

**Recommendations of the SEC (Endocrinology & Metabolism) made in its 05<sup>th</sup>/24 meeting held on 07.03.2024 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/19/24 Online Submission (41674)  NNC0519-0130	M/s. Novo-Nordisk	The firm presented Phase 2 clinical study protocol No.: NN9541-4945 version 2.0 dated 08 January 2024.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/83/23 Online Submission (31072)  Cagrilintide and Semaglutide (CagriSema)	M/s. Novo-Nordisk	The firm presented protocol amendment version 2.0 dated 05 October 2023 protocol No.: NN9388-4896.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.  (Dr. Rama Walia did not participate in this proposal).
3.	CT/69/20 Online Submission (31071)  Semaglutide	M/s. Novo-Nordisk	The firm presented protocol amendment version 5.0 dated 07 September 2023 protocol No.: NN9924-4437.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.  (Dr. Rajesh Khadgawat did not participate in this proposal).
4.	CT/96/23 Online Submission (31116)  LY3502970	M/s. Eli-Lilly	The firm didn't turn up for presentation.
5.	CT/62/23 Online Submission (31103)  LY3502970	M/s. Eli-Lilly	The firm didn't turn up for presentation
<b>Biological Division</b>			
6.	BIO/Form44/FF/2019 /13316  Insulin Inhalation Powder 4IU/8IU/12IU	M/s. Cipla Limited	The firm presented the results of the Phase III clinical trial conducted in India for the drug product Human insulin inhalation powder with inhaler [Technosphere® insulin 4U/ 8U/ 12U for seeking approval to import and market

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			<p>the drug product for the indication “to improve glycemic control in adult patients with diabetes mellitus”.</p> <p>After detailed deliberation, the committee recommended for grant of permission to import and market Human insulin inhalation powder with inhaler [Technosphere® insulin 4U/ 8U/ 12U] subject to the condition that the firm should conduct Active PMS study in the country.</p> <p>Accordingly, the firm should submit the active PMS study protocol to CDSCO within three months of grant of marketing authorization.</p> <p>(Dr. Rajesh Khadgawat did not participate in this proposal).</p>
7.	E-receipt no. 6244 Glucagon Hydrochloride 1 mg	M/s. Novo Nordisk	<p>The firm presented the proposal for update in package insert for the product Glucagon hydrochloride 1mg lyophilized powder in vial.</p> <p>After detailed deliberation, the committee recommended for approval of package Insert dated April 2023.</p>
<b>FDC Division</b>			
8.	FDC/MA/24/000031  Metformin Hydrochloride (SR) 500mg/1000mg + Vildagliptin IP 50mg/50mg + Glimepiride IP 1mg/1mg film coated bilayered tablet	M/s. Mascot Health Series Pvt. Ltd.	<p>The firm presented the proposal before the committee along with BE study &amp; Phase III clinical trial protocol.</p> <p>After detailed deliberation, the committee recommended for conduct of the BE study &amp; Phase III clinical trial.</p> <p>The result of the BE study should be presented for review by SEC before initiation of the clinical trial.</p>
9.	FDC/MA/24/000036  Empagliflozin 12.5mg/12.5mg/12.5 mg/12.5mg + Glimepiride 1mg/1mg/2mg/2mg + Metformin HCl (ER) 500mg/1000mg/	M/s. Exemed Pharmaceuticals	<p>The firm presented the proposal before the committee along with BE study protocol.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the BE study.</p> <p>The result of the study should be</p>

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	500mg/1000mg film coated bilayered tablet		presented before the committee for review along with Phase III clinical trial protocol.
10.	FDC/MA/24/000041  Alogliptin Benzoate 17 mg eq. to Alogliptin 25mg/25mg + Metformin Hydrochloride IP 500mg/1000mg ER tablet	M/s. Indoco Remedies Limited	<p>The firm presented the proposal along with justification for CT waiver before the committee.</p> <p>The firm informed the committee that firm has already been granted BE NOC from CDSCO for export purpose.</p> <p>After detailed deliberation, the committee recommended that firm should conduct BE study and clinical trial waiver is not considered at this stage.</p> <p>Accordingly, the result of the BE study for export purpose should be presented before the committee for review and further consideration of the clinical trial waiver.</p>
11.	FDC/MA/24/000043  Empagliflozin 10mg/10mg/25mg/25 mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg/100mg/50mg/ 100mg film coated Tablet	M/s. Ravenbhel Healthcare Pvt. Ltd.	<p>The firm presented the proposal along with Phase III CT Protocol for two strengths i.e., Empagliflozin + Sitagliptin (10mg+100mg, 25mg+100mg) tablet and requested for BE study waiver.</p> <p>After detailed deliberation, the committee considered the request for BE study waiver and recommended for grant of permission to conduct Phase III clinical trial.</p> <p>The results of the Phase III CT study should be presented before the committee for further review.</p>
12.	FDC/MA/24/000048  Empagliflozin 10mg/10mg/25mg/ 25mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg/100mg/50mg/ 100mg film coated Tablet	M/s. Mascot Health Series Pvt. Ltd.	<p>The firm presented the proposal along with Phase III CT Protocol for two strengths i.e., Empagliflozin + Sitagliptin (10mg+100mg, 25mg+100mg) tablet and requested for BE study waiver.</p> <p>After detailed deliberation, the committee considered the request for BE study waiver and recommended for grant of permission to conduct Phase III clinical trial.</p> <p>The results of the Phase III CT study</p>

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			should be presented before the committee for further review.