Recommendations of the SEC (Dermatology & Allergy) made in its 10th/25 meeting held on 08.10.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical devices Division			
1.	CI/MD/2024/125677 (Form MD-22) PVR system®	M/s. S.S. HEALTHCARE	The firm presented their proposal for grant of permission for conduct of Clinical investigation of the applied device i.e. PVR system® which is a non-invasive transdermal application of gaseous carbon dioxide intended for the treatment procedures of acute or chronic wounds, diabetic foot, and insufficient peripheral arterial circulation, manufactured by M/s. DERMA ART d.o.o., Slovenia, Europe. The said device is approved for marketing in European Union (EU) countries since year 2021. The firm has produced Clinical study data generated on more than 450 patients along with Post market clinical follow-up data on over 1000 patients in EU, demonstrating the safety and performance of the device. After detailed deliberation, the committee opined that the said proposal may be discussed in presence of General Surgeon, endocrinologist and diabetologist, before taking necessary action in the matter.
New Drugs Division			
2.	ND/MA/25/000113 Tapinarof Cream 1% w/w	M/s. Pure and Cure Healthcare Pvt. Ltd.	The firm presented the proposal for grant of permission to manufacture and market of the drug Tapinarof Cream 1% along with Phase III Clinical Trial protocol titled "A Multicenter, Randomized, Double-Blind, Active-Controlled Phase III Study to Evaluate the Efficacy, Safety, Pharmacokinetics, and Inflammatory Biomarker Modulation of Tapinarof 1% Cream Compared to Calcipotriol 0.005% Cream for the topical treatment of plaque psoriasis in adult patients." (Protocol ID: VRL-CT-25-041, Protocol Version No: 1.0 dated 28-Jul-2025), before the committee. After detailed deliberation, the committee suggested following changes in the protocol :

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			1) Not to include very severe patients of plaque psoriasis and to revise the inclusion criteria accordingly. 2) Washout period should be defined for severe patients who are already on treatment with other drugs and ethical consideration of the same should be justified. 3) Firm has not mentioned any concomitant medication (like moisturizer). 4) Age of the patients should be revised to 18-60 years. 5) Quantity of application should be defined by fingertip unit (FTU). Accordingly, firm should submit the revised protocol for further review by the committee.
SND Division			
3.	SND/MA/24/000038 Roflumilast Cream 0.3%w/w	M/s. Pure and Cure Healthcare Pvt. Ltd.	Firm presented their proposal along with Phase III CT Protocol. The committee noted that Roflumilast Cream 0.3% was approved for the proposed indication in USA. After detailed deliberation, the committee opined to submit the revised Phase III CT protocol with following changes-. 1. CT study should be active controlled comparative study. 2. Power of the study to be increased to 95%, accordingly the number of patients to be increased. 3. Point no.1 and 10 of exclusion criteria to be revised with supporting clinical data. Accordingly, firm should submit the revised Protocol for review by the committee.
4.	SND/MA/25/000045 Pentosan Polysulfate sodium 0.1% w/w and 0.5% w/w cream	M/s. Swathi Spentose Pvt. Ltd.	In continuation of earlier SEC recommendation dated 11.06.2025, the firm presented before SEC Committee (General Physician and Haematologist), the clinical data/literature for applied

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			product i.e. Pentosan polysulfate sodium cream 0.1 % w/w and 0.5 % w/w in following applied indication as Symptomatic local treatment of superficial venous disorders such as heaviness and tightness in the legs with varicose veins in adults and Superficial hematomas caused by blows, in adults. After detailed deliberation, the Committee noted that the firm has not presented adequate clinical data in proposed indication of symptomatic local treatment of superficial venous disorders such as heaviness and tightness in the legs with varicose veins in adults. Accordingly, the Committee recommended to consider for indication as Superficial hematomas caused by blows, in adults (Thrombophlebitis) and the firm should conduct Phase III clinical trial in indication as symptomatic local treatment of superficial venous disorders such as heaviness and tightness in the legs with varicose veins in adults.