F. No. 14-34/2019-DC
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
Legal Cell

FDA Bhawan, Kotla Road
Near ITO, New Delhi-110002

Dak 09-12-2024

CIRCULAR

Subject: Judgment dated 04.10.2024 passed in Writ Petition (C) No. 5315 of 2020 titled as Arnesh Shaw Vs. Union of India & Anr.and connected mattersof Hon'ble High Court of Delhi- regarding.

In compliance of the directions issued vide Judgment dated 04.10.2024 passed in Writ Petition (C) No. 5315 of 2020 titled as Arnesh Shaw Vs. Union of India & Anr and connected matters by the Hon'ble High Court of Delhi and as per Rule 101 of the New Drugs & Clinical Trial Rules, 2019 and Rule 63 of Medical Device Rules, 2017:

1. All State and UT Drugs Controllers are requested to monitor compliance with the directions regarding the timeline for the approval of all applications for rare disease drugs and devices (Class A& B), which should be processed within 90 days from the date of receiving.
2. All divisional head of the CDSCO are directed to monitor compliance of the directions in respect of timeline for approvals of application within 90 days from the date of receiving for rare disease drugs and devices (Class C & D).
3. All the concerned division's Heads of CDSCO are also requested to monitor andproactively keep a watch on Global Clinical Trial and Local Clinical Trials for rare diseases and to process such files expeditiously.
4. That, whenever any clinical trial for rare diseases, whether global or local, comes to attention or consideration, a fast track approval process shall be adopted in the approval process, including any post-approval changes in the application like increase in number of subjects to facilitate early enrolment of subject in the trial. Further, all import of rare drugs may also be facilitated in interest of patients.
5. That the expeditious disposal in issuance of Registration Certificate (RC) & Import of rare disease drugs and the sample of rare disease drugs should be tested with priority at Govt. laboratories for in the interest of patient.
6. That under the New Drugs and Clinical Trials Rules, 2019 and Medical Device Rules, 2017 provisions already exists under Chapter X for considering a waiver of local clinical trials for the approval of new drugs & medical device's respectively, including those intended for rare diseases & for Medical Device. This provision may be considered for rare diseases drugs and devices.

This is for kind information and compliance.

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

To,

1. All State/UT Drugs Controllers
2. Zonal/ Sub zonal office of CDSCO
3. All port offices/ Laboratories.
4. All divisions of CDSCO (HQ), New Delhi
5. Guard file