Recommendations of the SEC (Pulmonary) made in its 58th meeting held on 29.03.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-01/18-DC (Pt-337) Surfactant & Pulmonary Hemorrhage	SRP-NCC-PvPI, IPC, Ghaziabad	The SRP recommendation was deliberated before the committee. After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controllers to direct the manufactures of the drug to include Surfactant induced pulmonary hemorrhage as adverse drug reaction to the corresponding PIL of the drug.
2.	12-01/21-DC (Pt - 340) Dried Ivy Leaf Extract Cough Syrup	M/s. USV	In light of earlier SEC recommendation dated 25.02.2022, the firm presented their proposal of switching Dried Ivy Leaf Extract Cough Syrup from prescription to non prescription drug before the committee. During the presentation the committee noted that the product contains saponins and also the product is marketed in other countries. After detailed deliberation, the committee recommended that the firm should submit the details of concentration of saponins in the product and also the details of countries in which the product is marketed along with the package insert and regulatory status. Accordingly, the firm should submit the required details to CDSCO for further review by the committee.
3.	ND/MA/22/000027 Icatibant Injection 30mg/3ml (10mg/ml)	M/s.MSN	In light of earlier SEC recommendation dated 08.03.2022, the firm presented their proposal along with justification for local clinical trial waiver before the committee. The committee noted that the drug is already approved in the countries like USA, Europe, Canada and Australia and also drug is designated as orphan drug & indicated for rare and life threatening condition and there is an unmet medical need in the country. After detailed deliberation, the committee

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			recommended for grant of permission to manufacture and market of the drug subject to condition that firm should conduct Phase IV clinical trial for which protocol should be submitted to CDSCO within 3 months of approval of the drug. Further, the committee opined that opinion from expert in Internal medicine may be considered.
Biological Division			
4.	BIO/CT04/FF/2021/25522 Omalizumab 150mg/ml Pre-filled syringe	M/s. Synchron Research Services Pvt. Ltd	The firm presented the clinical safety report for already conducted PK-PD study along with proposal to conduct pivotal Phase I (PK-PD) study in healthy subjects. After detailed deliberation, the committee recommended for grant of permission to conduct the study and also accepted the proposal to change the CRO from Syncrhon to Veeda subject to the condition that firm should constitute an independent DSMB for trial monitoring. Further, the results of the study should be submitted to CDSCO for review. Accordingly, the firm should submit revised protocol to CDSCO for further consideration.
5.	BIO/CT04/FF/2021/26620 Omalizumab vial	M/s. Veeda Clinical Research Limited	The firm presented the proposal to conduct Phase I (PK-PD) study in healthy subjects. After detailed deliberation, the committee recommended for grant of permission to conduct the study subject to the condition that the firm should constitute an independent DSMB for trial monitoring and also the results of the study should be submitted to CDSCO for review. Accordingly, the firm should submit revised protocol to CDSCO for further consideration.
SND Division			
6.	SND/MA/21/000529 Glycopyrronium Pressurised Inhalation	M/s. Glenmark Pharma	In light of earlier SEC recommendation dated 07.12.2021, the firm presented the proposal of BE study of Glycopyrronium Pressurized Inhalation 35mcg with

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	35 mcg per actuation		justification and supportive R&D data for selection of proposed dose of 70 mcg of the proposed drug product. After detailed deliberation, the committee recommended for grant of permission to conduct said BE study of Glycopyrronium Pressurized Inhalation 35mcg as per the protocol submitted by the firm.