

Recommendations of the SEC (Endocrinology & Metabolism) made in its 86th meeting held on 26.04.2022 & 29.04.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000054 Lobeglitazole Sulphate 0.5 mg + Glimepiride 1 mg Tablet	M/s. Glenmark Pharma	<p>The firm presented their justification for BE study waiver for FDC of Lobeglitazone 0.5 mg + Glimepiride 1 mg before the committee.</p> <p>The committee noted that the firm has already conducted the BE study of Lobeglitazone with innovator product.</p> <p>After detailed deliberation, the committee recommended for accepting BE study waiver of the proposed FDC. The results of clinical trial being conducted should be presented before the committee for further consideration.</p>
2.	ND/MA/22/000050 Imeglimine HCL 500mg & 1000mg	M/s. Ravenbhel Healthcare Pvt. Ltd	<p>The firm presented their proposal for manufacturing and marketing of the drug Imeglimin 500 mg and 1000 mg tablet along with Phase III clinical trial study protocol and BE study protocol before the committee.</p> <p>After detailed deliberation, the committee recommended that the firm should submit bioequivalence study results before the committee for further consideration of the proposed Phase III clinical trial of the drug Imeglimin 500 mg and 1000 mg tablet.</p>
Biological Division			
3.	BIO/CT/22/000021 Insulin Glargine 100 IU	M/s. Wockhardt Limited	<p>The firm presented their proposal for conduct of PK-PD trial.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as per protocol W-GLA-I 06, version 01 dated 21.01.2022.</p>
SND Division			
4.	12-43/2007-DC(Pt-A-II) Hydroxychloroquine Sulphate Tablets 400mg	M/s. IPCA	<p>The firm presented the Phase IV clinical trial report of Hydroxychloroquine sulphate tablets 400mg before the committee.</p> <p>After detailed deliberation, the committee noted that there are cases of development</p>

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			of nonproliferative diabetic retinopathy (NPDR) condition in the patients. Accordingly, the committee opined that the firm should submit the detailed report with respect to the causality of NPDR in patients alongwith data on the occurrence, development and progression of NPDR in the type 2 diabetic patients treated with the other standard drugs for further review by the committee.
5.	SND/MA/21/000574 Metformin Hydrochloride Sustained Release Tablets 500mg/850mg/1000mg	M/s. USV Pvt. Ltd.	<p>The firm presented the proposal of additional indication – pre-diabetes for Metformin Hydrochloride Sustained Release Tablets 500mg/850mg/1000mg.</p> <p>The committee noted that Metformin HCl PR/SR tablets for pre-diabetes is already approved in UK and EU.</p> <p>After detailed deliberation, the committee recommended for grant of approval for the proposed additional indication.</p> <ul style="list-style-type: none"> • Reduction in the risk or delay of the onset of type 2 diabetes mellitus in adult, overweight patients with IGT and/or IFG, and/or increased HbA1C who are: <ul style="list-style-type: none"> ○ At high risk for developing over type 2 diabetes mellitus and ○ Still progressing towards type 2 diabetes mellitus despite implementation of intensive lifestyle changes for 3 to 6 months. • Treatment with Metformin SR must be based on a risk score incorporating appropriate measures of glycaemic control and including evidence of high cardiovascular risk. • Lifestyle modifications should be continued when Metformin is initiated, unless the patient is unable to do so because of medical reasons.
6.	12-11/2016-DC (Pt-Troikaa-SND)	M/s. Troikaa Pharmaceuticals	In light of earlier SEC recommendation dated 21-09-2021, the firm presented

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	Vitamin E Trocopheryl Acetate hard gelatin capsule 400mg (Water miscible)		<p>detailed justification / documented evidence /literature with respect to the desired therapeutic level of the drug in support of their claim vis-a vis the PK parameters observed in BE study.</p> <p>After detailed deliberation, the committee recommended for grant of approval for the indication, “For prevention and treatment of Vitamin E deficiency”.</p>
FDC Division			
7.	FDC/MA/22/000034 Vildagliptin +Dapagliflozin (50mg/50mg/100mg/100mg + 5mg/10mg/5mg/10mg) Tablets	M/s. Theon Pharmaceuticals Ltd.	<p>The firm presented their proposal along with BE and Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study.</p> <p>As regard to clinical trial, the firm should conduct non-inferiority trial by taking appropriate comparator and also include all the applied strengths in the clinical trial protocol.</p> <p>Accordingly, the firm should submit the revised Phase III clinical trial protocol for further review by the committee.</p>
8.	FDC/MA/21/000173 Dapagliflozin 5/10 mg+ Teneligliptin 20 mg/20mg Tablets	M/s. Ravenbhel	<p>The firm presented BE study report before the committee.</p> <p>After detailed deliberation, the committee recommended to initiate the Phase III clinical trial for which permission has already been granted on 01.10.2021.</p>
9.	FDC/MA/22/000090 Repaglinide, Voglibose and Metformin Tablets (1mg/0.5mg/1mg/0.5 mg + 0.2mg/0.3mg/0.2mg/0.3mg + 500mg/500mg/500mg /500mg)	M/s. Torrent Pharmaceuticals	<p>The firm presented their proposal before the committee along with BE protocol on the higher strength and requested for Phase III CT waiver. The firm also presented the Phase III CT data on the FDC of Repaglinide + Voglibose keeping Metformin as background therapy in 176 patients.</p> <p>After detailed deliberation, the committee recommended the following: 1. The indication should be revised to – “as 3rd line treatment of type 2 diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate</p>

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			<p>glycemic control.”</p> <p>2. The firm should conduct the Phase III CT in statistically significant no. of patients for the FDC of Repaglinide, Voglibose and Metformin Tablets (1mg/0.5mg + 0.2mg/0.2mg + 500mg/500mg)</p> <p>3. The firm should conduct the BE study in FDC of Repaglinide, Voglibose and Metformin Tablets (1mg + 0.2mg + 500mg)</p> <p>The committee recommended that the firm should submit Phase III clinical trial protocol and revise BE study protocol accordingly and present before the committee.</p> <p>As regard to the FDC of Repaglinide + Voglibose + Metformin Tablets (1mg/0.5mg + 0.3mg/0.3mg + 500mg/500mg), keeping in view of the safety concerns with higher dose of Voglibose, the committee did not recommend for approval.</p>
10.	FDC/MA/21/000235 Vildagliptin SR + Metformin (SR) (50mg/50mg/100mg/100mg+500mg/1000mg/500mg/1000mg) Tablets	M/s. Pure & Cure Healthcare Pvt. Ltd.	The firm didn't turn up for presentation.
11.	FDC/MA/22/000079 Pioglitazone HCl IP eq. to Pioglitazone 7.5/15 mg+ Vildagliptin 50/50 mg Tablets	M/s. Mascot Health	The firm didn't turn up for presentation.
12.	FDC/MA/22/000024 Dapagliflozin + Metformin Hydrochloride (Sustained Release) + Sitagliptin (5mg+500mg+50mg, 10mg+500mg+100mg, 5mg+1000mg+50mg,	M/s. Macleods	<p>The firm presented their proposal along with the BE study and Phase III clinical trial protocol before the committee.</p> <p>The committee noted that the firm presented Phase III clinical trial protocol for higher strength i.e FDC of Dapagliflozin + Metformin Hydrochloride (Sustained Release) + Sitagliptin (10mg+1000mg+100mg) tablets.</p>

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	10mg+1000mg+100mg) Tablets		After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE/CT Study. The committee also opined that other applied strengths will be considered based on the study results of the trials conducted by other firms.
13.	FDC/MA/20/000142 Metformin HCL IP(SR)500mg/1000mg + Vildagliptin SR 50mg/50mg/ 100mg/100mg Tablets	M/s. Mascot	The firm didn't turn up for presentation.
14.	FDC/MA/22/000061 Linagliptin 5mg/2.5mg/2.5mg+ Dapagliflozin 10mg/10mg/5mg tablets	M/s. Micro Labs Ltd	<p>The firm presented their proposal along with request for BE study waiver and Phase III clinical trial protocol before the committee.</p> <p>The committee noted that the firm presented Phase III clinical trial protocol for higher strength i.e FDC of Linagliptin 5mg + Dapagliflozin 10mg tablets.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III clinical trial study.</p>
15.	FDC/MA/22/000074 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg/10mg/5mg/10mg +Vildagliptin 50mg/50mg/100mg/100mg tablets	M/s. Logos Pharma	<p>The firm presented their proposal along with BE study and Phase III clinical trial protocols before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study.</p> <p>As regard to clinical trial, the firm should conduct non-inferiority trial by taking appropriate comparator and also include all the applied strengths in the clinical trial protocol.</p> <p>Accordingly, the firm should submit the revised Phase III clinical trial protocol for further review by the committee.</p>
16.	FDC/MA/22/000099 Dapagliflozin 10mg+Pioglitazone HCL IP eq to Pioglitazone 15mg	M/s. USV Pvt. Ltd	<p>The firm informed that they will present their proposal in next meeting.</p> <p>Accordingly, the proposal was deferred</p>

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	tablets		for the next SEC meeting.
17.	FDC/MA/21/000239 Pioglitazone Hydrochloride IP + Teneligliptin Hydrobromide Hydrate IP + Metformin Hydrochloride IP (15mg+20mg+1000mg & 15mg+20mg+500mg) tablets	M/s. Macleods Pharmaceuticals Ltd.	<p>The firm presented their proposal along with BE study and Phase III clinical trial protocol before the committee.</p> <p>The committee noted that the FDC of Teneligliptin + Pioglitazone is already approved.</p> <p>The committee also noted that the firm presented Phase III clinical trial protocol for higher strength i.e FDC of Pioglitazone 15mg + Teneligliptin 20mg + Metformin HCL 1000mg tablets.</p> <p>After detailed deliberation, the committee recommended for grant of permission for conducting the proposed BE Study. The committee also recommended for grant of permission to conduct Phase III clinical trial study with condition that the treatment duration should be 24 weeks.</p>
18.	FDC/MA/21/000016 Dapagliflozin + Teneligliptin Hydrobromide hydrate (5mg/10mg+20mg/20mg) flm coated tablet	M/s. Inventia Healthcare Limited	The firm didn't turn up for presentation.
19.	FDC/MA/20/000131 Pioglitazone 30mg/100mg + Vildagliptin 100mg/100mg film coated bilayered tablet	M/s. Synokem Pharmaceuticals	The firm didn't turn up for presentation.
GCT Division			
20.	CT/134/21 Online Submission (16321) Dapagliflozin + Metformin XR versus Metformin XR (BYL719)	M/s. Novartis	<p>The firm presented their justification for waiver of the previous conditions recommended by SEC before the committee.</p> <p>After detailed deliberation, the committee opined that the firm should submit proper justification for removal of condition no. 1 & 2 before the committee for further consideration.</p>
21.	CT/14/22 Online Submission (30398)	M/s. Pharma-Olam	The firm presented Phase III clinical trial protocol no CRN00808-08, version 2.0

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	Paltusotine		<p>dated 26/09/2021 before the committee.</p> <p>Risk versus benefit to the patients- The safety profile of the investigator drug from various preclinical and clinical phase studies justify the conduct of the study.</p> <p>Innovation vis-a-vis existing therapeutic option- To evaluate the safety and efficacy of Paltusotine in subjects with non- pharmacologically treated acromegaly.</p> <p>Unmet medical need in the country- The test drug may be better treatment option in subjects with non-pharmacologically treated acromegaly.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III CT as per the protocol presented.</p>
22.	CT/24/22 Online Submission (30822) Tirzepatide	M/s. Eli Lilly	The firm didn't turn up for presentation.
BA/BE Division			
23.	12-09/2022/BA-BE/Misc-04/DC (Application No. BABE/CT05/FF/2021 /27869) Vildagliptin 50 mg, Metformin HCl 500mg, Pioglitazone 15 mg Tablets	M/s. Ajanta Pharma Limited	The proposal was deferred for next SEC meeting.
24.	12-09/2022/BA-BE/Misc-06/DC (Application No. BABE/CT05/FF/2021 /29418) Dapagliflozin 10 mg and Teneligliptin 20 mg Tablets	M/s. Ajanta Pharma Limited	<p>The firm presented the proposal of BE study protocol for FDC of Dapagliflozin 10 mg and Teneligliptin 20 mg Tablets before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the BE study as per the protocol presented.</p>