**Recommendations of the SEC (Dermatology & Allergy) made in its 54th meeting held on 12.01.2021 at CDSCO HQ New Delhi:**

| S.No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---|---|---|---|
| **New Drugs Division** | | | |
| 1. | ND/IMP/20/000098<br>Crisaborole ointment 2% | M/s Pfizer | The firm presented their proposal for import & market of the drug along with local clinical trial waiver before the committee.<br>Committee noted that firm has presented inadequate data as well as justification for local clinical trial waiver as per requirements.<br>After detailed deliberation, the committee recommended that the firm should conduct the phase III clinical trial and accordingly firm should submit the phase III clinical trial protocol to CDSCO for further review by the committee. |
| 2. | ND/MA/20/000164<br>Crisaborole ointment 2% | M/s Dr Reddy's Labs | The firm presented their proposal for manufacture & market of the drug along with local clinical trial waiver and BE study report before the committee.<br>Committee noted that firm has presented inadequate data as well as justification for local clinical trial waiver as per requirements.<br>After detailed deliberation, the committee recommended that the firm should conduct the phase III clinical trial and accordingly firm should submit the phase III clinical trial protocol to CDSCO for further review by the committee. |
| **Biological Division** | | | |
| 3. | 4-82/Intas/PAC-R-Etanercept/2020-BD<br>Etanercept | M/s Intas Pharmaceutical Ltd. | Firm presented their proposal for approval of additional indications.<br>After detailed deliberation, the committee recommended for grant of approval of proposed indications subject to condition that, firm should conduct Post marketing observational study in proposed indication and submit the data for review within 2 years. |
| **Subsequent New Drug Division** | | | |
| 4. | 12-115/2017-DC (Pt-Synokem-SND)<br>Itraconazole Sustained | M/s Synokem Pharma | In light of earlier recommendation of SEC meeting held on 10/01/2019, the firm presented proposal with |

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| | Release 400mg tablets | | justification, PK/PD, safety, efficacy profile of the drug alongwith protocol for BE and Clinical trial study.<br>After detailed deliberation, committee noted that firm has not provided any valid justification for proposed product, and therefore the committee reiterated its earlier recommendation dated 10.01.2019. |
| 5. | SND/MA/19/000077<br>Tissue Human Amnion Chorion Membrane Dehydrated | M/s Lifecell | In light of earlier recommendation of SEC meeting held on 13/07/2020, the firm presented the Phase III Clinical Trial protocol.<br>After detailed deliberation the committee recommended for grant of permission for conduct of Phase III Clinical trial as per the protocol presented subject to the following revisions<br>- To include patients with Hb level be as per the Indian standard limits<br>- Define the Methodology adopted for measurement of depth and size of wounds.<br>- To document photographs of the wounds before and after the treatments and submit along with the study report.<br>Accordingly, the firm should submit the revised protocol to CDSCO prior to initiation of the study. |
| 6. | SND/CT/19/000052<br>Dutasteride Topical solution (0.05%, 0.1% and 0.2%) | M/s Shilpa Medicare | The firm presented the revised Phase – II Clinical Trial Protocol with respect to Secondary study objectives, Blood Sampling points, Blinding procedure, Clinical supply management, study visit, drugs accountability, retention sample etc.<br>After detailed deliberation the committee recommended for grant of permission for conduct of Phase II clinical trial as per the revised protocol presented, subject to condition that the firm should perform PK study in atleast 16 subjects in the treatment group with 0.2% concentration of proposed test product. The SOP for application of the proposed topical solution (area in sq cm) and efficacy evaluation (sq cm area, methods for |

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| | | | obtaining pictures and photomicrographs) should be detailed in the protocol.<br>Accordingly, the firm should submit the revised protocol to CDSCO prior to initiation of the study. |
| 7. | SND/MA/20/000377<br>Minocycline Hydrochloride Topical Gel 4% for Topical use | M/s. Glenmark Pharma | The firm presented the proposal along with report of IVPT, justification for BE and CT study waiver.<br>Minocycline Hydrochloride Topical Foam 4% already approved in USA.<br>After detailed deliberation the committee opined that grant of permission for Minocycline Hydrochloride Topical Gel 4% may be considered subject to condition that the firm should submit the following :<br>1. Propionibacterium acnes sensitivity to minocycline and incidence of Hyper pigmentation in Indian population.<br>2. The firm should present Phase IV CT protocol before the committee for further consideration. |
| **FDC Division** | | | |
| 8. | FDC/MA/20/000161<br>Alcohol IP eq to absolute alcohol + Minoxidil (40%v/v+10%w/v) topical solution | M/s Pure & cure healthcare pvt. Ltd. | The firm did not turn up for presentation. |
| 9. | FDC/MA/20/000070<br>Clobetasol Propionate 0.0500 % w/w +Terbinafine Hydrochloride 1.0000 % w/w + Ofloxacin 0.7500 % w/w + propyl Paraben 0.0200 % w/w +Methyl Paraben 0.2000% w/w cream | M/s. Akums | In light of earlier recommendations of the committee dated 05.08.2020, the firm presented justification for proposed FDC.<br>After detailed deliberation, committee opined that the firm did not present any additional information in support of the FDC. Committee also noted that FDC of Clobetasol+ Terbinafine+Ofloxacin + Ornidazole was prohibited. Further, Committee also opined that:<br>1. There is no therapeutic justification/study advocating for combining the three drugs in this FDC.<br>2. The proposed FDC is not recommended in any standard therapeutic guidelines.<br>3. The proposed FDC is not approved internationally.<br>4. The proposed FDC may result into |

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| | | | emergence of bacterial and fungal resistance. Further, patients may also be unnecessarily exposed to adverse effects of potent steroid.<br>In view of above, the committee did not recommend for the proposed FDC. |