

Recommendations of the SEC (Covid-19) made in its 234th meeting held on 25.08.2022at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/MA/22/000082 Chimpanzee Adenovirus vectored COVID-19 Nasal Vaccine	M/s Bharat Biotech International LTD. Hyderabad	The firm presented its proposal for grant of permission to manufacture ChAd36-SARS-CoV-S COVID-19 (Chimpanzee Adenovirus Vectored) recombinant COVID-19 Vaccine (BBV154) indicated for primary immunization against COVID-19 in adults aged 18 years and above for restricted use in emergency situation along with the interim clinical trial data/results including safety & immunogenicity of Phase I, II & III conducted in the country before the committee. The proposal was discussed and as per request of firm, it is deferred for further deliberation.
2.	4-18/Roche/PAC-R-Tocilizumab/2021-BD Tocilizumab	M/sRoche Products(I) Pvt. Ltd.	In light of the earlier SEC recommendation dated 25.05.2022, the firm again presented its proposal for grant of approval for additional indication in COVID-19 i.e., indicated for the treatment of coronavirus disease 2019(COVID-19) in hospitalized adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation with detailed presentation and results of global studies and retrospective India specific clinical studies. After detailed deliberation and in light of pandemic situation the committee recommended for approval of proposed indication for restricted use in emergency situation.
New Drug Division			
3.	IND/CT/20/000037 2-Deoxy-D-Glucose	M/s Dr. Reddy	The firm didn't turn up for presentation.
New Drug Division-Additional			
4.	IND/MA/22/0004 Glactomannan 1400mg Tablets.	M/s Murli Krishna	The proposal is deferred for the next meeting