SUO MOTTO DISCLOSURE UNDER SECTION 4 OF RTI ACT 2005 (CDSCO, Zonal Office, Hyderabad)

1. Organization and Function

- 1.1 Particulars of its organization, functions and duties [Section 4(1) (b) (i)]
 - (i) Name and address of the Organization

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ZONAL OFFICE, HYDERABAD

Central Drugs Standard Control Organization, Zonal Office, CDSCO, Bhavan, Vengal Rao Nagar, S.R. Nagar, 500 038 https://cdsco.gov.in/ (Website Designed, Developed and Maintained by CDAC as per requirements provided by CDSCO (HQ), New Delhi)

Head of the Organization

Deputy Drugs Controller (India)

(ii) Vision, Mission and Key objectives

Vision: To Protect and Promote public health in India.

Mission: To safeguard and enhance the public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices.

(iii) Function and duties

Technical: In fulfilling its mission, the CDSCO, Zonal office, Hyderabad has following functions:

- 1. Reply of RTI applications under RTI Act, 2005.
- 2. To participate in the joint-inspection for grant/ retention of license for manufacturing of Drugs and Cosmetics as per GSR 1337 (E) dated 27th October, 2017.
- 3. To participate in the joint-inspection for grant/retention of Vaccine / Sera manufacturing units for both human as well as veterinary.
- 4. To participate in the joint-inspection for grant/ retention of LVP manufacturing units.
- 5. To participate in the joint-inspection for grant/retention of Bio-tech (r-DNA) & Bio-similar products manufacturing units i.e. recombinant (r-DNA) products
- 6. To participate in the joint-inspection for issuance /revalidation of Certificate of Pharmaceutical Products (COPPs) as per WHO-GMP certification scheme.
- 7. To process application for Written Confirmation (WC) for export of API to European Union as per EU Directives and their inspection, if required.
- 8. To participate in the joint-inspection for grant of approval for Private Testing Laboratory (PTL) for test/ analysis of Drugs & Cosmetics as per the provisions of Drugs & Cosmetics Act and Rules there under.
- 9. To participate in the inspection of Clinical Trial facilities and BA/BE centers as directed

- by the Drugs Controller General (India) from time to time. To carryout inspection for grant of license of Medical Devices (Class C & Class D) and In-vitro Diagnostic Kit (Class C & Class D) manufacturing units under Medical Devices Rules, 2017.
- 10. To carry out Surprise check/Raids jointly or independently on the basis of complaint received under Whistle Blower scheme and also from other sources.
- 11. Drawing of legal samples of Drugs from the manufacturing & sales / distribution premises including the Govt. establishment.
- 12. Follow up action on NSQ drugs with State Licensing Authorities in the respective zone as well as with other zonal offices, on the basis of Govt. analyst test report.
- 13. To pursue the court cases pending in different courts under the zone.
- 14. Technical survey as and when directed by the Drugs Controller General (India) from time to time.
- 15. To discuss the matter with State Drugs Controllers in the zone in connection with enforcement of the provisions of D & C Act & Rules there under from time to time.
- 16. To co-ordinate for answering the Parliament Questions and for obtaining the data from State Licensing Authorities under the zone.
- 17. To participate as observer in inspections conducted by various international regulatory agencies as and when informed by HQ.
- 18. To organize workshop, seminar etc. as directed by the Controlling Authority.
- 19. To conduct the function of Drugs Controller General (I) as and when delegated by him under rule 22 (b) & 122L and other Rules of the Drugs and Cosmetics Rules, 1945. The following functions delegated to respective zonal officers for carrying out on his behalf:
 - i. Permission for grant of license to manufacture drugs for the purpose of examination, test or analysis under the New Drugs & Clinical Trials Rules, 2019 in form CT-11 for new drugs/investigational new drugs (Active Pharmaceutical Ingredients & formulations), CT-14 (Unapproved Formulations) and CT-15 (unapproved APIs) so as to obtain license from State Licensing Authority (SLA) of concerned State under Rules 89 of the Drugs and Cosmetics Rules, 1945 on Form-29 as per requirements.
 - ii. Grant of license for import of small quantities of old drugs in Form-11 for the purpose of examination, test or analysis as provided under Rule 33 of the Drugs and Cosmetics Rules, 1945 and for import of small quantities of new drugs in CT-17 under the provisions of NDCT Rules, 2019 through offline/manual procedures.
 - iii. Grant of license for import of small quantities of unapproved new drugs in Form CT- 25 by Government Institutions or Autonomous Medical Institutions for treatment of patients under Rule 86 of New Drugs and Clinical Trial Rules, 2019.
 - iv. No objection certificates (Dual use NOC) for grant of permissions for import of dual use items, not for medicinal use.
- 20. Any other functions as assigned by DCG (I).

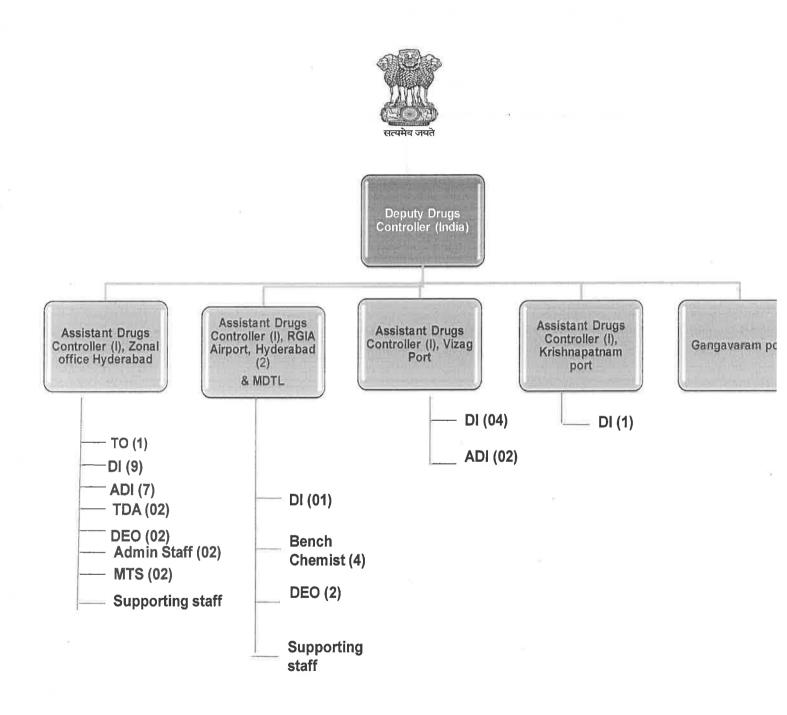
Administrative:

- 1. To Maintain the Service records/leave records of Gazetted and Non- Gazetted Staff and administrative Staff.
- 2. To maintain seniority list of Group –D employees. Under MACP Scheme to Group D Staff.
- 3. To prepare of annual budgets /preliminary and final estimate of expenditure etc.
- 4. To Prepare reports/replies concerning to the above administrative functions.
- 5. To purchase of stationeries and office items as per the requirements.
- 6. Annual Maintenance Contract (AMC) of office equipment etc.
- 7. Reply of RTI applications under RTI Act, 2005.
- 8. Any other functions assigned by DCG (I) from time to time.

(v) Organization Chart:

Table No.1

Deputy Drugs Controller (India), Hyderabad Zonal office



Page 4 of 34

..9 Monthly Remuneration received by officers & employees including system of compensation {Section 4(1) x)1

| s/N o | Name of the post | Total posts | Zonal Office Hydera bad | Sub-zone office Visakhapa tnam | Port office, Hyderaba d | Port office Visakhapatna m | Port office Krishnapatn am | | Pre- revised |
|----------|----------------------------------|----------------|----------------------------------|---|----------------------------------|----------------------------------|----------------------------------|-----------|---|
| 1 | Deputy Drugs Controller (I) | 1 | 1 | C | 0 | 0 | 0 | Level- 12 | Pay Band 15600- 39100 (GP- 7600) |
| 2 | Assistant Drugs Controller(I) | 4 | 1 | 1 | 1 | 0 | 1 | Level-11 | Pay Band 15600- 39100 (GP- 6600) |
| 3 | Drugs Inspectors | 15 | 9 | 4 | 1 | 0 | - 1 | Level-8 | Pay Band 9300- 34800 (GP- 4800) |
| 4 | Technical Officer | 1 | 1 | O | 0 | 0 | 0 | Level-8 | Pay Band 9300- 34800 (GP- 4800) |
| | Assistant Drugs Inspector | 9 | 7 | 0 | 0 | 2 | | Level-6 | Pay Band 9300 - 34800(GP 4200) |
| 6 | Upper Division clerk | 1 | 1 | 0 | 0 | 0 | 0 | Level 4 | Pay Band 5200- 20200 (GP- 2400) |
| 7 | Multi-Tasking Staff | 1 | 1 | 0 | 0 | 0 | 0 | Level-1 | Pay Band 5200- 20200 (GP- 1800) |

VI) Any other details:

The genesis, inception, formation of the department and the HoDs from time to time as well as the committees/ Commissions constituted from time to time have been dealt.

The Central Drugs Standard Control Organization (CDSCO), Zonal office, Hyderabad was started during the year 1996 at Begumpet Hyderabad headed by Deputy Drugs Controller (India).

The Zonal office of the CDSCO, Hyderabad Zonal office was initially created to co-ordinate with the various State Drugs Controllers (who are the Licensing Authority) under the Act for uniform implementation and smooth enforcement of the provisions of Chapter IV of the Drugs & Cosmetics Act and Rules. The Said office was shifted to S.R. Nagar, Vengal Rao Nagar, Hyderabad 500 038 in the Year 2010. The Zonal Office, Hyderabad had jurisdiction over the states of Telangana & Andhra Pradesh.

A new Sub-Zonal office Visakhapatnam headed by an Assistant Drugs Controller (India) with the jurisdiction over the State of Andhra Pradesh had started and is functioning w.e.f. July 2023

Power and duties of its officers and employees [Section 4(1) (b)(ii)] 1.2

Powers and duties of officers (administrative, financial and judicial) & Power and duties of other employees. i)

ii)

| Designation | Duties |
|---------------------------------------|---|
| Deputy Drugs Controller (India) | Acting as Appellate Authority for CDSCO Hyderabad Zone for responding to RTI, replying Parliamentary Questions, etc. as and when required. |
| | 2. Technical head of the office of CDSCO Zonal office, Hyderabad Sub-Zone, Visakhapatnam, CDSCO Port Offices at Airport Hyderabad, Seaport Visakhapatnam & Krishnapatnam. |
| | 3. Co-ordination and co-operation with the States Drugs Controllers under Telangana and Andhra Pradesh states in order to ensure uniform enforcement of Drugs& Cosmetics Act and rules and other related legislations for the work relating to inspections for Licensing of Blood Banks, manufacturing of Large Volume Parenterals, Biological Products including Vaccines, Medical Devices as per Medical Device Rules, 2017 and issuance of Certificate of Pharmaceutical Products(CoPP) as per WHOTRS guidelines by Drugs Inspectors of CDSCO and State Licensing Authorities. |
| | 4. Co-ordination with Zonal offices, Sub-Zonal and Port offices of CDSCO of other Zones for uniform administration of Drugs & Cosmetics Act and rules. Co-ordination with other organizations like Customs, DGFT, IPC, NIB, Pharmexcil etc. |
| | Deputation of inspectors for inspection on the basis of the applications received for joint inspections, raids, investigations, seizures and drawal of samples etc. as per Drugs & Cosmetics Act and rules. |
| | 6. Monitoring and evaluation of inspections conducted, report submitted, reviewing and forwarding to Drugs Controller General (India) and / or State Licensing Authority for necessary action as applicable. |
| 2 | 7. Review, monitoring, evaluation of all files, inspection reports submitted by all levels of staff including Drugs Inspectors and Technical officers. |
| | 8. Deputation, monitoring, evaluation and forwarding of report of joint inspections conducted by CDSCO and State Licensing Authorities under GSR 1337 (E) to concerned State Licensing Authority for necessary action (approval/compliance/rejection. |

- 9. Approval and signing authority of:
 - i) No Objection Certificates for grant of permissions for import of dual use items which are "Not for Medicinal use" by SUGAM Portal. No Objection Certificate to manufacture approved /un- approved new drugs in Form 29 for the purpose of examination, test and analysis.
 - ii) Grant of Test License for the import of Veterinary Drugs or Veterinary Vaccines imported for purpose of examination, tester analysis except for Clinical Trial by SUGAM Portal.
 - iii) Grant of Licenses in NSWS Portal.
- 10. Monitoring the establishment of Minilabs at Port offices and coordination with Customs Commissioners on matters related to Port offices.
- 11. Taking action on Not of Standard Quality drugs as per Drugs & Cosmetics Act and rules and as per CDSCO quidance document.
- 12. Monitoring of technical survey of drugs as and when directed by the Drugs Controller General (India).
- 13. Participation in various committees as Technical Expert, Workshops, Seminars as Speakers etc. and other related matters on behalf of DCG(I)including Stakeholders meetings and resolve any issues, matters pertaining to manufacture, testing, import and export of drugs etc.
- 14. Any other functions as assigned by the Drugs Controller General (India) from time to time.

Assistant Drugs Controller (India)

- 1. Acting as a Central Public Information Officer for RTI applications.
- 2. Responsible for coordination and compliance with the directions of the Dy. Drugs Controller (India), CDSCO, Hyderabad Zone for carrying out regulatory inspections (Certificate of Pharmaceutical Products, Blood Centres, Blood Products, Vaccines- Sera, rDNA, Large Volume Parenterals) Inspections, Complaints, Raids/Investigations as directed by Dy. Drugs Controller (India), CDSCO, Hyderabad Zone.
- 3. Monitoring of activities of Drugs Inspectors who are responsible for conduct of joint inspections, complaints investigations and sampling etc. as and when directed by the Dy. Drugs Controller (India), CDSCO, Hyderabad Zone
- 4. Coordination with Zonal Offices / State Licensing Authorities/Ports and Other Authorities as and when directed by the DDC (I) CDSCO, Hyderabad Zone.
- 5. Processing of On-line Medical Device applications through SUGAMPORTAL as a Nodal officer/Medical Device Officer and Reviewing Officer.
- 6. Processing of On-line Test License applications through SUGAM PORTAL and NSWS Portal as Nodal Officer.
- 7. Responsible for coordinating and compliance with the directions of the Dy. Drugs Controller (India), CDSCO Hyderabad Zone for carrying out regulatory inspections (COPPs, CLAA Inspections and Complaints, Raids/Investigations) as directed by DDC(I) Hyderabad Zone.
- 8. Deputation of Drugs Inspector for carrying out joint inspections, complaints investigations, sampling etc. In absence & as and when directed by the DDC (I) CDSCO Hyderabad Zone.
- 9. Handling queries from the applicants as a Public Relation Officer and as a Nodal Officer for resolving grievances received from general public.
- 10. Acting as a Drawing and Disbursing Officer (DDO) in administration matters.

Technical Officer

- 1. Entries of applications in the respective registers of applications received for grant / revalidation of WHO GMP Certificate / COPP, Written confirmations, Blood Centres, manufacturing licenses for Drugs & Cosmetics, vaccines, Public Testing Laboratories, rDNA, BA-BE State Wise (Hyderabad Zone) etc.
- 2. Providing of applications / files to officers as and when required when the inspections are planned.
- 3. Scrutiny of online Dual Use NOC issued for import of drugs intended for non-medicinal use prior approval of DDC (I).
- 4. Scrutiny of Bill of Entries for import of drugs referred by port officers for DDC clarification.
- 5. Assisting the SPC Govt. of India and DIs for preparing Petition and Counters for cases of Drugs imported by the various importers.
- 6. Preparing replies for the technical clarification in respect of import and export of drugs sought by Customs, importers and public.
- 7. Maintaining technical correspondence related to import and export of drugs and attending various queries by public, importer and exporter.
- 8. Timely preparation of pending list of Inspection to be carried out, Monthly & Quarterly.
- 9. Providing of data / details required in respect of framing of replies pertaining to RTI, Parliament Questions etc.
- 10. To co-ordinate for answering the parliament question and for obtaining data from various State Licensing Authorities under the Zone.
- 11. Maintaining of approved license records received from CLAA.

Drugs Inspector/ Medical Device Officer

- To participate in the joint inspections for issuance/ revalidation of Certificate of Pharmaceutical Products (COPPs) as per WHO Certification Scheme as and when allotted by the DDC (I).
- To participate in the joint inspections for grant/renewal of licenses with respect to the following as and when allotted by the DDC (I):
 - Blood Centre license, Vaccine/Sera manufacturing
 - units for both human as well as Veterinary, LVP manufacturing units etc.
 - For notified Medical Devices & Critical Diagnostics
 - manufacturing units.
 - For Biotech & Bio-similar products manufacturing units.
 - Inspections of Clinical Trial facilities and BA/BE centers as directed by the Drugs Controller General (India) from time to time.
 - Inspections for issue of Written Confirmation for export of API to EU.
 - To carry out joint inspection of Drug Testing Laboratory for the purpose of grant of approval for test/analysis of Drugs & Cosmetics.
- To carryout surprise check/raid jointly or independently on the basis of complaint received under whistle-Blower Scheme and also from other sources.
- To follow-up action on NSQ drugs with State Licensing Authorities in the respective zone as well as with other Zonal offices.
- Routine sampling of legal (Form 18) as well as Survey Samples for test/analysis by Central Laboratories.
- When the samples drawn by the central Drugs Inspectors are declared spurious/adulterated/grossly sub-standard etc., the cases are investigated and prosecutions are launched in the

- appropriate court after obtaining necessary sanction from the Drugs Controller General (India).
- 7. Deputation of Drugs Samplers at various places of suspicious nature and collect samples through them as surrogate patient from the sales premises by way of survey to monitor the quality of drugs. Further surprise check/raid is to be carried out by the Drugs Inspectors in case these samples are declared as NSQ by the testing laboratory.
- 8. To participate in the joint inspections with respect to grant of NOC in Form 29 as per requirements.
- 9. Technical Survey as and when directed by the DDC (I) from time to time.
- 10. To co-ordinate and assist in the training, workshops, seminars etc. as directed.
- 11. Review of online applications in Sugam Portal, NSWS, ONDLS and other portal as assigned.
- 12. Any other work assigned by the DDC (I)/ADC(I)

| Assistant Drugs Inspector |
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| | | Statutory audit and Internal Audit 7. All the work relating in GeM Procurement and services as well as its processing of bills |
|----------------|----------|---|
| Upper Clerk | Division | Supervision of administrative and accounts activities like general administration, preparation of salary bills, personal claims of officers & staff, TA claim. Updating and maintenance of service records, leave records. Preparation of letters/replies, correspondence related to administration matters. Assisting Administration staff in day-to-day work assigned by HOD and Seniors. Matters. Assisting administration staff in day-to-day Preparation of administrative replies, furnishing data for the RTI replies from administrative side, Validation of data in respect of officers and staff in the Personal Information system. Generating expenditure claims such as Office Expenditure, TA Claims, Professional services through PFMS portal. Monthly Expenditure statements, preparation of revised and budget estimate for the current and ensuing year. Reconciliation of accounts with Pay and Accounts Office. Typing the official correspondence. Preparation of pay bills, income tax, e- TDS. Preparation of pension and retirement benefits. Purchase of stationary and other office equipments through GeM Portal. Co-ordination with Audit Teams of Statutory Audit &Internal Audit. benefits. Purchase Co-ordination with Audit teams of Statutory audit and Internal Audit All the work relating in GeM Procurement and services as well as its processing of bills |

| Multi- Tasking Staff | To open and close the office before and after the arrival and departure of officers and staff. To assist the officers and staff in moving the files from one desk to other. To attend the personal needs of Head of office. In addition to the auxiliary support, have to do basic clerical work, whenever there is a need. |
|-------------------------|---|
| Data Entry Operator | Typing of letters related to technical as directed by Seniors. Digital Signing of online applications of NOCs, sending emails, scanning reports and hyperlink to respective statements., Maintaining data of inspection reports in the respective registers and computer, Work assigned by Seniors. |

- iii. Rules/ orders under which powers and duty are derived and
- iv. Exercises Deputy **Drugs** Controller (India) is working as Zonal Head & Controlling Officer under Drugs and Cosmetics Rules, 1945. Drugs Inspectors derive their powers from Drugs & Cosmetics Act, 1940 (Section 21, 22 and 23) and Rules made there under (Drugs and Cosmetics Rules, 1945) and Medical Device Officer (Medical Device Rules, 2017) and subsequent office orders issued by Directorate. Powers and duties of other posts are derived and exercised as per the practice in vogue. Copy of Drugs & Cosmetics Act and Rules under the said Act is available on CDSCO Website.
- v. Work allocation

The information is available in the Table no.2

1.1 Procedure followed in decision making process

[Section 4(1)(b)(iii)]

- a. Process of decision making Identify key decision-making points
- b. Final decision-making authority
- c. Related provisions, acts, rules etc.
- d. Time limit for taking a decision, if any
- e. Channel of supervision and accountability

As per Standard operating Procedure (SOP) the process of decision making based on the identified key decision-making points is done at every level. SOP, guidance document and directorate order define the hierarchy/channel of supervision of the office. The time limits for taking decisions are set by internal office orders issued from time to time. Final Decision-making authority is vested with the Deputy Drugs Controller(I).

1.2 Norms for discharge of functions

[Section 4(1)(b)(iv)]

- i. Nature of functions/ services offered
- ii. Norms/standards for functions/service delivery
- iii. Process by which these services can be accessed
- iv. Time-limit for achieving the targets
- v. Process of redress of grievances

The nature of functions /services offered by this office are listed under para no: 1.1.(iv). Various Licenses/Permissions are issued through the SUGAM PORTAL, NSWS Portal (www.cdscoonline.gov.in and www.cdscomdonline.gov.in).

Time limits are specified in the SOP. The grievances are redressed through Public Relation Office. Details of PRO is available on CDSCO website.

1.3 Rules, regulations, instructions manual and records for discharging functions [Section 4(1)(b)(v)]

- i. Title and nature of the record/ manual/instruction.
- ii. List of Rules, regulations, instructions manuals and records
- iii. Acts/ Rules manuals etc.
- iv. Transfer policy and transfer orders

The Drugs and Cosmetics Act, 1940 and Rules made there under (Drugs and Cosmetics Rules, 1945, Medical Device Rules, 2017 and New Drugs and Clinical Trials, 2019, Guidance document for Zonal, Sub-zonal & Port Offices and subsequent office orders issued by Directorate are followed by this office for discharging functions. Further, Manual of Office Procedure and Sugam portal User Manual in electronic format are also followed. Transfer policy is formulated and transfer orders are issued by the Directorate.

Copy of these Act, Rules, circulars, Notice is available on CDSCO website.

- 1.4 Categories of documents held by the authority under its control
 - i. Categories of documents
 - ii. Custodian of documents/categories

Documents are maintained as per the requirements of the following rules and manuals:-

- A. Technical:
- 1. Manual of Office Procedure
- 2. Drugs and Cosmetics Act, 1940
- 3. Drugs and Cosmetics Rules, 1945
- 4. Medical Device Rules, 2017
- 5. New Drugs and Clinical Trials, 2019
- 6. Cosmetic Rules, 2020

B. Administrative:

Various documents and records are maintained as per the norms of Government of India https://dopt.gov.in/download/acts

Boards, Councils, Committees and other Bodies constituted as part of the Public Authority [Section 4(1)(b)(viii)]

- i. Name of Boards, Council, Committee etc.
- ii. Composition
- iii. Dates from which constituted
- iv. Term/ Tenure
- v. Powers and functions
- vi. Whether their meetings are open to the public?
- vii. Whether the minutes of the meetings are open to the public?

Various Boards and Committees are constituted by the Directorate **and information is** available on CDSCO website.

- **1.6** Directory of officers and employees [Section 4(1) (b) (ix)]
 - (i) Name and designation: Dr A Ramkishan, Deputy Drugs Controller (India) Telephone, fax and email ID:

Tel: 040-23811481 Fax:040- 23811483

Email id: hyderabad@cdsco.nic.in

CONTACT DETAILS OF CDSCO HYDERABAD ZONE and Sub-Zonal Offices (VISAKHAPATNAM)

Refer organization website https://cdsco.gov. in/open cms/opencms/en/Home/

- 1.9 Monthly Remuneration received by officers & employees including system of compensation [Section 4(1) (b) (x)]
 - i. List of employees with Gross monthly remuneration
 - ii. System of compensation as provided in its regulations

| O/o. THE DEPUTY DRUGS CONTROLLER | R (INDIA) CDSCO, HYDERABAD ZONE |
|--|---|
| Salary details of various posts with F HYDERABAD ZONE, SUB-ZONE VISAR HYDERABAD, VISAKHAPATNAM AND K | Pay band and Pay level for CDSCO, KHAPATNAM AND PORT OFFICES AT KRISHNAPATNAM |
| Technical Officer | Pay Band 9300-34800 (GP- 4800) & Level 8 |
| Drugs Inspector | Pay Band 9300-34800 (GP- 4800) & Level 8 |
| Asstt. Drugs Inspector | Pay Band 9300-34800 (GP- 4200) & Level 6 |
| UDC | Pay Band 5200-20200 (GP- 2400) & Level 4 |
| MTS | Pay Band 5200-20200 (GP- 2000) & Level 1 |

- **1.10** Name, designation and other particulars of public information officers [Section 4(1) (b) (xvi)]
 - i. Name and designation of the public information officer (PIO), Assistant Public Information (s) & Appellate Authority
 - ii. Address, telephone numbers and email ID of each designated official.

| S.No | Designation | Technical/ Administration Matters |
|------|---|---|
| 1 | Appellate Authority | Deputy Drugs Controller (India) Hyderabad zone Hyderabad Email: <u>hyderabad@cdsco.nic.in</u> |
| 2 | Central Public Information Officer (CPIO) | Assistant Drugs Controller (India) Email: hyderabad@cdsco.nic.in |
| 3 | Assistant Public Information Officer (APIO) | Assistant Drugs Inspector, Email: hyderabad@cdsco.nic.in |

- 1.11 No. of employees against whom disciplinary action has been taken:
 - i. Pending for Minor penalty or major penalty proceedings Nil
 - ii. Finalised for Minor penalty or major penalty proceedings Nil
- **1.12** Programmes to advance understanding of RTI (Section 26)
 - i. Educational programmes

Training programme or workshop related to RTI is being attended regularly by CPIO of this office.

- ii. Efforts to encourage public authority to participate in these programmes

 The department encourages public authority by granting necessary permissions whenever necessary to participate in the training programmes of RTI.
- iii. Training of CPIO/APIO

 List of Training Programmes attended by the CPIO: One (01)
- iv. Update and Publish guidelines on RTI by the Public Authorities concerned

1 3

F. No. A. 22011/02/2023-D भारत सरकार /Government of India

स्वास्थ्य और परिवार कल्याण मंत्रालय /Ministry of Health and Family Welfare स्वास्थ्य सेवा महानिदेशालय /Directorate General of Health Services केंद्रीय औषधि मानक नियंत्रण संगठन /Central Drugs Standard Control Organization

> FDA Bhawan, Kotla Road, New Delhi Dated 3rd July, 2023

ORDER

Sub:- Transfer Policy for the officers/officials of CDSCO-reg.

In supersession of this Directorate's earlier Order No. A. 22013/01/2014-D (Pt) dated 24.06.2016 on transfer policy, the following transfer policy has been adopted with immediate effect:-

- (i) The policy covers officials upto the rank of Deputy Drugs Controller (India).
- (ii) All officials having completed three years on 30th June of a particular year will be considered for transfer for which three options can be made to the DCG(1) in order of preference. Seniority will be given due consideration followed by Govt. policy on working spouses, subject to provisions listed herein.
- (iii) No official will be posted in his/her home town.
- (iv) Officials with less than one year residual service will not be transferred except on their request.
- (v) No one shall be, allowed to remain in one metropolitan city/ district for more than 10 years irrespective of the rank of different times e.g. person posted in a metropolitan city and also in different ports in the same city will not be posted for more than 10 years during their service in the same city/ district.
- (vi) In CDSCO Headquarters, officials may be retained. for a further period of 1 year i.e. four years at a stretch in case of exigencies of work.
- (vii) Officials having been chargesheeted for disciplinary/vigilance cases shall not be given sensitive postings.
- (viii) It is the prerogative of CDSCO to post the officers on their promotion to any of the offices under CDSCO and no request for preference of posting will be entertained.

2. This issues with the approval of the Competent Authority.

(Dileep Kumar Rajput)
Director (Admn.)

To,

1. All officers/officials of CDSCO (HQ).

2. All Zonal/Sub Zonal/Port offices of CDSCO.

Copy to:-

- 1. PPS to Secretary (Health)/PPS to DGHS.
- 2. PPS to JS(R)
- 3. Deputy Secretary (DR)
- 4. DCG(I) Secretariat
- 5. IT Cell for uploading of CDSCO website.
- 6. Office Order Folder

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Speed Post/ e-mail

F.No.: Admin-17011(11)/1/2025 E.O. 20167

Government of India Ministry of Health and Family Welfare Directorate General of Health Service (DGHS) Central Drugs Standard Control Organisation (CDSCO) (Cash Section)

F.D.A. Bhawan, I.T.O., Kotla Road, New Delhi. Date: -20/2/2025

To,

Dy. Drugs Controller(I),

CDSCO, Sub. Zone, Hyderabad,

Besides APTB, Demonstration CENTRAL, S R Nagar,

Hyderabad-500038

Subject: -

Revised Estimate 2024-25 & Budget Estimates 2025-26 in respect of Major Head 4210-Capital Outlay on Medical and Public Health (Major Head), 04200-Other Programme

(Minor Head)-21 CDSCO, 2100 - Reg.

Sir/Madam,

I am directed to inform you that the Revised Estimate 2024-25 & Budget Estimates 2025-

26 in respect of your office under each sub, head is as given below: -

| Sr. No. | Object head (Capital) | B.E 2023-24 | B.E 2024-25 | R.E 2024-25 | B.E 2025- 26 |
|------------|--|----------------|----------------|----------------|--------------------|
| | Machinery and Equipment(52) | 7000 | 10000 | 200 | 6000 |
| 01 | | 0 | 0 | 0 | 500 |
| 02 | Furniture & Fixtures (74) | 100 | 500 | - 0 | 1500 |
| 03 | Information, computer Telecommunication (ICT) equipment (71) | 400 | 500 | 500 | 1500 |
| | | 3716 | 0 | 0 | 0 |
| 04 | Building & Structures(72) | 11116 | 10500 | | 8000 |
| | Total | 11116 | 10300 | 700 | |

Yours faithfully,

(Pawan Kumar)

Drawing & Disbursing Officer

आहरण एवं संवितरण अधिकारी Drawing & Disbursing Officer के.औ.मा.नि.सं. (मुख्या.), एफं.डी.ए. भवन,

C.D.S.C.O. (HQ), FDA Bhawan, नई दिल्ली/ New Delhi

Copy to: -

Pay & Accounts Officer, Ministry of Health & FW, Chennai

F.No.: Admin-17011(11)/1/2025 E.O. 20167

Government of India

Ministry of Health and Family Welfare Directorate General of Health Service (DGHS) Central Drugs Standard Control Organisation (CDSCO) (Cash Section)

F.D.A. Bhawan, I.T.O., Kotla Road, New Delhi. Date:- 4/2/, 2025

To,

Dy. Drugs Controller(I),

CDSCO, Sub. Zone, Hyderabad,

Beside APTB, Demonstration CENTRAL, S R Nagar,

Hyderabad-500038

Subject: -

Revised Estimate 2024-25 & Budget Estimates 2025-26 in respect of Major Head 2210-

06104-Drugs Control (Minor Head) 02-CDSCO-0201- General Component - Reg.

Sir/Madam,

I am directed to inform you that the Revised Estimate 2024-25 & Budget Estimates 2025-

26 in respect of your office under each sub. head is as given below: -

(amount in thousands)

| Sr. No. | Object head | B.E 2023-24 | B.E 2024-25 | R.E 2024- 25 | B.E 2025-26 |
|---------|-------------------------------|--------------------|----------------|-----------------|----------------|
| | Salarian (01) | 31000 | 29000 | 26500 | 30000 |
| 1 | Salaries (01) | 0 | 100 | 0 | 0 |
| 2 | Wages(02) | 0 | 200 | 117 | 150 |
| 3 | Rewards (05) | 1000 | 1500 | 1500 | 2000 |
| 4 | Medical Treatment (06) | 22000 | 30000 | 25300 | 25300 |
| 5 | Allowances (07) | 1000 | 1500 | 500 | 500 |
| 6 | Leave Travel Concession (08) | | 0 | 0 | 1000 |
| 7 | Training Expenses (09) | 0 | 0 | 0 | 0 |
| 8 | Pensionary Charges (04) | 300 | | 4550 | 4500 |
| 9 | Domestic Travel Expenses (11) | 3500 | 7000 | | 18000 |
| 10 | Office Expenses (13) | 20000 | 25000 | 16800 | |
| 11 | RRT for L&B (14) | 2200 | 3000 | 2000 | 3000 |
| | Printing & Publication (16) | 200 | 300 | 300 | 400 |
| 12 | | 0 | 0 | 1500 | 2000 |
| 13 | Rent for Others (18) | 200 | 1000 | 800 | 1500 |
| 14 | Digital Equipment (19) | 9000 | 7000 | 6000 | 5000 |
| 15 | Material & Supplies (21) | 0 | 100 | | 200 |
| 16 | Advertising & Publicity (26) | 2000 | | | 5500 |
| 17 | Minor Civil Work (27) | CANCELL CANCELLARY | | | 1000 |
| 18 | Professional Services (28) | 500 | | | |
| 19 | Repair & Maintenance (29) | 1000 | | | |
| 20 | Other Revenue Expenses (49) | 0 | | | 112250 |
| 20 | TOTAL | 93900 | 116600 | 101034 | faithfully, |

(Pawan Kumar)

Year

Drawing & Disbursing Officer

आहरण एवं संवितरण अधिकारी Drawing & Disbursing Officer के.औ.मा.नि.सं. (मुख्या.), एफ.डी.ए. भवन, C.D.S.C.O. (HQ), FDA Bhawan, नई दिल्ली/ New Delhi

| National Sciences 170000 26,046 21,046 | | Dank, 17 hands | | 100436 | ile to | Nap.16 | 100.00 | ***** | Ang 31 | Bep-24 | **** | Mm-26 | 25.00 | la p | 18.42 | 10.71 | Programme themsent | Balance Amount |
|--|---------------------|--------------------------------|----------|----------|-----------|-----------|------------|----------|----------|--------|--------|-------|-------|---------|----------|---------------|--------------------|----------------|
| Persistant changes | 2210-06104-02-01-01 | Salaries | 28500000 | 26500000 | 41 62 500 | 21 49 651 | 20 20 000 | - | + | | | Ť | 4 | + | | | | DE 24-25 |
| Penicipatry changes 0 | 4-02-01-02 | Wades | | 0 | 200 | 400 | 200000 | - | 4 | - | | | | | 0,57,459 | 0 | 2,62,73,458 | 2,26,542 |
| Parametris 17000 1220000 122000 122000 122000 1220000 1220000 1220000 122000 122000 122000 122000 1220000 122000 122000 12 | 4.02.04.04 | Danelonnan obsesse | | 2 | | -3,403 | 87468 | - | 0 | 0 | 0 | 0 | 0 | 0 | | | 0 | |
| Mactical Testment 1500000 1550000 0 0 0 0 0 0 0 0 | 10000000 | and and a contract | | 0 | 0 | 0 | 0 | D | 0 | 0 | | | 0 | 0 | | | C | |
| Modelacies 1500000 1650000 1 | CD-10-70-6 | Kewards | 117000 | 123000 | 0 | 0 | 0 | ٥ | D | 0 | 17.438 | L | 0 | | | 4 900 | 4 00 000 | 200 4 |
| Albertanese 25,000.000 25013000 2501 | 4-02-01-06 | Medical Treatment | 1500000 | 1650000 | 0 | 36,568 | 9.462 | 8.822 | ۲ | + | 15 | 1 | 1 | 00 7 00 | Ť. | 000000 | 1,22,230 | 9779 |
| Training Expenses 500000 463000 2576 2 | 4-02-01-07 | Allowances | 25300000 | 25013000 | 41.27.975 | 22 77 055 | 19.70.752 | 4 | ÷ | + | , | 1. | 1 | 20,163 | Ť. | 7,40,000 | 16,17,943 | -1,17,943 |
| Training Expenses 0 | 4-02-01-08 | LTC | 200000 | 463000 | 40,000 | 7.975 | 1.04 550 | - | + | + | | - | 1 | 100,410 | 0034,600 | | 2,50,12,577 | 2,87,423 |
| Travel Eventues | 4-02-01-08 | Training Expenses | 0 | 0 | c | - | c | | 0 | 4 | | 1 | + | - Ber's | 11017 | I | 4.62.30B | 37,69 |
| Office Exenses 1760000 177500 1775 | 4-02-01-11 | Travel Expenses | 430000 | 00000000 | 962788 | 2 54 Sh? | 2 87 440 | + | ٠ | + | 1 | t | 4 | + | 1 | - Contraction | 0 | |
| Particular State 1700000 17000 | 4-02-01-13 | Office Exnenses | 47500000 | O COOL | 200 40 00 | 2,04,006 | 0,07,410 | - | - | + | _ | - | Н | | | 3,04,852 | 45,99,763 | -2,99,763 |
| Printing & Publications 17,0000 19,000 19,0000 | M-02.01-14 | Poort Rate Town | 4700000 | 0000000 | 10,07,001 | 41,33,044 | 46,57, 993 | - | 23 | - | _ | | - | ,45,916 | ٠ | 2,74,072 | 1,77,17,394 | -1.17.394 |
| Printing Evulpations 2000000 1,200000 | 07 10 00 7 | MONE VALUE OF STREET | 1700000 | 2000000 | 66,435 | 58,495 | 58,435 | 68,495 | K | | _ | | | 8,495 | | 3.39.620 | 10 06 384 | 22 9R 7R |
| Procession Pro | 01-10-70-6 | Refil for others | 2000000 | 1500000 | 0 | 0 | 0 | 0 | 0 | - | | | 0 | - | H | 4 | 46 99 304 | 3 44 600 |
| Optial Equipment Biococco | 4-02-01-10 | Ponting & Publications | 300000 | 300000 | | 0 | 2,16,900 | a | | - | - | ľ | l | t | | 0 | 010000 | 2000 |
| Suppliers & Material Goldono Ge00000 1424,217 2,65,117 2,6 | 1-02-01-19 | Digital Equipment | 900000 | 000000 | | 1,80,949 | 1,68,388 | 2.35.500 | | 0 | 0 | L | ľ | 46.000 | A ORG | 20 350 | 2,30,050 | 4,350 |
| Advertising & Publicity 100000 67000 66296 0 | 1-02-01-21 | Supplies & Material | 6000000 | 6000000 | 14.24.217 | 2.05.117 | 251.175 | H | ÷ | L | ľ | _ | ľ | + | t | 200000 | 6,03,531 | 100'5 |
| Milror Works 300000 300000 300000 0 0 0 | 1-02-01-26 | Advertising & Publicity(| 100000 | 67000 | REZGE | c | 0 | | ÷ | 1 | ī | 4 | + | + | + | 0,44,003 | 46,64,324 | 13,35,676 |
| Professional Services 600000 800000 800000 111,000 66,000 87,500 87,500 89,500 13,500 13,500 14,00000 14,00000 14,00000 14,00000 14,00000 14,00000 14,00000 14,00000 14,00000 14,00000 14,00000 14,00000 14,0000 14,00000 14,00000 14,00000 14,00000 14,00000 14,0000 14,000 | 4-02-01-27 | Mirtor Works | 300000 | 300000 | | 0 | 299200 | 0 0 | 000 | | | _ | 0 0 | 0 | | | 66,296 | 33,704 |
| Repairs & Maintenance 12400000 14000000 20,03,422 4,13,319 15,51,420 5,88,395 2,02,175 75,90,207 35,724 0 0 0 0 0 0 0 0 0 | 4-02-01-28 | Professional Services | 900000 | 000008 | | 1,11,000 | 66,000 | 87.508 | t | ľ | Г | 1 | ł | 010 | out the | 200 0 000 | 2.99.200 | 800 |
| Offige Revenue Exori 200000 4500 6,000 0 0 0 0 0 0 0 1,80,589 Information & Tech 60000 500000 0 2,8699 1,89,600 0 0 0 0 0 0 4,60,589 Buildings & Shrictures (21072) 60000 500000 0< | 4-02-01-29 | Repairs & Maintenance | 12400000 | 14000000 | 20,03,422 | 4,13,319 | 15.51.420 | 88.395 | £ | 1 | T | 1 | ł | 200 | 1 | 000 000 | 5,92,800 | 1,200 |
| M&E 0 110000 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 | 4-02-01-49 | Other Revenue Expdr | 200000 | 187000 | 3.400 | 4.000 | 0 | | ٠ | 1 | 14545 | _ | 1 | 200 | + | 200,000 | 1,32,27,744 | -10,87,744 |
| Information & Tech. Buildings & Shuckures(210072) | 0-21-00-52 | M&E | 0 | 110000 | | | 0 | 0 | H | 200 | 200 | | 1 | 0440 | | 3,803 | 1,60,599 | 19,401 |
| Buildings & Shuckunes (210072) 0 0 0 0 0 0 0 0 0 0 0 | 0-21-00-71 | Information & Tech. | 600000 | 200000 | | | 0 | 2 90 999 | 1 69 900 | | c | _ | 0 | 3 0 | Ī | İ | 3 | |
| | 3-21-00-72 | Buildings & Structures(210072) | | 0 | | | 0 | 0 | 0 | 0 | , | | | 0 | | Ī | 4,50,899 | 39, 101 |
| | | | 1000 | | | | | | | , | | | 5 | | | | 5 | |

Expenditure Statement for the Year 2024-25

DEPUTY DRUGS CONTROLLER (I) CDSCO Zonal Office, DGHS, MH&FW S.R. Nagar, Hy: rabad-500 038. T.S.

Foreign and domestic tours

- i. Budget
- ii. Foreign and domestic Tours by ministries and officials of the rank of Joint Secretary to the Government and above, as well as the Heads of the Department.
 - a. Places visited
 - b. The period of visit
 - c. The number of members in the official delegation
 - d. Expenditure on the visit

Foreign Tours

| S/No | Name of the officer | Places visited | Period of visit | Number of members in the official delegation | Expenditure on the visit |
|------|-------------------------------|-------------------|-----------------|---|--------------------------|
| 1 | 2 | 3 | 4 | 5 | 6 |
| 1 | Deputy Drugs Controller(I) | Nil | Nil | Nil | Nil |

Domestic Tours

| OTTIOOTIC | 7 1 0 0 1 0 | | | | |
|-----------|-------------------------------|-------------------|-----------------|--|--------------------------|
| S/No | Name of the officer | Places visited | Period of visit | Number of members in the official delegation | Expenditure on the visit |
| 1 | 2 | 3 | 4 | 5 | 6 |
| 1 | Deputy Drugs Controller(I) | Nil | Nil | Nil | Nil |

Information related to procurements

- a. Notice/tender enquires, and corrigenda if any thereon,
- b. Details of the bids awarded comprising the names of the suppliers of goods/ services being procured,
- c. The works contracts concluded in any such combination of the above-and
- d. The rate /rates and the total amount at which such procurement or works contract is to be executed: Nil

2.2 Manner of execution of subsidy programme

[Section 4(i)(b)(xii)]

- i. Name of the programme of activity
- ii. Objective of the programme
- iii. Procedure to avail benefits
- iv. Duration of the programme/ scheme
- v. Physical and financial targets of the programme
- vi. Nature/ scale of subsidy /amount allotted
- vii. Eligibility criteria for grant of subsidy
- viii. Details of beneficiaries of subsidy programme (number, profile etc)

Nil

2.4 Discretionary and non-discretionary grants

- i. Discretionary and non-discretionary grants/ allocations to State Govt./ NGOs/other institutions
- ii. Annual accounts of all legal entities who are provided grants by public authorities

Nil

2.5 Particulars of recipients of concessions, permits of authorizations granted by the public authority

[Section 4(1) (b) (xiii)]

- i. Concessions, permits or authorizations granted by public authority
- ii. For each concession, permit or authorization granted
 - a. Eligibility criteria
 - b. Procedure forgetting the concession/ grant and/ or permits of authorizations
 - c. Name and address of the recipients given concessions/ permits or authorizations
 - d. Date of award of concessions /permits of authorizations

Nil

2.6 "CAG & PAC paras

CAG and PAC paras and the action taken reports (ATRs) after these have been laid on the table of both houses of the parliament.

Nil

4. Publicity Band Public interface

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 [Section 4(1)(b)(vii)]

Formulation of Policy and Implementation is carried out by Directorate

Arrangement for consultations with or representation by the members of the public

i. Relevant Acts, Rules, Forms and other documents which are normally accessed by

citizens at CDSCO website i.e., https://cdsco.gov.in/ for following information

| S.No. | Type of Information | | | |
|--------|---|--|--|--|
| 0.140. | Type of information | | | |
| 1 | Gazette Notifications | | | |
| 2 | Public Notices | | | |
| 3 | Bioequivalence and Bioavailability | | | |
| 4 | Blood Products | | | |
| 5 | Vaccines | | | |
| 6 | Global Clinical Trial | | | |
| 7 | Ethics Committee | | | |
| 8 | New Drugs | | | |
| 9 | Fixed Dose Combinations (FDCs) | | | |
| 10 | Investigational New Drugs (INDs) | | | |
| 11 | Subsequent New Drugs | | | |
| 12 | Medical Device and In-Vitro Diagnostics | | | |
| 13 | Cosmetics | | | |
| | | | | |

i. Arrangements for consultation with or representation by

- a) Members of the public in policy formulation/policy implementation Formulation of Policy and Implementation is carried out by Directorate
- b) Day & time allotted for visitors
- c) Contact details of Information & Facilitation Counter (IFC) to provide publications frequently sought by RTI applicants

Public Relation office has been established

Centralized PRO is established by Directorate to coordinate with respective division, Zone, Sub-Zone. The contact details are available on CDSCO website, additionally the Hyderabad Zonal office has specified following:

| Office | Designation | Act as | Contact details |
|---|--|-------------------------------------|-------------------------------|
| Officers of CDSCO, Hyderabad Zone | Assistant Drugs Controller (India) CDSCO, Hyderabad Zone | | hyderabad@cdsco.nic.in |
| | Drugs Inspector, CDSCO, Hyderabad Zone | Assisting Officer of the PRO cell | hyderabad@cdsco.nic.in |
| Sr. Officer of CDSCO Sub-Zone, Visakhapatnam | ADCI / Drugs Inspector | Assi ting Officer of PRO cell | vskp.subzone@cdsco.nic. in |

Functions of PRO Office:

- 1. To act as single window for disposal of grievance of stakeholders on regulatory issues.
- 2. To provide information to the innovator regarding regulatory norms.
- 3. To guide, assist handhold investors in various phases of business lifecycle as per existing focus on "Invest India / Make in India" without compromising quality of regulatory oversight.

Public- Private Partnerships (PPP)

- i) Details of Special Purpose Vehicle (SPV), if any
- ii) Detailed project reports (DPRs)
- iii) Concession agreements.
- iv) Operation and maintenance manuals
- v) Other documents generated as part of the implementation of the PPP
- vi) Information relating to fees, tolls, or the other kinds of revenues that may be collected under authorization from the government
- vii) Information relating to outputs and outcomes
- viii)The process of the selection of the private sector party (concessionaire etc.)
- ix) All payment made under the PPP project

Nil

- 2.1 Are the details of policies / decisions, which affect public, informed to them [Section 4(1) (c)] Publish all relevant facts while formulating important policies or announcing decisions which affect public to make the process more interactive;
 - i) Policy decisions/ legislations taken in the previous one year
 - ii) Outline the Public consultation process
 - iii) Outline the arrangement for consultation before formulation of policy

Policy decisions/ legislations is carried out by Directorate (https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/) Formulation of Policy and Implementation is also carried out by Directorate

Dissemination of information widely and in such form and manner which is easily accessible to the public

[Section 4(3)]

Use of the most effective means of communication

Internet (website): https://cdsco.gov.in/ for information like below:

| Sr. No. | Type of Information | | | |
|---------|---|--|--|--|
| 1. | Gazette Notifications | | | |
| 2. | Public Notices | | | |
| 3. | Alerts | | | |
| 4. | Bioequivalence & Bioavailability | | | |
| 5. | Blood Products | | | |
| 6. | Vaccines | | | |
| 7. | Global Clinical Trial | | | |
| 8. | Ethics Committee | | | |
| 9. | New Drugs | | | |
| 10 | Fixed Dose Combinations (FDCs) | | | |
| 11 | Investigational New Drugs (INDs) | | | |
| 12 | Subsequent New Drugs | | | |
| 13 | Medical Device and In-Vitro Diagnostics | | | |
| 14 | Cosmetics | | | |

3.4 Form of accessibility of information manual/ handbook

[Section 4(1)(b)]

Information manual/handbook available in

i) Electronic format

| Sr.No. | Topic | URLs |
|--------|-------|---|
| 1 | | https://cdsco.gov.in/opencms/export/sites/CDSCO WEB/Pdf- |
| | | documents/SUGAM user manual.pdf |

ii) Printed format

Available

3.5 Whether information manual handbook available free of cost or not [Section 4(1)(b)]

List of materials available

i) Free of cost

Electronic format can be accessed through website.

i) At a reasonable cost of the medium

When information required under RTI Act, fees wi1 be charged as per Rule 4 of The Right to Information (Regulation of Fee and Cost) Rules, 2005.

4 E. Governance

4.1 Languages in which Information Manual/Handbook Available

English

4.2 When was the information Manual/Handbook last updated?

Last date of Annual updation
Updation of Manual is carried out by Directorate

4.3 Information available in electronic form

[Section 4(1)(b)(xiv)]

- i) Details of information available in electronic form
- ii) Name/title of the document/record/other information (iii)Location where available

Refer Para 3.3

4.4 Particulars of facilities available to citizen for obtaining information [Section 4(1)(b)(xv)]

i) Name & location of the facility

Central Drug Standards Control Organization, Hyderabad Zonal office, S.R. Nagar, Hyderabad 500 038

i) Details of information made available

All Information available in the public domain of website (www.cdsco.gov.in) Assistance is provided to access required. Information available in the public domain through digitally using online system.

i) Working hours of the facility (MONDAY to FRIDAY)

9.30 AM to 6.00 PM (except Closed holidays)

i) Contact person & contact details (Phone, fax email)

All Information available in the public domain of website (www.cdsco.gov.in) Assistance is provided to access required. Information available in the public domain through digitally using online system.

Phone 04024811481

hyderabad@cdsco.nic.in

4.5 Such other information as may be prescribed under section 4(i) (b)(xvii)

a. Grievance redressal mechanism

Functions of PRO Office:

- 1. To act as single window for disposal of grievance of stakeholders on regulatory issues.
- 2. To provide information to the innovator regarding regulatory norms.
- 3. To guide, assist handhold investors in various phases of business life cycle as per existing focus on "Invest India / Make in India" without compromising quality of regulatory oversight.
- ii) Details of applications received under RTI and information provided

| S.No | Year | RTI applications received | RTI applications disposed |
|------|-----------|------------------------------|---------------------------|
| 1 | 2019 -20 | 1 | 1 |
| 2. | 2020 - 21 | 17 | 17 |
| 3. | 2021 - 22 | 19 | 19 |
| 4. | 2022 - 23 | 12 | 12 |
| 5 | 2023-24 | 7 | 7 |

iii) List of completed schemes/ projects/ Programmes-

This office has not been assigned any Schemes/ Projects/ Programmes.

iv) List of schemes/ projects/ programme underway-

This office has not been assigned any Schemes/ Projects/ Programmes.

v) Details of all contracts entered into including name of the contractor, amount of Contract and period of completion of contract.

i) Annual Report

Annual report of CDSCO is prepared by Directorate by compiling the information received under monthly KPIs from all Zonal and Sub-Zonal offices of CDSCO.

ii) Frequently Asked Question (FAQs) are available on CDSCO website i.e., https://cdsco.Nov.in/

| Sr.No. | Topic | URLs |
|------------|---|---|
| 1 | New Drugs | https://cdsco.gov.in/opencms/opencms/s stem/modules/CDS CO.WEB/elements/download file division.1s ?num id=ND MOMA== |
| | | Additional FAQs: https://cdsco.Nov.in/opencms/opencms/syste m/modules/CDS CO.WEB/elements/download file division.jsp?num id=ND g1Ng=— |
| | A. | https://cdsco.gov.in/opencms/opencms/system/modules/CDS CO.WEB/elements/download file division.jsp?num id=NT U4OA—= |
| 2 | Medical Devices | https://cdsco.gov.in/opencms/export/sites/CD SCO WEB/Pdf-documents/medical- device/Updated-FAQ-MDR 2017.pdf |
| <u>, 3</u> | Phytopharmace uticals | https://cdsco.gov.in/opencms/opencms/syst em/modules/CDSCO.WEB/elements/downlo ad file division.jsp?num id=MzI 0MA=— |
| 4 | Import of small quantities of drugs for the purposes of examination testing or analysis | https://cdsco.gov.in/opencms/opencms/en/ FAO/index.html |
| 5 | Blood Centres | https://cdsco.gov.in/opencms/opencms/en/ FAO/index.html |
| 6 | Cosmetics | https://cdsco.gov.in/opencms/export/sites/CD SCO_WEB/Pdf -documents/cosmetics/FAQcos.pdf |
| 7 | BA/BE | https://cdsco.gov.in/opencms/export/sites/CD SCO_WEB/Pdf -documents/BA_BE/revidsefaqbabe_df |

Contract Period of Services at CDSCO Zonal Office Hyderabad, Microbiology Hyderabad, Airport Office Shamshabad, Visakhapatnam Sub zone Office.

| Re mar ks | | | | | | | | | |
|-------------------------|---------------------------------------|------------------------------|---------------------------------------|--------------------------------------|---------------------------------|--------------------------------|--------------------------------|-------------------------------------|---------------------------------------|
| Amount | 1290101 | 234171 | 670320 | 220185 | 570000 | ã | 477840 | 2353410 | 000006 |
| Service Provider | M/s. AL-Akbar Manpower services | M/s. Axtram services | M/s. AL-Akbar Manpower services | M/s. Dynamic Engineering Works | M/s. Due and Technologies | ŭ. | M/s. Anitha Enterprises | M/s. Metro Management Service | M/s. AL-Akbar Manpower services |
| Order Date | 16.01.2 025 | 20.02.2 | 04.04.2 | 28.03.2 025 | 16.01.2 025 | ď | 25.02.2 025 | 14.08.2 024 | 23.07.2 024 |
| GeM Contract No | GEMC- 511687735232410 | GEMC- 511687711773251 | GEMC- 511687714439617 | GEMC- 511687743134174 | GEMC- 511687790753970 | i | GEMC- 511687772539497 | GEMC- 511687759421032 | GEMC- 511687790170196 |
| End Date | 19.01.2 026 | 23.02.2 | 10.04.2 | 31.03.2 026 | 19.01.2 026 | 4 | 28.02.2 026 | 20.08.2 025 | 31.07.2 025 |
| Start Date | 20.01.20 25 | 24.02.20 25 | 11.04.20 | 01.04.20 | 20.01.20 25 | Ľ | 01.03.20 | 21.08.20 | 01.08.20 |
| Location | CDSCO Zonal Office Hyderabad | Airport office Shamshabad | Microbiology Hyderabad | Visakhapatnam sub zone office | CDSCO Zonal Office Hyderabad | Airport office Shamshabad | Visakhapatnam sub zone office | CDSCO Zonal Office Hyderabad | CDSCO Zonal Office Hyderabad |
| Name of the Contract | Housekeeping Services | Housekeeping Services | Housekeeping Services | Housekeeping Services | Car vehicle Hiring Services | Car vehicle Hiring Services | Car vehicle Hiring Services | Security Services | Horticulture services |
| S. o | 1 | 2 | က | 4 | ιO | 9 | 7 | ∞ | 6 |

LIST OF ANNUAL MAINTENANCE CONTRACTS

| S.No | S.No Details of contract | Name & Address of the | Amount of contract | Period of completion |
|------|----------------------------------|------------------------------|--------------------|----------------------|
| | | contractor | | of contract |
| 1 | Annual Maintenance contract for | M/S. Hetero pest solutions, | @Rs. 8900/- per | 31.03.2025 |
| | the pest control services | Vidya nagar, Hyderabad | month excl.GST | |
| 7 | Annual Maintenance of Electrical | CPWD Hyderabad | 7363100/- | 31.03.2025 |
| | & Equipment of CDSCO Bhavan, | , | | |
| | CDTL & Airport Office, | | | |
| | Hyderabad | | | |
| 3 | Annual Maintenance of | CPWD Hyderabad | 1534900/- | 31.03.2025 |
| | Microbiology Lab | • | | |
| 5 | AMC for | M/s. Indoteq Office | 29736 | 30.06.2025 |
| | Canon IR 2002N Copier | automation systems, | | |
| | | Begumpet, Hyderabad | | |
| 9 | AMC for Printer Canon IR 4525 | M/s. Unicom Infotel Pvt ltd, | 70000/- | 30.09.2025 |
| | Printer -2 | Secunderabad | | |
| 7 | AMC for 4245 copiers | M/s. Indoteq Office | 49560 | 30.06.2025 |
| | | automation systems, | | |
| | | Begumpet, Hyderabad | | |

- iii) Any other information such as
- a) Citizen's Charter
- b) Result Framework Document (RFD)
- c) Six monthly reports on the
- d) Performance against the benchmarks set in the Citizen's Charter

Nil

4.6 Receipt & Disposal of RTI applications & appeals

(i) Details of applications received and disposed

| S.No | Year | RTI applications received | RTI applications disposed |
|------|-----------|---------------------------|---------------------------|
| 1. | 2019 - 20 | 1 | 1 |
| 2. | 2020 - 21 | 17 | 17 |
| 3. | 2021 - 22 | 19 | 19 |
| 4. | 2022 - 23 | 12 | 12 |
| 5 | 2023- 24 | 7 | 7 |

(ii) Details of appeals received and orders issued

| S.No | Year | RTI applications received | RTI applications disposed |
|------|-----------|---------------------------|---------------------------|
| 1 | 2019 - 20 | Nil | Nil |
| 2. | 2020 - 21 | Nil | Nil |
| 3. | 2021 - 22 | Nil | Nil |
| 4. | 2022 - 23 | Nil | Nil |
| 5 | 2023- 24 | Nil | Nil |

4.7 Replies to questions asked in the parliament [Section 4(1)(d)(2)1

Replies to questions asked in the Parliament pertaining to this office are forwarded to Directorate for their compilation.

- 1. Information as may be prescribed
- 5.1 Such other information as may be prescribed
- (i) Name & details of
- (a) Current CPIOs & FAAs
- b) Earlier CPIO & FAAs from 1.1.2015

(i) HOD Appointment of Nodal Officers not below the rank of Joint Secretary/ Additional

(a)

Date of appointment Name & Designation of the officers (b)

| Sr.No. | Designation | Technical/ Administration Matters | Year |
|--------|---|--|---------------------------|
| 1 | Shri A.Chandrasekhar Appellate Authority | Deputy DrugsController (Índia) Email: hyderabad@cdsco.nic.in | 7-7-2011 to 20-1- 2014 |
| 2. | Dr S.Manivannan Appellate Authority | Deputy Drugs Controller (Índia) Email: hyderabad@cdsco.nic.in | 22-1-2014 to 3-2- 2014 |
| 3. | Dr. P.B.N. Prasad, Appellate Authority | Deputy Drugs Controller (India) Email: hyderabad@cdsco.nic.in | 4-2-14 to 19-10- 2017 |
| 4. | Smt A.Vishala Appellate Authority | Deputy Drugs Controller (India) Email: hyderabad@cdsco.nic.in | 20-10-2017 to 11-05-22 |
| 5. | Sh. Dr A Ramkishan Appellate Authority | Deputy Drugs Controller (India) Email: hyderabad@cdsco.nic.in | 12-05-22 to Till Date |

| 1 | Mrs B.Sarla Devi, Central Public Information Officer (CPIO) | Assistant Drugs Controller (India) Email: hyderabad@cdsco.nic.in | Till 23-07-2023 |
|---|---|--|----------------------------------|
| 2 | rD Vinay Kumar Gupta, Central Public Information Officer (CPIO) | Assistant Drugs Controller (India) Email: hyderabad@cdsco.nic.in | 24th July – 2023 to till date |

- ii) Consultancy committee of key stake holders for advice on suo-motu disclosure
 - a. Dates from which constituted

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b. Name & Designation of the officers

No such consultancy committee was constituted so far.

- i) Committee of PIOs/FAAs with rich experience in RTI to identify frequently sought information unde RTI
 - a. Dates from which constituted
 - b. Name & Designation of the Officers

No such consultancy committee was constituted so far.

6. Information Disclosed on own Initiative

Item / information disclosed so that public have minimum resort to use of RTI Act to obtain information

| IIIIOIIIIalioii | | |
|-----------------|---|--|
| S.No. | Type of Information | Related URLs |
| 1 | Gazette Notifications | https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/ |
| 2 | Public Notices | https://cdsco.gov.in/opencms/opencms/en/Notifications/Public-Notices/ |
| 3 | Bio equivalence and Bio availability | https://cdsco.gov.in/opencms/opencms/en/bioequi |
| 4 | Blood Products | https://cdsco.gov.in/opencms/opencms/en/bio1ogica1s/Blood-Products/ |
| 5 | Vaccines | https://cdsco.gov.in/opencms/opencms/en/bio1ogica1s/Vaccines/ |
| 6 | Global Clinical Trial | https://cdsco.gov.in/opencms/opencms/en/Clinica l- Trial/Global-Clinical-Trial/ |
| 7 | Ethics Committee | https://cdsco.gov.in/opencms/opencms/en/Clinical- Trial/Ethics-Committee/ |
| 8 | New Drugs | https://cdsco.gov.in/opencms/opencms/en/Drugs/ New- Drugs/ |
| 9 | Fixed Dose Combinations (FDCs) | https://cdsco.gov.in/opencms/opencms/en/Drugs/ FDC/ |
| 10 | | https://cdsco.gov.in/opencms/opencms/en/Drugs/Investigati onal-New-Drugs-/ |
| 11 | Subsequent New Drugs | https://cdsco.Nov.in/opencms/opencms/en/Drugs/Subsequent-New-Drugs/ |
| 12 | Medical Device and In-Vitro Diagnostics | https://cdsco.gov.in/opencms/opencms/en/Medical- Device- Diagnostics/InVitro-Diagnostics/ |
| 13 | Cosmetics | https://cdsco.gov.in/opencms/opencms/en/Cosmetics/cosmetics/ |

- 6.2 Guidelines for Indian Government Websites (GIGW) is followed (released in February, 2009 and included in the Central Secretariat Manual of Office Procedures (CSMOP) by Department of Administrative Reforms and Public Grievances, Ministry of Personnel, Public Grievance and Pensions, Govt. Of India)
- (i) Whether STQC certification obtained and its validity.
- (ii) Does the websites how the certificate on the Website?
 Website of CDSCO (www.cdsco.gov.in) is maintained Designed, Developed and Maintained by CDAC as per request provider by CDSCO (HQ), New Delhi