

Recommendations of the SEC (Radio-diagnostic) made in its 12th meeting held on 29.12.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/IMP/21/000014 Kit for the Preparation of Technetium (99mTc) Sestamibi Injection 1 mg	M/s. IBA Molecular Imaging	The firm did not turn up for presentation.
2.	ND/MA/22/000117 Insoluble Prussian Blue capsule 340mg	M/s. Scott Edil Pharmacia Ltd.	<p>In light of earlier SEC recommendation dated 09.11.2022, the firm presented justification for waiver of Phase III clinical trial and BE study before the committee.</p> <p>The committee noted that the drug is already approved in other countries like USA on 2003 and the drug is designated as an 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 the drug Insoluble Prussian Blue Capsule 340 mg for the proposed indication with clinical trial and BE study waiver in the country subject to condition that the drug should be sold by retail under the prescription of the designated medical specialist only.</p>
3.	ND/MA/22/000121 Insoluble Prussian Blue 340mg and Magnesium Hydroxide 500mg capsule	M/s. Scott Edil Pharmacia Ltd.	<p>In light of earlier SEC recommendation dated 09.11.2022, the firm presented justification for waiver of Phase III clinical trial and BE study before the committee.</p> <p>The committee noted that the drug is already approved in other countries like USA on 2003 and the drug is designated as an 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 the drug</p>

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			Insoluble Prussian Blue 340mg and Magnesium Hydroxide 500mg capsule for the proposed indication with clinical trial and BE study waiver in the country subject to condition that the drug should be sold by retail under the prescription of the designated medical specialist only.
SND Division			
4.	SND/MA/22/000303 Ethiodized oil (Iodine Combined with ethyl esters of fatty acids of poppy seed oil) solution for injection 480mg l/mL	M/s. Biophore India Pharmaceuticals	<p>29.12.2022 (Biophore)</p> <p>The firm presented their proposal for manufacture and marketing of the drug product Ethiodized Oil (Iodine combined with ethyl esters of fatty acids of poppy seed oil) Solution for Injection 480.00mgI/ml for the following indication before the committee:</p> <p>“Used in Diagnostic Radiology, Lymphography and Diagnosis of liver lesions (Diagnosis of the spread of malignant lesions, whether hepatic or not, by selective hepatic arterial injection). In Interventional Radiology: Embolization with surgical glues (In association with surgical glues during vascular embolizations). In Endocrinology: Prevention of iodine deficiency disorders (This treatment should only be used when other methods of supplementation, particularly iodization of salt and/or drinking water, cannot be undertaken) Hysterosalpingography (HSG)”.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing the product subject to condition that the firm should conduct PMS study with additional indication and submit the PMS safety data.</p>