Recommendations of the SEC (Haematology) made in its 03rd/24 meeting held on 19.03.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/CT/22/000127 Ferrous Ascorbate Suspension 30mg/5ml (Additional dosage form)	M/s. Zuventus Healthcare Limited	The firm presented the proposal for the manufacturing and marketing permission for their product Ferrous Ascorbate suspension 30mg/5ml (additional dosage form) indicated for the treatment of iron deficiency anaemia and requested for CT study & BE study waiver. The firm informed that Ferrous Ascorbate10mg, 30mg + Folic acid is already approved by CDSCO in various FDC dosage form. After detailed deliberation, the committee opined as the formulation is to be used by children, firm is required to submit efficacy and safety data of proposed formulation along with absorption of Ferrous Ascorbate in children to CDSCO for further review by the committee.
2.	SND/MA/23/000267 Hydroxycarbamide Oral Solution 100mg/ml	M/s. Beta Drugs Limited	In light of earlier SEC recommendation in the meeting held on 21/12/2023 & 22/12/2023, the firm proposed to conduct Bioequivalence study instead of PK study and submitted BE protocol to conduct BE study for their product – Hydroxycarbamide oral solution 100mg/ml. It is informed by the firm that the product is to be stored at 2 to 8 degree centigrade temperature. After detailed deliberation, the committee opined that the proposed formulation is used in National Sickle Cell Elimination program and product must be stable in Indian climatic condition i.e. Room temperature (RT). Therefore, firm has been asked to revise their formulation as per Indian climatic condition (RT). Further, the firm is required to conduct the BE study with already approved / available products of Hydroxyurea oral solution / suspension.

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			Accordingly, the firm should submit the protocol with revised formulation to CDSCO for further review by committee.
New Drugs Division			
3.	ND/IMP/24/000001 Belumosudil Tablets 200 mg	M/s. Sanofi	The firm presented the proposal for grant of permission to import and marketing of drug Belumosudil tablets 200 mg with local Phase III clinical trial waiver along with request to considered Belumosudil as Orphan drug as defined in NDCT Rules 2019 as the Chronic graft versus-host disease (GvHD) is rare condition affecting less than 1000 patients in India. Belumosudil tablets 200 mg is approved in US, Canada, the Great Britain, Australia, China, Israel. Belumosudil is designated as breakthrough therapy by US FDA and also granted priority review in US and Canada. After detailed deliberation, the committee opined that Chronic graft versus-host disease (GvHD) is rare condition and there is unmet need in the country. However, committee opined that: - 1. The firm should submit the post marketing safety data from all the countries where the drug Belumosudil is approved from marketing. 2. The firm should submit proper interventional Phase IV clinical trial protocol with adequate methology and sample size. Accordingly, the firm should submit the post marketing safety data of drug Belumosudil from all the countries where the drug Belumosudil is approved for marketing and Phase IV clinical trial protocol before the committee for further consideration.