Recommendations of the SEC (Haematology) made in its 07th/24 meeting held on 18.06.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/23/000004 Ferumoxytol Injection 510mg of elemental Iron/17mL (30mg/ml)	M/s. MSN Laboratories	In light of earlier SEC recommendations dated 30.10.2023, the firm presented the pharmacokinetic study report of Ferumoxytol injection 510mg of elemental Iron/17mL (30mg/ml) along with published literature on global clinical trial data involving Indian patients carried out by the innovator. The committee has reviewed the pharmacokinetics study data and found acceptable. The firm has also presented the published literature on global clinical trial data involving 112 Indian patients and found acceptable. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Ferumoxytol injection 510mg of elemental Iron/17mL (30mg/ml) with a condition to conduct PMS study. Accordingly, the firm should submit PMS study protocol within 03 months from date of approval to CDSCO.
2.	ND/IMP/24/000001 Belumosudil Tablets 200 mg	M/s. Sanofi Healthcare	In light of the earlier SEC recommendations dated 19.03.2024, the firm presented the published literature on post marketing safety data of Belumosudil tablets 200 mg, of other countries along with Phase IV CT protocol before the committee. The committee noted that it is an orphan drug approved in other countries and also noted that it falls under unmet medical need. The committee agreed for Phase III CT waiver. After detailed deliberation, the committee recommended for grant of permission to import and market Belumosudil tablets 200 mg, with a condition to conduct Phase IV CT study involving high

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			volume transplant centers (more than 100) across the country. Accordingly, the firm should submit Phase IV study protocol within 03 months from date of approval to CDSCO, for further evaluation by the committee.
BA/BE Division			
3.	BABE/CT05/FF/2023 /40878 Lenalidomide TDS 8% (50.0 mg/50 cm2) and Lenalidomide TDS 5% (31.3 mg/50 cm2)	M/s. Raptim Research Pvt. Ltd.	In light of earlier SEC recommendations dated 18.04.2024, the firm presented the animal toxicity data for the applied product, Transdermal patch of Lenalidomide TDS 8% (50mg/50cm2) and Lenalidomide TDS 5% (31.3 mg/50cm2). After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BA/BE study for export purpose only.
SND Division			
4.	SND/MA/23/000254 Iron (III) Hydroxide Polymaltose syrup 50mg/5ml	M/s Ajanta Pharma Limited	In light of earlier SEC recommendations dated 21.12.2023 & 22.12.2023, the firm presented additional therapeutic clinical justification, published literature to support the clinical trial waiver before the committee. After detailed deliberation, the committee noted that the justification provided by the firm for clinical trial waiver was found inadequate and the committee reiterated its earlier recommendation. Therefore, the firm should submit Phase-III clinical trial protocol to CDSCO for further review by the committee.