Recommendations of the SEC (Antimicrobial & Antiviral) made in its 110th meeting held on 23.03.2022 & 24.03. 2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	12-01/19-DC(Pt.337) Itraconozole	SRP, IPC	The SRP recommendation was deliberated by the committee. After detailed deliberation, the committee recommended that CDSCO should communicate the State Drugs Controllers to direct the manufacturers of the drug Itraconozole to include AGEP as a potential signal in the drug PIL.
2.	ND/CT/19/000019 Dalbavancin Injection	M/s. Gufic	The firm has presented protocol amendment version 2.0 dated 15-Feb-2022 before the committee. After detailed deliberation, the committee recommended for the approval of proposed protocol amendment.
3.	ND/MA/21/000029 Inosine Pranobex	M/s. Themis Medicare Ltd	The firm presented the proposal along with justification of local clinical trial waiver for additional indication: Mucocutaneous infections due to herpes simplex virus (type 1 and/or type II), Genital warts as adjunctive therapy to podophyllin or carbon dioxide laser, Subacute sclerosingpanencephalitis, Influenza and other acute respiratory viral infections along with request to conduct Phase IV/PMS study before the committee. The committee noted that the drug already approved for restricted emergency use for Covid-19 in the country and also the justification submitted by the firm was adequate as per the requirements. In view of above, the committee recommended for grant of permission to manufacture & market of the drug for the indication as above subject to condition that, the firm should conduct Phase IV clinical trial for which protocol should be submitted to CDSCO within 3 month of the approval of the drug for further review by the committee.
4.	ND/IMP/21/000100	M/s. Water Freedom	In light of earlier SEC recommendation dated 23.02.2022 & 24.02.2022, the firm

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	Polyhexamethylene guanidine Hydrochloride 1.000 Ltr. (Uniko Next)	Revolution Industries Private Limited	made presentation on safety and efficacy of the product before the committee. After detailed deliberation, the committee recommended for grant of permission to import and market of product Polyhexamethylene guanidine Hydrochloride 1.000 Ltr. (Uniko Next) in the country subject to condition that the firm should submit do's and don'ts, advisory & leaflet before marketing of the proposed product.
5.	12-01/18-DC (Pt-32) Delamanid	Dr. ArunKowale B J Medical College	The proposal is deferred for next meeting as expert from TB Division could not participate in the meeting.
SND Division			
6.	SND/IMP/21/000060 Liposomal Amphotericin B Injection 50mg/ml (lyophilized)	M/s. Mylan Pharmaceuticals	In light of recommendations of the earlier committee meeting held on 23.09.2021 the firm presented the supporting data before the committee for approval of the proposed additional indications. After detailed deliberation, the committee recommended for grant of permission for import and marketing of Liposomal Amphotericin B Injection 50mg/ml (lyophilized) for the therapeutic indications which was already approved for the conventional Amphotericin B injection and the indications are as follows: • Febrile Neutropenia in cancer patients. • For the treatment of invasive fungal infection in patients who are refractory to or intolerant of conventional amphotericin-B therapy. • For the treatment of visceral leishmaniasis.
7.	SND/MA/21/000368 Pidotimod oral liquid 400/800mg &Pidotimod Tablets 400/800mg	M/s. Wockhardt Limited	The firm didn't turn up for presentation.
8.	SND/MA/21/000412 Faropenem sodium for oral suspension	M/s. Alkem Laboratories	In light of earlier SEC recommendation dated 23.02.2022 & 24.02.2022, the firm presented their justification along with request for waiver of Phase III clinical

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	100mg/5ml		trial. After detailed deliberation, the committee recommended for grant of approval for the amendment in the indication sproposed by the firm as follow: "For the treatment of superficial and deep skin infections like chronic pyoderma, pharyngitis/laryngitis and ENT infections like otitis media, tonsillitis, Sinusitis, acute tracheo-bronchitis, Bacterial pneumonia, UTIs like cystitis, pyelonephritis, lymphangitis/lymphadenitis, teeth periodontitis, scarlet fever and whooping cough in pediatric age group of two years and above**.**
9.	SND/CT/22/000008 Fosfomycin Trometamol Powder 3 gm	M/s. Clinexel Life Science	The firm presented the Phase III clinical trial protocol of Fosfomycin Trometamol Powder 3 gm versus ciprofloxacin tablets 750mg in patients with chronic bacterial prostatis before the committee for approval. After detailed deliberation, the committee recommended for grant of permission for conduct of the Phase III clinical trial study of Fosfomycin Trometamol Powder 3 gm as per the protocol presented.
10.	SND/MA/21/0000556 Feropenem Sodium Hyydrate Extended Release Tablets 300mg	M/s. Sun Pharma	The firm didn't turn up for presentation.
11.	SND/MA/ 21/000501 Biapenem 300mg injection	M/s. BDR Pharma	In light of recommendations of the earlier committee meeting held on 26.11.2021, the firm presented their justification requesting the Phase III clinical trial waiver for Biapenem 300mg injection. After detailed deliberation, the committee reiterated its earlier recommendation that "the firm should conduct the Phase III clinical trial for the proposed additional indication. Accordingly, the firm should submit the Phase III clinical trial protocol for review by the committee.
FDC Division			

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12.	FDC/MA/22/000031 TenofovirAlafenamide Fumarate 28 mg eq to TenofovirAlafenamide 25 mg+Lamivudine 300mg+Dolutegravir Sodium 52.8mg eq to Dolutegravir 50mg tablets	M/s. Laurus	The firm presented their proposal along with results of BE study conducted for export purpose before the committee. The committee noted that the firm has already received tentative approval from USFDA for proposed FDC. The committee also noted that FDC of Dolutegravir 50mg + Lamivudine IP 300mg + TenofovirDisoproxil 245 mg was approved by CDSCO on 08.03.2018. After detailed deliberation, the committee recommended for grant of permission for manufacture and market the proposed the FDC.
13.	FDC/MA/22/000037 Ritonavir 50mg +Atazanavir sulfate 150mg tablets	M/s. Laurus	The firm presented their proposal along with results of BE study conducted for export purpose before the committee. The committee noted that the product is approved in capsule dosage by CDSCO. After detailed deliberation, the committee recommended that the firm should conduct Bioequivalence study in comparison with approved product. Accordingly, the firm should submit the bioequivalence study protocol for review by the committee.
14.	FDC/IMP/22/000004 Alkyl Dimethyl Benzyl Ammonium Chloride 0.260% w/w/26%w/w+ Pyridine-2-thiol 1-oxide, sodium salt 0.250% w/w/2.5%w/w surface Disinfectant Solution	M/s. Darwin Platform Pharmaceuticals Ltd.	The firm presented their proposal before the committee. The committee noted that the proposed FDC is already approved in Germany, Canada, UK etc., After detailed deliberation, the committee recommended for grant of permission for import and marketing of the FDC for surface cleaning and disinfectant.
GCT Division			
15.	CT/33/20 Gepotidacin	M/s. PPD	The firm presented their proposal for proposed protocol amendment for protocol no 212390, amendment 3.0 dated 03-Nov-2021. After detailed deliberation, the committee recommended for approval of proposed protocol amendment.

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16.	CT/80/19 Gepotidacin	M/s. PPD	The firm presented their proposal for proposed protocol amendment for protocol no 204989, protocol amendment version 2.0 dated 03-Nov-2021. After detailed deliberation, the committee recommended for approval of proposed protocol amendment.
Medical Device Division			
17.	IMP/MD/2021/42702 Disinfevtant wipes for surfaces, non-immersible and non-invasive medical devices (WIP'ANIOS EXCEL)	M/s. Ecolab Food Safety & Hygiene Solutions Pvt Ltd.	The firm presented their proposal before the committee. After detailed deliberation, the committee recommended for grant of import & market permission of the proposed product in the country.
18.	IMP/MD/2021/39938 Aniospray Quick, Aniosyme Prime	M/s. Ecolab Food Safety & Hygiene Solutions Pvt Ltd.	The firm didn't turn up for presentation.