Recommendations of the SEC (Oncology & Haematology) made in its 112th meeting held on 08-09-2021 and 09-09-2021 at CDSCO HQ New Delhi.

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/21/000040 Pralsetinib Capsules	M/s Roche	The firm did not turn up for the presentation.
Biological division			
2.	BIO/IMP/18/000001 Durvalumab 120mg/2.4ml and 500mg/10ml	M/s Astrazeneca	The firm presented the proposal for additional dosing regimen of 1500 mg every four weeks of the drug. The committee noted that the additional dosing regimen is already approved in US and EU. After detailed deliberation the committee recommended for grant of approval for additional dosing regimen.
3.	BIO/CT04/FF/2021/23578 Recombinant Human albumin	M/s Shilpa Biologicals Pvt ltd	The firm presented the protocol to conduct Phase-I PK/PD study of the Recombinant Human Albumin product. After detailed deliberation, the committee recommended for the grant of permission to conduct the Phase I Clinical trial as per protocol CBCC/2020/026 version 3.0 dated 05.03.2021 presented.
4.	BIO/IMP/21/000048 Luspatercept	M/s BMS	The firm presented the proposal for grant of marketing authorization of Luspatercept in two strengths 25 mg/vial and 75mg/vial with waiver of local Phase III and Phase IV clinical trial in the country The committee noted that the drug is approved in major ICH countries like USA, EU, Canada etc as an orphan drug After detailed deliberation the committee recommended for grant of marketing authorization subject to the condition that the firm should submit the protocol for Phase IV

			clinical trial in appropriate number of patients within three months of grant of marketing approval.
5.	BIO/CT18/FF/2021/26589 Brentuximab Vedotin	M/s Takeda	The firm presented the proposal for grant of marketing authorization of Brentuximab Vedotin 50 mg with waiver of local Phase III and Phase IV clinical trial in the country. The committee noted that the drug is approved in major ICH countries like USA, UK, Canada, Japan, etc. as an orphan drug 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 appropriate number of patients, Accordingly firm should submit the protocol of Phase IV clinical trial within three months of grant of marketing approval.
6.	4-14/Intas/PAC-R-Bevacizumab/2021-BD(pt-I) Bevacizumab concentrate for infusion 300mg/12ml	M/s Intas Pharmaceuticals Limited	The firm submitted the proposal for the approval of new strength i.e 300 mg/12 ml vial for Bevacizumab. The committee noted that the drug in two strengths 100 mg/4 ml and 400 mg/16 ml is already approved to the firm for marketing and there is no change in the dosage form, qualitative composition and indications for proposed strength. Further the approval has been given for the proposed strength by CDSCO to other firms After detailed deliberation, the committee recommended for grant of approval for additional strength.
7.	BIO/CT04/FF/2021/27265 Pegfilgrastim Injection 6mg/0.6ml	M/s Reliance Life Sciences Pvt. Ltd.	The firm presented proposal for conduct of Phase 1 study (PK, PD, Safety and Immunogenicity) of already approved drug for data generation for overseas country. After detailed deliberation, the committee recommended for grant of permission for conduct of the study as per the proposed protocol.

8.	4-44/MSD/PAC-R-Pembrolizumab/2021-BD Pembrolizumab	M/s MSD Pharmaceuticals Private Limited	The firm presented the proposal for additional indication with respect to head and neck squamous cell carcinoma based on clinical trial results generated in overseas countries. The committee noted that the indication is already approved by US FDA & EU. After detailed deliberation, the committee recommended for grant of approval for the additional indication.
9.	4-44/MSD/PAC-R-Pembrolizumab/2021-BD Pembrolizumab	M/s MSD Pharmaceuticals Private Limited	In-light of the SEC minutes dated 13.07.2021 & 14.07.2021 firm presented the proposal for addition of two new indications with respect to metastatic urothelial and non-small cell lung cancer based on clinical trial results generated in overseas countries. The committee noted that the indication is already approved by US FDA & EU. After detailed deliberation, the committee recommended for grant of additional indication.
SND Division			
10.	SND/IMP/20/000015 Olaparib Film Coated Tablets 100/150 mg	M/s AstraZenca	The firm presented the proposal for non-inclusion of Vascular Thromboembolism (VTE) in Warning & Precaution section in package insert of Olaparib film coated Tablets 100mg & 150mg. After detailed deliberation, the committee did not agree to the request made by firm and recommended that Vascular Thromboembolism (VTE) should be included in 'Warning & Precaution' section in package insert of Olaparib film coated Tablets 100mg & 150mg as justification presented for non-inclusion of the same was not

			adequate.
11.	SND/CT/20/000045 Pegaspargase injection 3750IU/5ml	M/s Gennova Biopharmaceutical	The firm presented the proposal with request to reconsider the proposal for conducting Phase IV Clinical Trial in 100 patients instead of 200 patients for Pegaspargase injection 3750IU/5ml. After detailed deliberation committee did not agree to the request made by the firm and recommended that firm should conduct Phase IV Clinical trial in atleast 200 evaluable patients.
12.	SND/MA/21/000382 Carfilzomib for Injection 10mg/vial	M/s MSN Laboratories	The firm presented their proposal for manufacturing & marketing of Carfilzomib for Injection 10mg/vial (Additional strength). The committee noted that proposed product is already approved in USA, Australia, Canada and Europe After detailed deliberation the committee recommended for grant of permission to manufacture and market Carfilzomib for Injection 10mg/vial (Additional strength).
13.	SND/MA/21/000394 Azacitidine tablets 200mg and 300mg	M/s BDR Pharmaceuticals	The firm presented their proposal for manufacturing & marketing of Azacitidine tablets 200mg with request of BA/BE and CT waiver. The firm presented their proposal along with dissolution profile and BCS data of the applied drug products i.e. Azacitidine Tablets 200mg before the committee. The committee noted that Azacitidine Tablets 300mg is approved in India for the applied indication. After detailed deliberation, the committee recommended for grant

			of permission for manufacture and marketing of Azacitidine Tablets 200 mg for the approved indication.
14.	SND/MA/21/000398 Methotrexate injection 1000mg/10ml	M/s Naprod Life Sciences	The firm presented their proposal for manufacturing & marketing of Methotrexate injection 1000mg/10ml (Additional strength) with request of clinical trial waiver. The committee noted that Methotrexate 100mg/ml injection is approved in United Kingdom. After detailed deliberation the committee recommended for grant of permission to manufacturing and marketing of methotrexate injection 1000mg/10ml for applied indication.
GCT Division			
15.	CT/48/19 Online Submission Avastin®	M/s IQVIA	The firm presented their protocol amendment before the committee. After detailed deliberation committee recommended for the approval of protocol amendment 4.0 26-Feb-2021.
16.	CT/70/21 Online Submission Polatuzumab Vedotin	M/s Roche Products (India) Private Limited	The firm presented their Phase III clinical trial proposal before the committee. **Assessment of risk versus benefit to the patients-** The safety profile of the study drug from preclinical and clinical studies justify the conduct of the trial. **Innovation vis-a-vis existing therapeutic-** Evaluating the safety and efficacy of Polatuzumab Vedotin in combination with Rituximab plus Gemcitabine plus Oxaliplatin (r-gemox) versus r-gemox alone in patients with relapsed/refractory diffuse large B-cell lymphoma. **Unmet medical need in the country-** The test drug to be used in relapsed/refractory diffuse large B-cell lymphoma. After detailed deliberation, the committee recommended for grant of

			permission to conduct the clinical trial study
17.	CT/72/21 Online Submission GRN163L	M/s Parexel	The firm presented their Phase III clinical trial proposal before the committee. **Assessment of risk versus benefit to the patients-** The safety profile of the study drug from preclinical and clinical studies justifies the conduct of the trial. **Innovation vis-a-vis existing therapeutic-** To compare the overall survival of participants, treated with Imetelstat versus BAT, with intermediate-2 or high-risk MF whose disease is refractory to JAK inhibitor treatment. **Unmet medical need in the country-** The test drug to be used as specific inhibitor of telomerase. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial study.