Recommendations of the SEC (Endocrinology & Metabolism) made in its 12th/25 meeting held on 22.05.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	r-DNA-11011(11)/6/2024-eoffice RECOMBINATE - Recombinant Factor VIII I.P 250 IU, 500 IU, 1000 IU lyophilised powder for concentrate for solution for i.v injection	M/s Takeda Biopharmaceuticals India Pvt. Ltd	The firm presented the proposal to withdraw the product Recombinant Anti Hemophilic Factor VIII 250 IU or 500 IU or 1000 IU with 5mL or 10mL sWFI, Lyophilised powder for Concentrated solution for intravenous injection from Indian market. The committee noted that the firm has proposed for the withdrawal of product based on a business decision and not due to any safety or efficacy concerns and further noted that better alternative therapies are available in Indian market. After detailed deliberation, the committee consented for firm's proposal for withdrawal of product Recombinant Anti Hemophilic Factor VIII 250 IU or 500 IU or 1000 IU (RECOMBINATE) from Indian market.
2.	BIO/CT21/FF/2024/47121 Biphasic Insulin Aspart Injection I.P (rDNA origin), 100 IU/mL (30:70) in 3 mL cartridge and VDPen 60	M/s. Biogenomics Limited	The firm presented the proposal to manufacture and market the drug product Biphasic Insulin Aspart Injection I.P (rDNA origin) 100 IU/mL (30:70) in 3 mL cartridge and VD Pen 60 for the "Treatment of Diabetes Mellitus in Adults, adolescents and children 1 year and above" based on the complete results of comparative Phase III clinical trial conducted in India. After detailed deliberation, the committee recommended the firm to manufacture and market the drug product Biphasic Insulin Aspart Injection I.P (rDNA origin) 100 IU/mL (30:70) in 3 mL cartridge and VD Pen 60 for the "Treatment of Diabetes Mellitus in Adults 30 years and above" with the condition that firm shall conduct Phase IV study in the country. Accordingly, the protocol to conduct the Phase IV study shall be submitted within 3 months of grant of marketing authorization permission to manufacture

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			and market the drug product.
3.	BIO/CT04/FF/2025/47983 Afrezza Insulin human inhalation powder (r DNA origin) 4U/ 8U/ 12U per cartridge with inhaler	M/s Cipla Limited	The firm presented the proposal to conduct an active PMS study titled "A post marketing active surveillance of Insulin Human Inhalational Powder in Adult patients with Diabetes mellitus" vide Protocol No. CP/16/24 Version 01 dated 14.02.2025. After detailed deliberation, the committee recommended for the conduct of active PMS study with the condition that Pregnant women should be excluded from the study. Accordingly, firm should submit the revised protocol to CDSCO for evaluation.
4.	E-45672 Human Insulin IP 75 IU/150 IU (rDNA origin) USVCAP capsules	M/s. USV Private Limited	The firm presented the final CSR of clinical study titled "A Phase IIb, Open-label, Randomized, Comparative study to evaluate the safety and efficacy of USVCAP formulation in Type 2 Diabetes Mellitus uncontrolled with Metformin Hydrochlroide treatment" conducted as per Protocol No. USVCAP/USV/P2/001, Version 2.0, dated 14-Feb-2018. The firm has informed in their deliberation that desired efficacy is not achieved in the trial due to which firm has withheld the product development of USVCAP (Human Insulin IP 75 IU/150 IU capsules-rDNA origin). After detailed deliberation, the committee noted the results of the study and also the firm's decision to with held the product development of USVCAP Human Insulin capsules.
5.	BIO/CT04/FF/2025/47773 Insulin Degludec injection 100IU/ 3mL cartridge and pre filled pen	M/s LUPIN LIMITED	The firm presented the protocol to conduct Phase III clinical trial titled "A Multi-Centre Randomised, Open Label, Parallel Group, Active Controlled Phase III study to establish the Non-inferiority of Biosimilar Insulin Degludec Injection (rDNA origin) 100 IU/mL to Reference Insulin Degludec Injection (Tresiba ®) in the Treatment of Type 2 Diabetes

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			Mellitus" vide Protocol No. ECTS/24/010 Version No. 00 dated 17.10.2024. After detailed deliberation, the committee recommended the firm to conduct a PK/PD study in Indian population and submit the results to CDSCO for further evaluation before the committee.
Medical Devices Division			
6.	CI/MD/2024/116901 iSage Rx Version 3.3	M/s. PharmaLeaf India Private Limited	The firm has presented the revised protocol along with the explanation before the expert committee as per the points raised in the initial SEC deliberation dated 24/07/2024. After detailed deliberation, the experts have recommended for the grant of permission to conduct of the study as per the revised protocol number AML-RES-ISP-PRT-001 dated 29/10/2024
SND Division			
7.	SND/IMP/23/000069 Triptorelin Powder for Injection 22.5 mg	M/s. Dr. Reddys Laboratories Limited	Under Discussion.
8.	SND/MA/19/000074 Vildagliptin SR Tablets 100mg	M/s Synokem	The firm did not turn up for the presentation.
9.	SND/MA/20/000222 Vildagliptin Sustained Release Tablets 100 mg	M/s Pure & Cure Healthcare Pvt.Ltd	The firm presented the proposal for grant of permission to conduct Active Post Marketing Surveillance (PMS) Study vide protocol No. BSR/CT/010/24, Version 1.0 dated 18.09.2024 before the committee. After detailed deliberation, the committee recommended for approval to conduct the study as per the protocol presented by the firm.
10.	SND/MA/22/000363 Cholecalciferol Aqueous Injection 600,000 IU	M/s AKUMS DRUGS & PHARMACEUTICALS LIMITED	In continuation to the earlier SEC recommendations dated 25/03/2025, firm presented the revised PK/PD Protocol vide No BIOS/2025/082 Ver 01 dated 25/04/2025 before the committee.

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			After detailed deliberation committee recommended for grant of permission to conduct PK/PD study as per protocol presented subject to condition that: 1) Firm should use same method for estimation of vitamin D3 level at screening and end of study. 2) Firm should estimate the calcification level at screening and at end of treatment.
FDC Division			
11.	FDC/MA/25/000091 Empagliflozin 10mg/25mg + Linagliptin 5mg/5mg + Metformin Hydrochloride IP (ER) 500mg/500mg Film coated bilayer Tablet	M/s Theon Pharmaceuticals Ltd.	The firm presented the proposal before the Committee. After detailed deliberation, the committee noted that: 1. Firm did not present the rationality of the FDC in proposed strength and its significant benefits. 2. Firm did not present published scientific literature in peer reviewed journal in support of the FDC in proposed strength. 3. Firm did not submit justification on desirability and essentiality of the FDC in proposed strength. 4. The FDC in proposed strength is not approved internationally. Accordingly, the firm should submit the above data to CDSCO for further review by the committee.