

Recommendations of the SEC (Radio-Daigonostic) made in its 10th meeting held on 22.09.2021 at CDSCO HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drugs Division			
1.	ND/C/FF/2020/22648 Gadoteridol FF(Phase-IV)	Ms Imaging Products	The firm presented their proposal of phase-IV clinical trial for additional indication before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase - IV clinical trial subject to condition that KFT should be done between 24-48 hours of administration of the drug.
2.	12-01/17-DC (Pt-79) GBCA Products	M/s. Bayer Pharma Pvt. Ltd., M/s. Wipro GE Pvt Ltd., M/s. Dispo Surgical Ltd, and M/s. Imaging Product Pvt Ltd	In light of earlier recommendation, dated 13.08.2020, the firm presented their justification collectively before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the of active surveillance of the drug.
3.	12-01/20-DC(Pt-415) Radionuclide therapy with 177 Lu-PSMA Abiraterone	Ms Tata Memorial Hospital	The applicant presented their proposal of academic clinical trial before the committee. After detailed deliberation, the committee recommended for grant of permission of the clinical trial with condition that the applicant should conduct an interim safety analysis when they complete the study with 10 patients in each arm and submit the interim safety report to CDSCO, DSMB, and IEC for their review for continuation of the study further,
4.	ND/IMP/21/000014 KIT for preparation of Technetium (99 Tc) SestamibiInj	KIT for preparation of Technetium (99 Tc) SestamibiInj	The firm didn't turn up for the presentation.

