Recommendations of the SEC (Antimicrobial & Antiviral) made in its 109th meeting held on 23.02.2022 & 24.02.2022 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/21/000200 Squaric Acid 1.745 mg/m	M/s. Vital Therapeutics & Formulations Pvt. Ltd	In light of earlier SEC recommendation dated 2102.2022, the firm presented their proposal before the committee. During presentation, the firm has informed that the proposed product does not have any antiviral activity. The committee noted that the firm has not submitted the following: 1. Clear intended indication for the proposed product for manufacture and marketing. 2. Micro-efficacy data supporting intended use/indication in human as well as surfaces. 3. Data on Human/animal/environmental hazard. 4. Toxicological profile/eco-toxicological profile data. 5. Adequate data on human safety with respect to respiratory tract and mucosa. 6. Material safety data sheet. 7. Do's and don'ts, advisory & leaflet for use of the proposed product. In view of above, the committee recommended that the firm should submit above information/documents and also the firm should submit the proposal for conduct of the efficacy study for their proposed claim to CDSCO for further review by the committee.
2.	ND/MA/21/000201 SQUARIC ACID 0.748 mg/m	M/s. Vital Therapeutics & Formulations Pvt. Ltd	In light of earlier SEC recommendation dated 21.02.2022, the firm presented their proposal before the committee. During presentation, the firm has

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			informed that the proposed product does not have any antiviral activity. The committee noted that the firm has not submitted the following: 1. Clear intended indication for the proposed product for manufacture and marketing. 2. Micro-efficacy data supporting intended use/indication in humans as well as on surfaces. 3. Data on Human/animal/environmental hazard. 4. Toxicological profile/eco-toxicological profile data. 5. Adequate data on human safety with respect to respiratory tract and mucosa. 6. Material safety data sheet. 7. Do's and don'ts, advisory & leaflet for use of the proposed product. In view of above, the committee recommended that the firm should submit above Information/documents and also the firm should submit the proposal for conduct of the efficacy study for their proposed claim to CDSCO for further review by the committee.
3.	ND/IMP/21/000100 Polyhexamethylene Guanidine HCl 1.000 Ltr. (UnikoNext)	M/s Water freedom revolution Industries Pvt. Ltd.	In light of earlier SEC recommendation dated 21.02.2022, the firm presented their proposal before the committee. After detailed deliberation, the committee recommended that the firm should submit and present the detailed data on safety and efficacy of the product including data/information in light of the issue of carcinogenicity of the ingredient for further consideration.
SND Division			
4.	SND/IMP/21/000096 Benzalkonium	M/s. Sunmed	The firm presented the proposal before the committee for Benzalkonium chloride

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	chloride 0.13% Hand Sanitizer		0.13% hand sanitizer indicated for "Hand protectant and sanitizer for external use, effective upto 24 hours". The committee noted that the product is already approved in US, UK& EU. After detailed deliberation, the committee recommended for grant of permission to import and market the said product for the proposed indication.
5.	SND/MA/21/000412 Faropenem Sodium for Oral suspension 100mg/5ml	M/s. Alkem Laboratories	The firm presented the proposal for amendment in indication for the product Faropenem Sodium for oral suspension 100mg/5ml in pediatric age group of two years and above before the committee. After detailed deliberation, the committee opined that the firm should conduct clinical trial in Paediatric patients to generate more data in support of safety & efficacy in Indian children. Accordingly, the firm should submit Phase III clinical trial protocol for further review by the committee.
6.	SND/CT/21/000105 Liposomal tericin B Injection ıl (lyophilized)	M/s. Synapse Labs Pvt. Limited	The firm presented the Active Post Marketing Surveillance protocol for Liposomal Amphotericin B Injection 50mg/ml (lyophilized) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Active Post Marketing Surveillance for Liposomal Amphotericin B Injection 50mg/ml (lyophilized) and submit the report for review by the committee.
7.	SND/MA/22/000015 Povidone Iodine Nasal Solution 0.5% w/v	M/s. G. S. Pharma	In light of earlier recommendations of the SEC, the firm presented the proposal with justification for clinical trial waiver before the committee. After detailed deliberation, the committee opined that the firm should conduct a clinical trial for the proposed indication and should submit the clinical trial protocol for further review by the committee.
8.	SND/MA/21/000521 Rifapentine Tablets	M/s. Lupin Limited	The firm presented the proposal for manufacturing and marketing of

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	300mg		Rifapentine Tablets 300mg (Additional strength) along with BE study report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Rifapentine Tablets 300mg for already approved indication i.e. "For the treatment of latent tuberculosis infection caused by Mycobacterium tuberculosis in adults and children 2 years and older who are at high risk of progression to tuberculosis disease (including those in close contact with active tuberculosis patients, recent conversion to a positive tuberculin skin test, HIV-infected patients, or those with pulmonary fibrosis on radiograph). Active tuberculosis disease should be ruled out before initiating treatment for latent tuberculosis infection. Rifapentine Tablets 150mg must always be used in combination with isoniazid as a 12- week once-weekly regimen for the treatment of latent tuberculosis infection".
9.	SND/IMP/22/000002 Dichloroisocynaurate /Sodium Troclosene/NaDCC Tablets 0.5 gm /2.5gm/5.0 gm	M/s. Advanced Sterilization	The firm presented the proposal of Dichloroisocynaurate /Sodium Troclosene/NaDCC Tablets 0.5 gm /2.5gm/5.0 gm indicated for cleaning of work surfaces, cleaning of Hospital Surfaces with justification. After detailed deliberation, the committee recommended for grant of permission to import and market of the said products for proposed indication.
FDC Division			
10.	FDC/MA/20/000144 Lamivudine USP 300mg + Dolutegravir (As Dolutegravir sodium) 50mg film coated tablets	M/s. Emcure Pharmaceuticals	In light of the earlier SEC recommendation, the firm presented their proposal before the committee requesting for Phase IV clinical trial waiver. The firm presented various international studies on the FDC and also informed that that this use of the FDC is also recommended in WHO 2021 guidelines before the committee. The committee noted that the FDC of Dolutegravir + Lamivudine + Abacavir is already approved. Also, it was noted that

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			as part of the manufacturing and marketing permission the first PSUR of the FDC is likely to be submitted. After detailed deliberation, the committee recommended that the firm should present its first PSUR data on the FDC before committee for further consideration.
GCT Division			
11.	CT/163/21 Online Submission (29370) AT-752 (250 mg tabs)	M/s. PPD	The firm presented the proposed Phase II clinical trial protocol no**: AT-02A-002, Version 1.0 dated 20-SEP-2021 and Protocol Clarification Memo dt. 21-OCT-2021, dt. 12-NOV-2021 and 18-NOV-2021 with IP-AT752.** **Risk-Benefit Assessment:** To date submitted information, non-clinical and clinical safety studies have not revealed a definitive pattern of drug-attributable clinical adverse effects or consistent clinically significant laboratory abnormalities related to any body system. Treatment emergent adverse events in the ongoing first-in human study have been non-serious, mild to moderate in severity, and generally self-limiting. **Innovation Vs Existing Therapy:** The primary objective of this proposed study is to investigate the antiviral activity of AT-752 versus placebo in terms of reduction of DENV RNA from baseline in adult subjects with confirmed DENV infection. **Unmet Need:** As on date there is no effective therapeutics for dengue, and treatment options are limited to supportive care. A safe and effective antiviral therapy that targets all DENV serotypes is of unmet medical need. After detailed deliberation, the committee noted that present study proposes to include only the mild and moderate dengue subjects. The committee recommended for grant of permission for conduct of the proposed clinical trial subject to following conditions : **1)** The independent Safety Review Committee (SRC) should review the unblinded study data after each study cohort for safety, utility and guidance for further continuation of study. **2)** The firm should submit the study safety data along with SRC report of Cohort 1 to CDSCO after completion of Ist dose cohort. The report should be presented before the Committee for proceeding to

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			the next study Cohort 2 and Cohort 3 in the Country. **3)** Standard of care should be provided to study participants in each study arm. (Dr. Rachana Giri did not participate in the deliberation)
12.	CT/44/18 Online Submission (15733) Cefepime-Tazobactam	M/s. Wockhardt	The firm presented the proposed protocol amendment to protocol no.: W-4282-301, Amendment-3 dated 28-Oct-2021. After detailed deliberation, the committee recommended for grant of permission for the proposed protocol amendment.
Medical Device Division			
13.	IMP/MD/2021/42818 High-level disinfectant for thermo sensitive instruments and endoscopy equipment (ANIOXYDE 1000 LD)	M/s. Ecolab Food Safety and Hygiene Solutions Private Limited	In light of the earlier SEC recommendation dated 21.01.2022, the firm presented their proposal before the committee. After detailed deliberation, the committee recommended that the firm needs to submit the published data in peer reviewed journal to show the adequate activity of the product over the time in clinical settings for further review by the committee.
14.	CI/MD/2021/43252 AM-301 (Nasal Spray) Permission for Pivotal clinical Investigation	M/s. Ecron Acunova Limited	The firm presented their protocol before the committee. After detailed deliberation, the committee recommended that the firm should submit adequate supportive data, animal study data of the proposed product for clinical investigation for further review by the committee.