

Recommendations of the SEC (Endocrinology & Metabolism) made in its 21st/25 meeting held on 16.10.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2025/51015 Insulin Aspart Injection 100IU/mL	M/s. Wockhardt Limited	<p>The firm presented the proposal to conduct Phase III clinical trial titled “A prospective Randomized, Open Label, Parallel-group, Multi-center Phase 3 Study to Compare Efficacy and Safety of Recombinant Insulin Aspart R (Manufactured by Wockhardt Limited) with NovoRapid® (Manufactured by Novo Nordisk), in Adult Patients with Type 2 Diabetes Mellitus” as per Protocol Number- WOC/ASP/CT-02/25, Version 1.0 dated 23 June 2025.</p> <p>After detailed deliberation, the committee recommended for the grant of permission to conduct the Phase III clinical trial as per the presented protocol, subject to the following changes:</p> <ul style="list-style-type: none"> • The study design should be changed from open label to Accessor blind. • All PI’s of the clinical trial should be Qualified Endocrinologist. • Incidents of hypoglycemia should be recorded during the study. <p>Accordingly, the revised protocol shall be submitted to CDSCO for further evaluation.</p>
2.	BIO/CT21/BD/2025/50998 (Drugs Substance) BIO/CT21/FF/2025/52042 (Drug Product) Insulin Glargine (r-DNA origin) injection (100 IU/mL)	M/s. Genesys Biologics Pvt. Ltd.	<p>The firm presented the proposal to manufacture and market the drug product Insulin Glargine I.P (r-DNA Origin) Injection 100 IU/ml based on the results of Phase-III clinical trial conducted by the firm.</p> <p>The Committee noted that firm has conducted Non-Inferiority study to compare the Efficacy and Safety of GEN1501 (Insulin Glargine (r-DNA Origin) Injection 100 Units/mL) of</p>

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			<p>GeneSys Biologics Pvt. Ltd., India with LANTUS® (Insulin Glargine (r-DNA Origin) Injection 100 Units/mL) in subjects with Type 2 Diabetes Mellitus on Uncontrolled Oral Antidiabetic therapy (OAD).</p> <p>After detailed deliberation, the committee recommended for the grant of permission to the firm to manufacture and market Insulin Glargine I.P (r-DNA Origin) Injection 100 IU/ml for the “Treatment of Type II Diabetes Mellitus in Adults only” with a condition to conduct Phase IV study in the country.</p> <p>Accordingly, the protocol to conduct the Phase IV study shall be submitted to CDSCO within 3 months of grant of marketing authorization permission to manufacture and market the drug product.</p>
3.	<p>E-104102</p> <p>Somapacitan Injection 5 mg/1.5 ml, 10mg/1.5ml and 15 mg/1.5 ml solution for injection in PFP</p>	<p>M/s. Novo Nordisk India Pvt Ltd</p>	<p>The firm presented the proposal to conduct following India specific PMS studies for the approved drug product Somapacitan Injection 5 mg/1.5 ml, 10 mg/1.5 ml and 15 mg/1.5 ml solution for injection in PFP -</p> <p>i. A multi-centre, prospective, single-arm, observational, non-interventional, post-marketing surveillance study to investigate safety of somapacitan in adults with growth hormone deficiency (AGHD) under routine clinical practice in India vide Protocol No. NN8640-8387, Version 1.0 dated 29 Jul 2025.</p> <p>ii. A Non-Interventional, Observational Study to Investigate Long-Term Safety and Clinical Parameters of Somapacitan Treatment in Paediatric Patients with Growth Hormone Deficiency During Routine Clinical Practice in India vide Protocol No. NN8640-8388, Version 1.0 dated 29 Jul 2025.</p>

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			After detailed deliberation, the committee recommended for approval to conduct the proposed PMS studies as per protocols presented by the firm.
4.	E-106439 Semaglutide Injection 0.25 mg / 0.5 mg /1 mg /1.7 mg /2.4 mg (Wegovy and Wegovy Flextouch)	M/s. Novo Nordisk India Pvt Ltd	<p>The firm presented the proposal for update in Package Insert for the drug product Semaglutide Injection 0.25 mg /0.5 mg /1 mg /1.7 mg /2.4 mg [Brand name: Wegovy® (Single dose Pen injector)] & Semaglutide Injection 0.25 mg/0.5 mg/1 mg/1.7 mg/2.4 mg [Brand Name: Wegovy® FlexTouch®] to include updates in Section 4.8- Undesirable effects and Section 5.2- Pharmacodynamic properties based on the results of the conducted clinical trials (STEP HFpEF DM, STEP HFpEF and STEP 9 OA) in line with EMA approved PI.</p> <p>After detailed deliberation, the committee recommended for approval of updated package insert for the proposed changes.</p>
New Drugs Division			
5.	ND- 12011(13)/32/2025- eoffice Liothyronine 5 mcg & 20 mcg tablets	M/s ACME GENERICS PVT. LTD	<p>In the light of earlier SEC recommendations dated 19.10.2022 & 20.10.2022, the firm presented the Phase IV clinical trial report (Protocol ID: IBPL/ CT / PHASE-IV / 03 / 2022 – AG, Protocol Version 2.0; Date: 20-October-2022) of the drug Liothyronine 5 mcg & 20 mcg tablets.</p> <p>The committee noted that the firm did not present exact statistics of the data in form of tables and graphs in order for the experts to evaluate the same. Further, it was noticed that the CT sites had unequal distribution of patients and a GCP audit is recommended.</p> <p>The committee raised concerns about capturing of adverse events and noted that commonly suspected adverse events have not been reported. The committee</p>

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			did not consider Phase IV CT results presented by the firm and recommended the firm to present well-structured and detailed presentation for further review by the committee.
SND Division			
6.	SND/MA/25/000153 Diazoxide capsules 25 mg	M/s. Ekam Pharma	The firm presented the proposal for grant of permission for manufacturing and marketing Diazoxide capsules 25 mg along with Justification for BE and Clinical trial waiver before the Committee. After detailed deliberation, the Committee opined that firm should submit the Globally approved PI/reference document for usage and method of administration of Diazoxide Capsule 25 mg in pediatric populations for proposed indication to CDSCO for review by the Committee in presence of Pediatrician
7.	SND/MA/19/000014, E. No. 104564 Vildagliptin sustained Release Tablets 100mg	M/s. Abbott Healthcare Pvt. Ltd.,	The firm presented the Active PMS study report for Vildagliptin 100mg SR Tablets in Type 2 Diabetes Mellitus (T2DM) Patients before the committee. After detailed deliberation, the committee accepted the Active PMS study report.
FDC Division			
8.	FDC/CT/25/000014 Empagliflozin 5 mg/10 mg/12.5 mg/25 mg + Metformin Hydrochloride IP (ER) 1000 mg/1000 mg/ 1000 mg/ 1000 mg film coated bilayered tablet	M/s. Zydus Healthcare Limited	In light of earlier SEC recommendation dated 29.04.2025 and as per condition mentioned in permission in Form CT-23 dated 13.12.2024, the firm presented the revised Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee noted that. 1. Indication should be as per Form CT-23. 2. Inclusion/Exclusion criteria should be revised as per approved indication.

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			Accordingly, the firm should submit revised scientifically justified Phase IV clinical trial study protocol for further review by the committee.