

**Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 193<sup>nd</sup> meeting held on 18.11.2021 at CDSCO, HQ New Delhi:**

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
<b>New Drug Division</b>			
1.	ND/MA/21/000055 Molnupiravir 200mg capsules	M/s Dr. Reddy's Laboratories Limited	<p>The firm as a part of consortium with other firms and M/s MSD, presented their proposal including data of interim analysis of clinical trial of M/s MSD and local clinical trial.</p> <p>The committee noted that MHRA, UK has granted conditional approval of the drug for treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults with a positive SARS-COV-2 diagnostic test and who have at least one risk factor for developing severe illness.</p> <p>The committee also noted that the USFDA has fixed their advisory committee meeting on EUA application of M/s MSD on 30.11.2021</p> <p>As per the inclusion criteria of M/s MSD trial, patients of mild &amp; moderate COVID-19 patients with risk factors as per the criteria in their countries were included in the trial.</p> <p>Dr. Reddy's also presented the Clinical trial data on mild COVID-19 patients conducted in India.</p> <p>After detailed deliberation, the committee recommended that the firm should submit the following for further consideration by the committee:</p> <ol style="list-style-type: none"> <li>1. Updated clinical trial data including details of patients with risk factor(s) included in the trial and their sub group analysis with respect to efficacy &amp; safety.</li> <li>2. Details of patients who were hospitalised/died (if any) including various parameters that resulted in hospitalisation along with the raw</li> </ol>

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			data.
2.	ND/MA/21/000050 Molnupiravir 200mg capsules	M/s Hetero Labs Limited	<p>The firm presented the Indian Clinical trial data on mild COVID-19 patients.</p> <p>After examination of the EUA granted by MHRA, UK for the drug and assessing the request of the firm, the committee after detailed deliberation, recommended that the firm should submit the following for further consideration by the committee:</p> <ol style="list-style-type: none"> <li>1. Updated clinical trial data including details of patients with risk factor(s) included in the trial and their sub group analysis with respect to efficacy &amp; safety.</li> <li>2. Details of patients who were hospitalised/died (if any) including various parameters that resulted in hospitalisation along with the raw data.</li> </ol>
3.	ND/MA/21/000052 Molnupiravir Capsules 200mg & 400mg	M/s Natco Pharma	<p>The firm presented the Indian Clinical trial data on mild COVID-19 patients.</p> <p>After examination of the EUA granted by MHRA, UK for the drug and assessing the request of the firm, the committee after detailed deliberation, recommended that the firm should submit the following for further consideration by the committee:</p> <ol style="list-style-type: none"> <li>1. Updated clinical trial data including details of patients with risk factor(s) included in the trial and their sub group analysis with respect to efficacy &amp; safety.</li> <li>2. Details of patients who were hospitalised/died (if any) including various parameters that resulted in hospitalisation along with the raw</li> </ol>

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4.	ND/MA/21/000044 Molnupiravir Capsules 200mg, 400mg, 800mg	M/s Optimus Pharma Pvt. Ltd.	<p>The firm presented the Indian Clinical trial data on mild COVID-19 patients.</p> <p>After examination of the EUA granted by MHRA, UK for the drug and assessing the request of the firm, the committee after detailed deliberation, recommended that the firm should submit the following for further consideration by the committee:</p> <ol style="list-style-type: none"> <li>1. Updated clinical trial data including details of patients with risk factor(s) included in the trial and their sub group analysis with respect to efficacy &amp; safety.</li> <li>2. Details of patients who were hospitalised/died (if any) including various parameters that resulted in hospitalisation along with the raw data.</li> </ol>
5.	ND/MA/21/000046 Molnupiravir Capsules 200mg, 400mg	M/s Strides Pharma Pvt. Ltd.	<p>The firm presented the Indian Clinical trial data on mild COVID-19 patients.</p> <p>After examination of the EUA granted by MHRA, UK for the drug and assessing the request of the firm, the committee after detailed deliberation, recommended that the firm should submit the following for further consideration by the committee:</p> <ol style="list-style-type: none"> <li>1. Updated clinical trial data including details of patients with risk factor(s) included in the trial and their sub group analysis with respect to efficacy &amp; safety.</li> <li>2. Details of patients who were hospitalised/died (if any) including various parameters that resulted in hospitalisation along with the raw data.</li> </ol>

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6.	ND/MA/21/000052 Molnupiravir Capsules 200mg, 400mg	M/s MSN Pharma Pvt. Ltd.	<p>The firm presented the Indian Clinical trial data on mild COVID-19 patients.</p> <p>After examination of the EUA granted by MHRA, UK for the drug and assessing the request of the firm, the committee after detailed deliberation, recommended that the firm should submit the following for further consideration by the committee:</p> <ol style="list-style-type: none"> <li>1. Updated clinical trial data including details of patients with risk factor(s) included in the trial and their sub group analysis with respect to efficacy &amp; safety.</li> <li>2. Details of patients who were hospitalised/died (if any) including various parameters that resulted in hospitalisation along with the raw data.</li> </ol>
7.	IND/MA/21/000018 Molnupiravir 200 mg & 400 mg capsule	M/s BDR Pharmaceuticals International Pvt. Ltd.	<p>The firm presented the Indian Clinical trial data on mild COVID-19 patients.</p> <p>After examination of the EUA granted by MHRA, UK for the drug and assessing the request of the firm, the committee after detailed deliberation, recommended that the firm should submit the following for further consideration by the committee:</p> <ol style="list-style-type: none"> <li>1. Updated clinical trial data including details of patients with risk factor(s) included in the trial and their sub group analysis with respect to efficacy &amp; safety.</li> <li>2. Details of patients who were hospitalised/died (if any) including various parameters that resulted in hospitalisation along with the raw data.</li> </ol>
8.	ND/MA/21/000074 Molnupiravir Capsules 200 mg	M/s Aurobindo Pharma Limited	<p>The firm presented the Indian Clinical trial data on mild COVID-19 patients.</p>

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