

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

**LOK SABHA
UNSTARRED QUESTION NO. 938
TO BE ANSWERED ON 08TH DECEMBER, 2023**

TIMELINE FOR PROCESSING OF APPLICATION BY CDSCO

938: SHRI KOMATI REDDY VENKAT REDDY:

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

- (a) whether the Government has set any target timeline regarding processing and disposal of pending application at Central Drug Standard Control Organization (CDSCO) and if so, the details thereof;
- (b) whether due to delays in the approval processes, unnecessary queries, non-availability of updated information, etc., Indian companies that manufacture medicines/products are facing difficulties and are unable to export the same on time thereby losing marketing opportunities and revenue generation opportunities;
- (c) whether it is a fact that a number of companies are facing losses and closure due to aforementioned conditions/circumstances and if so, the details thereof along with corrective steps taken/proposed to be taken in this regard;
- (d) the number of applications received and processed by CDSCO HQ/Zonal Offices since 1970 along with the stakeholders invited to seek opinions/ clarifications on up-to-date regulatory requirements along with necessary steps taken in this regard;
- (e) whether CDSCO/Drugs Controller General of India (DCGI) have framed timelines and interacted with stakeholders to resolve issues related to various applications and if so, the details thereof; and
- (f) whether CDSCO/DCGI have been updating information in the public domain/website related to approvals, applications, meetings, Minutes of the Meetings, etc. and if so, the details thereof?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)**

(a): Procedures for processing of various applications received in CDSCO are provided under the provisions of the Drugs & Cosmetics Act, 1940 and Rules framed. The concerned Rules/office orders are available on the CDSCO website. The links are:

[\(https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/\)](https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/)

[\(https://cdsco.gov.in/opencms/opencms/en/Notifications/Circulars/\)](https://cdsco.gov.in/opencms/opencms/en/Notifications/Circulars/) Accordingly, applications are dealt under the provision of the said Act and Rules.

(b) & (c): Permissions/approvals for drugs are granted by CDSCO as per Drugs & Cosmetics Act, 1940 and Rules framed based on each case.

(d): The details of various drugs/ medicine products including vaccine/ r-DNA products etc. approved by CDSCO are available on CDSCO website.

(e): Procedures for processing of various applications received in CDSCO are provided under the provisions of the Drugs & Cosmetics Act, 1940 and Rules. CDSCO and its offices have consultations with stakeholders to resolve their issues.

(f): Various approvals/ Circulars/ Office-orders/ Minutes of various meeting like Minutes of Subject Expert Committee (SEC)/ Drug Consultative Committee (DCC)/ Drug Technical Advisory Board (DTAB) are uploaded on CDSCO website. The links of website are - [\(https://cdsco.gov.in/opencms/opencms/en/Notifications/Circulars/\)](https://cdsco.gov.in/opencms/opencms/en/Notifications/Circulars/)

[\(https://cdsco.gov.in/opencms/opencms/en/Committees/\)](https://cdsco.gov.in/opencms/opencms/en/Committees/)
