

Recommendations of the SEC (Dermatology & Allergy) made in its 85th meeting held on 13.09.2023 at CDSCO (HQ), New Delhi:

| S.No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|----------------------------|--|--------------------------------|---|
| Biological Division | | | |
| 1. | 4-7/Sandoz/PAC-R/Secukinumab/2020 Secukinumab 75mg/150mg/300mg | M/s. Novartis | The firm didn't turn up for presentation. |
| SND Division | | | |
| 2. | SND/CT/22/000020 Tofacitinib Ointment 2% w/w | M/s. Lyka Labs | <p>In light of earlier SEC recommendations dated 17.05.2023, the firm presented clarifications and corrective action plans against observations noted during CT inspection conducted on 18.07.2023 on their randomly selected two clinical trial sites for verification of raw data before the committee.</p> <p>The committee noted that the observations raised during inspection does not attribute to the quality of the product and there is no such observation which raises the question in respect of authenticity of data.</p> <p>After detailed deliberation, the Committee recommended for grant of permission for manufacturing and marketing of Tofacitinib Ointment 2% w/w for the treatment of mild to moderate atopic dermatitis (AD) in patients 18 years & above having flare up of disease with subject to condition that the firm should conduct Phase-IV clinical trial study. In addition to above the firm should also fulfill the CMC data requirement as per New Drugs and Clinical Trials Rules, 2019.</p> <p>Accordingly, the firm should submit Phase-IV clinical trial protocol to CDSCO within 03 months from date of approval of the drug product for further review by the committee.</p> |
| 3. | 12-124/2017-DC (Pt-Novalead-SND) Esmolol | M/s. NovaLead Pharma Pvt. Ltd. | In light of earlier SEC recommendations dated 15.02.2022, the firm presented the proposal for manufacture and marketing of Esmolol HCl Topical Gel 14.00% |

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| | Hydrochloride Topical Gel 14% w/w | | w/w along with clinical trial data before the committee. After detailed deliberation, the Committee recommended for grant of permission to manufacture and marketing of Esmolol HCl Topical Gel 14.00% w/w indicated for Diabetic Foot Ulcer with subject to condition that the firm should conduct Phase-IV clinical trial in the 400 population. In addition to above the firm should also fulfill the CMC data requirement as per Rules. Accordingly, the firm should submit Phase-IV clinical trial protocol to CDSCO within 03 months from date of approval of the drug product for further review by the committee. |
| FDC Division | | | |
| 4. | FDC/IMP/20/000044 Adapalene IP 0.3% w/w + Benzoyl Peroxide E.P 2.5% w/w topical gel | M/s. Galderma India Private Limited | In light of earlier SEC recommendation dated 10.12.2020, the firm presented Phase IV clinical trial report before the committee. After detailed deliberation, the committee noted the result of clinical trial report and agreed. |
| GCT Division | | | |
| 5. | CT/27/23 Online Submission (36577) Amlitelimab | M/s. Sanofi | In light of earlier SEC recommendations dated 17.05.2023, the firm presented the Phase II clinical trial protocol No. LTS17789 Version 1 dated 31 Oct 2022 before the committee. After detailed deliberation, the Committee recommended for grant of permission to conduct Phase II Clinical trial subject to condition that the firm should provide clear written direction/training to the principal investigator and sites that they should be liberal to the subjects who want rescue treatment and should not unnecessarily withhold it. |
| 6. | CT/125/21 Online Submission (25477) | M/s. Sanofi | In light of earlier SEC recommendations dated 17.08.2023, the firm presented their proposal for protocol amendment vide Protocol No. EFC16724, |

SEC (Dermatology & Allergy) meeting dated 13.09.2023

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| | Dupilumab | | Amendment 03 Version 1 dated 01 Mar 2023 before the committee. After detailed deliberation, the committee recommended for approval of the proposed amendment with the condition that the firm shall mention in the protocol that newly diagnosed cases of AFRS, who are included in study, should not be started on intranasal corticosteroids. |
| 7. | CT/59/19 Online Submission (26770) Baricitinib (LY3009104) | M/s. Eli-Lilly | The firm presented their proposal for protocol amendment vide protocol No. I4V-MC-JAIP(c)dated 14 Feb 2023 before the committee. After detailed deliberation, the committee recommended for approval of the proposed amendment as presented by the firm. |
| PvPI | | | |
| 8. | PvPI/WHO Alert/Botulinum/007/ 2023 Botulinum Neurotoxin Type A | WHO | With reference to WHO alert regarding Botulinum neuro toxin, PvPI, IPC has reported 10 cases of ADRs. The PV Division presented their agenda for opinion of the SEC. After detailed deliberation, the committee recommended for re-deliberation on following. <ol style="list-style-type: none"> 1. Reporting details of all the ten cases to be taken from PvPI, IPC. 2. Last two years ADR/CIOMS/safety data from importers and indigenous manufacturers should be taken. 3. Detailed investigation should be done in two cases reported by PvPI, IPC vide Safety report ID no. IN-IPC-2015-09161 and IN-IPC-2016-47217. |