## Centre takes state power of issuing NOC for drug export

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**NEW DELHI:** The Union government has become the sole authority for issuing manufacturing licences for new drugs meant for exports, withdrawing the power from state governments amid heightened global scrutiny of Indian made drugs.

The sole licencing authority from now on will be the Central Drugs Standard Control Organisation (CDSCO), India's apex drug regulatory body.

In an order issued by Drug Controller General India Dr Rajeev Raghuvanshi on April 30, a copy of which has been seen by Mint, the CDSCO has asked the industry to submit fresh online applications for no objection certificates (NOCs) from May 15 onwards.

State drug controllers were given complete jurisdiction to issue NOC certificates from 2018.

"Now it has been decided with the approval of the honourable health and family welfare minister that industry must be facilitated to file fresh applications for NOC for manufacture of unapproved/approved new drug/



The CDSCO told the industry to submit fresh applications for NOCs from May 15 onwards. AFP

banned drugs solely for export purpose from May 15 2024 on online mode through CDSCO zonal offices," the order stated.

NOCs are to be granted by the head of CDSCO zonal offices from May 15.

"Accordingly, power delegated to state/UT Licensing authority stands withdrawn with effect from May 15, 2024 and such NOCs shall be granted by the Head of respective CDSCO Zonal office with effect from May 15," it added.

Manufacturers will need to obtain the NOC from the respective zonal office of the CDSCO.

"Further all state/UT drugs Controllers are required to handover all NOC's issued from August 20, 2018 to May 14, 2024 to respective Zonal offices of CDSCO. All manufacturers may be informed that they are required to obtain NOC from respective zonal offices of CDSCO through online mode (SUGAM) w.e.f May 15 before issuing manufacturing licence from SLA for manufacture of unapproved/banned/ new drugs for export purpose," it stated.

For handling the change, Ranga Chandrashekhar Rao, Joint Drugs Controller, will be the nodal and designated point person at the CDSCO.

In 2018, the CDSCO had waived the provision of procuring NOC by pharmaceutical companies for exporting drugs, medical devices and cosmetics across ports in the country for ensuring ease of doing business.

Before 2018, licenced manufacturers of drugs and medical devices could export them only to the US, Canada, Japan, Australia and the European Union.