

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
UNSTARRED QUESTION NO. 4622
TO BE ANSWERED ON 20TH MARCH, 2026**

VACANCIES AND FUNCTIONING OF DRUG REGULATORY AUTHORITIES

4622. SHRI LAXMIKANT PAPPU NISHAD:

SHRI KALI CHARAN SINGH:

Will the **Minister of HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether the posts of Drug Controller in the Central and State Drug Regulatory Authorities have remained vacant for long periods, despite overseeing numerous drug manufacturing units, medical device firms, blood banks and thousands of pharmacies, if so, the details thereof;
- (b) the reasons for the Government's failure to appoint regular Drug Controllers and Joint Directors in a time-bound manner;
- (c) whether key statutory functions under the Drugs and Cosmetics Act, the Drugs and Magic Remedies Act, Drugs (Prices Control) Order, the Medical Devices Rules and the Cosmetics Rules are being handled on an ad-hoc or additional charge basis, if so, the details thereof;
- (d) whether key regulatory functions, including the grant of manufacturing licenses, product approvals, price monitoring, inspections and enforcement actions, are presently being handled on an ad-hoc or additional charge basis, if so, the details thereof;
- (e) the number of sanctioned and vacant posts of Assistant Directors, Joint Directors, and Drug Inspectors along with the number of product approvals, license renewals and other proposals currently pending, along with the average delay in disposal; and
- (f) the corrective steps taken by the Government to ensure transparent governance and strengthen regulatory oversight along with the timelines by which the Government proposes to appoint regular Drug Controllers and restore full regulatory capacity?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY
WELFARE
(SMT. ANUPRIYA PATEL)**

(a) to (f): As per Drug Rules 1945, the Central Licence Approving Authority means the Drugs Controller, India or the Joint Drugs Controller (India) or the Deputy Drugs Controller (India) appointed by the Central Government. Similarly, as per the provisions of the Medical Device Rules 2017, the New Drugs and Clinical Trial Rules 2019 and the Cosmetics Rule

2020, the Central Licencing Authority means the Drugs Controller, India. In the State government, the licensing authority is notified by respective State/UT as per the Drugs and Cosmetics Act, 1940. All the permissions/no objections certificates/licences/marketing authorizations under the said rules are issued by the licensing authorities as specified in the Rules.

Filling up of post of State Drugs Regulatory Authorities is undertaken by respective State/Union Territories. In so far, as Central Drugs Standard Control Organisation (CDSCO) is concerned, there are no posts of Assistant Directors & Joint Directors in CDSCO. However, the details of sanctioned, filled and vacant post of Deputy Drugs Controller, Assistant Drugs Controller and Drugs Inspectors are as under:

No. of post	Deputy Drugs Controller	Assistant Drugs Controller	Drugs Inspectors
Sanctioned	50	127	504
Filled	39	80	255
Vacant	11	47	249

Recruitment/filling up of various posts in CDSCO is done following due recruitment procedures.

Permissions/approvals for drugs are granted by CDSCO as per Drugs & Cosmetics Act, 1940 and Rules framed thereunder. Various approvals/ permissions issued by CDSCO are updated on its website. Procedures for processing of various applications received in CDSCO are provided under the provisions of the Drugs & Cosmetics Act, 1940 and Rules. The concerned Rules/office orders are available on the CDSCO website. The links are: (<https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/>).

The number of applications received by the CDSCO, the number of applications approved along with the number of applications under process in CDSCO during the last three years is provided below:

Calendar Year	No. of applications received	No. of applications approved	No. of applications under process in CDSCO
2023	791	366	59
2024	629	237	95
2025	696	95	221

*Certain applications have been withdrawn, rejected or are with the applicants for response.

Monitoring of prices of drugs in the country and Drugs (Prices Control) Order (DPCO) is carried out by the National Pharmaceutical Pricing Authority (NPPA) under Department of Pharmaceuticals.
