

Recommendations of the SEC (Pulmonary) made in its 42nd meeting held on 20.12.2019 at CDSCO HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1	12-01/18-DC (Pt-07)/PU-008 Fluticasone Furoate 100 mcg & Vilanterol Trifentate 25 mcg powder for inhalation	M/s. GSK Pharmaceuticals Ltd.	The firm didn't presented their proposal before the committee.
2	12-01/19-DC/PU-040 Powder for inhalation Fluticasone propionate 500 mcg/250mcg/100mcg and Salmeterol (as xinafoate) 50 mcg Accuhaler	M/s. GSK Pharmaceuticals Ltd.	Firm presented the proposal for update in package insert. After detailed deliberation the committee recommended for approval of the updated package insert for the indications as already approved by CDSCO.
Biological Division			
3	BIO/CT21/BD/2019/168 66 Omalizumab	M/s Reliance Life Sciences Pvt. Ltd	The firm presented their proposal for manufacture and marketing of drug along with the results of Phase III Clinical Trial. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the drug subject to condition that the firm should conduct a Phase IV clinical trial as per the guidelines and protocol for the Phase IV Clinical Trial should be submitted within 3 months of the approval of the drug. Dr. Sushant H. Meshram did not participate in the deliberation.
SND Division			
4	SND/MA/19/000133 Pirfenidone Tablets 267 mg and 801 mg	M/s MSN Laboratories	The firm presented the proposal along with BE study report of Pirfenidone tablets 801mg. Committee noted that the target therapeutic dose is 2400mg/day which can be achieved after dose titration till 3 rd week either by 3X 200mg tablets four times daily or 3X 267mg tablets three times daily. 801mg tablets also has similar justification. IPF is a life threatening rare disorder with very limited therapy. 267mg and 801mg tablets are already marketed in US, EU etc. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed

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			Pirfenidone tablets 267mg and 801mg.
5	12-142/2009-DC (Pt-II) Dextromethorphan Hydrobromide Extended Release suspension 30mg/5ml	M/s Rubicon	The firm didn't turn up for the presentation
6	SND/MA/19/000003 Pirfenidone Tablets 600mg (Additional strength)	M/s Cipla Ltd.	The firm presented the proposal along with results of BE study of Pirfenidone tablets 600mg. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Pirfenidone tablets 600mg.
7	SND/CT/19/000054 Tiotropium Bromide Inhalation Solution 5mcg/10mcg/20mcg	M/s. Glenmark Pharmaceutical Ltd.	The firm presented their proposal for comparative Bioavailability study. After detailed deliberation, committee recommended for grant of permission to conduct the study.
FDC Division			
8	FDC/MA/19/0000149 FDC of Glycopyrronium +Arformoterol tartrate (25mcg+15mcg) Isotonic Solution	M/s. Glenmark Pharmaceuticals Ltd.	The firm presented their proposal for Clinical Trial study. After detailed deliberation, committee recommended for grant of permission to conduct the study subject to the following conditions: 1. Intraocular tension should be monitored at the initial as well as at the end of the study. 2. In case of male patients aged more than 60, USG for BPH should be done at baseline and at the end of the study. 3. The nebulizers and the related accessories should be uniform in all the study sites.
9	FDSC/IMP/19/000049 Fluticasone Furoate 92mcg+Umeclidinium 55mcg+Vilanterol trifenate 22mcg Powder for Inhalation	M/s.GlaxoSmith Klein Pharmaceuticals	The firm presented their proposal alongwith the data of safety and efficacy from other countries for Import and Marketing of the drug with local clinical trial waiver. The drug is approved in many countries including US, EU, etc. Committee after detailed deliberation recommended that the firm should submit the following information for further consideration. 1. Subset analysis of safety data w.r.t to Pneumonia and cardiac adverse effect. 2. Analysis of PMS data generated so

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			far in countries where the drug is being marketed. 3. Subset analysis of data generated from Asian Region.
10	FDC/MA/19/000126 Bilastine 20 mg Montelukast Sodium IP equivalent to Montelukast 10 mg uncoated tablet	M/s. Exemed Pharmaceuticals	The firm presented their proposal for conducting BE study and Clinical Trial. After detailed deliberation, committee recommended for grant of permission to conduct the BE study and the Clinical Trial.
11	FDC/MA/19/000108 Glycopyrronium + Formoterol	M/s. Glenmark Pharmaceuticals Ltd.	The firm presented their proposal for comparative Bioavailability study. After detailed deliberation, committee recommended for grant of permission to conduct the study.
Medical Device Division			
12	CI/MD/2019/12188 ResPAP™ Kit	M/s Biodesign Innovation Labs Private Limited	The firm presented their proposal to conduct pilot clinical investigation. The committee recommended that firm should submit the details of pre-clinical data on performance of the device and comparative evaluation with available Bubble CPAP devices. The proposed clinical investigation should be a comparative efficacy study with available Bubble CPAP devices.