File No. 4-01/2024-DC (Misc. 08)
Govt. of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 16 APR 2024

NOTICE

Subject: Manufacturing and marketing of unapproved drug Meropenem 1gm + EDTA for Injection-regarding.

It has been brought to notice of this Directorate that some manufacturers are involved in manufacturing/marketing of **Meropenem 1gm + EDTA for Injection** which is not yet approved by this office for manufacturing/marketing in the country and falls under the category of "New Drug".

No new drug shall be manufactured for sale unless it is approved by the Licensing Authority as defined in Rule 3 of New Drugs and Clinical Trial Rules, 2019. Further, as per Rule 80 of New Drugs & Clinical Trials Rules 2019, a person who intends to manufacture new drug in the form of API or Pharmaceutical formulation, as the case may be for sale or distribution, shall make an application for grant of permission to the Central Licensing Authority in Form CT-21 alongwith a fee as specified in Sixth Schedule.

This information is for all the concerned stakeholders.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

To:-

All State/UT Drugs Controllers/All Zonal/Sub Zonal offices of CDSCO.

Copy to:-

1. PPS to Secretary/AS(F&D)/JS(R), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
2. Indian Drug &Pharmaceuticals Associations
3. All Indian Origin Chemists & Distributors Ltd.(AIOCD), 6th Floor, Corporate Park, V.N. Purav Mar, Chembur, Mumbai – 400071]
4. Website of CDSCO.