

**Recommendations of the SEC (Antimicrobial & Antiviral) made in its 12<sup>th</sup>/24 meeting held on 19.12.2024 at CDSCO (HQ), New Delhi:**

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/126/24 Online Submission (45066)  Oxfendazole	M/s Indian Council of Medical Research	The firm presented Phase 2a clinical study protocol number ICMR/OXF/2024/V1.0 Version: 1.0 dated 03 September 2024.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with the condition that participants with lymphatic filariasis who need surgical intervention shall be excluded.
2.	CT/64/23 Online Submission (35879)  EYU688	M/s Novartis Healthcare Private Limited	The firm presented protocol amendment version 01 dated 25 Sep 2024 protocol No. CEYU688A12201.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
<b>SND Division</b>			
3.	SND/IMP/22/000003  Azelastine Hydrochloride 1 mg/ml nasal spray	M/s Ursapharm India Pvt. Ltd.	In light of earlier recommendation of COVID-19 SEC meeting dated 05.04.22, firm presented the results of Phase II study before the committee.  Firm stated before the committee that product is not approved anywhere in the world. Firm has also informed that they have conducted Phase III trial in Germany and their application is under consideration at German and EU drug Regulatory Authority.  Based on Phase II Clinical trial study results in COVID-19 patients conducted in India and Phase I clinical trial in Germany, firm has requested for approval of the drug for use in COVID-19 indication.  After detailed deliberation, the committee opined that firm is required to submit Phase III clinical trial Protocol along with the approval status in Germany and results of Phase III clinical trial study conducted in Germany to CDSCO for further review & deliberation before the

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			committee.