Recommendations of the SEC (Endocrinology & Metabolism) made in its 12th/25_meeting held on 11.06.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	r-DNA-11016(13)/7/2025-eoffice Idursulfase (r-DNA origin)-2 mg/ml	M/s Takeda Biopharmaceuticals India Pvt. Ltd	The firm presented the CSR of Phase IV study titled "A Prospective, Multicenter, Single-arm, Open-label, Interventional Phase IV Study to Evaluate the Safety and Efficacy of Idursulfase (r-DNA origin) (Elaprase™) in Indian Pediatric and Adult Population with Hunter Syndrome (Mucopolysaccharidosis II)" conducted vide Protocol no. TAK-665-4001, Version: 3.0 dated 27.10.2022. After detailed deliberation, the committee noted the results of the Phase IV study presented by the firm.
SND Division			
2.	SND/MA/23/000290 Nano carrier Entrapped Vitamin D3 Oral Dispersion 60000 IU/ 5ml	M/s. Pulse Pharmaceuticals Ltd	In light of earlier SEC recommendations dated 10.04.2024, the firm presented the justification for the lab values with respect to 25(OH) Cholecalciferol along with clinical trial report before the committee After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Nano carrier Entrapped Vitamin D3 Oral Dispersion 60000IU/5ml. However, the firm should fulfil the requirements of CMC data before approval of the product
3.	SND/CT/24/000094 Semaglutide Injection (synthetic origin) 2 mg / 1.5 mL (1.34 mg/mL), Semaglutide Injection = 4 mg/ 3 mL (1.34 mg/mL)	M/s Hetero Labs Limited	In light of earlier SEC recommendation dated 06.02.2025, firm presented the BE study report protocol vide no. AZBE112405, Version No. 01, Dated 15.11.2024 along with Revised CT Protocol vide protocol No.: HCR/III/SEMADM/10/2024, Version no.: 1.1 dated 02.11.2024 for indication of an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus before the committee. After detailed deliberation, the committee accepted the BE study report and recommended to conduct the Phase III clinical trial as per protocol presented by

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			the firm.
4.	SND/MA/25/000020 Semaglutide Injection 0.25 mg/ 0.5 mg/ 1 mg Pre-filled pen (4 mg/ 3 ml) & Semaglutide Injection 2.0 mg Pre-filled pen (8 mg/ 3 ml) (Synthetic origin)	Macleods Pharmaceuticals Ltd.	Firm presented BE study protocol vide protocol no. BEQ-3991-SEMA-2025 Version No. 01 dated 29.01.2025 and Phase III CT protocol vide protocol no. CT-066-SEMG-2025 dated 30-Jan-2025 version no. 01 for indication for treatment of adults with insufficiently controlled type 2 diabetes mellitus before the Committee. Firm has informed that preclinical subacute toxicity study of Semaglutide Injection in two species is ongoing. After detailed deliberation, the Committee in principle agreed with presented BE protocol and Phase III CT protocol subject to following conditions: 1. The firm should submit and present preclinical toxicity study report to CDSCO before initiation of BE study. 2. 50% Govt. CT sites geographically distributed shall be included in Clinical trial study. Further, the firm should submit BE Study report to CDSCO for further evaluation by the committee.
5.	SND/MA/24/000250 Metformin Hydrochloride Granules for Oral Solution 500 mg and 1000 mg	M/s BDR Pharmaceuticals International Pvt Ltd	Firm presented the proposal for grant of permission to manufacture and market Metformin Hydrochloride Granules for Oral Solution 500 mg and 1000 mg along with BA study Protocol. Firm did not present the Phase III CT protocol before the committee. After detailed deliberation, the Committee recommended for grant of permission to conduct the BE study as per protocol presented by the firm subject to condition that firm should change Power of the sample from 80% to 90% and sample size accordingly. Accordingly, firm should submit revised BA study protocol to CDSCO
FDC Division			

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6.	FDC/75/2024-eoffice Canagliflozin 50 mg/ 50 mg + Metformin Hydrochloride 500 mg/ 1000 mg film coated tablet	M/s Johnson & Johnson Pvt. Ltd.	Firm did not turn up for presentation.
7.	FDC/83/2024-eoffice Canagliflozin 50 mg/ 50 mg + Metformin Hydrochloride 500 mg/ 1000 mg film coated tablet	M/s Johnson & Johnson Pvt. Ltd.	Firm did not turn up for presentation.
8.	FDC/MA/24/000238 Acarbose IP 25 mg/25 mg/ 50 mg/ 50 mg + Sitagliptin phosphate monohydrate IP 50 mg/ 50 mg/ 50 mg/ 50 mg + Metformin hydrochloride IP 500 mg/ 1000 mg/ 500 mg/ 1000 mg film coated tablet	M/s Hetero Labs Limited	In light of the earlier SEC recommendation dated 13.11.2024, the firm presented their proposal along with justification for the proposed FDC. After detailed deliberation, the committee opined that: 1. The firm did not present the rationality of the three drug combination for better efficacy and safety. 2. GI adverse effect will be high for proposed three drug combination. In view of above, the committee did not recommend for the approval of the FDC.