Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 208th meeting held on 04.02.2022 at CDSCO (HQ), New Delhi.

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	[BIO/IMP/21/000056] Recombinant human adenovirus serotype number 26 (rAd26) COVID-19 vaccine [SPUTNIK-Light]	M/s Dr. Reddy's Laboratories, Ltd. Hyderabad.	In light of recommendations of SEC meeting dated 31.01.2022, the firm presented its proposal for grant of permission to import Recombinant human adenovirus serotype number 26 (rAd26) COVID-19 vaccine [SPUTNIK-Light] for restricted use in emergency situation and booster dose vaccination along with PI, SmPC & Factsheet along with the analysis of latest safety & efficacy data including its benefit against Omicron variant. Further, the firm presented that Sputnik Light vaccine is approved in 29 countries including Argentina, Russia, etc. The committee noted that the safety & immunogenicity data presented by the firm from the Indian study is comparable with that of the ongoing Phase III clinical trial interim data from Russia. The interim data of efficacy trial from Russia has shown the efficacy of 65.4% against COVID-19, 21 days after immunization. The committee deliberated on various critical areas for consideration including safety, immunogenicity, efficacy data from overseas clinical studies, indication, age group, dosing schedule, precautions, storage, warnings, adverse effects of special interest, risk benefit evaluation, proposed factsheet, PI, SmPC etc. After detailed deliberation, in the light of current pandemic situation, the committee recommended for grant of permission for restricted use in emergency situation subject to various regulatory provisions including following: 1. The vaccine is indicated for active immunization to prevent COVID-19 disease in individuals of age over 18 years. 2. The vaccine should be administered intramuscularly in single dose of 0.5 ml.

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			3. The firm should submit revised PI, SmPC & Factsheet to CDSCO after incorporating the latest safety & efficacy data and other suggestions made during the meeting. 4. The vaccine should be supplied along with factsheet & separate leaflet for the guidance of the healthcare provider. 5. The firm should ensure that factsheet for the vaccine recipient/attendant is provided prior to administration of the vaccine. 6. The firm should disseminate the instructions & educational material including factsheet, PI, SmPC, storage instructions etc. in their website. 7. The firm should submit safety, efficacy & immunogenicity data from the ongoing clinical trials in India and Russia for review as and when available. 8. The firm should submit safety data including the data on AEFI and AESI with due analysis every 15 days for the first two months & monthly thereafter till the completion of the ongoing clinical trial in the country. Thereafter, the firm should submit the safety data as per the provisions and standard procedures. 9. The firm should submit India specific Risk management plan. With regard to use of Sputnik Light vaccine as a booster dose, the applicant may provide clinical data including immunogenicity data in Indian population for further evaluation.