INFORMATION PUBLISHED IN PURSUANCE OF SECTION 4(1) (b) OF THE RIGHT TO INFORMATION ACT, 2005

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THE DETAIL INFORMATION ALONGWINTH THE URL LINK IN PURSUANCE OF SECTION 4(1) (B) OF THE RIGHT TO INFORMATION ACT, 2005 IS PROVIDED AS BELOW:

01	**Particulars of the organization, its functions and duties:** The Central Drugs Standard Control Organisation (CDSCO)under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is the National Regulatory Authority (NRA) of India. Its headquarter is located at FDA Bhawan, Kotla Road, New Delhi 110002. CDSCO is the Central Drug Authority for discharging functions assigned to the Central Government under the Drugs and Cosmetics Act. CDSCO has zonal offices, sub-zonal offices, port offices and laboratories under its control. Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organizations by providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics act. Further CDSCO along with state regulators, is jointly responsible for grant of licenses of certain specialized categories of critical Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera. Other information on Name and address of the Organization, Head of the organization, Vision, Mission and Key objectives, Function and duties, Organization Chart, any other details etc are as following link: https://cdsco.gov.in/opencms/opencms/en/About-us/contact-us/ https://cdsco.gov.in/opencms/opencms/en/About-us/who/ https://cdsco.gov.in/opencms/opencms/en/About-us/Vision/ https://cdsco.gov.in/opencms/opencms/en/About-us/Values/ https://cdsco.gov.in/opencms/opencms/en/About-us/Functions/ https://cdsco.gov.in/opencms/opencms/en/About-us/Introduction/ https://cdsco.gov.in/opencms/opencms/en/Notifications/Circulars/ https://cdsco.gov.in/opencms/opencms/en/Achievements/
02	**Power and duties of its officers and employees:** For regulation of drugs, cosmetic, medical device are as per Drugs and Cosmetics

	Act, 1940 & Rules there under viz. (1) Medical Device Rules, 2017 (2) New Drugs & Clinical Trials Rules, 2019 (3) The Cosmetic Rules, 2020 (4) Pharmacopoeia like IP, USP, BP/EP including notifications, notice & circulars available on public domain https://cdsco.gov.in/opencms/opencms/en/Home Drawing & Disbursing Officer (DDO) for budget & purchase as available on; (5) https://pfms.nic.in/NewDefaultHome.aspx (Public Finance management System, Ministry of Finance, Government of India (6)https://gem.gov.in/ (GeM for purchase) (7) http://iconnect.cdscoonline.gov.in/iConnect/ in administrative matters, and the CCS (Conduct) Rules, 1964, Department of Personnel & Training https://dopt.gov.in/ccs-conduct-rules-1964 For Administrative power and duties of other employees like administrative Staff (Group B & C) are performing their duties as per job description. Drugs Controller General of India (DCG(I)) is the Head of the organization and the work allocation is done by him in technical and administrative matters as per order which is available under https://cdsco.gov.in/opencms/opencms/en/Notifications/Circulars/
03	**Procedure followed in the decision making process, including channels of supervision and accountability:** DCG(I) as organizational head is responsible for work allocation to JDC(I), DDC(I), ADC (I) & other employees i.e. DIs, ADIs etc,. DCG(I) is also responsible for administrative work through Director(Drugs)/ Dy. Director Admin (Drugs). Regulatory and Statutory process is governed as per Drugs and Cosmetics Act, 1940 & Rules there under *viz.* (1) Medical Device Rules, 2017 (2) New Drugs & Clinical Trials Rules, 2019,(3) The Cosmetic Rules,2020 (4) Pharmacopoeia like IP, USP, BP/EP and related guidelines and notifications, notices & circulars available on public domainhttps://cdsco.gov.in/opencms/opencms/en/Home https://cdscomdonline.gov.in/NewMedDev/Homepage & https://cdscoonline.gov.in/CDSCO/homepage and for technical matters under supervision of DDC(I), JDC(I) and under direction of DCG(I) as organization head. Drawing & Disbursing Officer (DDO) for budget & purchase as per as available on

	public domain; (5) https://pfms.nic.in/NewDefaultHome.aspx (Public Finance management System, Ministry of Finance, Government of India) (6)https://gem.gov.in/ (GeM for purchase) (7)http://iconnect.cdscoonline.gov.in/iConnect/ in administrative matters, and the CCS (Conduct) Rules, 1964, Department of Personnel & Training https://dopt.gov.in/ccs-conduct-rules-1964 (8) https://bhavishya.nic.in/ for pensioners i.e. settlement of pensionary benefit of pensioners. Time limit for taking decisions are in accordance to said Act & Rules and guidelines which is available on public domain https://cdsco.gov.in/opencms/opencms/en/Home, https://cdscomdonline.gov.in/NewMedDev/Homepage & https://cdscoonline.gov.in/CDSCO/homepage as notifications, public notices & circulars.
04	**Norms set by it for the discharge of its functions:** Norms/standards for functions/ service delivery for Regulatory & Statutory process are as per Drugs and Cosmetics Act, 1940 & Rules there under viz. (1) Medical Device Rules, 2017 (2) New Drugs & Clinical Trials Rules, 2019, (3) The Cosmetic Rules, 2020 (4) Pharmacopoeia like IP, USP, BP/EP and notifications, notices & circulars available on public domain https://cdsco.gov.in/opencms/opencms/en/Home, https://cdscomdonline.gov.in/NewMedDev/Homepage https://cdscoonline.gov.in/CDSCO/homepage for technical matters. WHO-TRS guidelines available on https://www.who.int for CoPPs consideration, Active substances/Active Pharmaceutical Ingredients (API) imported into the European Union (EU) for medicinal products for human use in accordance with Article 46b (2)(b) of Directives No. 2001/83/EC latest amended vide Directive no. 2011/62/EU. Nature of functions/service offered are available in https://cdsco.gov.in/opencms/opencms/en/About-us/Functions/ and process to obtain

	services can be accessed through online https://cdscoonline.gov.in/CDSCO/homepage for drugs & cosmetics and https://cdscomdonline.gov.in/NewMedDev/Homepage for medical devices. Public Grievances Cells and Public Relation Officer (PRO) service are available in https://cdsco.gov.in/opencms/opencms//en/PRO/. Further all the Central Govt. rules and regulations relating to establishment, administration and financial matters are applicable to the CDSCO.
05	**Rules, regulations, instructions, manuals and records, held by it or under its control or used by its employees for discharging its functions:** For regulatory & statutory activity are in accordance to Drugs and Cosmetics Act, 1940 & Rules there under *viz.* (1) Medical Device Rules, 2017 (2) New Drugs & Clinical Trials Rules, 2019 (3) The Cosmetic Rules, 2020 (4) Pharmacopoeia like IP, USP, BP/EP and notifications, public notices & circulars available on public domain https://cdsco.gov.in/opencms/opencms/en/Home. For non-statutory activity as per guidelines, circulars, public notice as per directions given by directorate https://cdsco.gov.in/opencms/opencms/en/Home and Drawing & Disbursing Officer (DDO) for budget & purchase as per as available on public domain (5) https://pfms.nic.in/NewDefaultHome.aspx (Public Finance management System, Ministry of Finance, Government of India (6) https://gem.gov.in/ (GeM for purchase) (7) http://iconnect.cdscoonline.gov.in/iConnect/ in administrative matters, and the CCS (Conduct) Rules, 1964, Department of Personnel & Training https://dopt.gov.in/ccs-conduct-rules-1964 List of Rules, regulations, instructions manuals and records available in link https://cdsco.gov.in/opencms/opencms/en/Home https://cdsco.gov.in/opencms/opencms/en/Acts-Rules/ Transfer Policy is formulated and Transfer Orders are available on https://cdsco.gov.in/opencms/opencms/en/Home under public notice section.
06	**Statement of the categories of documents that are held by it or under its control:** CDSCO in pursuance implementation of e-Governance has launched an online portal 'SUGAM' www.cdscoonline.gov.in) for various types of application i.e. Import &

	Registration, New Drugs, Clinical Trials, Cosmetic, Biological products etc., and also created for medical Device link https://cdscomdonline.gov.in/NewMedDev/Homepage. Various documents are available in public domain like (1) Drugs and Cosmetics Act, 1940 & Rules, 1945 made there under (2) Medical Device Rules, 2017 (3) New Drugs & Clinical Trials Rules, 2019 and notifications, public notice & circulars available on public domain https://cdsco.gov.in/opencms/opencms/en/Home (4) https://pfms.nic.in/NewDefaultHome.aspx (Public Finance management System, Ministry of Finance, Government of India (5) https://gem.gov.in/ (GeM for purchase) (6) http://iconnect.cdscoonline.gov.in/iConnect/ 7) https://bhavishya.nic.in/ for pensioners. External documents available in public domain- https://www.gmp-compliance.org/guidelines/gmp-guidelines https://www.who.int/biologicals/technical_report_series/en/ https://www.ich.org/page/quality-guidelines . Further the custodian of documents in Central Drugs Standard Control Organization (CDSCO), HQ, New Delhi are the concerned Divisional Head for Technical matter and DDA(D) for administrative section.
07	**Particulars of any arrangement that exists for consultation with, or representation by, the members of the public in relation to the formulation of its policy or implementation thereof:** Particulars for any arrangement for consultation with or representation by the members of the public in relation to the formulation of policy or implementation there of is part of Ministry and CDSCO- HQ, New Delhi. It is done in accordance to Drugs and Cosmetics Act , 1940 & Rules, 1945 there under (2) Medical Device Rules, 2017 (3) New Drugs & Clinical Trials Rules, 2019 and notifications & circulars available on public domain https://cdsco.gov.in/opencms/opencms/en/Home. Consultation is done as above, by prior communication. In general the Public Relations Office (PRO) number is 91-11-23216367(CDSCO /23236975.
08	**Statement of boards, councils, committees or other bodies consisting of two or more persons constituted as its part or for the purpose of its advice, and as to whether meetings those boards, councils, committees and other bodies are**

	open to the public, or the minutes of such meetings are accessible for public: Board and council constituted under Drugs and Cosmetics Act (Under Section 5 & 7), 1940 & Rules, 1945 made there under (2) Medical Device Rules, 2017 (3) New Drugs & Clinical Trials Rules, 2019 and notifications & circulars available on public domain and (https://cdsco.gov.in/opencms/opencms/en/Home). Committee as decided, constituted and delegated from time to time are available on (https://cdsco.gov.in/opencms/opencms/en/Home). The Drug Technical Advisory Board (DTAB) under said Act was inserted on 15.09.1964 and The Drugs Consultative Committee (DCC) was in the Year 1951. Subject Expert Committee (SEC) are constituted for evaluation of applications of New drugs, medical device & clinical trial approval. Additionally the function and recommendation of SEC are also available in cdsco website: https://cdsco.gov.in/opencms/opencms/en/Committees/SEC/ Powers and functions are of said Board, Committee prescribed in Drugs and Cosmetics Act, 1940 & there under viz. (1) Medical Device Rules, 2017 (2) The Cosmetic Rules, 2020 (3) New Drugs & Clinical Trials Rules, 2019 and notifications & circulars available on public domain https://cdsco.gov.in/opencms/opencms/en/Home.
09	**Directory of officers and employees :** Telephone Directory along with name & designation is available https://cdsco.gov.in/opencms/opencms/en/About-us/Telephone_Directory/index.html https://cdsco.gov.in/opencms/opencms/en/About-us/Seniority-List/
10	**Monthly remuneration received by each of its officers and employees including the system of compensation as provided in its regulations:** The monthly Pay and allowance received by the officer is available on https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/RTIfhq.pdf
11	**Budget allocated to each of its agency, indicating the particulars of all plans, proposed expenditure and reports on disbursements made:** The detail of Budget allocated are in link-

	https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/rtibuge.pdf
12	**Manner of execution of subsidy programmes, including the amounts allocated and the details of beneficiaries of such programmes:** CDSCO does not operate any subsidy programmes.
13	**Particulars of recipients of concessions, permits or authorisations granted by it:** This office is responsible for approval of New Drugs, Clinical Trials in the country, laying down the standards for Drugs, control over the quality of imported Drugs, coordination of the activities of State Drug Control Organisations and providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act. Drug Controller General of India is the head of CDSCO is responsible for approval of licenses of specified categories of Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera. Central Drugs Standard Control Organization Head quarter is located at FDA Bhawan, Kotla Road, New Delhi 110002 and functions under the Directorate General of Health Services.
14	**Details in respect of the information, available to or held by it, reduced in an electronic form:** Electronic form as available on website as per Drugs and Cosmetics Act,1940 & Rules made there under *viz.* (1) Medical Device Rules, 2017 (2) New Drugs & Clinical Trials Rules, 2019 (3) The Cosmetic Rules, 2020 and notifications, notices & circulars available on public domain: https://cdsco.gov.in/opencms/opencms/en/Home https://cdscoonline.gov.in/CDSCO/homepage https://cdscomdonline.gov.in/NewMedDev/Homepage For non-technical matter: https://pfms.nic.in/NewDefaultHome.aspx https://gem.gov.in/

	http://iconnect.cdscoonline.gov.in/iConnect/ https://bhavishya.nic.in/
15	**Particulars of facilities available to citizens for obtaining information, including the working hours of a library or reading room, if maintained for public use:** CDSCO office remains open for public dealing on all working days. Office working hours is from 9.30 A.M. to 6.00 P.M with lunch break from 1.30 P.M. to 2.00 P.M. The office remains closed on Saturdays, Sundays and other declared Holidays. The applicant can file application at any time in online portal https://cdscoonline.gov.in/CDSCO/homepage https://cdscomdonline.gov.in/NewMedDev/Homepage and offline application/receipts can submit in office hours. CDSCO officer's general review/processing timing of those applications is from 9.30am to 6.00 pm.
16	**Names, designations and other particulars of the Public Information Officers:** The name and designation of CPIO & FAA (for both technical & Admin.) of this office are in link: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/rightoinformation.pdf .
17	**Such other information as may be prescribed and thereafter update these publications every year:** Public Relations Office is set up with a mandate to act as an interface between CDSCO and its stakeholders including general public for the exchange and dissemination of information and is functional from 10:00 AM to 05:30 PM on all working days. https://cdsco.gov.in/opencms/opencms//en/PRO/ . Quarterly report is submitted in CIC portal having information on details of applications received/disposed, transferred etc under RTI Act is provided.

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