Recommendations of the SEC (Dermatology & Allergy) made in its 87th meeting held on 09.11.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/CT04/FF/2023/38184 Trifarotene 50µg/g Cream	M/s Galderma India Pvt. Ltd.	The firm presented its proposal for Phase IV CT protocol. After the detailed deliberation, the committee recommended for conduct of Phase IV study as per the presented protocol with the follow up of upto 6 months with monitoring the relapse of the acne. Further, the committee suggested the firm to conduct an active controlled comparative study with their drug product Trifarotene 50µg/g cream already available treatments in the country.
FDC Division			
2.	FDC/MA/23/000308 Clobetasol Propionate IP 0.05%w/w + Iodochlorhydroxy quinoline IP 1%w/w+ Ketoconazole IP 2%w/w + Neomycin sulphate eq. to Neomycin IP 0.1%w/w cream	M/s. Leeford Healthcare Limited	The firm presented the proposal before the committee along with Phase III clinical trial study protocol. After detailed deliberation, committee opined the following: 1. There is no therapeutic justification/study advocating for combining the four drugs in this FDC. 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 for the proposed strengths of the FDC. 4. The proposed FDC may result into emergence of bacterial and fungal resistance. Further, patients may also be unnecessarily exposed to adverse effects of potent steroid. In view of above, the committee did not recommend for approval of the FDC.
GCT Division			
3.	CT/84/23 Online Submission (38275) Spesolimab	M/s. IQVIA RDS	The firm presented Phase IIIb/IV Clinical trial Protocol no. 1368-0120

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			After detailed deliberation, the committee recommended for grant of permission to conduct the trial subject to condition that at least 10 subject should be enrolled from India .
4.	CT/85/23 Online Submission (38464) Norketotifen Capsules 4mg	M/s. Veeda	The firm presented Phase II Clinical trial Protocol no. 22-VIN-0194 After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by firm.
5.	CT/146/22 Online Submission (34845) Remibrutinib (LOU064)	M/s. Novartis	In light of earlier recommendation dated 13.04.2023 the firm presented the proposal of grant of phase III Clinical trial permission with protocol no. CLOU064A2303B. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by firm.
Medical Device Division			
6.	IMP/MD/2023/85284 Surgical glue (Brand Name: Glubran 2)	M/s. Advanced Lifesciences Pvt. Ltd.	The firm presented proposal for grant of permission to import the medical device Surgical Glue (Brand Name: Glubran 2) which has an adhesive, sealant, haemostatic, sclerosing, embolic and bacteriostatic effect on tissues. The said device is intended to be used in various types of surgical applications and there is no predicate device approved by Central Licensing Authority. Committee observed that clinical data of the device presented by the firm is not adequate to establish safety, performance and effectiveness of the device for each of the claimed indication. After detailed deliberation committee recommended that the firm should submit following data for further review by Subject Expert Committee: 1. Adequate clinical study data for establishing safety, performance and efficacy of the device for each of the claimed indication in various surgical applications. 2. The clinical data submitted to other regulatory authorities for obtaining

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			approval along with published data in any the peer journal.
BA/BE Division			
7.	File No.: 12-09/2023/BA-BE/MISC-25/DC (BABE/CT05/FF/2023/38611) Acetaminophen 325 mg + Dextromethorphan HBr 15 mg + Doxylamine Succinate 6.25 mg soft gelatin Capsule	M/s Micro Therapeutic Research Pvt. Ltd Labs Ltd.	The firm presented their proposal along with the Protocol of the BE study for Export purpose. After detailed deliberation, the committee opined that:- I. Firm should submit the revised protocol with exclusion criteria with all screening test parameters. II. Firm needs to submit documents for therapeutic justification of the proposed test product. III. Firm is required to provide justification to conduct BE study as the product is available as an OTC product. IV. The committee also recommended to include experts such as ENT Specialist and General Medicine in the re-deliberation in meeting.
8.	File No.: 12-09/2023/BA-BE/MISC-31/DC (BABE/CT05/FF/2023/39149) Epinephrine 4.5 mg Nasal spray, Epinephrine 5.25 mg Nasal spray Epinephrine 7.0 mg Nasal spray	M/s Veeda Clinical Research Limited, Ahmedabad	The firm presented their proposal along with the Protocol of the BE study for Export purpose. After detail deliberation the committee did not recommended for grant the proposal of the BE study for export purpose due to varied dose, lack of justification and due to safety concern.
SND Division			
9.	SND/MA/23/000105 HAM membrane with PHM Biguanide Powder Particulars 2.00 % w/w	M/s Lifecell International Pvt.Ltd.	In light of earlier SEC recommendation dated 14.06.2023. The firm presented specific justification and Phase-III report of AmchoPlast PHMB patch and extensive studies done to ensure the equivalence and functionality of applied product along with request for waiver of Phase-III clinical trial study before the Committee.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
			After detailed deliberation, the committee opined that firm should submit more clinical trial evidence and other country approval status to CDSCO for further review by the committee.