**Recommendations of the SEC (Antimicrobial & Antiviral) made in its 107th meeting held on 23.12.2021 at CDSCO HQ, New Delhi:**

| S.No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| **New Drugs Division** | | | |
| 1. | 12-01/19-DC(Pt-337) Itraconazole | SRP-PvPI | The recommendation of the SRP-PvPI was apprised to the committee.<br><br>After detailed deliberation, the committee recommended that CDSCO may request State Drugs Controllers to direct the manufacturers of the drug to incorporate drug associated Photosensitivity in the package insert of the drug. |
| 2. | 12-01/19-DC(Pt-337) Amoxicillin/Clavulanate Potassium | SRP-PvPI | The recommendation of the SRP-PvPI was apprised to the committee.<br><br>After detailed deliberation, the committee recommended that CDSCO may request State Drugs Controllers to direct the manufacturers of the drug to incorporate drug associated Stevens-Johnson Syndrome (SJS) / Toxic Epidermal Necrolysis (TEN) in the package insert of the drug. |
| 3. | 12-01/19-DC(Pt-337) Ciprofloxacin | SRP-PvPI | The recommendation of the SRP-PvPI was apprised to the committee.<br><br>After detailed deliberation, the committee recommended that CDSCO may request State Drugs Controllers to direct the manufacturers of the drug to incorporate drug associated Stevens-Johnson Syndrome (SJS) / Toxic Epidermal Necrolysis (TEN) in the package insert of the drug. |
| 4. | 12-01/19-DC(Pt-337) Ceftriaxone | SRP-PvPI | The recommendation of the SRP-PvPI was apprised to the committee.<br><br>After detailed deliberation, the committee recommended that CDSCO may request State Drugs Controllers to direct the manufacturers of the drug to incorporate drug associated Stevens-Johnson Syndrome (SJS) in the package insert of the drug. |
| 5. | 12-01/19-DC(Pt-337) Azithromycin | SRP-PvPI | The recommendation of the SRP-PvPI was apprised to the committee.<br><br>After detailed deliberation, the committee recommended that CDSCO may request State Drugs Controllers to direct the manufacturers of the drug to incorporate drug associated Acute Generalized Exanthematous Pustulosis (AGEP) in the package insert of the drug. |

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| 6. | 12-01/19-DC(Pt-337) Cloxacillin | SRP-PvPI | The recommendation of the SRP-PvPI was apprised to the committee.<br><br>After detailed deliberation, the committee recommended that CDSCO may request State Drugs Controllers to direct the manufacturers of the drug to incorporate drug associated Acute Generalized Exanthematous Pustulosis (AGEP) in the package insert of the drug. |
| 7. | 12-01/19-DC (Pt-337) Doxycycline | SRP-PvPI | The recommendation of the SRP-PvPI was apprised to the committee.<br><br>After detailed deliberation, the committee recommended that CDSCO may request State Drugs Controllers to direct the manufacturers of the drug to incorporate drug associated Fixed Drug Eruption (FDE) in the package insert of the drug. |
| 8. | 12-01/19-DC (Pt-337) Tinidazole | SRP-PvPI | The recommendation of the SRP-PvPI was apprised to the committee.<br><br>After detailed deliberation, the committee recommended that CDSCO may request State Drugs Controllers to direct the manufacturers of the drug to incorporate drug associated Fixed Drug Eruption (FDE) in the package insert of the drug. |
| 9. | 12-01/19-DC(Pt-252) Phytopharmaceutical Herbal microbicide | M/s. HLL life care | In light of earlier recommendation dated 27.10.21, the firm presented their proposal along with Phase I clinical trial protocol before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct proposed Phase I clinical trial as per the protocol presented subject to the following condition:<br>1. Dose ranging studies for safety and pharmacokinetics should be conducted at 3 dose levels.<br>2. The firm should include assay for change in vaginal flora in the study design<br>3. The firm should prepare questionnaire for adverse events monitoring.<br>4. The firm should constitute DSMB and submit the report to CDSCO. |
| 10. | ND/CT04 FF 2021/29273<br><br>Colloidal Nano Silver Gel (Silver Sol®) | M/s. Biosphere Clinical Research Pvt.Ltd | The firm presented their proposal to conduct Phase II clinical trial before the committee.<br><br>After detailed deliberation, the committee recommended that the firm should submit the |

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| | | | following data along with the proposal for conduct of Phase I clinical trial to CDSCO for further review:<br>1) Approval status of the drug for the proposed indication and route of administration in other countries.<br>2) Evidence with respect to local and systemic reaction, PK-PD, bioavailability, adverse reaction etc.<br>3) Rationale for proposed indication of drug against bacterial vaginosis, vulvovaginal candidiasis and tsrichomoniasis caused by three organisms.<br>4) Published data/literature for the proposed indication. |
| **SND Division** | | | |
| 11. | SND/MA/21/000368<br><br>Pidotimod Oral Liquid 400/800mg& Pidotimod Tablets 400/800mg | M/s. Wockhardt Limited | In light of recommendations of the earlier committee meeting held on 27.10.2021 the firm presented detailed justification for the proposed indication & dose rationality along with published data.<br><br>After detailed deliberation, the committee recommended that the firm should submit the following data for further review:<br>1. Dose defining study in pediatric patients in respect of dose per kg body weight/ body surface area.<br>2.) Parameter for immunity enhancement.<br>3.) Safety data to be submitted for evidence in children below 3 years of age. |
| 12. | 12-53/2016-DC (Pt-Lyka-SND)<br>Liposomal Amphotericin B Injection 50mg/ml (lyophilized) | M/s. Lyka Labs | The firm presented protocol for active post marketing surveillance study for Liposomal Amphotericin B injection 50mg/ml.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the active post marketing surveillance study for Liposomal Amphotericin B injection 50mg/ml subject to condition that the data of safety monitoring report should be submitted on monthly basis. |
| 13. | SND/MA/19/000112<br>Lincomycin Hydrochloride Sustained Release Tablets 1000 mg | M/s. Wallace Pharma | In light of earlier SEC recommendation dated 27.10.2021, the firm presented the justification of CT waiver.<br><br>After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Lincomycin Hydrochloride Sustained Release Tablets 1000 mg subject to condition that the firm should |

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| | | | submit safety data of the product to CDSCO every two months for next one year. |
| 14. | SND/MA/20/000215 Povidone Iodine Throat Spray 0.045% w/v | M/s. G.S. Pharma | In light of earlier SEC recommendation dated 24.09.2021, the firm presented the supportive scientific literature on the effectiveness of the proposed drug product.<br><br>After detailed deliberation, the committee noted that there is lack of convincing safety data for the proposed drug and did not recommend for approval of the drug. |
| 15. | SND/IMP/21/000096<br><br>Benzalkonium Chloride 0.13% Hand Sanitizer | M/s. Sunmed Pharma | The firm didn't turn up for presentation. |
| **FDC Division** | | | |
| 16. | FDC/MA/20/000232 Tinidazole 100mg +Norfloxacin 100mg suspension | M/s. Rivpra Formulation Pvt. Ltd. | The firm didn't turn up for presentation. |
| **GCT Division** | | | |
| 17. | CT/80/19 Online Submission (12669). Gepotidacin to Nitrofuratoin | M/s. PPD | The firm presented protocol amendment version 1.0 dated 06-May-2021 before the committee.<br><br>After detailed deliberation, the committee recommended for approval of the proposed protocol amendment. |
| 18. | CT/102/21 Online Submission (27618) LXE408 | M/s. Qascent Research Solutions | The firm presented Phase II clinical trial proposal before the committee.<br><br>**Assessment of risk versus benefit to the patients-** The firm has justified pre clinical and clinical data.<br>**Innovation vis-a-vis existing therapeutic option**- To assess the efficacy of a 7-day and a 14-day treatment course of LXE408 in adult patients with primary VL at Day 28.<br>**Unmet medical need in the country-** The test drug is used for treatment of visceral leishmaniasis.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the study. |
| **Medical Device Division** | | | |
| 19. | CI/MD/2021/43252 AM-301(Nasal Spray) | M/s. EcronAcunova Limited | The proposal will be deliberated in the next SEC meeting. |

**SEC (Antimicrobial &Antiviral) meeting dated 23.12.2021**

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| 20. | IMP/MD/2021/44998 Fast acting, sporicidal ready -to -use surface cleaning and disinfection wipe (IncidinOxyWipe S) | M/s. Ecolab Food Safety and Hygiene Solutions Private Limited | The proposal will be deliberated in the next SEC meeting. |