Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 204nd meeting held on 19-01-2022 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/MA/22/000002 Whole Virion Inactivated SARS-CoV-2 vaccine [BBV152] [COVAXIN]	M/s Bharat Biotech International Limited, Hyaderabad	In light of the recommendations of the SEC meeting dated 14.01.2022, the firm presented six months safety data after last dose of ongoing Phase III trial along with the in-vitro efficacy data of vaccine against variants including Wuhan (NIV-2020-770) & Omicron from its Phase II sera samples at 6 months time point both after 2nd and 3rd dose. The committee noted that 1. Firm presented safety, immunogenicity and efficacy data of Phase I and II clinical trials along with safety data of 6 months Phase III clinical trial including data of Serious Adverse events till date. 2. Risk Management Plan has been submitted. 3. Firm has supplied more than 200 million doses of COVAXIN in the country. 4. Firm has requested for grant of permission to manufacture Whole Virion Inactivated SARC-CoV-2-Vaccine excluding the conditions of permission for restricted use in emergency situation. The committee reviewed safety, immunogenicity and efficacy data of Phase I, II & III clinical trials conducted in the country & noted that there has been no safety issues and vaccine maintains efficacy specially to avoid hospitalization and severe infections in given epidemiological situation also. Further, the firm has supplied more than 200 million doses in the country and there has been no significant safety concerns/ issues after vaccination with COVAXIN. After detailed deliberation, the committee recommended to update the status of approval of COVAXIN from Restricted use in Emergency situation to the New Drug permission as per rules in adult population with conditions that the firm shall submit data of ongoing clinical trials & the vaccine to be supplied for programmatic setting & AEFI, AESI shall be continued to be monitored.

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
2.	BIO/MA/20/000102 ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) [COVISHIELD]	M/s Serum Institute of India Pvt. Ltd. Pune	In light of the recommendations of the SEC meeting dated 14.01.2022, the firm presented stratified data of neurological and other events with regards to safety specifically in Indian population and clarification of Conditional Marketing Authorization of AZD1222 vaccine in UK-MHRA. Further, the firm presented AEFI and AESI data available. The committee noted that the firm has requested for grant of permission to manufacture ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) excluding the conditions of permission for restricted use in emergency situation and other conditions on the lines of Marketing Authorization by UK-MHRA for parent vaccine. The committee reviewed safety, immunogenicity and efficacy data from Indian and overseas clinical trials. The committee also noted that there has been no safety issues and vaccine maintains efficacy specially to avoid hospitalization and severe infections in given epidemiological situation also. Further, the firm has supplied more than 1.36 billion doses in the country and there has been no significant safety issues/concerns after vaccination. After detailed deliberation, the committee recommended to update the status of approval of COVISHIELD from Restricted use in Emergency situation to the New Drug permission as per rules in adult population with conditions that the firm shall submit data of ongoing clinical trials & the vaccine to be supplied for programmatic setting & AEFI, AESI shall be continued to be monitored.