

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

Order

File No. DC-DT-15011(11)/85/2024

Date 07 AUG 2024

Subject: Specifying names of countries under the Rule 101 of New Drugs and Clinical Trial Rules, 2019 related to new drug approval – Regarding

As per Rule 101 of New Drugs and Clinical Trials Rules, 2019 the Central Licensing Authority, with the approval of the Central Government, may specify, by an order, the name of the countries, from time to time, for considering waiver of local clinical trial for approval of new drugs under Chapter X and for grant of permission for conduct of clinical trial under Chapter V of the said rules.

In exercise of the powers conferred under Rule 101 of the said rules with the approval of the Central Government, the countries namely; **USA, UK, Japan, Australia, Canada and EU** are hereby specified for following categories of new drugs:-

- Orphan Drugs for rare diseases
- Gene and cellular therapy products
- New drugs used in pandemic situation
- New drugs used for special defense purpose
- New Drugs having significant therapeutic advance over the current standard care.


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

To,

1. CDSCO Website

CC to:

1. PS to Adviser Cost, MoHFW, Nirman Bhawan, New Delhi