Chapter 8

Adequacy and effectiveness of the regulatory mechanism

Highlights

- In State of Chhattisgarh, 16,439 applications were received from the private medical establishments and against these 3,949 licenses were issued and 579 were rejected as of March 2023. District Committee failed to conduct inspection of remaining 11,911 medical establishments that had applied for issue of licences. Due to non-conducting of inspection by District Committee, it could not be ensured that these clinical establishments complied to the minimum standards prescribed in the *UTRSSAA*, 2010.
- Regulatory mechanism framework, has not been developed by the GoCG for monitoring the private medical educational institutions in the State.
- In CGMC, there was shortage of members in the Council ranging from six to nine.
- Pharmacy Inspector was not appointed till July 2022 by the Council for the inspection of drugs dispensation places, inspection of complaint and institute prosecution in the cases of violation of Pharmacy Act, 1948.
- Due to shortage of manpower and infrastructure in FDCA, testing of 80 *per cent* of collected samples were not done within the prescribed limit of 60 days.
- Out of 2,099 Government Healthcare Institutions (HIs) in the State, 766 (36.49 *per cent*) HIs were running and managing BMW at facility level without authorisation of CECB.
- Establishment of ETPs in 120 public HIs was not completed (November 2022) despite advancing funds of ₹ 29.62 crore to CGMSCL.
- Three Autoclave cum Shredders costing ₹ 1.04 crore and supplied to DH Baikunthpur (Korea), CHC Manendragarh and Khadgawa for BMW treatment were kept idle since 2019 as a result, medical waste disposed-off using deep pit and sharp pit methodology.

8.1 Introduction

State Government adopted various Acts and Rules for ensuring constitution of the Councils made for regulatory mechanism in the health delivery system through registration of medical practitioners, maintenance of a register of medical practitioners and issue of certificate of registration in the State.

Implementation of the following Acts have been covered in this chapter:

- Clinical Establishment Act 2010
- Drugs and Cosmetics Act 1940 and Rules 1945
- Bio-Medical Waste Management Rules, 2016

Registration of healthcare professionals in Chhattisgarh is carried out by various State Councils is shown in ***Table - 8.1:***

Table - 8.1: Details of the Councils and their enabling act

Sl. N	Name of the Council	Enabling Act
1	Chhattisgarh Medical Council (CGMC)	a Statutory Body constituted under section 3 of the Chhattisgarh Medical Council Act, 1987 which was notified (26 February 2001) by the Government of Chhattisgarh (GoCG) by exercising the power of section 79 of Madhya Pradesh Reorganisation Act 2000.
2	Chhattisgarh Nurses Registration Council (CGNRC)	a statutory body under the Health & Family Welfare Department of Chhattisgarh. The Chhattisgarh Nurses Registration Council came in force from 21 May 2003 onwards.
3	Chhattisgarh *Ayurvedic Tatha Unani Chikitsa Paddhati Avam Prakritic Chikitsa* Board (CGAUPB)	constituted (28 March 2001) under the Chhattisgarh *Ayurvedic, Unani tatha Prakritic Chikitsa Vyavsai Adhiniyam*, 1970 as adopted by the GoCG.
4	Chhattisgarh Homoeopathy Council (CGHC)	constituted (28 March 2001) under the Chhattisgarh Homoeopathy *Parishad Adhiniyam*, 1976 as adopted by the GoCG.
5	Chhattisgarh Paramedical Council (CGPC)	constituted under the *Chhattisgarh Sah Chikitsa Parishad* Act 2001 by gazette notification
6	Chhattisgarh Dental Council (CGDC)	constituted in Chhattisgarh as stipulated by the Dentist Act 1948.
7	Chhattisgarh Physiotherapy Council (CGPTC)	constituted under Physiotherapy and Occupational Therapy Act, 2015 by the State government on 07 January 2016.
8	Chhattisgarh State Pharmacy Council (CGSPC)	a statutory body constituted by the GoCG under the provisions of the Pharmacy Act of 1948. CGSPC was formed in the year 2003 after the State formation.

8.2 Implementation of the Clinical Establishments Act and Rules in the State

The Central Government passed the Clinical Establishment (Registration and Regulation) Act, 2010 (Act No. 23 of 2010) (CEA, 2010) dated 18 August 2010. The aim of this Act is to provide registration and regulation of clinical establishment with a view to prescribe minimum standards of facilities and services which may be provided by them so that mandate of Article 47 of the Constitution for improvement in public health may be achieved. The GoI further framed the Clinical Establishment (Central Government) Rules, 2012 in May 2012. An Act to provide for licensing of Nursing Home and Clinical Establishment and for matters connected therewith to ensure standardization and thereby achieving improvement of health care services enacted (September 2010) by the GoCG called the Chhattisgarh State *Upcharyagriha Tatha Rogopchar Sambandhi Sthapanaye Anugyapan Adhiniyam*, 2010 (UTRSSAA, 2010) and subsequently notified (August 2013) rules through gazette the Chhattisgarh State *Upcharyagriha Tatha Rogopchar Sambandhi Sthapanaye Anugyapan Niyam*, 2013 (UTRSSAN, 2013).

As per Rule 10 (1) of UTRSSAN, 2013, every clinical establishment, liable to

obtain a license under the Act must fulfill the standards prescribed in schedule (1) appended to these rules, which may be amended from time to time. (2) No clinical establishment shall be allowed to operate without a valid license after the expiry of nine months from the date of notification of these rules. The time period includes the initial three months for application, followed by six months for inspection and rectification of gaps found during the inspection by the district committee. Any delay in the inspection by the district committee beyond nine months from the date of notification of these rules shall entitle the clinical establishment to continue its operation until the inspection is done by the committee.

As per Rule (11) - procedure for issue of license, point 1(c), the supervisory authority shall issue a registration certificate upon receipt of such application with the prescribed fee. The registration certificate shall be valid for a period of six months from the date of issuance.

Point 1(e) - where the establishment is certified to be operating as per the prescribed standards, the supervisory authority shall issue a license under sections 3 and 6 of the Act, which shall be valid for a period of five years, as prescribed under section 8 of the Act.

The deficiencies observed in monitoring and regulatory mechanism in the implementation of *UTRSSAA*, 2010 and *UTRSSAN*, 2013 are discussed in succeeding paragraphs:

(i) Audit observed that 16,439 applications were received from the private medical establishments and against these 3,949 licenses were issued and 579 were rejected as of March 2023. District committee failed to conduct inspection of remaining 11,911 medical establishments that had applied for issue of licences. The timelines prescribed in the *UTRSSAN*, 2013 were not adhered to by the district level authorities while issuing licences. Due to non-conducting inspection by District Committee, it could not be ensured that these clinical establishments were complying to the minimum standards prescribed in the Act.

(ii) The role of GoCG in the private healthcare system was limited to issue of licenses to private HIs under *UTRSSAN*, 2013. There was no system for obtaining periodic returns/MIS regarding healthcare infrastructure, manpower, funding etc., from private hospitals, clinics, diagnosis centre and pathology labs in the State except for reporting notifiable disease and birth death data.

(iii) DME conducts inspection of private medical colleges, and nursing colleges for issuance of essential and eligibility certificates for opening colleges in the private sector, though no regulatory mechanism framework has been developed by the GoCG for monitoring the private medical educational institutions in the State.

(iv) There is no system for obtaining periodic returns/MIS regarding healthcare infrastructure, manpower, funding etc. from private medical educational institutions in the State.

8.3 Registration Services

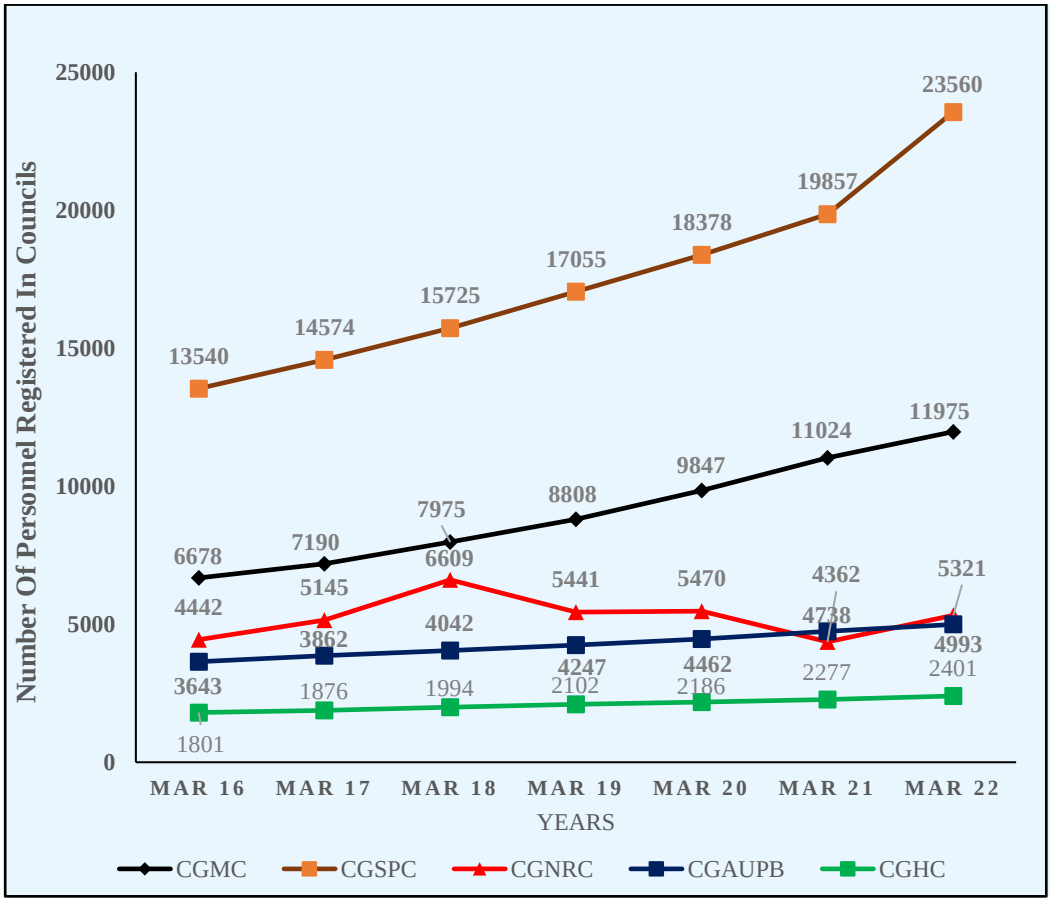
The main function of the various councils is to provide the registration of healthcare professionals, who possess any of the recognized medical qualifications and maintain a register of the same. The year wise status of registered healthcare professionals under various councils is shown in the ***Table - 8.2 and Chart - 8.1***.

Table - 8.2: Details of year wise personnel registered in councils

As on	Number of personnel registered				
	CGMC	CGSPC	CGNRC	CGAUPB	CGHC
March 2016	6678	13540	4442	3643	1801
March 2017	7190	14574	5145	3862	1876
March 2018	7975	15725	6609	4042	1994
March 2019	8808	17055	5441	4247	2102
March 2020	9847	18378	5470	4462	2186
March 2021	11024	19857	4362	4738	2277
March 2022	11975	23560	5321	4993	2401

(Source: Data furnished by the respective councils)

Chart - 8.1: Year wise trend of number of personnel registered in the five councils



No information was furnished by the remaining councils (CGDC, CGPTC, and CGPC) regarding the year wise number of registrations in the councils.

8.4 Deficiencies in functioning of councils

The major deficiencies observed in the functioning of councils are as below:

- Section 4 of the Chhattisgarh Medical Council Act, 1987 stipulates that CGMC shall consist of 11 members. Audit however, observed that except during the year 2020-21, the composition of the members of the council was less than the required number of members which ranged between six and nine during the period 2016-22.
- Section 8 stipulates that the council shall meet at least twice in each year, it was however observed that no meeting was conducted during the year 2019-20. The Registrar, CGMC stated that the quorum of the meeting was fulfilled in the presence of six members, and due to the Covid pandemic, meeting of the Council was conducted through video conferencing in the year 2019-20. However, Minutes of meeting for the year 2019-20 was not produced to audit.
- Section 48 of Chhattisgarh State Pharmacy Council's Rules 1978 stipulates that Chhattisgarh State Pharmacy Council will hold meetings twice in a calendar year. It was however observed that no meetings were held in the year 2020 and 2021.
- No information was furnished by Chhattisgarh Dental Council, Chhattisgarh Paramedical Council, Chhattisgarh Physiotherapy Council regarding meeting of the Council.
- As per section 26A of the Pharmacy Act 1948, Chhattisgarh Pharmacy Council has to appoint Inspectors to inspect any premises where drugs are compounded or dispensed; enquire whether a person who is engaged in compounding or dispensing of drugs is a registered pharmacist; investigate any complaint made in writing in respect of any contravention of this Act; institute prosecution under the order of the Executive Committee of the State Council and submit a written report to the Registrar; however Audit observed that no Pharmacy Inspector was appointed till July 2022 by the Council for the inspection of drugs dispensation places, inspection of complaint and to institute prosecution in the cases of violation of Pharmacy Act, 1948.

8.5 Functioning of Food and Drug Administration in Chhattisgarh

Food and Drugs Control Administration (FDCA) under the Department is discharging its mandate to have effective and efficient control over the illegal import, manufacture, sale and distribution of not of standard quality, misbranded, spurious, adulterated and banned drugs and adulterated and unsafe food products in the State by implementing various Acts and Regulations *viz*., Drugs and Cosmetic (D&C) Act 1940 and Rule 1945, the Drug (Price control) order 2013, Drugs and Magic Remedies Act,1954, Food Safety and Standards (FSS) Act 2006 and Food Safety and Standards Rules, 2006 to safeguard public health.

As on 31 March 2022, there were 27 District Offices of FDCA in the State. The District Offices also issue drug licenses for the establishment of drug manufacturing units, medical shops drug licenses, blood banks, medicine shops

except Indian System of Medicines (ISM) and drug stores for a period of five years to the applicants who fulfill the required criteria. This license is renewed after five years on the basis of an application received from the applicants.

- ***Inspection of Drug Selling Units:*** Drug and Cosmetic Rules provides that Drug Inspectors (DIs) shall inspect all premises licensed for sale of drugs not less than once in a year. Details of number of drugs selling units inspected in the State by the DIs during 2017-22 are given in ***Table - 8.3***:

Table - 8.3: Statement showing year wise shops and number of units inspected

Year	No. of Shops	Number of units Inspected	Percentage of units Inspected
2017-18	10358	9804	94.65
2018-19	11054	9257	83.74
2019-20	12262	10178	83.00
2020-21	13999	8041	57.43
2021-22	14727	8663	58.82

(Source: Compiled from information provided by the pharmacy council)

It could be seen from the above table, that though the number of selling units increased by 42 *per cent* from 2017-18 to 2021-22, the percentage of inspections conducted by the DIs had decreased to 58.82 *per cent* during 2021-22 as against 95.65 *per cent* during 2017-18.

- ***Analysis of Drug and Cosmetic Samples:*** As per guidelines issued by the FDCA, samples should be lifted from clinics/ hospitals/ dispensaries/ nursing homes and report of the same should be given within 60 days from receipt of the sample.

Audit observed that there was only one laboratory at Raipur in the State for testing of food and drugs sample. Due to shortage of manpower and infrastructure, testing of 80 *per cent* of collected samples were not done within the prescribed limit of 60 days.

The details of sample taken as of March 2022 and inspected drugs during 2017-22 is as detailed in ***Table - 8.4***:

Table - 8.4: Year wise drugs sample taken, tested and rejected

Year	Sample taken during the year	Outstanding from previous year	Total samples	Total rejected	Sample tested	Total under process
1	2	3	4 (2+3)	5	6	7 (4-5-6)
2017-18	377	31	408	12	286	110
2018-19	423	110	533	07	458	68
2019-20	884	68	952	35	480	437
2020-21	816	437	1253	41	689	533
2021-22	608	533	1141	43	591	507

(Source: Compiled from information provided by drugs testing laboratory, Raipur)

- ***Idling of Equipment at Laboratory:*** One Fourier Transform Infrared (FTIR) spectroscopy machine costing ₹ 18.61 lakh and one Atomic Absorption Spectroscopy (AAS) machine costing ₹ 21.44 lakh was supplied and installed at the laboratory on 21 June 2013 and on 13 March 2014 respectively.

Audit observed that the FTIR machine was not put to use due to technical problems with the instrument. Further, the AAS was not in working condition either, due to fault in instrument wiring and technical issues in UPS, motherboard.

8.6 Bio Medical Waste Management

With the objective of providing a regulatory framework for management of Bio-Medical Waste (BMW) generated in the country, the Ministry of Environment and Forests, GoI framed (July 1998) the Bio-Medical Waste (Management and Handling) Rules, 1998 under the Environment (Protection) Act, 1986. Thereafter, GoI reviewed these rules and with the objective of implementing these rules more effectively, to improve the collection, segregation, processing, treatment and disposal of these bio-medical wastes in an environmentally sound management, thereby reducing the bio-medical waste generation and its impact on the environment, framed a more comprehensive set of Rules in supersession of the existing rules called 'Bio-Medical Waste Management Rules, 2016' (BMWM Rules) in March 2016. These Rules prescribe the procedures for handling, treatment and disposal of BMW generated by hospitals, nursing homes, blood banks, veterinary institutions, etc.

Under Rule 10 of the BMW Rules, every state government is required to establish a prescribed authority for granting authorization and implementing BMW Rules. In compliance with this codal provision, Chhattisgarh Environment Conservation Board (CGECB) was constituted in 2001. CGECB is responsible for enforcing and monitoring the implementation of these rules in respect of all healthcare facilities. Audit noticed in test checked districts that BMW was being dumped in open areas at CHC Arang and DH Kondagaon.

BMW is generated during procedures related to diagnosis, treatment and immunisation in the hospitals and its management is an integral part of infection control within the hospital premises. The Bio-Medical Waste Management Rules, 2016 (BMWM) framed by GoI inter alia stipulate the procedures for collection, handling, transportation, disposal and monitoring of the BMW with clear roles for waste generators and Common Bio-Medical Waste Treatment Facility (CBWTF). Details of HIs available, BMW generated and CBWTF operated in the State as per the records of CECB is shown in ***Table - 8.5***:

Table - 8.5: Details of HIs, BMW generated and CBWTF operated in the State including Government HI and Private HI

Calendar Year	Number. of HIs (Bedded)	Number of His (Non-Bedded)	Total HIs	Generation of waste per day (in KG)	No of HIs have captive treatment and disposal facility	No. of CBWTF
2017	307	248	555	1104.49	289	4
2018	254	324	578	853.91	319	4
2019	1186	687	1873	3743.06	1620	4
2020	2529	1879	4408	7234.31	1483	4
2021	1924	2404	4328	7906.73	1816	4

(Source: Data collected from Chhattisgarh Environment Conservation Board)

Audit observed that generation of waste had increased seven times during 2017-21. However, the number of CBWTF remained constant during the same period. Thus, the number of CBWTC needs to be increased for effective management of BMW in the State.

(a) Operation of Healthcare Institutions without Authorization

Rule 10 of BMWM Rules, 2016 provides that every occupier or operator handling BMW, irrespective of quantity must make an application to Chhattisgarh Environment Conservation Board (CECB) for grant of authorisation. Rule 4(j) provides segregation of the waste at source and its pre-treatment or neutralisation prior to mixing with other effluent generated from hospitals.

Audit observed that out of 2,099 Government HIs in the State, 766 (36.49 *per cent*) HIs were running without authorisation of CECB. The details of HIs running without authorisation in the test-checked districts are depicted in the following ***Table - 8.6:***

Table - 8.6: Details of HIs operating without authorization

District	No of HIs	Nos. of HIs running without proper authorization	HIs running without proper authorization (in *per cent)*
Balod	102	20	19.60
Bilaspur	123	47	38.21
Kondagaon	53	26	49.05
Korea	67	31	46.26
Raipur	123	51	41.46
Sukma	30	2	6.66
Surajpur	59	42	71.18
Total	**557**	**219**	**39.32**

(Source: As per data provided by CECB)

It is evident from ***Table - 8.6*** that in the test checked districts, Government HIs ranging between 6.66 *per cent* (Sukma) and 71.18 *per cent* (Surajpur) of total HIs, were running without proper authorisation.

(b) Status of authorisation of selected GMCHs and DKS PGI

The main objective of Effluent Treatment Plant (ETP) is to remove as much of the suspended solids and organic matter as possible before the water is discharged back to the environment or re-used for various hospital purposes. When untreated wastewater mixes with groundwater it can create significant health risks by causing serious infectious diseases to people who have suppressed immune systems.

Status of authorization under BMW Management Rules and establishment of Effluent Treatment Plant (ETP) are mentioned in following ***Table – 8.7***:

Table - 8.7: Status of authorisation by CECB, ETP availability, BMW and segregation of waste in color coded bin

GMCHs	Authorisation from CECB	ETP availability	Management of bio medical waste	Segregation of waste in color coded bins
Ambikapur	No	No	Facility level	Yes
Bilaspur	No	No	CBWTF	Yes
Jagdalpur	Yes	Yes	Facility level	Yes
Raipur	No	No	CBWTF	Yes
Rajnandgaon	No	Yes	CBWTF	Yes
DKS PGI Raipur	Yes	No	CBWTF	Yes

(Source: Information compiled from selected GMCHs and DKS PGI)

It could be seen from the above table that GMCH Ambikapur, Bilaspur, Raipur and DKS PGI Raipur did not have effluent treatment facility and thus the entire liquid and chemical wastes were being discharged into the public drains by these four GMCHs without chemical treatment in violation of BMWMR. One GMCH, Rajnandgaon did not obtain authorization from CECB for operating ETP facility.

The Government stated (April 2023) that ETP construction work has been completed in GMCH Bilaspur. In GMCH Ambikapur, BMW treatment has been outsourced and instructions have been issued to GMCH Raipur and DKS PGI for taking necessary action to comply with BMWMR.

Fact remains that GMCHs did not obtain authorisation from CECB and ETP was still not established in GMCH Ambikapur, Raipur and DKS PGI Raipur.

(c) Bio-Medical Waste handling in test checked DHs

Audit noticed that two out of seven test checked DHs handled BMW through CBTWF and remaining five DHs managed at facility level through deep pit and sharp pit. DH Kondagaon, Sukma and Surajpur did not obtain authorisation from CECB under BMW Rules.

Audit noticed in joint physical verification that waste was being dumped in open area in CHC Arang and DH Kondagaon as shown in the ***Photograph number 1 and 2:***

1. CHC Arang, Raipur (08 May 2023)

2. DH Kondagaon (22 May 2023)

It was further observed that the NHM earmarked (2018-19) funds of ₹ 3.68 crore (₹ 16 lakh per unit) to install ETP in 23 DHs (100 bedded) and transferred (October 2018) ₹ 3.65 crore to CGMSCL for this purpose. The DHS further transferred (October 2020 and February 2022) ₹ 25.97 crore for installation of 199 ETP in CHCs/ Civil Hospitals.

Audit observed that even after lapse of four years, installation of ETPs in 120 HIs had not been completed (November 2022). Non-installation of the ETP has not only led to non-compliance with the provisions of BMWMR but has also enhanced the risk of infectious diseases due to unscientific disposal of BMW.

It is pertinent to mention that due to non-segregation of BMW and non-installation of ETP, CECB imposed (June 2020) the environment compensation of ₹ 19.25 lakh on DH Kanker.

DHS stated (January 2023) that the installation of ETPs in all the DHs and CHCs is in progress. DHS has been continuously monitoring the progress of ETP installation.

The reply indicates that HIs were being operationalized without ETP.

(d) Non obtaining authorisation resulted in idling of equipment of ₹1.04 crore

Before establishing a captive Biomedical Waste Treatment Facility, the HI must take the authorisation from the CECB under BMWM Rules, 2016.

Audit observed that CMHO, Korea (Baikunthpur) procured (March 2019) three Autoclave cum Shredder costing ₹ 1.04 crore and supplied to DH Baikunthpur (Korea), CHC Manendragarh and Khadgawa for biomedical waste treatment. However, even after lapse of three years, mandatory authorization from CECB was not obtained and high value equipment worth ₹ 1.04 crore were kept idle as shown in photograph number 3 and 4:

3. CHC Khadgawa, Korea (Date 03 May 2022)

4. Autoclave cum Shredder, DH Baikunthpur, Korea (05 May 2022)

The DHS assured (January 2023) that corrective action will be taken to operationalize the equipment.

Conclusion

District Committee did not conduct inspection of 11,911 private medical establishments within a time limit stipulated under *Upcharyagriha Tatha Rogopchar Sambandhi Sthapanaye Anugyapan Adhiniyam*, 2010 *(UTRSSAA*, 2010) and *Upcharyagriha Tatha Rogopchar Sambandhi Sthapanaye Anugyapan Niyam*, 2013 (*UTRSSAN*, 2013).

Pharmacy inspectors were not appointed till July 2022 by the Pharmacy council for the inspection of drugs dispensation places, inspection of complaint and to institute prosecution etc., in the cases of violation of Pharmacy Act, 1948

In FDCA, shortage of manpower of drug inspectors (30 *per cent*) and in drug testing laboratory (97 per cent) resulted in less inspection of medical shops, short collection of samples and delay in testing of samples collected indicating lack of control to ensure quality of drugs.

Out of 2,099 Government HIs in the State, 766 (36.49 *per cent*) HIs were managing Bio Medical Waste at facility level without obtaining authorisation from Chhattisgarh Environment Conservation Board.

Establishment of Effluent Treatment Plants (ETPs) in 120 HIs out of 222, had not been completed (November 2022) despite release of funds of ₹ 29.62 crore by the Director Health Services.

Three Autoclave cum Shredder costing ₹ 1.04 crore and supplied to DH Baikunthpur (Korea), CHC Manendragarh and Khadgawa for biomedical waste treatment were kept idle since 2019. As a result, medical wastes were disposed off using deep pit and sharp pit methodology.

Recommendations

The GoCG should:

37. ***ensure the inspection of private medical establishments by District Committee within a time limit stipulated under the UTRSSAA, 2010 and UTRSSAN, 2013;***

38. ***appoint the Pharmacy Inspectors and Drug Inspectors in Pharmacy Council and FDCA for monitoring of drugs dispensation and inspection of medical shops to ensure quality of drugs dispensed in public health facilities in compliance to relevant Acts; and***

39. ***make efforts to establish ETP in all HIs and obtain authorisation from CECB for all Government HIs in the State for handling Bio Medical Waste.***