**Recommendations of the SEC (Antimicrobial & Antiviral) made in its 123rd meeting held on 28.02.2023 at CDSCO (HQ), New Delhi:**

| S.No. | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---|---|---|---|
| **New Drug Division** | | | |
| 1. | ND/MA/22/000088<br><br>Doravirine tablets 100 mg | M/s. Emcure & M/s. MSD | M/s MSD along with M/s. Emcure Pharmaceuticals presented their proposal for Phase III clinical trial waiver with the drug Doravirine tablet 100mg and Doravirine bulk drug before the committee.<br>After detailed deliberation, the committee noted that:<br>(i) M/s MSD submitted this application to support application submitted by M/s. Emcure Pharmaceuticals for obtaining manufacturing marketing permission of Doravirine tablet 100mg and Doravirine bulk drug<br>(ii) M/s MSD entered into an exclusive agreement with M/s. Emcure Pharmaceuticals to accelerate the availability of drug Doravirine in India.<br>(iii) M/s Emcure has been granted permission to conduct bioequivalence study vide permission no. BE/ND/21/2022 dated 12.08.2022.<br>(iv) M/s MSD has presented safety and efficacy data of DRIVE-FORWARD, DRIVE-AHEAD and DRIVE-SHIFT Phase III clinical studies data with Doravirine drug.<br>(v) There were no treatment-emergent RT K103N, G190A, or Y181C substitutions in any DOR clinical trial, supporting the distinctive resistance profile of DOR.<br>(vi) M/s MSD also presented non-clinical toxicity data including genotoxicity, carcinogenicity, antigenicity, immunotoxicity, or dependence, reproductive and developmental toxicology data.<br>(vii) Doravirine tablet for oral use is approved in more than 70 countries including USA, EU, Japan, UK, Australia and Canada. |

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| | | | FDC of Doravirine, Lamivudine and Tenofovir Disoproxil fumerate tablet is approved in more than 65 countries including USA and EMEA.<br>In view of above, committee opined that there is unmet need in the country and hence recommended for the grant of Phase III clinical trial waiver to support application of M/s Emcure Pharmaceuticals for manufacturing marketing permission of Doravirine tablet 100mg and Doravirine bulk drug subject to the following conditions:<br>1. M/s Emcure should submit BE study report before the committee.<br>2. M/s Emcure should conduct Phase IV clinical trial study for which firm should submit Phase IV clinical trial protocol within 3 months of approval.<br>3. M/s Emcure should submit pharmaceutical equivalence data with innovator product i.e. PIFELTRO<br>4. M/s MSD should submit CMC data to support pharmaceutical equivalence with M/s Emcure's Doravirine tablet 100mg and bulk drug.<br>5. The proposed indication should be "indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg with no prior antiretroviral treatment history only" (treatment naive). |
| **FDC Division** | | | |
| 2. | FDC/MA/22/000350<br><br>Rifaximin BP 200 mg + Metronidazole Benzoate IP Eq. to Metronidazole 400 mg tablet | M/s. Mascot Health Series Pvt. Ltd | The firm did not turn up for presentation. |
| 3. | FDC/IMP/22/000025 | M/s. Pfizer Ltd. | In light of the earlier SEC recommendations dated 26.07.2022 & 27.09.2022, the firm presented its |

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| | Avibactam Sodium eq. to Abibactam 0.5 mg + ceftazidine 2 gm Powder for concentrate for solution for infusion | | proposal before the committee along with the justification for Phase IV clinical trial study waiver.<br><br>The committee opined that:<br><br>1. The product is already approved on 12.02.2021 in different indication<br><br>2. The request for Phase III clinical trial study waiver was already considered by SEC for the proposed product in proposed indication for which permission was already issued on 14.10.2022 with condition to conduct Phase IV clinical trial study.<br><br>3. There is no unmet need for Phase IV clinical trial study waiver.<br><br>After detailed deliberation, the committee reiterated with its earlier recommendation dated 27.09.2022.<br><br>In view of above, the firm should present the Phase IV clinical trial study protocol before the committee |
| **GCT Division** | | | |
| 4. | CT/170/22<br>Online Submission (35232)<br><br>Ibrexafungerp | M/s. PSI CRO Pharma Pvt. Ltd | The firm presented the Phase-III clinical trial protocol number SCY-078-302, Version 2.1, dated 24 Nov 2022 before the committee.<br><br>After detailed deliberation, the committee recommended for grant permission to conduct the study. |