Recommendations of the SEC (Endocrinology & Metabolism) made in its 20th/25 meeting held on 23.09.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT21/FF/2025/47384 Insulin Injection, Soluble (Neutral) IP 100 IU/mL	M/s. Regenix Drugs Ltd	In light of earlier SEC recommendation dated 29.04.2025, the firm presented the results of complete Phase III clinical trial conducted in India for grant of permission to manufacture and market Insulin Injection Soluble (Neutral) 100 IU/mL (rDNA origin) in India for the treatment of patients with diabetes mellitus who require insulin for the maintenance of glucose homeostasis. After detailed deliberation, the committee recommended the firm to submit the following data- 1. Complete center/clinical trial site wise raw data of patients included in the trial. 2. Comparative data of concomitant medications used in both the arms during the trial. 3. Comparative data of basal insulin dose provided in both the arms during the trial. 4. Details of events including patient details where basal insulin dose was changed during the trial. 5. Comparative raw data of age and body weight of patients enrolled in the trial at the beginning of intervention between both the arms. 6. Correlation of insulin dose and anti insulin antibodies for both the arms. 7. Bioanalytical method validation for laboratory procedures measuring Anti Insulin Antibodies, Hb1Ac levels, fasting and PP Glucose levels during the trial. Accordingly, firm should submit the additional data to CDSCO for further evaluation by the committee.
SND Division			
2.	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-	M/s. Macleods Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 11.06.2025, firm presented Subcutaneous Toxicity Study of Semaglutide Injection Pre filled pen in Wistar Rats & New Zealand White Rabbits.

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	filled pen (8 mg/3 ml) (Synthetic origin)		After detailed deliberation, the Committee opined that: 1) Firm should submit histopathological data and organ section duly certified by pathologist observed during the Subcutaneous Toxicity Study. 2) Firm should submit statistical comparison of biochemical parameters and parameters related to regulatory toxicity observed during Subcutaneous Toxicity Study. Accordingly, firm should submit the above mentioned data/ information to CDSCO for further review by Committee
3.	SND/MA/25/000014 Semaglutide Injection 0.25 mg/0.5 mg/1 mg Pre-filled pen (4 mg/3 ml) & Semaglutide Injection 1.7 mg/2.4 mg Pre-filled pen (9.6 mg/3 ml)	M/s. Macleods Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 22.04.2025, firm presented Subcutaneous Toxicity Study of Semaglutide Injection Pre filled pen in Wistar Rats & New Zealand White Rabbits. After detailed deliberation, the Committee opined that: 1) Firm should submit histopathological data and organ section duly certified by pathologist observed during the Subcutaneous Toxicity Study. 2) Firm should submit statistical comparison of biochemical parameters and parameters related to regulatory toxicity observed during Subcutaneous Toxicity Study. Accordingly, firm should submit the above mentioned data/ information to CDSCO for further review by Committee.
4.	SND/CT/25/000002 Semaglutide Solution for injection in pre-filled pen 2 mg/1.5 mL, 4 mg/3 mL, & 8	M/s. Biocon Pharma Limited	In light of earlier SEC recommendation dated 08.04.2025, firm presented the data/ information of survived and dead animals along with causality assessment of animals died during subacute toxicity study and data/ information on SAE

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	mg/3 mL (synthetic origin)		reported in BE study. After detailed deliberation Committee opined that 1) Firm should present the daily monitoring data for physiological parameters particularly animals with mortality. Also, firm should submit the report by veterinary pathologist stating the cause of mortality in the animals. 2) Firm should present the causality assessment and clear history on the number of studies in which the SAE reported subject had participated at the site and health status. 3) Firm should submit the complete CRF as well as admission and discharge summary of SAE reported in the subject. Accordingly, firm should submit the above mentioned data/ information to CDSCO for further review by Committee.
5.	SND/CT/25/000086 Semaglutide Solution for injection in pre-filled pen 2 mg/1.5 mL, 4 mg/3 mL, 6.8 mg/3 mL, 9.6 mg/3 mL (synthetic origin)	M/s. Biocon Pharma Limited	In light of earlier SEC recommendation dated 08.04.2025, firm presented the data/ information of survived and dead animals along with causality assessment of animals died during subacute toxicity study and data/ information on SAE reported in BE study. After detailed deliberation Committee opined that: 1) Firm should present the daily monitoring data for physiological parameters particularly animals with mortality. Also, firm should submit the report by veterinary pathologist stating the cause of mortality in the animals. 2) Firm should present the causality assessment and clear history on the number of studies in which the SAE reported subject had

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			participated at the site and health status. 3) Firm should submit the complete CRF as well as admission and discharge summary of SAE reported in the subject. Accordingly, firm should submit the above mentioned data/ information to CDSCO for further review by Committee.
6.	SND/CT/25/000078 Tirzepatide 2.5 mg/0.6 ml, 5 mg/0.6 ml, 7.5 mg/0.6 ml, 10 mg/0.6 ml, 12.5 mg/0.6 ml and 15 mg/0.6 ml solution for injection in a multiple-dose prefilled pen.	M/s. Eli Lilly and Company (India) Pvt. Ltd.	Firm presented their proposal along with Phase IV Clinical Trials Protocol before the Committee. After detailed deliberation, the Committee recommended for grant of permission to conduct the Phase IV Clinical Trials study as per the protocol presented before Committee.