Recommendations of the SEC (Endocrinology & Metabolism) made in its 09th/26 meeting held on 23.04.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/30/26 Online Submission (55121) RO7795068 (CT-388)	M/s. Roche Products (India) Private Limited	The firm presented phase III clinical study protocol no.: WC45726 version no. 1.0 dated 24-SEP-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition. 1) The firm shall develop SOP for uniform monitoring hypoglycemia for all the participating sites. 2) The firm shall update subject withdrawal and rescue criteria as suggested by expert for overall safety of the participants. 3) The firm shall submit phase II study report to CDSCO.
2.	CT/29/26 Online Submission (55111) RO7795068 (CT-388)	M/s. Roche Products (India) Private Limited	The firm presented phase III clinical study protocol no.: WC45725 version no. 1.0 dated 24-SEP-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition. 1) The firm shall develop SOP for uniform monitoring hypoglycemia for all the participating sites. 2) The firm shall update subject withdrawal and rescue criteria as suggested by expert for overall safety of the participants. 3) The firm shall submit phase II study report to CDSCO.
Biological Division			
3.	BIO/CT18/FF/2025/50951 Velaglucerase Alfa (r-DNA Origin)	M/s. Takeda Biopharmaceuticals India Pvt. Ltd	The firm presented a proposal for grant of approval of extension of indication of Velaglucerase Alfa (r- DNA Origin) Brand name: (VPRIV®); Powder for Solution for Infusion wherein proposed indication is read as: Velaglucerase alfa is indicated for long-term enzyme replacement therapy (ERT) in patients with type-1, and chronic neuronopathic (Type 3) Gaucher disease

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			who exhibit clinically significant non-neurological manifestations of the disease. The non-neurological manifestations of Gaucher disease include one or more of the following conditions: • anaemia after exclusion of other causes, such as iron deficiency • thrombocytopenia • bone disease after exclusion of other causes such as Vitamin D deficiency • hepatomegaly or splenomegaly Precautions about Indication: • Velaglucerase alfa should be administered only the patients with a confirmed diagnosis of Gaucher disease. • The effectiveness to the neurological symptoms is not expected. • The effects on the symptoms in Type 3 Gaucher disease patients are not sufficiently demonstrated (especially on the bone symptoms) The committee noted that the subject drug is approved in India since 21.05.2018 for Velaglucerase Alfa (r- DNA Origin) Brand name: (VPRIV®); Powder for Solution for Infusion for long-term enzyme replacement therapy (ERT) in patients with type 1 Gaucher disease. After detailed deliberation, the committee recommended that the subject proposal shall be re-deliberated by inviting Pediatric Neurologists (who has not been part of clinical trials as an investigator of M/s Takeda Biopharmaceuticals India Pvt. Ltd.) to provide an opinion on the proposed extension of indication.
4.	BIO/CT18/FF/2025/52834 Idursulfase Beta 6 mg/3 mL Concentrate for solution for infusion	M/s. Cliniexperts Services Private Limited	The firm presented the proposal for grant of permission to import and market the drug product Idursulfase Beta 6 mg/3 mL Concentrate for solution for infusion for the treatment of patients with Hunter Syndrome (Mucopolysaccharidosis II, MPS II) as an enzyme replacement therapy. The committee noted that the aforesaid drug is an orphan drug for the treatment of rare disease and is already approved and

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			marketed internationally. After detailed deliberation, the committee recommended for grant of permission to import and market the drug product Idursulfase Beta 6 mg/3 mL Concentrate for solution for infusion for the treatment of patients with Hunter Syndrome (Mucopolysaccharidosis II, MPS II) as an enzyme replacement therapy. With a condition that firm shall conduct Phase IV study in India. The said Phase IV study must be carried out exclusively in denovo patients i.e. patients who have not been previously exposed to drug and that previously treated patients should not be included so as to ensure generation of meaningful real word evidence. Accordingly, firm shall submit Phase IV Clinical Trial protocol to CDSCO within 03 months of grant of marketing authorization permission.
5.	BIO/CT18/FF/2025/53185 Semaglutide Injection 0.25mg / 0.5mg /1mg /1.7mg /2.4mg	M/s. Novo Nordisk India Private Limited	The firm presented a proposal for grant of approval of additional indication of Semaglutide Injection 0.25 mg / 0.5 mg /1mg /1.7 mg /2.4 mg [Brand Name: Wegovy] (r-DNA Origin). The committee noted that the subject drug is approved in India since 20.04.2022 for Semaglutide Injection 0.25 mg, 0.5 mg, 1.0 mg, 1.7 mg & 2.4 mg; Solution for injection in prefilled pen for chronic weight management in adults. After detailed deliberation, the committee recommended for grant of conditional approval for the proposed additional indications where subject drug is indicated for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults; considering the significant therapeutic advancement over the current standard of care, in-line with US accelerated approval for proposed indication subject to the following conditions:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			1. Firm shall submit the complete Phase-III CSR for the subject confirmatory ESSENCE Trial NN9931-4553(Part-2). 2. Continued approval for proposed indication is subject to verification of safety and clinical benefit in a subject confirmatory trial NN9931-4553 (Part-2) titled as "A randomized, double-blind, placebo-controlled, parallel-group 240-week trial in patients with metabolic dysfunction-associated steatohepatitis (MASH) with liver fibrosis to demonstrate clinical benefit on the composite endpoint of progression to cirrhosis, hepatic decompensation events, liver transplant, and mortality
FDC Division			
6.	FDC/MA/25/000022 Dapagliflozin Propanediol eq. to Dapagliflozin 10mg + Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg + Metformin Hydrochloride IP (SR) 1000mg film coated bilayered tablet	M/s. Eris Lifesciences Limited	In light of the earlier SEC recommendation dated 17.07.2025, the firm presented the proposal along with BE study report (both fasting and fed condition) and justification for Phase III CT waiver before the committee. Committee noted that firm has already conducted Phase III CT study on FDC of Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg film coated tablets and Metformin as a background therapy. After detailed deliberation, the committee considered the BE study report (both fasting & fed condition) and request for Phase III CT waiver and recommended for grant of permission for manufacturing and marketing of the FDC with the condition to conduct Phase IV clinical trial. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of approval of the FDC for review by the committee.
7.	FDC/MA/22/000360 Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin	M/s. Exemed Pharmaceutical	In light of earlier SEC recommendation dated 08.05.2025, the firm presented their proposal along with justification for CT results before the committee.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	100mg/100mg + Glimepiride IP 1mg/2mg + Metformin Hydrochloride IP (as ER) 1000mg/1000mg film coated tablet		Committee noted the following: 1. The Phase III CT results are in line with the pre-defined parameters of Phase III CT Protocol. 2. The lower strength is already approved by CDSCO i.e., i. Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin + Metformin Hydrochloride IP + Glimepiride IP (50 mg + 1000 mg + 1 mg & 50 mg + 1000 mg + 2 mg) tablets and ii. Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin + Metformin Hydrochloride IP + Glimepiride IP (50 mg + 500 mg + 1 mg & 50 mg + 500 mg + 2 mg) film coated tablet After detailed deliberation, the committee considered the justification and recommended for grant of permission for manufacturing and marketing of the proposed FDC.