Recommendations of the SEC (Endocrinology & Metabolism) made in its 3rd/24 SEC meeting held on 13.02.2024 & 14.02.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/22/23 Online Submission (30953) TP -102	M/s. JSS Medical Research Asia Pacific Private Limited	The firm presented protocol amendment version 4.2 dated 04 January 2024 protocol No. TP-102_102. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
2.	BIO/CT04/FF/2023/ 40197 ALT-P1 30 mg/vial	M/s. Cliantha Research Limited	The firm presented the proposal for conduct of clinical trial titled "A Randomized, Multicenter, Active-controlled Open-labelled, Multiple-Dose, Dose Finding, Parallel Group Trial, Investigating the Efficacy, Safety, Immunogenicity, Tolerability, Pharmacokinetics and Pharmacodynamics of Three Different Weekly Doses of ALT-P1 Compared to Daily Growth Hormone Treatment of GENOTROPIN® (Somatropin) for Injection in Growth Hormone Treatment naive Pre-pubertal Children with Growth Hormone Deficiency vide Protocol no. C2A03447 Version no. 1 dated 17.10.2023. After detailed deliberation, the committee recommended the firm to conduct the study with the following change in the protocol. 1. Firm should use IAP growth charts for evaluation in the study. Accordingly, firm should submit the revised protocol to CDSCO.
3.	BIO/IMP/22/000015 Semaglutide	M/s. Novo Nordisk	The firm presented the proposal for amendment in the warning statement for inclusion of Obstetricians & Gynaecologists, Bariatric surgeons in the approved warning statement i.e. "To be sold by retail on the prescription of an Endocrinologist, and Internal medicine". The committee noted that the approved drug is not yet launched in India for marketing.

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			After detailed deliberation, the committee recommended the firm to submit post marketing safety data of Indian population for further evaluation by the committee.
4.	BIO/IMP/21/000050 Semaglutide	M/s. Novo Nordisk	The firm presented the proposal for amendment in the warning statement for inclusion of Obstetricians & Gynecologists, Bariatric surgeons in the approved warning statement i.e. "To be sold by retail on the prescription of an Endocrinologist, and Internal medicine". The committee noted that the approved drug is not yet launched in India for marketing. After detailed deliberation, the committee recommended the firm to submit post marketing safety data of Indian population for further evaluation by the committee.
5.	BIO/CT04/FF/2023/39609 Insulin Glargine and Lixisenatide Injection	M/s. Sanofi Healthcare India Pvt. Ltd.	The firm presented the proposal to conduct Phase IV clinical trial titled "Multicentre Phase IV single arm clinical trial to evaluate the safety and efficacy of a fixed ratio combination of Glargine 100 U/mL and Lixisenatide 33/50 mcg/mL in adults with type 2 diabetes who are sub optimally controlled on oral antihyperglycemic drugs and/or basal Insulin/GLP-1 RA"vide Protocol No: LPS18016Version 1.0 dated 16.08.2023. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV study with the following changes in protocol- 1. Patients on premixed and basal bolus therapy should be excluded from the study 2. Wash out period of 5 half lives to be given to patients who is on DPP-4 inhibitors. Accordingly, firm should submit the revised protocol to CDSCO
6.	BIO/CT04/FF/2024/41562 Insulin Glargine 100IU/ml	M/s. Virchow	The firm presented the clinical trial protocol titled "A Phase III, Randomized, Controlled, Open-Label, Multicenter, Parallel Comparative study to assess the Efficacy and Safety of VB70G (Insulin

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			Glargine Injection 100 Units/mL) with LANTUS® in Type 2 Diabetes Mellitus patients with Uncontrolled Oral Antidiabetic therapy" vide Protocol number: VB70G/2024-CT2 Version 1 dated 12.01.2024. After detailed deliberation, the committee recommended to conduct the clinical trial as per the protocol presented by the firm.
7.	BIO/CT04/FF/2023/ 40654 Biphasic Insulin Aspart Injection (30/70) 100 IU/mL	M/s. Wockhardt Limited	The firm presented the clinical trial protocol titled "A randomized, single center, double blind, two-period, crossover glucose clamp study to test for bioequivalence between two recombinant human insulin analogues – Wockhardt's biphasic insulin aspart injection (30/70) and novomix®30, in healthy subjects." vide Protocol No. W-ASP (B)-104; Version No.01 dated 03.11.2023. After detailed deliberation, the committee recommended to conduct the clinical trial as per the protocol presented by the firm.
8.	BIO/CT04/FF/2024/ 41652 Insulin Aspart Mix 70/30 Injection	M/s. Mankind Pharma	In light of earlier SEC recommendation dated 24.11.2023, the firm presented the results of PK/PD study along with their proposal to conduct Phase-III clinical study titled "A randomized, open label, Phase 3 study to compare the efficacy and safety of Recombinant Insulin Aspart (RapilinTM 30) with Recombinant Insulin Aspart (NovoMix 30) in Adult Patients of Type 2 Diabetes Mellitus" vide Protocol No CCS/INS/21/v2 Version 2 dated 03.02.2023. After detailed deliberation, the committee recommended for conduct of the study with the following change in the protocol. 1. The full name of test and reference products including their combination should be mentioned in the protocol. 2. Number of study sites to be increased. Accordingly, firm should submit the protocol to CDSCO for further evaluation.

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BA/BE Division			
9.	File No. 12-09/2024/BA-BE/MISC-06/DC BABE/CT05/FF/2023/39855 Alogliptin 25 mg Tablets and Metformin Hydrochloride 1000 mg Extended Release Tablets	M/s. AnaCipher Clinical Research Organisation (A Division of Indoco Remedies Limited) Telangana-500 013	The firm presented Bioequivalence study protocol No. 035-BE-2023, Version No. 02 dated 30-08-2023. After detailed deliberation, the committee recommended for grant of permission to conduct the BE Study as presented by the firm.
SND Division			
10.	SND/MA/23/000039 Semaglutide 14mg tablets	M/s. Torrent Pharmaceuticals Limited	In light of earlier SEC recommendation on dated 21/03/2023 &22/03/2023, the firm has been issued BE-NOC on Form CT-07 vide no. - BE/SND/12/2023 dated 15.05.2023 for BE study protocol no. 22-143, Ver no. 01, dated 23.11.2022. The present proposal of the firm is for amendment in the Protocol no. 22-143 Amendment no. 01 dated 04-Dec-2023. After detailed deliberation, the committee recommended for consideration of the amendment in the study protocol vide Protocol no. 22-143 Amendment no. 01 dated 04-Dec-2023.
11.	SND/MA/21/000249 Vitamin D3 Oral Liposomal solution 60000IU/5ml (Additional Dosage form)	M/s. Solistaa Pharmaceuticals Private Limited	The firm presented the proposal for Manufacturing and marketing permission of Vitamin D3 Oral Liposomal solution 60000 IU/5ml (Additional Dosage form) along with their justification for BE and CT Waiver before the committee. It is informed that proposed liposomal formulation is having more bio-availability than the conventional formulation and such liposomal formulation is approved in Australia only. After detailed deliberation, the committee opined that the firm should conduct CT study & BE study to provide the clinical efficacy and safety of proposed liposomal

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			formulation. Accordingly, firm should submit BE study protocol and Phase III clinical trial protocol to CDSCO for further review by the committee.
New Drug Division			
12.	ND/CT/22/000068 Imeglimin HCL Tablets 1000 mg	M/s. Exemed Pharmaceuticals Ltd.	The firm presented Phase IV clinical trial report of drug Imeglimin HCL Tablet 1000 mg before the committee. After detailed deliberation, the committee noted and agreed with the results of the presented phase IV CT study with drug Imeglimin HCL Tablet1000 mg.
FDC Division			
13.	04-17/2015-DC Dapagliflozin + Metformin Hydrochloride (ER) 10mg/10mg + 1000mg/500mg film coated tablet	M/s. AstraZeneca Pharma India Limited	The firm presented the proposal for update in prescribing information for said FDC, changes based on the updated company core data sheet (CCDS) version 4 dated 17.07.2023. After detailed deliberation, the committee recommended for grant of approval for the proposed update in prescribing information with the modification that "Vitamin B-12 decrease/deficiency" should be categorized as possible adverse reaction instead of common adverse reaction.
14.	04-16/2018-DC (Pt. AstraZeneca) Dapagliflozin 5mg + Metformin Hydrochloride IR 1000mg film coated tablet	M/s. AstraZeneca Pharma India Limited	The firm presented the proposal for update in prescribing information for said FDC, changes based on the updated company core data sheet (CCDS) version 3 dated 17.07.2023. After detailed deliberation, the committee recommended for grant of approval for the proposed update in prescribing information with the modification that "Vitamin B-12 decrease/deficiency" should be categorized as possible adverse reaction instead of common adverse reaction.
15.	FDC/MA/19/000111 -112 Alogliptin Benzoate 17 mg eq. to Alogliptin	M/s. Indoco Remedies Limited	In light of earlier SEC recommendation dated 15.10.2020 and as per condition of Form CT-23 dated 18.05.2020, the firm presented Phase IV clinical trial report before the committee.

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	12.5mg/12.5mg + Metformin Hydrochloride IP 500mg/1000mg film coated tablet		After detailed deliberation, the committee noted and agreed to the result of the clinical trial report.
16.	FDC/IMP/18/000012 Saxagliptin 5mg + Dapagliflozin 10mg film coated tablet	M/s. AstraZeneca Pharma India Limited	The firm presented the proposal for update in prescribing information for said FDC, changes based on the updated company core data sheet (CCDS) version 4 dated 23.11.2022. After detailed deliberation, the committee recommended for grant of approval for the proposed update in prescribing information with the modification under special warning and precautions for use as "If a patient presents with severe joint pain after starting the drug, continuation of drug therapy should be individually assessed."
SND Division			
17.	SND/IMP/23/000076 Tirzepatide 2.5 mg/0.5 ml,5mg//0.5ml,10mg/0.5,12.5 mg/0.5 ml and 15mg/.5 ml solution for injection	M/s Eli Lily	The firm presented the proposal for import and marketing permission of Tirzepatide 2.5 mg/0.5 ml, 5mg/0.5ml, 10mg/0.5 ml, 12.5 mg/0.5 ml and 15mg/.5 ml solution for injection (Single dose vial) along with their justification for BE and CT Waiver before the committee. The firm has informed that the similar formulation i.e Tirzepatide 2.5 mg/0.5 ml, 5mg/0.5ml, 10mg/0.5 ml, 12.5 mg/0.5 ml and 15mg/.5 ml injection in Prefilled pen is already approved by the CDSCO for the same indication and now firm has proposed for formulation in single dose vial presentation. After detailed deliberation, the committee has recommended for import and marketing permission of Tirzepatide 2.5 mg/0.5 ml, 5mg/0.5ml, 10mg/0.5 ml, 12.5 mg/0.5 ml and 15mg/.5 ml solution for injection (single dose vial) subject to condition that the firm should conduct Phase-IV clinical trial.. Accordingly, the firm should submit Phase-IV clinical trial

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			protocol .to CDSCO within 03 months from date of approval for further review by the committee Further, firm should fulfil the requirement of CMC data along with comparative data with that of already approved pre-filled pen.