Recommendations of the SEC (Endocrinology & Metabolism) made in its 95th meeting held on 24.11.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000125 Trelagliptin Tablets 25/50/100mg	M/s. Zuventus	The firm presented their Phase-III clinical trial and BE study protocols for drug Trelagliptin tablets 25mg/50mg/100mg before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase-III clinical trial along with BE study of drug Trelagliptin tablets 25mg/50mg/100mg tablets subject to the following amendments in the CT protocol 1. In inclusion criteria the provisions for safety monitoring for pancreatitis should be included in the trial. 2. The firm should include the eGFR level below which they can exclude the patients in exclusion criteria. 3. The firm should mention exclusion of patients with previous history of pancreatitis in exclusion criteria.
Biological Division			
2.	BIO/CT21/BO/2022/ 33538 Teriparatide Injection 600 mcg/2.4 ml & 750 mcg/3ml.	M/s. Enzene	The firm presented the proposal for inclusion of following additional indications- 1) Treatment of postmenopausal women with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy 2) Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy 3) Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy The product Teriparatide Injection 600 mcg/2.4 ml & 750 mcg/3ml is already approved for the treatment of osteoporosis in postmenopausal women. After detailed deliberation, the committee noted the justification for the inclusion of above indications and recommended for

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			approval of proposed additional indications.
3.	BIO/CT04/FF/2022/ 31494 Insulin Aspart mix 70/30 Injection	M/s Mankind Pharma	The firm presented the protocol for conduct of Phase-III clinical study titled "A randomized, open label, Phase 3 study to compare the efficacy and safety of Recombinant Insulin Aspart (RapilinTM 30) with Recombinant Insulin Aspart (NovoMix 30) in Adult Patients of Type 2 Diabetes Mellitus" vide Protocol No CCS/INS/21/v1 Version 1 dated 6th Nov 2021. After detailed deliberation, the committee recommended that the firm should include evaluation of the PK-PD parameters in the proposed clinical trial design and should revise the inclusion criteria with respect to patients with OAD as per National guidelines. Accordingly, the firm should submit revised clinical trial protocol with statistically significant sample size for further deliberation by the SEC.
SND Division			
4.	SND/MA/22/000280 Nitisinone Capsules 2mg/5mg/10mg/20mg	M/s. Zenara Pharma	The firm presented their proposal alongwith BE study report of Nitisinone capsules 20mg before the committee. Nitisinone capsules 2mg/5mg,10mg is approved in India on 09.06.2022 and is indicated for the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine, but Nitisinone Capsules 20mg is not yet approved in India. Further, Nitisinone Capsules 2 mg, 5 mg, 10 mg, and 20 mg were approved by the USFDA, Australia and United Kingdom. After detailed deliberation, the committee recommended for grant of permission of the applied drug products, i.e. Nitisinone capsules 2mg/5mg/10mg/20mg for already approved indication.
5.	SND/MA/18/000025 Cholecalciferol aqueous injection 600	Ms/. Cadila Pharmaceuticals	The firm has presented their proposal alongwith PK/PD study report of product Cholecalciferol Aqueous Injection 600 IU before the committee.

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			Cholecalciferol Injection (3,00,000IU/6,00,000IU) and Cholecalciferol Tablets (0.25mg/1mg) are listed in IP 2014. Vitamin D3 2000IU ODS was approved for the treatment of Vitamin D3 deficiency by this office on 01-10-2015. Vitamin D3 (Cholecalciferol) 60000 IU Orally disintegrating strips for the treatment of Vitamin D3 deficiency was approved on 25/08/2017. The firm has claimed that currently marketed products are oily injection. Oily injections are associated with very common adverse effect of pain at injection site due to slower diffusion of oily content while aqueous content diffuses easily from site of injection and hence it should have lower pain associated with injection. Thus, delivering Vitamin D3 as aqueous injection would be helpful in avoiding common side effect of pain on injection site. After detailed deliberation, the committee opined that the firm should submit serum calcium level data of both the groups (reference vs test) after drug administration for further review by the committee.
6.	12-11/2016-DC (Pt-Triokaa-SND) Vitamin E Hard Gelatin Capsule 400 mg	M/s. Triokaa Pharmaceuticals Ltd.	Firm presented proposal for change in name of Vitamin E capsule USP 400 mg to water miscible Vitamin E 400 mg along with their justification. Committee noted that water miscible Vitamin E 400mg is not approved as a drug anywhere in the world. Vitamin E capsule is official in USP. After detailed deliberation, the committee recommended that permission should be granted for Vitamin E Capsule USP 400 mg. If firm intends to market the product with claim as water miscible Vitamin E Capsule then the firm is required to conduct clinical trial. Accordingly firm should submit clinical trial protocol for further review by the committee.
7.	SND/MA/22/000297 Imeglimin HCl SR	M/s Exemed Pharmaceuticals	The firm presented their proposal alongwith BE study as well as Phase III CT protocol for grant of manufacture and marketing permission of Imeglimin Hydrochloride SR

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	tablets 500mg and 1000mg		Tablets 500mg and 1000mg before the committee. **Approval status of the applied drug products:** (1) Imeglimin Hydrochloride sustained release tablet is not approved in India. However the immediate release dosage formulation i.e. Imeglimin Hydrochloride Tablets 500 mg is approved in India since 06.10.2022 for the indication "For the treatment of Type II diabetes mellitus". (2) Similar applications made by other firm were deliberated in SEC (Endocrinology & Metabolism) meeting on 19.10.2022 & 20.10.2022. The committee recommended to conduct BE study as per the protocol presented and submit the BE study results before the committee for further consideration. (3) The Subject expert committee (Endocrinology & Metabolism) in meeting held on 19.10.2022 & 20.10.2022 also recommended for the approval of Imeglimin Hydrochloride Tablets 1000mg and the application is under approval process. (4) The product i.e. Imeglimin Hydrochloride Tablets 500mg is also approved in Japan under brand name "Twymeeg 500 mg" by Sumitomo Dainippon Pharma Co., Ltd. For the indication: For the treatment of Type II diabetes mellitus. After detailed deliberation, the committee recommended that the firm should conduct BE study and Phase III clinical trial as per the protocols presented by the firm.
FDC Division			
8.	FDC/MA/22/000301 FDC of Lobeglitazone Sulfate 0.5mg + Glimepride IP 1mg uncoated tablets	M/s. Akums	The firm presented their proposal along with justification for BE study waiver before the committee. The committee noted that earlier this proposal was discussed for another firm who had been asked to present result of clinical trial being conducted. The committee also noted that the applicant is conducting the BE study on Lobeglitazone 0.5mg.

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			After detailed deliberation, the committee recommended that firm should present the BE results of Lobeglitazone 0.5mg before the committee for further deliberation.
9.	FDC/MA/22/000320 Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg/100mg + Glimepiride IP 1mg/2mg + Metformin Hydrochloride IP (as ER) 1000mg/1000mg tablets	M/s. Sun Pharma Laboratories Ltd.	The firm presented their proposal along with BE study protocol and CT protocol before the committee. After detailed deliberation, the committee recommended for grant of permission for conducting the BE and CT study as per the present protocol. The result of the studies should be presented before the committee.
10.	FDC/MA/22/000322 Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg/15mg + Sitagliptin Phosphate monohydrate IP eq. to Sitagliptin 50mg/100mg tablets	M/s. Pure & Cure Healthcare Pvt. Ltd.	The firm presented their proposal along with CT protocol as well as BE study protocol in higher strength i.e. Pioglitazone 15mg + Sitagliptin 100mg tablets before the committee. After detailed deliberation, the committee recommended for grant of permission for conducting the BE study and clinical trial. The results of the studies should be presented before the committee.
11.	FDC/MA/22/000325 Dapagliflozin Propanediol monohydrate eq to Dapagliflozin 5mg/5mg/10mg/10mg /5mg/5mg/10mg/ 10mg + Linagliptin 2.5mg/2.5mg/2.5mg/ 2.5mg/5mg/5mg/5mg + Metformin HCl eq to Metformin (as sustained release) 500mg/1000mg/ 500mg/1000mg/ 500mg/ 1000mg/500mg/1000 mg tablets	M/s. Theon Pharmaceuticals Ltd.	The firm presented their proposal along with the rationality of the product before the committee. After detailed deliberation, the committee recommended that firm should present the BE study protocol as well as clinical trial protocol for further review by the committee.

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12.	FDC/MA/20/000039 Vildagliptin SR 100mg/100mg + Metformin HCl SR500mg/1000mgfilm coated bilayered tablet	M/s. Synokem Pharmaceuticals	In light of earlier SEC recommendation dated 19.01.2021 & 20.01.2021, the firm presented the BE & CT report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture & market the applied product.
GCT Division			
13.	CT/73/22 Online Submission (33271) LY3209590	M/s. Eli Lilly	The proposal was deferred for next meeting.
14.	CT/74/22 Online Submission (33286) LY3209590	M/s. Eli Lilly	The proposal was deferred for next meeting.
15.	CT/112/22 Online Submission (34060) LY3298176	M/s. Eli Lilly	The proposal was deferred for next meeting.
16.	CT/07/22 Online Submission (21675) Insulin Icodec	M/s Novo-Nordisk	The proposal was deferred for next meeting.