

**Recommendations of the SEC (Dermatology & Allergy) made in its 79<sup>th</sup> meeting held on 15.03.2023 at CDSCO (HQ), New Delhi:**

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drugs Division</b>			
1.	12-01/18-DC (Pt-337)  Betamethasone induced Photosensitivity reaction	Pharmacovigilance Programme of India (PvPI)	I In light of earlier SEC recommendation dated 13.10.2021, the SRP recommendation was appraised to the committee along with the additional data as received from PvPI-IPC.  After detailed deliberation, the committee recommended that –  1. Betamethasone is a topical corticosteroid. 2. It is not clear if the molecule is being marketed as solo molecule (single constituent) or as fixed drug combination which are banned. 3. The experts also deliberated that Betamethasone should never be used in combination with antifungal ± antibiotic ± antiprotozoal molecules as these combinations are not scientifically logical. 4. If as betamethasone containing FDC, than adding Photosensitivity as ADR is not sufficient.
<b>SND Division</b>			
2.	SND/IMP/22/000073  Clostridium Botulinumneutotoxin type a 50 units	M/s Clini Experts Services Private Limited	The firm did not turn up for presentation.
<b>FDC Division</b>			
3.	FDC/MA/23/000016  Halobetasol propionate USP 0.1mg + Tazarotene 0.45mg topical lotion	M/s. Sun Pharmaceuticals	The firm presented its proposal before the committee along with BE study report which was conducted for export purpose as well justification for Phase III CT study waiver. After detailed deliberation, the committee recommended that: 1. Firm should conduct the PK study for repeated dose. 2. The firm should conduct the Phase III CT study. Accordingly, PK study protocol and Phase III CT study protocol should be

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			presented before the Committee for review.
4.	FDC/IMP/23/000001  Latanoprost 0.03% w/v + Finasteride 0.1% w/v + Minoxidil 5% w/v topical solution	M/s. Apodictic	The firm presented its proposal before the committee along with Phase III clinical trial study protocol. After detailed deliberation, the committee recommended that: 1. The firm should present justification or scientific rationality for adding Latanoprost along with FDC of Finasteride + Minoxidil. 2. The firm should present complete dermal toxicity study data along with raw data for proposed FDC as per NDCT Rules 2019. Accordingly, firm should present the justification on aforesaid points before SEC for further decision on Phase III clinical trial study.
<b>GCT Division</b>			
5.	CT/109/20 Online Submission (21453)  Efgartigimod PH20 SC	M/s. PPD	The firms presented protocol amendment version 3.0 dated 05 Sep 2022, before the committee. After detailed deliberation, the committee recommended that firm needs to submit more data with reference to the following: 1. Data with modified Phase-I and Phase-II. 2. Data of all adverse effects. 3. Proof of concept study. 4. Justification as well as safety comparability between Hyaluronic acid and IP.  The firm should provide the data for further review by the committee.
<b>SND Division</b>			
6.	SND/CT/22/000020  Tofacitinib Ointment 2% W/W	M/s Lyka Labs Ltd.	The firm presented its proposal for manufacture and marketing of Tofacitinib Ointment 2% w/w alongwith Phase III Clinical Trial final report and statistical evaluation of clinical trial data before the committee.  After detailed deliberation, the committee recommended that the firm needs to present following data or information for further evaluation by the committee:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			<ol style="list-style-type: none"> <li>1. Enrollment details of first 50 subjects in the clinical trial.</li> <li>2. Enrollment details of subsequent subjects in the clinical trial after approval of study continuation permission issued to the firm.</li> <li>3. Number of subjects categorized in mild and moderate groups based on disease progression.</li> <li>4. Sleep quality measurement of enrolled subjects in details.</li> <li>5. Number of subjects enrolled in the study with lesion on faces.</li> </ol> <p>In view of above, the committee recommended that the firm should submit above mentioned data to CDSCO for further evaluation by the committee.</p>