Recommendations of the SEC (Pulmonary)made in its 73rdmeeting held on 08.08.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
BiologicalDivision			
1.	BIO/CT18/FF/2023/35930 Palivizumab 50mg/0.5mL & 100mg/1mL solution for injection	M/s. AstraZeneca Pharma India Limited	The firm presented their proposal for grant of permission to import and marketing of Palivizumab 50 mg/0.5 ml & 100 mg/mlsolutionfor injectionwith local clinical trial waiver under unmet medical need indicated for the prevention of serious lower respiratory tract infection (LRTI) caused by respiratory syncytial virus (RSV) in infants and young children at high risk of RSV disease. • Infants born at 35 weeks of gestation or less and less than 6 months of age at the onset of the RSV season. • Children less than 2 years of age and requiring treatment for broncho pulmonary dysplasia (BPD) within the last 6 months. • Children less than 2 years of age and with haemodynamically significant congenital heart disease (CHD) Committee noted that the drug is approved in 86 countries globally including USA, UK and Japan. After detailed deliberation, the committee recommended for grant of permission for import and marketing of Palivizumab 50 mg/0.5 ml & 100 mg/mlsolution for injection with local clinical trial waiver subject to the condition that the firm shall conduct Phase-IV study in India. Accordingly, firm should submit the protocol to conduct Phase-IV study within 3 months of approval of marketing authorization.
FDC Division			
2.	FDC/MA/22/000239 Glycopyrronium Bromide + Fluticasone Furoate+ VilanterolTrifenatate (50mcg/50mcg+100m	M/s. Glenmark Pharmaceuticals Ltd.	The proposal was deferred for next SEC meeting.

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	cg/200mcg+25mcg/25 mcg) Dry Powder for inhalation		
3.	FDC/CT/23/000039 Budesonide 80mcg USP + Formoterol Fumarate Dihydrate 4.5mcg USP Inhalation aerosol	M/s. Cipla Ltd.	The proposal was deferred for next SEC meeting.
4.	FDC/MA/23/000206 Indacaterol Maleate Eq. to Indacatero l55mcg + Glycopyrronium bromide Eq. to Glycopyrronium 25mcg inhalation powder	M/s. Lupin Ltd.	The proposal was deferred for next SEC meeting.
5.	FDC/MA/23/000201 Combo kit for Macitentan 10mg + Tadalafil 20mg Tablets	M/s. MSN laboratories Pvt. Ltd.	The proposal was deferred for next SEC meeting.
6.	FDC/MA/23/000152 Fluticasone Furoate 100mcg + Glycopyrronium Bromide eq. to Glycopyrronium 50mcg + VilanterolTrifenatate eq. to Vilanterol 25mcg Inhalation Powder	M/s. Lupin Ltd.	The proposal was deferred for next SEC meeting.
GCT Division			
7.	CT/127/22 Online Submission (34427) Tozorakimab (MED 13506)	M/s. AstraZenica	In light of earlier SEC deliberation dated 07.12.2023, 08.02.2023, 10.05.2023 & 06.06.2023,the firm presented their proposal of Phase –III clinical trial vide protocol No: D9185C00001, version 1.0, dated 15 Sep 2022 and local addendum IND-1 version: 1.01 dated 14 Oct 2022. After detailed deliberation, the committee recommended for grant of permission to conduct the trial subject to condition that DSMB shall actively & frequently

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			monitor each subject enrolled in the study for adverse events especially in non-viral groups.
8.	CT/62/22 Online Submission (23593) SAR440340/ REGN3500/ itepekimab	M/s. Sanofi	The firm presented their proposal for amendment in protocol number: EFC16750, amendment number 01, dated 20 September 2022. After detailed deliberation, the committee recommended for approval of the protocol amendment as proposed by the firm.
9.	CT/18/23 Online Submission (36387) BLU-5937	M/s. IQVIA	The proposal was deferred for next SEC meeting.
10.	CT/29/23 Online Submission (36625) Benralizumab (Medi-563)	M/s. Labcorp	The proposal was deferred for next SEC meeting.
11.	CT/131/20 Online Submission (25565) Budesonide, Glycopyrronium, and Formoterol Fumarate	M/s. AstraZeneca	The firm presented their proposal for amendment version: 4.0,21Feb 2023, for protocol number: D5982C00007. After detailed deliberation, the committee recommended for approval of theprotocol amendment as proposed by the firm.
12.	CT/77/23 Online Submission (38215) Tezepelumab	M/s. AstraZeneca	The proposal was deferred for next SEC meeting.
Medical Device Division			
13.	IMP/MD/2023/92837 Antiviral Nasal Spray (Brand Name: Viraleze™ Antiviral Nasal Spray)	M/s. Clini Experts Services Private Limited	The firm presented their proposal for grant of permission to import medical device which does not have predicate medical device before the committee. The firm informed that the proposed product (Antiviral Nasal Spray (Brand Name: Viraleze™ Antiviral Nasal Spray)) is approved in United Kingdom and presented the post market surveillance data showing that the device is marketed for more than 2 years in United Kingdom. After detailed deliberation the committee

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			recommended for grant of permission to import & marketing the said product with condition that the firm needs to conduct post marketing clinical investigation on Indian population. Accordingly, the firm should submit protocol as per requirement under Medical Devices Rules, 2017.