

Recommendations of the SEC (Gastroenterology & Hepatology) made in its 51st meeting held on 24.08.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/22/000129 Tofacitinib SR Tablets 22 mg	M/s. Mascot Health Series Pvt. Ltd.	<p>In light of earlier SEC recommendation of (Gastroenterology & Hepatology) meeting held on 17.05.2022, the firm presented their proposal for manufacture and marketing permission of Tofacitinib Sustained Release Tablets 22mg indicated for the treatment of adult patients with moderate to severe active ulcerative colitis (UC) who have an inadequate response or intolerance to one or more TNF blockers, alongwith BE study report of the applied drug product before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Tofacitinib Sustained Release Tablets 22mg for proposed indication as mentioned above.</p>
2.	SND/MA/22/000222 Loperamide Hydrochloride 2 mg Orally Disintegrating Tablets	M/s. Tenshi Kaizen Pvt. Ltd	<p>The firm presented their proposal of manufacture and marketing permission Loperamide Hydrochloride 2 mg Orally Disintegrating Tablets for the indication “symptomatic treatment of acute diarrhoea in adult and adolescent aged 12 years and over along with the results of BE studies conducted in fasting and fed condition” .</p> <p>After detailed deliberation, the committee recommended for grant of permission for Loperamide Hydrochloride 2mg Orally Disintegrating Tablets for already approved indication.</p>
3.	SND/MA/22/000224 Zinc Acetate Oral Drops 10.0 mg/ml	M/s. Zuventus Healthcare	<p>The firm presented their proposal of manufacture and marketing permission of Zinc Acetate Oral Drops 10.0 mg/ml for the indication of in treatment of acute diarrhoea in children as an adjunct to oral rehydration alongwith published data before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Zinc Acetate Oral Drops 10.0 mg/ml for proposed indication as mentioned above.</p>

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4.	SND/MA/22/219 Tofacitinib SR Tablet 22 mg	M/s. MSN Labs	The firm did not turn up for presentation.
5.	SND/MA/22/000223 Tofacitinib SR Tablet 22 mg	M/s. Synokem	<p>The firm presented their proposal for manufacture and marketing permission of Tofacitinib Sustained Release Tablets 22mg along with BE study protocol.</p> <p>After detailed deliberation, the committee recommended for grant of conduct of BE study as per protocol presented with the following condition: -</p> <ol style="list-style-type: none"> 1. The reference product shall be "One tablet of XELJANZ XR Tablet 22 mg". 2. Subjects with BMI between 18.50 to 25 kg/m² should be included in the study. 3. Subjects with dermal and fungal infection should be excluded from study. <p>The results of the BE study should be submitted to CDSCO for further review by the committee.</p>
FDC Division			
6.	FDC/MA/20/000098 Trimcinoloneacetone 0.01% + Lidocaine hydrochloride 2 % + Pentosan 1% polysulfatesodium Oint ment	M/s. Swati Spentose Pvt. Ltd.	<p>In light of earlier SEC recommendation dated 25.11.2020, the firm presented their proposal along with justification for waiver of Phase III clinical trial.</p> <p>The firm informed the committee that drug is already approved in Spain since 1974, in Argentina and Hongkong.</p> <p>After detailed deliberation, the committee noted that the firm could not produce any safety and efficacy data on proposed FDC.</p> <p>Therefore, the committee reiterated it's earlier recommendation and accordingly, the firm should submit the Phase III clinical trial protocol before the committee.</p>
GCT Division			
7.	CT/18/20 Online Submission (18426) Novel Hydrocortisone Acetate 90 mg	M/s. Novotech Clinical Research	<p>The firm has presented protocol amendment 2.0, dated 09 May 2022 before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of approval to the proposed protocol amendment.</p>

SEC (Gastroenterology & Hepatology) meeting dated 24.08.2022

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8.	CT/127/20 Online Submission (18766) Semaglutide	M/s. Novo Nordisk	The firm has presented protocol amendment 11, dated 11 Feb 2022 before the committee. After detailed deliberation, the committee recommended for grant of approval to the proposed protocol amendment.