Chapter-VIII Adequacy and effectiveness of the Regulatory Mechanisms

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Adequacy and effectiveness of the Regulatory Mechanisms

There were delays in issuing licenses for manufacturing units. Action against firms manufacturing not of standard quality (NOSQ) drugs was significantly delayed.

The test reports of the samples collected during inspection of pharmacies were received with huge delays, often in or after the month of expiry of the drugs. There was significant shortfall in the number of quality inspection of retail pharmacies.

Neither the composition nor the functioning of the Rajasthan Medical Council was according to norms. Pharmacy Inspectors had not been appointed since the constitution of Rajasthan Pharmacy Council in 1978.

A significant number of Government Medical Institutions had not obtained license from Atomic Energy Regulatory Board for operation of X-ray equipment.

There were significant deficiencies in the regulation of Biomedical Waste generated by the Government Medical Institutions, such as lack of required authorisation from State Pollution Control Board, lack of protective gear/equipment to handlers and non-segregation of liquid chemical waste.

8.1 Regulatory Mechanisms in the State

The role of regulatory bodies 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 through which various regulatory bodies have been constituted. In Rajasthan, Drug Control Organisation, Rajasthan Nursing Council, Rajasthan Medical Council, Rajasthan Pharmacy Council and Rajasthan Para-Medical Council are responsible for effective regulation of the health sector. Apart from examining the functioning of some of these regulatory bodies, Audit also examined aspects related to Biomedical Waste Management, Quality Certification from National Accreditation Board of Laboratories, National Accreditation Board for Hospitals & Healthcare Providers and other mandatory requirements.

8.2 Regulation of Manufacturing of Drugs

The Drug Control Organization is a regulatory agency under Department of Medical, Health & Family Welfare, GoR and is responsible for implementation and enforcement of Drugs and Cosmetics Act, 1940. It regulates the manufacture of drugs and cosmetics and sale of drugs in the State. Its duties and responsibilities also include grant of manufacturing and sales licences for allopathic drugs, cosmetics and medical devices, grant and renewal of licences for operation of blood banks and blood storage units of the State, monitoring and issuance of good manufacturing practices certificate, good laboratory practices certificate, etc.

The Drug Control Organisation also monitors the quality of medicines and cosmetics through routine and statutory sampling, post marketing surveillance and recall of Not of Standard Quality (NOSQ) medicines and cosmetics from the market. It is also responsible for investigation of complaints and detection of spurious, adulterated and misbranded drugs, cosmetics and medical devices and launching prosecution against the offenders.

8.2.1 Issue of Licenses to Manufacturing Units

License for manufacturing of drugs is issued under the provisions of Drugs & Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945. Once a manufacturer applies for manufacturing license and meets all the requirements, the State Drug Controller conducts joint inspection of factory premises along with Central Drug Standards Control Organisation, GoI. If any shortcoming/ discrepancies are observed during the joint inspection, the applicant is intimated to rectify the same and submit compliance report. Upon receipt of compliance report from the applicant, it is verified by the officer¹⁴⁰ concerned and the license is issued if it is found satisfactory.

Rule 52 of Drugs and Cosmetics Rules, 1945 states that all the manufacturing firms are to be inspected at least once in a year. Further, Rule 83 states that on an application being made for renewal, the licensing authority may cause an inspection to be made and if satisfied that the conditions of the license and the rules under the act are continued to be observed, it shall issue a certificate for renewal. The renewal of manufacturing license is done for five years.

Further, according to Rajasthan Guaranteed Delivery of Public Services Act, 2011, the manufacturing license is supposed to be issued within three months from the date of application. As per circular dated 11 February 2020 issued by Medical and Health Department, GoR, the certificate of Good Manufacturing Practices¹⁴¹ (GMP) should be issued within five days.

¹⁴⁰ Assistant drug controller or drug control officer posted in the concerned districts.

¹⁴¹ Good Manufacturing Practices (GMP) ensure that products are consistently produced and controlled according to quality standards. The requirements of Good Manufacturing Practices are laid down in Schedule M of Drugs and Cosmetics Rules 1945.

Audit analysed the records of the office of the Drug Controller of State pertaining to licenses issued to eight manufacturing units¹⁴² and found that except for one annual inspection of one firm¹⁴³ (in May 2020), regular annual inspection was not carried out in any of the eight test-checked manufacturing units by the Drug Control Officers of the districts where the manufacturing units were located.

It was also observed that in case of these eight manufacturing firms, licenses were issued with delays in two¹⁴⁴ cases, with the delay ranging from 23 to 36 days. In three¹⁴⁵ cases, the licenses were renewed with the delay of 7 days to 327 days.

Further, delay in issue of GMP certificate was observed in one¹⁴⁶ case. In one¹⁴⁷ case, it was observed that renewal of license was done without any inspection.

The State Government stated (January 2024) that issuance of new manufacturing license and GMP certificates within the stipulated time will be ensured. It was also stated that joint inspection of the manufacturing units will be carried out within the stipulated time as per rules.

Recommendation 15: The State Government should ensure that issue and renewal of manufacturing licenses are done in a time bound manner and annual inspections are conducted regularly.

8.2.2 Action in cases of manufacturing of Not of Standard Quality (NOSQ) Drugs

To control manufacturing of spurious drugs in the State, Drug Control Officers in the districts collect samples from the manufacturing units which are then sent to Drug Testing Laboratory, Jaipur for testing. If the tested drugs are found to be sub-standard/fake/spurious, then proposal for action to be taken should be sent to Drug controller, Rajasthan within three months. Further, the Drug controller should send report in this regard to the State Government in seven working days and in case the Drug Control Officer recommends judicial action, approval will necessarily be decided by the Drug Controller within 15 days.

¹⁴² Eight manufacturing units: M/s Enzi Healthcare, Udaipur; M/s Vardhman Pharma, Udaipur; M/s Shreyans Healthcare Private Limited, Ajmer; M/s Parth Formulation Private Limited, Ajmer; M/s Shakambhari Stone Crusher Co., Jhunjhunu; Firm Dhanuka Laboratory Limited, Jodhpur; Neelkanth Menachem, Jodhpur, Ananta Medicare Ltd., Sriganganagar.

¹⁴³ Ananta Medicare Limited, Sriganganagar.

¹⁴⁴ M/s Shakambhari Stone Crusher Company, Jhunjhunu (23 days delay), Ananta Medicare Limited, Sriganganagar (36 days delay)

¹⁴⁵ M/s Enzi Healthcare, Udaipur (327 days delay); M/s Parth Formulation Private Limited, Ajmer (44 days delay); Neelkanth Menachem, Jodhpur (07 days delay).

¹⁴⁶ M/s Vardhman Pharma, Udaipur (43 days delay).

¹⁴⁷ Neelkanth Menachem, Jodhpur.

Audit selected ten cases¹⁴⁸ of inspections by Drug Control Officers (inspections carried out in August 2016-October 2017) in six districts involving four drugs which were declared NOSQ by Drug Testing Laboratory. Audit noticed that:

- In nine out of the ten cases, the Drug Control Officers of the six districts took more than the mandated three months to move the necessary proposals regarding prosecution/judicial action to the Drug Controller. No evidence of sending report to the State Government as required was found.
- In all the ten cases, the State Drug Controller delayed the issue of sanction to prosecute the offenders. The delay was three months in one case, four to 12 months in six cases, and 13 months, 33 months and 35 months in one case each.
- In eight out of ten test-checked cases, the District Drug Control Officers did not file suit against the delinquent firms even after more than 14 months of receiving sanction for prosecution by the State Drug Controller. Details are given in *Appendix 8.1*.

The State Government stated (January 2024) that in most of the cases the delay in filing the prosecution is due to non-availability of constitution of firm especially out of State firms. It was further stated that to overcome this problem Drug Control Officers are being sent to the other States to bring the constitution of culprit firms and expedited the process of filing the prosecution against the culprits.

GoR informed reasons for delay in filing the prosecution. The fact remains that timely action could not be initiated by the department against manufacturers for manufacturing of Not of Standard Quality Drugs.

Recommendation 16: The State Government should fix responsibility of officers concerned for failure to ensure timely and appropriate action against the manufacturers of not of standard quality drugs.

¹⁴⁸ Ten cases: ADC, Alwar: Three cases (Cefixime Tab IP (Jonfix-200) Batch No. 17131, Amoxycillin Trihydrate & Potassium Claulanate Tab (Batch 17207) and Cefixime Ofloxacin & Lactobacillus Tab (Batch No. 170102); ADC, Jodhpur: Three cases (Nicorandil Tab 5 mg (Batch No. MTA 151089), Cefixime Tab IP 200 mg (Batch No. CKM 0161001) and Amoxycillin Trihydrate & Potassium Claulanate Tab Batch No. BT 15-580); ADC, Chittorgarh: One case (Amoxycillin Trihydrate & Potassium Claulanate Tab Batch 16065); ADC, Ajmer: One case (Cefixime Tab IP (Jonfix-200) (Batch No. 17131); ADC, Jaipur: One case (Pregabalin Capsules Batch No. SC-15028); ADC, Udaipur: One case (Amoxycillin Trihydrate & Potassium Claulanate Tab (Batch No. 17017).

8.2.3 Quality inspection of retail pharmacies

To monitor the quality of drugs, staff of Drug Control Organization conducts inspection of sales wherein samples are drawn and sent to Drug Testing Laboratory, Jaipur for testing. If the drugs are found 'Not Of Standard Quality (NOSQ)', they are removed from circulation. Drug Testing Laboratory, Jaipur was the only Government testing laboratory in Rajasthan.

As per Rule 45(1) of the Drugs and Cosmetics Rules 1945, samples of drugs should be analyzed and test reports furnished within a period of 60 days of receipt of the sample.

Audit observed that 77 *per cent* of the test reports were furnished by the Drug Testing Laboratory, Jaipur after 60 days of receipt of sample for testing from Drug Control Officers. Details are given in *Appendix 8.2*. Audit also found huge pendency¹⁴⁹ (e.g. 6,077 samples pending in 2021-22) in testing of drug samples at Drug Testing Laboratory, Jaipur.

To further assess the efficiency of the testing process, audit examined the details of drugs sample testing during three selected months i.e. April 2016, March 2021 and March 2022 at Drug Testing Laboratory, Jaipur. Audit observed that 99 *per cent* of the samples took more than the prescribed 60 days for testing. About 40 *per cent* of the samples took more than 150 days to one year, while 55 *per cent* of the samples took more than one year for testing.

It was further observed that 17 *per cent* test reports were received by the Drug Control Officers concerned from the laboratory in the month in which the drug was expiring, and another 12 *per cent* test reports were received after the expiry of the drugs. Details are given in *Appendix 8.3*. Year-wise details are shown below in **Table 8.1**:

Financial Year	Total Number of test reports received	Total Number of test reports received in expiry month	Total Number of test reports received after expiry month	
2016-17	3,540	682	395	
2017-18	3,217	700	520	
2018-19	2,995	760	664	
2019-20	4,504	946	609	
2020-21	4,826	532	356	
2021-22	4,732	420	359	
Total	23,814	4,040 (17 per cent)	2,903 (12 per cent)	

Table 8.1: Test reports received in or after expiry month

Source: Information provided by Drug controller, Rajasthan.

Audit observed that total 1,207 samples were declared as 'Not Of Standard Quality' during 2016-22 at Drug Testing Laboratory, Jaipur and 70 out of these were received from DTL in the month in which the drugs were expiring, as shown below in **Table 8.2**:

^{149 4,606} samples in 2016-17; 5,888 samples in 2017-18; 5,625 samples in 2018-19; 7,483 samples in 2019-20; 6,345 samples in 2020-21; 6,077 samples in 2021-22.

Financial Year	Total samples declared as 'Not of Standard Quality'	Total Number of Test reports received in expiry month
2016-17	182	-
2017-18	300	08
2018-19	206	13
2019-20	193	16
2020-21	155	05
2021-22	171	28
Total	1,207	70

Table 8.2: Not Of Standard Quality (NOSQ) reports received in expiry month

Source: Information provided by Drug Testing Laboratory, Rajasthan, Jaipur.

Thus, the possibility of these 'NOSQ' drugs being sold out from circulation cannot be ruled out.

The Drug Testing Laboratory, Jaipur stated (January 2022) that it was possible to test only 250-300 samples in a month due to huge shortage of technical staff and around 600-700 samples are being received in each month. Further, it was also stated that among the samples received, priority is given to expiring samples.

The Government of Rajasthan announced (2012-13) establishment of three new Drug Testing Laboratories in Jodhpur, Bikaner and Udaipur districts to augment the testing capacity. Audit observed that the three Testing Labs were constructed and handed over¹⁵⁰ between October 2014 and May 2018, at an expenditure of \gtrless 6.81 crore¹⁵¹. However, these labs were not made functional even after nine years of approval as of March 2022.

The State Government stated (May 2023) that the two Drug Testing Laboratories in Bikaner and Udaipur have been made functional w.e.f. August 2022. It was further stated that recruitments are being done to make Drug Testing Laboratory in Jodhpur operational. It was further stated (January 2024) that Assistant Drug Analyst have been joined in laboratories and orders have been issued by State Government for appointments of technical staff in laboratories.

¹⁵⁰ Handed over: Drug Testing Lab, Bikaner: 02.10.2014, Drug Testing Lab, Udaipur: 12.01.2018 and Drug Testing Lab, Jodhpur: 09.05.2018.

^{151 ₹ 6.81} crore: DTL Jodhpur: ₹ 2.13 crore, DTL Bikaner: ₹ 1.85 crore and DTL Udaipur: ₹ 2.83 crore.

8.2.4 Shortfall of inspections at retail pharmacies

As per norms prescribed (November 2019) by the Department of Medical, Health and Family Welfare, GoR, each Drug Control Officer is required to conduct 20 inspections of sales premises (retail and wholesale) per month.

Audit observed that out of their prescribed cumulative inspection target¹⁵² of 94,800 inspections during 2016-22, there was a shortfall of 29,665 (31 *per cent*) inspections in the State as shown in **Table 8.3** below:

Annual target for Inspection	Achievement	Shortfall	Percentage shortfall
12,960	7,376	5,584	43.09
10,320	7,907	2,413	23.38
15,120	8,808	6,312	41.75
16,560	11,820	4,740	28.62
18,000	12,476	5,524	30.69
21,840	16,748	5,092	23.32
94,800	65,135	29,665	(31 per cent)
	12,960 10,320 15,120 16,560 18,000 21,840	12,960 7,376 10,320 7,907 15,120 8,808 16,560 11,820 18,000 12,476 21,840 16,748	12,9607,3765,58410,3207,9072,41315,1208,8086,31216,56011,8204,74018,00012,4765,52421,84016,7485,092

Table 8.3: Shortfall in inspection at retail pharmacies

Source: Information provided by the office of the Drug controller, Rajasthan.

Audit noticed a wide variation in shortfall of inspections which varied from 5.28 *per cent* in Sriganganagar to 67.08 *per cent* in Banswara as detailed in *Appendix 8.4*.

The State Government stated (May 2023) that shortfall of inspections during 2020-2021 and 2021-2022 was due to Covid pandemic. It was further stated (January 2024) that out of 116 female officers, 28 female officers were on maternity leave during the period mentioned above.

The fact remains that GoR could achieved the target for inspection of retail pharmacies upto 69 *per cent* only and targets were also not achieved during 2016-20. Further, the Department has not taken any measures to achieve the targets.

8.3 Rajasthan Medical Council

The Rajasthan Medical Council was established (March 1952) under the Rajasthan Medical Act, 1952. The Council registers the qualified medical practitioners working in private as well as in public sector. The Rajasthan Medical Council maintains the bio-data of the qualified doctors and keeps a watch on the conduct and upholding of ethics of the medical profession.

Section 4 of the Rajasthan Medical Act, 1952 prescribes the regulation of membership of the Council. The Council shall consist of the following members, namely:- (a) A President to be nominated by the Government; (b) Three members to be nominated by the Government; (c) One member to be elected from amongst the members of the faculty of medicine of Rajasthan University of Health Sciences (RUHS); (d) One member to be elected by and

¹⁵² Annual inspection target calculation= Number of Drug Control Officers in the district X target per month X 12 months.

from the staff of each Medical College affiliated to the RUHS; (e) Three members to be elected from amongst themselves by registered practitioners who are graduates in Medicine or Surgery; and (f) Three members to be elected from amongst themselves by registered practitioners other than those referred to in clause (e).

Further, Sub-Section 1(b) of Section 9 of the Rajasthan Medical Act, 1952 dealing with cessation of membership prescribes that a member of the Council shall be deemed to have vacated his seat on his absence (without excuse which is deemed sufficient in the opinion of the Council) from three consecutive meetings of the Council.

Scrutiny of records provided by Rajasthan Medical Council for the period 2016-22 revealed that:

- Three members who were to be nominated to the Council by the Government were not nominated from August 2018 to July 2019;
- No member was ever elected to the Council from amongst the members of the faculty of medicine during 2016-21.
- Elected members from amongst the staff of College of Medical Science under RUHS, Jaipur since its constitution in the year 2014-15, and from the six Medical Colleges¹⁵³ had not been a part of the Council for periods ranging from 49 to 615 days.
- Two members nominated under clause 4(d) did not attend three consecutive meetings¹⁵⁴. However, their seats were not vacated as required under Section 9 (1) (b) of the Rajasthan Medical Council Act.

Thus, neither the composition nor the functioning of the Rajasthan Medical Council was in accordance with the requirements of the Rajasthan Medical Act.

The State Government stated (January 2024) that due to excess time taken in election process the member could not be elected from the attached medical colleges of RUHS. However, members are now elected from Medical colleges.

It was further stated that members from the college councils could not attend the meetings due to their pre-occupation in work and therefore, consent of the members are taken telephonically to take unanimous decisions in important matters. It was also stated that the member from the medical colleges could not attend council meetings due to their engagement in teaching work and treatment of patients.

¹⁵³ Six Medical Colleges: Medical College, Jodhpur: 49 days (23.04.2019 to 10.06.2019), Medical College, Jhalawar: 63 days (26.03.2020 to 27.05.2020), Medical College, Ajmer: 60 days (29.08.2017 to 23.10.2017 & 24.10.2020 to 27.10.2020), Medical College, Udaipur: 169 days (05.11.2017 to 22.04.2018), Medical College, Kota: 615 days (18.11.2017 to 20.07.2018 and 04.12.2020 to 08.12.2021) and Medical College Bikaner 490 days (27.11.2020 to 31.03.2022).

¹⁵⁴ JLN Medical College, Ajmer: (10.01.2020, 27.02.2020 and 19.09.2020) and RNT Medical College, Udaipur: (23.11.2015, 18.01.2016 and 20.06.2016).

The fact remains that the functioning of the Rajasthan Medical Council was not in accordance with the requirements of the Rajasthan Medical Act.

8.4 Rajasthan Pharmacy Council

The Rajasthan Pharmacy Council is a statutory body constituted under the Central Pharmacy Act, 1948. It regulates the profession and practice of pharmacy in the State.

As per Section 26A (1) of the Central Pharmacy Act, 1948, the State Council may appoint Inspectors¹⁵⁵ with the previous sanction of the State Government.

Audit observed that Pharmacy Inspectors had not been appointed in the State since the constitution of Rajasthan Pharmacy Council in 1978.

The State Government stated (January 2024) that inspectors were not appointed due to non-availability of service rule for appointment and qualification of inspectors in the Central Pharmacy Act, 1948. It was further stated that post of Drug Control Officers are created under the control of Food Safety and Drug Controller directorate who inspect the Drug Pharmacy in the State.

Non-appointment of Pharmacy Inspectors negatively impacts the control over sale, distribution of fake/spurious drugs and operation of unregistered medical stores in the State.

Recommendation 17: The State Government should monitor the functioning of the State Medical Council and State Pharmacy Council to ensure effective regulation by these bodies.

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

Atomic Energy (Radiation Protection) Rules, 2004, provide that hospitals should obtain license for operation of X-ray equipment from Atomic Energy Regulatory Board. Further, as per IPHS, protective gear¹⁵⁶ should be available with all the staff working in X-ray rooms and these should be periodically sent to Bhabha Atomic Research Centre (BARC) for assessment.

Audit of the 46 test-checked GMIs¹⁵⁷ revealed that 14 (30 *per cent¹⁵⁸*) of these institutions did not obtain the required licenses from Atomic Energy Regulatory Board to operate the X-ray equipment. Further, out of the remaining 32 GMIs,

¹⁵⁵ An Inspector may inspect any premises where drugs are compounded or dispensed and submit a written report to the Registrar and enquire 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 the Act and report to the Registrar and Institute prosecution under the order of the Executive Committee of the State Pharmacy Council.

¹⁵⁶ Lead Aprons and Thermo Luminescent Dosimeters badges.

^{157 46} Government Medical Institutions: 34 DHs, Four SDHs and Eight CHCs.

^{158 14} Government Medical Institutions: DHs Baran, Salumber, Phalodi, Balotra, Sagwara, Gangapur City, Jaisalmer, Nokha, SDHs Salawas and Vallabhnagar and CHCs Sarada, Srikaranpur, Anta and Singhana.

five GMIs¹⁵⁹ (16 *per cent*) had not been renewed their licenses from Atomic Energy Regulatory Board before their expiry.

In 19^{160} of the 46 GMIs, adequate protective ceiling, suspended screens and table curtains/flaps were not used in the X-ray rooms as required under Rule 7.3 (i) of Atomic Energy Regulatory Board Safety Code¹⁶¹. In 43 GMIs¹⁶² (93 *per cent*), Radiological Safety Officers were not appointed for X-Ray department as required under Rule 7 (2)(e)(iii) of Atomic Energy (Radiation Protection) Rules, 2004. Thermo Luminescent Dosimeter (TLD) badges were not being sent to BARC on regular basis for assessment of radioactivity by 22 GMIs¹⁶³ (48 *per cent*).

The State Government stated (January 2024) that to obtain AERB license, work related to GAP analysis of DH/SDH/SH has completed and its implementation is under process. It was further stated that directions will be issued to concerned for compliance of rules.

8.6 Regulation of Biomedical Waste Management

Bio Medical Waste is generated during procedures related to diagnosis, treatment and immunization in the hospitals and its management is an integral part of infection control within the hospital premises. The GoI framed the Bio-Medical Waste Management Rules, 2016 which *inter alia* stipulates the procedures for collection, handling, transportation, disposal and monitoring of the Bio Medical Wastes with clear roles for waste generators and Common Bio-Medical Waste Treatment Facility.

In the DHs of the State, Audit observed that Bio Medical Waste Rules and IPHS for proper management of Bio Medical Waste were not being properly complied with by the DHs. The instances of non-compliance in 34 DHs are depicted in **Chart 8.1** below:

¹⁵⁹ Five Government Medical Institutions: DHs Jhunjhunu, Pipar City, Bundi and CHCs Asop and Jobner.

^{160 19} Government Medical Institutions: 11 DHs: Jhunjhunu, Baran, Phalodi, Beawar, Sawai Madhopur, Neem ka Thana, Sheoganj, Gangapur City, Hanumangarh, Nokha, Chittorgarh; SDH Vallabhnagar and Seven CHCs: Asop, Sanchore, Singhana, Srikaranpur, Jobner, Anta, Sarada.

¹⁶¹ AERB Safety Code No. AERB/RF-MED/SC-3 (Rev.2) regarding radiation safety in manufacture, supply, and use of medical diagnostic X-ray equipment.

^{162 43} Government Medical Institutions: 31 DHs: Kishangarh, Phalodi, Jalore, Baran, Jhunjhunu, Salumber, Nagaur, Dausa, Sawai Madhopur, Kekri, Rajsamand, Pratapgarh, Neem ka Thana, Banswara, Balotra, Sheoganj, Karauli, Tonk, Alwar, Pipar City, Sagwara, Sirohi, Gangapur City, Jaisalmer, Hindaun, Bundi, Hanumangarh, Dholpur, Shahpura, Chittorgarh and Nokha; Four SDHs: Bijainagar, Salawas, Sanganer and Vallabhnagar; all test-checked eight CHCs.

^{163 22} Government Medical Institutions: 14 DHs: Phalodi, Sawai Madhopur, Pratapgarh, Neem ka Thana, Sheoganj, Karauli, Tonk, Pipar City, Sagwara, Gangapur City, Jaisalmer, Hindaun, Bundi, and Nokha, Two SDHs Sanganer, Vallabhnagar, Six CHCs: Asop, Singhana, Jobner, Anta, Sanchore and Sarada.

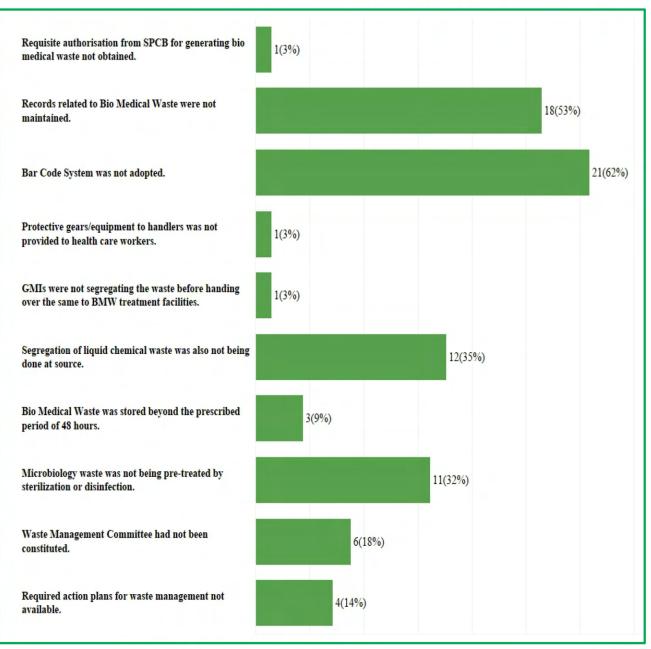


Chart 8.1: Instances of non-compliance in DHs as of 31 March 2022

Source: Information provided by DHs.

In the other 28 test-checked GMIs¹⁶⁴ also, Audit observed that Bio Medical Waste Rules and IPHS for proper management of Bio Medical Waste were not being properly complied with by the GMIs. The instances of non-compliance are depicted **Chart 8.2** below:

^{164 28} GMIs: Four SDHs, Eight CHCs and 16 PHCs.

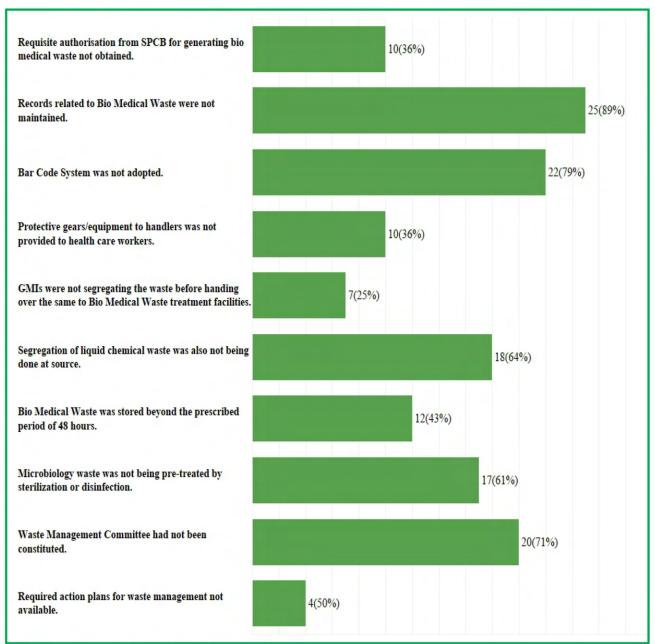


Chart 8.2: Instances of non-compliance in test-checked GMIs as of 31 March 2022

Source: Information provided by the test-checked GMIs.

The State Government stated (January 2024) that the training of Bio Medical Waste Management has been given to Medical Officers, Nursing Officers posted at DHs/SHs by State Institute of Health and Family Welfare. It was further stated that there is no specific Bio Medical Waste Management cell at State level for monitoring and evaluation.

Non-compliance of Bio Medical Waste Management rules contributes to health and environment hazards and directly impacts the health and safety of both the handlers and patients.