Recommendations of the SEC (Oncology & Haematology) made in its 86th meeting held on 16.07.2019at CDSCO HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
Introductory remarks			
New drugs Division			
1	12-01/19-DC/PU-016 Ribociclib 200 mg tablet	M/s Sandoz Private Limited	The firm presented their proposal for updating the package insert. After detailed deliberation, committee recommended for approval of the updated package insert of the drug.
2	12-01/19-DC/PU-003 Nintedanib Soft gelatin capsule 100 , 150mg	M/S Boehringer	The firm presented their proposal for updating the package insert. After detailed deliberation, committee recommended for approval of the updated package insert of the drug.
3	F. No. ND/IMP/19/000051 Talazoparib Capsules 0.25 mg and 1mg	M/s. Pfizer Products India Private Limited	The firm presented their proposal for approval of import and marketing of the drug. The committee opined that there is an unmet medical need for this drug for the proposed indication. The drug is already approved in U.S.A and other countries. After detailed deliberation, committee recommended for grant of permission to import and market the drug in India subject to condition that Phase IV clinical trial is required to be conducted in minimum 100 patients, for which the protocol should be submitted within 3 months of the approval of the drug.
4	12-01/18-DC (Pt-07)/PU-001 Trametinib 0.5mg & 2mg	M/s. Novartis Health Care Pvt. Ltd.	The firm presented their proposal for updating the package insert. After detailed deliberation, committee recommended for approval of the updated package insert of the drug.
5	12/01/19-DC/PU-028 Ibrutinib 140mg	M/S Janssen	The firm presented their proposal for updating the package insert. After detailed deliberation, committee recommended for approval of the updated package insert of the drug.
6	12-01/12-DC(Pt-9 Novaritis/Daptomycin Daptomycin powder for concentrate for	M/s. Novartis Health Care Pvt. Ltd.	Committee recommended that the proposal should be deliberated in SEC (Antimicrobial).

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	solution for infusion 350mg/500mg		
Global Clinical Trial Division			
7	CT/48/19 HD204	IQVIA	The firm presented the proposal along with protocol before the committee. **Assessment of risk vs. Benefit to the** patients: The safety profile of the study drugs from preclinical toxicology studies including repeat dose toxicity and Phase clinical study justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic option:** The Purpose of the study is to Compare the Efficacy, Safety, Pharmacokinetics and Immunogenicity of HD204 to Avastin® in patients with Metastatic or Recurrent Non-squamous Non-small Cell Lung Cancer. **Unmet Medical need in the country:** The test drug may potentially provide treatment in patients with Metastatic or Recurrent Non-squamous Non-small Cell Lung Cancer. After detailed deliberation the committee recommended for grant of permission to conduct the study.
8	CT/64/18 Trastuzumab	Fermish	Firm didn't turn up for presentation.
9	CT/49/19 FEIBA	Baxalta	Applicant has presented the proposal along with protocol before the committee. After detailed deliberation the committee recommended for grant of permission to conduct the study subject to condition that the study should be titled as phase III. Accordingly revised protocol should be submitted to CDSCO for approval.
10	CT/08/19 Ribociclib	Novartis	In light of recommendation of previous SEC meeting held on 09/04/2019, the firm presented their justification along with additional guidance document for the investigators. **Assessment of risk versus benefit to the patients**- The safety profile of the study drug from various preclinical toxicology studies including single dose, repeated dose, reproductive toxicity, genotoxicity

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			and clinical studies justify the conduct of the trial. **Innovation vis-a-vis existing therapeutic-** To determine whether treatment with NSAI + goserelin+ ribociclib prolongs PFS compared to treatment with combination chemotherapy in premenopausal or perimenopausal women with HR+, HER2 negative locally advanced or metastatic breast cancer.. **Unmet medical need in the country-** The treatment may be an alternative treatment option in premenopausal or perimenopausal women with HR+, HER2 negative locally advanced or metastatic breast cancer After detailed deliberation, committee recommended for grant of permission to conduct the trial subject to condition that the additional guidance document should be made mandatory for the investigators by implementing the same as mandatory check list for inclusion of the subjects.
Biological Division			
11	BIO/Form44/FF/2019/14022 (BIO/CT/19/000030) Moroctocogalfa	Pfizer Products India Private Limited	The firm presented their Phase IV clinical trial protocol before the committee. After detailed deliberations, the committee recommended for grant of permission to conduct Phase IV clinical trial subject to condition that the word "Pragmatic" should be deleted from the title of the study. The committee noted that the as per the marketing permission, the Phase IV clinical trial should have been completed within 2 years. However the firm is yet to initiate the study. Now that the protocol is approved, the firm should proactively complete the study and submit the final results within 2 years from the date of approval of the drug, otherwise, it should be viewed as non-compliance to the conditions of the permission.
12	4-406/Hetero/17-BD Trastuzumab	Hetero	The firm presented the proposed changes in the approved Phase III clinical trial protocol. After detailed deliberation, the committee recommended for the proposed changes. Dr. C.K. Bose did not participate in the deliberation.

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13	4-BIO/IMP/18/000006 Inotuzumab ozogamicin	Pfizer	The firm presented their request for waiver of Phase IV clinical trial. After detailed deliberation, the committee however did not agree for waiver of Phase IV clinical trial. The committee reiterated that as per earlier condition the firm should complete the study within the timelines of 2 years of approval of the drug otherwise, it should be viewed as non-compliance to the conditions of the permission.
14	4-30/Roche/PAC-R-Atezolizumab/19-BD Atezolizumab	M/s Roche	The firm presented their request for approval of 2 additional indications based on clinical data generated in other countries. After detailed deliberations, the committee recommended for grant of approval for addition of 2 indications.
15	4-394/Roche/16-BD Atezolizumab	M/s Roche	The firm presented their request for changes in the DHPC. After detailed deliberations, the committee noted the same.

S.No	SEC –Experts Name & Designation	Signature
1.	Dr. Sanjay Kumar Singh, Associate Professor, Gajara Raja Medical College, Gwalior, M.P	
2.	Dr. Sameer Bakshi, Professor, Dept. of Medical Oncology, AIIMS, New Delhi	
3.	Dr. C K Bose, Assistant Professor, Netaji SubhashChander Bose Cancer Research Institute, Kolkata	
4.	Dr. Renu Saxena, Prof. & Head, Dept. Of Haematology, AIIMS, Ansari Nagar Delhi	
5.	Dr. Lalit Kumar Gupta, Professor, Dept. of Pharmacology, Lady Hardinge Medical College, Delhi.	
6.	Dr. H. P. Pati, Prof., Dept. Of Haematology, AIIMS, Ansari Nagar Delhi	