

**Recommendations of the SEC (Gastroenterology &Hepatology) made in its 53<sup>rd</sup> meeting held on 18.10.2022 at CDSCO (HQ), New Delhi:**

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>Biological Division</b>			
1.	4-25/Roche/PAC-R-Atezolizumab/2022-BD  Atezolizumab Injection 1200mg/20ml and 840mg/14ml vials	M/s. Roche Products India Pvt. Ltd	<p>The firm presented their proposal for amendment in warning statement from “Warning: To be sold by retail on the prescription of a Registered Oncologist only” to “Warning: To be sold by retail on the prescription of a Registered Oncologist, <b>Gastroenterologist or Hepatologist</b> only”.</p> <p>The committee noted that, the firm has been granted approval for additional indication: “Atezolizumab in combination with Bevacizumab, for the treatment of patients with unresectable or metastatic hepatocellular carcinoma who have not received prior systemic therapy” as per recommendation of SEC (Oncology &amp; Hematology) dated 06.08.2021 &amp; 10.08.2021.</p> <p>After detailed deliberation, the committee recommended for the proposed amendment in the warning statement and also advised to refer the proposal to SEC (Oncology &amp; Hematology) for their comments.</p>
<b>SND Division</b>			
2.	SND/IMP/20/000021  Mesalazine Prolonged Release Granules 1 gm & 2 gm	M/s. Ferring Pharmaceuticals	<p>The firm has presented the updated package insert of Mesalazine Prolonged Release Granules 1 gm &amp; 2 gm before the committee.</p> <p>After detailed deliberation, the committee recommended for the approval of the proposed Package Insert.</p>
3.	SND/MA/20/000083  Ursodeoxycholic Acid Tablets IP 150mg/300mg/450mg/600mg	M/s. Abbott Healthcare	<p>The firm presented their proposal for amendment of Phase III clinical trial protocol for Ursodeoxycholic Acid Tablets IP 150mg/300mg/450mg/600mg vide protocol number UDIL3002, version 4 dated 26-07-2022.</p> <p>After detailed deliberation, the committee recommended that the proposal should be deliberated in presence of Gynecology and Obstetrics Expert in next meeting.</p>

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<b>FDC Division</b>			
4.	FDC/MA/22/000253 Domperidone (SR) 30mg+Rabeprazole Sodium IP20mg capsules	M/s. Dr. Reddy's Laboratories Ltd.	The product is already approved by CDSCO. The proposal has been deferred.
5.	FDC/MA/18/000006 Dicyclomine 20mg + 50mg + Tapentadol 10mg + 25mg tablets	M/s. Wockhardt	In light of earlier SEC recommendation dated 20.07.2022, the firm presented the revised Phase III CT protocol before the committee.  After detailed deliberation, the committee recommended for conducting the Phase III CT study. The result of the study should be presented before the committee for further review.
<b>GCT Division</b>			
6.	CT/31/16 Online Submission (11913) Vedolizumab	M/s. PPD	The applicant presented the protocol amendment 7 dated 19.10.2021 before the committee.  After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
<b>Medical Device Division</b>			
7.	IMP/MD/2021/45970 Flat sheet mesh (Pearltene)	M/s. India Medtronic Pvt. Ltd.	The firm presented their proposal before the committee.  After detailed deliberation, the committee recommended for grant of approval of the proposed product with new indication (Flat Sheet Mesh).