

**Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 175<sup>th</sup> meeting held on, 13-08-2021 , 14 -08-2021 & 19-08-2021at CDSCO, HQ New Delhi:**

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
<b>Biological Division</b>			
1.	BIO/MA/21/000063  Novel Corona Virus - 2019-nCov vaccine	M/s. Cadila Healthcare	<p>In continuation to the earlier meetings, the firm presented their proposal for grant of Emergency approval of Novel Corona Virus - 2019-nCov vaccine in the age group of 12 years and older along with the interim safety, efficacy &amp; immunogenicity data of Phase III clinical trial of 2 mg dose (three dosing regimen day 0, 28 &amp; 56), interim safety &amp; immunogenicity data of Phase I/II clinical trial of 3 mg (two dose regimen day 0 &amp; 28) along with Summary Product Characteristics (SmPC), Prescribing information (PI) &amp; Factsheet.</p> <p>The committee noted that in the Phase III efficacy study during the interim analysis 61 cases of COVID-19 infection in placebo group &amp; 20 cases in vaccine group were reported which gives efficacy of 66.6% for symptomatic COVID-19 infection.</p> <p>Further the committee noted that Phase I/II clinical trial of 3 mg dose (two dose regimen) was conducted in the age group of 18 years and older. Firm has submitted details of ADR, narration of SAE as requested by the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission for restricted use in emergency situation of Novel Corona Virus - 2019-nCov vaccine (2 mg) administered intradermally in three doses of 0.2 ml each with Pharmajet device at 0, 28 &amp; 56 days in the age group of 12 years and above, subject to the condition that the firm should continue the conduct of Phase I/II &amp; Phase III clinical trials as per the protocol and submit the data for review by the committee.</p> <p>Firm's request for unblinding of participants in Phase III trial of three doses after 8 week of last dose (third dose, day 56) is also recommended by the committee.</p> <p>Further, with regards to two dose (3mg) regimen the committee recommended that the firm should generate additional data and also submit safety protocol for further consideration.</p>

