Recommendations of the SEC (Oncology & Haematology) made in its 127th meeting held on 15.06.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/MA/22/000028 Rituximab	Zydus Lifesciences Limited	The firm presented the proposal to manufacture and market Rituximab in the country based on the results of Phase I (PK-PD) and Phase III clinical trial conducted in the country. After detailed deliberation, the committee recommended for grant of marketing authorization subject to the condition that the firm should conduct Phase IV clinical trial in not less than 231 subjects in the country. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of marketing approval.
2.	BIO/CT/22/000023 Nivolumab	Zydus Lifesciences Limited	The firm presented the proposal to conduct Phase III clinical trial in the country to evaluate efficacy, safety and PK in subjects with locally advanced or metastatic non-small cell lung cancer with indigenously developed Nivolumab. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the proposed protocol.
3.	BIO/CT21/FF/2022/31800 Pegfilgrastim (r-DNA origin) solution for Injection 6mg/0.6mL, PFS for domestic purpose	M/s. Biocon Biologics Limited	The firm presented their proposal to manufacture and market Pegfilgrastim with the request for waiver of Phase III clinical trial in the country. The committee noted that the firm has conducted pre-clinical studies in the country and has established comprehensive structural and functional biosimilarity with the reference drug. The committee also noted that the firm is already holding export NOC since 2017 to manufacture the drug in the country. Further, the committee noted that the drug is already approved for marketing by USFDA, EMA, Australia, Canada etc. After detailed deliberation, the committee recommended for grant of marketing

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			authorization subject to condition that the firm should submit protocol for conduct of the Phase IV study in the country which should also evaluate safety, efficacy and PK/PD (in sub-group population) within 3 months of marketing authorization approval.
New Drug Division			
4.	ND/MA/22/000084 Apalutamide 60 mg tablet	M/s. BDR Pharmaceuticals International Pvt. Ltd.	The firm presented their proposal for manufacture and market of Apalutamide 60mg tablets along with Bioequivalence study protocol and justification for waiver of Phase III clinical trial before the committee. The committee noted that the drug is already approved in countries like US, European countries, Australia, Canada etc. The committee opined that the drug is indicated for a disease which is serious and life threatening and there is an unmet medical need in the country. After detailed deliberation, the committee recommended for local clinical trial waiver and grant of permission for conduct of the BE study as per the protocol presented. The results of the BE study should be presented before the committee for further consideration.
SND Division			
5.	SND/MA/21/000504 Hydroxyurea Capsules 500 mg	M/s. Cipla Limited	The firm presented their protocol for conduct of PMS study with Hydroxyurea Capsules 500mg indicated for the prevention of recurrent painful vaso-occlusive crises including acute chest syndrome in adults, adolescents and children older than 2 years suffering from symptomatic sickcell syndrome. After detailed deliberation, the committee recommended for grant of permission to conduct the PMS study subject to the following conditions: 1. More study sites should be included in the study. 2. Study sites should be geographically distributed.

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6.	SND/IMP/20/000015 Olaparib film-coated tablets 100 mg and 150 mg	M/s. AstraZenca Pharma	As per the recommendation of SEC (Oncology & Haematology) meeting dated 11.11.2021, the firm presented the updated PI and complete data for inclusion of Vascular Thromboembolism (VTE) in Warning & Precaution section in package insert of Olaparib film coated Tablets 100mg & 150mg. After detailed deliberation, the committee recommended for grant of approval for updation of PI of Olaparib film coated Tablets 100mg & 150mg as presented.
GCT Division			
7.	CT/150/21 Online Submission (16951) Elranatamab (PF-06863135)	M/s. Pfizer	The firm presented the proposed protocol no. C1071005, amendment:3.0 dated 23-Mar-2022 before the committee. The firm mentioned that India is participating in the part 2 of this trial. The committee noted that there was no increase in number of subjects from India owing to the proposed amendment. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented.
8.	CT/07/19 Online Submission (17390) Rituximab Biosimilar (DRL_RI)	M/s. Parexel	The firm presented the proposed protocol no. RI-01-006, amendment 4, version 5.0 dated 27-Oct-2021 before the committee. The committee noted that there was no increase in number of subjects from India as the trial recruitment completed in 09Mar2022. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented.