Chapter 8 –Adequacy and Effectiveness of Regulatory Mechanisms

Goa enacted the Goa Clinical Establishments (CE) Act, 2019, nine years after the enactment of the Central Act and notified the Goa CE Rules with a further delay of two years in July 2021. The Council of Clinical Establishments and the District Registering Authorities were constituted in April 2022 with a delay of three years from the enactment of the Goa CE Act.

Audit of the Food and Drug Administration (FDA) Department, the State Drug regulator indicated shortfall in the number of mandated inspections of establishments, shortages in drawal of drug samples for testing, absence of National Accreditation Board of Laboratories (NABL) certification of FDA's laboratory and follow up action where drugs were found to be sub-standard. Thirty seven out of 38 Public Health Institutions (PHIs) did not apply for National Quality Assurance Standards (NQAS) certification. None of the four test-checked public health institutions' laboratories had obtained NABL certification.

The Goa Medical Council, Goa Pharmacy Council and Goa Nursing Council, responsible for the regulation of medical practitioners, pharmacists and nurses in the State did not publish the list of the respective professionals registered with them in the public domain as mandated. Pharmacy Council had not appointed inspectors as a result of which licensed premises where drugs are compounded and dispensed remained uninspected in the State.

Several health facilities were functioning in the State without authorisation from Goa State Pollution Control Board (GSPCB) for handling of Bio-Medical Waste (BMW) showing poor monitoring by GSPCB. Gaps were noticed in Bio-Medical Waste Management (BMWM) by the test-checked Public Health Institutions relating to constitution of BMWM Committee and its working.

8.1 Introduction

Regulation is an important aspect of the healthcare sector, as public health needs to be safeguarded, healthcare consumers need protection from health risks and medical professionals need a safe working environment. Regulatory bodies are responsible for compliance of medical facilities and medical professionals with public health policies, guidelines and standards to ensure that appropriate and safe healthcare to all patients is provided.

8.2 Regulatory mechanisms in the State

In Goa, Goa Medical Council, Goa Pharmacy Council, Goa Nursing Council and State Drug Controller are among the important health sector regulatory bodies. Apart from examining the functioning of these regulatory bodies, Audit

also examined aspects related to Bio-Medical Waste Management, Quality Certification from NABL and other mandatory requirements. Audit findings on aspects related to regulation and regulatory bodies in the State are discussed below.

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

The Clinical Establishments (CE) Act was enacted by the Parliament in August 2010 to provide for registration and regulation of all clinical establishments in the country with a view to prescribing minimum standards of facilities and services in pursuance of the directive under Article 47 of the Constitution for improvement of public healthcare. Clinical Establishments Rules were framed by the Government of India in May 2012. The NHP, 2017 (Para 14.2) advocated the regulation of clinical establishments by the States through the adoption of the Clinical Establishments (Registration and Regulation) Act, 2010.

8.3.1 Inordinate delay in enactment of State Clinical Establishments Act and Rules

The CE Act prescribed Minimum Standards Requirement (MSR)[1] to be complied with for grant of license for establishment and operation of clinical establishments. Section 3 of the Goa Clinical Establishments (Registration and Regulation) Act, 2019 stipulated the constitution of 'Goa Council for Clinical Establishments' (GCCE) to monitor, compile and update the State Register of clinical establishments, furnishing monthly returns for updating the National Register of clinical establishments and ensuring implementation of minimum standards by the clinical establishments. Further, Section 7 of the Act requires the constitution of 'District Registering Authority' (DRA) for each district to carry out the registration of clinical establishments.

The Goa Clinical Establishments (Registration and Regulation) Act was enacted in September 2019 after a delay of nine years from the date of enactment of the Central CE Act, 2010. The Goa Clinical Establishments (GCE) Rules, which prescribed minimum standards for clinical establishments was notified only in July 2021.

Further, the Council for Clinical Establishments and the DRA were not constituted even after the notification of GCE Rules. The GCCE and DRA were constituted only in April 2022 after a lapse of three years from the enactment of the CE Act. Hence, none of the private clinical establishments could be registered or brought under the ambit of the Goa Clinical Establishment Act, 2019, between October 2019 and April 2022.

[1] MSR provides for an exhaustive list of the scope of services, infrastructure, medical equipment, drugs and medicines, human resources, support services, legal/statutory requirements, record maintenance and reporting requirements.

The Secretary, Health directed (February 2023) the concerned officials for corrective action.

The Director, DHS accepted the audit observation (November 2023).

8.4 Functioning of Regulatory bodies in the Health Sector

Regulatory bodies in the State are established under Central/State Acts for registration, regulation of medical practitioners, nursing personnel, pharmacists, *etc*., practicing in the State for ensuring safety standards and quality control.

8.4.1 State Drug Controller

The Directorate of Food and Drugs Administration (FDA) is the State drug controller responsible for regulation of manufacturing and sales of drugs in the State and for implementation and enforcement of Drugs and Cosmetics Act, 1940 and Rules, 1945. The vision and mission of FDA is to ensure the availability of safe food and drugs to the general public at large. Audit noticed the following shortfalls in the functioning of FDA.

8.4.1.1 Shortfall in conducting inspections as per norms

Section 22 of the Drugs and Cosmetics Act, 1940 provides for the Drug Inspector to inspect any premises and take samples of drugs which are being sold or stocked or exhibited or offered for sale or distributed. Further, Rules 51 and 52 of Drugs and Cosmetics Rules, 1945 provide that the Drug Inspector shall inspect not less than once a year all establishments licensed for the sale and manufacture of drugs respectively, within the area allotted to him.

Audit observed that during 2016-22 there was shortage in the inspection of manufacturing and sale units by the Drug Inspectors as shown in **Table 8.1** below:

Table 8.1: Details of coverage of inspections of manufacturing and sale units

Year	Manufacturing units	Sale units	Total units in the State to be inspected	Inspections carried out by the Drug Inspectors	*Shortfall in inspection carried out (in per cent)*
2016-17	165	993	1158	741	*417 (36.01)*
2017-18	148	1019	1167	725	*442 (37.87)*
2018-19	144	1077	1221	626	*595 (48.73)*
2019-20	139	1111	1250	650	*600 (48.00)*
2020-21	139	1201	1340	626	*714 (53.28)*
2021-22	146	1310	1456	827	*629 (43.20)*

(Source: Information provided by FDA)

As per the table above, the shortfall in the inspections ranged from 36 to 53 *per cent* during 2016-22.

8.4.1.2 Non-achievement of targets for samples drawn as per norms

FDA norms stipulate (November 2016) drawing a minimum of three samples per month by the Drugs/Assistant Drugs Inspectors from Government establishments supplying drugs and medicines. Further, FDA revised (April 2019) its norms for drawing of minimum of ten samples per month of drugs from retail stores, wholesale dealers, doctors' clinic and Government establishments (minimum three should be from Government establishments) supplying drugs and medicines. Also, FDSI guidelines stipulate that the drug samples shall be tested by the empanelled laboratories within a reasonable time frame of 30 days for stopping the distribution of sub-standard drugs to patients.

Audit observed shortfall in number of samples drawn by FDA as shown below in **Table 8.2:**

Table 8.2: Details of shortfall in number of samples drawn by the FDA

Year	No. of Drugs/Asst. Drugs Inspectors	Minimum no. of samples of drugs and medicines to be drawn for testing during the year[2]	Actual samples of drugs and medicines drawn during the year[3]	*Shortfall in number of samples drawn (in per cent)*
2017-18[4]	09	324	116	*208 (64.20)*
2018-19	08	288	78	*210 (72.92)*
2019-20	06	720	560	*160 (22.22)*
2020-21	10	1200	476	*724 (60.33)*
2021-22	10	1200	852	*348 (29.00)*
Total		**3732**	**2082**	***1650 (44.21)***

(*Source: Information furnished by FDA*)

Shortfall in the drawal of sample of drugs and medicines during the period 2017-22 was on an average 44.21 *per cent* against the FDA norms.

Further, FDA tested 3,768 samples of batches of drugs during the period 2016-22 of which 85 drugs were found to be Not of Standard Quality (NOSQ) and details of such drugs which were found to be NOSQ required to be intimated to the centre concerned immediately to stop the sale. But FDA took 06 days to 126 days from the date of receipt of such NOSQ reports from the laboratory in intimating the test reports to the centre concerned.

FDA replied (November 2022) that the shortfall in drawing of samples was due to shortage of vehicles/drivers for enforcement purposes and corrective action has been taken to upload the NOSQ results immediately on their website. It was further stated that department has purchased five new vehicles for

[2] 3 per month upto 2018-19, 10 from 2019-20 to 2021-22.

[3] 2017-18 and 2018-19 actual samples taken only for Government establishments due to non-availability of norms for other establishments and for 2019 to 2022, total samples taken for all establishments.

[4] 2016-17 is not considered as the FDA norms were issued in November 2016.

enforcement purpose and the Drugs Inspectors are drawing samples as the per the plan submitted to them.

However, no evidence of the action taken were furnished to Audit by the Department.

8.4.1.3 Absence of NABL certification for FDA laboratory

MoH&FW, GoI, had proposed providing financial assistance to strengthen the State Drugs Regulatory System across the country. The funding pattern was in the ratio of 60:40 between GoI and the State. MoH&FW sanctioned grants amounting to ₹ 4.05 crore (₹ 2.43 crore for GoI and ₹ 1.62 crore for State) in July 2018 to the FDA for the up-gradation of Microlab (₹ 1.50 crore), procurement of equipment (₹ 1.41 crore), National Accreditation Board for Testing and Calibration Laboratories (NABL) accreditation, recurring costs (₹ 0.75 crore) *etc.*

Audit observed that FDA incurred an expenditure of ₹ 1.51 crore for civil work and ₹ 0.02 crore for NABL accreditation up to September 2022. The process for procurement of equipment and other work for strengthening its testing capacity[5] has not been initiated even after a lapse of four years from receipt of the grant.

The absence of NABL certification raises concerns regarding reliability of testing, measurement and calibration of equipment in the FDA and the results therefrom.

The Secretary, Health directed (February 2023) the concerned officials for corrective action during the exit meeting.

8.4.2 Goa Medical Council

Goa Medical Council was established in 1993 under the Goa Medical Council Act, 1991. It is vested with powers, duties and functions of regulating the practice of modern scientific system of medicine in the State of Goa. The Goa Medical Council provides for registration of Medical Practitioners (MPs) and maintains the State Register for MPs.

Rule 21 of Goa Medical Council Rules, 1995 prescribes the publishing of list of registered practitioners annually. Audit observed that the Council did not publish the list as required, in the public domain.

8.4.3 Goa Pharmacy Council

Goa Pharmacy Council (GPC) was constituted in the year 1994 for regulation of the profession and practice of pharmacy in the State under the Pharmacy Act, 1948 (Central Act). As per Section 29 of the Pharmacy Act, 1948, the State Government shall cause to be prepared a register of pharmacists for the State and publish the same. Further, as per Rule 52 of Goa State Pharmacy

[5] Samples tested 770 (2018-19), 585 (2019-20), 389 (2020-21) and 774 (2021-22).

Council Rules, 1990, the Executive Committee shall superintend the publication of the said register.

Audit noticed that such a register was not published in the public domain.

Further, sub-section (2) of Section 26A of the Pharmacy Act, 1948 stipulates that the State Pharmacy Council may with the previous sanction of the Government appoint Inspectors who may inspect premises where drugs are compounded or dispensed, enquire whether a person who is engaged in compounding or dispensing of drugs is a registered pharmacist and investigate any complaint made in writing for contravention of the provision of the Act.

However, the GPC did not appoint Inspectors as stipulated under sub-section (2) of Section 26 (A) of Pharmacy Act, 1948. As a result, the GPC did not carry out any inspection of premises where drugs are compounded or dispensed during the period 2016-21.

8.4.4 Goa Nursing Council

Goa Nursing Council (GNC) is a statutory body constituted under the Goa Nursing Council Act, 2012. As per Section 24 of the GNC Act, a Register shall be printed and published once in every three years with a list of all nursing personnel in the State.

However, the list of registered nurses was not published in the public domain.

The Secretary, Health (February 2023) while accepting the observations *(Para 8.4.2, 8.4.3 and 8.4.4)* stated that the Goa Medical Council was instructed to take appropriate action and directed others for taking corrective action.

Recommendation 17: PHD may ensure that the Councils comply with the requirement of publishing the list of registered medical practitioners, nurses and pharmacists in the public domain. They may be advised to make these databases available online as per regulation.

8.5 Quality Certification

IPHS norms stipulate that public healthcare facilities should obtain certification/accreditation for quality assurance from quality assurance institutions. National Quality Assurance Standards (NQAS) framework developed by National Health Systems Resource Centre is for quality assurance of services in public healthcare facilities and National Accreditation Board for Testing and Calibration Laboratories (NABL) certification provides a ready means for customers to identify and select reliable testing, measurement and calibration services that are able to meet their needs.

Audit noticed the following:

- Out of the two District hospitals, two Sub-district hospitals, four UHCs, six CHCs and 24 PHCs where IPHS norms were applicable, 37 public health

institutions (except CHC, Sankhali-certified in May 2022) did not apply for NQAS certification.

- None of the test-checked public health institutions' laboratories had obtained NABL certification.

After being pointed out by Audit (June 2022), seven out of 37 PHIs have acquired NQAS certificate between March and December 2023. But the fact remains that such certificate is yet to be obtained by the remaining 30 PHIs while no progress has been reported by DHS regarding acquiring NABL certification.

Recommendation 18: The State may ensure validation and certification of its health centres and laboratories as per IPHS norms.

8.6 Regulation of Bio-Medical Waste

As per the Bio-Medical Waste Management (BMWM) Rules, 2016, hospital should ensure that BMW is handled without any adverse effect to human health and the environment. The Goa State Pollution Control Board (GSPCB) is responsible for enforcement of the provisions of BMWM Rules, 2016. The waste is to be stored in appropriate colour coded bags at the point of generation and collected by the Common Bio-Medical Waste Treatment Facility (CBWTF).

8.6.1 Absence of authorisation to handle BMW

As per BMW Management Rules, 2016 (Rule 10), the health facilities established in Goa should take authorisation[6] from GSPCB. The details of health facilities and authorisations granted are shown below for the six years (as per annual report-calendar year) from 2017-22[7] in **Table 8.3**.

Table 8.3: Table on number of applications received for the year 2017-22

Year	Total applications received for authorisation	Total authorisations granted	No. of health facilities whose application were neither approved nor rejected*	Applications rejected
2017	603	601	02	0
2018	141	76	65	0
2019	407	121	286	0
2020	401	139	177	85
2021	159	90	69	0
2022	405	241	164	0

(Source: Annual report submitted by GSPCB)
**Such application pending authorisation, lapses at the end of the calendar year and further processed on receipt of fresh application.*

[6] for the generation, collection, reception, storage, transportation, treatment, processing, disposal or any other form of handling of bio-medical waste in accordance with these rules and guidelines issued by the Central Government or Central Pollution Control Board as the case may be.

[7] BMW rules were notified in March 2016, hence 2016 data is not available. Health facilities submit annual report for calendar year.

As evident from the above table, out of 2116 applications received for authorisation during the period, only 59.93 *per cent* were authorised. While 4.01 *per cent* applications were rejected, the remaining 36.06 *per cent* applications were pending for reasons such as non-payment of fee, applications being incomplete or non-receipt of compliance to further clarification sought by the GSPCB.

GSPCB issued Show Cause Notices[8] (SCN) to facilities functioning without authorisation for BMW, but no further action was taken on defaulting facilities.

No reply on this matter has been received from the Government.

8.6.2 Bio-Medical Waste Management by test-checked PHIs

BMWM Rules (Rule 4 (r)), stipulates that occupier[9] should constitute a BMWM Committee for reviewing and monitoring the activities related to BMWM which shall meet every six months and the record of the minutes of the meetings of this committee shall be submitted along with the annual report to the prescribed authority.

Audit observed the following discrepancies related to BMWM in test-checked hospitals:

- North Goa District Hospital (NGDH), Mapusa constituted BMWM Committee in March 2022 *i.e.* six years after the notification of BMWM Rules, 2016.
- Sub-District Hospital, Chicalim did not constitute the Committee during the audit period 2016-22 and stated (August 2022) that the Committee was constituted recently.
- Eight[10] out of 20 test checked PHIs[11] had submitted annual report for the year 2021.
- The BMWM Committee in Goa Medical College and Hospital (GMCH) did not meet every six months as per the rules.
- In SDH, Chicalim, the appointed agency did not collect BMW regularly during the period from February to November 2021 despite repeated reminders by SDH, Chicalim, exposing patients to health hazards.

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8 582 in 2018, 582 in 2019, 419 in 2020 and 346 in 2021.

9 a person having administrative control over the institution and the premises generating bio-medical waste, which includes a hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank, health care facility and clinical establishment, irrespective of their system of medicine and by whatever name they are called.

10 GMCH, NGDH Mapusa, SDH Chicalim, CHC Canacona, PHC Porvorim, PHC Chimbel, PHC Chinchinim, PHC Balli.

11 10 SCs, 4PHCs, 2 CHCs, 1 SDH, 1 DH, T.B Hospital and GMCH.

The Director, DHS stated (November 2023) that in NGDH, Mapusa Inspection Control Committee/Bio-Medical Waste Committee is constituted and meets regularly and disposes off Bio-Medical Waste as per the Waste Disposal Act, 2016. As far as SDH, Chicalim is concerned, Health Officer has stated that the BMWM committee was constituted in June 2022 and meets every six months.

The Dean, GMCH accepted the observation and stated (October 2023) that BMWM Committee meetings would be conducted as per norms.

Recommendation 19: The State Government may ensure compliance with the BMW Management Rules for monitoring the collection and disposal of Bio-Medical Waste in the State at the earliest.