Recommendations of the SEC (Endocrinology & Metabolism) made in its 13th/24 meeting held on 11.07.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/112/22 Online Submission (33403) Tirzepatide	M/s. Eli Lilly	The firm presented protocol amendment (b) dated 24 April 2024 protocol no. I8F-MC-GPIJ. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. Dr. Rajesh Khardgawat didn't participate in the deliberation.
2.	CT/04/20 Online Submission (33330) Somapacitan	M/s. Novo Nordisk India Pvt. Ltd.	The firm presented protocol amendment version 12.0 dated 21 March 2024 protocol no. NN8640-4245. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. Dr. Rajesh Khardgawat didn't participate in the deliberation.
3.	CT/01/19 Online Submission (33513) Semaglutide	M/s. Novo Nordisk India Pvt. Ltd.	The firm presented protocol amendment version 7.0 dated 06 March 2024 protocol no. NN9535-4352. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
SND Division			
4.	SND/MA/23/000044 Liraglutide 6 mg/mL Solution for Injection in Prefilled Pen and Cartridges (18mg/3mL Pre-filled Pen and Cartridges) (Synthetic Peptide)	M/s. Biocon Pharma Limited	The firm presented their proposal for grant of permission to manufacture and marketing of synthetic Liraglutide 6mg/ml solution for injection in pre-filled pen (18mg/3mL Pre-filled Pen) indicated for the treatment of type 2 Diabetes Mellitus along with Bioequivalence study report and justification for waiver of Phase-III clinical trial before the committee. The firm has informed that they have got approval of BIOLIDE synthetic Liraglutide 6mg/ml solution for injection in pre-filled pen in the United Kingdom on April 12/2024 and submitted approved

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			copy of SMPC which is issued by MHRA along with Approval letter for the following indication: Adults: as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of: • ≥30 kg/m² (obesity), or • ≥27 kg/m² to <30 kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea. Adolescents (≥12 years): BIOLIDE injection can be used as an adjunct to a healthy nutrition and increased physical activity for weight management in adolescent patients from the age of 12 years and above with: • obesity (BMI corresponding to ≥30 kg/m2 for adults by international cut-off points)* and • body weight above 60 kg. After detailed deliberation, the committee noted that the approved indication for BIOLIDE synthetic Liraglutide 6mg/ml solution for injection in pre-filled pen in UK-MHRA is for weight management. However, the firm has proposed indication for the treatment of type 2 Diabetes Mellitus. Therefore, the committee opined that the firm should submit more clinical trial data for proposed indication along with immunogenicity data or submit Phase-III clinical trial protocol to CDSCO for further review by the committee.
New Drugs Division			
5.	ND-12011/3/2024-eoffice Saxagliptin (Onglyza) tablets 2.5 mg & 5 mg	M/s. Astrazaneca Pharma India Ltd.	The firm presented the proposal for amendment in Package Insert from Version-11 to Version-12 for drug Onglyza (Saxagliptin) tablets 2.5mg & 5mg. After detailed deliberation, the committee recommended for approval of

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			amendment in PI from Version-11 to Version-12 for drug Onglyza (Saxagliptin) tablets 2.5mg & 5mg.
FDC Division			
6.	FDC/MA/24/000129 Linagliptin + Glimepiride IP + Metformin Hydrochloride IP (SR) (2.5mg+1mg+500mg, 2.5mg+1mg+ 1000mg, 2.5mg+2mg + 500mg & 2.5mg+2mg+1000mg) film coated tablet	M/s. Pure & Cure Healthcare Pvt. Ltd.	The firm presented the proposal before the committee along with BE study protocol and Phase III clinical trial protocol in two strengths i.e. Linagliptin + Glimepiride IP + Metformin Hydrochloride IP (SR) (2.5mg+1mg+ 1000mg & 2.5mg+2mg+1000mg) tablet. After detailed deliberation, the committee recommended for conduct of BE study. As regard to Phase III clinical trial protocol, the committee opined that firm needs to define withdrawal criteria in the protocol. Accordingly, revised Phase III clinical trial protocol should be submitted to CDSCO for further review.
7.	FDC/MA/23/000249 Empagliflozin + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin + Metformin HCl IP (ER) (10mg+100mg+ 500mg/10mg+100mg +1000mg/25mg+ 100mg+500mg/ 25mg+100mg+ 1000mg) tablet	M/s. Exemed Pharmaceuticals	In the light of earlier SEC recommendation dated 19.09.2023, the firm presented the proposal along with BE study report before the committee. After detailed deliberation, the committee considered the BE study report and recommended to initiate Phase III clinical trial study for which permission is already granted by CDSCO. The Phase III clinical trial report should be submitted to CDSCO for further review by the committee.
8.	FDC/MA/22/000099 Dapagliflozin 10mg + Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg film coated tablet	M/s. USV Pvt. Ltd.	In the light of earlier SEC recommendation dated 18.05.2022, the firm presented the proposal along with BE study report before the committee. After detailed deliberation, the committee considered the BE study report and recommended to initiate Phase III clinical trial study for which permission is already granted by CDSCO. The Phase III clinical trial report should be submitted to CDSCO for further review by the committee.