Recommendations of the SEC (Dermatology & Allergy) made in its 88th meeting held on 12.12.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
2.	FDC/MA/23/000262 Naftifine Hydrochloride USP 2%w/w + BeclomethasoneDipropionate IP 0.025% w/w Cream	M/s. Synokem Pharmaceutical Ltd.	In light of the earlier SEC recommendation dated 12.10.2023, the firm presented their proposal along with the rationality and justification for the proposed FDC. After detailed deliberation, committee opined the following: 1. Naftifine Hydrochloride is a novel molecule and may result into emergence of bacterial and fungal resistance if combined with steroids. Further, patients may also be unnecessarily exposed to adverse effects of potent steroid. 2. The proposed FDC is not recommended in any standard therapeutic guidelines. 3. The firm did not present any published literature in support of significant clinical need and proposed indication of the FDC. 4. There is no rationality or therapeutic justification and study advocating for combining the drug Naftifine with steroids. In view of above, the committee reiterated its earlier recommendation and did not recommend for approval of the FDC.
3.	FDC/CT/23/000074 Test formulation A: Dutasteride 0.05 % w/w + Minoxidil 5 % w/w & Test formulation B: Dutasteride 0.05 % w/w Latanoprost 0.03 % w/w Topical Solution	M/s. Glenmark Pharmaceuticals Ltd.	The firm presented their proposal along with Phase II clinical trial protocol. After detailed deliberation, the committee opined the following: 1. More government sites to be included which should be geographically distributed so that there should be 50% site each from Government and Private sites. 2. Number of subjects should be increased. Accordingly, revised Phase II clinical

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			trial protocol should be submitted to CDSCO for further review by the committee.
GCT Division			
4.	CT/141/23 Online Submission (40470) SAR445229	M/s. Sanofi	The firm presented Phase III clinical study protocol No. EFC17559. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as presented by the firm
5.	CT/139/23 Online Submission (40368) LOU064	M/s. Novartis	The firm presented Phase IIIb clinical study protocol No. LOU064A2304 After detailed deliberation, the committee recommended for grant of Permission to conduct the Phase IIIb clinical trial as presented by the firm
Medical Device Division			
6.	CI/MD/2023/98744 BTM Wound Dressing	M/s. Clinnex Research Private Limited	The firm presented their proposal for the grant of permission to conduct Clinical Investigation for the applied product (BTM Wound Dressing, Brand name- NovoSorb® Biodegradable Temporizing Matrix (BTM)). The said product is currently approved for the treatment of acute and chronic wounds under valid import license no. IMP/MD/2022/000357 and is being imported and sold in India since 2018. The study is proposed to assess the safety and performance of the applied product (already marketed) for expansion of current indication to include "deep dermal and full thickness burn injuries". After detailed deliberation, the committee recommended for the grant of permission to conduct the Clinical Investigation of the applied product in the country.
BA/BE Division			
7.	File No. 12-09/2023/BA-BE/MISC-25/DC (BABE/CT05/FF/2023/38611) Acetaminophen 325	M/s. Micro Therapeutic Research Pvt. Labs Ltd.	The firm presented their proposal along with the Protocol of the BE study for Export purpose and documents related to the queries raised in the 87th SEC meeting. After detailed deliberation, the committee

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	mg + Dextromethorphan HBr 15mg + Doxylamine Succinate 6.25 mg Soft Gelatin Capsule		recommended for conduct of BE study with note that the study proposal is only for Overseas Market.