

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

**LOK SABHA
UNSTARRED QUESTION NO. 930
TO BE ANSWERED ON 08TH DECEMBER, 2023**

CENTRAL DRUGS STANDARDS CONTROL ORGANISATION (CDSCO)

930: SHRI KANUMURU RAGHU RAMA KRISHNA RAJU:

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

- (a) whether the Government has any details of processing applications received by Central Drugs Standards Control Organisation (CDSCO) HQ/Zonal Offices since 1970 along with inviting stakeholders to seek opinion and to give clarifications on up-to-date regulatory requirements and if so, the details thereof;
- (b) whether CDSCO/DCGI have framed fixed timelines and interacted with stakeholders and resolved issues related to various applications and if so, the details thereof;
- (c) whether CDSCO/DCGI have updated information in the public domain/website related to approvals, applications, meetings, Minutes of the Meetings, etc. from time to time and if so, the details thereof;
- (d) whether it is a fact that due to delays in the approval processes, unnecessary queries, non-availability of updated information, etc., Indian companies that manufacture medicines/products are facing lot of difficulties and are unable to export the same on time thereby losing marketing opportunities and revenue generation; and
- (e) whether it is a fact that a number of companies are facing losses and closure and if so, the details thereof along with corrective steps taken/proposed to be taken till now?

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

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

[\(https://cdsco.gov.in/opencms/opencms/en/Notifications/Circulars/\)](https://cdsco.gov.in/opencms/opencms/en/Notifications/Circulars/) CDSCO and its offices have consultations with stakeholders to resolve their issues.

(c): 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/)

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