

Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 198th meeting held on 27.12.2021 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/MA/21/000144 SARS-CoV-2 (Covid-19) Vaccine containing RBD antigen of SARS-CoV-2	M/s Biological E Ltd., Hyderabad	<p>In light of the recommendations of the SEC meeting dated 10.12.2021, the firm presented their proposal for grant of marketing authorization to SARS-CoV-2 (Covid-19) Vaccine containing RBD antigen of SARS-CoV-2 for restricted use in emergency situation in the age group of 18 years and above along with the updated interim safety and immunogenicity data of Phase II/III clinical trial and updated interim safety & immunogenicity data of Phase III active comparator trial.</p> <p>The committee noted that the firm has submitted six months safety follow up post second dose from Phase I clinical trial, 90 days safety data from the Phase II part & 60 days safety data from Phase II/III & Phase III active comparator study.</p> <p>The firm has submitted interim immunogenicity data from Phase III active comparator trial which showed superiority against the comparator with respect to viral neutralization antibody titres. Further, the firm has also shown the T-cell mediated response which was skewed towards Th1. Further, the committee also reviewed proposed factsheet, PI, SmPC etc.</p> <p>After detailed deliberation, the committee recommended for grant of marketing authorization permission of SARS-CoV-2 (Covid-19) Vaccine containing RBD antigen of SARS-CoV-2 for restricted use in emergency situation subject to various regulatory provisions including following:</p> <ol style="list-style-type: none"> 1. The vaccine is indicated for active immunization to prevent COVID-19 disease in individuals of ≥ 18 years of age. 2. The vaccine should be administered intramuscularly in two doses of 0.5 ml each with interval of 28 days. (Day 0 & 28). The vaccine has to be stored

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			<p>between 2°C to 8°C.</p> <ol style="list-style-type: none"> 3. The vaccine should be supplied along with factsheet & separate leaflet for the guidance of the healthcare provider. 4. The firm should ensure that factsheet for the vaccine recipient/attendant is provided prior to administration of the vaccine. 5. The firm should disseminate the instructions & educational material including factsheet, PI, SmPC, storage instructions etc. in their website. 6. The firm should submit safety & immunogenicity data from the ongoing clinical trials in India for review as and when available. 7. 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. 8. The firm should submit India specific Pharmacovigilance and Risk management plan.
2.	BIO/CT/21/000142 SARS-CoV-2 (Covid-19) Vaccine containing RBD antigen of SARS-CoV-2	M/s Biological E Ltd., Hyderabad	<p>In light of the recommendations of the SEC meeting dated 10.12.2021, the firm presented its revised clinical trial protocol for conduct of Phase III clinical trial for administration of booster dose of SARS-CoV-2 (Covid-19) Vaccine containing RBD antigen of SARS-CoV-2.</p> <p>The committee noted that the firm has submitted six months safety follow up post second dose from Phase I clinical trial, 90 days safety data from the Phase II part & 60 days safety data from Phase II/III & Phase III active comparator study.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct proposed Phase III clinical trial subject to the following conditions:</p> <ol style="list-style-type: none"> 1. Administration of booster dose after

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			<p>primary immunization should be studied in 2 cohorts of 6 and 9 months with age wise stratification and including 50% subjects with high risk or comorbid condition.</p> <p>2. Safety follow up should be extended to 9 months.</p>
3.	<p>BIO/MA/21/000055 BIO/MA/21/000056</p> <p>SARS-COV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-COV-2 rS)</p>	M/s Serum Institute of India Pvt. Limited	<p>In light of the recommendations of the SEC meeting dated 24.11.2021, the firm presented proposal for grant of market authorization of SARS-COV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-COV-2 rS) for restricted use in emergency situation in the age group of 18 years and above along with the interim safety and immunogenicity data of Phase II/III bridging clinical trial conducted in the country along with interim safety, immunogenicity and efficacy of Phase III clinical trials conducted in UK & US.</p> <p>The committee noted that the vaccine is manufactured by technology transfer from Novavax and is approved by European Medicines Agency (EMA) for conditional marketing authorisation & also granted emergency use listing by WHO.</p> <p>The committee also noted that the safety & immunogenicity data of the vaccine manufactured by M/s Serum is comparable to the vaccine manufactured by M/s Novavax. Further, the committee reviewed factsheet, PI, SmPC etc.</p> <p>After detailed deliberation, the committee recommended for grant of marketing authorization of SARS-COV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-COV-2 rS) for restricted use in emergency situation subject to various regulatory provisions including following:</p> <ol style="list-style-type: none"> 1. The vaccine is indicated for active immunization to prevent COVID-19 disease in individuals of ≥ 18 years of age. 2. The vaccine should be administered intramuscularly in two doses of 0.5 ml each with interval of 21 days. (Day 0 &

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			<p>21). The vaccine has to be stored between 2°C to 8°C.</p> <ol style="list-style-type: none"> 3. Firm should submit revised PI, SmPC & Factsheet to CDSCO after incorporating the latest safety & immunogenicity 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 & overseas 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 Pharmacovigilance and Risk management plan.
4.	BIO/CT/20/000186 SARS-COV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-COV-2 rS)	M/s Serum Institute of India Pvt., Ltd., Pune	<p>The firm presented interim safety data of Phase II/III clinical trial of SARS-CoV-2rS Protein Nanoparticle Vaccine for 460 subjects of 12-17 years, 230 subjects of 07 to 11 years & first 100 subjects of 02 to 06 years age group before the committee. After detailed deliberation, the committee noted the results of the study and recommended for continuation of clinical trial as per the approved protocol.</p>

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5.	BIO/IMP/21/000056 SARS-CoV-2 vaccine (Ad.26) [SPUTNIK-Light]	M/s Dr. Reddy's Laboratories, Ltd, Hyderabad	<p>The firm presented its proposal for grant of market authorization of SARS-CoV-2 vaccine (Ad.26) [SPUTNIK-Light] for restricted use in emergency situation in the age group of 18 years and above along with the interim safety and immunogenicity data of Phase III bridging clinical trial conducted in the country & interim Phase III efficacy trial in Russia.</p> <p>The committee noted that the immunogenicity data of Indian Phase III trial is available up to day 42.</p> <p>After detailed deliberation, the committee recommended that firm should submit comparative immunogenicity data between seronegative & seropositive subjects at base line and complete efficacy data from Russian trial for further evaluation.</p>
6.	BIO/CT/21/000156 SARS-CoV-2 vaccine (Ad.26) [SPUTNIK-Light]	M/s Dr. Reddy's Laboratories, Ltd, Hyderabad	<p>In view of the recommendations on the proposal for grant of marketing authorisation of Sputnik Light vaccine mentioned above, the proposal to conduct clinical trial with booster dose will be examined simultaneously along with the complete data of safety, immunogenicity and efficacy from earlier trials.</p>
7.	BIO/CT/21/000004 Equine Anti Covid Antibody Fragments F (ab') ₂	M/s JSS Medical Research India Pvt., Ltd.,	<p>Firm has requested more time for deliberation of its proposal.</p>
New drug Division			
8.	ND/MA/21/000055 Molnupiravir 200mg capsules	M/s Dr. Reddy's Laboratories Limited in consortium with M/s Cipla Limited, M/s Mylan, M/s Torrent, M/s Emcure and M/s Sun Pharma	<p>In light of earlier recommendation of SEC (COVID) dated 06.12.2021, firm presented their proposal for approval of Molnupiravir 200mg Capsules for approval in emergency situation along with various supporting documents, including clinical data in the country.</p> <p>Considering the emergency & unmet medical need in Covid-19, the Committee recommended for grant of permission to manufacture and market the Molnupiravir 200mg capsule for restricted use under emergency situation in the country for treatment of adult patients with COVID-19,</p>

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			<p>with SpO2 >93% and who have high risk of progression of the disease including hospitalization or death subject to following conditions: -</p> <ol style="list-style-type: none"> 1. The drug should be sold by retail only under prescription of medical specialists. 2. The recommended dose should be 800mg b.d. (twice daily) for 5 days 3. Molnupiravir is not authorized – <ol style="list-style-type: none"> i. for use in patients less than 18 years of age ii. for initiation of treatment in patients requiring immediate hospitalization due to COVID-19 at that stage, (however, if it was initiated before hospitalization due to COVID 19, it may be continued). iii. for use for longer than 5 consecutive days. iv. for pre-exposure or post-exposure prophylaxis for prevention of COVID-19 v. for pregnant women vi. Females of childbearing potential should use a reliable method of contraception correctly and consistently, as applicable, for the duration of treatment and for 4 days after the last dose of molnupiravir. vii. Males of reproductive potential who are sexually active with females of child bearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose 4. The fact sheet containing the factual details about the drug, its restricted use under emergency situation, alternative therapy available etc. should be provided to the Health care professionals.

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			<p>5. Active PMS study should be conducted on 1000 patients to assess the safety.</p> <p>6. The updated details of the clinical trial should be submitted within three months.</p>
9.	ND/MA/21/000050 Molnupiravir 200mg capsules	M/s Hetero Labs Limited	<p>In light of earlier recommendation of SEC (COVID) dated 06.12.2021, firm presented their proposal for approval of Molnupiravir 200mg Capsules for approval in emergency situation along with various supporting documents, including clinical data in the country.</p> <p>Considering the emergency & unmet medical need in Covid-19, the Committee recommended for grant of permission to manufacture and market the Molnupiravir 200mg capsule for restricted use under emergency situation in the country for treatment of adult patients with COVID-19, with SpO2 >93% and who have high risk of progression of the disease including hospitalization or death subject to following conditions: -</p> <ol style="list-style-type: none"> 1. The drug should be sold by retail only under prescription of medical specialists. 2. The recommended dose should be 800mg b.d. (twice daily) for 5 days 3. Molnupiravir is not authorized – <ol style="list-style-type: none"> i. for use in patients less than 18 years of age ii. for initiation of treatment in patients requiring immediate hospitalization due to COVID-19 at that stage, (however, if it was initiated before hospitalization due to COVID 19, it may be continued). iii. for use for longer than 5 consecutive days. iv. for pre-exposure or post-exposure prophylaxis for prevention of COVID-19 v. for pregnant women

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			<ul style="list-style-type: none"> vi. Females of childbearing potential should use a reliable method of contraception correctly and consistently, as applicable, for the duration of treatment and for 4 days after the last dose of molnupiravir. vii. Males of reproductive potential who are sexually active with females of child bearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose 4. The fact sheet containing the factual details about the drug, its restricted use under emergency situation, alternative therapy available etc. should be provided to the Health care professionals. 5. Active PMS study should be conducted on 1000 patients to assess the safety. 6. The updated details of the clinical trial should be submitted within three months.
10.	ND/MA/21/000052 Molnupiravir Capsules 200mg & 400mg	M/s Natco Pharma	<p>In light of earlier recommendation of SEC (COVID) dated 06.12.2021, firm presented their proposal for approval of Molnupiravir 200mg Capsules for approval in emergency situation along with various supporting documents, including clinical data in the country.</p> <p>Considering the emergency & unmet medical need in Covid-19, the Committee recommended for grant of permission to manufacture and market the Molnupiravir 200mg capsule for restricted use under emergency situation in the country for treatment of adult patients with COVID-19, with SpO2 >93% and who have high risk of progression of the disease including hospitalization or death subject to following conditions: -</p>

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			trial should be submitted within three months.
11.	ND/MA/21/000044 Molnupiravir Capsules 200mg, 400mg, 800mg	M/s Optimus Pharma Pvt. Ltd.	<p>In light of earlier recommendation of SEC (COVID) dated 06.12.2021, firm presented their proposal for approval of Molnupiravir 200mg Capsules for approval in emergency situation along with various supporting documents, including clinical data in the country.</p> <p>Considering the emergency & unmet medical need in Covid-19, the Committee recommended for grant of permission to manufacture and market the Molnupiravir 200mg capsule for restricted use under emergency situation in the country for treatment of adult patients with COVID-19, with SpO2 >93% and who have high risk of progression of the disease including hospitalization or death subject to following conditions: -</p> <ol style="list-style-type: none"> 1. The drug should be sold by retail only under prescription of medical specialists. 2. The recommended dose should be 800mg b.d. (twice daily) for 5 days 3. Molnupiravir is not authorized – <ol style="list-style-type: none"> i. for use in patients less than 18 years of age ii. for initiation of treatment in patients requiring immediate hospitalization due to COVID-19 at that stage, (however, if it was initiated before hospitalization due to COVID 19, it may be continued).. iii. for use for longer than 5 consecutive days. iv. for pre-exposure or post-exposure prophylaxis for prevention of COVID-19 v. for pregnant women vi. Females of childbearing potential should use a reliable method of contraception

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			<p>correctly and consistently, as applicable, for the duration of treatment and for 4 days after the last dose of molnupiravir.</p> <p>vii. Males of reproductive potential who are sexually active with females of child bearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose</p> <p>4. The fact sheet containing the factual details about the drug, its restricted use under emergency situation, alternative therapy available etc. should be provided to the Health care professionals.</p> <p>5. Active PMS study should be conducted on 1000 patients to assess the safety.</p> <p>6. The updated details of the clinical trial should be submitted within three months.</p>
12.	ND/MA/21/000046 Molnupiravir Capsules 200mg, 400mg	M/s Strides Pharma Pvt. Ltd.	<p>In light of earlier recommendation of SEC (COVID) dated 06.12.2021, firm presented their proposal for approval of Molnupiravir 200mg Capsules for approval in emergency situation along with various supporting documents, including clinical data in the country.</p> <p>Considering the emergency & unmet medical need in Covid-19, the Committee recommended for grant of permission to manufacture and market the Molnupiravir 200mg capsule for restricted use under emergency situation in the country for treatment of adult patients with COVID-19, with SpO2 >93% and who have high risk of progression of the disease including hospitalization or death subject to following conditions: -</p> <p>1. The drug should be sold by retail only under prescription of medical</p>

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			<p>specialists.</p> <ol style="list-style-type: none"> 2. The recommended dose should be 800mg b.d. (twice daily) for 5 days 3. Molnupiravir is not authorized – <ol style="list-style-type: none"> i. for use in patients less than 18 years of age ii. for initiation of treatment in patients requiring immediate hospitalization due to COVID-19 at that stage, (however, if it was initiated before hospitalization due to COVID 19, it may be continued). iii. for use for longer than 5 consecutive days. iv. for pre-exposure or post-exposure prophylaxis for prevention of COVID-19 v. for pregnant women vi. Females of childbearing potential should use a reliable method of contraception correctly and consistently, as applicable, for the duration of treatment and for 4 days after the last dose of molnupiravir. vii. Males of reproductive potential who are sexually active with females of child bearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose 4. The fact sheet containing the factual details about the drug, its restricted use under emergency situation, alternative therapy available etc. should be provided to the Health care professionals. 5. Active PMS study should be conducted on 1000 patients to assess the safety. 6. The updated details of the clinical trial should be submitted within three months.

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13.	ND/MA/21/000052 Molnupiravir Capsules 200mg, 400mg	M/s MSN Pharma Pvt. Ltd.	<p>In light of earlier recommendation of SEC (COVID) dated 06.12.2021, firm presented their proposal for approval of Molnupiravir 200mg Capsules for approval in emergency situation along with various supporting documents, including clinical data in the country.</p> <p>Considering the emergency & unmet medical need in Covid-19, the Committee recommended for grant of permission to manufacture and market the Molnupiravir 200mg capsule for restricted use under emergency situation in the country for treatment of adult patients with COVID-19, with SpO2 >93% and who have high risk of progression of the disease including hospitalization or death subject to following conditions: -</p> <ol style="list-style-type: none"> 1. The drug should be sold by retail only under prescription of medical specialists. 2. The recommended dose should be 800mg b.d. (twice daily) for 5 days 3. Molnupiravir is not authorized – <ol style="list-style-type: none"> i. for use in patients less than 18 years of age ii. for initiation of treatment in patients requiring immediate hospitalization due to COVID-19 at that stage, (however, if it was initiated before hospitalization due to COVID 19, it may be continued). iii. for use for longer than 5 consecutive days. iv. for pre-exposure or post-exposure prophylaxis for prevention of COVID-19 v. for pregnant women vi. Females of childbearing potential should use a reliable method of contraception correctly and consistently, as

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			<p>applicable, for the duration of treatment and for 4 days after the last dose of molnupiravir.</p> <p>vii. Males of reproductive potential who are sexually active with females of child bearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose</p> <p>4. The fact sheet containing the factual details about the drug, its restricted use under emergency situation, alternative therapy available etc. should be provided to the Health care professionals.</p> <p>5. Active PMS study should be conducted on 1000 patients to assess the safety.</p> <p>6. The updated details of the clinical trial should be submitted within three months.</p>
14.	IND/MA/21/000018 Molnupiravir 200 mg & 400 mg capsule	M/s BDR Pharmaceuticals International Pvt. Ltd.	<p>In light of earlier recommendation of SEC (COVID) dated 06.12.2021, firm presented their proposal for approval of Molnupiravir 200mg Capsules for approval in emergency situation along with various supporting documents, including clinical data in the country.</p> <p>Considering the emergency & unmet medical need in Covid-19, the Committee recommended for grant of permission to manufacture and market the Molnupiravir 200mg capsule for restricted use under emergency situation in the country for treatment of adult patients with COVID-19, with SpO2 >93% and who have high risk of progression of the disease including hospitalization or death subject to following conditions: -</p> <p>1. The drug should be sold by retail only under prescription of medical specialists.</p>

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			<ol style="list-style-type: none"> 2. The recommended dose should be 800mg b.d. (twice daily) for 5 days 3. Molnupiravir is not authorized – <ol style="list-style-type: none"> i. for use in patients less than 18 years of age ii. for initiation of treatment in patients requiring immediate hospitalization due to COVID-19 at that stage, (however, if it was initiated before hospitalization due to COVID 19, it may be continued). iii. for use for longer than 5 consecutive days. iv. for pre-exposure or post-exposure prophylaxis for prevention of COVID-19 v. for pregnant women vi. Females of childbearing potential should use a reliable method of contraception correctly and consistently, as applicable, for the duration of treatment and for 4 days after the last dose of molnupiravir. vii. Males of reproductive potential who are sexually active with females of child bearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose 4. The fact sheet containing the factual details about the drug, its restricted use under emergency situation, alternative therapy available etc. should be provided to the Health care professionals. 5. Active PMS study should be conducted on 1000 patients to assess the safety. 6. The updated details of the clinical trial should be submitted within three months.

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15.	ND/MA/21/000074 Molnupiravir Capsules 200 mg	M/s Aurobindo Pharma Limited	<p>In light of earlier recommendation of SEC (COVID) dated 06.12.2021, firm presented their proposal for approval of Molnupiravir 200mg Capsules for approval in emergency situation along with various supporting documents, including clinical data in the country.</p> <p>Considering the emergency & unmet medical need in Covid-19, the Committee recommended for grant of permission to manufacture and market the Molnupiravir 200mg capsule for restricted use under emergency situation in the country for treatment of adult patients with COVID-19, with SpO2 >93% and who have high risk of progression of the disease including hospitalization or death subject to following conditions: -</p> <ol style="list-style-type: none"> 1. The drug should be sold by retail only under prescription of medical specialists. 2. The recommended dose should be 800mg b.d. (twice daily) for 5 days 3. Molnupiravir is not authorized – <ol style="list-style-type: none"> i. for use in patients less than 18 years of age ii. for initiation of treatment in patients requiring immediate hospitalization due to COVID-19 at that stage, (however, if it was initiated before hospitalization due to COVID 19, it may be continued). iii. for use for longer than 5 consecutive days. iv. for pre-exposure or post-exposure prophylaxis for prevention of COVID-19 v. for pregnant women vi. Females of childbearing potential should use a reliable method of contraception correctly and consistently, as applicable, for the duration of treatment and for 4 days after

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			<p>the last dose of molnupiravir.</p> <p>vii. Males of reproductive potential who are sexually active with females of child bearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose</p> <p>4. The fact sheet containing the factual details about the drug, its restricted use under emergency situation, alternative therapy available etc. should be provided to the Health care professionals.</p> <p>5. Active PMS study should be conducted on 1000 patients to assess the safety.</p> <p>6. The updated details of the clinical trial should be submitted within three months.</p>