

**Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 218<sup>th</sup> meeting held on 05.04.2022 at CDSCO, HQ New Delhi:**

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
<b>New Drug Division</b>			
1.	ND/CT-21/20/23164  Aviptadil Injection 150 ug/10ml (FF)	M/s. Zuventus Healthcare Limited.	<p>In light of the earlier recommendation of the SEC (COVID) meeting held on 23.02.2022, the firm presented their proposal along with various supporting documents, including clinical data in the country and requested for emergency approval of Aviptadil Injection 150 µg/ml in the treatment of the Severe Covid-19 with ARDS patients before the committee.</p> <p>Considering the emergency &amp; unmet medical need in Covid-19, the Committee recommended for grant of permission to manufacture and market the Aviptadil Injection 150 µg/ml for restricted use under emergency situation in the country for treatment of Severe Covid-19 with ARDS patients subject to the following conditions:</p> <ol style="list-style-type: none"> <li>1. The drug should be sold by retail only under prescription of medical specialists.</li> <li>2. 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.</li> </ol>
2.	12-01/20-DC (Pt-340)  Quercetin	M/s. DIPAS, DRDO	<p>The firm presented their Phase I clinical trial report before the committee.</p> <p>The committee noted the results of the report as presented by the firm .</p>
3.	IND/MA/22/000004  Glactomannan 1400 mg Tablets (Prolectin M)	M/s. Murli Krishna Pvt. Ltd.	<p>The firm presented their proposal along with Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended that the firm should present supportive In-vitro data, animal data, proof of concept along with published Clinical trial data, justification for Phase III CT before the committee to take further necessary action.</p>

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4.	ND/MA/22/000013  Nirmatrelvir Tablets 150/300 mg and Ritonavir Tablets 100/100 mg	M/s. Hetero Labs	<p>The firm presented their bioequivalence study results of the Combi pack of Nirmatrelvir Tablets 300mg ( 150mg x 2) and Ritonavir Tablets IP 100mg and Phase IV clinical Trial protocol seeking approval for emergency use of the drug before the committee</p> <p>The committee noted that, drug is already approved in USA, Europe etc. under EUA</p> <p>Considering the emergency &amp; unmet medical need in Covid-19, the Committee recommended for grant of permission to manufacture and market the Combi pack of Nirmatrelvir Tablets 300mg ( 150mg x 2) and Ritonavir Tablets IP 100mg for restricted use under emergency situation in the country for treatment of adult patients COVID-19, with SpO2 &gt;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"> <li>1. The drug should be sold by retail only under prescription of medical specialists.</li> <li>2. 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.</li> <li>3. The Combi pack of Nirmatrelvir Tablets 300mg and Ritonavir Tablets IP 100mg is not authorized-               <ol style="list-style-type: none"> <li>1. For initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19.</li> <li>2. For pre-exposure or post-exposure prophylaxis for prevention of COVID-19.</li> <li>3. For use longer than 5 consecutive days</li> </ol> </li> </ol>

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			<p>The committee also recommended that, permission to conduct the Post Marketing Restricted Emergency Use clinical trial may be granted as per the protocol presented on submission of separate application for conduct of Post Marketing Restricted Use clinical trial by the firm within 3 month of approval of drug.</p>
<b>SND Division</b>			
5.	SND/IMP/22/0000003  Azelastine Hydrochloride 1mg/ml Nasal Spray	M/s. Ursa pharm India	<p>The firm presented amended protocol for Phase II with an extension Phase III clinical study for Azelastine Hydrochloride 1mg/ml Nasal Spray.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the phase II clinical study as per protocol presented.</p> <p>The firm should submit the results of phase II study before the committee.</p> <p>The firm is required to conduct phase III clinical trial with primary endpoint as “prevention of hospitalization of COVID-19 patients”. Accordingly revised Phase III protocol should be submitted to CDSCO along with results of Phase II trial.</p> <p>Dr. Shushant Meshram did not participated in deliberation.</p>
6.	SND/CT/21/000084 1. Nitazoxanide Tablet 2000mg/day  2. Inhaled ciclesonide 640mcg/day  3. Artesunate and Amodiaquine (ASAQ) Tablet (Artesunate 200 mg/day and Amodiaquine 540mg/day)  4. Ivermectin Tablet 0.4mg/kg/day  5. Paracetamol 500mg upto 2g/day	M/s Qascent Research Solutions Private Limited	<p>Inlight of the earlier recommendations of the SEC meeting dated 08.03.2022 the firm presented their justification in support of the new study arm containing Fluoxetine.</p> <p>After detailed deliberation, the committee did not recommended for inclusion of the new study arm of Fluoxetine 40mg/day + inhaled budesonide 400mcg bid for 7 days, as supporting data presented was not adequate.</p>

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7.	CT/19/22 INO-4800	M/s. Inovio	The firm didn't turn up for presentation.
8.	CT/69/21 PF- 07321332/Ritonavir	M/s. Pfizer	The firm presented Clinical Trial Protocol Amendment no-3, dated 26-Oct-2021 before the committee. After detailed deliberation the committee recommended for grant approval to the protocol amendment.