Recommendations of the SEC (Antimicrobial & Antiviral) made in its 111th meeting held on 06.04.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000051 Cy-Tb	M/s. Serum	The firm presented their proposal for manufacturing and marketing of the Cy-Tb along with the published clinical study data, conducted in other countries along with comparability data in respect of manufacturing details, analytical and release profile, product characterization stability study data etc. including drug substances, product manufactured at Serum Institute, India and Statens Serum Institute, Denmark. The firm also stated that the product will be manufactured by Serum Institute, India using the same technology as Statens Serum Institute, Denmark. ICMR has also presented the clinical study data in the Indian population along with the recommendations of the ICMR Expert Group on the study conducted with C-Tb manufactured by Statens Serum Institute, Denmark as following: 1. C-Tb has shown similar safety profile as that of PPD and is safe in Indian population at 48-72 hrs and at 28 days. 2. C-Tb has shown overall better sensitivity in General population and Household contacts/high risk population of TB patients as compared to PPD `while specificity was comparable in both groups in detecting latent TB taking IGRA as the reference standard. 3. C-Tb can be used for detection of Latent –TB under the NTEP for population 18 yrs and above. 4. More data need to be generated in less than 18 yrs of age. 5. Lack of availability of PPD necessitates use of C-Tb which is more sensitive than PPD from programmatic point of view.

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			ICMR also requested for extension of the trial on additional 400 subjects less than 18 yrs of age as per the initial approved protocol. After detailed deliberation and varying requests from ICMR & SII, the committee recommended that Serum Institute India (SII) and ICMR should deliberate the matter amongst themselves & present the combined view with regards to the application for approval of the product of SII in adult population and proposal to conduct clinical trial in additional subjects including the population less than 18 years for further consideration by the committee.
2.	12-01/18-DC (Pt-32) Delamanid	M/s. B.J. Medical College	In light of earlier recommendation dated 27.10.2021, the applicant presented the amendment in Clinical Protocol IMPAACT 2005, Version 3.0 dated 11.06.2021 along with response of queries raised by Central TB Division, before the committee. After detailed deliberation, the committee recommended for approval of the protocol amendment subject to submission of clarification on use of Delamanid in the age group more than 06 years in light of the National T.B. Guidelines and assessments of psychiatric aspects prior to enrollment of the patients as discussed in the meeting.
SND Division			
3.	SND/MA/21/000368 Pidotimod Oral Liquid 400/800mg &Pidotimod Tablets 400/800 mg	M/s. Wockhardt Ltd	The firm didn't turn up for presentation.
4.	SND/MA/21/000556 Feropenem Sodium Hydrate Extended Release Tablets 300 mg	M/s. Sun Pharma	The firm didn't turn up for presentation.
Medical device Division			
5.	IMP/MD/2021/39938 Aniospray Quick+	M/s. EcoLab	The firm didn't turn up for presentation.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Aniosyme Prime		