Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 196th meeting held on 06.12.2021 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drug Division			
1.	ND/MA/21/000055 Molnupiravir 200mg capsules	M/s. Dr. Reddy's Laboratories Limited in consortium with M/s Cipla, M/s Sun Pharma, M/s Torrent Pharmaceuticals, M/s Emcure and M/s Mylan	In light of earlier SEC recommendation dated 18.11.2021, the firm presented M/s Merck's global data which included the Phase III MOVE-OUT interim primary efficacy and safety analysis as well as analysis on full population, sub group analysis of the mITT population, along with the updated clinical trial data from the ongoing Indian clinical trial, current regulatory status of the drug in other countries, etc. The committee noted that - 1. UKMHRA granted approval under special condition, EMA issued advice to EU member state countries regarding use of the drug while the marketing authorisation application is under review by the EMA. 2. Advisory committee of USFDA on 30.11.2021 voted 13-10 that the known and potential benefits of the drug outweigh its known and potential risks. However as informed by the firm, USFDA has sought further questions and clarifications for which M/s Merck's has replied. The committee also noted that in the primary efficacy analysis, significant treatment effect was demonstrated in the overall trial population. However, safety issues including embryo-foetal toxicities, bone marrow toxicity, mutagenicity etc. were reported either in-vitro or in some species of animals. Committee also observed that there was reduction in efficacy when compared with the Merck's data of the earlier interim analysis with that of full population. USFDA has not yet given final decision on the Merck's EUA application.

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			The firm has not submitted the package insert fact sheet, risk mitigation plan, etc. in line with their local clinical trial results and request for restricted use under emergency situation. Present proposed package insert indicates its use in mild to moderate COVID-19 patients without mention of risk factor(s). In light of above, after detailed deliberation, the committee recommended that the firm should present the details of regulatory communications along with the following: 1. Proposed Package insert 2. Fact sheet 3. Details of Risk Mitigation Plan and; 4. Specific category of COVID Patients that is likely to receive the greatest benefit of the treatment, for which the drug may be indicated.
2.	ND/MA/21/000050 Molnupiravir 200mg capsules	M/s. Hetero Labs Limited	In light of earlier SEC recommendation dated 18.11.2021, the firm presented updated safety and efficacy analysis data before the committee. The firm has not submitted the package insert, fact sheet, risk mitigation plan, etc. in line with their local clinical trial results and request for restricted use under emergency situation. Present proposal with respect to package insert indicates its use in mild to moderate COVID-19 patients without mention of risk factor(s). The committee after detailed deliberation recommended that the firm should submit further subgroup analysis along with the following: 1. Proposed Package insert 2. Fact sheet 3. Details of Risk Mitigation Plan and; 4. Specific category of COVID patients that is likely to receive the greatest benefit of the treatment, for which the drug may be indicated.

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3.	ND/MA/21/000052 Molnupiravir Capsules 200mg & 400mg	M/s. Natco Pharma	In light of earlier SEC recommendation dated 18.11.2021, the firm presented updated safety and efficacy analysis data before the committee. The firm has not submitted the package insert, fact sheet, risk mitigation plan, etc. in line with their local clinical trial results and request for restricted use under emergency situation. Present proposal with respect to package insert indicates its use in mild to moderate COVID-19 patients without mention of risk factor(s). The committee after detailed deliberation recommended that the firm should submit further subgroup analysis along with the following: 1. Proposed Package insert 2. Fact sheet 3. Details of Risk Mitigation Plan and; 4. Specific category of COVID patients that is likely to receive the greatest benefit of the treatment, for which the drug may be indicated.
4.	ND/MA/21/000044 Molnupiravir Capsules 200mg, 400mg, 800mg	M/s. O ptimus Pharma Pvt. Ltd.	In light of earlier SEC recommendation dated 18.11.2021, the firm presented updated safety and efficacy analysis data before the committee. The firm has not submitted the package insert, fact sheet, risk mitigation plan, etc. in line with their local clinical trial results and request for restricted use under emergency situation. Present proposal with respect to package insert indicates its use in mild to moderate COVID-19 patients without mention of risk factor(s). The committee after detailed deliberation recommended that the firm should submit further subgroup analysis along with the following : 1. Proposed Package insert 2. Fact sheet 3. Details of Risk Mitigation Plan and;

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			4. Specific category of COVID patients that is likely to receive the greatest benefit of the treatment, for which the drug may be indicated.
5.	ND/MA/21/000046 Molnupiravir Capsules 200mg, 400mg	M/s. Strides Pharma Pvt. Ltd.	In light of earlier SEC recommendation dated 18.11.2021, the firm presented updated safety and efficacy analysis data before the committee. The firm has not submitted the package insert, fact sheet, risk mitigation plan, etc. in line with their local clinical trial results and request for restricted use under emergency situation. Present proposal with respect to package insert indicates its use in mild to moderate COVID-19 patients without mention of risk factor(s). The committee after detailed deliberation recommended that the firm should submit further subgroup analysis along with the following: 1. Proposed Package insert 2. Fact sheet 3. Details of Risk Mitigation Plan and; 4. Specific category of COVID patients that is likely to receive the greatest benefit of the treatment, for which the drug may be indicated.
6.	ND/MA/21/000052 Molnupiravir Capsules 200mg, 400mg	M/s. MSN Pharma Pvt. Ltd.	In light of earlier SEC recommendation dated 18.11.2021, the firm presented updated safety and efficacy analysis data before the committee. The firm has not submitted the package insert, fact sheet, risk mitigation plan, etc. in line with their local clinical trial results and request for restricted use under emergency situation. Present proposal with respect to package insert indicates its use in mild to moderate COVID-19 patients without mention of risk factor(s). The committee after detailed deliberation recommended that the firm should submit further subgroup analysis along with the following:

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			1. Proposed Package insert 2. Fact sheet 3. Details of Risk Mitigation Plan and; 4. Specific category of COVID patients that is likely to receive the greatest benefit of the treatment, for which the drug may be indicated.
7.	IND/MA/21/000018 Molnupiravir 200 mg & 400 mg capsule	M/s. BDR Pharmaceuticals International Pvt. Ltd.	In light of earlier SEC recommendation dated 18.11.2021, the firm presented updated safety and efficacy analysis data before the committee. The firm has not submitted the package insert, fact sheet, risk mitigation plan, etc. in line with their local clinical trial results and request for restricted use under emergency situation. Present proposal with respect to package insert indicates its use in mild to moderate COVID-19 patients without mention of risk factor(s). The committee after detailed deliberation recommended that the firm should submit further subgroup analysis along with the following: 1. Proposed Package insert 2. Fact sheet 3. Details of Risk Mitigation Plan and; 4. Specific category of COVID patients that is likely to receive the greatest benefit of the treatment, for which the drug may be indicated.
8.	ND/MA/21/000074 Molnupiravir Capsules 200 mg	M/s. Aurobindo Pharma Limited	In light of earlier SEC recommendation dated 18.11.2021, the firm presented updated safety and efficacy analysis data before the committee. The firm has not submitted the package insert, fact sheet, risk mitigation plan, etc. in line with their local clinical trial results and request for restricted use under emergency situation. Present proposal with respect to package insert indicates its use in mild to moderate COVID-19 patients without mention of risk factor(s). The committee after detailed deliberation recommended that the firm should submit

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