

**Recommendations of the SEC (Endocrinology & Metabolism) made in its 9<sup>th</sup>/24 meeting held on 09.05.2024 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/96/23 Online Submission (31116)  LY3502970	M/s. Eli Lilly	The firm presented protocol amendment (protocol J2A-MC-GZGT (b) dated 06 September 2023.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/62/23 Online Submission (31103)  LY3502970	M/s. Eli Lilly	The firm presented protocol amendment (protocol J2A-MC-GZGP (c) dated 23 October 2023.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/43/24 Online Submission (42430)  LY3437943 (Retatrutide)	M/s. Eli Lilly	The firm presented Phase III clinical study protocol no. J1I-MC-GZBY dated 29 November 2023.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
4.	CT/62/24 Online Submission (42992)  Cagrilintide & Semaglutide	M/s. Novo-Nordisk	The firm presented Phase 3b clinical study protocol no. NN9388-7741, version 1.0 dated 05 February 2024.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
<b>Biological Division</b>			
5.	BIO/CT18/FF/2024/41677  Dulaglutide 0.75mg and 1.5mg solution for Injection	M/s. Eli Lilly And Company India Pvt. Ltd.	The firm presented the proposal for modification of approved indication of the drug Dulaglutide 0.75 mg and 1.5 mg solution for Injection in pre-filled pen for including the paediatric indication i.e, for treatment of paediatric patients 10 year of age and older with type 2 diabetes mellitus along with clinical result generated from the global clinical trial study including limited number of Indian subjects.  The firm has also presented the proposed

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			<p>package insert of the drug.</p> <p>The committee noted that the proposed indication has already approved in US &amp; Europe.</p> <p>After detailed deliberation, the committee has recommended for the approval of modification of indication by including the paediatric patients 10 year of age and older with type 2 diabetes mellitus treatment in approved indication with following conditions –</p> <ol style="list-style-type: none"> <li>1. The firm is required to conduct phase IV clinical trial in India for establishing safety and effectiveness of the drug in the paediatric population (10 year of age and above). The Phase IV protocol should be submitted to CDSCO for evaluation by the committee. The approval for modified indication shall be considered after approval of the Phase IV clinical protocol only.</li> <li>2. The drug should be prescribed for the paediatric patients (10 year of age and above) who are obese and overweight.</li> <li>3. The modified indication along with revised package insert shall be submitted to CDSCO.</li> </ol> <p>Accordingly, the Phase IV clinical trial protocol should be submitted by the firm to CDSCO for further evaluation.</p>
<b>New Drugs Division</b>			
6.	ND/MA/22/000112 CDSCO File Number: ND/CT-21/FF/2022/33155  Imeglimin Hydrochloride and Sitagliptin Tablets (1000mg+50mg)	M/s. Exemed Pharmaceuticals	<p>The firm presented the proposal for grant of permission for manufacturing and marketing of the FDC Imeglimin Hydrochloride and Sitagliptin Tablets (1000mg/50mg) along with protocol for BE study and protocol for Phase III clinical trial before the committee.</p> <p>The firm presented published data for the Phase III Clinical trial conducted in Japan. However, the said FDC is not yet</p>

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			approved in Japan or any other country in world. So, the committee is of opinion that rationality for the said FDC needs to be evaluated further and since the both drugs are now approved by CDSCO, the same may be evaluated through FDC committee along with proof of concept study.
<b>FDC Division</b>			
7.	FDC/MA/22/000301 Glimepiride IP 1mg + Lobeglitazone sulfate 0.5mg tablets	M/s. Akums Drugs and Pharmaceuticals Ltd.	In light of earlier recommendation of SEC dated 18.07.2023, the firm presented the BE report before the committee.  After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC with the condition that firm should conduct Phase-IV clinical trial for which protocol should be submitted to CDSCO within three months of approval of the FDC.
8.	FDC/MA/22/000360 Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg/100mg + Glimepiride IP 1mg/2mg + Metformin Hydrochloride IP (as ER) 1000mg/1000mg tablets	M/s. Exemed Pharmaceutical	The firm didn't turn up for presentation.
9.	FDC/MA/23/000134 Ferrous Fumarate IP 30mg + Niacinamide IP 10mg + Pyridoxine Hydrochloride (Vit B6) IP 1mg + Folic Acid IP 250mcg + Riboflavin IP 1.2mg + Zinc Sulphate Monohydrate eq. to elemental Zinc 20mg + Thiamine Mononitrate IP 1.2mg + Cyanocobalamin (Vit B12) 2.5mcg + Ascorbic Acid (Coated) (Vit.C) 40mcg Capsules	M/s. Hindustan Laboratories Limited	In light of the earlier SEC recommendation dated 07.06.2023, 27.09.2023 & 29.09.2023, the firm presented the proposal along with justification for the proposed FDC.  After detailed deliberation, the committee noted the following: 1. The firm did not present any published literature, desirability and justification of doses of the proposed FDC. 2. The doses of various ingredients are sub-optimal. 3. The indication proposed by the firm i.e. vitamins deficiency is not appropriate as FDC contains Vitamins

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			along with Ferrous Fumarate. 4. The product is not approved internationally. 5. There is no unmet need for the proposed FDC.  In view of above, the committee did not recommend for the approval of the FDC.