Recommendations of the SEC (Oncology & Haematology) made in its 83th meeting held on 09.04.2019at CDSCO HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
Introductory remarks			
New drugs Division			
1	12-01/18-DC(Pt-07) Ceritinib 150 mg hard gelatin capsule	M/s Novaritis	Firm presented their updated package insert before the committee. After detailed deliberation, committee recommended for approval of the updated package insert.
Subsequent New Drug Division			
2	12-20/09-DC (Pt-Intas) & 12-01/18-DC (Pt-370) Docetaxel lipid suspension for Injection 20mg/80mg/vial	M/s Intas Pharma	Firm didn't turn up for presentation.
3	SND/IMP/19/000001 Carfilzomib sterile lyophilized power for injection (30mg/vial) (add. Strength)	M/s Amgen Technology	The Firm presented their proposal for additional pack size of the drug. After detailed deliberation, committee recommended for grant of permission to import & market the additional pack size of 30mg/vial of the drug.
Global Clinical Trial Division			
4	CT/86/17 MB02-C-02-17	Kendle	Firm presented their proposal for protocol amendment before the committee. After detailed deliberation, committee recommended for approval of the protocol amendment. Dr. CK Bose didn't participate in the deliberation.
5	CT/08/19 Ribociclib + Goserelin Acetate	Novartis	The firm presented their proposal for phase II clinical trial before the committee. The committee however noted that the inclusion & exclusion criteria allow a lot of physician's discretion rather than specific objective patient selection criteria. Endocrine therapy alone or in combination with targeted agents is generally less toxic than chemotherapy & hence it is preferred for patients with hormone positive breast

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			cancer. Chemotherapy is reserved for patients whose cancer is refractory to endocrine therapy or those who have extensive **symptomatic visceral involvement** such as dyspnea, evidence of pulmonary lymphangitic disease or elevated liver function test. Presence of visceral metastasis alone in the absence of these findings is not an indication to proceed with chemotherapy in lieu of a trial of endocrine therapy alone or in combination with targeted therapies (Ref. Cochrane Data Base Systematic Review, 2003 Wilcken N et-al & review in UpToDate (reviewed till March 29/2019) for treatment approach to metastatic hormone positive HER2 negative Breast cancer). After detailed deliberation, in view of the above concerns the committee didn't recommend for approval of the trial in the current form.
6	CT/10/19 Durvalumab	AstraZeneca	The firm presented their proposal for Phase III global clinical trial. After detailed deliberation, committee recommended for grant of permission to conduct the trial.
Biologicals Division			
7	6-5/C-T-Bharat serum /1/14-BD Phase –III Clinical trial study report of Drug Rhoclone® **Monoclonal Anti Rho (D) Immunoglobulin**	M/s Bharat Serums and Vaccines	The firm presented their clinical trial data. The committee noted that the product is already approved and marketed in country. The committee noted the results of the trial.
8	1/Phase IV/Biocad/19-BD Trastuzumab	M/s Biocad India Private Limited	The firm presented their phase IV clinical trial protocol before the committee. After detailed deliberation, committee recommended for grant of permission to conduct the phase IV Clinical trial.
9	4-468/Baxalta/18-BD Human coagulation factor VIII (rDNA), Octocogalfa(advate)	M/s Baxalta Bioscience India Pvt. Ltd	The firm presented the safety efficacy data of the product generated in other countries.

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			After detailed deliberation, committee recommended that the firm should conduct a phase IV Clinical trial in Indian patients.
10	BIO/IMP/18/000001 Durvalumab 120mg and 500mg	M/s AstraZeneca Pharma India Limited	The firm presented their request for waiver of Phase IV clinical trial citing that many global clinical trials is ongoing in which India is one of the participating countries. However the results of these trials are not yet available. After detailed deliberation, committee did not recommend for waiver of Phase IV clinical trial.
11	BIO/CT/18/000047 Pembrolizumab	M/s MSD	Firm presented their proposal for protocol amendment before the committee. After detailed deliberation, committee recommended for approval of the protocol amendment.
12	4-10/Roche/PAC-R-Emicizumab/19-BD Emicizumab	M/s Roche Products (India) Pvt Ltd	Firm presented their proposal for additional indication before the committee. The proposed indication is already approved in many countries including USA, EMA, Japan etc. The indication is a very rare genetic disorder. After detailed deliberation, committee recommended for grant of approval of the proposed indication. Dr. Prantar Chakrabarti did not participate in the deliberation.
13	4-53/Novo Nordisk/PAC-Turoctocog alfa/18BD	M/s Novo Nordisk	The SEC in its meeting dated 18/01/2019 recommended to obtain opinion from Hematologist for the proposal in respect of change of frequency of administration & alteration of administered dose of the drug. After detailed deliberation, committee recommended for approval of the same. Dr. Prantar Chakrabarti did not

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			participate in the deliberation
14	4-08/Novo Nordisk/PAC-Eptacog alfa/19BD Eptacog alfa	M/s Novo Nordisk	The Proposal of modification of the indication of Eptacog alfa was discussed. After discussion, committee recommended for approval of the modification.
BA/BE division			
15	12-09/2019/BA-BE/MIsc-18DC Doxorubicin Hcl Liposomal Injection 20 mg/10 ml(2mg/1ml)	M/s CBCC Global Research LLP	Firm presented their proposal to conduct BA/BE study. After detail deliberation committee recommended for grant of permission to conduct the study.