Recommendations of the SEC (Endocrinology & Metabolism) made in its 14th/24 meeting held on 13.08.24 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2024/ 41564 Liraglutide injection (rDNA origin) 6mg/mL	M/s. Virchow Biotech Private Limited	In light of earlier SEC recommendation dated 21.03.2024, the firm presented the revised protocol no. VBLG01/2024-CT1 Version 2 dated 04.04.2024 for the conduct of Phase III study titled "A Phase III, Randomized, Parallel, Double Blind, Non-inferiority, Multicenter Study to Compare Efficacy, Safety and Immunogenicity of VBLG01 to Victoza in Patients With Type 2 Diabetes". After detailed deliberation, the committee recommended the firm to conduct the proposed Phase III study as per presented protocol no. VBLG01/2024-CT1 Version 2 dated 04.04.2024 with a condition that withdrawal criteria should also include intolerance to doses of Liraglutide used in the study. Accordingly, the firm should submit the revised protocol to CDSCO for further evaluation.
2.	r-DNA-11011(18)/ 95/2024-eoffice Algalsidase Alfa (REPLAGAL®)	M/s. Takeda Biopharmaceuticals India Pvt. Ltd.	The firm presented the proposal for update in the package insert regarding home infusion and administration by the patient in presence of a responsible adult or administration by the patient's caregiver for patients who are tolerating their infusions well. After detailed deliberation, the committee recommended that the proposal should be deliberated in presence of Pediatrician and Geneticist (specialized physician).
3.	E. 37859 Dulaglutide solution for Injection	M/s. Eli Lilly and Company (India) Pvt. Ltd.	The firm has presented interim post marketing surveillance clinical study report H9X-IN-B012(b) version 1.0 dated 28.07.2023 for the study period from 04 Sept 2018 to 14 Oct 2022 with request to discontinue the study for the remaining subjects of post marketing surveillance study claiming that the firm have already completed Phase IV study as per the condition of marketing authorization

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			granted and the phase IV study report is under review which shall be submitted to CDSCO. After, detailed deliberation the committee recommended the firm to submit the results of post marketing surveillance study and Phase IV clinical study to CDSCO for further evaluation.
4.	E-19274 Insulin Glargine 300 U/mL	M/s. Sanofi	The firm presented the Clinical study results of Phase IV Clinical study titled "Multicentre, Phase IV, Single arm, clinical trial to evaluate the safety and efficacy of Gla-300 in Insulin-naive patients with Type 2 Diabetes uncontrolled on oral hypoglycaemic drugs" vide Protocol No. LPS16665, Version FINAL dated 26 Jun 2020. After detailed deliberation, the committee noted the results of the study presented by the firm.
SND Division			
5.	SND/IMP/24/000041 Tirzepatide Multiple Dose Pen (addition of new presentation-KwikPen) 12.5mg/0.6ml, 7.5mg/0.6ml, 15mg/0.6ml, 2.5mg/0.6ml	M/s. Eli Lilly and Company (India) Pvt. Ltd.	Firm presented their proposal for grant of permission to import and marketing of Tirzepatide multiple dose pen (addition of new presentation-Kwikpen) 2.5mg/0.6ml, 5.0mg/0.6ml, 7.5mg/0.6ml, 10.0mg/0.6ml, 12.5mg/0.6ml, and 15.0mg/0.6ml along with Bioequivalence study report of Tirzepatide subcutaneously by a fixed dose multi use prefilled pen versus single dose pen in healthy participants conducted in USA and with request for waiver of Phase-III clinical trial before the committee. Firm has informed that the Tirzepatide single dose prefilled pen 2.5mg/0.5ml, 5.0mg/0.5ml, 7.5mg/0.5ml, 10.0mg/0.5ml, 12.5mg/0.5ml, 15.0mg/0.5ml is approved by CDSCO on 19.01.2024 indicated as an adjunct to diet and exercise to improve glycemic control in adult with type 2 diabetes mellitus with condition to conduct Phase IV clinical trial. Firm has presented the BE study report of tirzepatide 5.0mg/0.6ml using the preserved formulation administered through the multi-dose PFP- prefilled pen (test) compared to non-preserved

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			formulation administered through an SDP-single dose pen (Reference), carried out in USA before the committee. The committee noted that that the prespecified criteria for the Cmax was not met during the study. The committee also noted that submitted BE study was carried out in USA for Single dose pen without preservative Vs multi dose prefilled pen with preservative. Therefore, after detailed deliberation, the committee opined that the firm should submit interim efficacy data of Phase IV Clinical Trial of already approved Single Dose Prefilled Pen formulation in Indian population along with global safety and efficacy data on Multidose Prefilled Pen product with preservative to CDSCO for further review by the committee.
6.	SND/MA/24/000127 Cholecalciferol (Vitamin D3) Drops 400 IU/0.5ml	M/s. Alkem Laboratories Limited	Firm has presented their proposal for the grant of permission to manufacture and marketing of Cholecalciferol (vitamin D3) drops 400IU/0.5 ml for the prevention of Vitamin D3 deficiency along with justification for waiver of phase-III clinical trial and BE study before the committee. Firm presented that the formulation has already been approved in India in strength 800 IU/ml and the proposed formulation is same as approved one with difference in the way of presentation (400 IU/0.5ml) in line with the daily recommended doses as per Indian academy of pediatrics (IAP) Guidelines 2017, American Academy of Paediatrics (AAP) and other international guidelines. After detailed deliberation, the committee recommended for the grant of permission for manufacture and marketing of Cholecalciferol (vitamin D3) drops 400IU/0.5 ml for the approved indication. In addition to this firm should fulfil the requirement of CMC data in compliance with NDCT Rules, 2019.
7.	SND/MA/22/000104 Semaglutide Injection 15mg/3ml (Synthetic	M/s. Zydus Lifesciences Limited	Firm presented their proposal for grant of permission to manufacture and marketing of Semaglutide injection 15 mg/3ml (Synthetic Origin) along with

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	Origin)		Bioequivalence study Protocol no. C1B04557 ver. 01 dated 05.06.2024 and CT Protocol no. CT/2024/31 ver. 00 dated 31.05.2024 before the committee for the proposed indication as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 Diabetes Mellitus. Firm has informed that the formulation of Semaglutide solution for injection in prefilled pen (Single dose pen injector) 0.25mg, 0.5mg, 1.0 mg, 1.7mg & 2.4 mg (Biological origin) and Semaglutide 3mg tablets, 07 mg tablets and 14 mg (Biological origin) are approved by CDSCO on 20.04.2022 & 27.07.2020 respectively for various indication. Further, Semaglutide injection (synthetic origin) is not approved globally. After detailed deliberation, the committee recommended to conduct Phase III clinical trial and BE study as per protocol presented by the firm with subject to condition that the firm should submit BE Study report to CDSCO and BE report should be evaluated from the committee before initiation of Phase-III clinical trial.
8.	SND/MA/22/000105 Semaglutide Injection 15mg/3ml (Synthetic Origin)	M/s. Zydus Lifesciences Limited	Firm presented their proposal for grant of permission to manufacture and marketing of Semaglutide injection 15 mg/3ml (Synthetic Origin) along with Bioequivalence study Protocol no. C1B04558 ver. 01 dated 05.06.2024 and CT Protocol no. CT/2024/32 ver. 00 dated 01.06.2024 before the committee for the proposed indication as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adult patients with an initial BMI of 1) 30 kg/m^2 or greater (obesity) 2) 27 kg/m^2 or greater (Overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus or dyslipidemia). Firm has informed that the formulation of Semaglutide solution for injection in prefilled pen (Single dose pen injector) 0.25mg, 0.5mg, 1.0 mg, 1.7mg & 2.4 mg

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			(Biological origin) and Semaglutide 3mg tablets, 07 mg tablets and 14 mg (Biological origin) are approved by CDSCO on 20.04.2022 & 27.07.2020 respectively for various indication. Further Semaglutide injection (synthetic origin) is not approved globally. After detailed deliberation, the committee recommended to conduct Phase III clinical trial and BE study as per protocol presented by the firm with subject to condition that the firm should submit BE Study report to CDSCO and BE report should be evaluated from the committee before initiation of Phase-III clinical trial.
9.	SND/MA/23/000044 Liraglutide 6mg/ml soln for inj. In prefilled pen & cartridges (synthetic peptide)	M/s. Biocon Pharma Limited	In light of earlier SEC recommendation dated 11.07.2024, the firm presented their proposal along with immunogenicity data and request for Phase III CT waiver before the committee. The committee noted that Liraglutide Biocon 6mg/ml solution for injection in pre-filled pen has already been approved by UK MHRA on 12.04.2024 for the following therapeutic indication: Liraglutide Biocon injection is indicated for the treatment of adults, adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise • as monotherapy when metformin is considered inappropriate due to intolerance or contraindications. • in addition to other medicinal products for the treatment of diabetes After detailed deliberation, the committee recommended for grant of permission to manufacture and market Liraglutide 6mg/ml solution for injection in pre-filled pen with Phase-III CT waiver subject to condition that the firm should conduct Phase-IV clinical trial. In addition to above, firm should fulfil the requirement of CMC data in compliance with NDCT Rules, 2019. Accordingly, the firm should submit Phase IV Clinical trial protocol to CDSCO within three months of approval

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			of the drug for further review by the committee.