CHAPTER VIII

ADEQUACY AND EFFECTIVENESS OF REGULATORY MECHANISMS

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The Tamil Nadu Clinical Establishments (Regulation) Act, 1997 was not being enforced effectively as adequate structure for enforcement was not created at the field level. Significant number of clinical establishments functioned without registration, and GoTN did not even have a reliable data on the number of private clinical establishments. Shortfall of up to 47 *per cent* in inspection and lifting samples by Drug Inspectors adversely impacted drug testing in the State. Segregation and disposal of biomedical wastes remains to be a huge challenge as the HCFs did not attach due importance for this crucial service.

8.1 Private Clinical Establishments (Regulation) Act

The Tamil Nadu Private Clinical Establishments (Regulation) Act, 1997 came into effect from February 1997 for private clinical establishments (CE). This Act was amended to bring both public and private CEs under the ambit of the Act, with effect from 23 April 2018. As per the Act, no person shall carry on with a clinical establishment unless a certificate of registration was granted by the competent authority[1]. The CEs were to meet the prescribed minimum standards for getting registered under the Act.

8.1.1 Inordinate delay in framing of Rules

The TN Act was enacted in February 1997, but GoTN started enforcing the Act only after framing the Rules in 2018. Thus, the CEs were not regulated for more than 20 years. The delay in the amendment to bring in Government HCFs under this Act was one of the reasons for the delay in framing Rules and enforcing the Act.

The issues relating to the enforcement of the Act are as follows:

8.1.2 Non-registration of clinical establishments in the State

During 2018-22, 44,237 CEs applied for registration in the State; out of which, 32,655 (74 *per cent*) were granted registration. In the sampled six districts[2], 1,250 out of 5,413 (23 *per cent*) CEs, that applied for registration, were not granted registration due to non-fulfilling of the stipulated conditions for registration.

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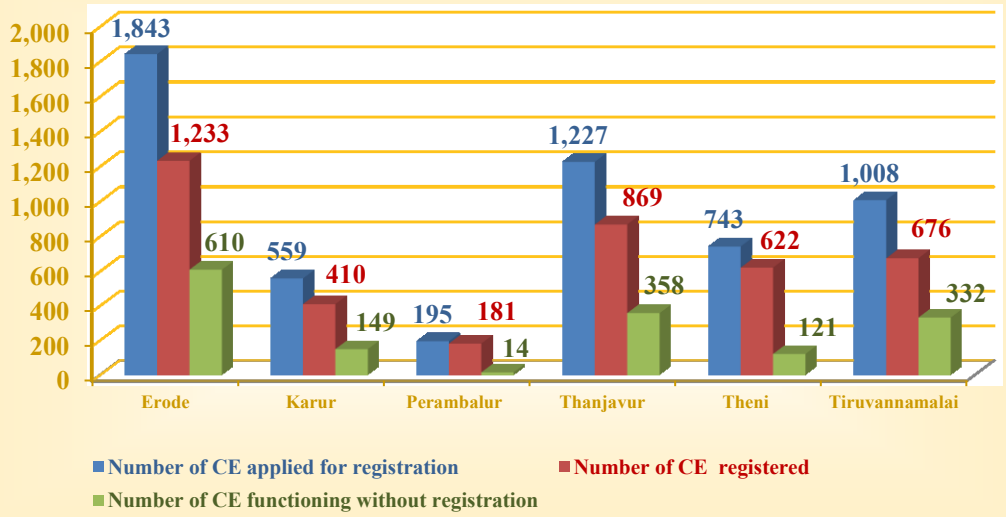
1 The Joint Director of the Medical and Rural Health Services in Districts is the 'competent authority'.

2 Erode - 1,235 out of 1,481; Karur - 416 out of 575; Perambalur - 181 out of 207; Thanjavur - 1,021 out of 1,458; Theni - 630 out of 789 and Tiruvannamalai - 680 out of 903.

The district-wise details of CEs awaiting registration is given in **Exhibit 8.1**.

Exhibit 8.1: Clinical Establishments awaiting registration



(Source: JDHS of respective districts)

Out of the 1,584 CEs pending as of March 2021, 625 were pending for over 180 days due to non-conformation of the minimum standards prescribed under Section 5A of the Act. This included 15 hospitals and 619 consulting rooms and other establishments. Audit found that all these 15 hospitals pending registration were continuing to function **(Appendix 8.1)** without the required registration.

Audit observed that the department failed to enforce the statutory provision of banning functioning or to ensure proper corrective actions in the CEs for registration. The Act was not enforced in the State, in its letter and spirit, and CEs without registration continue to function.

Thus, the quality of services rendered by private CEs was not enforced, as required in the Act.

8.1.3 Annual publication of lists of clinical establishments

The list of registered CEs should be published by the Competent Authority annually in the TN Government Gazette[3] during the month of January every year for the period from 01 January to 31 December of the previous year. It was seen that such lists were not published as envisaged under the Act and Rules even after a lapse of nearly four years after the implementation of the Act. DMRHS stated (March 2022) that the proposal was under the consideration of Government for publishing the list of CEs in the State.

Audit observed that by not publishing the list of registered CEs, the compliance to the Act was not ensured.

8.1.4 Non-availability of data on private Clinical Establishments

Audit found that there was no system to ensure that all CEs apply for registration. According to DMRHS the details of un-registered CEs in the State were not available. Though the Joint Directors of Health Services (JDHS) are

[3] Section 5-C of the Act and Rule 13.

entrusted with the responsibility for enforcing this Act at the district level, JDHSs were not provided with any medical team exclusively to inspect and initiate action for registration/deregistration.

Thus, in the absence of reliable data and manpower to enforce the Act, registration of CEs is still seen as a voluntary effort by the CEs, rather than an obligation on their part.

8.1.5 Poor monitoring in enforcement of Clinical Establishment Act

The Act provides for an Advisory Committee at the State level under the chairmanship of DMRHS and district level Committees headed by Deputy Director DMRHS.

Audit found that the District level Committee was not constituted in Perambalur District. In Thanjavur District, the Committee met only thrice during 2018-21, against the requirement of six meetings. In Theni District, the Committee met only twice during 2018-21.

The slackness in monitoring was the main reason for the deficient enforcement of the Act.

Recommendation 13:

Government should ensure that all clinical establishments (both public and private) in the State are registered under the Tamil Nadu Clinical Establishments (Regulation) Act, 1997 and DMRHS should deploy adequate manpower to effectively enforce this Act.

8.2 Enforcement of Drugs and Cosmetics Act, 1940

8.2.1 Non-renewal of licenses by the Blood Banks

As per Drug and Cosmetics Rules 1945, the licence for the Blood Banks shall be renewed periodically and the Drug Controller monitors the functioning of Blood Banks. It was noticed that four out of 96 Blood Banks at Government Hospitals were functioning as of December 2021 without renewal of licences for a period ranging from nine to 18 months **(Table 8.1)**.

Table 8.1: Government Blood Banks functioning without valid licence

Sl. No.	Blood Bank	License number	License valid up to
1	GMCH, Vellore.	217/28C dated 27/03/2006	26/03/2021
2	GMCH, Theni (Sampled GMCH)	267/28C dated 08/12/2005	07/12/2020
3	DHQH, Padmanabhapuram, Thuckalay	323/28C dated 30/03/2011	29/03/2021
4	DHQH, Ariyalur	374/28C dated 15/06/2015	14/06/2020

(Source: Details furnished by the Directorate of Drug Control)

Similarly, out of 359 Blood Storage Centres (BSC) at Government Hospitals and PHCs, 127 BSCs were functioning without renewal of licences for a period ranging from nine months to nine years as of December 2021 **(Appendix 8.2)**.

Due to non-renewal of licences for four Blood Banks and 127 Blood Storage Centres, the blood supplied to the general public was not properly quality assured.

GoTN replied (August 2022) that out of 127 BSCs pointed out, licences of 45 were since renewed, licences of 67 BSCs were either cancelled or not proposed to be renewed and only 15 applications were pending for renewal. While appreciating the action taken by Government, the proposal for non-renewal of licences of 67 BSCs would lead to reduction in the number of BSCs and consequent difficulties in meeting the requirement of blood during emergencies.

8.2.2 Shortfall in lifting of drug samples and inspections

The Drugs Controller monitors the quality, safety, efficacy and drawal of samples of drugs and cosmetics. The Drug Inspectors shall inspect the premises licensed and draw samples of drugs and cosmetics from various retail, wholesale outlets, manufacturers, private and government hospitals for the purpose of test or analysis to ascertain its quality, purity and safety for consumption and usage by the public.

The Drugs Controller fixes the targets for inspection by Drug Inspectors and also for lifting samples. Audit found that the shortfall in inspection ranged between 34 *per cent* and 40 *per cent* and for lifting of samples it ranged between 45 *per cent* and 54 *per cent* **(Appendix 8.3)**. It was also found that the shortfalls in achievement for inspection and lifting of sample were due to vacancies in the posts of Drug Inspectors.

Thus, due to inadequate staff, the targets for drug inspection and sample testing were not achieved, causing shortfalls in checking the quality of drugs.

GoTN replied (August 2022) that 45 new Drug Inspectors were recruited during 2021 and the targets for inspection and drawal of samples were being achieved.

8.3 Biomedical Waste Management

In 1998, GoI framed Biomedical Waste (Management and Handling) Rules, 1998 (BMW Rules) under the Environment (Protection) Act, 1986. BMW Rules laid down the procedures for collection, handling, transportation, disposal and monitoring of biomedical waste with clear roles for waste generators and Common Biomedical Waste Treatment Facility (CBMWTF).

8.3.1 Non-segregation of biomedical waste

Rule 4(i) and Rule 5(c) of the BMW Rules provides that the HCFs and the CBMWTF should establish a bar-code system for bags or containers containing biomedical wastes for safe disposal. Audit noticed that 11 out of the 21 sampled hospitals (52 *per cent*) and 12 out of the 26 PHCs (46 *per cent*) did not comply with the above provisions of properly segregating and handling biomedical wastes in bar-coded bags so as to ensure that they reach the correct disposal point.

The Tamil Nadu Pollution Control Board (TNPCB), the enforcing agency of the Rules, stated that 100 *per cent* implementation of the bar coding could not be achieved due to the cost involved.

In October 2020, GoTN issued orders[4] for levying environmental compensation on HCFs and CBMWTF, which are non-compliant with the BMW Rules. During 2020-21, TNPCB levied environmental compensation of ₹3.85 crore, on 11 Government HCFs for not obtaining authorisation and non-establishment of Effluent Treatment Plant. Audit found that DME and DMRHS, who administer the major hospitals, did not devise an action plan with timelines for making all HCFs BMW Rules compliant.

Further, Rule 13 (1) of the BMW Rules states that every occupier or operator of a CBMWTF shall submit an Annual Report to the prescribed authority (in Form IV) on or before 30th of June of every year. Audit noticed that six hospitals and 17 PHCs did not submit the Annual Report during 2016-22 to the TNPCB **(Appendix 8.4)**. Thereby the prescribed authority could not monitor the activities**.**

Thus, by not adhering to the provisions of BMW Rules, Government HCFs evaded responsibility towards environmental protection.

8.3.2 Accumulation and mishandling of biomedical waste

All the 18 DHQHs in the State were having facilities for segregation of biomedical wastes. However, in the sampled HCFs, the following deficiencies were noticed:

- In four[5] sampled hospitals and in nine[6] PHCs, the biomedical wastes were not collected on daily basis, as provided in the BMW Rules.
- In PHC, Kaikalathur, it was noticed that biomedical wastes such as empty plastic saline bottles, plastic bottles, plastic cans and used needles were kept in a room for years together without disposal **(Exhibit 8.2)**. The cotton wastes were burned off.
- In UPHC, Ammapalayam, cotton wastes were burned off and used needles were buried in a pit **(Exhibit 8.2)**.
- In two[7] PHCs, no segregation was done before disposal.
- Four[8] hospitals and five[9] PHCs did not impart training on biomedical waste to their healthcare workers.

4 G.O. (Ms) No.77 of Environment and Forests (EC.2) Department dated 28/10/2020.
5 TKHs at Karai and Orathanadu; NTKHs at Kavandapadi and Thanipadi.
6 BPHCs at Chennimalai, Karapattu, Modakuruchi and Nammiyampattu; UPHCs at Ammapalayam and Jamunamarathur; PHCs at Kaikalathur and Poondi; and Urban PHC - II, Bommayakoudanpatti (Theni).
7 UPHC, Ammapalayam and PHC, Kaikalathur.
8 TKHs at Andipatti, Karai and Orathanadu; NTH, Thirukkattupalli.
9 BPHC, Naducauvery; UPHCs at Ammapalayam and Kadamalaigundu; PHCs at Kaikalathur and Poondi.

Exhibit 8.2: Accumulation of biomedical waste in PHC and improper disposal

Biomedical waste dumped at PHC, Kaikalathur

Cotton wastes were burned off at UPHC Ammapalayam

(Source: Joint Physical Verification)

Thus, Audit observed that the HCFs did not attach due importance for proper disposal of biomedical waste, and hence the possibility of health hazards to patients and staff could not be ruled out. These deficiencies could delay achievement of SDG goals as well.

8.3.3 Deficiencies in final disposal of biomedical wastes

Final disposal of biomedical waste is entrusted to private agencies, who were to establish a Common Treatment Facility in accordance with the biomedical waste Rules, for proper disposal of biomedical waste.

During joint field inspection at the final disposal point of biomedical waste in three[10] sampled districts, Audit found that (i) Bar code system was not in Operation (ii) needles were not disposed, (iii) dumping of waste in the open space, etc., **(Exhibit 8.3)**. The details of deficiencies noticed are given in **Appendix 8.5**.

Exhibit 8.3: Deficiencies in Common Treatment Facility

(Source: Joint physical verification of Common Treatment Facility, Thanjavur)

Audit observed that the final disposal of biomedical waste also lacked safety to prevent health hazards.

[10] Thanjavur, Theni and Tiruvannamalai.