

Recommendations of the SEC (Antimicrobial & Antiviral) made in its 114th meeting held on 25.05.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	Itraconazole associated AGEP	SRP-NCC-PvPI	<p>The recommendation of the SRP was deliberated on the committee.</p> <p>After detailed deliberation, the committee recommended that CDSCO should request the State Drug Controllers to direct the manufacturers to include Itraconazole associated Acute Generalized Exanthematous Pustulosis (AGEP) as adverse effect in the corresponding PIL of the drug.</p>
SND Division			
2.	SND/MA/21/000023 Liposomal Amphotericin B 50mg/vial for injection	M/s. Gufic Biosciences	<p>The firm presented the protocol for active post marketing surveillance of Liposomal Amphotericin B injection 50mg.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the active post marketing surveillance as per protocol presented.</p>
FDC Division			
3.	FDC/MA/21/000232 Tinidazole 100mg +Norfloxacin 100mg suspension	M/s. Rivpra Formulation Pvt. Ltd	<p>The firm presented the BE & Phase III CT protocol before the committee.</p> <p>After detailed deliberation, the committee opined that :</p> <ol style="list-style-type: none"> 1. The product is not approved internationally. 2. It may lead or develop antibiotic drug resistance. 3. There is no scientific literature available from good indexed journal/peer reviewed journal in support of proposed FDC. 4. There is no unmet need of proposed FDC. <p>In view of above, the committee did not recommend for approval of the proposed FDC.</p>
Medical Device Division			
4.	CI/MD/2021/43252 AM-301 (Nasal	M/s. Ecron Acunova Limited	In light of earlier SEC recommendation dated 24.02.2022, the firm presented their proposal before the committee.

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	Spray) Permission for Pivotal clinical Investigation		After detailed deliberation, the committee recommended for the grant of permission to conduct the pivotal clinical investigation with the proposed device (AM-301) on Indian population.