TeamLease™
RegTech
Helping India Comply

Simplifying Compliance Management for Pharmaceutical Companies

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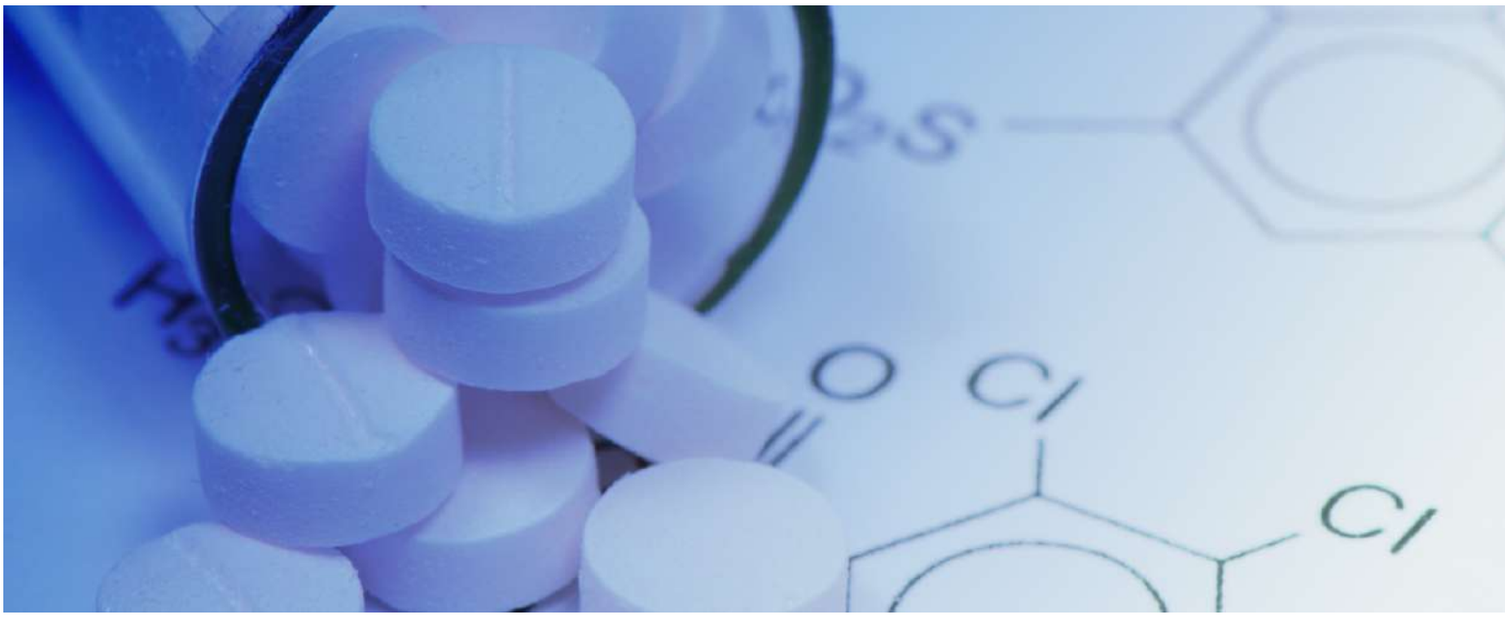

Introduction

According to the Reserve Bank of India (RBI), the pharmaceutical sector contributes approximately 2% to India's GDP and around 8% to its overall merchandise trade. India ranks third in the production of pharmaceuticals across the world and is the largest generic drug manufacturer in the world (RBI 2021). The success of India in manufacturing vaccines and other essentials during the ongoing pandemic does not need a retelling. It is readily evident that the pharmaceutical industry is one of the most promising sectors within the country, having registered an 18 per cent growth in its exports during 2021-21. The primary drivers of growth in the industry are Innovation and R&D, Medical Tourism, Infrastructure Development, Strong Drug Manufacturing and a strong domestic demand for indigenously developed and manufactured products (Invest India 2021).

However, this does not necessarily imply that the sector is devoid of bottlenecks to its smooth functioning. Very often, these come in the form of extensive general and industry-specific compliances that apply to the pharmaceutical companies of different types. Notwithstanding the known challenges associated with the replacement of process patents, driving up the export of pharmaceuticals requires many other domestic regulatory requirements to be met. Then there is the added burden of contending with overseas regulators which will be discussed at some length in the upcoming sections. Compliance officers and the senior executives in a company are often saddled with the responsibility and management of hundreds of different compliances at a time. These can be in the nature of both one-time and ongoing compliances and consume considerable bandwidth for their management.

The purpose of this report therefore, is to shed some light on the state of regulatory compliance for the pharmaceutical sector, discuss some of the problems encountered by the industry and propose actionable recommendations to reduce the compliance burden on pharmaceuticals.

Types of Pharmaceutical Companies

While there are different ways of classifying them, in an overarching sense, pharmaceutical companies in India typically include drug manufacturers, Pharma marketing, distribution entities, retailers, API manufacturers, producers of surgical and cosmetic products, makers of dietary supplements and so on (Progressive Life Care; n.d). One study identified four types of businesses within the pharmaceutical sector: marketing of generic medicines; marketing of branded generic medicines; marketing of innovator medicines; and manufacture and supply of active pharmaceutical ingredients (Nishith Desai Associates, 2021).There are also emerging areas such as clinical trials where India is fast becoming a recognised destination(Nishith Desai Associates, 2021). The Exim Bank of India(2018) describes the structure of the pharmaceutical companies as being divided into the following sectors:

- APIs
- Formulations
- CRAMS (Contract Research and Manufacturing Services)
- Biosimilars

All of these are broadly governed by the Drugs and Cosmetics Act, 1940 and broadly characterised as semi-regulated sectors (EXIM Bank, 2018). The provisions of the legislation are frequently amended and new rules are introduced in accordance with the guidelines of the World Health Organization. The regulatory bodies at the very top of the pyramid, in charge of overseeing the larger compliance environment include Central Drugs Standard Control Organization, Department of Pharmaceuticals under the Ministry of Chemicals and Fertilizers, National Pharmaceutical Pricing Authority, Controller General of Patents as well as bodies governing the environmental clearances under the Ministry of MoEFCC (Exim Bank, 2018).

All in all, pharmaceutical companies, irrespective of their type, are always looking at a complex regulatory environment with multiple legal obligations to fulfill at any given time. The following section will present a vantage point of the overall regulatory environment for pharmaceuticals.

Overview of Compliance Obligations

Compliances in India are broadly divided into one-time and ongoing compliances. On an average, a pharmaceutical company is easily subject to 70 odd one-time registrations and approvals across four stages- Setting Up, Pre-Commissioning stage, Post-Commissioning Stage and Post-Production stage. These approvals relate to land allotment, project-related approvals, construction approvals, approvals related to labour, safety and health, tax-related registrations, etc.. Then there are the ongoing compliances which the company must adhere to at every stage of production. These include a mix of Central and state specific compliances.

1 Union, State and Local Compliances

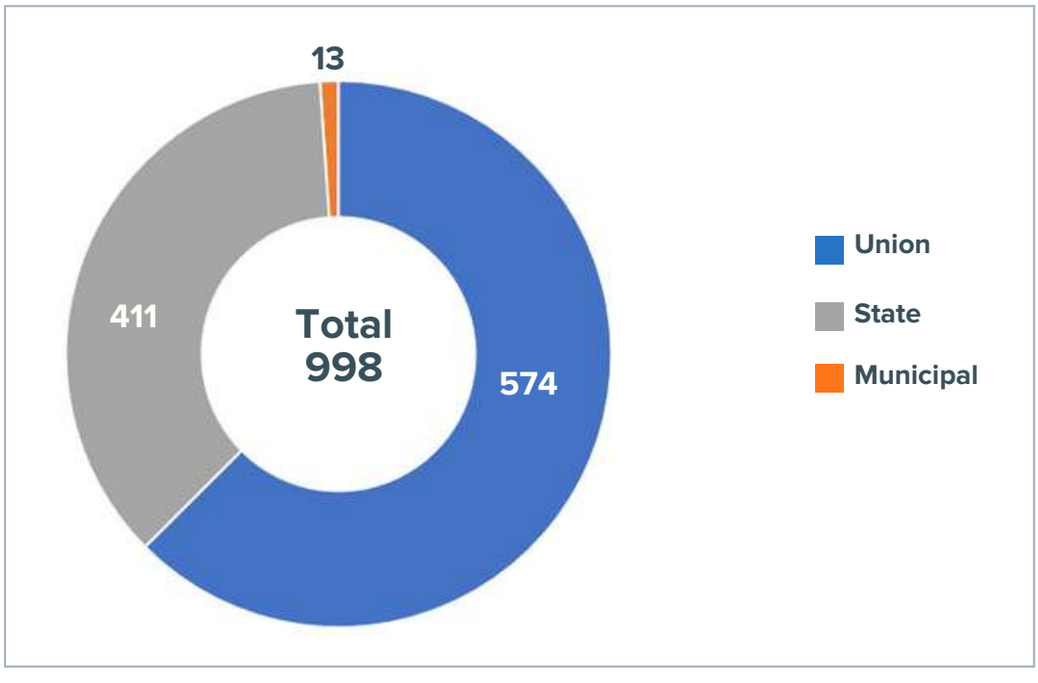

Fig.1

Compliances at Union, State and Municipal level for a single manufacturing unit in a single state
Source: Teamlease Regtech

Pharmaceutical companies have to deal with a layered web of compliances with many aspects of compliance split across the Union and States or being placed in the concurrent list. For example, Labour Laws fall in the Concurrent List where both the Union and State are entitled to legislate. This means that at any given point a company would have to ensure compliance with a parent legislation drafted by the Centre and rules and regulations. Similarly, under Environmental Laws there is a Central Board and there are State Pollution Control Boards to regulate compliance. Meanwhile, 'land' falls under the state list although acquisition of property falls under concurrent list. Electricity is again a subject on the concurrent list with laws at both the state and central level. Besides this, there are also municipal rules to comply with.

2 Categories of Compliances

Compliance is distributed across a range of categories. Details are as given below:

Labour

Labour typically includes around 29 central laws (now condensed into four labour codes). Being a concurrent subject, labour laws are further legislated upon by the states and each parent act is then accompanied by a host of state legislations, alongside the central and state rules. Examples of some of the Acts include Apprentices Act, 1961 and Apprenticeship Rules, 1992; Contract Labour (Regulation & Abolition) Act, 1970; Employees Compensation Act, 1923; Equal Remuneration Act, 1976 and Equal Remuneration Rules, 1976; Factories Act, 1948; Sexual Harassment of Women at Workplace (Prevention, Prohibition & Redressal) Act, 2013 & Sexual Harassment of Women at Workplace (Prevention, Prohibition & Redressal) Rules 2013; Payment of Wages Act, 1936; Maternity Benefit Act, 1961

EHS (Environment, Health & Safety)

EHS is predominantly constituted by the Environment Protection Act, 1986 and its related rules such as Environment (Protection) Rules, 1986; Batteries (Management and Handling) Rules, 2001; Bio-Medical Waste Management Rules, 2016; E-Waste (Management) Rules, 2016, Plastic Waste Management Rules 2016, etc. Other important legislation include the Air (Prevention and Control of Pollution) Act, 1981; Water (Prevention and control of pollution) Act 1974; Explosives Act, 1884 and Gas Cylinders Rules, 2016, etc.

Corporate Laws

Under Corporate Laws, the main legislation include, Companies Act, 2013 & Companies (Incorporation) Rules, 2014 along with other rules and regulations.

Commercial

Commercial category includes legislation such as Boilers Act, 1923 and Boiler Regulations, 1950; Bureau of Indian Standards Act, 2016 and Bureau of Indian Standard Rules, 1987; Collection of Statistics Act, 2008 and Collection of Statistics (Central) Rules, 1959; Food Safety & Standards Act, 2006 and regulations such as Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011; Legal Metrology Act, 2009 and Legal Metrology (Packaged Commodities) Rules, 2011; Motor Vehicles Act, 1988 and Central Motor Vehicle Rules, 1989, etc.

Finance and Taxation

Finance & Taxation Laws include the Central Goods and Services Tax Act, 2017 and state specific legislation on taxation.

Industry-specific

The Industry-specific legislations applicable to a pharmaceutical company are discussed at some length in the section below. Predominantly, the overarching legislation for the pharmaceutical industry is the Drugs and Cosmetics Act, 1940 and its rules and schedules such as the schedule on Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products. Other important industry-specific regulations include, Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 and Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955; Essential Commodities Act, 1955 and Drugs (Price Control) Order, 2013 etc.

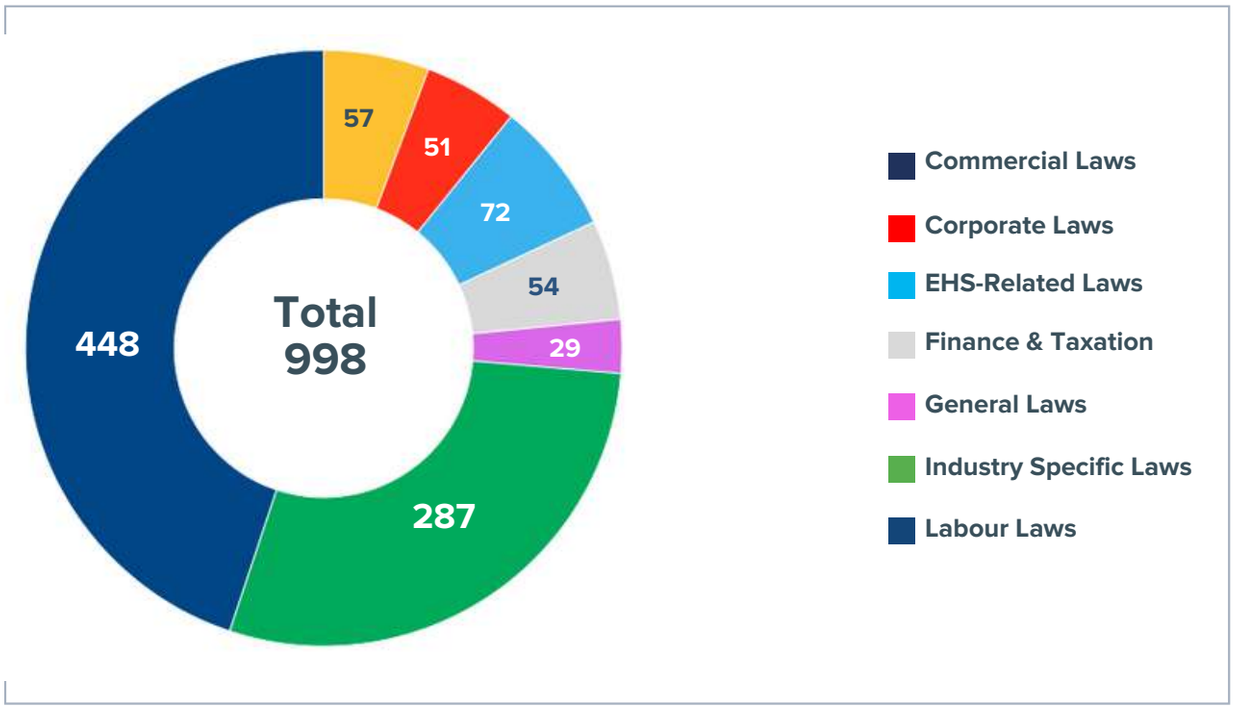

Fig.2

Category-wise compliances for a single pharmaceutical manufacturing facility
Source: Teamlease Regtech

Types of Compliances

The compliances under the legislation discussed above may be divided into the following types:

Inspection-related Compliances	These typically relate to inspections under central legislations such as the Bureau of Indian Standards Act, 2016, the Drugs and Cosmetics Act, 1940 read with the Rules of 1945 and the Electricity Act, 2003 read with the related regulations. In most cases inspections can range from monthly to annual basis.
Audit and Accounts	These are typically compliances found under the Factories Act, 1948 and its related state rules, Drugs and Cosmetics Act, 1940 and related rules, Central Goods and Services Tax Act, 2017, Companies Act 2013, etc. Many of these are trivial obligations but are nonetheless subject to high penalties under the concerned legislation. For example, under the Factories Act, the owner/manager of the manufacturing plant is required to carry out annual auditing of accounts pertaining to canteen facilities. Not doing so can lead to imprisonment of upto two years. Under the Drugs and Cosmetics Act discussed in greater detail below, every manufacturer or drug licensee is required to conduct a periodical audit of warehousing practices followed at distribution centers.
Display Requirements	There are extensive display requirements under a number of legislations that a company must follow through. Many of these fall under labour laws. However, several other categories of compliances including extensive industry-specific compliances also contain such requirements. These include labelling requirements, the requirement to display the abstract of acts in the premises and so on. There are also microscopic obligations such as displaying the notice period of work for adult workers in the factory, under the Factories Act, 1948. Labour laws are particularly demanding in display-related compliances.
Register and Records	Under labour legislations, pharmaceutical companies are required to maintain a register of employees or workers on their roll. Other particulars such as leave records also need to be maintained in the form of registers. The Factories Act even requires companies to maintain records of white-washing, varnishing etc. Apart from labour, registers and records are required to be maintained under the Environment Protection Act, 1986 and its related rules, especially when it comes to hazardous wastes. Detailed record-keeping requirements also form a feature of the Drugs and Cosmetics Act, discussed in detail in the subsequent section on Industry-Specific compliances.
Employee Safety and Welfare	These compliances are again, most extensively found in Labour Laws followed by Industry-Specific and other compliances. Broadly, these compliances cover both labourers and workers as well as the actual maintenance of manufacturing facilities. For example, under the Maternity Benefits Act, 1961 every establishment is required to intimate female employees of benefits available to them. Under the Electricity Act, companies must maintain safety clearances for electrical apparatus as per Bureau of Indian Standards. All in all, on an average, a pharmaceutical company can be subjected to over 140 compliances just on Employee safety and welfare.
Payments	Any pharmaceutical company will have a number of payment related compliances across Central and State Laws. For example, under the Employees State Insurance Act, 1948 along with the rules and regulations of 1950, a company is required to make a monthly payment contribution in respect of an employee to the ESIC. Similarly, maternity benefits need to be paid under the Maternity Benefits Act, 1961. Similarly, there are a number of payment requirements under Taxation laws, particularly under the Income Tax Act, 1961.
Cleanliness	The Factories Act contains extensive provisions for the cleanliness of the factory premises including canteens and washing facilities. For example, lime washing of canteen walls, re-painting inside walls and partitions of the factory, etc. Similarly, the Environment Protection Act, 1986 contains detailed provisions on storing and disposing of waste, particularly hazardous waste.There are also state-specific compliances on cleanliness which the company must adhere to.
Appointments	Under Factories Act, 1948, a facility is required to appoint a safety officer in the factory along with other staff such sweepers, welfare officers for workers (500 or more) etc. Under Companies Act, 2013, a company is required to appoint an internal auditor and a cost auditor.

Types of Compliances

Examination and Testing	There are a number of examinations and testings a company has to carry out in accordance with a number of laws. For example, under the Factories Act, a manufacturer must conduct a two-yearly testing of pressure plants or vessels where internal examination is not possible. There are also compliances requiring medical examination of workers employed in the factory. Under the Drugs and Cosmetics Act, testing of both raw materials and final products is a requirement given the high level of associated risk for any failure to do so. Similarly, extensive testing is also a mandate under the Boilers Act, 1953 and Boiler Regulations, 1950. Under the Legal Metrology Act, 2009, two yearly re-verification of weights and measures is mandatory.

Especially important among the compliances discussed above are the ones related to Environment, Health and Safety, and their violation can be subject to hefty penalties under the Environment Protection Act, 1986. For instance, under the Environment Protection Rules, 1986, a pharmaceutical company is required to submit an annual environmental audit report in Form V to the respective State Pollution Control Board. Under the Biomedical Waste Management Rules 2016, an occupier or operator is not allowed to mix untreated bio-medical waste with other wastes. Similarly, under the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016, the operator of a captive facility has to file an annual return with the State Pollution Control Board. The occupiers of facilities also have to maintain a record of sale, transfer, storage, recycling, recovery, pre-processing, co-processing and utilisation of hazardous and other wastes. Many more such regulations can easily be made applicable for pharma businesses. And any contravention of these rules can attract imprisonment of up to five years which may even extend to seven years in case of repeated offences under the Act. All in all there are over forty such compliances just under environment protection.

At an aggregate level, a company can easily accrue anything between 900-1000 ongoing compliances across various categories only in order to be able to operate in a single state.

3 Industry-Specific Compliances for Pharmaceuticals

Outside of the general compliances outlined above, pharmaceutical companies are also subject to a host of Industry-Specific compliances. The foremost among these are regulations under the Drugs and Cosmetics Act, 1940 along with the Rules of 1945. When it comes to a pharmaceutical manufacturing facility, regulations under these typically consist of the following:

- The obligation of the manufacturers to have drainage systems for the proper maintenance and prevention of water logging in laboratories
- Maintaining cleanliness of instruments and surrounding areas
- Maintaining cleanliness of equipment used for packaging operations
- Providing regular and adequate water supply at quality control laboratories for cleaning and testing purposes
- Annual pest control to be done in the warehousing area
- Constituting a complaint committee in an association and its handling
- Maintenance of records and furnishing of information to the relevant authorities
- Display of name and address of the manufacturer on the container of any drug
- Display of Manufacturing license number
- Labelling date of manufacturing and date of expiry of drugs, etc

Additional legal obligations are also contained under the two Schedules of the Act.

Under the Medical Device Rules, 2017 of the Drugs and Cosmetics Act every license holder is required to maintain a record or audit book, as well as an inspection book. The failure to keep such records can result in an imprisonment of up to a year. Additionally, companies are required to maintain quarterly records of manufacturing and sales.

There are also one-time industry-specific approvals under the Act and its rules. These include the license to sell, stock or exhibit or offer for sale, or distribute other than those specified in Schedule C; the license to manufacture cosmetic products for sale and distribution; and licenses for importing drugs and undertaking clinical trials. In 2019, the Ministry of Health and Family Welfare notified the New Drugs and Clinical Trials rules under the Drugs and Cosmetics Act. Under the new rules, a pharmaceutical company engaged in the development of new drugs must obtain permission of the Central Licensing Authority for the conduct of clinical trials, or bioavailability or bioequivalence study. The rules lay down specific labelling requirements for the grant of permission by the Central authority. Similarly, for the import of a new drug to be used in clinical trials, a company must obtain a license from the Central Licensing Authority, valid for a period of three years.

4 Other Industry-Specific Compliances [Non-DCA]

Other than the Drugs and Cosmetics Act, 1940, pharma companies are also subject to regulations under several other legislations. For instance, under the ICMR Code-Ethical Guidelines for Biomedical Research on Human Participants, all centres doing stem cell research are required to be registered with the National Apex Committee for Stem Cell Research. Besides this, there are rules relating to provision of compensation for subjects of medical trials as well as notifications to Ethics Committees in case of termination or suspension of trials.

Then we have the Drugs Price Control Order, 2013 under the Essential Commodities Act. It is enforced through the National Pharmaceutical Authority and contains rules for pricing and selling for schedules and non-scheduled drugs. Obligations under the order include, inter alia:

- Display of prices of non-scheduled formulations
- Maintaining records of individual active pharmaceutical ingredients
- Display of information on the pack offered for retail sale, etc

Under the Narcotic Drugs and Psychotropic Substances Act, 1940 a company is required to submit quarterly returns of receipt, import, sale, consumption or export of controlled substances. Obligations also accrue under the Prevention of Cruelty to Animals Act, 1960. A registered establishment is required to make an application for permission from the Committee constituted under the Act, for control and supervision of experiments on animals. Permissions are also required for the breeding and trade of animals for the purpose of experiments.

As is apparent from the discussion above, Pharmaceutical Companies in India operate in a complex regulatory environment that is often accompanied by a high level of liability and moral responsibility on the compliance officers and the executive management of these companies. With a largely ad-hoc, manual and paper-based system of compliance relying on multiple sources of expertise, the probability of lapses is high. The next section discusses some of the challenges associated with compliance management.

State of Criminalisation in the Pharmaceutical Industry

A thorough review of India's business laws reveals that imprisonment has been used as a tool of control against entrepreneurs over the years. A new monograph titled Jailed for Doing Business, co-authored by Gautam Chikermane and Rishi Agrawal, uncovers the nature and extent of the risks of imprisonment faced by entrepreneurs in the country. Of the 1,536 laws that govern doing business in India, more than half (54.9%) carry imprisonment clauses. Among the 69,233 compliances contained in these laws, every two out of every five (37.7%) prescribe jail terms for non-compliance.

The monograph highlights that a sizable portion of these clauses criminalise procedural violations and technical lapses rather than serious offences involving wilful harm. It illustrates that in many cases, there is equivalence between punishment for minor errors by entrepreneurs and for death due to negligence under the Indian Penal Code, 1860. Resultantly, the current business environment reflects a sense of distrust and hostility towards companies and raises barriers to the seamless flow of innovation, wealth and jobs in the economy.

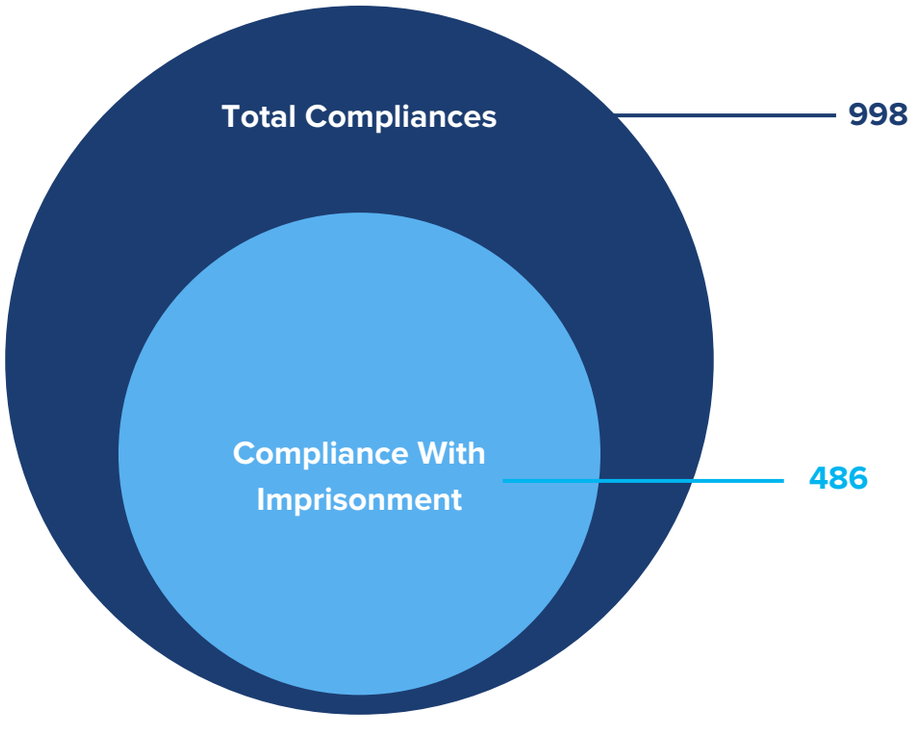

Fig.3

Imprisonment clauses as a share of total compliances in the pharmaceutical industry
Source: Teamlease Regtech

With this basic premise of the monograph, Teamlease Regtech has compiled data on the imprisonment clauses facing companies in the pharmaceutical industry. An MSME with a single entity having manufacturing operations and corporate office in a single state deals with 998 compliances in a year. Among them 486 (or 48.7%) compliances contain imprisonment clauses. Approximately 60% of these clauses are contained in state laws while the rest are within Union laws. 2 out of 5 (or 44%) of these clauses prescribe imprisonment for a duration of 1-3 years. Labour laws account for as high as 66% of all the clauses.

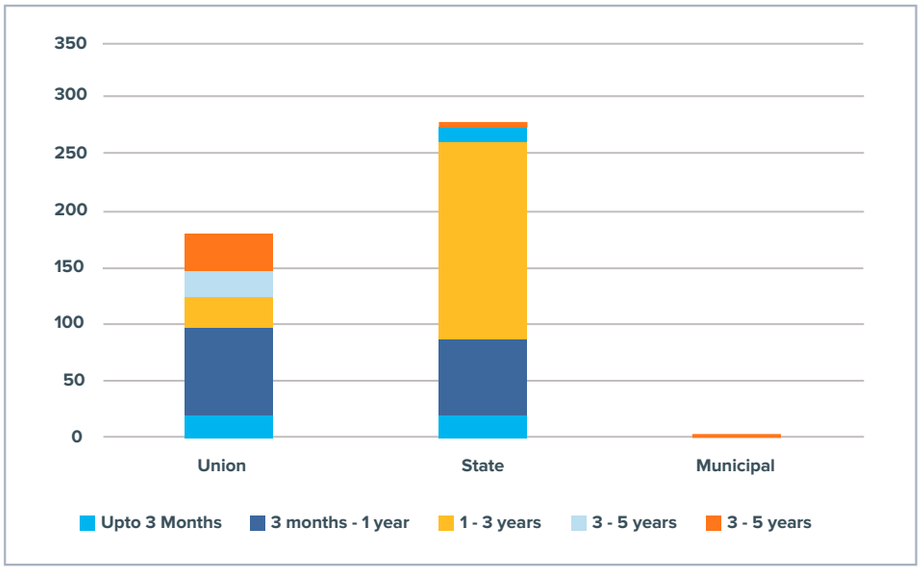

Fig.4

Duration of imprisonment terms across Union, State and Municipal compliances
Source: Teamlease Regtech

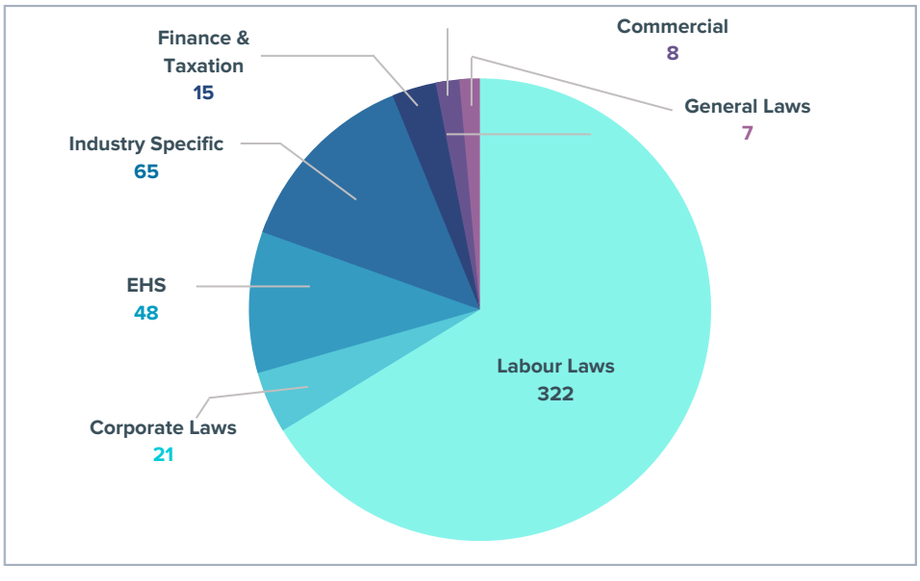

Fig.5

Distribution of imprisonment clauses across compliance categories
Source: Teamlease Regtech

As evidenced by the data, the implications of non-compliance can be severe. Hence, pharmaceutical companies must focus on establishing a strong control over their compliance obligations. Staying on top of the regulatory changes, filings, permissions, approvals, among others, must assume priority in the company.

Compliance Challenges for Pharmaceutical Companies

Between the Drugs and Cosmetics Act, 1940 and the Prevention of Cruelty to Animals Act, 1960 compliance officers of pharmaceutical companies have several hundred acts and thousands of rules depending on the size of the business, to comply with.

Depending on the type of pharma company, between the several acts by the state, and centre, there is also an additional pressure of keeping up with the Central Drugs Standard Control Organisation (CDSCO), National Pharmaceutical Pricing Authority (NPPA), and department of chemicals and petrochemicals.

Given below are some of the major compliance challenges faced by the pharma sector. Many of these are in congruence with a larger survey of clients conducted by Teamlease Regtech on regulatory complexity and the Ease of Doing Business in India (forthcoming in the India Compliance Report, 2022).

1 Lack of an accurate list of Applicable Compliances

A small pharmaceutical company operating in a single state in India deals with at least 913 compliances in a year. As the company grows its geographical footprint, the number of compliances multiply. These compliances are at three levels; Center, State and Local. In addition, they are in seven compliance categories; Labour, Finance & Taxation, Commercial, Secretarial, EHS, Industry Specific and General. Identification of applicable compliances for a pharmaceutical company requires deep expertise.

The applicability changes based on the use of specific equipment (hoists, lifts, cranes, pressure vessels, weights and measures, fire extinguishers, centrifuges among others), inputs (methanol, ethanol, hydrogen peroxide, ammonium hydroxide, alkalising agents, dyes, food colours and other hazardous chemicals) and end products (APIs, Vaccines, Formulations, Dermaseuticals, testing kits, medical devices, stem cell banks among others). In addition, there are challenges pertaining to obtaining necessary licenses from Central and State Drugs Councils. In case a company is engaged in conducting clinical trials, New Drugs & Clinical Trial Rules, 2019 adds to the applicability and complexity of compliance. The Drug & Cosmetic Rules, 1945 has a number of schedules which specify requirements and guidelines for the pharmaceutical industry. Most organisations in India find it really challenging to track compliance with the said schedules.

In addition, the laws constantly undergo amendments leading to periodic change of applicability. Legislation of new regulations also affect the organisation's compliance obligations. Recent bill (introduced in the lower house of parliament on Dec, 06, 2021) on The Narcotic Drugs and Psychotropic Substances (Amendment) Bill, 2021 is a case in point. In addition, the Data Protection bill, 2021 is already in advanced stages of deliberation in the parliament. Once legislated and notified, the bill will have serious implications on the compliance burden of Pharmaceutical companies in India.

2 Fluid Regulatory Environment

India's regulatory environment is fluid. There are over 3,500 regulatory updates annually published on any of the 2,233 websites of Central, State and Local Government websites via notifications, gazettes, circulars, ordinance, master circulars, press releases among others. These changes typically lead to changes in forms, dates, timelines, frequencies, fines, interest rates calculations, applicability threshold values, letters of law among others. These are often applicable almost immediately and require a time sensitive interpretation and implementation. Based on a recent study done by TeamLease Regtech, it was found that there were over 600 regulatory updates that affected an MSME company in the Pharmaceutical industry.

Unfortunately, there is no centralized repository of regulatory updates that provides national, realtime, comprehensive and personalised of all applicable regulatory changes that affects the compliance burden. As a result, the Compliance officer is often expected to periodically visit literally hundreds of websites to ensure that they are not missing any critical update.

3 Poor Tracking & Managing Applicable Licenses

A typical pharmaceutical company in India deals with tens if not hundreds of licenses. These include factory licenses, shop and establishment registration, drug manufacturing licenses, wholesale drug licenses, licenses to import drug and medical equipment, boiler registrations, consent to operate, permission to manufacture post successful clinical trials, license to manufacture notified medical devices, loan licenses among many others.

Each license has many parameters including:

- Issue Date
- Expiry Date
- Categorisation of Industry (Red, Orange, Green, White)
- Conditions of License (Client Specific)
- Days for application for next renewal

Licenses, Registrations, Permissions, Consent Orders & NOCs need to be tracked meticulously to ensure that they are in good order failing which there are serious business consequences. Most organisations lack robust processes which provide adequate assurance for statutory license management.

4 Poor tracking Event Based Compliances

In the pharmaceutical industry, there are many instances where the applicability of licenses and compliances changes based on occurrence of specific business events. As a result, the compliance officer needs to keep his eyes peeled to identify such occurrences and be ready to interpret and implement their impact on the organisation's compliance obligations.

As an example, a pharmaceutical company with its manufacturing facility based in the state of Karnataka needs to take permission from the drugs control department for manufacturing unapproved banned new drugs solely for export purposes. This particular permission does not allow the said company to manufacture at will. Each time the company receives an export order for a specific quantity, it needs to apply for the permission with all the details of the order including documentation pertaining to procurement of the drug. In case, the company receives many such bulk orders, it may end up making an equivalent number of applications for obtaining the permissions.

Pharmaceutical companies deal with the challenge of tracking all these applications and their statuses to stay on the right side of the law.

5 Poor tracking of on-going Compliances

A typical pharmaceutical company deals with a large number of compliances that are on-going in nature. These include displays (licenses, registrations, abstracts of legislations, employee related social security based displays, no smoking, fire exits, danger signs, display of areas storing hazardous waste etc). In addition, the company also needs to maintain a variety of registers which should be current at any time. These include examples such as leave and attendance, fines & deductions, muster rolls, wage registers, temperature registers, records of disposal of waste, seven copies of manifest in form 10 among at least 40 other unique registers in various formats.

Creating, maintaining, reviewing and certifying that these registers are in compliance with the law of the land is the responsibility of different people across the organization. Unfortunately, there are no enterprise processes to track and maintain the digital copies of these registers and obtain periodic self certification from the relevant stakeholders.

6 Challenge of compliance with External Regulators

Pharmaceutical industry is a highly regulated industry and its products are not only expected to be in compliance with domestic regulations but also follow regulatory requirements of international drug controllers. These include USFDA, South African Medicines Control Council, European Medicines Agency, Federal drug control service of Russia, Federal institute for drugs and medical devices, Germany and many other country specific regulators.

Each regulator has their own demand on processes, documentation and controls. They have their own requirements of social audit which involves in-person plant visits going into days and weeks. A large pharmaceutical company has to be always audit ready. The cost of failure in the industry is disproportionately high. Poor compliance can lead to loss of reputation, business and leaked revenue. Over a period of time, the fines and penalties have continued to increase. India currently has the second highest number of US FDA approved plants in the world. There have been several instances in the past where foreign drug regulators have blacklisted Indian manufacturing plants for failure to adhere to required controls.

6 Lack of Awareness at Management Level

Based on a recent survey conducted by TeamLease Regtech, it was discovered that the KMPs (Key Management Personnel) in Indian Pharmaceutical Companies have a poor understanding of compliance obligations in over 80% of the instances. As a result, they are often unpleasantly surprised in the events of show cause notices, instances of financial fines and penalties, cancelled licenses, revoked permissions and leaked revenue.

Most executives were found to have very poor handle on the status of key compliances, dates, documentation and residual risk of non-compliance.

8 Manual, Paper Based & People Dependent Compliance

A typical mid-sized Pharmaceutical company deals with a few thousand compliances in a year. There are at least 50-100 people in different departments (Human Resources, Finance & Tax, Company Secretarial, Administration, Environment Health & Safety, Warehouse, Research & Development) directly involved in day to day compliance functions. Unfortunately, while compliance is a key binding constraint in an organisation's growth, a number of Indian organisations are yet to adopt technology platforms for transparent and accountable compliance programs. The compliance officers often use spreadsheets to track status manually. As a result, there are several instances where there are inadvertent misses, delays, lapses, defaults, expired licenses and missed legal updates.

It is not uncommon to see them firefighting and highly stressed during regulatory audits.

9 Anecdotal Compliance Certification

The Companies Act, 2013 Section requires the issue of Compliance Certificates to the Board. Since the organization is low on technology based tracking systems, the compliance officer has no other choice but to prepare the statutory compliance certificates manually. These certificates often miss key information such as the specific data on an instance of non compliance, delayed filing and the residual risk of poor compliance.

In such instances, the board is often flying blind. They do not have a framework to establish the level of compliance in the company.

Industry Perspective

In a recent survey conducted by TeamLease Regtech on compliance officers of major Pharmaceutical Compliances, here are the key findings:

- 90% agreed to have missed at least one critical compliance during the 12 month period
- 95% agreed to pay fines and penalties in the 12-month period
- 97% believed that they do not have the required visibility and control in their organization's compliance program
- 80% agreed that their Compliance needs a serious rethink
- 78% of Compliance officers believe that third party consultants have better liaisoning experience than they have internally
- 65% agreed to have poor control on their compliance documents
- The average cost of compliance consultants stood at approximately INR 100,000 per month; Labour contributed approximately 35% of the cost
- 56% believed that keeping track of regulatory updates is challenging

The survey was conducted for compliance professionals from 26 pharmaceutical companies. These were mid to large companies with revenue starting from INR 250 Cr.

Rethinking Compliance Management

1 Conduct a baseline applicability assessment

An accurate list of applicable compliances is the first and perhaps the most important step in streamlining an organization's compliance management. The applicability of compliance changes with the use of specific equipment, input raw material and end products. Clinical trials, schedules from the drug and cosmetic rules further add to the complexity of the compliances. Engaging with a partner vendor to track and create a consolidated assessment of all applicable acts and compliances is critical to effective compliance management.

Companies must engage a partner who brings the depth and width of experience to assess and document the compliance obligations across Union, State and Local laws. In addition, the partner should help classify all the compliance requirements in seven categories; Labour, Finance & Taxation, Environment health and Safety, Secretarial, Commercial and Industry specific. The list should be subclassified by compliance type; licenses, registrations, permissions, consent orders, returns, registers, challans, payments, displays, audits and examinations, committees, exemptions among others.

This checklist should serve as a baseline and should be periodically reviewed and refreshed based on the business changes.

2 Subscribe to National, Realtime & Personalised Regulatory Updates

It is arduous for a compliance officer to browse a few hundred government websites periodically to discover the applicable compliance changes. It is recommended that the company subscribe to national, real time, personalised and comprehensive regulatory updates from a third party vendor. These updates should be available on a daily, weekly and monthly basis; categorized by Act, category of the law, union / state, regulator, nature of change, date of change applicability among others. The update should have search, sort and filter capabilities for easy consumption. Mobile app (IOS and Android) and email based updates are highly recommended.

There are industry leading players such as TeamLease Regtech (www.teamleaseregtech.com) who provide personalised updates in daily / weekly / monthly newsletters and mobile apps.

3 Create a culture of Compliance

Compliance management becomes a breeze if all the stakeholders hold their end of the stick. While one compliance officer takes responsibility, many key folks within the organisation bring their shoulder to the load. Periodic reviews at department level, functional level and organisational level help make people accountable. In addition, reviews help bubble up issues before they become urgent and important. You should work with your human resources team and add compliance goals as a part of goal setting, mid term assessment and annual assessments. Good compliance behaviour should be rewarded.

4 Digitize Compliance Management

Technology is transforming key business processes. It is making them faster, easier and cheaper. Technology enables enhanced collaboration and improves human productivity. Data is the new oil. Compliance is a key business process and needs to go digital. Your preferred software solution should have the features given below:

- **Smart Dashboards** – Easy to use, real time, colour-coded with drill down capabilities
- **Native Mobile Apps** – IOS & Android based mobile apps
- **Flexible Workflows** – Configurable workflows which adapt to your business processes
- **Integrated Comprehensive Compliance Database** – Comprehensive and accurate compliance database covering the law of the land
- **Strong Analytics and Reporting** – Automated and on-demand analytics and reporting capabilities to flag non-compliance and risks
- **Integration with your Office email** – Legal updates / alerts / notifications / reminders / escalations / reports on your office email
- **Integrated Document Management System** – Manage all your compliance documents and working files with version management
- **SAAS Based** – Quick and Easy to on-board without any additional IT infrastructure and licenses
- **Secure & Available** – Best in class information security with availability when you need it

Ease of Use

Compliance cuts across your organisation. Employees at various levels of skill, experience and technology-savviness need to feel comfortable using it. You should ensure that your software vendor has a product which has a user-friendly interface for end user adoption.

Quick and easy Deployment

Ensure that end to end on-boarding happens in a few weeks as IT projects are notorious for time and budget overruns. If it takes more than a few weeks to go-live, chances are the project will lose momentum and will cause headaches. In addition, ensure that your vendor has strong capabilities in business discovery, compliance applicability assessment, product configuration and end user training. SAAS and cloud based products should be preferred as they do not require any on-premises technology infrastructure (virtual machines, network resources, storage, firewalls, load balancing among others).

Pay as you go Pricing Option

IT budgets are stretched. There is a constant tussle between CIO and CFO on additional capital allocation for digitisation projects. Perpetual licensing options can be extremely capital intensive. It is highly recommended that you evaluate and prefer 'pay as you go' pricing, as budgetary allocation and approval might become a breeze. Such price options are typically cheaper than the salary of a junior compliance officer.

Policy Recommendations for Enabling Ease of Doing Business

Employer compliance in India needs a thorough reimagination. The country's entrepreneurs cannot compete in the 21st century with the 19th and 20th century regulatory environment. Teamlease Regtech recommends a three vector framework to undertake policy reforms for facilitating ease of doing business in the country.

1 Rationalisation

- There is a lot of duplication, redundancy and overlap across compliances. It is recommended that a detailed analysis of such opportunities be conducted. The list should be classified into items that can be executed by an executive order and those requiring legislative change. Based on an initial assessment, at least 20 to 30% of the compliances can be reduced without affecting the outcomes

- The current process of inspections is ad-hoc, manual, paper-based and people-dependent. There is limited transparency and accountability. The inspection process should be reviewed and a risk based, faceless, presenceless, cashless inspection process should be implemented.

- Opportunities for self-certification and third-party inspections should be rolled out.

- Digital interfaces (new licence applications / renewals / return filings / request for inspection etc) should be identified and developed.

2 Digitisation

- There should be a single digital portal for a centralised publishing of all regulatory updates across various departments and ministries and at all governance levels. The portal should be a technology utility that should be extended to all relevant stakeholders. It should provide capability to subscribe to automated alerts based on filters such as type, industry, location and compliance category, among others.

- A digital platform to automate creation of all regulatory records for compliance should be created. It should also facilitate safe storage and authentication of such records

3 Decriminalisation

- Criminal penalties in business laws should be used with extreme restraint. Misdemeanours such as procedural lapses and technical non-compliances should be punished with financial penalties only whereas criminal penalties should be retained only for serious crimes involving intentional harm

- A general and indicative set of standards should be adopted to guide lawmakers, executive authorities and regulators in making laws, rules and regulations. Such standards should include principles of necessity and proportionality

- All imprisonment clauses must go through legislative scrutiny at least once in five years. For this, sunset clauses can be introduced in the legislative process to ensure either the renewal or termination of imprisonment clauses depending on their need and relevance in light of the evolving business climate

TeamLease™ RegTech
Helping India Comply

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