/2022/77755 BIP Central Venous Catheter	M/s. Biosphere clinical research Pvt. Ltd.	<p>The firm presented its proposal for post marketing clinical investigation of the proposed product before the committee.</p> <p>After detailed deliberation, the committee recommended that the protocol of the proposed post marketing clinical investigation should be deliberated with expert of anesthesia and critical care medicine.</p> <p>Accordingly, expert of anesthesia and critical care medicine needs to be invited in next meeting.</p>
3.	CI/MD/2022/72489	M/s. RCUPE Life sciences	The proposal was deferred for next meeting.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Sterile Intraosseous Access / Infusion Device (Ozyn-D™)	Private Limited	
GCT Division			
4.	CT/66/22 Online Submission (33152) Dated 29/07/22 Crovalimab 340 mg/2 ml	M/s. Roche	The committee reiterated its earlier recommendations.
5.	CT/77/22 Online Submission (33262) Dated 09/08/22 Crovalimab	M/s. Roche	The committee reiterated its earlier recommendations.