Recommendations of the SEC (Antimicrobial & Antiviral) made in its 56th meetingheld on 25.04.2019 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
Introductory remarks			
GCT Division			
1	CT/20/19 Sulbactam	Medpace	The firm presented the proposal for the phase III clinical trial. The committee noted that the preclinical data is not properly compiled & the trial design is not as per the hypothesis. The committee recommended that fresh presentation incorporating all the above observation may be submitted for further review.
SND Division			
2	SND/MA/18/000025 Posaconazole DR tablet 100mg (Additional strength & Dosage form)	M/s Hetero Labs Ltd	Firm presented their proposal for BA/BE study and CT waiver. Drug is already approved in USA and EU in 2013. After detailed deliberation, the committee recommended for grant of permission to conduct BA/BE study as per the protocol submitted. CT waiver will be considered after reviewing the BA/BE study result.
New Drug Division			
3	ND/IMP/18/000043 Hydrogen Peroxide 0.5% spray	M/s Diversey	Firm presented the safety & efficacy data of Oxivir-1 (Hydrogen Peroxide 0.5% Spray) before the committee. The product is already approved by USFDA for similar indication. Hydrogen peroxide is already approved by CDSCO in various concentration/formulation. The committee after detailed deliberation recommended for grant of permission to import and market the said product.
4	F. No. ND/IMP/19/000002 Isavuconazole 200 mg powder for concentrate for solution for infusion	M/s.Pfizer Products India Private Limited	The firm presented their proposal for import and marketing of Isavuconazole 200 mg powder for concentrate for solution for infusion for treatment of invasive aspergillosis and invasive mucormycosis. Detailed non-clinical, clinical data including data from Global Clinical trial in which India was one of the participating countries was presented. The Committee opined that invasive aspergillosis and invasive mucormycosis are life threatening rare conditions and there is

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			unmet medical need for this indication. Although only 5 patients from India participated in the Global Clinical Trial, the overall non-clinical and clinical data of the drug provides evidence in support of use of the drug for the above indications in Indian patients. The drug is approved in many countries including US, EU, Switzerland, Canada etc. After detailed deliberation, the committee recommended for grant of permission to import and market the drug subject to condition that the firm should conduct active PMS on at least 50 patients of confirmed cases of invasive aspergillosis and 20 patients of confirmed cases of invasive mucormycosis for which protocol should be submitted within 3 months of approval of the drug. Active PMS should be completed within 2 years of approval of the PMS.
5	F. No. ND/IMP/19/000001 Isavuconazole 100 mg capsule	M/s.Pfizer Products India Private Limited	The firm presented their proposal for import and marketing of Isavuconazole 200 mg powder for concentrate for solution for infusion for treatment of invasive aspergillosis and invasive mucormycosis. Detailed non-clinical, clinical data including data from Global Clinical trial in which India was one of the participating countries was presented. The Committee opined that invasive aspergillosis and invasive mucormycosis are life threatening rare conditions and there is unmet medical need for this indication. Although only 5 patients from India participated in the Global Clinical Trial, the overall non-clinical and clinical data of the drug provides evidence in support of use of the drug for the above indications in Indian patients. The drug is approved in many countries including US, EU, Switzerland, Canada etc. After detailed deliberation, the committee recommended for grant of permission to import and market the drug subject to condition that the firm should conduct active PMS on at least 50 patients of confirmed cases of invasive aspergillosis and 20 patients of confirmed cases of invasive

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6	CDSCO F. No. ND/MA/18/000032 Tafenoquine Tablets 150mg	M/s. GlaxoSmithKline Pharmaceuticals Ltd.	The firm presented their proposal alongwith clinical trial data generated through global clinical trial including Phase 2b trial in which India was one of the participating country. The proposal is for manufacture and marketing of Tafenoquine Tablets 150mg for the radical cure (prevention of relapse) of P. vivax. Tafenoquine is a long acting 8-aminoquinoline, synthetic analogue of Primaquine with half life of approx. 15 days. In phase 2b trial 57 Indian patients were involved. The drug is approved in USA and Australia. While Tafenoquine has advantage of only single administration for radical cure as compare to 14 days treatment in case of Primaquine. However both Tafenoquine and Primaquine reported to cause hemolytic aneamia in G6PD deficient patients and G6PD test is recommended. Tafenoquine has a disadvantage in case use of inadvertent use of the drug in G6PD deficient patients, as with single dose administration, the effect of the drug will remain in the body for considerable period of days. After detailed deliberation, the committee considering both the advantages and disadvantages recommended that the firm should submit the detailed strategy/modalities that should be followed to address the above concerns for further review the proposal including the requirement of clinical trial. CDSCO should also take opinion of NVBDCP on the proposal.
7	12-21/18-DC FDC of Bictegravir Emtricitabine & Tenofovir alafenamide	M/s Hetro	After detailed deliberation, the committee recommended for status quo to be maintained with reference to minutes of meeting held on 16.01.2019.

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	50mg/200mg/25mg		
Medical Device Division			
8	IMP/MD/2018/8118 Silhouette Soft Suture	M/s Morulaa Health Tech Pvt. Ltd.Chennai	Firm didn't turn up for presentation.
FDC Division			
9	FDC/MA/18/000029 Ceftriaxone Sodium 2gm + Sulbactam Sodium 2gm injection	M/s. Aristo Pharmaceuticals	The firm made a detailed presentation before the committee. The firm presented *in vitro* study data which was published in 1990 and may not be relevant in current scenario. Firm also did not present any proof of concept to prove the hypothesis for the proposed additional higher strength. Hence, the committee recommended that the firm should first generate data to support the proposed hypothesis and submit the same for further consideration of Clinical Study for the FDC.
10	04-58/2018-DC	M/s. B. Braun Medical India Pvt. Ltd.	The firm made a presentation before the committee. Committee recommended that firm shall present justification for the proposed formulation along with standard treatment guidelines for the total parenteral Nutrition for which the formulation is indicated.
11	FDC/MA/19/000021 Pyridoxine Hydrochloride + Myo-Inositol + Chromium Polynicotinate + Folic acid + Benfotiamine + Methylcobalamin (3mg+100mg+200mg+1.500 mg+200mg+1500mcg) Tablets	M/s. Stanford Laboratories Pvt. Ltd.	Firm didn't turn up for presentation.