

NIL

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

Tele. No. : 011-23236965
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FDA Bhawan, Kotla Road
New Delhi-110002

Dated:

To,
All State/UT Drugs Controllers

08 MAR 2024

Subject: Manufacturing and marketing of unapproved drug Meropenem & Disodium EDTA for Injection -regarding.

Sir,


It has been brought to notice of this Directorate that some manufacturers are involved in manufacturing/marketing of unapproved drugs 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.

In view of the above, you are hereby directed to convey the matter to all the manufacturer under your jurisdiction and cancel the product permission granted by you of subject drug.

The necessary information about the status and action taken in the matter may please be intimated to this Directorate at the earliest.

Yours sincerely,


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

Copy of information and necessary action to:-

1. All Zonal/Sub Zonal Offices of CDSCO
2. Indian Drug/Pharmaceuticals Association Forum
3. Website of CDSCO