

**Recommendations of the SEC (Endocrinology & Metabolism) made in its 100<sup>th</sup> meeting held on 20.04.2023 & 21.04.2023 at CDSCO (HQ), New Delhi:**

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drugs Division</b>			
1.	ND/IMP/23/000017  Tirzepatide 2.5mg, 5mg, 7.5mg, 10mg, 12.5mg and 15mg per 0.5ml solution for injection in a single dose prefilled pen	M/s. Eli Lilly & Company	<p>The firm presented the proposal for grant of permission for import and marketing of Tirzepatide 2.5mg, 5mg, 7.5mg, 10mg, 12.5mg and 15mg per 0.5ml solution for injection in a single dose prefilled pen along with global Phase-III clinical trial report in which India is one of the participating country.</p> <p>The committee noted that Tirzepatide is approved in USA, European Union, Australia, Japan, Switzerland, Canada, UAE, Kuwait, Qatar, Saudi Arabia and United Kingdom.</p> <p>After detailed deliberation, the committee recommended for grant of permission to import and market the drug Tirzepatide 2.5mg, 5mg, 7.5mg, 10mg, 12.5mg and 15mg per 0.5ml solution for injection in a single dose prefilled pen subject to following conditions:</p> <ol style="list-style-type: none"> <li>1. The drug should be sold by retail under prescription of Endocrinologist or internal medicine specialists only.</li> <li>2. The firm should conduct Phase-IV clinical trial for which the firm should submit Phase IV clinical trial protocol within 3 months of approval of the drug for review by the committee.</li> </ol>
<b>SND Division</b>			
2.	SND/MA/23/000047  Cholecalciferol Chewable Tablets 800IU	M/s Quality Pharma Products Pvt. Ltd.	<p>The firm presented the proposal for manufacture and marketing of Cholecalciferol Chewable Tablets 8000 IU alongwith the justification for waiver of bioequivalence study and Phase III clinical trial before the committee.</p> <p>The committee noted that Cholecalciferol chewable Tablets 8000 IU administered daily is equivalent to weekly dose of Cholecalciferol 60000 IU. Committee also noted that Cholecalciferol chewable Tablets 60000 IU is also approved in India on 19.04.2022 for the treatment and</p>

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			<p>prevention of Vitamin D deficiency.</p> <p>After detailed deliberation, the committee considered BE and Phase III Clinical Trial waiver for the applied drug product. In view of above, the committee recommended for grant of manufacture and marketing of Cholecalciferol Chewable Tablets 8000 IU for the proposed indication.</p>
3.	<p>SND/MA/22/000254</p> <p>Semaglutide Injection 2mg/1.5ml(1.34mg/ml) and 4mg/3ml (1.34mg/ml)</p>	M/s. Dr. Reddy's Laboratories Ltd.	<p>The firm presented the proposal for manufacture and marketing of synthetically developed Semglutide injection 2mg/1.5ml (1.34mg/ml) PFP and Semglutide injection 4mg/3ml (1.34mg/ml) PFP for already approved indication alongwith the justification for waiver of BE study and Phase-III clinical trial.</p> <p>After detailed deliberation, the committee recommended that the firm should conduct bioequivalence study with already approved rDNA product and Phase III Clinical Trial of the applied drug product. Accordingly, the firm should submit the protocol for bioequivalence study and Phase-III Clinical Trial for further review by the committee.</p>
4.	<p>12-11/2016-DC (Pt-Troikaa-SND)</p> <p>Vitamin E Capsule 400mg</p>	M/s. Troikaa Pharmaceuticals Ltd	<p>The firm presented updated package insert of Vitamin E Capsule 400mg. Firm also presented the Cmax and Tmax of the applied product.</p> <p>After detailed deliberation, the committee recommended for grant of approval for the Package insert presented by the firm</p>
5.	<p>SND/MA/23/000018</p> <p>Liraglutide 6 mg/ml solution for injection in PFP (18mg/3ml PFP)</p>	M/s Sun Pharma	<p>The firm presented the proposal for manufacture and marketing of synthetically developed Liraglutide 6mg/ml solution for injection in PFP (18mg/3ml PFP) for already approved indication alongwith bioequivalence study report and justification for waiver of Phase III clinical trial.</p> <p>After detailed deliberation, the committee recommended that firm should conduct Phase III clinical trial of the applied drug</p>

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			product. Accordingly, the firm should submit the protocol for Phase III clinical trial for further review by the committee.
6.	SND/MA/23/000044  Liraglutide 6 mg/ml solution for injection in PFP (18mg/3ml PFP)& Cartridge (18mg/3ml)	M/s. Biocon Pharma Ltd.	<p>The firm presented the proposal for manufacture and marketing of synthetically developed Liraglutide 6mg/ml solution for injection in PFP (18mg/3ml PFP) and Liraglutide 6mg/ml solution for injection in Cartridges (18mg/3ml) for already approved indication alongwith bioequivalence study report and justification for waiver Phase III clinical trial.</p> <p>After detailed deliberation, the committee recommended that firm should conduct Phase III clinical trial of the applied drug product. Accordingly, the firm should submit the protocol for Phase III clinical trial for further review by the committee.</p>
7.	SND/MA/22/000262  Vildagliptin SR tablets 100mg	M/s. Eris Lifesciences Limited.	<p>The firm presented the active PMS study protocol (Protocol No.: CT/2023/16, Version No.: 00, Date: 29.03.2023) for Vildagliptin sustained release (SR) tablets 100 mg as per the condition of Form CT-23 permission, before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission for conduct the active PMS study as per the protocol presented by the firm.</p>
<b>FDC Division</b>			
8.	FDC/MA/21/000043  Teneligliptin hydrobromide hydrate eq. to Teneligliptin IP +Metformin hydrochloride (SR) IP + Dapagliflozin propanediol monohydrate eq. to Dapagliflozin (20mg/20mg/20mg/20 mg+500mg/1000mg/500mg/1000mg+5mg/5 mg/10mg/10mg) Film coated bilayered tablet	M/s. Synokem Pharmaceuticals Ltd.	<p>Inlight of the earlier recommendation dated 19.01.2023 &amp; 20.01.2023, firm presented its justification for Phase III CT study waiver for the proposed FDC based on Phase III clinical trial study conducted on FDC of Dapagliflozin + Teneligliptin (5mg+20mg &amp; 10mg+20mg) tablets. The Committee noted that firm has conducted Phase III CT study for the FDC of Dapagliflozin + Teneligliptin (5mg+20mg &amp; 10mg+20mg) tablets along with background therapy with Metformin.</p> <p>After detailed deliberation, the committee considered the request of the firm for Phase III CT waiver and recommended</p>

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			for grant of permission to manufacture and market the product with the condition that Phase IV clinical trial should be conducted. Accordingly, Phase IV clinical trial protocol should be submitted to CDSCO within 03 months from the date of approval for review by SEC.
9.	FDC/MA/23/000025  Sitagliptin Phosphate monohydrate IP Eq. to Sitagliptin 50mg/100mg + Lobeglitazone sulfate 0.5mg/0.5mg tablets	M/s. Akums Drugs and Pharmaceuticals Ltd.	The firm presented its proposal along with justification for BE & Phase III CT waiver.  After detailed deliberation, the committee recommended that: 1. Firm should present the justification on rationality for combining this FDC and its significant benefit. 2. Justification on dose titration. 3. International approval status. 4. Scientific literature available from peer reviewed journal in support on combining this FDC. Accordingly, the firm should submit the justification to CDSCO for review by SEC.
10.	FDC/MA/23/000026  Sitagliptin Phosphate monohydrate IP 100mg + Lobeglitazone sulfate 0.5mg Film Coated tablets	M/s. Synokem Pharmaceuticals Ltd.	The firm presented its proposal and requested for deliberation of BE & Phase III CT protocol.  After detailed deliberation, the committee recommended that firm should justify on following points before presenting the protocol: 1. Firm should present the justification on rationality for combining this FDC and its significant benefit. 2. Justification on dose titration. 3. International approval status. 4. Scientific literature available from peer reviewed journal in support of combining this FDC. Accordingly, firm should submit the justification to CDSCO for review by SEC.
11.	FDC/MA/23/000033  Lobeglitazone sulfate 0.5mg/0.5mg + Dapagliflozin propanediol	M/s. Glenmark Pharmaceuticals Ltd.	Firm presented its proposal along with Phase III CT protocol as well as justification for BE study waiver.  After detailed deliberation, the committee considered the request of the firm for BE study waiver and recommended for

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	monohydrate eq. to Dapagliflozin 5mg/10mg tablets		conducting the Phase III CT for the FDC of Lobeglitazone sulfate 0.5mg + Dapagliflozin 10mg tablet. The result of the study should be presented before the committee for review.
12.	FDC/MA/23/000041  Rosuvastatin Calcium IP eq. to Rosuvastatin 5mg/10mg + Linagliptin 5mg/5mg Tablets	M/s. Exemed Pharmaceuticals	The firm presented its proposal along with BE & Phase III CT protocol.  After detailed deliberation, the committee recommended that firm should justify on following points before presenting the protocol: 1. Firm should present the justification on rationality for combining this FDC and its significant benefit. 2. Justification on dose titration. 3. International approval status. 4. Scientific literature available from peer reviewed journal in support on combining this FDC.
13.	FDC/MA/23/000043  Metformin HCl IP (As extended release form) 500mg / 1000mg / 500mg / 1000mg + Glimepiride IP 1mg/1mg/2mg/2mg + Lobeglitazone sulfate 0.5mg/0.5mg/0.5mg/0.5mg tablets	M/s. Akums Drugs and Pharmaceuticals Ltd.	The firm presented its proposal along with BE study protocol along with justification for Phase III CT waiver.  After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. The result of the BE study should be presented before the committee along Phase III CT protocol.
14.	FDC/MA/22/000301  Glimepiride IP 1mg+ Lobeglitazone sulfate 0.5mg tablets	M/s. Akums Drugs and Pharmaceuticals Ltd.	In light of the earlier SEC recommendation dated 16.09.2022, the firm presented the BE study report before the committee. The committee noted that the firm has already conducted the BE study and considered the results of the BE study and the justification for Phase III CT study waiver at this stage.  After detailed deliberation, the committee recommended for grant of permission to manufacture and market the product after issuance of permission to main applicant who had already conducted the CT study.

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15.	FDC/MA/22/000402  Glimepiride IP 1mg+Lobeglitazone Sulfate 0.5 mg Film Coated Tablets	M/s Synokem Pharmaceuticals Ltd	The firm did not turn up for presentation.
16.	FDC/MA/23/000057  Rosuvastatin calcium IP eq. to Rosuvastatin 5mg/10mg/20mg + Sitagliptin phosphate monohydrate IP eq. to sitagliptin 100mg/100mg/100mg	M/s Exemed	The firm presented its proposal and requested for deliberation of BE & Phase III CT study protocol.  After detailed deliberation, the committee recommended that firm should justify on following points before presenting the protocol: 1. Firm should present the justification on rationality for combining this FDC and its significant benefit. 2. Justification on dose titration. 3. International approval status. 4. Scientific literature available from peer reviewed journal in support on combining this FDC.
17.	FDC/MA/23/000056  Metformin HCL IP (as ER) 1000mg/500mg/1000 mg+Sitagliptin phosphate monohydrate eq. to sitagliptin 100mg/100mg/100mg + Empagliflozin 10mg/25mg/25mg tablets	M/s. Pure & Cure	The firm presented its proposal and requested for deliberation of BE study protocol.  After detailed deliberation, the committee recommended that firm should justify on following points before presenting the protocol: 1. Firm should present the justification on rationality for combining this FDC and its significant benefit. 2. Justification on dose titration. 3. International approval status. 4. Scientific literature available from peer reviewed journal in support on combining this FDC.
18.	FDC/MA/23/000061  Glimepiride 1mg/1mg/2mg/2mg+ Vildagliptin 50mg/50mg/50mg/50 mg + Metformin HCl 500mg/1000mg/500m g/1000mg Film	M/s. Synokem	The firm presented its proposal and requested for deliberation of BE & Phase III CT study protocol.  The committee noted that the similar proposal of FDC containing Vildagliptin in SR form was deliberated before Technical committee on 18.01.2022 whereby "Committee did not recommend for approval of the FDC with given justification due to possibility of

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	coated tablets		<p>hypoglycemia and difficulties for dose titration for such patients and committee opined that the firm should submit the justification in light of said recommendation of the technical committee”.</p> <p>After detailed deliberation, the committee recommended that firm should justify on following points before presenting the protocol:</p> <ol style="list-style-type: none"> <li>1. Firm should present the justification on rationality for combining this FDC and its significant benefit.</li> <li>2. Justification on dose titration.</li> <li>3. International approval status.</li> <li>4. Scientific literature available from peer reviewed journal in support on combining this FDC.</li> </ol>
19.	FDC/MA/23/000082 Metformin HCl 500mg + Dapagliflozin 10mg tablets	M/s. Aeon	The proposal was deferred for next meeting.
20.	FDC/MA/23/000085 Lobeglitazone sulfate 0.25mg/0.25mg+ Sitagliptin Phosphate monohydrate 50mg/100mg tablets	M/s. Akums	The proposal was deferred for next meeting.
21.	FDC/MA/23/000089 DapagliflozinPropane diol monohydrate eq. to Dapagliflozin5mg/5m g/10mg/10mg + Linagliptin 5mg/5mg/5mg/5mg + Metformin HCl eq. to Metformin (as sustained release) 500mg/1000mg/500m g/1000mg tablets	M/s. Exemed	The proposal was deferred for next meeting.
22.	FDC/MA/22/000145	M/s. Alkem Laboratories Ltd.	The proposal was deferred for next meeting.

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	Linagliptin 2.5mg/5mg /5mg+Metformin Hydrochloride (ER) 1000mg/500mg/1000 mg film coated bilayered tablet		
23.	FDC/MA/22/000333  Metformin Hcl IP as extended release 500mg/500mg/1000mg/1000mg+Glimepiride IP 1mg/2mg/1mg/2mg +Sitagliptin phosphate monohydrate eq. to Sitagliptin IP 50mg/50mg/50mg/50 mg Tablets	M/s. Innova Captab Limited	The proposal was deferred for next meeting.
24.	FDC/MA/22/000264  Sitagliptin Phosphate monohydrate 100mg + Pioglitazone HCl IP 15mg film coated tablets	M/s. Synokem	The proposal was deferred for next meeting.
25.	FDC/MA/22/000360  Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg/100mg+Glimepiride IP 1mg/2mg + Metformin HCl IP (as ER) 1000mg/1000mg tablets	M/s. Exemed	The proposal was deferred for next meeting.
26.	FDC/MA/22/000168  Linagliptin 5mg/5mg+Dapagliflozin 10mg/5mg tablets	M/s. Alkem Health Science	The proposal was deferred for next meeting.
27.	FDC/MA/23/000057  Rosuvastatin calcium	M/s. Exemed	The proposal was deferred for next meeting.

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	IP eq. to Rosuvastatin 5mg/10mg/20mg + Sitagliptin phosphate monohydrate IP eq. to Sitagliptin 100mg/100mg/100mg		
28.	FDC/MA/23/000083  Vildagliptin (as sustained release) 100mg/100mg/100mg + Rosuvastatin calcium IP eq. to Rosuvastatin 5mg/10mg/20mg tablets	M/s. Exemed	Firm presented the proposal before the committee. Committee noted that- 1. Firm has not presented any scientific justification with rationality along with published literature. 2. There is no unmet need.  After detailed deliberation, the committee rejected the proposed FDC.
<b>GCT Division</b>			
29.	CT/174/22 Online Submission (35319)  Cagrilintide 2.4 mg s.c.	M/s. Novo-Nordisk	The proposal was deferred for next meeting.
30.	CT/14/22 Online Submission (23788)  Paltusotine	M/s. Pharm- Olam	The proposal was deferred for next meeting.
31.	CT/16/19 Online Submission (24567)  Somapacitan	M/s. Novo-Nordisk	The proposal was deferred for next meeting.