

Recommendations of the SEC (Endocrinology & Metabolism) made in its 05th/25 meeting held on 20.02.2025 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	r-DNA-11011(18)/11/2025-eoffice Semaglutide Injection 0.25mg/0.5mg/1mg/1.7mg/2.4mg	M/s Novo Nordisk India Pvt. Ltd.	In light of earlier SEC recommendation dated 13.02.2024 and 14.02.2024, the firm presented the proposal for amendment in warning statement by including Obstetricians & Gynecologists and Bariatric surgeons. In the earlier SEC meeting, the committee recommended to submit the post marketing safety data in Indian population for evaluation by the committee. The Committee noted that the drug is not yet launched in India. Further, post marketing safety data in Indian patients are not presented. After detailed deliberation the committee didnot consider for amendment in the warning statement at this stage.
2.	BIO/CT21/FF/2024/46338 Liraglutide 6mg/ml solution for injection (In prefilled pen)	M/s M.J.Biopharm Pvt.Ltd.	The firm presented the proposal for approval of additional indication of the drug product Liraglutide 6mg/ml solution for injection (In prefilled pen)i.e. “for the treatment of chronic weight management for adults and Pediatric patients aged 12 years and older” along with the request of Phase III clinical trial waiver. The committee noted that the subject drug product is of recombinant origin and there is no safety and efficacy data available with the firm for the proposed indication of obesity. The committee further noted that there is no clinical data presented for the age group of 12 to 18 years. After detailed deliberation, the committee did not consider the firm’s proposal for approval of additional indication with waiver of Phase III clinical trial in India.
3.	BIO/CT21/FF/2024/46563 Recombinant Insulin Aspart Injection I.P (r-DNA origin) 100U/ml or 3.5 mg/ml	M/s Bio Genomics Limited	The firm presented the proposal for extension of indication of the drug product “Recombinant Insulin Aspart I.P 100 U/mL solution for injection in 3mL cartridge and 10mL vial” from the approved indication i.e. “for the treatment of Diabetes Mellitus (DM) in Adults” to

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	of Insulin Aspart in 3 ml Cartridge and 10 ml Vial		“for the treatment of Diabetes Mellitus in Adults, adolescents and children 1 year and above”. After detailed deliberation, the committee recommended the firm to submit safety and efficacy results generated from Phase IV clinical trial in India before the committee for further review of this proposal.
4.	BIO/CT04/FF/2024/45156 Recombinant Insulin Aspart Injection I.P (r-DNA origin) 100U/ml or 3.5 mg/ml of Insulin Aspart in 3 ml Cartridge and 10 ml Vial	M/s. Biogenomics Limited	In light of earlier SEC recommendation dated 13.11.2024, the firm presented the revised protocol for the conduct of Phase IV clinical trial titled “A multicenter, open-label, single-arm, Phase IV study to assess the safety and efficacy of InsuQuick® (Insulin Aspart) in adult patients with Type 2 Diabetes Mellitus” vide protocol No. BGL-IA-CTP-401-V3, Version 3.0 dated 06 Dec 2024”. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV study as per the Protocol No. BGL-IA-CTP-401-V3, Version 3.0 dated 06 Dec2024 as presented by the firm.
5.	BIO/CT04/FF/2024/46221 Insulin degludec & Insulin aspart injection	M/s GC Chemie Pharmie Ltd.	The firm presented the proposal to conduct PK/PD trial titled “A double blind, balanced, randomized, two-treatment, two-sequence, two-period, single dose, crossover, pharmacokinetic and pharmacodynamic bioequivalence study of insulin degludec and insulin aspart injection 100 units/mL of G. C Chemie Pharmie Limited, India comparing with Ryzodeg (Insulin degludec/Insulin aspart)100 units/mL of Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark, in healthy, adult, human male subjects using Euglycemic clamp technique under fasting conditions” vide protocol number no.: AR136-24Version 01 dated 24 Oct 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the PK/PD clinical study as per the protocol presented by the firm.
Medical Devices Division			

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6.	CI/MD/2024/134921 Magnamosis 23 System (Magnetic Compression Anastomosis System)	M/s Haleus Life Science LLP	<p>The proposal of the Clinical Investigation study having protocol number 2024/01/EDIT, Version 2, dated 02-Sep-2024 for the conduct of pilot clinical investigation on the applied device Magnamosis 23 System (Magnetic Compression Anastomosis System), in the country on Indian population, was discussed before the expert committee.</p> <p>The committee observed that the data presented by the firm were inadequate to establish the safety, effectiveness, and performance of the device.</p> <p>Specifically, the applicant failed to provide a clear indication of the proposed device, lacked clarity in inclusion and exclusion criterias, presented insufficient safety and efficacy data, and mentioned that the subject study is not conducted in anywhere in the world.</p> <p>After detailed deliberation, the committee recommended that permission to conduct a pilot study for the proposed device shall not be granted.</p>
FDC Division			
7.	FDC/MA/25/000001 Alogliptin 12.5mg + Metformin hydrochloride 850mg Tablet	M/s Torrent Pharmaceuticals Ltd.	Under Discussion
8.	FDC/MA/23/000249 Empagliflozin + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin + Metformin HCl IP (ER) (10mg+100mg+500mg/ 10mg+100mg+1000mg/ g/	M/s Exemed Pharmaceuticals	<p>In light of the earlier SEC recommendation dated 11.07.2024, the firm presented the proposal along with Phase III Clinical trial report before the committee.</p> <p>Committee noted that firm has conducted proposed Phase III Clinical trial in two strengths i.e. Empagliflozin + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin + Metformin HCl IP (ER) 10mg+100mg+1000mg/</p>

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	25mg+100mg+500mg / 25mg+100mg+1000mg) tablet		25mg+100mg+1000mg) tablet. After detailed deliberation, the committee recommended for grant of permission to manufacture and market for the proposed FDC in above two strengths.