Recommendations of the SEC (Dermatology & Allergy) made in its 76th meeting held on 15.12.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/22/000353 Luliconazole 1%+ Miconazole IP 2% cream	M/s. Zenvision Pharma Ltd.	The firm presented their proposal before the committee. After detailed deliberation the committee opined that : 1. The firm did not present any justification or scientific rationality to support their proposal, in terms of published peer-reviewed original studies in reputed journal(s), or even in the form of references. 2. The firm did not present supportive documentation or evidence to support their claim, that their combination would work in cases of documented resistance to antifungal drugs, including azoles. Also, the firm neither provided scientific basis or evidence to support that combination of two azole drugs would overcome azole resistance, nor could the firm provide data to support their claims. 3. The firm appeared to presume that fungal infection was the sole cause of itch, and had apparently proposed this combination as a treatment of itchy skin. In view of above, the committee did not recommend the proposed FDC.
GCT Division			
2.	CT/107/20 Online Submission (20362) Efgartigimod PH20 SC	M/s. PPD	The firm presented the proposed protocol amendment version 4.0 (amendment 3.0) dated 09-Jun-2022 under the Phase III ADDRESS study protocol no. ARGX-113-1904 before the committee. After detailed deliberation, the committee recommended for the grant of permission for the proposed protocol amendment with a condition that there would be no change in the approved no. of subjects from the country owing to the proposed protocol amendment.

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Medical Device Division			
3.	CI/MD/2022/56988 Nitric Oxide Releasing Collagen Wound Patch	M/s. Cologenesis Healthcare Pvt. Ltd.	In light of earlier SEC recommendation dated 13.10.2022, firm presented their amended pivotal clinical investigation protocol of the proposed product in the country by changing the comparator dressing from normal saline to collagen dressing. After detailed deliberation, the committee recommended for grant of permission to conduct the pivotal clinical investigation with amended clinical investigation protocol No.: MCR/CT/0222/01, version 02 dated 31.10.2022.
New Drug Division			
4.	ND/MA/21/000192 Naftifine HCL Cream 2% w/w	M/s. Synokem Pharmaceutical Ltd	The firm was granted permission to conduct Phase III clinical trial vide permission number CT/ND/15/2022, dated 18th April 2022. Now the firm presented Phase III clinical trial report before the committee. After detailed deliberation, the committee noted that 1. Naftifine HCL Cream 2% w/w cream is already approved for manufacture and market in the country on 09.11.2022. 2. Total 218 male and female patients aged between 18 to 65 years were screened, 198 randomized, and 193 completed the study. 3. Total 24 AEs were reported in 24 patients. 11 AEs were reported in test product arm i.e., Naftifine Hydrochloride Cream 2% w/w and 13 AEs were reported in reference product arm i.e., Miconazole Nitrate Cream 2% w/w. All the AEs were mild in nature. 4. No SAE was reported during the study. 5. The patients in test arm i.e. Naftifine Hydrochloride Cream

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			2% w/w and reference arm i.e. Miconazole Nitrate Cream 2% w/w showed clinical cure. Both the treatments were well tolerated. 6. The difference in proportion of patients showing clinical cure between the test arm i.e. Naftifine Hydrochloride Cream 2% w/w and reference arm i.e. Miconazole Nitrate Cream 2% w/w lies within the defined non-inferiority margin. Accordingly, the committee recommended for the grant of permission to manufacture and market the drug Naftifine Hydrochloride Cream 2% w/w for the treatment of superficial fungal infection of the skin (Tinea corporis and Tinea Cruris).
SND Division			
5.	SND/MA/22/000020 Tofacitinib Ointment 2%w/w	M/s. Lyka Labs	The firm presented Tofacitinib Ointment 2% w/w study data and drug safety assessment report of first 30 patients enrolled in Phase III clinical trial before the committee. After detailed deliberation, the committee opined that the firm should present drug safety assessment report after enrolment of 50 patients for further evaluation by the committee, prior to further recruitment of the patients in the clinical trial, as specified in condition of Phase III permission.