

Recommendations of the SEC (Pulmonary) made in its 64th meeting held on 04.11.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/22/000027 Icatibant Injection 30mg/3ml (10mg/ml)	M/s. MSN Laboratories Ltd.	<p>In light of earlier SEC recommendations dated 29.03.2022 and 29.09.2022, the firm presented the raw data of the in-vitro comparative evaluation report of test drug vs innovator drug products before the committee.</p> <p>The committee noted that the drug is already approved in the countries like USA, Europe, Canada and Australia and drug is designated as orphan drug & indicated for rare and life threatening condition and there is an unmet medical need in the country.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market of the drug for the proposed indication subject to condition that the firm should conduct Phase IV clinical trial for which protocol should be submitted within 3 months of approval of the drug for review by the committee.</p> <p>The drug should be sold by retail under the prescription of the designated medical specialist only.</p>
Biological Division			
2.	BIO/CT/19/000014 Mepolizumab 100 mg	M/s. GSK Pharmaceuticals Ltd.	<p>The firm presented the proposal for amendment of protocol for conduct of Phase IV study of Mepolizumab Powder for Solution for Injection 100mg.</p> <p>After detailed deliberation, the committee recommended for grant of approval for amendment in the Phase IV study protocol No. 209682, amendment no. 04 dated 23 Aug 2022 as presented by the firm in line with Prescribing Information of the product.</p>
3.	BIO/CT18/FF/2022/ 32804 Tezepelumab solution for injection	M/s Astrazeneca Pharma India Ltd	<p>The firm presented the proposal for import & marketing of the drug Tezepelumab Solution for Injection (210 mg) intended for subcutaneous administration with local Phase III</p>

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			<p>clinical trial waiver for the indication as an add-on maintenance treatment in patients with severe asthma aged 12 years and older.</p> <p>The committee noted that the drug is approved in USA, Switzerland, Brazil, Canada, EU, Japan & UK as presented by the firm.</p> <p>The committee also noted that there was no clinical trial data in Indian population.</p> <p>After detailed deliberation, the committee recommended that the firm should conduct Phase III study in India initially in adult patients for consideration of the proposed indication in adult patients. Subsequently study may be planned in adolescents population. Accordingly the firm should submit Phase III protocol for further review.</p>
4.	BIO/IMP/21/000110 Mepolizumab 100 mg	M/s. GSK Pharmaceuticals Ltd.	<p>The firm presented the proposal for amendment in warning statement from “To be sold by retail on the prescription of a Registered Pulmonologist only” to “To be sold by retail on the prescription of a Registered Medical Specialists”.</p> <p>After detailed deliberation, the committee recommended for amendment in warning statement as “To be used on prescription of Registered Medical Specialists experienced in treating the diseases for which drug is approved”.</p> <p>Accordingly, the firm should submit the revised label and package insert to CDSCO.</p>
FDC Division			
5.	FDC/MA/20/000043 Blisatine 10 mg + Montelukast 4mg orodispersible tablets	M/s. Synokem Pharmaceuticals Ltd.	The firm didn't turn up for presentation.
6.	FDC/MA/22/000203 Levosalbutamol Sulphate IP eq. to Levosalbutamol 0.25mg + Ambroxol Hydrochloride IP	M/s. Akums	<p>The firm presented their proposal along with request for Phase III CT study waiver.</p> <p>After detailed deliberation, the committee noted that the indication is proposed for pediatrics population.</p> <p>Therefore, the committee opined that</p>

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	7.5mg + Guaiphenesin IP 12.5mg Oral drops		proposal may defer and deliberated in presence of pediatrician in next meeting for expert opinion.
7.	FDC/MA/22/000280 Budesonide 200mcg + Glycopyrronium 12.5mcg+Formoterol Fumarate Dihydrate 6mcg Aerosol for inhalation	M/s. Cipla Ltd.	The firm presented their proposal along with justification for Phase III CT study waiver. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC with condition to conduct Phase IV CT study. The protocol should be submitted to CDSCO within 03 months and should be presented before the committee for review.
8.	FDC/MA/22/000297 Vilanterol trifenate eq. to Vilanterol 12.5mg + Glycopyrrolate IP eq. to Glycopyrronium 25mcg meterd dose inhalation	M/s. Zydus Healthcare Ltd.	The firm presented their proposal along with Phase III CT study protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III CT study with the condition that inhalation toxicity study should be conducted before initiating the clinical trail study.
GCT Division			
9.	CT/93/22 Online Submission (33643) LYT-100	M/s. Novotech	The firm presented Phase IIb clinical trial protocol no. LYT-100-2022-204 before the committee. After detailed deliberation the committee recommended for grant permission to conduct the study.
Medical Device Division			
10.	IMP/MD/2022/59761 Nasal Spray-Bentrio	M/s. Wellesta Healthcare Private Limited	The firm presented their proposal for grant of permission to import for sale or for distribution of the medical device before the committee. After detailed deliberation, the committee observed that the product (Nasal Spray-Bentrio) consist various constituents like Bentonite, Mannitol etc. The firm needs to submit the evidence & proof with supporting documents to claim that all the constituents are inert & biologically inactive in nature as the firm has claimed that the proposed product is a medical device in other countries.

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			Further, the firm should carry out a clinical Investigation with the proposed product on Indian population & accordingly need to submit the clinical investigation protocol for review by SEC.
GCT Division			
11.	CT/168/21 Online Submission (21361) Fluticasone propionate inhalation aerosol USP 44 mcg	M/s. Glenmark	The firm presented protocol amendment to a clinical endpoint bioequivalence study for protocol no. GLK-2101 version 4.0 dated 13 Oct 2022 before the committee. After detailed deliberation the committee recommended for grant of approval for amendment as presented by the firm.