

**Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 01<sup>st</sup>/24 SEC meeting held on 27.02.2024 at CDSCO, (HQ) New Delhi:**

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
<b>GCT Division</b>			
1.	CT/172/22 Online Submission (28407)  Bemnifosbuvir	M/s. IQVIA	The firm presented protocol amendment version 2.0 dated 15 June 2023 protocol No. AT-03A-017.  After detailed deliberation, the committee recommended for approval of protocol amendment and increase of sample size from 200 to 450 in India as presented by the firm with condition that more government sites shall be included in the study .
2.	CT/38/22 Online Submission (29979)  Anti-COVID-19 AKS-452 Vaccine	M/s. Veeda Clinical Research	The firm presented protocol amendment version 5.1 dated 28 November 2023 protocol No. 22-VIN-0076.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.