Recommendations of the SEC (Antimicrobial & Antiviral) made in its 65th meeting held on 28.01.2020 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1	ND/MA/19/000074 Efinaconazole (Topical solution 10% w/w)	M/s Oxalis Labs	The firm presented their proposal for manufacture and marketing permission for the product with local clinical trial waiver. After detailed deliberation, the committee recommended that the firm should conduct a Phase III clinical trial to assess the safety, efficacy of the drug in Indian scenario for which the firm should submit protocol etc. The protocol should be deliberated in the SEC (Dermatology).
2	ND/IMP/18/000092 Baloxavir Marboxil Tablets 20 mg/40mg	M/s. Roche Product (India)Private Limited	. The firm didn't turn up for presentation.
3	12-01/19-DC (Pt-211) Sofosbuvir +Velpatasvir	M/s. YRGCARE, Chennai	The proposal was discussed in the SEC **(**Antimicrobial & Antiviral**)** meeting held on 19-11-2019 and approved the protocol and directed the applicant to submit the IEC approval. The applicant has submitted the same.
4	NA/MA/19/000041 Pretomanid Tablets 200mg	M/s. Mylan Laboratories Ltd.	In light of recommendation committee date 19.09.2019, the firm presented their proposal for manufacture and marketing permission for the product with local clinical trial waiver with their justification. Committee noted that there is unmet need for the drug in patient with XDR TB. The use of Pretomanid in combination with Bedaquiline and Linezolid is reported to be advantageous in respect of reduction of duration of treatment from 20 month to 6 month. However, the drug should be used under restricted condition to prevent its misuse and development of resistance etc. After detailed deliberation committee recommended for grant of permission manufacture the drug to be used only as Conditional Access under National TB Elimination Programme (NTEP) subject

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			to condition that Phase IV CT should be conducted under the Programme.
Subsequent New Drugs Division			
5	12-118/2015-DC(Pt-Thinq-SND) Clotrimazole Troche/Lozenges 16mg	M/s. Unique Pharma	The firm didn't turn up for presentation.
FDC Division			
6	FDC/MA/19/000116 Dolutegravir Sodium eq. to Dolutegravir 50 mg eq. to 52.60 mg of Dolutegravir sodium + Emtricitabine 200 mg + Tenofovir Alafenamide 25 mg eq. to 28.043 mg of Tenofovir Alfamenamide hemifumarate film coated tablets 245mg film coated tablets	M/s. Hetero Labs	The firm presented their proposal alongwith the BE study report before the Committee. The Committee also noted that the proposed FDC is already approved with Tenofovir Alfamenamide Fumarate. The firm presented that, Tenofovir Alfamenamide Fumarate and Tenofovir Alfamenamide Hemifumarate are chemically same and having two different name in EU and USA. After detailed deliberation, the Committee recommended for grant of permission to manufacture and market the proposed FDC.
GCT Division			
7	CT/27/18 KAF156+Lumefentrine	M/s. Novartis	The firm didn't turn up for the presentation.
8	CT/91/19 Bedaquiline + Delamanid	M/s. Doctors without Borders	Applicant presented their proposal along with study protocol for Phase III clinical trial before the committee. After detailed deliberation the committee recommended for grant of permission to conduct the study subject to condition that the investigators should be provided by the applicant guidelines on treatment failure and withdrawal criteria.
09	CT/94/19 Bedaquiline + Delamanid	M/s. Doctors without Borders	Applicant presented their proposal along with study protocol for Phase III clinical trial before the committee. After detailed deliberation the committee recommended for grant of permission to conduct the study subject to condition that the investigators should be provided by the applicant guidelines on treatment failure and withdrawal criteria.
10	CT/97/19 Tosatoxumab	M/s. Pharm-Olam	Applicant presented their proposal along with study protocol before the committee.

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			Assessment of risk versus benefit to the patients- The safety profile of the study drug from various preclinical toxicology studies and clinical studies justify the conduct of the trial. **Innovation vis-a-vis existing therapeutic-** To evaluating the study of efficacy and safety of AR-301 as adjunct therapy to antibiotics in the treatment of Ventilator-Associated Pneumonia (VAP) caused by S. aureus. **Unmet medical need in the country-** To develop safe and efficacious treatment of Ventilator-Associated Pneumonia (VAP) caused by S. aureus After detailed deliberation the committee recommended for grant of permission to conduct the study.
11	CT/34/18 5-aminolevulinic acid hydrochloride (5-ALA-HCl) and sodium Ferrous Citrate (SFC)	M/s. Clinsync Clincal Research	The applicant presented their protocol amendment Version 3.0 before the committee. The applicant also brought to notice that IEC suggested "to initiate the trial with two arms (In one arm Standard treatment and 2nd arm 600mg 5ALA+472 SFC mg/day) in first 10 patients in each out of 35 proposed. If more than two participants are non-responders to trial drug then results should presented to Ethics committee to take decision on continuation." The applicant has presented the data of 2nd arm where drug was shown to be non-effective. This data has still not be presented to IEC. Accordingly, the proposed protocol amendment version 3.0 dated 26-Dec-2019 is not considered in present form.
BA/BE Division			
12	12-09/2019/BA-BE/Misc-60/DC Flucytosine Granules 3000 mg	M/s. Macleods Pharmaceuticals Ltd.	The firm presented their proposal of BE study for Flucytosine Granules 3000 mg before the committee. After detailed deliberation, committee recommended for grant of permission to conduct the BE study for export purpose only.