

Recommendations of the SECmeeting to examine COVID-19 related proposal under accelerated approval process made in its 186th meeting held on 01.10.2021 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drug Division			
1.	ND/CT/21/000040 RP7214	M/s JSS Medical Research	The firm presented the proposal for amendment in the protocol. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented.
2.	ND/CT/21/000079 101-PGC-005	M/s Laxai Pharmaceuticals	The firm presented the proposal for the conduct of Phase II/III clinical trial of 101-PGC-005. After detailed discussion, the committee recommended that the firm should submit information/ justification on following points- <ol style="list-style-type: none"> 1. Repeat dose toxicity study is conducted only in one species and no mutagenicity, allergenicity study is conducted. 2. Supporting documents regarding release of Dexamethasone from 101-PGC-005 only in macrophages and not in systemic circulation. 3. PK/PD data in human not presented. 4. Justification for directly proposing to conduct Phase II/ III with fixed dose of Investigational product without any dose finding study.
GCT Division			
3.	CT/58/21 Niclosamide	M/s. CBCC	The firm presented their proposal for protocol amendment before the committee. After detailed deliberation the committee recommended for approval of the proposed protocol amendment version 3.0 dated 30-JUL-2021. Other condition(s) shall remain same as mentioned in the Clinical Trial permission issued by CDSCO.
4.	CT/69/21 PF-07321332/Ritonavir	M/s. Pfizer	The firm presented the interim safety analysis data of 60 subjects (blinded sentinel cohort safety summary report with data cut off dated 09 Aug 2021) in the phase 2/3 trial protocol no. C4671005 (to comply with CT NOC condition) before the committee. After detailed deliberation, the

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			committee reviewed the data and opined to continue the trial as it was proposed.
5.	CT/99/21 Ad26.COV2.S	M/s. J&J	<p>In light of earlier SEC dated 27 Aug2021, the firm presented justification on various conditions of clinical trial permission recommended by the committee.</p> <p>After detailed deliberation, the committee reiterated the previous recommendations and recommended for grant of permission to conduct the proposed study with the following conditions:</p> <ol style="list-style-type: none"> 1) The firm should submit the interim safety data from Part I (28 days-post vaccination) of the study before the Committee and only after its review the Part II study may be initiated. 2) The firm should actively monitor the AEs including MIS-C, post vaccine dose 1 and 2 for 42 days to 3 months under the primary endpoint. 3) The firm should use only the ICMR approved kits for rapid serological test for anti-SARS-CoV-2 antibody.
6.	CT/69/21 PF 07321332/Ritonavir	M/s. Pfizer	<p>The firm presented the proposed amendment to Protocol no. C4671005, Amendment 2.0 dated 02Aug2021 before the committee.</p> <p>The committee deferred the proposal for the next SEC meeting as presentation for Protocol Amendment 2.0 and Protocol Amendment 1.0 vis-à-vis initial study protocol was required.</p>
7.	CT/92/21 Proxalutamide	M/s. IQVIA	<p>The firm presented the proposed study before the study protocol no. GT0918-US-3002 Version 1.0 dated 11-JUN-2021 before the committee.</p> <p>After detailed deliberation, the committee did not recommend the study in its presented form, due to the following:</p> <ol style="list-style-type: none"> 1) There was no in-vivo pharmacodynamic study and no proof of concept clinical study presented in support of the proposed study. 2) The IP is still under investigation for prostate cancer. 3) The result of the Phase II COVID study conducted in Brazil shows high mortality in placebo arm. However, reason was not clear

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			for the very high mortality rate in the study-placebo arm, given the fact that available COVID data do not show such high mortality.
SND Division			
8.	SND/CT/21/000084 Nitazoxanide Tablet	M/s Qascent Research	The firm has presented the Phase III clinical trial study protocol before the committee for approval. After detailed deliberation the committee recommended thatthe firm should submit the revised Phase III CT study protocol by revising the primary endpoint. Accordingly, revised protocol should be submitted for further review by the committee.