Recommendations of the SEC (Dermatology & Allergy) made in its 08th/25 meeting held on 06.08.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/96/25 Online Submission (50743) EXOB-001	M/s BIODEV SERVICES PRIVATE LIMITED	The firm presented phase Ib clinical study Protocol no. BDS/ExoBio/049 version no. 1.0 dated 07-JUL- 2025. After detailed deliberation, the committee has made following observation : i) The title of the study shall be appropriately revised to reflect the true phase of the study as phase Ia is not carried out. ii) Dermal toxicity from appropriate animal models with the same formulation shall be submitted. iii) The secondary objective should include demonstration of proof of concept for the intended indication. For further review by subject expert committee.
Medical Devices Division			
2.	IMP/MD/2025/148264 Prefilled Syringes (Jalupro HMW, Jalupro Super Hydro, Jalupro Young Eye)	M/s Manju Enterprises Pvt. Ltd.	The firm presented proposal for grant of permission to import for marketing of proposed medical devices manufactured by M/s. Professional Derma SA, Switzerland, before the committee. The firm presented the Clinical study data and PMS data on the said products on its safety and performance. The product is approved by National Regulatory Authority of United Kingdom and marketed for more than 2 years. After detailed deliberation, the committee recommended for the grant of permission to import of said devices in the country with the condition that the firm shall conduct Post Marketing Clinical Investigation of the said devices in the country to generate the safety data on Indian population. Accordingly, the firm shall submit the Clinical study protocol to this office within 03 months from the date of launch of the said devices in the country.

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3.	IMP/MD/2025/146084 Antimicrobial wound dressing with copper oxide	M/s BL LIFE SCIENCE PVT LTD	The firm presented proposal for Grant of permission to import the device viz, (Antimicrobial wound dressing with copper oxide) manufactured by M/s MedCu Technologies Ltd., Israel for marketing in the country. The product is approved and marketed in USA for more than two years. The firm has presented safety data, clinical data and PMS data generated on the said device globally before committee. After detailed deliberation, the expert opined that the product is wound dressing with antimicrobial property; therefore proposal may be deliberated with the expert committee belonging to anti-bacterial/antimicrobial.
SND Division			
4.	SND/MA/25/000100 Rolfumilast cream 0.3% w/w	M/s. Sun Pharmaceuticals Limited	Firm presented their proposal for grant of permission to manufacture and marketing of Roflumilast cream 0.3% w/w with Phase III clinical trial protocol for the proposed indication of effective alternative for treatment of plaque psoriasis along with BE study waiver. The firm informed the drug product Roflumilast cream 0.3% w/w is approved in Canada and USA for the proposed indication. After detailed deliberation, the committee recommended the following changes in the presented Phase III clinical trial protocol: 1. Toxic dose level for systemic absorption from the skin to be mentioned. 2. Power of the study to be increased to 95%, accordingly the number of participants to be increased. 3. The duration of the study to be increased to 12 weeks. 4. At least 50% of the Patients shall be followed up for 6 to 8 months after the end of the treatment for the clearance/reduction of lesion. 5. At least 10% or (30 nos) of patients shall undergo biopsy

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			testing with pathological opinion at the end of the follow up study. Preferably biopsy study also to be done at base line. 6. Photographic records of the measurement of the size of the lesion against Ruler/scale shall be submitted as a part of CSR to verify the change in the colour/size of the lesions.
5.	SND/MA/25/000027 Ruxolitinib cream 1.5% w/w	M/s. Sun Pharmaceutical Industries Limited	In light of earlier SEC recommendation dated 22.04.2025, the firm presented justification on selection of comparator arm and Standardization of Sunlight/ Commercial UVB light. After detailed deliberation, the committee recommended for approval to conduct the Phase-III clinical study as per the protocol presented by the firm.