Recommendations of the SEC (Dermatology & Allergy) made in its 09th/25 meeting held on 23.09.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/25/000124 Roflumilast Cream 0.3 % w/w	M/s. Lyka Labs Ltd.	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 topical treatment of plaque psoriasis along with Phase III clinical trial protocol before the committee. The firm informed the drug product Roflumilast cream 0.3% w/w is approved in USA, Canada, EU, UK and Australia for the proposed indication. After detailed deliberation, the committee opined that the firm should revise their protocol to include following points: 1. CT study should be active controlled comparative study. 2. Toxic dose level for systemic absorption from the skin to be mentioned. 3. Power of the study to be increased to 95%, accordingly the number of participants to be increased. 4. The duration of the study to be increased to 12 weeks. 5. 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. 6. Detailed Rescue medication should be mentioned in the protocol. 7. At least 10% or (30 nos) of patients shall undergo biopsy testing with pathological opinion at the end of the follow up study. Preferably biopsy study also to be done at base line. 8. 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

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			Accordingly, firm should submit revised Phase-III protocol to CDSCO for further review by the committee.