Chapter-VIII

Adequacy and effectiveness of the regulatory mechanisms

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National Health Accounts[1] (NHA) is a tool to describe health expenditures and flow of funds in both Government and private sector in the country. Focus of NHA is on describing (1) entities[2] that provide resources to spend for health goods and services in the health system; (2) entities[3] receiving and managing funds from financing sources to pay for or to purchase health goods and services; (3) entities[4] receiving finances to produce/provide health goods and services; and (4) use of funds across various healthcare services[5].

NHA shows the expenditure incurred through Government sector as well as private sector to provide healthcare. Thus, the role of Government is not limited to Government hospitals but also to regulate the private sector hospitals, clinics, pharmacies, etc. in the healthcare sector. Therefore, the existence of regulatory mechanism is important to protect healthcare consumers from health risks, provide a safe working environment for healthcare professionals and ensure public health and welfare provided through health programmes.

Regulatory agencies monitor individual and corporate healthcare practitioners and facilities, inform the government about changes in the way the healthcare industry operates, ensure higher safety standards and attempt to improve healthcare quality and follow local, State and Central guidelines. With a view to check the adequacy and effectiveness of the regulatory mechanisms, implementation of the following Acts/Rules have been analysed in audit:

- Clinical Establishment (Registration and Regulation) Act, 2010;
- Standards prescribed under National Medical Commission Act, 2019;
- Drugs and Cosmetics Act, 1940 and Rules, 1945; and
- Bio-Medical Waste Management Rules, 2016.

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1 National Health Accounts (NHA) Estimates for India for the financial year 2018-19 released in the year 2022.

2 (a) Union Government: 11.71 *per cent;* (b) Enterprises: 5.51 *per cent;* (c) Others: 2.03 *per cent;* (d) State Government: 19.63 *per cent*; (e) Local Bodies: 1.01 *per cent;* and (f) Household Revenues: 60.11 *per cent.*

3 (a) Other Schemes: 5.07 *per cent*; (b) Private Health Insurance: 7.25 *per cent;* (c) Union Government: 11.30 *per cent;* (d) Government Health Insurance (GHI): 6.04 *per cent;* (e) State Government: 14.27 *per cent;* (f) Local Bodies: 2.84 *per cent;* and (g) Out of Pocket Expenditure: 53.23 *per cent.*

4 (a) Providers of Preventive Care: 5.34 *per cent; (*b) Government Hospitals: 17.34 *per cent;* (c) Others: 2.49 *per cent;* (d) Private Hospitals: 28.69 *per cent;* (e) Patient Transport: 3.50 *per cent;* (f) Government Clinics: 7.75 *per cent;* (g) Private Clinics: 4.37 *per cent*; (h) Diagnostic Labs: 3.92 *per cent;* (i) Pharmacies: 22.60 *per cent;* and (j) Admin Agencies: 4.00 *per cent.*

5 (a) Governance and Administration: 3.96 *per cent;* (b) Preventive Care: 9.44 *per cent;* (c) Other functions: 3.03 *per cent;* (d) Pharmaceutical and other medical goods: 22.49 *per cent;* (e) Patient transport: 3.50 *per cent;* (f) Inpatient Curative Care: 34.55 *per cent;* (g) Outpatient Curative Care: 18.86 *per cent;* and (h) Lab and Imaging: 4.17 *per cent.*

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

8.1.1 Clinical Establishment Act

The Central Government passed the Clinical Establishments (Registration and Regulation) Act, 2010 (Act No. 23 of 2010) (CEA, 2010) dated 18 August 2010. It is considered expedient 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 State Governments were to adopt this Act. Section 56 of the Act *ibid* provides that the provisions of this Act shall not apply to the States in which the enactments specified in the Schedule are applicable. As per the Schedule, Punjab State has its own Act i.e. "The Punjab State Nursing Home Registration Act, 1991".

Audit observed that 'The Punjab State Nursing Home Registration Act, 1991' was never enacted and hence, no rules were ever framed thereunder. It was, however, noticed that The Punjab Clinical Establishments (Registration and Regulation) Act, 2020 was enacted in October 2020, however, rules thereunder were not framed (July 2022). Thus, it is evident that healthcare facilities in the State have been functioning in an unregulated manner.

The provisions of the Act are meant to act as a deterrent against quackery and unethical practices. Due to delay in implementation of the Act *ibid,* the following issues remained unresolved:

- Absence of Punjab State Master Register of Clinical Establishments;
- Non-setting up of minimum standards of facilities and services including emergency care and referral services;
- Non-setting up of Fair Price Medicine Shop and a Fair Price Diagnostic Centre by every clinical establishment having more than one hundred beds;
- Missing active participation of the clinical establishment in the implementation of all National and State Health Programmes;
- Non-compliance with all the applicable laws including any rules, regulations, instructions, guidelines, notifications, circulars, by-laws, etc. by clinical establishment; and
- Non-providing of first aid to all the victims of road traffic accidents, rail accidents, air accidents, explosions, natural disasters and calamities who come or are brought to the clinical establishment.

On being pointed out, the Department admitted (December 2022) the facts in the exit conference.

8.1.2 Registration of Private Clinics/Hospitals in the State under Clinical Establishment Act, 2020 was restricted to Clinics/ Hospitals with more than 50 beds

As per provision of Section 2(a) of the Punjab Clinical Establishments Act, 2020, clinical establishment means "a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services and facilities providing diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognised system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not", and shall include a clinical establishment owned, controlled or managed by (a) a Government or a department of the Government; (b) a trust, whether public or private; (c) a corporation (including a society) registered under a Central, Provincial or State Act, whether or not owned by the Government; (d) a local authority; and (e) a single doctor.

Further, as per the provision of Section 11, no person shall keep or carry on a clinical establishment without being duly registered by the concerned registration authority in respect thereof.

However, as per Section 8(i) of Punjab CEA, clinical establishments with one hundred or more beds only are required to be registered and subsequently this limit was revised (June 2021) to more than 50 beds through a notification issued by the State Government. Accordingly, private clinics or establishments which have bed capacity up to 50 beds are not required to be registered. However, there is no exclusion in this regard for any clinical establishment in terms of bed capacity or otherwise in the CEA 2010 (Central Act). The prescribed minimum standards of facilities and services cannot be ensured in unregistered clinical establishments having bed capacity up to 50 beds. Also, as rules were not framed, there is no methodology/mechanism to check those that are unregistered. Unless rules are framed, the Act cannot be operationalised.

Thus, the objective for registration and regulation of clinical establishments to prescribe minimum standards of facilities and services remained unfulfilled.

On being pointed out, the Department admitted (December 2022) the facts in the exit conference.

8.2 Directorate of Medical Education and Research

The Directorate of Medical Education and Research, Punjab was established in 1973. The main aim of this Directorate is development of medical manpower, quality education in the field of medicine and preparation of specialist and super-specialist doctors in the State to improve the standard of medical education and promote research activities in the medical colleges of Punjab State.

The shortcomings observed in regulatory role of the Director, Medical Education and Research (DMER) are discussed in the succeeding paragraphs:

8.2.1 Establishment and infrastructure of Medical Education Institutes

In exercise of the powers conferred by Section 33 of the Indian Medical Council Act, 1956, the Medical Council of India with the previous sanction of the Central Government formulated the 'Minimum Requirements for 150[6]/200/250 MBBS Admissions Annually Regulations, 2010' (amended up to January 2018) with an objective to establish the minimum requirements for accommodation in the college and its associated teaching hospitals, staff (both teaching and technical) and equipment in the college departments and hospitals.

Further, the National Medical Commission[7] Act (NMC), 2019 provides for a medical education system that improves access to quality and affordable medical education, ensures availability of adequate and high-quality medical professionals and enforces high quality and ethical standards in all aspects of medical services. In exercise of power conferred by Section 57 of NMC Act, 2019 (Act No. 30 of 2019), the 'Minimum Requirements for Annual MBBS Admissions Regulations, 2020' were notified by NMC in October 2020. These Regulations are applicable for the Medical Colleges being established from the academic session 2021-22 onwards.

In pursuance of these Regulations, all four Government Medical Colleges were recognised in the State. However, shortcomings in minimum requirements (infrastructure and buildings) as prescribed by NMC were benchmarked with respect to 'Minimum Requirements for 150/200/250 MBBS Admissions Annually Regulations, 2010' in three[8] educational institutes (Medical Colleges), as shown in **Table 8.1**.

Table 8.1: Status of facilities not available in Medical Colleges

Name of College	Particulars as per Schedule I of Regulations, 2010	Requirement as per provision	Actual position
GMCH, Amritsar	Lecture Theatre	Lecture theatre (preferably air-conditioned) – Minimum four (three with seating capacity of 300 students and one in the hospital with capacity for 300 student)	Four lecture theatres with capacity of 150 students each
	Examination Hall	Three (capacity of 250 with 250 Sqm. each)	Two examination halls with capacity of 250 are available

6 'Minimum Requirements for 150 MBBS Admissions Annually Regulations, 1999' were applicable.

7 Earlier named as Medical Council of India.

8 The fourth Government Medical College i.e. Dr. B.R. Ambedkar State Institute of Medical Science, SAS Nagar, which started admissions of 100 MBBS students from the academic year 2021-22, on which 'Minimum Requirements for 150/200/250 MBBS Admissions Annually Regulations, 2020' were applicable. Though new building of the Medical College was under construction, it was functioning in the State Training Institute of Punjab and was attached with the existing District Hospital, SAS Nagar.

Name of College	Particulars as per Schedule I of Regulations, 2010	Requirement as per provision	Actual position
	Central Workshop	Central workshop having facilities for repair of mechanical, electrical and AC and Refrigeration equipment of college and the hospitals	Not available
	Rural Health Training Centre	Health Centre shall be within a distance of 30 kms with separate residential arrangements for boys, girls and interns and mess facilities. Hostel accommodation shall be provided for 10 *per cent* of annual intake	Hostel arrangement in Rural Health Training Centre is not available
	Day Care Centre	Day care centre with adequate facilities for taking care of the infants and the children of female students/working personnel and patients	Not available
Guru Gobind Singh Medical College, Faridkot	Administrative Block	Separate common room for Male and Female students with attached toilets (150 Sq.m. each)	Not available
	Central Library	Seating arrangement for at least 300 students	For 200 students only
		One Room for 150 students (inside)	For 100 students only
		One Room for 150 students (outside)	For 100 students only
	Lecture Theatre	Lecture theatre (preferably air-conditioned) – Minimum four with seating capacity of 180 students and one with capacity of 200 students	One with capacity of 240 seats Three with 180 seats (each)
	Biometric fingerprint attendance	Fingerprint attendance machine for capturing faculty attendance, using Online Faculty Attendance Monitoring Systems (OFAMOS) under the Digital Mission Mode Project (DMMP)	Not available
Government Medical College, Patiala	Administrative Block	Separate common room for Male and Female students with attached toilets (200 Sqm. each)	Not available
	Central Photographic Section	Central Photographic Section and audiovisual section with accommodation for studio, dark room, enlarging and Photostat work along with facilities for microphotography and mounting	Not available
	Incinerator	An incinerator plant commensurate with hospital bed strength	Not available
	Intercom Network	Intercom network including paging and bleep system between various sections, hospitals and college shall be provided for better services, coordination and patient care	Not available
	Day care centre	Day care centre with adequate facilities for taking care of the infants and the children of female students/working personnel and patients	Not available

Source: Information supplied by DMER

Colour Code:

Green denotes 'least shortage'
Yellow denotes 'moderate shortage'
Red denotes 'most shortage'

The reply of the State Government was awaited (February 2024).

8.3 Drug Controller of the State

The Commissionerate, Food and Drugs Administration, Punjab (FDA) is a Regulatory Agency under DH&FW. It regulates the manufacture of drugs and cosmetics and sale of drugs in the State. The mission of the FDA is to protect public health and to strive for pharmaceutical excellence by ensuring the availability of safe, effective and quality drugs. FDA is responsible for implementation and enforcement of the Central Act, namely 'Drugs and Cosmetics Act, 1940' and Rules framed thereunder.

Some important responsibilities of the FDA include grant of manufacturing and sales licenses for Allopathic Drugs (Modern Medicine) through inspection; monitoring of quality of medicines and cosmetics through routine and statutory sampling; post-marketing surveillance; detection of spurious, adulterated and misbranded drugs and cosmetics; conducting investigation of complaints and filing prosecution against the offenders; etc.

8.3.1 Shortfall in inspections of manufacturing/selling units by Drug Inspectors

Rules 51 and 52 of Drugs and Cosmetics Rules, 1945 provide that Drug Inspectors (DI) should inspect the manufacturing and selling units minimum once in a year to ensure compliance of conditions of license.

Scrutiny of records of Zonal Licensing Authority (ZLA), Bathinda out of six selected ZLAs revealed that against the due 3,360 inspections of selling units, 2,802 inspections were carried out by the DIs during 2016-2021 resulting in shortfall of 558 inspections (17 *per cent*). Moreover, against 45 due inspections of manufacturing units during 2016-21, only 34 inspections were carried out which resulted in shortfall of 11 inspections (24 *per cent*) of manufacturing units due to shortage of DIs. DIs carried out the requisite inspections in the remaining five sampled districts.

On being pointed out, the Department admitted (December 2022) the facts in the exit conference.

8.3.2 Selling/Manufacturing without valid/renewed license

Section 27(b) of Drugs and Cosmetics Act, 1940 provides for punishment in case of manufacture and sale of drugs without a valid license as required under Clause(c) of Section 18.

Audit observed from FDA records that during the inspections carried out by the Drug Inspectors during 2016-2022 that 160 selling/manufacturing units were running without valid/renewed licenses. Of these, eight cases were under investigation and in three cases, the investigation was completed but further

action in the Court of law was yet to be initiated and in the remaining cases, action was taken with delay up to 1,427 days.

On being pointed out, the Department admitted (December 2022) the facts in the exit conference.

8.3.3 Delay in grant of license to new manufacturing units

For grant of license for manufacturing drugs, Commissioner, Food and Drugs Administration, Punjab fixed (January 2019) timeline of 60 days from the date of application.

During test-check of records of Joint Commissioner (Drugs), Punjab, it was noticed that the licenses were granted to the following manufacturing units with delay ranging between 16 days and 354 days as detailed in **Table 8.2**.

Table 8.2: Details of delay in granting licenses to manufacturing units

Sr. No.	Name of Manufacturing unit	Date of application	Date of grant of license	Delay (in days)
1.	Henkel Solutions	05.04.2017	24.05.2018	354
2.	Prolific Consumer Healthcare	20.02.2018	07.05.2018	16

Source: FDA, Punjab

Audit further noticed that licenses were issued late due to delay in inspections as well as compliance of shortcomings by the applicant firms.

On being pointed out, the Government admitted (December 2022) the facts in the exit conference.

8.4 Bio-Medical Waste Management

Government of India in exercise of the powers conferred by the Environment (Protection) Act, 1986 and in supersession of Biomedical Waste (Management and Handling) Rules, 1998, published the Bio-Medical Waste Management Rules, 2016 (BMW Rules) on 28 March 2016. These Rules stipulate duties of the occupier or operator of a common Bio-medical Waste Treatment Facility as well as the identified authorities. These rules apply to all persons who generate, collect, receive, store, transport, treat, dispose or handle bio-medical waste in any form including healthcare facility. Punjab Pollution Control Board (PPCB) has been entrusted with the task of implementation of environment laws in the State of Punjab, which includes implementation of BMW Rules framed under the provisions of Environment (Protection) Act, 1986.

As per BMW Rules, "Bio-medical waste" means any waste, which is generated during the diagnosis, treatment or immunisation of human beings or animals or research activities. "Bio-medical waste treatment and disposal facility" means

any facility wherein treatment, disposal of bio-medical waste or processes incidental to such treatment and disposal are carried out and includes common bio-medical waste treatment facilities. "Healthcare facility" (HCF) means a place where diagnosis, treatment or immunisation of human beings or animals is provided irrespective of type and size of health treatment system and related research activity. "Occupier" means a person having administrative control over the institution and the premises generating bio-medical waste. "Operator of a common bio-medical waste treatment facility" means a person who owns or controls a Common Bio-medical Waste Treatment Facility (CBMWTF) for the collection, reception, storage, transport, treatment, disposal or any other form of handling of bio-medical waste.

During scrutiny of records of Punjab Pollution Control Board (PPCB), it was noticed that the Department was publishing on its website the list of authorised HCFs with regard to BMW generation treatment and disposal. Further, the Department has adopted bar coding and GPS system for tracking purpose of bio-medical wastes. Though no specific grievance redressal mechanism with regard to bio-medical waste management was in operation, however, all types of complaints related to various types of pollution received through the online portal were being disposed of after taking required action.

However, some shortcomings with regard to the authorisation and operation of HCFs were noticed which are being discussed in the succeeding paragraphs:

8.4.1 Health Care Facilities generating Bio-Medical Wastes without obtaining authorisation from PPCB

Section 10 of Bio-Medical Waste Management Rules, 2016 provides that every occupier or operator handling bio-medical waste, irrespective of the quantity shall apply to PPCB, for grant of authorisation, who shall grant the provisional authorisation. Further, Section 13(1) of these rules provides that every occupier or operator of common bio-medical waste treatment facility shall submit an annual report to the prescribed authority on or before 30th of June of every year, giving the details of the respective treatment facility including location, waste quantities generated, etc. This information is to be compiled, reviewed and analysed for the whole State and sent to the Central Pollution Control Board on or before 31st July every year. Besides, Section 15 of the Environment (Protection) Act, 1986 stipulates that failure to comply with or contravention of any of the provisions of this Act shall be punishable with imprisonment for a term which may extend to five years with fine which may extend to one lakh rupees, or with both.

From the annual reports on Bio-medical Waste Management submitted by PPCB, it was noticed that there were many HCFs which were in operation without applying for authorisation from PPCB. It was further noticed that all the

authorised HCFs were not submitting the annual reports. The year-wise details of such HCFs are shown in **Table 8.3.**

Table 8.3: Operation of HCFs without authorisation during the period 2016 to 2021

Year	Total Number of HCFs in operation	Number of HCFs operating without authorisation	*Percentage* of HCFs operating without authorisation	Number of Occupiers who did not submit annual report	*Percentage* of non-submission of annual report
2016	6,475	1,875	29	2,233	34
2017	7,137	1,987	28	4,262	60
2018	8,234	3,765	46	4,165	51
2019	9,595	5,193	54	5,465	57
2020	12,554	2,314	18	8,066	64
2021	13,426	1,519	11	8,550	64

Source: Information/data furnished by PPCB

From the above table, it is evident that during 2016 to 2021, HCFs ranging between 11 *per cent* and 54 *per cent* were operating without authorisation. Further, non-submission of annual reports by HCFs was on an increasing trend, which ranged between 51 *per cent* and 64 *per cent* with an average of 6,561 units during the years 2018-2021. This indicates inadequate compliance of the regulatory mechanism on Bio-Medical Waste Management in the State and non-adherence to the provisions of Section 15 of the Environment (Protection) Act 1986.

On being pointed out, the Department admitted (December 2022) the facts in the exit conference.

8.4.2 Non-conduct of third-party audit of the existing Common Bio-Medical Waste Treatment Facilities (CBWTF)

Schedule-III of Bio Medical Waste Management Rules, 2016 specifies that it is the duty of State Pollution Control Board to undertake and support third party audits of the Common Bio-Medical Waste Treatment Facilities (CBWTF) in the State.

During scrutiny of records of PPCB, as per annual report submitted to the CPCB for the year 2021, it was noticed that there were five CBWTFs in operation in the State, but no third-party audit had been conducted so far.

8.4.3 Inadequate training of health workers

Section 4(g) of Bio-Medical Waste Management Rules, 2016 provides that all HCFs should provide training to all its workers involved in handling of bio-medical waste at the time of induction and thereafter, at least once in a year. Details of training programmes conducted, number of personnel trained, and number of personnel who had not undergone any training shall be provided in the Annual Report.

Audit observed that trainings were not imparted by HCFs as required under the Rules, as detailed in **Table 8.4.**

Table 8.4: Shortfall in imparting trainings by HCFs during the period 2016 to 2021

Year	Total number of HCFs	Number of HCFs which organised trainings for health workers	Shortfall in organising trainings (*percentage*)
2016	6,475	373	6,102 (94)
2017	7,137	642	6,495 (91)
2018	8,234	1,164	7,070 (86)
2019	9,595	1,346	8,249 (86)
2020	12,554	1,593	10,961 (87)
2021	13,426	1,331	12,095 (90)

Source: Information/data furnished by PPCB

It is evident from the above table that the shortfall in organising training for the health workers by HCFs was ranging between 86 *per cent* and 94 *per cent* contrary to the provision of the Rules *ibid*.

On being pointed out, the Department admitted (December 2022) the facts in the exit conference.

8.4.4 Non-constitution of Bio-Medical Waste Management Committee

Section 4(r) of Bio-Medical Waste Management Rules, 2016 provides that all Health Care Facilities (HCF) shall establish a system to review and monitor the activities related to bio-medical waste management, either through an existing committee or by forming a new committee.

Audit observed that out of total 13,426 HCFs as of December 2021, only 5,994 HCFs (45 *per cent*) constituted Bio-Medical Waste Management Committees during 2016-2021 and the remaining 7,432 HCFs did not constitute the Committee. Non-formation of the requisite committee in 55 *per cent* HCFs indicated lack of system to review and monitor the activities relating to bio-medical waste management in HCFs.

On being pointed out, the Department admitted (December 2022) the facts in the exit conference.

8.4.5 Non-practicing pre-treatment of Microbiology and Biotechnology waste

Section 8(8) of Bio-Medical Waste Management Rules, 2016 provides that Microbiology waste and all other clinical laboratory waste shall be pre-treated by sterilisation to Log 6 or disinfection to Log 4[9], as per the World Health

[9] Disinfectant effectiveness of Microbiology and all other clinical laboratory waste are measured with different levels e.g. Log 6 denotes sterlisation by 99.9999% and Log 4 denotes disinfection by 99.99%.

Organisation guidelines before packing and sending to the Common Bio-Medical Waste Treatment Facility.

Audit noticed that lab microbiology and biotechnology waste was pre-treated by 14 *per cent* to 19 *per cent* HCFs only during the period 2016 to 2021 as depicted in **Table 8.5**. HCFs ranging from 81 *per cent* to 86 *per cent* did not follow the provisions as laid down in the Rules *ibid* which indicated improper monitoring by PPCB. Lapse in pre-treatment of microbiology and biotechnology waste could result in spreading of infection due to such untreated highly infectious waste.

Table 8.5: Position of pre-treatment of lab microbiology and biotechnology waste

Year	Total number of HCFs	Number of HCFs in which pre-treatment of lab microbiology and biotechnology waste was done	Number of HCFs in which pre-treatment of lab microbiology and biotechnology waste was not done (*percentage*)
2016	6,475	898	5,577 (86)
2017	7,137	1,377	5,760 (81)
2018	8,234	1,405	6,829 (83)
2019	9,595	1,861	7,734 (81)
2020	12,554	1,792	10,762 (86)
2021	13,426	2,117	11,309 (84)

Source: Information and data furnished by PPCB

On being pointed out, the Department admitted (December 2022) the facts in the exit conference.

8.4.6 No punitive action for violation

Rule 15 of the Environment (Protection) Act, 1986 provides that whosoever fails to comply with or contravenes any of the provisions of this Act or the rules made or orders or directions issued thereunder, shall, in respect of each such failure or contravention, be punishable with imprisonment for a term which may extend to five years with fine which may extend to one lakh rupees or with both and in case the failure or contravention continues, with additional fine which may extend to five thousand rupees for every day during which such failure or contravention continues after the conviction for the first such failure or contravention.

Audit observed that a total of 13,174 violations in HCFs and 26 violations in the Common Bio-Medical Waste Treatment Facilities (CBWTF) were noticed during 2016-2021. Though show cause notices were issued to all such HCFs/CBWTF, no punitive action was taken against the violators.

On being pointed out, the Department admitted (December 2022) the facts in the exit conference.

8.4.7 Shortfall in meetings of Advisory Committee

Section 11 of Bio-Medical Waste Management Rules, 2016 provides that every State Government shall constitute an Advisory Committee for the respective State under the chairmanship of the respective Health Secretary to oversee the implementation of the Rules in the respective State and to advise any improvements. Moreover, the Advisory Committee shall meet at least once in six months and review all matters related to the implementation of the provisions of these Rules in the State.

Audit observed that the first meeting of the Advisory Committee was conducted (September 2018) after a gap of 29 months after publication of notification of Bio-Medical Waste Management Rules, 2016 (March 2016). The position of meetings of Advisory Committee is detailed in **Table 8.6.**

Table 8.6: Position of meetings of Advisory Committee

Year	Number of meetings required to be held	Number of meetings held	Shortfall
2016-17	2	0	2
2017-18	2	0	2
2018-19	2	1	1
2019-20	2	1	1
2020-21	2	1	1
2021-22	2	0	2
Total	**12**	**3**	**9**

Source: Information and data furnished by PPCB

Table 8.6 shows that only three meetings of Advisory Committee were held during the period 2016-2022 against the requirement of twelve meetings, thereby resulting in 75 *per cent* shortfall in conduct of the meetings.

On being pointed out, the Department admitted (December 2022) the facts in the exit conference.

8.5 Conclusion

The envisaged regulatory mechanism was not functioning effectively to ensure responsible provision of health services to the people. For the registration and regulation of the clinical establishments, the State Government adopted Clinical Establishments (Registration and Regulation) Act in October 2020 i.e. after a gap of ten years from the date when the Clinical Establishments (Registration and Regulation) Act was enacted in 2010 by the Union Government. Rules under the State Act were yet to be framed. Provisions of Punjab Clinical Establishments (Registration and Regulation) Act, 2020 do not bind the private clinics or establishments having capacity up to 50 beds to get themselves registered unlike Clinical Establishments (Registration and Regulation) Act, 2010 passed by the Central Government which provides that all the clinics or

establishments should be registered. As a result, the prescribed minimum standards of facilities and services could not be ensured in these unregistered clinical establishments. Adequacy of infrastructure in the Medical Colleges as per norms was not ensured. Further, 160 selling/manufacturing units were running without valid/renewed licenses. Some Health Care Facilities were working without valid authorisation and the requisite annual reports were not submitted by most of the HCFs. Further, most of the HCFs did not impart any training to the Health Workers and also did not constitute Bio-Medical Waste Management Committees to review and monitor the activities related to bio-medical waste management and the Advisory Committee was not actively overseeing the implementation of the BMW Rules. These were being poorly implemented in the State posing a serious health hazard.

8.6 Recommendations

In light of the audit findings, the State Government may consider:

(i) expediting framing of rules under the Clinical Establishments (Registration and Regulation) Act and ensure implementation thereof at the earliest;

(ii) ensuring adequate infrastructure at medical colleges for smooth functioning;

(iii) giving direction to the Drug Inspectors for conducting inspections of manufacturing and selling units as per extant Rules;

(iv) ensuring adequate monitoring mechanism to check selling/ manufacturing without valid/renewed licenses and taking timely action against those units running without valid licenses; and

(v) ensuring compliance with Bio-Medical Waste Management Rules by all HCFs in public as well as in private sector with regard to obtaining requisite authorisation from PPCB, submission of annual returns, conducting adequate training, constitution of Bio Medical Waste Management Committees, etc.