# Chapter VIII: Regulatory Mechanism

To provide a sufficient level of quality healthcare in public/private health institutions throughout the country, various acts/regulations have been laid down. These acts/ regulations are made to standardise and supervise healthcare, ensure that health institutions comply with public health policies and provide safe healthcare to all patients.

## 8.1 State Medical Council

In terms of Para 30 (1) of the National Medical Commission (NMC) Act 2019, the State Government is to establish a State Medical Council (SMC) if no such council exists in that State. In Himachal Pradesh, the Medical Council was constituted under Himachal Pradesh Medical Council Act, 2003 and came into force in 2004.

The State Medical Council is required to:

- Maintain the live register and provide for the registration of medical practitioners.
- Prescribe a code of ethics for regulating the professional conduct of practitioners.
- Reprimand a practitioner, or suspend or remove his name from the register, or take such other disciplinary action.
- Receive complaints from the public (including patients or their relatives) against misconduct or negligence by a medical practitioner.
- Ensure that no unqualified person practices modern scientific systems of medicine.
- Provide protection to its members in discharging professional duties.

As per Section 3(3) of the Himachal Pradesh Medical Council Act 2003, the State Medical Council shall consist of (a) four members having requisite qualification as prescribed in the Indian Medical Council Act, 1956 (102 of 1956), to be nominated by the Government; (b) one member from each Government Medical College, elected by members of the medical faculty of that college from amongst its permanent members of teaching faculty; (c) nine members to be elected by registered practitioners from amongst themselves including one member elected by the Himachal Pradesh Medical Officers Association (d) Director of Medical Education (e) Principals of the Government Medical Colleges of the State and (f) Director of Health Services. Further, as per Section 3 (9), the Government shall, by notification in the official gazette, publish the names of the members. Presently, the Council is working with the strength of President and ex-officio members and there are no elected/nominated members (March 2023).

Audit noticed from the records of the SMC that:

- Section 31(6) of the National Medical Commission (NMC) Act, 2019 prescribes that every State Medical Council shall maintain and regularly update the State register in the specified electronic format and supply a physical copy of the same to the Ethics and Medical Registration Board within three months of the commencement of this Act.

Audit noted that SMC had not published the list of all registered practitioners in the public domain on yearly basis; however, it was stated that it had maintained a list of registered medical practitioners manually and quarterly reports were sent to NMC.

- Rule 15(7) of Himachal Pradesh Medical Council Act, 2003 says that no person though qualified in modern scientific system of medicine, shall practice in the State of Himachal Pradesh without having a certificate of registration. Any person serving or practising modern scientific system of medicine in Himachal Pradesh shall be registered with the Council under this Act.

  In this regard, it was noted that:

  - Not all the employed doctors in Himachal Pradesh were registered with the SMC and no mechanism was adopted by the SMC to track the non-registered employed/non-employed doctors.
  - No procedure was developed by the SMC to de-register/cancel the names of doctors who had expired or migrated to other states or stopped practicing in the State.
  - SMC had published a public notice on 03/07/2015 in leading newspapers for re-registration of doctors requiring renewal of their registration. Audit observed that as of September 2022, 2779 doctors had not renewed their registration. No action was taken by the SMC against those doctors who were practicing without renewals/registration.

## 8.2 Regulation through Clinical Establishments Act (CEA), 2010

Clinical Establishments Act aims to register and regulate clinical establishments based on minimum standards to improve quality of public healthcare in the country. The Act is applicable to all types (both therapeutic and diagnostic types) of clinical establishments from the public and private sectors, belonging to all recognised systems of medicine, including single doctor clinics.

In exercise of the powers conferred by Section 54 of the Clinical Establishments (Registration and Regulation) Act 2010, the Government of Himachal Pradesh had framed the Himachal Pradesh Clinical Establishments (Registration and Regulation) Rules, 2012.

As per Section 8 of CEA 2010, the State Council for Clinical Establishments was constituted in 2012 and reconstituted in 2018. The State Council shall perform the following functions:

- Compiling and updating the state register of clinical establishments.
- Sending quarterly returns for updating the national register (including in the digital format).
- Hearing of appeals against the orders of the authority, publication on annual basis of a report on the state of implementation of standards in the State.
- Monitoring the implementation of the provisions of the Act and rules in the State.

### 8.2.1 Non-functioning of State Council of Clinical Establishments

Section 8(1) of the Clinical Establishments (Registration & Regulation) Act, 2010 stipulates that the State Government shall constitute a State Council for clinical establishments. Subsequently, the State Council of Clinical Establishments was constituted in November 2012 and was reconstituted in December 2018 with Chairman[1] and 18 other ex-officio members (all heads of health directorates, one representative each to be nominated by the executive committee of the State medical/dental/nursing/pharmacy council and other members). Audit scrutiny revealed the following:

- The Council had not compiled and updated the State registers of clinical establishments as mandated in Para 4 (a) of the Himachal Pradesh Clinical Establishments (Registration and Regulation) Rules, 2012, due to which the position of the number of clinics and nature of clinics running in the State could not be ascertained.
- In terms of Para 7 of the Himachal Pradesh Clinical Establishments (Registration and Regulation) Rules, 2012, the State Council is to conduct meetings every six months. It was, however, noticed that since the constitution of the State Council, only one meeting was held on September 2017. Due to non-conducting of meetings on a regular basis, important regulatory issues relating to clinical establishments remained undiscussed.

  The Department in its reply stated that the State Council meeting could not be held due to frequent change of officers at senior level and due to Covid pandemic.
- In terms of Para 11 of the Himachal Pradesh Clinical Establishments (Registration and Regulation) Rules, 2012, the Council was to prepare the annual accounts and get it audited annually by a chartered accountant. The Council had not prepared annual accounts since its formation.

Thus, the State Council of Clinical Establishment at the apex level had not been functioning effectively, which could be a major reason for poor implementation of the CEA in the State as discussed in the succeeding paragraphs.

The Government (January 2024) admitted the facts and stated that the Government of India is developing a portal for maintenance of register for clinical establishments.

### 8.2.2 Non-initiating permanent registration

In April 2016, Government of India directed the State Government to start the process of permanent registration of all clinical establishments. Subsequently, all the District Registering Authorities (DRA) were directed during May 2016 by the Director, Health Safety & Regulation, Himachal Pradesh to start permanent registration. The Act provided that no enquiry is to be conducted prior to grant of provisional registration and provisional registration issued by the authorities is valid for a period of one year only.

Audit observed that though directed by GoI in 2016, there was no mechanism put in place for permanent registration of the clinical establishments. The process of permanent registration was yet to be initiated till date (January 2024).

[1] Chairman: Additional Chief Secretary/ Principal Secretary/ Secretary (Health).

Further, the Act and the Himachal Pradesh Clinical Establishments (Registration and Regulation) Rules, 2012, did not provide for specific number of regular inspections of establishments with provisional registration. Thus, due to lack of proper monitoring provisions, clinical establishments were operating without provisional registration or without renewal of provisional registration as discussed in succeeding paragraphs.

The Department, in reply, admitted the facts and stated that most of the clinical establishments were being inspected only on complaint basis.

This indicates serious flaws in implementation of the provisions since regular inspections are necessary for ensuring operation of the establishments as per the rules.

In the Exit Conference, Secretary (Health) admitted the facts and stated that detailed modalities have not been received from Government of India regarding permanent registration.

The Government in its reply (January 2024) stated that the registration and renewal process under the Act is being addressed through the Government of India portal where there is no provision of permanent registration till date. They are dependent on Government of India for permanent registration under the Act and they are in constant touch with them for the same.

### 8.2.3 Non-renewal of registration by clinical establishments

In terms of Section 17 of the CEA 2010, the validity of provisional registration shall be the last day of the twelfth month from the date of issue of the certificate of registration and such registration shall be renewable.

Details of clinics provisionally registered in the selected districts are given in **Table 8.1**.

**Table 8.1: Details of provisionally registered clinical establishments**

| Year | Kinnaur | Solan | Kangra | Total |
|---|---|---|---|---|
| 2016-17 | 5 | 99 | 530 | 634 |
| 2017-18 | 9 | 34 | 547 | 590 |
| 2018-19 | 11 | 18 | 591 | 620 |
| 2019-20 | 7 | 10 | 679 | 696 |
| 2020-21 | 10 | 25 | 708 | 743 |
| 2021-22 | 8 | 113 | 206 | 327 |
| **Total** | **50** | **299** | **3,261** | **3,610** |

*Source: Departmental figures.*

From **Table 8.1**, it can be seen that 3,610 clinics were provisionally registered in the three selected districts during the period 2016-22.

During joint physical verification of 23 private clinical establishments in the selected districts, it was noticed that 11 clinics/hospitals were running without renewal of their provisional registration and one clinic was not registered at all.

The health authority had not developed any mechanism to track and monitor the clinics running without registration, closed clinics, clinics running with unqualified staff etc., as no notices were issued by the DRAs in the selected districts to the clinics who were not renewing their registration.

### 8.2.4 Fixing of rates in private clinics without consultation with the Government

As per the operational guidelines for private clinical establishments, rates for procedures and services to be charged by the private clinics/hospitals were to be determined by the Central Government from time to time in consultation with the State Government. However, in Himachal Pradesh, Audit observed during joint physical verification that as the State Government did not prescribe any rates to be charged by the private clinics/ hospitals, the rates were fixed by the owners themselves. Hence, there is every possibility of overcharging by private clinics, nursing homes, etc. entailing more financial burden on the patients.

The guidelines further prescribed that the private clinics should display the details of charges at a conspicuous place. During joint physical verification of 23 private clinics, it was noticed that charges of treatment were not displayed in 18 clinics.

## 8.3 Regulation through Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) (PCPNDT) Act, 2002

The Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) (PNDT) Act, 1994, amended and renamed as the Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) (PCPNDT) Act, 2002 is an act to provide for the prohibition of sex selection, before or after conception, and for regulation of pre-natal diagnostic techniques for the purpose of detecting genetic abnormalities or metabolic disorders or chromosomal abnormalities or certain congenital malformations or sex linked disorders and for the prevention of their misuse for sex determination leading to female foeticide; and, for matters connected therewith or incidental thereto.

As per the Annual Administrative Report 2016-17 published by Directorate of Health Safety and Regulation, Himachal Pradesh, CMO and BMOs were authorised and required to conduct the inspection of ultrasound clinics at least once in three months.

The details of inspections of private clinics having ultrasound facility conducted by health authorities in the State are shown in **Table 8.2**.

**Table 8.2: Details of inspection of ultrasound clinics in the State**

| Year | Total number of ultrasound clinics registered in the State | No. of inspections required to be conducted (4 X number of ultrasound clinics in a year) | Total number of inspections conducted during the year | Shortfall | *Per cent* shortfall |
|---|---|---|---|---|---|
| 2016-17 | 357 | 1,428 | 843 | 585 | 40.97 |
| 2017-18 | 376 | 1,504 | 952 | 552 | 36.70 |
| 2018-19 | 401 | 1,604 | 1,121 | 483 | 30.11 |
| 2019-20 | 417 | 1,668 | 1,037 | 631 | 37.83 |
| 2020-21 | 439 | 1,756 | 591 | 1,165 | 66.34 |
| 2021-22 | 353 | 1,412 | 716 | 696 | 49.29 |

*Source: Director Health Safety & Regulation.*

From **Table 8.2**, it can be seen that there was shortfall ranging from 30.11 *per cent* to 66.34 *per cent* in conducting inspections of the ultrasound clinics during 2016-22.

The authorities of the Directorate of Health Safety & Regulation stated that due to shortage of staff and Covid pandemic, the targeted inspections could not be conducted.

Status of inspections conducted by health authorities in the private clinics having ultrasound facility in the test-checked districts is shown in **Table 8.3**.

**Table 8.3: Details of inspections of clinics having ultrasound facilities in the selected districts**

| Year | Total number of ultrasound clinics registered in the test-checked district | | | Number of inspections required to be conducted (4 X number of ultrasound clinics in a year) | | | Total number of inspections conducted during the year | | | Shortfall (*Per cent*) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Kinnaur | Solan | Kangra | Kinnaur | Solan | Kangra | Kinnaur | Solan | Kangra | Kinnaur | Solan | Kangra |
| 2016-17 | 0 | 26 | 58 | NA | 104 | 232 | NA | 104 | 145 | NA | No shortfall | 87 (37.50) |
| 2017-18 | 1 | 27 | 65 | 4 | 108 | 260 | 0 | 123 | 207 | 4 (100) | --do-- | 53 (20.38) |
| 2018-19 | 0 | 30 | 68 | NA | 120 | 272 | NA | 139 | 163 | NA | --do-- | 109 (40.07) |
| 2019-20 | 1 | 31 | 73 | 4 | 124 | 292 | 0 | 104 | 198 | 4 (100) | 20 (16.13) | 94 (32.19) |
| 2020-21 | 0 | 31 | 79 | NA | 124 | 316 | NA | 95 | 63 | NA | 29 (23.39) | 253 (80.06) |
| 2021-22 | 0 | 33 | 80 | NA | 132 | 320 | NA | 92 | 62 | NA | 40 (30.30) | 258 (80.63) |

*Source: Respective district CMOs. NA- Not applicable.*

From **Table 8.3**, it can be seen that there was shortfall in conducting inspection of the ultrasound clinics every year, ranging from 16.13 *per cent* to as much as 100 *per cent* in the selected three districts during 2016-22 except during 2016-19 in Solan district, when inspections exceeded the prescribed targets.

Further, during joint physical verification of six private clinics having ultrasound facility in the selected districts, it was noticed that only four of these clinics were inspected by the health authorities, however, no inspection reports of the same were provided to Audit.

Thus, shortfall in inspection of ultrasound clinics could be a major contributing factor towards low child sex ratio in Himachal Pradesh in 2015-16 (919) to 2019-21 (929) as per the data of NFHS-4 and NFHS-5 respectively and demands attention.

The Government in its reply (January 2024) stated that there was a noticeable shortfall of inspections in the years 2020-21 and 2021-22 only because of Covid pandemic but now there is substantial improvement in the number of inspections in the year 2022-23.

## 8.4 Regulation through Drugs & Cosmetics Act, 1940

The Drugs and Cosmetics Act, 1940 regulates the import, manufacture and distribution of drugs in India. In exercise of the powers conferred by Sections 6(2), 12, 33 and 33N of the Drugs and Cosmetics Act, 1940 (XXIII of 1940), the Central Government made the Drugs and Cosmetics Rules, 1945.

In Himachal Pradesh, State Drug Controller, Baddi is assisted by Deputy Drug Controller, Assistant Drug Controllers and Drug Inspectors for implementation of the Act in the State. The authorities of this office have the power to grant, renew, suspend, cancel licences for manufacturing of drugs and cosmetics. The Drug Inspectors are required to collect drug samples from the drug manufacturers, suppliers/wholesalers/retailers and different drug stores of government health institutions and send them to the government analyst (Composite Testing Laboratory, Kandaghat) for testing the standard of the drugs. The Composite Testing Laboratory (CTL), Kandaghat is the only government analyst in the State.

### 8.4.1 Shortfall in conducting inspections as required under Drugs and Cosmetics Rules, 1945

As per provisions contained in Rule 51 of the Drugs and Cosmetics Rules, 1945 it shall be the duty of an inspector to inspect premises licensed for the sale of drugs, to inspect not less than once a year in all establishments licensed for the sale of drugs within the area assigned to him/her to satisfy himself/herself that the conditions of the licenses are being observed, to procure and send for test or analysis, if necessary, imported packages and to make record of all inspections etc. Further, Rule 52 prescribes similar provisions applicable on manufacturing.

Audit noticed that there was shortfall of 20 *per cent* to 35 *per cent* in inspections conducted in the State during 2016-22.

The details of inspections conducted in the State during 2016-22 are shown in **Table 8.4**.

**Table 8.4: Shortfall in conducting of inspection in the State**

| Year | Total wholesalers, retailers, manufacturers in the State | Inspections conducted | Shortfall | Shortfall in percentage |
|---|---|---|---|---|
| 2016-17 | 4,462 | 3,215 | 1,247 | 27.94 |
| 2017-18 | 4,731 | 3,776 | 955 | 20.18 |
| 2018-19 | 5,247 | 3,425 | 1,822 | 34.72 |
| 2019-20 | 6,019 | 4,596 | 1,423 | 23.64 |
| 2020-21 | 6,653 | 4,840 | 1,813 | 27.25 |
| 2021-22 | 7,550 | 5,941 | 1,609 | 21.31 |

*Source: State Drug Controller, Baddi.*

In the selected zones (Dharamshala and Baddi), Audit noticed that:

- In Baddi zone, there was shortfall in conducting inspections ranging between 46 *per cent* and 74 *per cent* during 2016-21.
- In Dharamshala zone, there was shortfall in conducting inspections ranging between 48 *per cent* and 72 *per cent* during 2016-21.

The State Drug Controller, in its reply (March 2022), stated that due to shortage of staff, multifarious duties, geographical conditions and non-availability of government vehicles, the targeted inspections could not be achieved.

The reply is not acceptable as shortfall in inspections by the Department can lead to unsupervised sale of spurious/ adulterated/ low quality drugs, which may cause health hazards, even resulting in fatalities.

The Government in its reply (January 2024) stated that all the Drug Inspectors have been directed to achieve the targets and to cover the backlog, if any. Further, they have also been directed to prepare the roster for the coming year so that the inspections can be planned for the year and to ensure that every sales & manufacturing establishment is inspected at least once in a year.

### 8.4.2 Sale of drugs by wholesalers/retailers without adhering to prescribed norms and parameters

The norms and parameters prescribed in the rules were not adhered to by the wholesalers/retailers as observed during the inspection of six randomly selected inspection reports of drug wholesalers/retailers conducted by Drug Inspectors as tabulated in **Table 8.5**.

**Table 8.5: Probable impact of not following norms**

| Parameters | Number of selling premises | Probable impact |
|---|---|---|
| Running without pharmacist | 2 | Dispensing the wrong drugs or giving incorrect usage instructions can have serious consequences for patients |
| Drug license not displayed | 3 | Authenticity of the store could not be ascertained |
| Failure to produce sale bill book/ purchase invoices | 6 | Sale records of drugs could not be assessed |
| Running retail business on wholesaler license | 2 | Unauthorised sale of drugs |

*Source: Inspection reports of the Department.*

**Table 8.5** indicates that the drug retailers/wholesalers in Himachal Pradesh were not adhering to the Drugs & Cosmetics Act, 1940 and Rules, 1945 fully, which is a scenario necessitating even more frequent inspections. The Government needs to take effective steps to increase the inspection percentage of the sales premises.

The Government in its reply (January 2024) stated that the State Drug Regulator through its Drugs Inspectors is regularly inspecting the retailers/wholesalers to ensure that they comply with the conditions of license laid down under Rule 65 of Drugs & Cosmetics Rules. The fact, however, remains that the provisions of the Drugs & Cosmetics Act, 1940 and Rules, 1945 were not adhered to by the drug retailers/wholesalers which is evident from the deviations observed from the inspection reports of the Department.

### 8.4.3 Non-inspection of firms with deemed expired licenses

As per Rule 63 of the Drugs and Cosmetics Rules, 1945, an original license for selling and manufacturing of drugs shall be valid for a period of five years. The license shall be deemed to have expired if application for its renewal is not submitted within six months after its expiry.

Audit noticed that as of March 2022, there were 8,770 firms (retailers, wholesalers, retailers + wholesalers and restricted units) as per Xtended Licensing, Laboratory & Legal Node (XLN)[2] software. During test-check of records of Baddi zone, it was noticed that the names of 878 firms as on 20/02/2022 were shown in XLN software, out of which 221 firms had not renewed the licenses. Out of these 221 firms, licenses of 205 firms were in the category of deemed expired as per the rules *ibid* and licenses of the remaining 16 firms had expired and they were yet to submit application as on 20/02/2022. However, the names of these firms with deemed expired licenses were not removed from the list of license holders on the website. The Department had not carried out any inspection of these firms to ascertain the present status of their working and to ensure that unauthorised sale/manufacture of

[2] XLN software shows the list of license details, application status of retailer/wholesalers, registered pharmacist details, cancelled/suspended licenses details and retailer/wholesaler details.

drugs/cosmetics was not being carried out by these firms. Neither were notices issued to the respective firms for non-renewal of licenses. Thus, the probability of unauthorised sale/manufacture of drugs cannot be ruled out.

The Department, while confirming the facts, stated that the licensees had not applied for renewal even after expiry of the license validity period and the licenses were deemed to have expired.

The reply is not tenable as this does not absolve the responsibility of the Department from conducting inspections/issuing notices and removing these firms from the database of licensed firms.

The Government in its reply (January 2024) stated that directions have been issued to all the licensing authorities to shortlist the names of all the firms whose drugs license (sale/manufacturing) have been deemed cancelled/expired or not renewed after a period of six months of expiry. They had further directed the concerned Drugs Inspectors to inspect these firms within one month positively and take further necessary action, as per law, against these firms.

### 8.4.4 Shortfall in lifting of Drugs and Cosmetics samples

As per provision contained in Section 22(1)(b) of the Drugs and Cosmetics Act, 1940, the Drug Inspector shall take the samples of any drug and cosmetic which is being manufactured or being sold or is stocked or exhibited or offered for sale or is being distributed. As per instruction of the State Government issued in October 2019, 10 samples of drugs and cosmetics were required to be collected by each Drug Inspector every month. The number of samples collected against the samples required to be collected for the State is shown in **Table 8.6**.

**Table 8.6: Samples collected against the samples required to be collected**

| Year | Number of Drug Inspectors in position | Samples required to be collected | Samples collected | Shortfall | Percentage of shortfall |
|---|---|---|---|---|---|
| 2016-17 | 17 | No such target fixed | 2020 | - | - |
| 2017-18 | 20 | -do- | 1902 | - | - |
| 2018-19 | 26 | -do- | 1,622 | - | - |
| 2019-20 | 26 | 3,120 | 2,344 | 776 | 24.87 |
| 2020-21 | 26 | 3,120 | 2,839 | 281 | 9.01 |
| 2021-22 | 39 | 4,680 | 4,012 | 668 | 14.27 |
| **Total** | **91*** | **10,920** | **9,195*** | **1,725** | **15.79** |

*Source: State Drug Controller, Baddi.*
**Total has been calculated from 2019-20 onwards as no targets to lift the samples were instructed earlier.*

From **Table 8.6**, it is evident that the authorities of the State Drug Controller, Himachal Pradesh were not able to achieve the target fixed by the Government in lifting the samples as overall shortfall of 15.79 *per cent* had been observed during 2019-22. Shortfall in collection of drugs and cosmetics samples is an indicator of laxity in the regulatory process and has an associated risk of supply/sale of substandard/spurious/ wrong drugs to consumers.

The Government in its reply (January 2024) stated that Drug Inspectors in the State have been directed to achieve the targets for sample collection.

### 8.4.5 Delay in analysing samples

Section 23 of the Drugs and Cosmetics Act, 1940 provides that the Drug Inspector is required to submit the drug samples to the government analyst for analysis. Further, Section 25 says that the government analyst to whom a sample of any drug or cosmetic has been submitted for test or analysis under sub-section (4) of Section 23, shall deliver to the Inspector submitting it a signed report in triplicate in the prescribed form.

Audit scrutiny revealed that there was pendency in analysing the drug samples in CTL, Kandaghat to the extent of 55.10 *per cent* to 66.65 *per cent* during the period 2016-17 to 2021-22. The number of samples received and analysed are shown in **Table 8.7**.

**Table 8.7: Drug samples received and analysed**

| Year | Opening balance of the drug samples | Samples received during the year | Total samples | Samples analysed during the year | Balance | *Per cent* of samples not analysed at the end of the year |
|---|---|---|---|---|---|---|
| 2016-17 | 1,009 | 1,885 | 2,894 | 1,023 | 1,871 | 64.65 |
| 2017-18 | 1,871 | 1,832 | 3,703 | 1,235 | 2,468 | 66.65 |
| 2018-19 | 2,468 | 1,689 | 4,157 | 1,628 | 2,529 | 60.84 |
| 2019-20 | 2,529 | 1,899 | 4,428 | 1,829 | 2,599 | 58.69 |
| 2020-21 | 2,599 | 2,777 | 5,376 | 2,414 | 2,962 | 55.10 |
| 2021-22 | 2,962 | 3,426 | 6,388 | 2,303 | 4,085 | 63.95 |

*Source: Composite Testing Laboratory, Kandaghat.*

The Government in its reply (January 2024) stated that the new Drug Testing Laboratory will be made operational soon at Baddi and this will enhance the capacity of testing.

#### 8.4.5.1 Non-analysing of samples within prescribed period and Not of Standard Quality (NSQ) Drugs

Rule 45 of Drugs and Cosmetics Rules, 1945 stipulates that government analyst shall furnish report of the analysis within a period of sixty days from the receipt of the sample.

Further, Section 18 of Drugs and Cosmetics Act, 1940 states that no person shall himself or by any other person on his behalf manufacture drugs for sale or for distribution or stock or exhibit or distribute any drugs, which is not of a standard quality or is misbranded, adulterated or spurious.

Status of time taken to analyse the samples by the government analyst of the State are detailed in **Table 8.8**.

**Table 8.8: Time taken to analyse samples by the government analyst**

| Year | Number of samples received for analysis | Number of samples found not of standard quality | Time taken to analyse the samples | | | *Per cent* of samples whose analysis took more than prescribed time to total samples received |
|---|---|---|---|---|---|---|
| | | | Within 60 days | More than 60 days to 1 year | More than 1 year | |
| 2016-17 | 1,885 | 35 | 1 | 267 | 1,617 | 99.95 |
| 2017-18 | 1,832 | 25 | 10 | 156 | 1,666 | 99.45 |
| 2018-19 | 1,689 | 27 | 1 | 118 | 1,570 | 99.94 |
| 2019-20 | 1,899 | 42 | 0 | 117 | 1,782 | 100 |
| 2020-21 | 2,777 | 59 | 7 | 249 | 2,521 | 99.75 |
| 2021-22 | 3,426 | 33 | 0 | 193 | 3,233 | 100 |

*Source: Composite Testing Laboratory, Kandaghat.*

From **Table 8.8**, it can be seen that there had been considerable delay in analysing the samples by the government analyst. During those periods, the drugs were already available in the market and consumers may have already consumed those "Not of Standard Quality" (NSQ) drugs.

The Government in its reply (January 2024) stated that the samples could not be analysed during the prescribed limit and there was considerable delay in the analysis of samples due to receipt of samples in excess of the capacity of the existing drug testing laboratory.

### 8.4.5.2 Delay in analysing the lifted drugs from Government Health Institutions

In the selected districts, in the health institutions having drug stores, Audit noticed that Drug Inspectors had not lifted the drug samples from five out of 13 Government hospital medical stores (CMO/DH/BMO).

Details of time taken to analyse the samples by the government analyst from the selected district stores are given in **Table 8.9**.

**Table 8.9: Time taken to analyse the samples by the government analyst**

| Year | Number of samples lifted | | | Stock of medicines during the time of samples taken (in lakh) | | | Time taken to receive the test report (in months) | | | Stock of drugs at the time of receipt of report (in lakh) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Kinnaur | Solan | Kangra | Kinnaur | Solan | Kangra | Kinnaur | Solan | Kangra | Kinnaur | Solan | Kangra |
| 2016-17 | 0 | 4 | 27 | NA | 6.28 | 88.47 | NA | 10- 22 | 1-35 | NA | 0 | 0.01 |
| 2017-18 | 0 | 4 | 26 | NA | 1.72 | 108.31 | NA | 5- 26 | 3-39 | NA | 0 | 0 |
| 2018-19 | 0 | 4 | 0 | NA | 0.48 | NA | NA | 15-19 | NA | NA | 0 | NA |
| 2019-20 | 4 | 5 | 22 | 0.55 | 0.65 | 77.12 | 3-25 | 9-16 | 1-23 | 0 | 0 | 0.30 |
| 2020-21 | 6 | 5 | 18 | 5.82 | 1.08 | 34.48 | 10[@] | --[$] | 14-17* | 5.11 | 0 | 0 |
| **Total** | **10** | **22** | **93** | **6.37** | **10.21** | **308.38** | | | | **5.11** | **0** | **0.31** |

*Source: Information furnished by respective CMOs*
*NA- Not Applicable as no sample was lifted. $Report not received.*
*@Test reports of three samples yet to be received as of October 2021.*
**Test reports of sixteen samples yet to be received as of November 2021.*

From **Table 8.9**, it can be seen that a total of 125 samples were lifted and at the time of lifting, 3.25 crore quantity of medicines were in the stores of the selected districts. The reports of 101 samples out of 125 samples were received after a period of one to 39 months and by that time, 3.19 crore quantity of medicines was already issued/dispensed. Thus, the purpose of conducting the tests of the samples of the drugs was largely defeated as by the time of receipt of the reports, almost all the medicines were already issued.

Further, it was noticed in one (Kangra) out of the three selected districts that the sample of two medicines (B Complex and Paracetamol Suspension) were declared substandard by Drug Inspector, Central Drugs Standard Control Organisation (CDSCO) and one medicine (Tab Telmisartan) was declared substandard by CTL Kandaghat during July 2018 and February 2020. However, 11.08 lakh quantities of these medicines were distributed by the Government health institutions as per the details given in **Table 8.10**.

**Table 8.10: Details of medicines which were declared substandard in Kangra district**

| Sl. No. | Name of drug | Date of sample found substandard | Name of the procuring authority | Purchased quantity (in lakh) | Available stock at the time of receipt of report (in lakh) | Remarks |
|---|---|---|---|---|---|---|
| 1 | B Complex | July 2018 | CMO, Kangra | 8.00 | 1.97 | 6.03 lakh quantity already issued and balance still lying in stock. |
| 2 | Paracetamol Suspension | March 2019 | --do-- | 0.25 | 0.01 | 0.24 lakh quantity already issued and balance replaced by the firm. |
| 3 | Tab Telmisartan 40 mg | February 2020 | --do-- | 5.00 | 0.19 (available in stock of lower health institutions) | 4.81 lakh quantity already issued and balance lying in stock. |
| **Total** | | | | **13.25** | **2.17** | |

*Source: Departmental figures.*

Poor quality of drugs is a threat to health because they can inadvertently lead to healthcare failures, such as antibiotic resistance and the spread of disease within a community, as well as death or additional illness in individuals. Concerted effort is required on the part of the Government, including the regulators, drug manufacturers and healthcare providers to ensure that testing of drugs is done without any delay so that only drugs of acceptable quality reach the patients.

### 8.4.5.3 Action taken by State Drug Controller on poor quality of drugs

The details of action taken by the State Drug Controller against the manufacture/sale of poor-quality drugs are shown in **Table 8.11**.

**Table 8.11: Action taken by SDC against the manufacture/sale of poor quality of drugs**

| Financial year | Number of NSQ/spurious/adulterated samples related to drug manufacturer cases | Administrative action | Legal action | Sample challenged & further passed by Central Drug Laboratory, Kolkata |
|---|---|---|---|---|
| 2016-17 | 25 | 20 | 5 | - |
| 2017-18 | 23* | 13 | 8 | 1 |
| 2018-19 | 19 | 16 | 3 | - |
| 2019-20 | 27 | 22 | 4 | 1 |
| 2020-21 | 48** | 37 | 6 | 1 |
| 2021-22 | 44 | 36 | 8 | - |
| **Total** | **186** | **144** | **34** | **3** |

*Source: Information provided by SDC.*

**In 2017-18, two samples of same batch were declared NSQ (Nahan and Paonta Sahib) and legal action taken by one inspector, **Four cases are under investigation.*

It can be seen from **Table 8.11** that administrative action was taken in 144 cases, legal action in 34 cases, three samples were challenged and further passed by Central Drug Laboratory, Kolkata and four remaining cases were under investigation.

Audit noticed that a total of 542 prosecution cases were pending in the courts as of March 2022. It was also noticed that during 2016-22, licenses of 106 manufacturers and

630 sale premises were cancelled due to contravention of Drugs & Cosmetics Act, 1940 & Rules, 1945 and by own request.

The Department should expedite action against the manufacturers/retailers for contravention of the Act, so that it acts as a deterrent for any further contraventions.

The Government in its reply (January 2024) stated that the State Drugs Controller Administration is taking action against the manufacture/sale of poor quality of drugs regularly as per the guidelines.

### 8.4.6 Non-completion of the work of Drug Testing Laboratory at Baddi

To ensure the quality, safety and efficacy of medicines, both for domestic use and for exports, the State regulatory system is required to be strengthened.

A Memorandum of Understanding (MoU) was signed in February 2015 between the State Government and the Ministry of Health & Family Welfare, Government of India, for strengthening the State drug regulatory system. Under this MoU, a drug testing laboratory was to be constructed at Baddi.

As discussed in **Para 7.4.2** of this report, Audit observed that the testing laboratory constructed at Baddi was not made functional till date (January 2023) despite availability of funds sanctioned by the Government. Presently, the drug tests were being done only by the CTL Kandaghat which was short staffed.

The Government had increased the sanctioned strength of Drug Inspectors from 22 (2017-18) to 44 (2018-19) in the State. Drug Inspectors were required to draw at least 10 samples a month. Thus, due to strengthening of staff strength of Drug Inspectors, more samples would be lifted. However, the testing capacity of the CTL had not been increased and the new laboratory at Baddi was yet to be made functional. As of March 2023, in CTL Kandaghat, there was overall shortage of 29.41 *per cent* of staff. Major shortage was noticed in the cadre of Public Analyst-cum-Chemical Examiner (100 *per cent*), Deputy Public Analyst (100 *per cent*), Sr. Scientist (60 *per cent*), Sr. Analyst (28.57 *per cent*) and Sr. Laboratory Technician (50 *per cent*). With the available manpower and infrastructure, the monthly capacity of drug testing in CTL, Kandaghat was on an average 20-25 samples per month against minimum lifting of 440 samples as per existing sanctioned strength of Drug Inspectors.

Thus, due to delay in establishment of the drug testing laboratory at Baddi coupled with inadequate manpower, the test reports of the samples were not analysed within the stipulated time and huge number of samples were remaining unanalysed at the end of every year. As a result, there is a high possibility of sale of poor-quality drugs during the intervening period leading to health hazards/deaths.

In the Exit Conference (January 2023), the Secretary (Health) stated that the work was not complete and necessary action was being taken.

The Government in its reply (January 2024) admitted the facts and stated that the construction work of the Drug Testing Laboratory at Baddi has been completed and 95 *per cent* of the equipment has been procured.

### 8.4.7 Non-testing of samples of Oxygen Indian Pharmacopoeia (IP) due to non-availability of testing facility

As per provision contained in Section 22(1)(b) of Drugs and Cosmetics Act, 1940, the Drug Inspector shall take the samples of any drug and cosmetic, which is being manufactured or being sold or is stocked or exhibited or offered for sale or is being distributed. Oxygen is considered as a drug in the form of Oxygen IP in terms of standards provided in Indian Pharmacopeia, 2018 and thus samples were to be lifted. For oxygen (IP), a licence is required under the Drugs and Cosmetics Rules, 1945. Rule 71 of the Drugs and Cosmetics Rules provides the condition for grant and renewal of license in Form 25, which includes medicinal gases.

During audit of the State Drug Controller, Audit noticed that license for manufacturing of oxygen IP by the licensing authority was issued/renewed to 14 oxygen (IP) manufacturers from 1996 to 2021 in the State. The samples of oxygen (IP) were required to be taken and sent to the Government laboratory for testing and analysis. However, the facility for testing of oxygen (IP) samples was not available in CTL Kandaghat and thus, the State lacked capacity for testing of oxygen (IP). Therefore, no samples of oxygen (IP) were lifted by the Drug Inspectors till the date of audit (February 2022) from all these 14 manufacturing units. In the absence of this, the quality standard of oxygen manufactured by these units could not be ensured.

The Department stated (March 2022) that the Drug Inspectors conduct inspection of manufacturing units to ensure that oxygen conforms to all standards and analysis will be done as soon as the new laboratory is functional. Further, Assistant Drug Controller, Dharamshala stated (August 2022) that there was no facility for quality testing of oxygen in the Government laboratory.

However, the fact remains that oxygen (IP) manufacturers were issued/renewed licences without lifting oxygen (IP) samples for quality testing.

The Government in its reply (January 2024) stated that all Drug Inspectors have already been directed to ensure that medicinal oxygen conforms to standards laid down under Drugs & Cosmetics Act.

### 8.4.8 Running of Blood Banks without renewal of licences

Rule 122F of the Drugs and Cosmetics Rules, 1945 provides for renewal of license before its expiry for the health institutions for running of blood banks. In Himachal Pradesh, 25 health institutions (public and private) were operating blood banks. Audit noticed that 12 (11 Government and one charitable trust) out of 25 health institutions had not renewed their licenses for operation of the blood bank till the date of audit (March 2022).

The Department, in its reply (March 2022), stated that licenses of these health institutions were not renewed due to pending process of renewal.

The reply was not acceptable as timely action was required to be taken before expiry of the license. In the absence of renewal of licenses of these blood banks, the quality of blood being

issued for patient use cannot be assured, and the risk of spread of diseases/deaths due to contamination of blood cannot be ruled out.

The Government, in its reply (January 2024), stated that directions have been issued to all the licensing authorities to expedite the matter of renewal of licenses of blood banks under their jurisdiction at the earliest.

### 8.4.9 Overcharging of drugs by manufacturers

National Pharmaceutical Pricing Authority (NPPA) was constituted vide Government of India resolution dated 29th August 1997 as an attached office of the Department of Pharmaceuticals (DoP), Ministry of Chemicals & Fertilisers as an independent regulator for pricing of drugs and to ensure availability and accessibility of medicines at affordable prices.

In terms of Para 14(1) of the Drug Price Control Order, 2013 (DPCO), the Government shall fix and notify the ceiling prices of scheduled formulations and no manufacturer shall sell the scheduled formulations at a price higher than the ceiling price. Further, Para 14(2) stipulates that if any manufacturer sells a scheduled formulation at a price higher than the ceiling price, such manufacturers shall be liable to deposit the overcharged amount along with interest thereon from the date of such overcharging.

Government of Himachal Pradesh vide notification dated May 2015 authorised all the CMOs, Assistant Drug Controllers and Drug Inspectors within their jurisdiction, in addition to their duties, to comply with the order and perform the functions as specified in the DPCO, 2013.

During the audit of the State Drug Controller, Audit noticed that the manufacturers were charging prices of medicines higher than the notified prices and NPPA had issued show cause notices to different firms during 2016-22 for overcharging. During random check of eight notices issued by NPPA to the firms, it was observed that the manufacturers had overcharged ₹ 112.87 crore from the consumers/patients as detailed in **Appendix 9**. In some other cases, only MRP and price fixed by NPPA was available, but quantities sold were not available, due to which the overcharged amount could not be ascertained as detailed in **Appendix 10**.

Audit noticed that details of recovery of the overcharged amount from the manufacturers were neither available on record nor did the State Drug Controller take follow-up action to recover the overcharged amount. Thus, due to lack of coordination between NPPA and the State Drug Controller, overcharging of drugs by the manufacturer was not acted upon.

The Government in its reply (January 2024) stated that fixation of prices of drugs and recovery of overcharged amount by the manufacturers is not under the purview/domain of the State Government. The reply was not acceptable as no action had been taken by the State Government in terms of notification dated May 2015.

### 8.4.10 Fixation of retail price by manufacturer of a new drug without price approval

In terms of Para 15(2) of DPCO, 2013, where an existing drug manufacturer launches a new drug with dosages and strengths as specified in the National List of Essential Medicines, such existing manufacturers shall apply for prior price approval of such new drug from the Government.

Audit noticed that several drug manufacturing firms in Himachal Pradesh had launched new drugs for which prior price approval from NPPA was not obtained. Random check of seven show cause notices issued by NPPA to firms revealed that during 2016-22, different firms were engaged in manufacturing/marketing of schedule formulations without prior price approval (**Appendix 11)**. Audit further noticed that not a single case of overcharging was reported by SDC to NPPA.

## 8.5 Regulation through Atomic Energy Act, 1962

The Atomic Energy Regulatory Board (AERB) was constituted in 1983 under Atomic Energy Act, 1962 to carry out certain regulatory and safety functions under the Act. The mission of the AERB is to ensure that the use of ionizing radiation and nuclear energy in the country does not cause undue risk to the health of people and the environment.

Functions of the AERB *inter alia* include:

- Developing safety policies, safety codes, guides and standards for siting, design, construction, commissioning, operation and decommissioning of different types of nuclear and radiation facilities.
- Granting consents for siting, construction, commissioning, operation and decommissioning, after an appropriate safety review and assessment, for establishment of nuclear and radiation facilities.
- Ensuring compliance with the regulatory requirements prescribed by AERB through a system of review and assessment, regulatory inspection and enforcement.
- Prescribing the acceptance limits of radiation exposure to occupational workers and members of the public and acceptable limits of environmental releases of radioactive substances.

Any person duly authorised under Sub-section (4) of Section 17 of the Act may inspect any premises, or radiation installation, or conveyance as per Rule 30 of Atomic Energy (Radiation Protection) Rules, 2004.

### 8.5.1 Operation of x-ray machines without license

As per Rule 3 of the Atomic Energy (Radiation Protection) Rules, 2004, no person shall, without a license (a) establish a radiation installation for siting, design, construction, commissioning, and operation; and (b) decommission a radiation installation.

Audit observed that in 18 selected health institutions having x-ray facility, seven[3] were functioning without license from AERB.

During joint physical inspection, it was observed that five out of eight private clinical establishments having x-ray facility were operating without license from AERB.

The Government in its reply (January 2024) stated that due to non-availability of Radiological Safety Officer and Technical Assistant (Radiation Safety) staff as per AERB norms, the Department is unable to conduct inspections. However, Assistant Director

[3] CHC Syri, CH Chango, PHC Spillow, PHC Ribba, PHC Sultanpur, CH Jawalamukhi and CHC Sangla.

(Radiation Safety) is conducting the inspections in a routine manner and discrepancies found during the inspection are conveyed to the concerned.

### 8.5.2 Thermoluminescent dosimeters (TLD) badges for Radiation Protection

Thermoluminescent dosimeter badges are used to detect radiation at levels that can be harmful to humans. All the staff working in the x-ray room should wear TLD badges and/or pocket dosimeters[4] as per Atomic Energy (Radiation Protection) Rules, 2004 and AERB safety codes.

Audit observed that:

- TLD badges were provided to the technicians of the x-ray room only in six (IGMC, RPGMC, CH Shahpur, CH Kandaghat, CHC Sangla and CHC Dharampur) out of 18 selected health institutions having x-ray facility.
- Pocket dosimeters were provided to the technicians of the x-ray room only in two (IGMC and RPGMC) out of 18 selected health institutions having x-ray facility.

The Government in its reply (January 2024) stated that TLD badges are provided to the technicians of the x-ray room of all the Medical colleges and the health institutions. The reply was not acceptable as TLD badges were not found issued in selected health institutions as detailed above.

### 8.5.3 Directorate of Radiation Safety (DRS)

The Supreme Court had directed in the year 2001 for setting up of a Directorate of Radiation Safety (DRS) in each State for regulating medical x-rays. DRS was not formed in Himachal Pradesh, though an MoU for its formation was executed during February 2013 between AERB and Government of Himachal Pradesh. Functions which were to be done by DRS, are being carried out by Director, Health Safety and Regulation (DHSR) in the State.

AERB was mandated to carry out quality assurance performance test of x-ray units once in two years and to conduct periodic inspections by authorised personnel under Section 17 of the Atomic Energy Act, 1962. However, no inspections were conducted during 2016-17 to 2018-19. Further, during 2019-21, no targets were fixed for inspection of x-ray installations both in Government and private health institutions although 86 inspections were conducted.

The Government in its reply (January 2024) stated that there is no Radiation Safety Agency in Himachal Pradesh till date but the inspections under the provisions of Atomic Energy (Radiation Protection) Rules, 2004 are being conducted by the Assistant Director (Radiation Safety), Office of the DHSR, Shimla. No inspections were conducted before 2018-19 due to non-availability of staff trained as per AERB norms.

## 8.6 Regulation through Bio-Medical Waste Management Rules, 2016

The Himachal Pradesh State Pollution Control Board is a nodal agency in the administrative structure of the State Government for planning, promotion, coordination and overseeing the implementation of environmental programs.

4 TLD badges and pocket dosimeters are used for monitoring beta and gamma doses of radiation in workers.

In terms of Rule 10 of Bio Medical Waste Rules, 2016, one-time authorisation is to be obtained from State Pollution Control Board (SPCB) in Himachal Pradesh for generation, storage, treatment/disposal and handling of bio-medical wastes.

Audit noticed that 61 out of 85 CHs, 40 out of 94 CHCs and 98 out of 575 PHCs had not obtained SPCB authorisation for generation of bio-medical waste as of November 2021. Thus, 199 out of 754 health institutions had not obtained SPCB authorisation for generation of bio-medical waste. In the selected districts, 47 out of 204 health institutions (15 out of 25 CHs, 12 out of 30 CHCs and 20 out of 149 PHCs) had not obtained SPCB authorisation for generation of bio-medical waste as of November 2021.

The Government in its reply (January 2024) stated that the monitoring of authorisation under bio-medical waste of the health institutions is presently being done by the Director of Health Services.

## 8.7 Conclusion

The employed/practising doctors in Himachal Pradesh were not renewing their registration regularly with the State Medical Council. No mechanism was adopted by the State Medical Council to track and monitor the list of non-registered doctors. State Council of Clinical Establishment was not working effectively resulting in poor implementation of the Clinical Establishment Act, 2010. All private health institutions were running on provisional registration and the process of permanent registration was not initiated. Even provisional registration had expired for many health institutions. Shortfall was noticed in conducting inspections required under Drugs and Cosmetics Rules, 1945. There was shortfall in targets of lifting drugs and cosmetics samples, delay in lifting samples and also delay in analysis of samples. Consequently, drugs declared 'not of standard quality (NSQ)' were already issued to the patients, putting their health at risk. The new drug testing laboratory at Baddi was yet to be completed and the only drug testing laboratory in the State at Kandaghat was short-staffed. In Himachal Pradesh, some manufacturers were charging higher prices of medicines than the notified prices. NPPA had issued show cause notices to different firms for overcharging of medicines. Price approval was not being taken by manufacturers for a new drug. Blood Banks and x-ray machines were running without licenses. Health institutions had not obtained SPCB authorisation for generation of bio-medical waste.

## 8.8 Recommendations

*Government may ensure that:*

- *State Medical Council maintains the data of all registered medical practitioners in the State in electronic form.*
- *SMC develops a communication mechanism with the Government as well as private health institutions to check the existence/updation of the registration of the doctors.*
- *The process of permanent registrations of clinical establishments is initiated and regular inspections are conducted.*
- *Maximum number of drug samples are lifted and testing capacities of the laboratories are increased so that the test results are obtained within the stipulated time frame.*

- *Overpricing of drugs by the manufacturers is checked.*
- *Timely action for obtaining license from concerned authorities for running various facilities is taken.*
- *A mechanism is put in place to ensure that all Health Institutions have proper authorisation from State Pollution Control Board (SPCB) for generation, storage, treatment/disposal and handling of bio-medical waste.*