Recommendations of the SEC (Dermatology &Allergy) made in its 86th meeting held on 12.10.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	4-7-/Sandoz/PAC-R/Secukinumab/2020 Secukinumab 75mg/150mg/300mg	M/s. Novartis	The firm presented the proposal for update in package insert for change in posology and pharmacodynamic properties. The committee noted that, the changes proposed in the package insert are in line with approval of EU SmPC. After detailed deliberation, the committee recommended for approval of the updated package insert dated 12.04.2022.
2.	BIO/CT21/FF/2023/37090 Adalimumab 100mg/ml	M/s. Enzene Biosciences Limited	The firm presented the proposal for approval of additional indications for Adalimumab injection. The Adalimumab injection is earlier approved for the indication "Ankylosing Spondylitis''. The firm intend to extrapolate the following additional indications: 1.Psoriasis 2.Paediatric plaque psoriasis 3.Hidradenitis suppurativa (HS) After detailed deliberation, the committee recommended for approval of following indications i.e., Psoriasis and Hidradenitis suppurativa (HS) in adult population. The committee recommended the firm to conduct Phase III study in paediatric patients for approval of Paediatric plaque psoriasis idication. Accordingly, the firm should submit Phase III protocol for clinical trial in paediatric population. The other applied additional indications may be deliberated in SEC (Gastroenterology and Ophthalmology).
3.	BIO/CT04/FF/2023/39009 Ustekinumab 45mg/0.5mL, 90mg/ml	M/s. Reliance Life Sciences	The firm presented Phase IV clinical trial protocol titled "A prospective, multi-centre, open label ,Phase IV study to evaluate safety and efficacy profile of Ustekinumab in patients with moderate to severe plaque psoriasis vide Protocol No. RLS/PMS/2023/05, version: 1.0 dated 31 Jul 2023 before the committee. After detailed deliberation, the committee recommended for grant of

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			permission to conduct the Phase IV clinical trial as presented by the firm.
SND Division			
4.	SND/MA/23/000105 HAM Membrane with PHM with Biguanide Powder Particulates 2.00% w/w	M/s.LifeCell International Pvt. Ltd.	The firm did not turn up for presentation
5.	SND/CT/23/000051Diperoxochloric acid 1.16 mg Topical solution (New Indication)	M/s. Centaur Pharmaceuticals Private Limited	The firm presented proposal for grant of permission to conduct Phase-III clinical trial of Diperoxochloric Acid 1.16 mg Topical solution for New Indication"in the treatment of pressure ulcers" along with Phase-III clinical trial protocol before the Committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase-III clinical trial of Diperoxochloric Acid 1.16 mg Topical solution subject to condition that the firm should increase the statistical power of the study to 90% (from 80%) and accordingly make changes to the sample size to achieve it, along with certification from biostatistician and intimate the same to CDSCO.
6.	12-54/2023-DC(Pt-Misc/SND) Triamcinolone Acetonide Cream 0.1% w/w	M/s. Abbott Healthcare Private Limited	The firm presented proposal for change in warning from "To be sold by retail on the prescription of Dermatologist only" to "To be sold by retail on the prescription of Dermatologist and Physician only" along with justification for proposed amendment before the Committee. After detailed deliberation, the committee recommended for approval of the change in warning condition No. 3 of the permission to"To be sold by retail on the prescription of Dermatologist and specialist only" instead of "To be sold by retail on the prescription of Dermatologist only"
FDC Division			
7.	FDC/MA/23/000262 Naftifine	M/s. Synokem Pharmaceutical Ltd.	The firm presented the proposal before the committee along with Phase III

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	Hydrochloride USP 2%w/w + BeclomethasoneDipropionate IP 0.025 % w/w Cream		clinical trial study protocol. The committee noted that: 1. The proposed FDC is not approved anywhere in the world. 2. The firm did not present any published literature in support of significant clinical need for the proposed strengths of the FDC. 3. Dosing frequency of the proposed strengths of the FDC is not matching. 4. Patients may also be unnecessarily exposed to adverse effects of steroid. 5. There is no rationality for the FDC. After detailed deliberation, the committee did not recommend for approval of the FDC.
Medical Devices Division			
8.	IMP/MD/2023/85284 Surgical glue (Brand Name: Glubran 2)	M/s. Advanced Lifesciences Pvt. Ltd.	The firm presented the proposal for grant of permission to import and market the proposed product Surgical Glue (Brand Name: Glubran 2) in the country before the committee. After detailed deliberation committee recommended that proposal needs to be deliberated in next SEC meeting in presence of experts of surgical application areas such as Cardiac surgery, Paediatric surgery, vascular surgery, Interventional radiology & General Surgery etc.