CHAPTER 8

Adequacy and Effectiveness of the Regulatory Mechanisms

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Clinical Establishment Act, 2010 was not adopted in Maharashtra as of March 2023 and the private nursing homes/healthcare facilities in the State were regulated as per the provisions of the Maharashtra Nursing Homes Registration Act. This Act with limited scope did not cover dispensaries, clinics, sanatoriums and diagnostic centres. Moreover, Local Supervising Authorities did not conduct periodic inspections of registered private Nursing Homes.

The Food and Drugs Administration had persistent shortage of manpower leading to shortfalls in its functioning like inspections, sample testing etc.

Instances of HCIs not having authorisation from Maharashtra Pollution Control Board for generation, collection, storage, transportation, etc., of bio-medical waste and disposal of liquid waste without treatment were noticed.

8.1 Regulatory Mechanism in the State

The role of regulatory bodies in the health and medical sector is to protect healthcare consumers from health risks, provide a safe working environment for healthcare professionals, and ensure that public health and welfare are served by health programs.

The healthcare system is regulated through various Union and State Acts under which various regulatory bodies have been constituted. In Maharashtra, Food and Drugs Administration, Maharashtra Medical Council, Maharashtra Para-Medical Council, Maharashtra State Pharmacy Council, and Maharashtra Nursing Council monitor individual and corporate healthcare practitioners and facilities. These regulatory bodies ensure higher safety standards and attempt to improve healthcare quality.

8.2 Regulation of Clinical Establishments

The Clinical Establishments (Registration and Regulation) Act, 2010 (CEA) of GoI provides for registration and regulation of all clinical establishments in the country with a view to prescribe minimum standards of facilities and services provided by them. The CEA was applicable to all kinds (both therapeutic and diagnostic) of clinical establishments from public and private sectors of all recognised systems of medicine including single-doctor clinics. The CEA, *inter alia,* provides for the constitution of State Council, compiling and updating the State registers of clinical establishment, publication on annual basis a report on the state of implementation of standards prescribed by the National Council.

Audit observed that the CEA was not adopted in Maharashtra as of March 2023. However, private nursing homes in Maharashtra are regulated as per the provisions of the Maharashtra Nursing Homes Registration Act (erstwhile Bombay Nursing Home Act, 1949).

Compared to CEA, the scope of the Maharashtra Nursing Homes Registration Act was very limited as it covered the registration and inspection of nursing homes only.

The non-adoption of CEA had resulted in non-coverage of dispensaries, clinics, sanatoriums and diagnostic centres and thereby increased the risk of clinical establishments running in the State without registration and also deficiencies in providing proper healthcare by these clinical establishments as per prescribed standards.

Recommendation 16: Government may explore the possibility of adopting the Clinical Establishment Act, 2010 so that all the clinical establishments in the State are registered and are adequately monitored to ensure that minimum standards of facilities and services are provided to public. Government may also ensure that updated database of medical facilities is maintained.

8.3 Drug Controller of the State

The Food and Drugs Administration (FDA) functioning under the administrative control of MEDD, was responsible for the implementation of the Drugs and Cosmetic Act, 1940 (D&C Act), the Drugs & Cosmetic Rules, 1945 (D&C Rules) and orders made thereupon to safeguard public health and to ensure the quality of drugs. Manufacturing of drugs was a controlled process under D&C Act and D&C Rules. Allopathic, Ayurvedic, Unani and Homeopathic drugs and cosmetics cannot be manufactured in the State without a valid Licence. The sale and distribution of drugs, transfer of drugs right from manufacturing of the drugs to wholesaler and retailer and selling to patients was controlled through valid licence and compulsory billing.

The FDA was headed by the Commissioner. The Joint Commissioner of each division has the Licensing Authority for the manufacturing units and the Assistant Commissioner of each district was the Licensing Authority for the selling units at the district level. The Joint Commissioner (Headquarters) also acted as the Drugs Control Authority of the State. The Drug Control Laboratory at Mumbai and Chhatrapati Smabhajinagar carried out the work of testing drug samples.

Section 18 (c) of the D&C Act provides that no person shall himself or by any other person on his behalf, manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale or distribute any drug, except under, and in accordance with the conditions of a licence issued for such purpose.

8.3.1 Human Resources in Food and Drugs Administration

For the smooth functioning of FDA, it is vital that persons are in position against sanctioned strength of various technical as well as non-technical posts. Huge vacancies in various cadres would adversely affect the functioning of the offices and hamper delivery of public service.

Scrutiny of records related to staff position for the period 2016-17 to 2021-22 in the office of the Commissioner, FDA, Mumbai, revealed that there were vacancies prominently in the technical posts throughout the period covered by Audit. Vacancy position in some of the key posts is shown in **Table 8.1**.

Table 8.1: Vacancy position in key posts in the State as of March 2022

Name of the post	Sanctioned strength	Persons in position	Vacant posts	Vacancy percentage
Joint Commissioner (Drugs)	8	1	7	87
Assistant Commissioner (Drugs)	67	43	24	36
Senior Scientific Officer	11	5	6	55
Scientific Officer	44	25	19	43
Drugs Inspectors	200	83	117	58
Analytical Chemist	40	27	13	32
Senior Technical Assistant	45	16	29	64
Lab Assistant	2	1	1	50

Source: Information furnished by Food and Drugs Administration, Mumbai

Persistent vacancies at the State level pose problems in functioning, leading to non-achievement of target of inspections and drawing and testing of samples as discussed in the succeeding paragraphs.

8.3.2 Inspection

As per Rule 51 of D&C Rules, the Drug Inspectors (DIs) were required to inspect all establishments licensed for the sale of drugs at least once a year. Rule 52 of D&C Rules states that the DI had to inspect all premises licensed for the manufacture of drugs or cosmetics at least once a year to check if the conditions of the licence and provisions of the Act and Rules are being observed. As per Rule 162 of D&C Rules, all the premises licensed for the manufacture of Ayurvedic (including Siddha) or Unani drugs have to be inspected by the DI not less than twice a year.

As per the information furnished by the FDA, Audit noticed that all firms licensed for manufacture of Allopathy drugs were inspected by FDA during 2016-17 to 2021-22. Audit further noticed that as against 4,954 inspections of firms licensed for the manufacture of Ayurvedic drugs only 1,182 firms were inspected during 2016-17 to 2021-22.

Further, scrutiny revealed that the FDA failed to achieve the target of inspections of the sales licensees in the State as shown in **Table 8.2**.

Table 8.2: Inspection of sales licensees (State)

Year	No. of Firms	Target of inspection	Actual inspections	Shortfall	Shortfall percentage
2016-17	63,930	63,930	25,958	37,972	59
2017-18	67,208	67,208	28,594	38,614	57
2018-19	71,730	71,730	24,760	46,970	65
2019-20	79,833	79,833	25,851	53,982	68
2020-21	84,662	84,662	25,340	59,322	70
2021-22	93,448	93,448	21,220	72,228	77

Source: Information furnished by the Food and Drugs Administration

As seen from **Tables 8.2**, there were huge shortfalls in inspection of sales licences in the State.

In reply, MEDD stated (January 2023) that due to shortage of staff and as per internal order, 100 *per cent* Ayurvedic manufacturing units were not inspected. The shortfall in inspection of licensed establishments during 2016-17 to 2021-22 was also accepted by MEDD. The fact remained that inspection of Ayurvedic manufacturing units and licensed establishments was not carried out as per the provisions of D&C Rules.

8.3.3 Drawing of drugs samples and sample testing

The drawing of samples, testing and follow-up action is extremely important to ensure that spurious drugs are not consumed by the public. Section 22 (1) (b) of D&C Act provided power to DIs to take samples of any drug or cosmetic (i) which is being manufactured or sold or is stocked or exhibited or offered for sale or is being distributed and (ii) from any person who is conveying, delivering, or preparing to deliver such drug or cosmetic to a purchaser or a consignee.

As per circulars issued by the Commissioner, Food and Drugs Administration, Maharashtra from time to time, Drug Inspectors were provided targets[77] for drawing drug samples and each Drug Inspector was required to draw the targeted samples per month from the licensed premises.

Analysis of information furnished to Audit revealed that there were shortfalls in drawing and testing of samples during 2016-17 to 2020-21. The target for 2021-22 was, however, achieved as shown in **Table 8.3**.

Table 8.3: Details of samples drawn and tested

Year	No. of DIs	Total samples required to be drawn	Total samples actually drawn	Shortfall (-)/ excess (+)	Samples tested	Shortfall in testing of samples *(per cent)*	Samples declared as of non-standard quality
2016-17	88	4,752	4,576	(-) 176	4,153	423 (*9.2*)	365
2017-18	88	5,280	5,240	(-) 40	4,762	478 (*9.1*)	407
2018-19	89	4,806	4,669	(-) 137	4,615	54 (*1.1*)	350
2019-20	92	4,508	4,189	(-) 319	3,823	366 (*8.7*)	205
2020-21	82	3,936	3,817	(-) 119	2,914	903 (*23.6*)	241
2021-22	70	2,520	2,574	(+) 54	2,533	41 (*1.6*)	320
Total		**25,802**	**25,065**	**737**	**22,800**	**2,265 (*9*)**	**1,888**

Source: Information furnished by the Food and Drugs Administration

As seen from **Table 8.3**, there was an average shortfall of nine *per cent* in testing of samples during 2017-18 to 2021-22. Further, out of 22,800 samples tested during 2016-17 to 2021-22, 1,888 samples (8.28 *per cent*) were found to be of non-standard quality.

In reply, MEDD stated (January 2023) that due to COVID-19, the sampling was hampered during 2019-20 to 2020-21.

8.4 Maharashtra Medical Council

The Maharashtra Medical Council (MMC) was established (November 1965) under the Maharashtra Medical Council Act 1965 (MMC, Act). The MMC, registers qualified medical practitioners working in private as well as public sector. MMC maintains biodata of the qualified doctors and keeps a watch on the conduct and upholding of ethics of the medical profession.

Section 31(6) of the National Medical Commission Act, 2019 stipulates that the State Register of Licensed Medical Practitioner should be maintained and regularly updated in the specified electronic format. A physical copy of the register was required to be furnished to the Ethics and Medical Registration

[77] Target of number of samples to be drawn by each Drug Inspector per year was 54 (2016-17), 60 (2017-18), 54 (2018-19), 48 (2019-20 and 2020-21) and 36 (2021-22).

Board, established under the National Medical Council within three months of commencement of the Act. As per Section 22 of the MMC, Act if Registered Medical Practitioner (RMP) was found guilty of any misconduct, the MMC, after due inquiry, may direct to remove the name of the RMP from the Register.

Section 23 (c) of the MMC, Act provided that every RMP registered with the MMC was required to renew the certificate of registration every five years thereafter, on payment of renewal fees.

Rule 28 of the MMC Rules, 1967 provided that the State Council shall meet in February and September of each year. Rule 43 of the MMC Rules provided for meetings of the Executive Committee (EC) once every two months.

Scrutiny of records and information provided by MMC for the year 2016-17 to 2021-22 revealed the following:

- Except for the year 2017, the State Council of MMC conducted its meetings as prescribed. However, the Executive Committee did not conduct the required number of meetings in any of the years from 2017 to 2022.
- 1,71,282 doctors were registered as RMPs till 2021-22, out of which, registration of 68,665 RMPs were due for renewal up to March 2022, but not renewed till May 2022. Audit noticed that out of these 68,665 RMPs, the registration of 4,071 RMPs was before 1st May 1960 (the date on which Maharashtra State was created), which indicated that there was no regular updation of the State Register of RMPs. In reply, MMC stated (December 2022) that in case a RMP does not renew registration in a specific time period, then MMC sends a reminder through email to RMP for renewal of registration. The fact remained that despite emails sent to RMPs, the renewal of registration by RMPs was poor.

***Recommendation 17**: The Maharashtra Medical Council may have appropriate mechanism for updating the register of Registered Medical Practitioners (RMPs) to ensure accurate information on the actual number of active RMPs in the State.*

8.5 License for operation of radiation generating equipment from Atomic Energy Research Board

Atomic Energy (Radiation Protection) Rules, 2004, provides that hospitals should obtain licence for operation of X-ray equipment from the Atomic Energy Regulatory Board (AERB). Further, as per IPHS, protective equipment such as Lead Aprons and Thermo Luminescent Dosimeters (TLD) badges should be available with all the staff working in X-ray room and these should be periodically sent to Bhabha Atomic Research Centre (BARC) for assessment.

8.5.1 Non-registration of X-ray Machines, CT scan and MRI machines

As per the provisions of Atomic Energy (Radiation Protection) Rules, 2004, (Rules) a licence is required to be issued for sources and practices associated with the operation of telegamma and accelerators used in radiotherapy, CT scan units, *etc.* The licence is valid for five years from the date of issue of such licence. AERB, Mumbai is the competent authority for issuing the licence.

Audit noticed instances of HCIs not having obtained the licence from AERB, Mumbai as shown in **Table 8.4**.

Table 8.4: Hospitals operating without obtaining or renewing AERB license

Sr. No.	Name of the selected district	Test-checked HCI operating without obtaining or renewing AERB license
1	Amravati	District Hospital
		Regional Referral Service (Super Speciality Hospital)
2	Chhatrapati Sambhajinagar	Government Medical College and Hospital, District Hospital, Sub-District Hospital, Vaijapur, Sub District Hospital, Sillod, Rural Health Training Centre, Paithan, Rural Hospital, Pishor, Rural Hospital, Khultabad and Municipal Hospital, Chhatrapati Sambhajinagar.
3	Chandrapur	Government Medical College and Hospital
4	Jalgaon	Government Medical College and Hospital, Municipal Hospital, Sub-District Hospital, Muktainagar, Sub-District Hospital, Chopada, Rural Hospital, Erandol, Rural Hospital, Parola and Rural Hospital, Pachora
5	Mumbai City and Mumbai Suburban	G. T. Hospital
6	Nanded	Sub District Hospital, Hadgaon, Sub-District Hospital, Mukhed, Government Ayurved Medical College, Rural Hospital, Naigaon and Rural Hospital, Bhokar
7	Pune	T. B. Hospital, Regional Mental Hospital and Rural Hospital, Chakan
8	Kolhapur	Rural Hospital, Kagal and Rural Hospital, Panhala

Source: Information furnished by HCIs concerned

As seen from **Table 8.4**, out of 84 test-checked HCIs (RH and above), 29 HCIs were operating X-ray machines, CT scan and MRI machines without obtaining licence from AERB as per the Atomic Energy (Radiation Protection) Rules, 2004.

The MEDD stated (January 2023) that the renewal of the said licence of the HCIs from AERB, Mumbai was under process. Reply in respect of other HCIs was awaited.

8.5.2 Non-issue of Thermo Luminescence Dosimeter badges

Hospitals while providing radiological diagnostic services must adhere to the safety and regulatory norms to protect healthcare professionals and patients from the detrimental effects of radiation. The revised IPHS (for District Hospitals), 2012 stipulated that the technicians manning the X-ray units should be provided TLD badges to indicate levels of exposure to radiation.

Audit noticed (March 2022) that TLD badges were not provided to the technicians in 27 (56 *per cent*) out of 48 test-checked HCIs in the five selected districts (Amravati, Jalgaon, Kolhapur, Pune and Nanded) having Radiology Department, thereby endangering the lives of technicians. Information from remaining HCIs was not received.

8.6 Implementation of Maharashtra Nursing Homes Registration Act

As per Section 4 of the Maharashtra Nursing Homes Registration Act, every person intending to carry on a nursing home shall make, every year, an application in prescribed form for registration or the renewal of registration to

the local supervising authority[78]. Further as per Rule 6 of the Maharashtra Nursing Homes Registration (Amendment) Rules, 2021, an application for renewal of registration shall be made in Form 'B' in advance in the month of January of the year in which registration or renewal expires.

The shortcomings noticed in the implementation of the Maharashtra Nursing Homes Registration Act are discussed in the succeeding paragraphs.

8.6.1 Inspection of Nursing home by Local Supervising Authority

As per the provisions of Rule 11A of the Maharashtra Nursing Homes Registration (Amendment) Rules, 2021, the local supervising authorities are required to inspect the nursing homes in their jurisdiction twice in a year.

There were 5,679 registered nursing homes in the nine selected districts. Out of this, in 1,383 nursing homes, no such inspections were conducted by any of the local supervising authorities. In the absence of periodical inspections, it could not be ascertained that the nursing homes continued to adhere to the staffing norms, equipment, operation theatres, ICU requirements, *etc*., based on which registration was granted.

8.6.2 Renewal of registration of nursing homes

Scrutiny of records of local supervising authorities in selected districts revealed that in five[79] out of nine selected districts, 884 out of 2,947 private nursing homes had not renewed their registrations as of March 2022. The details are shown in **Table 8.5**.

Table 8.5: Details of renewal of nursing homes

Local Supervising Authority	No. of Nursing Homes	
	Total No. of Nursing Homes	Non-renewal of registration
Civil Surgeon, Chhatrapati Sambhajinagar	253	68
Jalgaon Municipal Corporation	339	16
District Health Officer, Kolhapur	442	372
Civil Surgeon, Kolhapur	257	39
Kolhapur Municipal Corporation	325	16
Civil Surgeon, Nanded	227	93
District Health Officer, Nanded	55	13
Nanded-Waghala Municipal Corporation	311	139
Pune Municipal Corporation	738	128
Total	**2,947**	**884**

Source: Information furnished by the Local Supervising Authority

[78] (i) In the areas falling within the jurisdiction of the Municipal Corporation- the Health Officer of the concerned Municipal Corporation, (ii) In the areas falling within the jurisdiction of the Municipal Council- the Civil Surgeon of the of the District in which such council is situated, (iii) In the areas falling within the jurisdiction of a Cantonment the Health Officer of the concerned Cantonment, (iv) In the areas not falling in (i), (ii) and (iii) the District Health Officer of the concerned Zilla Parishad.

[79] Amravati, Chandrapur, Mumbai City and Mumbai Suburban districts did not furnish information.

Non-renewal of registration increases the risk of these nursing homes functioning without adhering to the staffing norms, equipment, operation theatres, ICU requirement, *etc*.

Recommendation 18*: *Government may fill the vacancies in Food and Drugs Administration in a time bound manner to strengthen its regulatory function. Government may also direct and ensure that the Local Supervising Authorities conduct periodical inspections of registered private nursing homes as per the provision of Maharashtra Nursing Home Registration (Amendment) Rules, 2021.

8.7 Bio-Medical Waste Management

Bio-Medical Waste (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 GoI framed Bio-Medical Waste (Management and Handling) Rules, 1998 under Environment (Protection) Act, 1986, which were superseded by Bio-Medical Waste Management Rules, 2016 (BMW Rules). The BMW Rules *inter alia* stipulated 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 (CBMWTF) operators.

As per Rule 10 of BMW Rules 2016, every occupier or operator handling bio-medical waste, irrespective of the quantity shall make an application to the State Pollution Control Board for grant of authorisation and the authority shall grant the provisional authorisation and the validity of such authorisation for bedded healthcare facility and operator of a common facility shall be synchronised with the validity of the consents.

Scrutiny of records and physical verification in 84 test-checked HCIs (excluding 35 PHCs) in the selected districts revealed the following:

- As per BWM Rules, 2016, an authorisation was to be obtained from the Maharashtra State Pollution Control Board (MPCB) for generation, collection, reception, storage, transportation, treatment, processing, disposal or any other form of handling of the bio-medical waste. However, six[80] HCIs had not obtained authorisation from MPCB and eight[81] HCIs had not renewed their authorisation.
- Agencies in seven HCIs to whom the contract for disposal of bio-medical waste was awarded did not have the required combined consent and authorisation from MPCB as per the Rules.

[80] (i) Sub-District Hospital, Varora, (ii) Government Medical College and Hospital, Jalgaon, (iii) Sir J. J. Group of Hospitals, Mumbai (iv) Seth G. S Mediacal College and KEM and Hospital, Mumbai, (v) Babha Hospital, Kurla and (vi) YCMH, Pimpri-Chinchwad Municipal Corporation.

[81] (i) Government Medical College and Hospital, Chhatrapati Sambhajinagar, (ii) Sub-District Hospital, Vaijapur, (iii) Sub-District Hospital, Sillod, (iv) Municipal Corporation Hospital, Chhatrapati Sambhajinagar, (v) Sub-District Hospital, Chimur, (vi) R A Podar Government Ayurved Medical College, Mumbai (vii) Bharatratna Babasaheb Ambedkar Municipal Corporation Hospital, Mumbai and (viii) T B Hospital, Pune.

- As per standards relating to disposal of liquid waste, the Occupier is required to treat the liquid waste in its effluent treatment plant (ETP) before discharge into the sewer and sludge from ETP shall be given to CBMWTF for incineration or to hazardous waste treatment, storage and disposal facility for disposal. Four HCIs had neither treated liquid waste nor had ETP.

Recommendation 19: Government may ensure that the provisions of the Bio-Medical Waste Management Rules are strictly followed for safe storage, collection and disposal of bio-medical waste generated in Health Care Institutions.