Recommendations of the SEC (Dermatology & Allergy) made in its 72nd meeting held on 18.08.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/IMP/21000046 Tildrakizumab Injection 100mg/ml	M/s. Sun Pharmaceutical Industries Limited	The proposal of the firm was earlier deliberated on 12.08.2021 for import and marketing with local clinical trial waiver wherein the committee recommended that the firm should submit safety and efficacy data of the drug in Indian population for further consideration. Accordingly, the proposal for Phase III clinical trial was deliberated on 15.03.2022 wherein the committee recommended that the firm should present more data on unmet medical need for the drug in the country along with the rationale for proposed trial design for further review by the committee. Further the firm vide their letter dated 03.05.2022 requested to withdraw CT application and to consider again their proposal for import and marketing permission with local clinical trial waiver for SEC deliberation. Accordingly, the firm presented their proposal for import and marketing of the drug with local clinical trial waiver. After detailed deliberation, the committee recommended that the firm should conduct a Phase III bridging clinical trial with at least 100 patients which should include 5% patients of psoriasis with tuberculosis.
SND Division			
2.	SND/CT/22/000195 Loratadine Orally Disintegrating Tablets 10 mg	M/s. Tenshi Kaizen	The firm presented the proposal for manufacturing and marketing of Loratadine Orally Disintegrating Tablets 10 mg along with the results of BE studies conducted in Fed and Fasting conditions. After detailed deliberation, the committee recommended for grant of permission for manufacture and marketing of Loratadine Orally Disintegrating Tablets

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			10 mg for the indication symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria in adults and children.
3.	SND/CT/22/000041 Triamcinolone Acetonide Cream 0.01 % w/w	M/s. Abbott Healthcare	The firm presented Phase IV protocol No: TRIA4002 version 01 dated 17.03.2022 before the committee. After detailed deliberation, the committee recommended for approval of the Phase IV clinical trial protocol in line with the conditions of CT-23.
4.	SND/MA/21/000304 Ozenocacin Lotion 2% w/v	M/s. Precise Pharma at OM Sai Pharma	The firm presented their proposal with Phase III clinical trial data of Ozenocacin Lotion 2% w/v before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market of applied drug product Ozenocacin Lotion 2% w/v for proposed indication "For the treatment of superficial skin infections and acne" .
5.	SND/CT/22/000020 Tofacitinib ointment 2% w/w	M/s. Lyka Labs	The firm presented their proposal of amendment in approved protocol of Phase III clinical trial of Tofacitinib ointment 2% w/w (Protocol No. LL/CT/Phase III/03/21, Version No. 1, dated 30.09.21) with respect to comparator product before the committee. After detailed deliberation, the committee recommended for proposed amendment in approved Phase III protocol with respect to comparator product from Hydrocortisone Butyrate ointment 0.1% to Hydrocortisone Butyrate cream/ointment 0.1%.
Medical Device Division			
6.	MD/Post Appr/2021/7209 Haemostatic Powder (HaemoCer™ PLUS Haemostatic powder)	M/s. Morulaa Health Tech Pvt Ltd	In light of earlier SEC recommendation dated 14.09.2021, the firm presented their proposal for post approval change in indication before the committee. After detailed deliberation, the committee recommended that proposal needs to be deliberated in presence of Gynecologist and General Surgeon in forthcoming meeting.
7.	CI/MD/2022/56347 Artificial Skin (Bio-inspired Bi-layer	M/s. AIIMS, New Delhi	The firm presented their proposal for pilot clinical investigation of the proposed medical device in the country before the committee.

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	Polymeric Hybrid Scaffold)		After detailed deliberation, the committee recommended for grant of permission for conduct of pilot clinical investigation of the proposed medical device in the country.