Recommendations of the SEC (Covid-19) made in its 235th meeting held on 26.08.2022at 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	In continuation to SEC meeting dated 25.08.2022, M/s BBIL, Hyderabad presented its proposal for grant of permission to manufacture ChAd36-SARS-CoV-S COVID-19 (Chimpanzee Adenovirus Vectored) recombinant COVID-19 Nasal 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 firm presented the following: 1. ChAd36-SARS-CoV-S COVID-19 (Chimpanzee Adenovirus Vectored) recombinant COVID-19 Nasal Vaccine (BBV154) is developed using construct received from technology collaborator i.e. University of Washington, USA. 2. Technology collaborator has performed animal challenge studies in mice, hamster and rhesus macaques. 3. M/s BBIL, Hyderabad has conducted preclinical (animal) studies in BALB/c mice, Swiss Albino mice, Wister rats, Syrian Hamsters and New Zealand Rabbits 4. M/s BBIL, Hyderabad presented interim safety & immunogenicity data from Phase I, II & III trials. The data of Phase II included Interim safety(Day 180) and immunogenicity data (GMT by MNT and PRNT assays, serum IgG and IgA and Saliva IgA) of Day 42 (14 day's post dose 2)of 200 subjects. The data of Phase III (Immunogenic Superiority trial over Covaxin) included Interim Safety data till day 90 (60 day's post dose 2) of 3141 participants and immunogenicity data of Day 42 (14 day's post dose 2) of 640 subjects (immunogenicity cohort) including immunogenic superiority over Covaxin in terms of neutralizing antibody titers (NAbs) by PRNT assay along with Geometric Mean Titres of Serum IgG & IgA binding antibody titers, and saliva IgA.

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			M/s BBIL, Hyderabad also presented Summary of product characteristics (SmPC), Prescribing information (PI) and Fact sheets before the committee. The committee noted that: 1. The vaccine has been evaluated in animals BALB/c mice, Swiss Albino mice, Wister rats and New Zealand Rabbits for intranasal immunogenicity, safety & toxicity study 2. The vaccine has been found to be safe and immunogenic in Phase I, II& III trials. 3. The vaccine is found to be immunogenic superior over Covaxin in terms of neutralizing antibody titers (NAbs) by PRNT Assay along with Geometric Mean Titres of Serum IgG & IgA binding antibody titers, and saliva IgA. 4. Human Sera samples from Phase III clinical trial of (BBV154) have been evaluated against different variants of concern i.e beta, delta omicron (including BA.5) using live virus neutralizing Assay PRNT 50, which has shown the immune response as reported. 5. Further, the committee noted that M/s BBIL has presented cell mediated immune response from phase I and phase III trials uptil. Cell mediated immune response have been tested against ancestral Wuhan strain and Omicron variant of concern. The committee also reviewed the Summary of product characteristics, Package Insert (PI) and Fact sheet in detail. After detailed deliberation, in light of pandemic situation, the committee recommended for grant of permission to manufacture ChAd36-SARS-CoV-S COVID-19 (Chimpanzee Adenovirus Vectored) recombinant COVID-19 Nasal Vaccine (BBV154) indicated for primary immunization against COVID-19 in adults aged 18 years and above when administered at Day 0 and Day 28 (0.5ml, 4 drops in each

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			nostril) for restricted use in emergency situation with the following conditions: 1. This permission is for restricted use in emergency situation in public interest. 2. Vaccine to be supplied for programmatic settings as per Immunization program. 3. The firm should submit updated Package Insert (PI), Summary of Product Characteristics (SmPC) and Factsheet for ChAd36-SARS-CoV-S COVID-19 (Chimpanzee Adenovirus Vectored) recombinant COVID-19 Nasal Vaccine (BBV154) 4. The vaccine should be supplied along with Factsheet for recipients and Package Insert (PI). 5. The firm should ensure that factsheet for the vaccine recipient/his attendant is provided prior to the administration of vaccine. 6. The firm should disseminate the instructions & educational material including factsheet, PI, SmPC, storage instructions etc. through their website prior marketing/supplies of the product. 7. The firm should submit India specific Risk Management Plan 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. M/s BBIL, Hyderabad shall continue to follow up the subject participants and submit the trial results as and when completed, as per approved protocol for review.