

Recommendations of the SEC (Endocrinology & Metabolism) made in its 07th/24 meeting held on 10.04.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/96/23 Online Submission (31116) LY3502970	M/s. Eli Lilly	The firm didn't turn up for presentation.
2.	CT/62/23 Online Submission (31103) LY3502970	M/s. Eli Lilly	The firm didn't turn up for presentation.
3.	CT/43/24 Online Submission (42430) LY3437943 (Retatrutide)	M/s. Eli Lilly	The firm didn't turn up for presentation.
4.	CT/70/23 Online Submission (31815) CRN04894	M/s. PPD	The firm presented protocol amendment version 3.0 dated 13 October 2023 protocol no. CRN04894-03. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
5.	r-DNA-11011(18)/ 22/2024-eoffice Somapacitan Injection 5 mg/1.5 ml, 10mg/1.5ml and 15 mg/1.5 ml solution for injection in PFP	M/s. Novo Nordisk	The firm presented the proposal for waiver of Phase-IV clinical study imposed in the marketing authorization permission granted for the drug Somapacitan. After detailed deliberation, the committee agreed for waiver of Phase-IV study condition and recommended to conduct Active Post Marketing Surveillance (PMS) study. Accordingly, the firm shall submit protocol to conduct Active PMS study within three months. (Dr. Rajesh Khadgawat didn't participate in the deliberation)
6.	BIO/CT18/FF/2023/3 9333 Insulin Icodec 700U/1mL, 1050	M/s. Novo Nordisk India Pvt. Ltd.	In continuation to the earlier SEC dated 11.01.2024, firm presented their proposal to import and market Insulin Icodec 700 U/ml, 1050 U/1.5 ml, 2100 U/3ml solution for injection in prefilled pen

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	U/1.5 mL & 2100 U/3 mL		<p>indicated for the treatment of diabetes mellitus in adults based on the data generated from global clinical trials including Indian patients.</p> <p>The Committee noted that firm has received opinion from EMA (NRA of country of origin) regarding grant of marketing authorization for subject drug and the drug is approved by Health Canada and Swissmedic.</p> <p>After detailed deliberation, the committee reiterated the earlier SEC meeting recommendations dated 11.01.2024 as the drug is not yet approved in the country of origin. (Dr. Rajesh Khadgawat didn't participate in the deliberation.)</p>
SND Division			
7.	SND/MA/23/000115 Metformin Hydrochloride SR Tablets 500mg/1000mg	M/s. USV Private Limited	<p>In light of earlier SEC recommendations dated 27.09.2023 & 29.09.2023, the firm presented their proposal for amendment in package insert with respect to the statement is to be included in the section of Fertility, Pregnancy and Lactation "if clinical needed, the use of metformin can be considered during pregnancy and in the periconceptional phase as an addition or an alternative to insulin" before the committee along with gynecologist & neonatologist.</p> <p>After detailed deliberation, the committee opined that the firm should submit the teratogenicity data/animal toxicity data and clinical data on their own product to CDSCO for further review by the committee.</p>
8.	SND/MA/21/000290 Nano carrier Entrapped Vitamin D3 Oral Dispersion 60000IU/5ml	M/s. Pulse Pharma Limited	<p>In light of earlier SEC recommendations dated 22.02.2024, the firm presented causality assessment data of all the adverse events as per WHO Scale and justification for major discrepancy observed in the lab values with respect to 25(OH) Cholecalciferol before the committee.</p>

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			After detailed deliberation, the committee opined that the raw data submitted by the firm is required to be verified for major discrepancy observed in the lab data with respect to 25(OH) cholecalciferol and report will be deliberate before the committee.
9.	SND/MA/22/000365 Cholecalciferol Granules 60000 IU	M/s. Zuventus Healthcare Limited	<p>In light of earlier SEC recommendations dated 21.03.2023 & 22.03.2023, the firm now presented justifications for waiver of Clinical trial and bioequivalence study including safety and clinical evidence supporting 60000IU dosage before the committee.</p> <p>The firm informed that CDSCO has approved Cholecalciferol 60000 IU orally disintegrating strips (in 2017), Cholecalciferol oral drops 800 IU/ml (in 2021), Cholecalciferol 2000 IU orally disintegrating strips (in 2015), Cholecalciferol 60000 IU chewable tablets (in 2022) and Cholecalciferol 60000 IU Oral solution (in 2022).</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Cholecalciferol Granules 60000 IU with CT and BE waiver subject to condition that the firm should conduct the Phase-IV clinical trial. In addition to above firm should fulfill the requirement of CMC data before approval of the product.</p> <p>Accordingly, the firm should submit Phase-IV clinical trial within 03 months from date of approval of the product to CDSCO for further review by the committee.</p>
10.	SND/CT/24/000001 Liraglutide Solution for injection in pre filled pen (Synthetic peptide) 6mg/ml	M/s. Biocon Limited	<p>In light of earlier SEC recommendations dated 20.04.2023, the firm presented the Phase-III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee opined that the firm should revised protocol with respect to sample size, inclusion and exclusion criteria, withdrawal criteria, some of biochemical</p>

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			parameters. Further, the committee also mentioned that the clinical trial sites shall be geographically distributed and have equal govt. & private sites. Accordingly, the firm should submit the revised Phase-III clinical trial protocol to CDSCO for further review by the Committee.
FDC Division			
11.	FDC/MA/24/000070 Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 100mg/100mg + Glimepiride IP 1mg/2mg + Metformin Hydrochloride IP (ER) 500mg/500mg Film Coated Tablet	M/s. Sun Pharma Laboratories Limited	The firm didn't turn up for presentation.
12.	FDC/MA/24/000074 Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg/100mg + Gliclazide IP (SR) 30mg/60mg + Metformin Hydrochloride IP (SR) 500mg/500mg film coated bilayered tablet	M/s. Eris Lifesciences Limited	The firm presented the proposal along with BE study protocol and justification for CT waiver based on the Phase III Clinical Trial report conducted on FDC of Sitagliptin 100mg + Gliclazide XR 60mg Tablets kept Metformin as background therapy, before the committee. After detailed deliberation, the committee considered the request for CT waiver with the condition to conduct Phase IV Clinical Trial with the proposed FDC. Further, the committee recommended for conducting the BE study as per presented protocol. Accordingly, the firm should submit the BE study report to CDSCO for further review by the committee.