Technical Guide on Internal Audit of Pharmaceutical Industry

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Foreword

Indian pharmaceutical industry has grown at a high pace during the last few years. The major challenges faced by the companies in the pharmaceutical industry are developing new products and services through research, shifting demographics, evolving governing regulations, transforming business models and increased expectations from stakeholders.

Risk is central to pharmaceutical companies as they are dependent on continuous research and development with long gestation periods, compliance issues with environmental laws, heavy capital investments as well as expenditures for environmental liabilities, management of their intellectual property rights, etc. Most innovative pharmaceutical companies are undergoing transition from their traditional business model and resort to diversification, mergers & acquisitions to deal with the growing competition for low cost generics.

The Chartered accountants can play a crucial role in helping pharmaceutical companies to address the said challenges presented by today's complex, competitive and risk driven environment by strategizing and channelizing the threats into opportunities and assist the management of the said companies in taking future course of action.

I congratulate CA. Rajkumar S. Adukia, Chairman, Internal Audit Standards Board of The Institute of Chartered Accountants of India and other members of the Board for bringing out this "Technical Guide on Internal audit of Pharmaceutical Industry" which is one of the rapidly growing industries of the country. This comprehensive publication would surely help the members to conduct value added internal audits and provide inputs that will help to improve operational efficiencies, risk management, capital allocation and market reach of the pharmaceutical companies in the country.

I am confident that the members and other interested readers will make best use of this publication.

February 4, 2013
New Delhi

CA. Jaydeep Narendra Shah
President, ICAI

Preface

The Indian Pharmaceutical industry is witnessing trends such as innovation in drugs at a faster pace, increasing investment, deeper penetration in rural markets, growth in insurance coverage and changing government regulations. These positive trends, along with favourable macro environment will help to propel the pharmaceutical industry to the next level of growth. Pharmaceuticals companies are facing competition and they need to optimally leverage financial, relational, technology and reputational capital to create strategies and provide value to consumers.

Keeping this in mind, the Internal Audit Standards Board is issuing the Technical Guide on Internal Audit of Pharmaceutical Industry, so as to provide guidance to internal auditors in carrying out internal audit of companies operating in pharmaceutical industry. The objective of this Technical Guide is to provide an insight into the functioning of the pharmaceutical industry, the key drivers of pharmaceutical industry, technical aspects peculiar to the industry and internal audit procedures with respect to certain processes which would help the readers in conducting internal audit of a pharmaceutical company. This Guide explains in brief the key drivers of Indian pharmaceutical industry which include low cost of manufacture, research & development, highly educated and specialized scientists, experience in international servicing, bio-pharmaceutical sector, etc. The Guide also covers in brief technical aspects of pharmaceutical industry which includes drug discovery and development solutions, exclusive synthesis and radiopharmaceuticals. The Guide also discusses regulatory framework for pharmaceutical industry in India especially, National Pharmaceuticals Pricing Policy, 2012. Internal audit aspects with respect to procurement to pay cycle, order to cash, statutory compliances, production and inventory management have been discussed in detail for each underlying activity alongwith it's controls objectives and the key controls to be verified in this regard.

At this juncture, I am grateful to Dr. Sanjeev Singhal and his study group members *viz.* C.A. R. Sankariah and C.A. Akshat Kedia for sharing their experiences and knowledge with us and preparing the draft of the Guide.

I wish to thank CA. Jaydeep N. Shah, President and CA. Subodh Kumar Agrawal, Vice President for their continuous support and encouragement to the initiatives of the Board. I must also thank my colleagues from the Council at the Internal Audit Standards Board, *viz.*, CA. Rajendra Kumar P., Vice-

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I am certain that this Technical Guide will help the members and others in efficiently discharging their responsibilities.

February 6, 2013
Mumbai

CA. Rajkumar S. Adukia
Chairman
Internal Audit Standards Board

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Glossary

Biotechnology	Use of living organisms or their products to modify human health and the human environment. The United Nations Convention on Biological Diversity defines biotechnology as "Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use."
Non Prescription Drugs	Drugs that are sold over the counter, which means they are sold without a prescription from a doctor. They are also referred as the over-the-counter (OTC) drugs, e.g., cough-suppressants, antiseptics, aspirin, etc.
Pharmaceuticals	Pertaining to the knowledge or art of pharmacy; or to the art of preparing medicines according to the rules or formulas of pharmacy; as, pharmaceutical preparations.
Pharmacy	The art or practice of preparing and preserving drugs, and of compounding and dispensing medicines according to prescriptions of physicians.
Pharmaceutical Drugs	Defined as chemical substances used for treating, curing and preventing different types of diseases.
Prescription Drugs	Drugs that are not locally available without a physician's prescription. A prescription drug is a licensed medicine which is obtained only by prescription. The prescription drugs are regulated by legislation, e.g., anti-obesity drugs, anti-viral drugs, anti-malarial drugs, etc.

Chapter 1
History of Pharmaceutical Industry in India

1.1 Indigenous medicines were in use even prior to the British rule in India. Western medicine, scientifically termed as “allopathic”, came to be known only during the British Era. The pioneering efforts of some few indigenous people led to the steady establishment of the modern pharmaceutical industry. Drug production meeting around 13% of Indian requirement, was produced by several other indigenous firms during and after the Second World War. By 1930’s efforts were also made in the direction of producing synthetic bulk drugs.

1.2 Before the therapeutic revolution, there wasn‘t much difference between the activities of indigenous and foreign firms in India since they were essentially manufacturers and not inventors. Indigenous sector dominated the pharmaceutical industry in India until 1950. The therapeutic revolution led to the change in equations between Indian pharmaceutical industry and global multinationals. 1940’s and 1950’s saw new medicines being marketed by multi-national companies in India. This strengthened the skills in developing new manufacturing technologies. A collaborative effort between Council of Scientific and Industrial Research (CSIR) and private manufacturing industry led to development, application and advancement of substantial skills in the pharmaceutical industry in India. However, post 1950 MNC’s gained the ground with new medicines being introduced in the Indian markets. A strong product patent system then prevailing under the British Patents and Designs Act, 1911 (prevailing in India even after independence) led to increasing influence of MNCs in the Indian pharmaceutical markets. System of industrial licensing favoured easy entry for MNCs prior to 1970 at the peril of indigenous industry. Thus by 1970s, the share of indigenous companies was reduced from 62% (1950) to 32% in 1970. The share of MNCs stood at 68% in 1970s, which increased from 32% held in 1952.However, during this period, the government established the India Dicey and Pharmaceutical Ltd. (IDPL) and Hindustan Amtibiotics Ltd (HAL) with both indigenous and foreign technology collaboration which provided the necessary impetus to the private industry players. CSIR laboratories also contributed by developing substantial reverse engineering skills post 1970.

1.3 During late 1960s and in 1970s, there was a conscious attempt to give preference to national industry. After a thorough review of the failure of Patents and Designs Act, 1911, introduction of Patents Act, 1970 was done, which limited patents only to process in case of pharmaceuticals and agricultural chemicals. Further, the term of patents was also reduced to 7 years. Apart from this, the Foreign Exchange Regulation Act, 1973 and the National Drug Policy, 1978 provided essential impetus to the growth of the Indian generic industry. Thus, post 1970 reversed foreign domination of the pharmaceutical industry in India. Large scale bulk drug production was possible and this led to the change in industry landscape.

1.4 A decade later, in late 1980 and early 1990, the Indian generic industry steadily increased the exports and came to be recognised as an important player in global generic industry. Substantial price controls were initiated in 1979 through the Drug Price Control Orders, based on National Drug Policy, 1978. This led to entry of large number of firms. After 1990s, export led growth and increase in domestic consumption led to a dominating share of Indian firms in the market. In 1998, the domestic companies held 68% of the market share which grew to 77% in 2003.

Chapter 2
Current Scenario

2.1 Indian Pharmaceutical Industry has witnessed a robust growth over the past few years moving on from a turnover of approx. US $ 1 billion in 1990 to over US $ 20 billion in 2010 (of which the export turnover is approximately US $ 8 billion). The industry ranks 3rd in terms of volume and is 14th in terms of value globally. It has shown tremendous progress in terms of infrastructure development, technology base creation and a wide range of products. It has established its presence and determination to flourish in the changing environment.

2.2 The industry now produces bulk drugs belonging to all major therapeutic groups requiring complicated manufacturing technologies. Formulations in various dosage forms are being produced in GMP compliant facilities. Strong scientific and technical manpower and pioneering work done in process development have made this possible. The country now ranks 3rd worldwide by volume of production and 14th by value thereby accounting for around 10% of world's production by volume and 1.5% by value. Globally, it ranks 4th in terms of generics production and 17th in terms of export value of bulk actives and dosage forms. Indian exports are destined to more than 200 countries around the globe including highly regulated markets of US, West Europe, Japan and Australia.

2.3 Recognising the potential for growth, the Government of India took up the initiative of developing the Indian Pharmaceuticals sector by creating a separate Department in July 2008. The Department is entrusted with the responsibility of policy, planning, development and regulation of Pharmaceutical Industries.

2.4 An assessment of the Indian Pharmaceutical Industry strength reveals the following key features:

(a) India exported drugs worth US$ 8 billion to more than 200 countries including highly regulated markets in the US, Europe, Japan and Australia. Large Indian pharma companies have emerged as among the most competitive in the evolving generic space in North America and have created an unmatched platform in this space. Indian companies are also making their presence felt in the emerging

markets around the world, particularly with a strong portfolio in anti-infective and anti-retrovirals.

(b) Large domestic pharma companies have continued to grow, assuming leadership position in many therapies and segments in the Indian market as well as creating a strong international exports back bone.

(c) Competitive market with the emergence of a number of second tier Indian companies with new and innovative business modules.

(d) Indian players have also developed expertise in significant biologics capabilities.

(e) Biologic portfolio (while still nascent in India) is being built with an eye on the future.

(f) Multinational companies have continued to invest significantly in India and are making their presence felt across most segments of the Indian pharma market. Companies have also begin to invest in increasing their presence in tier II cities and rural areas and making medical care more accessible to large section of the Indian population.

(g) There is massive investments by Indian pharma. Currently, projects worth more than 1.2 billion dollars are under implementation on various products.

(h) Self-reliance displayed by the production of 70% of bulk drugs and almost the entire requirement of formulations within the country.

(i) Low cost of production.

(j) Low R&D costs.

(k) Innovative Scientific manpower.

(l) Excellent and world-class national laboratories specializing in process development and development of cost effective technologies.

(m) Increasing balance of trade in Pharma sector.

(n) An efficient and cost effective source for procuring generic drugs, especially the drugs going off patent in the next few years.

(o) An excellent centre for clinical trials in view of the diversity in population.

2.5 Top 20 Indian companies in terms of revenue from operations

S. No.	Company Name	Net Sales* (₹ in crores)
1	Ranbaxy Laboratories Ltd.	7,690.12
2	Cipla Ltd.	6,977.50
3	Dr. Reddy's Laboratories Ltd.	6,739.70
4	Lupin Ltd.	5,384.83
5	Aurobindo Pharma Ltd.	4,281.45
6	Sun Pharmaceutical Industries Ltd.	4,015.56
7	Cadila Healthcare Ltd.	3,150.80
8	Jubilant Life Sciences Ltd.	2,641.07
9	Wockhardt Ltd.	2,560.40
10	IpcaLaboratories Ltd.	2,338.03
11	GlaxoSmithKline Pharmaceuticals Ltd.	2,329.37
12	Torrent Pharmaceuticals Ltd.	1,986.69
13	Divis Laboratories Ltd.	1,844.93
14	Orchid Chemicals & Pharmaceuticals Ltd.	1,736.33
15	Sterling Biotech Ltd.	1,661.95
16	Surya Pharmaceuticals Ltd.	1,622.95
17	Glenmark Pharmaceuticals Ltd.	1,564.67
18	Biocon Ltd.	1,555.80
19	Abbott India Ltd.	1,445.57
20	Alembic Pharmaceuticals Ltd.	1,375.28

** Revenue from operations for the year ending 31st December, 2011/ 31st March, 2012 as the case may be.*

Source: Annual reports of various companies put as foot not.

2.6 Top 20 Indian companies in terms of market capitalisation

S.No.	Company Name	Market Cap as on 26th December, 2012 (₹ in crores)
1.	Sun Pharmaceutical Industries Ltd.	77,772.20
2.	Cipla Ltd.	33,807.00
3.	Dr. Reddy's Laboratories Ltd.	30,851.19
4.	Lupin Ltd.	27,310.16
5.	Ranbaxy Laboratories Ltd.	21,472.23
6.	Cadila Healthcare Ltd.	17,854.07
7.	GlaxoSmithKline Pharmaceuticals Ltd.	17,584.35
8.	Wockhardt Ltd.	17,323.70
9.	Glenmark Pharmaceuticals Ltd.	14,332.18
10.	Divis Laboratories Ltd.	14,193.94
11.	Piramal Enterprises Ltd.	9,577.25
12.	Strides Arcolab Ltd.	6,737.14
13.	Ipca Laboratories Ltd.	6,643.71
14.	Torrent Pharmaceuticals Ltd.	5,957.06
15.	Biocon Ltd.	5,643.00
16.	Aurobindo Pharma Ltd.	5,637.56
17.	Sanofi India Ltd.	5,414.50
18.	Jubilant Life Sciences Ltd.	3,481.89
19.	AstraZeneca Pharma India Ltd.	3,462.50
20.	Pfizer Ltd.	3,446.54

Chapter 3
Objectives of Technical Guide

3.1 The objective of the Technical Guide is to provide an insight into the functioning of the pharmaceuticals industry, the key drivers of pharmaceuticals industry, technical aspects peculiar to the industry and internal audit procedures with respect to certain processes which would help the readers in conducting internal audit of a pharmaceuticals company. The Guide briefly covers the following:

(i) Key Drivers of Pharmaceutical Industry.

(ii) Technical Aspects of Pharmaceutical Industry.

(iii) Regulatory Framework

(iv) Internal Audit Aspects of Pharmaceutical Industry

(v) Research and Development

(vi) Clinical Trials

(vii) Enterprise Risk Management (ERM) in Pharmaceutical Industry.

Chapter 4
Key Drivers of Pharmaceuticals Industry

Experience and Expertise

4.1 India is the only country with largest number of US-FDA compliant plants (more than 100) outside USA. We have 793 WHO-GMP approved Pharma Plants, 153 European Directorate of Quality Medicines (EDQM) approved plants with modern state of Art Technology. No other country can boast of such infrastructure. Thus, Indian pharma companies have a wide variety of experience in manufacturing as per global standards. Through intensive competition in the Indian market, Indian companies are experienced in the manufacturing of a variety of formulations that makes them efficient and competitive in their operations.

4.2 The Indian pharma market is mature with decades of experience in generics manufacturing, catering to the needs of the general population. These companies have the experience and knowhow to produce quality drugs in an efficient, high-quality, cost effective manner without compromising on any aspect. There are many companies manufacturing drugs for oncology, AIDS and other complex therapies.

Low Cost of Manufacture

4.3 India is capable of manufacturing low cost generic alternatives due to a number of economic factors favouring the industry. Some of these include:

(i) competitive land rates;

(ii) cheap labour available;

(iii) low resource costs like water, electricity, etc.;

(iv) lower cost of production machinery.

Importantly, companies manufacturing various drugs, e.g., intermediates, APIs and Formulation, etc. are seamlessly integrated while following international regulations of safety.

Research and Development

4.4 Government has taken several policy initiatives for strengthening research and development in pharmaceuticals sector such as, fiscal incentives to R&D units sector and streamlining of procedures concerning development of new drug molecules, clinical research and new drug delivery systems leading to new R&D set-ups with excellent infrastructure in the field of original drug discovery.

India has a large branded generics market which enables most companies to launch their version of a generic drug in the market place. Research and Development is an important aspect for development of generics that match the quality and cost targets. India is now increasingly recognized as a strategic partner in the drug discovery value chain. Further, there are Indian companies who are investing in their R&D centres and are offering early stage discovery services as well as promising molecules. A large scientific pool in India is dedicated to research and development of patent non-infringing methodologies for drugs.

Highly Educated, Specialized Scientists

India's rich human capital is the strongest asset for Indian Pharmaceuticals Industry which is a knowledge-led industry. Various studies show that the scientific talent pool of Indians is the second largest english-speaking group worldwide, after the US. This enables easier access to qualifications that handle the basic work in a plant or an R&D set-up in India.

National Institute of Pharmaceutical Education and Research (NIPER) at Chandigarh is a premier institute in the field of pharmaceuticals. The institute is a member of Association of Commonwealth Universities. Further, six new NIPERs have been established recently and all are working extensively to address HR needs of pharma including regulators' training.

Experience in International Servicing

4.6 Many of the Indian pharmaceutical companies are experienced in servicing top multinational companies for their highly regulated markets, meeting their stringent quality expectations. The same experience enables Indian organizations to cater to the needs of the regulatory authorities of most nations across the world. Further, technical consultancy capability of NIPERs is contributing to the growth of the industry.

Indian clinical trials industry has developed a complete gamut of clinical research services capabilities of global standards. From medical writing to site management, data management, regulatory submissions to patient recruitment, the expertise meets the highest standards of stringent regulatory conditions internationally.

4.7 There is an effective control system to monitor the quality of pharmaceuticals at all the levels in India. There are various agencies/ bodies under Ministry of Health and Family Welfare and Department of Pharmaceuticals. They are responsible for standard of drugs, market authorizations, import licenses, CGMP, monitoring of quality of drugs and cosmetics manufactured, pre and post licensing inspection, and price control, etc. The recent initiatives through new legislations and optimized processes are targeted towards regulating the industry better and effectively.

Drugs have to comply with stringent quality provisions under the Drugs and Cosmetic Act of India. Any drug including API confirm to the specifications of the prescribed pharmacopeias or those claimed on the label ensuring that all the products manufactured in India are of highest quality. All the pharmaceutical products are inspected at the customs port of the country by competent authorities before they are shipped out. Today "MADE IN INDIA" means a highest quality product.

Bio-Pharmaceutical Sector

6.1.1 The vaccines sector (including human and animal vaccines) represented the largest size of pie, with estimated sales of $ 475 million in 2009-10, up from $ 436 million the previous year. Human vaccines generated about 80% of this revenue, with domestic sales reaching $ 218 million and exports reaching $163 million. Demand for newer products like, the pneumococcal conjugate, meningococcal conjugate and human papillomavirus vaccines is also stimulating the paediatric and adolescent segment of the market, while flu vaccines will continue to play a big role in expanding the adult segment. Breakthrough products like, Schanchot- the bivalent oral cholera vaccine jointly developed by Shantha Biotech and the international Vaccine Institute- will build international manufacturing capacities.

Diagnostics and Targeted Therapeutics

4.9 The diagnostics and therapeutics sectors have also expanded in recent years. The diagnostics market is currently worth about $436 million,

with molecular diagnostics accounting for sales of about $300 million in 2009-10. The market is growing at 15-20% annually, with revenues split equally between the multinationals, e.g., Roche, Siemens (which has acquired Bayer Diagnostics) and Abbott, etc. and domestic players, e.g., Tulip Group, Transasia Biomedicals, RFCL (Diagnova), Span Diagnostics and Trivitron, etc., gradual acceptance of the concept of personalized medicine is driving much of the growth.

4.10 Meanwhile, the therapeutics sector accounted for 15% of India's biologics market in 2009-10, with cancer therapies clocking up sales of $68 million. Oncology products are a very profitable line of business for many Indian biopharmaceuticals manufacturers because they address an area of high unmet need and thus command premium prices. Uptake of such medicines is also increasing, as domestic producers make less expensive versions than those made by the multinationals and a growing number of Indian patients get medical insurance.

Oral Diabetes Drugs and Insulins

4.11 The oral diabetes market is currently worth about $338 million, while the insulin (and insulin analogues) market is worth about $ 133 million. Markets are growing rapidly at a compound annual growth rate of 32%, measured in terms of value, in 2007-09. Novel delivery devices will also contribute to the expansion of the market in the future.

Biosimilars

4.12 About 20 Indian companies are already producing biosimilars. Dr Reddy's Laboratories, Ranbaxy, Biocon, Shantha Biotech, Reliance Life Sciences, Panacea Biotec and Intas Biopharmaceuticals are among those that lead the way. But several other well-known companies have recently entered the field, including Glenmark, Cipla and Lupin Pharma. In June 2010, e.g., Cipla announced that it was spending $65 million on stakes in two biotechnology companies: MabPharm and BioMab, based in India and Hong Kong respectively, to bolster its presence in the global biosimilars space.

4.13 In 2009-10, domestic sales of erythropoietin rose to $22 million while sales of c-GCF rose to $ 11million, sales of interferons rose to $22 million and sales of streptokinase rose to $15 million. Moreover, demand is likely to grow considerably, as India becomes more affluent. US investment bank Goldman Sachs estimates that the number of Indians with annual income of

between $6,000and $30,000 (measured in terms of purchasing power parity) will increase by 250-300 million during the next decade alone.

4.14 India is one of the largest (by volume) exporters of malaria and anti-retroviral drugs at affordable costs. WHO, UNDP, Clinton Foundation, etc., source a large number of their drug requirements to fulfill their worldwide demands from India.

4.15 The Indian Pharmaceutical fraternity has spread beyond the boundaries of the country with presence all over the world. Through satisfied customers and high quality products, the industry is growing in its presence across the world, in highly stringent economies like USA, EU, Australia and Japan topping the list of exporting countries. The ability to supply to highly regulated markets catering to their stringent requirements is an evidence of quality standards of Indian medicines. These investments and commitments from different market participants is what have allowed the Indian Pharma market to prosper and bring about a more holistic growth to Industry.

Chapter 5
Technical Aspects of Pharmaceuticals Industry

5.1 The pharmaceutical industry develops, produces, and markets drugs or pharmaceuticals licensed for use as medications. Pharmaceutical companies are allowed to deal in generic and/ or brand medications and medical devices. They are subject to a variety of laws and regulations regarding the patenting, testing and ensuring safety and efficacy and marketing of drugs. Overview of few of the areas under pharmaceutical industry has been discussed in following paragraphs.

Drug Discovery and Development Solutions (DDDS)

5.2 DDDS business offers integrated services platform across target validation, discovery, pre-clinical and clinical development. The DDDS division works in accelerating both early and late stage drug development in therapeutic areas of oncology, metabolic disorders, CNS, pain/ inflammation, dermatology as well as infectious diseases. Stages of DDDS business are as follows:

Discovery		Clinical Development		Market Launch
Discovery	*Pre-clinical*	*Phase I*	*Phase II & Phase III*	*Phase IV*
Bioinformatics	Medicinal Chemistry	Bio availibility Studies	Clinical trial management	Data management
Path art	Analytical Chemistry	Bioequivalence Studies	Study Feasibility	Biostatistics
Chemoinformatics	Custom Synthesis	Bioanalytics Analysis	Site identification	Quality Assurance
ChemBioBase	Library Design	Pharmacokentic Support	Site initiation/ Close out	Regulatory Affairs
Crystallogr-aphy	Combina	Statistical support	Medical monitoring	Drug Safety

Structure Directed	Focused			Consulting Services
Molecular design	Lead Optimisation			Staffing solutions
Information technology				
Services				

5.3 Clinical Research division provides pharmaceutical, biotechnology and medical device companies with a broad range of clinical research services in support of Phase I-IV drug and device development, including project management, clinical monitoring, scientific and medical support, investigator and patient recruitment, site management, biostatistics, data management, drug safety, quality assurance, regulatory affairs, medical writing, etc.

Clinical Research Services

5.4 The following are examples of areas covered under DDDS:

- Medicinal Chemistry
- Biology
- Structural Biology
- Computational Chemistry
- Pharmacology
- Clinical Sciences

- Domain-specific Information Technology (Life sciences and Biotech)
- Highly specialized therapeutic areas including:
    - oncology
    - cardiovascular
    - central nervous system
    - dermatology
    - respiratory
    - allergy/ immunology, etc.

Contract Research and manufacturing Services (CRAMS) : Exclusive Synthesis

5.5 In Exclusive Synthesis Business, a pharma company may offer following services:

(i) Custom Research and Development Services

- Early phase clinical projects in pre-clinical/ phase I/ phase II
- Offer services such as route design, process development and analytical method development on FTE as well as on fee for services basis
- Lab and Pilot scale synthesis

(ii) Custom Scale-up Services

- Late phase clinical projects in phase II / phase III;
- Offer fast and efficient scale-up and manufacturing services.

(iii) Exclusive Custom Manufacturing

- In-market product either already launched in market or moved from phase III;
- Offer exclusive manufacturing for multiple years on long term contractual basis;
- Process Given by Customers, e.g., process familiarization, contractual agreement, complete technology transfer, commercial manufacturing, etc.;

- Process developed, e.g., route selection, sample preparation, sample approval, process optimization, contractual agreement, pilot trial, commercial manufacturing, etc.

Radiopharmaceuticals

5.6 The focus of radio-pharmaceuticals division is on nuclear medicine, imaging and therapeutic agents. The radiopharmaceutical division develops, manufactures and markets innovative diagnostic imaging and radiopharmaceutical solutions for the global market. Radiopharmaceuticals are used in Nuclear Medicine for the characterization of various disease conditions and the treatment of thyroid disorders/cancer. Applications of these products include cardiology, oncology, thyroid uptake and scans, lung scans, kidney and brain imaging and bone scans.

Various other businesses under Pharma industry are as follows:

Generics	Allergenic Extracts	Major therapeutic and diagnostic extracts for allergy derived from pollens, animals and stinging insects venoms
	Dosage Form	Provider of high quality finished dosage forms (tablets and capsules)
CMO	Sterile & Non Sterile Products	CMO services for lyophilized products, liquid fills, biologics, suspensions, WFI/ diluents, clinical trial quantities, ointment, cream, liquid, etc.
Healthcare		Providing affordable high-quality health care services in India as well as abroad

Chapter 6
Regulatory Framework

6.1 List of laws governing the pharmaceutical sector are as follows:

- National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012)
- The Drugs and Cosmetics Act, 1940
- The Drugs and Cosmetics Rules, 1945
- The Pharmacy Act, 1948
- The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954
- The Narcotic Drugs and Psychotropic Substances Act, 1985
- The Narcotic Drugs and Psychotropic Substances Rules, 1985
- The Prevention of illicit traffic in Narcotic Drugs and Psychotropic Substances Act, 1988
- Narcotic Drugs and Psychotropic Substances (Regulation of Controlled Substances) Order, 1993
- Drug Policy, 1986
- The Medicinal and Toilet Preparations (Excise Duties) Act, 1955
- The Medicinal and Toilet Preparations (Excise Duties) Rules, 1956
- The Drugs (Prices Control) Order 1995 (under the Essential Commodities Act)
- Clinical Establishments (Registration and Regulation) Act, 2010
- Clinical Thermometers (Quality Control) Order, 2001
- Good Laboratory Practice (GLP) Guidelines
- Guidelines for I.V Fluids distribution, storage and administration
- Guidelines for Blood Banks
- Good Clinical Practice Guidelines
- Guidelines for import and manufacture of medical devices
- Guidelines on Recall and Rapid Alert System for Drugs

- Guidelines on Fixed Dose Combinations (FDC)
- The Patents Act, 1970
- The Industries (Development and Regulation) Act, 1951
- Trade Marks Act, 1999
- Labour related laws
- Foreign Exchange laws
- Taxation laws
- Environmental laws, etc.

National Pharmaceuticals Pricing Policy, 2012 *(vide notification dated 7th December, 2012)*

Objective

6.2 The central objective of NPPP, 2012 is to promulgate the principles for pricing of Essential Drugs as laid down in the "National List of Essential Medicines- 2011, which was declared by the Ministry of Health and Family Welfare, Government of India vide communication No.12-01/essential medicines/08-DC/DFQC, dated 8th June, 2011. The objective is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines ("essential medicines") at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well being for all.

Key Principles of NPPP, 2012

6.3 The key principles for regulation of prices in the National Pharmaceuticals Pricing Policy 2012 are:

- Essentiality of Drugs
- Control of Formulations prices only
- Market Based Pricing

Principles for Drugs Price Control and Determination in NPPP, 2012

6.4 Price regulation would be on the basis of 'Essentiality' of the drug as laid down in the "National List of Essential Medicines- 2011" declared by the

Ministry of Health and Family Welfare, and modified time to time, in public interest under Drug Price Control Order.

Price regulation would be applied only to formulations, i.e., the medicine actually used by the consumers, and not to any upstream products such as bulk drugs and intermediates. The Span of Price Control shall be as per the dosages and strengths as listed in NLEM- 2011. The methodology of fixing a ceiling price of NLEM medicines, by adopting the Simple Average Price of all the brands having market share (on the basis of Moving Annual Turnover) more than and equal to 1% of the total market turnover of that medicine, will be as per the formula below:

$$\text{Ceiling price} = \frac{\text{Sum of prices of all the brands of the medicine having market share more than and equal to 1\% of the total market turnover of that medicine}}{\text{Total number of manufacturers producing such brands of the medicine}}$$

6.5 The formulations will be priced only by fixing a Ceiling Price (CP). Manufacturers would be free to fix any price for their products equal to or below the CP. The CP's would be fixed on the dosage basis, such as per tablet / capsule / standard injection volume as listed in NLEM- 2011. The Ceiling Price will be fixed on the basis of readily monitorable Market Based Data (MBD). To begin with, the basis for this readily monitorable market data would be the data available with the pharmaceuticals market data specializing company – IMS Health (IMS). Wherever required this data would be checked by appropriate survey/ evaluation by the National Pharmaceutical Pricing Authority (NPPA). As the IMS data gives price figures for stockist level prices hence in order to arrive at ceiling price (which will be the maximum retail price), the IMS price will be further increased by 16% as margin to the retailer so as to arrive at a reasonable ceiling price chargeable from the consumers.

For drugs not in the IMS data, NPPA would collect data by commissioning the same. For the medicines where there is no reduction of price due to absence of competition, the overall percentage reduction in the price of same molecule with other dosage and strength will be applied; otherwise the overall percentage reduction in the price of medicines in the same therapeutic category will be applied.

6.6 The CP for a drug listed in the NLEM would be the Simple Average of Prices as calculated on the basis of IMS data six months prior to the date of announcement of the new National Pharmaceutical Pricing Policy, i.e., the "Appointed Date" for bringing the new Policy into effect. For a drug whose data is not available in IMS, the NPPA will commission the data within a reasonable time for determining the Simple Average Prices also on the basis of prices prevailing six months prior to the Appointed Date. Once the Simple Average Price is fixed, NPPA would monitor its implementation on a continuous basis through a proper methodology and system.

6.7 The prices of these NLEM-2011 medicines will be allowed an annual increase on 1st April of every year as per the Wholesale Price Index for the previous year as notified by the Department of Industrial Policy and Promotion. In case of decline in Wholesale Price Index, a corresponding reduction in the ceiling price will be obligatory. The NPPA itself will also separately notify the revised ceiling prices as applicable as on the 1st of April each year, and in case any company has fixed the prices not consistent with the revised ceiling prices, the NPPA will take appropriate action.

6.8 The Reference Prices for calculation of Simple Average Price may also change on an annual basis due to changes in the MAT value. However, there would be no annual revision of Ceiling Prices on the basis of MAT. Revision of Ceiling Prices on the basis of MAT value would be carried out only once in five years or as and when NLEM is updated/ revised. However, the Government will revise the ceiling price of a medicine under NLEM, if there is a significant change in the market structure of the particular medicine even in between 5 years.

Non-price Control Drugs

6.9 In the policy, all essential drugs are under price control. It would follow that non-essential drugs should not be under a controlled regime and their prices should be fixed by market forces. However, in order to keep a check on overall drug prices, prices of such drugs be monitored on regular basis, and where such prices increase at a rate of above 10% per annum is observed, the Government would be empowered to have the price of these drugs reduced to below this limit, for next 12 months.

Imported Drugs

6.10 The Ceiling Prices determined for drugs falling under the span of control shall also be applicable to such drugs that are imported.

Overlap Drugs between DPCO 1995 and NLEM- 2011

6.11 The prices of medicines which are a part of DPCO 1995 but not in NLEM-2011 would be frozen for one year and thereafter a maximum increase of 10% per annum, as in case of other non-NLEM medicines will be allowed.

Exemptions

6.12 To promote innovation and R&D following drugs will be kept out of any type of price control:

S. No.	Exemption to	Period of exemption	Exemption from
(i)	A manufacturer producing a new drug patented under the Indian Patent Act, 1970 (product patent) and not produced elsewhere, if developed through indigenous R&D	5 years	The date of commencement of its commercial production in the country
(ii)	A manufacturer producing a drug in the country by a new process developed through indigenous R&D and patented under the Indian patent Act, 1970, (process patent)		
(iii)	A formulation involving a new delivery system developed through indigenous R&D		The date of its market approval in India*(refer note below)*

Note: The certification of innovation and R&D may be provided by the office of Drug Controller General of India (DCGI).

6.13 The revision of NLEM for the purpose of price control is a dynamic process and any drug can be added in NLEM in public interest under Drug Price Control Order on the recommendation of Ministry of Health and Family Welfare. The production levels, availability and accessibility to the NLEM drugs and formulations should not fall after price control is introduced and the Department of Pharmaceuticals will ensure that production levels are maintained by an appropriate mechanism. If a manufacturer of a NLEM drug with dosages and strengths as specific in NLEM, launches a new drug by

combining the NLEM drug with another NLEM drug or a non-NLEM drug or by changing the strength and dosages of the same NLEM drug, such manufacturers shall be required to seek price approval from the Government before launching the new drug. Ministry of Health and Family Welfare will consider making prescription of drugs by generics names mandatory. The distribution of quality affordable generics drugs through Jan Aushadhi Stores will be strengthened.

Measures to Strengthen Pharmaceuticals Industry

6.14 The following are measures be required to strengthen pharmaceuticals industry:

a) Strengthening and rationalizing the drug regulatory system.

b) Bringing on a common platform all the regulatory authorities related to drug standards, bio-pharmaceuticals, clinical trials and Pharmacopeia.

c) Promotion of research and development in the pharmaceutical sector, directly through research institutions and universities, as well as through provision of seed capital, venture capital funding and subsidies to innovative drug companies.

d) Enablement of domestic pharmaceutical companies to achieve international GMP/GLP and GCP standards.

e) Development of human resource, particularly in critical areas to meet the requirements of pharmaceutical industries.

f) Rationalization of excise duties on pharmaceuticals.

g) Setting up of common infrastructure through pharma development parks, pharma cluster schemes in order to strengthen and facilitate the smaller units in the pharmaceutical industries.

h) Rationalization of pharma retail trade and strengthening of pharma supply chains.

The Drugs and Cosmetics Act, 1940

Objective

6.15 The objective of the Act is to regulate the import, manufacture, distribution and sale of drugs and cosmetics. The Act consists of 38 sections under 5 chapters and 2 schedules.

Definitions (Chapter I)

6.16 The terms defined in the Act are as follows:

(i) Ayurvedic, Siddha or Unani drug includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic, Siddha andUnaniTibb systems of medicine, specified in the First Schedule

(ii) The Board means:

(a) in relation to Ayurvedic, Siddha or Unani drug, the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board

(b) in relation to any other drug or cosmetic, the Drugs Technical Advisory Board

(iii) Cosmetic means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic.

(iv) Drug includes:

(a) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like, mosquitoes;

(b) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

(c) all substances intended for use as components of a drug including empty gelatin capsules; and

(d) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board

(v) Manufacture in relation to any drug or cosmetic includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale or distribution but does not include the compounding or dispensing of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business.

(vi) Import means to bring into India.

(vii) Patent or proprietary medicine means:

(a) in relation to Ayurvedic, Siddha or UnaniTibb systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha or UnaniTibb systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books.

(b) in relation to any other systems of medicine, a drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being or any other Pharmacopoeia authorised in this behalf by the Central Government after consultation with the Drugs Technical Advisory Board.

Bodies under the Act (Chapter II)

6.17 The following bodies have been defined under the Act:

(i) The Drugs Technical Advisory Board—The Central Government shall, as soon as may be, constitute a Board (to be called the Drugs Technical Advisory Board) to advise the Central Government and the State

Governments on technical matters arising out of the administration of this Act and to carry out the other functions assigned to it by this Act.

(ii) The Central Drugs Laboratory—The Central Government shall, as soon as may be, established a Central Drugs Laboratory under the control of a Director to be appointed by the Central Government, to carry out the functions entrusted to it by this Act or any rules made under this Chapter.

(iii) The Drugs Consultative Committee—The Central Government may constitute an advisory committee to be called "the Drugs Consultative Committee" to advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any other matter tending to secure uniformity throughout India in the administration of this Act.

Definitions under Chapters III and IV

6.18 The followings are terms defined under Chapter III and IV

(i) Standards of quality means:

(a) in relation to a drug, that the drug complies with the standard set out in the Second Schedule, and

(b) in relation to a cosmetic, that the cosmetic compiles with such standard as may be prescribed.

(ii) Misbranded drugs*:* A drug shall be deemed to be misbranded:

(a) if it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; or

(b) if it is not labelled in the prescribed manner; or

(c) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

(iii) Adulterated drugs: A drug shall be deemed to be adulterated:

(a) if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(c) if its container is composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) if it contains any harmful or toxic substance which may render it injurious to health; or

(f) if any substance has been mixed therewith so as to reduce its quality or strength.

(iv) Spurious drugs.— For the purposes of this Chapter, a drug shall be deemed to be spurious:

(a) if it is imported under a name which belongs to another drug; or

(b) if it is an imitation of, or a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

(c) if the label or the container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or

(d) if it has been substituted wholly or in part by another drug or substance; or

(e) if it purports to be the product of a manufacturer of whom it is not truly a product.

(v) Misbranded cosmetics: A cosmetic shall be deemed to be misbranded:

(a) if it contains a colour which is not prescribed; or

(b) if it is not labelled in a prescribed manner; or

(c) if the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.

(vi) Spurious cosmetics: a drug shall be deemed to be spurious:

(a) if it is imported under the name which belongs to another cosmetic; or

(b) if it is an imitation of, or is a substitute for, another cosmetic or resembles another cosmetic in a manner likely to deceive or bears upon it or upon its label or container the name of another cosmetic, unless it is plainly or conspicuously marked so as to reveal its true character and its lack of identity with such other cosmetic; or

(c) if the label or the container bears the name of an individual or company purporting to be the manufacturer of the cosmetic, which individual or company is fictitious or does not exist; or

(d) if it purports to be the product of a manufacturer of whom it is not truly a product.

Import of Drugs and Cosmetics: Prohibition of Import of Certain Drugs or Cosmetics (Chapter III)

6.19 No person shall import:

(a) any drug or cosmetic which is not of standard quality

(b) any misbranded drug or misbranded or spurious cosmetic

(c) any adulterated or spurious drug

(d) any drug or cosmetic for the import of which a licence is prescribed, otherwise than under, and in accordance with, such licence

(e) any patent or proprietary medicine, unless there is display in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it, together with the quantities thereof

(f) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect, as may be prescribed

(g) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended

(h) any drug or cosmetic the import of which is prohibited by rule made under this Chapter.

Manufacture, Sale and Distribution of Drugs and Cosmetics: Prohibition of Manufacture and Sale of Certain Drugs and Cosmetics (Chapter IV)

6.20 No person shall himself or by any other person on his behalf:

(i) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale or distribute:

(a) any drug which is not of a standard quality, or is misbranded, adulterated or spurious

(b) any cosmetic which is not of a standard quality or is misbranded or spurious

(c) any patent or proprietary medicine, unless there is display in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities thereof

(d) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to prevent, cure or mitigate any such disease or ailment, or to have any such other effect as may be prescribed

(e) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended

(f) any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder

(ii) sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder

(iii) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic, except under, and

in accordance with the conditions of, a licence issued for such purpose under this Chapter.

Note: Every person holding a licence shall keep and maintain such records, registers and other documents as may be prescribed and shall furnish to any officer or authority exercising any power or discharging any function under this Act such information as is required by such officer or authority for carrying out the purposes of this Act.

Provisions relating to Ayurvedic, Siddha and Unani drugs (Chapter IVA)

6.21 The following are Bodies under the chapter:

a) Ayurvedic, Siddha and Unani Drugs Technical Advisory Board: The Central Government shall, by notification in the Official Gazette and with effect from such date as may be specified therein, constitute a Board (to be called the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board) to advise the Central Government and the State Governments on technical matters arising out of this Chapter and to carry out the other functions assigned to it by this Chapter.

b) The Ayurvedic, Siddha and Unani Drugs Consultative Committee: The Central Government may constitute an Advisory Committee to be called the Ayurvedic, Siddha and Unani Drugs Consultative Committee to advise the Central Government, the State Governments and the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board on any matter for the purpose of securing uniformity throughout India in the administration of this Act in so far as it relates to Ayurvedic, Siddha or Unani drugs.

Regulation of Manufacture for Sale of Ayurvedic, Siddha and Unani Drugs

6.22 No person shall manufacture for sale or for distribution any Ayurvedic, Siddha or Unani drug except in accordance with such standards, if any, as may be prescribed in relation to that drug.

Prohibition of Manufacture and Sale of Certain Ayurvedic, Siddha and Unani Drug

6.23 No person, either by himself or by any other person on his behalf, shall:

(a) manufacture for sale or for distribution:

  (i) any misbranded, adulterated or spurious Ayurvedic, Siddha or Unani drugs;

  (ii) any patent or proprietary medicine, unless there is display in the prescribed manner on the label or container thereof the true list of all the ingredients contained in it; and

  (iii) any Ayurvedic, Siddha or Unani drug in contravention of any of the provisions of this Chapter or any rule made thereunder

(b) sell, stock or exhibit or offer for sale or distribute, any Ayurvedic, Siddha or Unani drug which has been manufactured in contravention of any of the provisions of this Act, or any rule made thereunder

(c) manufacture for sale or for distribution, any Ayurvedic, Siddha or Unani drug, except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter by the prescribed authority.

Drugs Prices Control Order (DPCO), 1995

6.24 The drug prices in India are controlled by the Drugs (Prices Control) Order (DPCO).The DPCO is an order issued by the government under Section 3 of the Essential Commodities Act, 1955 empowering it to fix and regulate the prices of essential bulk drugs and their formulations. The order incorporates a list of bulk drugs, whose prices are to be controlled, the procedure for fixation and revision of prices, the procedure for implementation, the procedure for recovery of dues, the penalties for contravention and various other guidelines and directions. The order is subject to the guidelines of Drug Policy and aims to ensure equitable distribution, increased supply and cheap availability of bulk drugs.

Pricing of Bulk Drugs

6.25 The 76 bulk drugs, the prices of which are controlled under DPCO 1995, have been enlisted in the First Schedule annexed to the order. The methodology through which prices of DPCO-controlled bulk drugs are fixed is as follows:

(i) While fixing the maximum sale price of a bulk drug, the government has to provide a post tax return of:

  (a) either 14% on net worth or

(b) 22% on capital employed

(ii) Each company can choose one of the two methods mentioned above as per its own free will. So, the choice of method is company-specific and not product-specific.

(iii) Based on the chosen method, each company submits to the government, a detailed working of the prices of various bulk drugs that it requires. The prices submitted by the companies are such that the allowed profitability parameters are achieved.

(iv) The government subsequently studies the applications made by the major players for every bulk drug and cost audits reports of manufacturers, before arriving at the final price. The price so decided will be binding on all manufacturers, irrespective of their actual cost of production.

Pricing of Formulations

6.26 The Drug Price Control Order covers all the formulations that utilize the bulk drugs listed in the First Schedule. The methodology through which prices of formulations are fixed is as follows:

A uniform MAPE (Maximum Allowable Post-manufacturing expenses) of 100% is given on all formulations under price control, i.e., the retail price of a DPCO formulation is fixed equal to [(MC+CC+PM+PC) x 2] + excise duty.

Details	Amount
(a) Material Cost (MC)	xxx
(b) Conversion Cost (CC)	xxx
(c) Packing Material Costs (PM)	xxx
(d) Packing Charges (PC)	xxx
(e) Ex-factory Cost [(a)+ (b) + (c) +(d)]	xxx
(f) MAPE 100% on (e) above	xxx
(g) Excise Duty	xxx
(h) Retail Price [(e) + (f) + (g)]	xxx

Note: It is this price that is printed on the pack of a DPCO controlled formulation. This price is not the Maximum Retail Price (MRP). Local taxes are additional.

6.27 In order for the government to decide the price of a controlled formulation, each manufacturer is supposed to submit to the government details of material cost, manufacturing process etc. The ceiling prices, once decided, are notified in the Official Gazette.

For imported drugs and formulations, the landed cost including customs duty and clearing charges is the benchmark to fix prices. The margin allowed to the importer is such that selling and distribution expenses including interest and profit are covered. However, the margin allowed cannot exceed 50% of the landed cost.

The Pharmacy Act, 1948

6.28 In India there was no restriction to practise the profession of pharmacy. One could practise this profession as any other profession. Persons, having no knowledge and having no education in pharmacy or pharmaceutical chemistry or pharmacology, were engaged in this profession. Hundreds of cases were brought to the notice of the Government wherein the compounding, mixing, or dispensing of medicines was being done by persons who were not adequately educated in this line. The system was causing great harm to the health of people by wrong compounding, mixing or dispensing. It was found necessary to enact a law for the regulation of the profession and practice of pharmacy. To achieve this goal the Pharmacy Bill, 1947 was introduced in the Legislature which was later referred to the Select Committee. The recommendations of the Select Committee were incorporated in the Bill.

Object of the Act

6.29 It was desirable that, as in most other countries, only persons who have attained a minimum standard of professional education should be permitted to practise the Profession of Pharmacy. It was accordingly proposed to establish a Central Council of Pharmacy, which will prescribe the minimum standards of education and approve courses of study and examinations for Pharmacists, and Provincial Pharmacy Councils, which will be responsible for the maintenance of provincial registers of qualified pharmacists. It was further proposed to empower Provincial Governments to prohibit the dispensing of medicine on the prescription of a medical practitioner otherwise than by, or under the direct and personal supervision of, a registered pharmacist.

Important Provisions of the Act

6.30 The Pharmacy Act consists of 46 sections under 5 chapters. Most of the states in India have also enacted state specific Pharmacy Council Rules. Registration of a pharmacist is done by the State Pharmacy Council constituted under Section 19 of the Pharmacy Act. According to Section 32(2) of the Act, the minimum requirements for registration as a pharmacist are:

(a) Applicant should have attained the age of 18 years and paid the prescribed fee;

(b) Applicant should reside or carry on the business or profession of pharmacy in the state;

(c) Applicant should have successfully completed Diploma /Degree in Pharmacy from an Institution approved by the Pharmacy Council of India; or

(d) is a registered pharmacist in another state.

No person other than a Registered Pharmacist should compound, prepare, mix, or dispense any medicine on the prescription of a medical practitioner.

The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954

6.31 It is an Act to control, the advertisement of drugs in certain cases, to prohibit the advertisement for certain purpose of remedies alleged to possess magic qualities and to provide for matters connected therewith. The Act came into force on 1st April, 1955. It consists of 16 sections and one schedule.

Note: The schedule lists a number of diseases, disorders or conditions such as, diabetes, cataract, cancer, fevers (in general), obesity, rheumatism, impotence, high or low blood pressure, female diseases, epilepsy, stature of persons, venereal diseases, glaucoma, sterility in women, dropsy, etc.

6.32 According to Act, the magic remedy includes a talisman mantra kavacha, and any other charm of any kind which is alleged and possess miraculous powers for or in the diagnosis, cure, mitigation treatment or prevention of any disease in human beings or animals or for affecting or influencing in any way the structure or any organic function of human beings or animals.

Unless prescribed by registered medical practitioners or after consultation with the Drugs and Cosmetics Act 1940, no person or company, should take any part in the publication of any advertisement referring to any drug that is used for:

(a) the miscarriage in woman or prevention of conception in women,

(b) maintenance or improvement of the capacity of human beings for sexual pleasures,

(c) correction of menstrual disorder in women, and

(d) the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule to the Act.

No person or company should take part in advertisement which gives a false impression or makes a false claim for the drug or mislead the people.

The Narcotic Drugs and Psychotropic Substances Act, 1985

6.33 The Narcotic Drugs and Psychotropic Substances Act, 1985 came into force on 14thNovember, 1985. The Act describes itself as 'an Act to consolidate and amend the law relating to narcotic drugs, to make stringent provisions for the control and regulation of operations relating to narcotic drugs and psychotropic substances, to provide for the forfeiture of property derived from, or used in, illicit traffic in narcotic drugs and psychotropic substances, to implement the provisions of the International Convention on Narcotic Drugs and Psychotropic Substances and for matters connected therewith.'

6.34 This Act has 83 sections and one schedule giving the list of psychotropic substances. Under the NDPS Act, it is illegal for a person to produce/ manufacture/ cultivate, possess, sell, purchase, transport, store, consume any narcotic drug or psychotropic substance. Narcotic drug means coca leaf, cannabis (hemp) opium straw and includes all manufactured drugs.

6.35 The Act is designed to fulfill India's treaty obligations under the Single Convention on Narcotic Drugs, Convention on Psychotropic Substances, and United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. The Act provides power to the Central government to add to or omit the list of psychotropic substances, to take measures for preventing and combating abuse of and illicit traffic of narcotic

drugs. There is a Consultative Committee to advise the Central Government for the implementation of this Act. The Narcotics Commissioner looks after the production of opium. The coca plant and coca leaves can be used in the preparation of flavoring agents with the permission of central government. No person should be engaged in or control any trade in which a narcotic drug or psychotropic substance is obtained from outside India and supplied to any person staying outside India.

Chapter 7
Internal Audit — Pharmaceutical Industry

7.1 Internal Audit with respect to following have been discussed in this chapter:

(i) P2P cycle (Procurement to Pay)

(ii) OTC (Order To Cash)

(iii) Statutory Compliances

(iv) Production

(v) Inventory Management

P2P cycle (Procurement to Pay)

7.2 The following table gives a brief description of various activities, control objectives and key controls in procurement to pay cycle:

S.No.	Activity	Controls Objective	Key Control
1.	*Vendor master: creation and maintenance*	Complete, accurate and updated data should exist in the vendor master.	Review of the vendor master including documentation requirements.
		All changes to the vendor master should be duly authorized and accurately captured and no duplicate/redundant data should exist in the vendor master.	Monitor all changes to the master file, i.e., review log of changes to the vendor master.
2.	*Item master: creation and maintenance*	Complete, accurate and updated data should exist in the item master.	Review of the item master including documentation requirements.

		All changes to the item master should be duly authorized and accurately captured and no duplicate/redundant data should exist in the item master.	Monitor all changes to the master file, i.e., review log of changes to the item master.
3.	*Purchase Planning: Production related purchases: raw material*	All purchases should be supported by valid business needs and should be duly authorized.	Review of monthly procurements and annual budgets for purchases along with its approval.
4.	*Purchase Planning: Production related purchases: project*	All purchases should be supported by valid business needs and should be duly authorized.	Review of monthly procurements and annual budgets for purchases along with its approval.
5.	*Purchase Planning: Production related purchases: engineering spares*	All purchases should be supported by valid business needs and should be duly authorized	Review of monthly procurements and annual budgets for purchases along with its approval.
6.	*Purchase Planning: Non production related planning: IT*	All purchases should be supported by valid business needs and should be duly authorized	Review of budgets along with its approval.
7.	*Purchase: Raw materials & packing materials*	All purchase orders are duly authorised and valid	Review of system based purchase order (PO).
			Review of list of amended PO along with the re-approval process in case of

			amended PO.
			Review of regularisation procedures in case of emergency purchases.
			Review of open PO report.
		All PO's should be legally enforceable. Further, the terms and conditions of PO's should not be prejudicial to the interest of the company.	Review of legal enforceability of PO's pre-printed stationery with standard terms.
8.	*Purchase: Capital Asset*	All purchase orders should be duly authorized and valid.	Review of approval process of purchase proposal.
			Review of list of amended PO from ERP including controls on amendments and re-authorisation.
			Review of open POs report of capital expenditure.
		All PO's should be legally enforceable. Further, the terms and conditions of PO's should not be prejudicial to the interest of the company.	Review of legal enforceability of PO's pre-printed stationery with standard terms.
9.	*Receiving: Material received at warehouse*	All receipts should be duly approved and correctly accounted for in a timely manner.	Review of MRN.
			Review of process at the time of unloading and physical count of receipts raw material received in tankers.
			Review of receipt of engineering goods/ project items.

			Review of pending MRNs.
			Review of system based approval of materials.
10.	*Invoice processing*	Rates of goods/ services should be consistent with PO/ contract, should matching with receipts of goods/ services and no duplicate payments should be made.	Review of invoices and comparison with PO and MRN including the approval process for payments.
		Liability should be correctly and completely recorded for invoices that have been processed.	Review of authorisation of deviations.
			Review of reconciliation of sub-ledger with general ledger.
			Review of reconciliation of Purchase bills to be received with general ledger.
11.	*Vendor advances*	All the advances should be duly authorised by relevant authorities.	Review of approval process for vendor advances.
		Advances should be correctly, completely and timely recorded in books of accounts and advances are adjusted as per the contracted terms with the vendors.	Review of vendor accounts.
12.	*Imported Material Purchase Accounting*	Purchase Accounting should be done as per the Accounting Policy of the Company.	Review of purchase accounting.

7.3 In case of purchase of raw material, special consideration should be given to the qualitative aspect, e.g., material should be of desired quality. It should be checked and analysis report should be prepared by the QC team and reviewed by the management as well as the internal auditor. It should be ensured that there is a process of sealed quotes or e procurement system in case of purchases. In case of any capital expenditure, it should be ensured that the said capital expenditure is justified. Before disposal of a capital asset, it should be checked that whether the life of the asset has elapsed or not. Also, the disposal should be done at appropriate prices. In this regard, minimum three quotations should be obtained.

Order to Cash (OTC)

7.4 The following table given a brief of internal audit activity related to order to cash:

S.No.	Activity	Controls Objective	Key Control
1.	*Credit control*	Customer credit worthiness should be properly evaluated and credit limits should be accordingly set, in line with the policy of the Company.	Review of credit limits.
			Revision of credit limits.
			Auto Blocking of SOC(sales order confirmation) when credit limit is exceeded.
			Approvals for releasing the credit blocks to customer orders.
2.	*Credit notes*	Sales returns are accurately and completely recorded in the books of accounts.	Matching report: Duplicate SRCNs (sales returns credit notes).
		Sales Returns Credit Notes issued should be duly authorised.	Approval for returns by business heads.
		Credit notes raised on account of shortages, etc., should be duly authorised and supported by	Authorisation and processing of Credit notes for shortages.

		adequate backup.	
		Credit notes raised on account of insurance claim should be duly authorised.	Review of credit notes for Insurance claims.
3.	*Customer master*	All updations to the Customers Master should be duly authorised and accurately captured.	Review of existing Customer Master
			Authorisation of Credit Limit rating form for customer code updation.
		Duplicate and inactive customer codes should not exist in the customer master file.	Configuration of System Control to prevent recording of duplicate customer codes.
4.	*Receipt and processing of customer Orders*	Customers orders received should be completely and correctly entered in the system.	Verification of SOC Norms.
			Review of Open orders.
		Orders should be genuine and should be processed accurately and only for approved customers.	Approval of SOC.
			ERP restriction for modification of orders.
5.	*Collections*	Collections should be accurately and completely accounted in the proper period.	Review of ERP generated invoices pending collections list.
			Posting collection journals in ERP.
			Review of Monthly cheque pending realisation report.
		Cheques received should be adequately safeguarded and timely deposited in bank.	Review of safeguards for cheques received.

		Duplicate accounting of collections should not take place and all collections should be duly authorised.	Monthly review of collections exception report.
		Balance confirmation certificates should be obtained on a periodic basis and discrepancies should be correctly accounted for in the books of accounts.	Annual balance confirmation
6.	*Invoicing and Dispatches to Customers*	Goods (as per invoices)should be dispatched immediately and there should be no time lag between invoicing and dispatches.	Review of ERP based daily dispatch report.
7.	*Revenue Recognition*	Revenue recognition should be done on the basis of accounting policy of the Company which should be as per Indian GAAP.	Review of revenue Recognition Policy.
8.	*IT access*	The access to relevant modules in ERP should be restricted to the authorised personnel.	Review of user access rights list.
9.	*Agreement execution and monitoring*	All International Supply/ Sale/ Distribution agreements should be OFAC (Office of	Review of related terms and conditions of the agreement/ contracts with OFAC Regulation compliances.

		Foreign Asset Control) regulation Compliant (i.e., not supplied/ sold/ distributed to the restricted/ sanctioned countries).	
10.	*Cheque Bouncing*	All cheques returns should be promptly and correctly accounted.	Review of cheque bounced legal file.
11.		Cheques bounced (returned) are received by authorised personnel.	Safeguarding of bounced cheques received.

Statutory Compliances

Excise

7.4 The following are important internal audit aspects with respect to excise:

S.No.	Activity	Controls Objective	Key Control
1.	*Refund/ rebates/ Claims*	All refunds/ rebates/ claims should be filed within statutorily permissible period.	Review of refunds/ rebates/ claims to ensure that all the refunds/ rebates/ claims have been filed within period of limitation expiring on the end of the quarter.
2.	*CENVAT Credit*	All eligible CENVAT credit should be accounted accurately and on timely basis.	Verification of CENVAT credit.
			Verification of CENVAT Credit on rejected material (review of invoices generated for returning rejected materials).

3.	*Excise Rates*	Change in excise rates should be accurately and completely communicated and updated into the system.	Review of changes/ amendments.
4.	*Excise valuation*	Excise valuation for materials dispatched for exports should be accurately valued and authorised.	Review and authorisation of invoices.
		Excise valuation for materials dispatched to depots should be accurately valued and authorised.	Review and authorisation of invoices.
		Excise valuation for materials dispatched for domestic sale should be accurately valued and authorised.	Review and authorisation of invoices.
		Excise valuation for materials dispatched to contract manufacturer should be accurately valued and authorised.	Review and authorisation of invoices.
5.	*Incidence of Tax*	Accrual of excise duty liability should be booked as per the statute.	Review of accounting entry for excise duty on closing stock.
			Review of statement of

			material sent to contract manufacturer.
6.	*Excise Returns*	All returns should be submitted with adequate documents and on a timely manner.	Review of Excise Returns.
7.	*Excise Duty Payment*	Excise duty payment should be on a timely manner as per the statute.	Review of duty payment and its authorisation.
8.	*Excise Duty Reconciliation*	Excise duty records should be reconciled with the financial records on a timely basis.	Verification of debit and credit entries in excise records.
9.	*Notices/ claims*	All claims and notices should be appropriately received and actioned upon on a timely basis.	Review of the actions taken for notices/ claim received.
			Review of deposit with government account.
10.	*Document retention*	All excise related documents should be adequately maintained.	Review of physical control.
11.	*Contingent liability*	All contingent liabilities are correctly identified and disclosed in the notes to the accounts.	Review the process for approving the amount of contingent liability.

Service Tax

7.5 The following are important internal audit aspects with respect to service tax:

S. No.	Activity	Controls Objective	Key Control
1.	*Payment to Vendors*	Service tax should be paid as per the service tax law.	Review of payment of service tax to ensure that tax element in the invoice has been paid only against valid invoice and only to the extent of service tax applicable under the service tax law.
2.	*Incidence of Tax*	Accrual of Service Tax liability should be booked as per the Statute.	Review of liability created on service received.
			Review of liability created on specified services covered under reverse charge, e.g., goods transport agency.
3.	*Service tax payment*	Payments to service providers should be made within six months.	Review of payment of interest on service tax.
		Service Tax payment should be within timelines as per the statute.	Review of service tax payment and its authorisation.
4.	*Service valuation*	Valuation for services received from person not having business establishment in India should be done accurately.	Review of rate of Tax and computation of Service Tax.
		Valuation for services received from GTA, supply of manpower, works contract, hiring of motor	Review of calculation of Service Tax.

		vehicle designed to carry passengers, sponsorship, services of an advocate (collectively referred to as specified services) should be done accurately.	
5.	*Service tax rate*	Change in Service Tax rate should be accurately and timely communicated.	Review of changes/ amendments.
6.	*CENVAT credit*	All eligible Service Tax Credit should be accounted accurately and on timely basis.	Review of documents.
		All eligible Service Tax credits should be distributed to Plant accurately and on timely basis.	Review and finalisation of Challans for transfer of service tax credit to plants.
7.	*Service tax returns*	All returns should be submitted with adequate documents and on a timely manner.	Review of Service Tax Returns.
8.	*Notices/ claims*	All claims and notices should be appropriately received and actioned upon on a timely basis.	Review of the actions taken for notices/ claim received
			Review of deposit with government account.

9.	*Document retention*	All service tax related documents should be adequately maintained.	Review of physical control.
10.	*Contingent liability*	All contingent liabilities are correctly identified and disclosed in the notes to the accounts.	Review the process for approving the amount of contingent liability.

VAT/ CST

7.6 The following are important aspects related to VAT/CST:

S. No.	Activity	Controls Objective	Key Control
1.	*Statutory forms*	Status of pending statutory forms should be reviewed.	To ensure review of the status of pending C Forms which are overdue and exercise of due diligence in following up with the customers.
			To ensure review of the stock transfers at monthly intervals and issuance of 'F' Forms within the specified period, review of status of pending 'F' forms status and periodic reminder to the consignees for obtaining forms and steps to seek extension of time (if required) from the jurisdiction authority for submission of 'C' Forms and 'F' Forms.
		Statutory forms should be issued to sellers on timely basis and	To ensure that item detail mentioned in Forms tallies with the details as items contained in Registration

		are accurate.	Certificate issued by the Sales Tax Department.
		Statutory forms should be received and accounted for in books of account accurately and on timely basis.	To ensure that forms have been issued to customers/ consignors/ sellers on a timely basis and register of forms C and F have been maintained and updated on a timely basis.
2.	*VAT/CST Rates*	Change in Sales Tax rates should be accurately and timely communicated and updated into the system	To ensure that sales tax master is updated properly on the basis of request send by business unit accountant and after review by the Indirect Tax team.
			To ensure review of the sales tax rates charged as reflected in the sales tax register and communication of the discrepancies to all business accountants.
3.	*Incidence of tax*	Accrual of Sales Tax liability should be booked as per the statute.	To ensure correct calculation of the sales tax liability for month end.
4.	*VAT/CST Returns*	All returns should be submitted with adequate documents and on a timely manner.	To ensure that sales Tax returns have been correctly and completely filled, amounts have been verified with ERP, all necessary documents (proof of payment of service tax, etc) have been attached with the return and return has been duly filed on timely basis.
5.	*VAT/CST payment*	Sales Tax payment should	To ensure review of the sales tax rates charged as reflected

		be on a timely manner as per the statue.	in the sales tax register, necessary action on the discrepancies identified (if any) and deposit of sale tax within due dates.
6.	*VAT/CST reconciliation*	Sales Tax records should be reconciled with the financial records on a timely basis.	To ensure proper reconciliation of Sales tax records and finance records and necessary action on the discrepancies identified (if any).
7.	*VAT Credit*	All eligible VAT credit should be accounted accurately and on timely basis.	To ensure that all eligible VAT credit has been availed and VAT credit has been reversed on account of Stock transfers.
8.	*VAT/ CST valuation*	Sales Tax valuation for materials dispatched should be accurately determined and authorised.	To ensure review and authorisation of SOC for materials and correctness of sales tax charged.
9.	*Notices/ claims*	All claims and notices should be appropriately received and actioned upon on a timely basis.	To ensure adequate actions are taken for notices/ claim received.
			To ensure review of the deposit with government on account of sales tax at each quarter end for their recoverability.
10.	*Document retention*	All sales tax related documents should be adequately maintained	To ensure that adequate physical controls have been established for custody of sales tax records by placing them in separate storage rooms under the custody of authorised personnel.

11.	*Contingent liability*	All contingent liabilities are correctly accounted for and authorised.	To ensure that verification of contingent liability note with the relevant backup documents (list of legal cases filed, etc.) for completeness and accuracy, consideration of all pending sales tax cases for estimation of contingent liabilities and adequate and complete disclosure of contingent liabilities in respect of sales tax in the Financial Statements.

Export Benefits

7.7 The following are internal audit aspects related to export benefits:

S. No.	Activity	Controls Objective	Key Control
1.	*Documentation of Direct Export*	Comparative analysis of export benefits and documentation should be done.	To ensure comparative analysis of export benefits available on each export consignment being done before exercising the option of specified benefits in the shipping bill.
			To ensure that there is no deficiency in the document for claiming export benefits and in case of any deficiency, corrective action has been taken.
2.	*Export obligation*	Export obligations should be timely discharged.	To ensure that Direct Export obligation(EO) in respect of advance authorisation (AA)/ Duty free Import authorisation (DFIA)/ Export Promotion Capital Goods (EPCG) have been discharged on time or

			extension has been obtained for completing EO.
			To ensure that all AA/DFIA/EPCG licences in respect of which export obligation has been completed have been submitted with DGFT for redemption of all documents within time.
			To ensure exercise of due diligence for redemption of AA/DFIA/EPCG and discharge of the related Bonds and Bank guarantees.
			To ensure that there are no pending imports of the relevant required material against AA/DFIA for which export obligation has been fulfilled and license has expired.
			To ensure maintenance of inventory of open AA/ DFIA/ EPCG/ DEPB licenses and physical verification of the same at least once in each quarter.
			To ensure that material imported against AA/ DFIA have been properly accounted for in the prescribed format and have been used only for the permitted purposes.
3.	*Documentation of Export*	Documentation of Exports should be forwarded	To ensure forwarding of the required documents related to exports (i.e., Bank

		within time.	Realisation Certificate & related Shipping Documents) within 30 days of receipt of payment.
			To ensure forwarding of a Monthly listing of Export Benefits due by 10th of each month to licensing cell of commercial department.
			To ensure preparation of application within the prescribed time limit for accrued post shipment benefits for which completed documents have been received.
			To ensure that no accrued post shipment benefit has lapsed on account of delay in filing after receipt of complete documents.
4.	*Bond Filling*	Bonds and Bank Guarantees (BG) filings with the custom authorities should be complete and accurate.	To ensure maintenance of the list of total Bonds and BG filed with the custom authorities (Including Bonds filed against duty for normal imports).
			To ensure updation of the status of all bonds filed by the company and initiation of action for cancellation of the bonds where liability is discharged.
			To ensure exercise of due diligence in following with custom authorities where obligations under the Bond is discharged but bond has not been released.

5.	*Rate of Duty*	Bill of entry should be correct and accurate.	To ensure that all Bills of entry have been assessed at the rate of duty claimed by the company for the clearance of the goods.
			To ensure that no additions have been made to the value declared by the company in the Bills of entry and valuation of the goods declared by the company has been accepted by the custom authorities.
			To ensure that Imports from Related Parties have been declared with custom authorities.
			To ensure that all the bills of entry where the duty rate or valuation claimed by the company have not been accepted by the custom authorities have been reported to the relevant authority as per the DOA matrix for further action.
			To ensure that complete disclosures have been made to the custom authorities for the purchase price paid for the imported goods including the debit notes or the service charges paid in respect of the goods.
6.	*Provisional Assessment*	All the provisional assessments for imports should be reviewed.	To ensure review of all the provisional assessments for imports and exercise of due diligence for finalisation of the same.

Direct tax

7.8 The following are internal audit aspects related to direct tax:

S. No.	Activity	Controls Objective	Key Control
1.	*Exemptions u/s 10 and deductions*	Exemption u/s 10(34) in respect of the dividend income received from domestic company should be correctly computed and fully claimed.	To ensure that all incomes are duly supported, all computations made are reviewed and duly accounted in books, authorised JVs are posted in correct code.
		Deductions u/s 35 & 35(2AB) should be correctly computed and fully claimed.	To ensure that accurate calculation is done to arrive at the amount for claiming deduction and checked for arithmetical accuracy, proper reconciliation is done for R&D assets eligible for deduction, all conditions for claiming deduction are checked whether fully complied with or not, and review by the authorised personnel as per the DOA (Delegation of authority) matrix.
		Deductions u/s 80G should be correctly computed and fully claimed.	To ensure that accurate calculation is done for claiming deduction for donation, proper documents are collected to be filed with return for claiming deduction and review by the authorised personnel as per the DOA matrix for eligibility.

		Deductions u/s 80IA should be correctly computed and fully claimed.	To ensure that Financial Statements are duly reviewed.
			To ensure that Financial Statement sent by unit is duly reviewed, the calculation and basis of cost bifurcation is checked for accuracy, accurate deduction is computed and duly reviewed for arithmetical accuracy, calculated amount is duly deducted from Gross total income and review by the authorised personnel as per the DOA matrix.
2.	*Transfer Pricing*	All international transactions with associated enterprise should be identified and considered at arms length price for the purpose of taxable income.	To ensure that relevant documents are called from the associated enterprises which have the effect of Transfer Pricing and proper documents are maintained.
			To ensure that associated enterprises are recognised, transactions are done on arm's length basis, proper method is taken to arrive at arm's length price, accurate computation is done and review by the authorised personnel as per the DOA matrix.

3.	*Taxable Income*	The taxable income should be correctly computed in accordance with the provisions of Income Tax Act.	To ensure that all tax laws are complied with at the time of preparation, effect of exemptions and deductions are duly given, and it is reviewed for arithmetical accuracy, checking calculations. It is discussed with the relevant authority as per the DOA matrix for any critical issues and after discussion, it is duly signed by the authorised personnel as per the DOA matrix.
4.	*Corporate Tax Return*	The corporate tax return should be duly prepared and submitted on a timely basis.	To ensure that it is prepared in accordance with Income Tax Act,1961, it is reviewed for verification of amounts and tax return is filed only after final discussion with the authorised personnel as per the DOA matrix.
5.	*Wealth tax*	Wealth tax applicable to the Company should be correctly calculated and deposited on a timely basis.	To ensure that relevant data for computation of wealth is collected, wealth statement is prepared by considering applicable tax laws, calculation is checked for arithmetical accuracy, statement is reviewed by the authorised personnel as per the DOA matrix and discussed for any critical issues and

			approval is taken from the relevant authority as per the DOA matrix.
6.	*TDS*	TDS should be deducted and deposited as per the provisions of Income Tax Act, 1961.	To ensure that monthly TDS Compliance Report is collected from different units and properly documented, it is reviewed that TDS is duly deducted and timely deposited and statement is duly reconciled with payment challans.
7.	*Assessment proceedings*	All notices raised by the Income Tax department on the Company should be complied within timely basis to ensure that there is minimum difference between the assessed income and returned income to keep the effective tax rate low.	To ensure that all notices are duly kept in relevant file, proper presentation is done for the assessment proceedings before the Assessing Officer on due date and relevant papers filed are properly documented.
8.	*Appellate proceedings*	All disallowances as per assessment orders should be identified and all disallowances as per the assessment/ appellate orders are reduced to keep the effective tax rate low.	To ensure that disallowances are duly considered whether it is correctly disallowed or not, reconciliation Statement is prepared for Returned and Assessed Income and it is duly reviewed by the authorised personnel as per the DOA matrix.
9.	*Adaption of tax laws*	Correct and applicable tax laws and rules should be followed	To ensure that changes and amendments in Tax Laws are duly applied,

		and amendments should be adapted as applicable.	proper summary is prepared for recent case laws and major amendments which have the impact on company are discussed by the authorised personnel as per the DOA matrix.
10.	*Advance Tax*	Advance tax should be correctly estimated and deposited on a timely basis.	To ensure that it is accurately computed and arithmetically checked, computed as per applicable tax laws, it is approved and signed by the authorised personnel as per the DOA matrix and is timely deposited.
11.	*Provision for tax*	Provision for tax should be correctly and completely provided for in the books of accounts	To ensure that effective tax rate is duly calculated, effective tax rate is reviewed and approved by the authorised personnel as per the DOA matrix and annual provision for tax is correctly provided in books on the basis of Effective Tax Rate.
			To ensure that draft statement of computation of tax is duly prepared as per tax laws and it is reviewed by the authorised personnel as per the DOA matrix.
			To ensure that accounting entry is duly passed in books in correct code as per the

			workings for annual effective tax rate.
12.	*Deferred tax*	Deferred tax liability / asset should be correctly calculated and recorded in the books of accounts.	To ensure that differences are identified and properly classified into permanent and temporary differences, deferred tax assets and liabilities are accurately calculated and arithmetically checked and it is reviewed by the authorised personnel as per the DOA matrix.
			To ensure that deferred tax assets and liabilities are separately and properly disclosed in Financial Statements and authorised JV's are passed in correct code.
13.	*Depreciation*	The tax depreciation should be correctly computed and reconciled with the book depreciation.	To ensure that all capital assets are properly classified as per Income Tax Act and taken into block of assets, R&D assets are not taken as additions for income tax purpose, proper reconciliation is made for capital additions/ deletions as per accounting and income tax books and reconciliation is reviewed by the authorised personnel.
			To ensure that opening balances are properly

			taken from last year closing balance as per tax audit report, depreciation and additional depreciation is accurately computed as per Sec 32 of Income Tax Act, 1961, Written Down Value is properly calculated by using correct formulas and it is reviewed by the authorised personnel.

Production

7.9 The following are important internal audit aspects rated to productions:

S. No.	Activity	Controls Objective	Key Control
1.	*Booking of consumption*	Consumption of material should be correctly and completely booked.	To ensure that consumption entries for all closed batches are completely posted in financial books and in case of any difference in consumption, the same has been reconciled and rectified through journal vouchers after necessary approval.
			To ensure that for all closed batches the consumption of raw material has been booked in ERP, all batches made during the month have been completely closed at each month end (i.e., no

			batch of the particular month is being kept open, and in case of any wrong batches is prepared, the same is deleted after the necessary approval from the authorised personnel as per the DOA matrix.
			To ensure that purchase price variance is completely reconciled and the adjustment entries are made with proper approval, raw material consumption is adjusted for freight provisions and debit/ credit note issued to suppliers.
2.	*Issue of raw material*	Issue of raw materials should be correctly and timely recorded in the books of account.	To ensure that all the tank materials are issued based on the authorised request from the plant, dip reading is properly taken and noted before as well as after the issue of material and the Replenishment (RPL) order is prepared on the basis of the required/measured quantity.
			To ensure that after the issue of tank material, entries in ERP has been accounted completely and accurately
3.	*Issue of Raw*	Issues of raw	To ensure that all

	Material, Packing Material and Intermediates	material/ packing material/ intermediates should be correctly and timely recorded in the books of accounts.	expired/ rejected material are labelled with expiry tags and separately stored and no issue are made from the expired/ rejected material.
			To ensure that all the materials are first issued against the pending quantities of the open order before creating the new order and in case of any old pending order against which the issue are not to be made, those orders are completely cancelled/ closed.
			To ensure that all materials issued through RPL order are on the basis of authorised material issue vouchers, the quantities issued are completely and accurately booked in ERP and all issues through service order is supported by the proper service order entry in the ERP by the concerned store person.
			To ensure that all the materials are issued on FIFO basis as per receipt date of Material Receipt Note (MRN).
			To ensure that month

			end reconciliation of inter-company transfers of different ERP Companies is made and the consumption value is updated in transferee company completely and accurately.
4.	*Tolling Operations: Captive Material Issues*	All receipt of material at toller should be accurately and completely booked.	To ensure that all the captive issue from other division is through the Inter Divisional sales invoices/ replenishment orders, all the issues from the division is through the proper RPL order and all the quantities issued are recorded in ERP completely and accurately.
5.	*Tolling Operations: CENVAT*	CENVAT credit should be accounted correctly and accurately.	To ensure that CENVAT credit reconciliation received has been checked and reviewed, any variation is promptly intimated to toller and corrections are made accordingly and necessary entries are passed in the books with proper approval.
6.	*Tolling Operations: Consumption Booking*	Consumption of material should be correctly and completely booked.	To ensure that for all goods received in plant, consumption of material has been booked through approved Journal vouchers and the consumption is

			booked completely and accurately for the finished goods quantities received.
7.	*Tolling Operations: Material Issue to toller from suppliers*	All receipt of material at toller should be accurately and completely booked.	To ensure that all the purchased material issued to tollers are based on the approved purchase orders, for all the goods received at toller directly from vendor adequate acknowledgement have been received from the toller, for all goods supplied to the toller directly by the vendor, MRN has been prepared completely.

9.4 Inventory Management

S. No.	Activity	Controls Objective	Key Control
1.	*Physical verification*	Balance of inventories as per books of accounts should be in agreement with the physical balance of inventories.	To ensure that the physical stock verification has been carried out on a periodic basis and any discrepancies in physical stock and book stock is properly reviewed.
			To ensure that the stock adjustment note is prepared for the difference between the book stock and physical count, the reason for differences are highlighted in the note, the note prepared by the

			plant have been reviewed by the authorised personnel as per the DOA matrix and necessary approval has been obtained.
2.	*BoM Updation*	BoM updation should be accurately and timely captured.	To ensure that each new recipe is approved by R&D and the approved recipe is completely and accurately entered in ERP.
			To ensure that all BoM updation cut off dates have been entered in ERP and all BoM updation cut off dates are informed to the respective division and plant heads.
3.	*Cost price updation*	All relevant components of costs should be taken into account for valuation of inventory at various stages.	To ensure that cost price updation session run is made on daily basis, the cost price is completely and accurately updated for all the products for which MRN is matched during the day/ previous day and transport cost updation session run is made on daily basis to update the freight surcharge.
4.	*Stock reconciliation*	Closing stock of finished goods should be reconciled with the closing stock of finished goods as per the excise records.	To ensure that stock of finished goods at plant has been cross checked with excise records and the discrepancies, if any, are reconciled and

			communicated to concerned authorised personnel as per the DOA matrix.
5.	*Item master*	Complete, accurate and updated data should exist in the item master and all changes to the item master are duly authorised and accurately captured.	To ensure that each new item code of finished goods and work-in-progress is created on the basis of request received from concerned plant/ division and each item code is created after the adequate approval received from the authorised personnel as per the DOA matrix.
6.	*Scrap*	All sale of scrap should be duly approved and correctly accounted for in books of accounts on a timely basis.	To ensure that all scrap sales are based on the invitation of the quotation and sale is awarded to the approved best rates.
			To ensure that quantity of scrap is matched with invoice generated for scrap before dispatch.
7.	*Transfer of Finished Goods: Dispatch against SOC*	All transfers of finished goods should be authorised and correctly updated in inventory records.	To ensure that all dispatches are based on the Sales Order Confirmation (SOC), All SOCs are properly approved by the authorised personnel as per the DOA matrix and no dispatches have been made outside plant without approved SOC.
			To ensure that all the goods in transit in same ERP division is shown in

			Transit warehouse report accurately and old pending transfers, if any, are due for any reason, is promptly highlighted by the recipient and actions taken accordingly by the transferor.
8.	*Obsolete inventories*	All obsolete inventories should be identified and accounted completely and correctly.	To ensure that all obsolete inventories are identified, stock adjustment note is prepared for obsolete inventories identified during physical verification and sent to the authorised personnel for approval.

Note: In case of physical stock verification of materials in tankers, it must be ensured that the dipstick should not be faulty.

Few other internal audit controls that should be kept in mind with respect to various areas:

- Sales
  - It should be ensured that there are no cases of sales push (i.e., booking of sales without a valid sales order) to meet quarterly/ yearly sales targets. Here, special focus should be given to the review of sales returns including analysing the reasons for sales returns.
  - Auditor should also review the discounting policy of the company for sales to its customers. It should be ensured that there is a transparent policy for discounts and if there is any favoured term schemes, then the same should be justified and duly approved.
- Contract manufacturing
  - There should be adequate control with respect to contract manufacturing. The contract manufacturing agreement

should be reviewed and analysed. It should be ensured that there is no clause which is prejudicial to the interest of the company. Also, the relevant clauses should be adhered with.

- Input-output ratio norms should be monitored.

- Job design and rotation of duties
  - It should be ensured that the job design in the organisation is such that no single employee should be given authority for performing multiple interdependent jobs where it may lead to abuse of authority, e.g., the employee performing invoice processing should not be the one who is authorised to make payment as well.
  - It will be a good practice to ensure that there is rotation of duties at regular intervals.

Chapter 8
Research and Development

8.1 Research and development is the key to the future of pharmaceutical industry. The pharmaceutical advances for considerable improvement in life expectancy and health all over the world are the result of a steadily increasing investment in research. There is considerable scope for collaborative R & D in India. India can offer several strengths to the international R & D community. These strengths relate to availability of excellent scientific talents who can develop combinatorial chemistry, new synthetic molecules and plant derived candidate drugs.

8.2 The government has identified the pharmaceutical industry as one of the most important knowledge-based industries in which India has a comparative advantage. In order to turn India into a global R&D hub, the government has offered several R&D promotion measures to attract greater investment into the sector in order to update the existing technologies and to bring into the country technologies that were not yet available. In 1999, the Government set up the Pharmaceutical Research and Development Committee (PRDC) to study and identify the measures needed to strengthen the R&D base of the Indian pharmaceutical industry. The Committee recognized that priority must be given to initiating new drug development for diseases of relevance to the Indian population, while at the same time seizing opportunities to become a global player by introducing globally competitive products based on new molecules, new delivery systems, and so forth.

8.3 Until the mid-1990s, R&D in the Indian pharmaceutical industry has focused on R&D for development of new processes for manufacturing drugs. Since that time, the new R&D focus is on the following aspects:

(a) Nobel Drug Delivery Systems (NDDS)

(b) R&D for generic products for the regulated market and non-infringing processes

(c) New Drug Development Research (NDDR).

8.4 Indian companies are increasingly focusing on R&D for Nobel Drug Delivery System (NDDS). NDDS is the most vigorous R&D area where most of the top Indian companies are increasing investment. The leading

pharmaceutical companies in India have increased their R&D expenditures for development of generic products for the regulated market to satisfy quality and regulatory requirements for marketing off-patented drugs. Indian companies also have increased the development of non-infringing processes for filing Drug Master Fillings (DMFs) and Abbreviated New Drug Applications (ANDAs).

8.5 During the first quarter of 2011, Indian pharmaceutical companies filed 90 and total 271 Drug Master Fillings (DMFs) with US FDA during 2009 and 311 DMFs in 2010. In 2010, Indian pharmaceutical companies maintained their number one position in the US generics market, by bagging 33.17% (i.e., 139 of 419) original Abbreviated New Drug Application (ANDA) approvals from the US Food and Drug Administration (USFDA).

8.6 Since the introduction of pharmaceutical product patent encouraged R&D for new drug development, Indian companies in the private sector began investing in R&D for New Drug Development Research (NDDR) in the mid-1990s.The leading Indian pharmaceutical companies are all now engaged in R&D for new chemical entities (NCEs)and have set up their own research centre for NDDR. Indian companies have reported some successes in NDDR. A number of new chemical entities (NCEs) have been developed which are at different stages of clinical trials.

8.7 The process of new drug development is classified into two stages:

(a) The pre-clinical stage: At the pre-clinical stage, the objective of research is to develop a promising molecule using animal models.

(b) The clinical stage: At the clinical stage, the molecule is tested in humans and developed for manufacturing and marketing. About 40% of expenditure of new drug development goes to funding clinical development.

8.8 Recently, Contract Research and Manufacturing Services (CRAMS) business has been growing rapidly in India. CRAMS deals with manufacturing and research activities. Many Indian companies entered into CRAMS, and the number of the specialized CRAMS companies has increased. Now, India is one of the most preferred outsourcing destinations for foreign pharmaceutical companies and is becoming a global manufacturing and R&D hub.

Let us see few of the internal controls with respect to R&D.

S. No.	Activity	Controls Objective	Key Control
1.	*Research &Development Expenditure*	Research and development expenditure should be correctly and completely identified and disclosed.	To ensure that recording of transactions is as per the Company's accounting policy and as per AS 26 on 'Intangible Assets'.
			To ensure that R&D details have been correctly and completely disclosed in the financial statements and the R&D expenditure has been grouped under appropriate heads and disclosed in the financial statements.
			To ensure that in respect of each R&D facility, approvals from "Department of Scientific and Industrial Research" have been obtained for eligible tax deductions and the approval is valid for the current financial year.

Note: It should be ensured that there is a 'confidentiality clause' in relation to Research and Development activities and the same is being adhered to so as to prevent leakage of confidential data.

Chapter 9
Clinical Trials

9.1 Under the Drugs and Cosmetics Rules, no clinical trials for a new drug, whether for clinical investigation or any clinical experiments shall be conducted except under, and in accordance with the permission granted by the Drugs Controller General of India (DCGI). Clinical trials of pharmaceuticals products are conducted on human subjects to discover or verify the clinical, pharmacological (including pharmacodynamics/ pharmacokinetics), and/or adverse effects with the object of determining their safety and/or efficacy. The protocols of such trials are examined by the office of DCGI before these permissions are granted.

9.2 Every approval/ permission for conducting clinical trials also, inter alia, includes a condition that in case of study related injury or death, applicant will provide complete medical care as well as compensation for the injury or death and statement to this effect should be incorporated in the informed consent form. Further in case of such injury or death the details of compensation provided should be intimated to the office of DCGI.

9.3 Guidelines for conducting Clinical Trial inspection of site and sponsor/ Clinical Research Organisations (CROs) are also available.

9.4 The Clinical Trials Registry - India (CTRI), hosted at the ICMR's National Institute of Medical Statistics (NIMS), is a free and online public record system for registration of clinical trials being conducted in India that was launched on 20th July 2007 (www.ctri.nic.in). Initiated as a voluntary measure, since 15th June 2009, trial registration in the CTRI has been made mandatory by the Drugs Controller General of India (DCGI).Today, any researcher who plans to conduct a trial involving human participants, of any intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioral treatment, rehabilitation strategies as well as trials being conducted in the purview of the Department of AYUSH (http://indianmedicine.nic.in/) is expected to register the trial in the CTRI before enrollment of the first participant. Trial registration involves public declaration and identification of trial investigators, sponsors, interventions, patient population, etc., before the enrollment of the first patient. Submission of Ethics approval and DCGI approval (if applicable) is essential for trial registration in the CTRI. Multi-country trials, where India

is a participating country, which have been registered in an international registry, are also expected to be registered in the CTRI. In the CTRI, details of Indian investigators, trial sites, Indian target sample size and date of enrollment are captured. After a trial is registered, trialists are expected to regularly update the trial status or other aspects as the case may be. After a trial is registered, all updates and changes will be recorded and available for public display. Being a Primary Register of the International Clinical Trials Registry Platform (ICTRP)(http://www.who.int/ictrp/search/en/), registered trials are freely searchable both from the WHO's search portal, the ICTRP as well as from the CTRI (www.ctri.nic.in).

9.5 Good clinical practice: The history of Good Clinical Practice (GCP) statute traces back to one of the oldest enduring traditions in the history of medicine: The Hippocratic Oath. As the guiding ethical code it is primarily known for its edict to do no harm to the patient. However, the complexities of modern medicine research necessitate a more elaborate set of guidelines that address a Physician's ethical and scientific responsibilities such as obtaining informed consent or disclosing risk while involved in biomedical research. Good Clinical Practice is a set of guidelines for biomedical studies which encompasses the design, conduct, termination, audit, analysis, reporting and documentation of the studies involving human subjects. The fundamental tenet of GCP is that in research on man, the interest of science and society should never take precedence over considerations related to the well-being of the study subject. It aims to ensure that the studies are scientifically and ethically sound and that the clinical properties of the pharmaceutical substances under investigation are properly documented. The guidelines seek to establish two cardinal principles:

(a) protection of the rights of human subjects and

(b) authenticity of biomedical data generated

Note: These guidelines have been evolved with consideration of WHO, ICH, USFDA and European GCP guidelines as well as the Ethical Guidelines for Biomedical research on Human Subjects issued by the Indian Council of Medical Research. They should be followed for carrying out all biomedical research in India at all stages of drug development, whether prior or subsequent to product registration in India.

Chapter 10
Enterprise Risk Management (ERM) in Pharmaceuticals Industry

Definition of ERM

10.1 Enterprise Risk Management is a structured, consistent and continuous process of measuring or assessing risk and developing strategies to manage risk within the risk appetite. It involves identification, assessment, mitigation, planning and implementation of risk and developing an appropriate risk response policy. Management is responsible for establishing and operating the risk management framework.*(Standard on Internal Audit (SIA) 13 on Enterprise Risk Management issued by ICAI)*

10.2 Enterprise Risk Management is a process, effected by an entity's Board of Directors, management and other personnel, applied in strategy setting and across the enterprise, designed to identify potential events that may affect the entity, and manage risks to be within its risk appetite, to provide a reasonable assurance regarding the achievement of entity objectives. *(COSO ERM- Integrated Framework, 2004)*

Overview of ERM

10.3 Enterprise risk management (ERM) includes the methods and processes used by organizations to minimize surprises and seize opportunities related to the achievement of their objectives.

10.4 ERM is an approach to aligning strategy, process, and knowledge in order to curtail surprises and losses as well as to capitalize on business opportunities. Many individuals associate risk with negative outcomes. However, there is a potential value component to risk assessment and management. Risk management is about balancing risk and reward. A well-designed risk management program encourages and allows an organization to take intelligent risks. It involves assessing quantitative factors and information as well as considering management experience and judgment. An effective risk management program entails balancing people and processes. Ultimately, an entity's risk profile is affected by the actions and decisions of its board of directors, management, and employees.

10.5 One cannot talk about risk management without discussing risk assessment. The vast majority of organizations conduct some type of

informal risk assessment process. As a result, these organizations have some form of risk management plan. This plan, in most cases, is not documented.

10.6 Initial introduction of formal risk assessment and risk management within an organization is critical to the ultimate success of the initiative. An entity must consider its culture and develop an approach that is most likely to result in success. The organization should take care not to overcomplicate or overwhelm individuals with technical terminology. Initial discussions should focus on the importance and the benefits of risk management. Employees should been encouraged to think and talk about the business and what could go wrong that might result in failure to achieve entity objectives and, as a result, have a negative effect on performance and/or perception.

10.7 Good risk management is essentially choice management. It is a continuous work in progress. An entity must identify risks and subsequently determine how it will address each one. The organization must decide the degree of risk it is willing to assume and address other identified risks, likely through mitigation. It is important to consider both tangible consequences, such as loss of revenue or drop in stock price, as well as intangible possibilities, such as public perception. Perception often is a major consideration in assessing positive or negative consequences.

10.8 Organizations often evaluate risks in somewhat of a soloed process, i.e., considering the risk consequence to a single area of the business. Risks are inherently dynamic and interdependent. Consequences of unforeseen or unpredictable events typically affect multiple areas of a business. Therefore, aggregate entity consequences should be considered when conducting a risk assessment and designing a risk management program. Risks should not be separated into components and managed independently. Such an approach is rarely effective or successful. A holistic view of risk should be taken, including the contemplation of interdependencies.

10.9 Every organization is faced with uncertainty and risk. The challenge for management is to determine how much uncertainty to accept as it strives to improve stakeholder value. Risk identification is a process designed to identify first both the strategic objectives and goals and then the potential internal and external events that can adversely affect the enterprise's ability to achieve those objectives and goals.

10.10 Each entity should strive to build an integrated risk organization. This would include three components:

(a) centralized risk management reporting to the chief executive officer and the board of directors

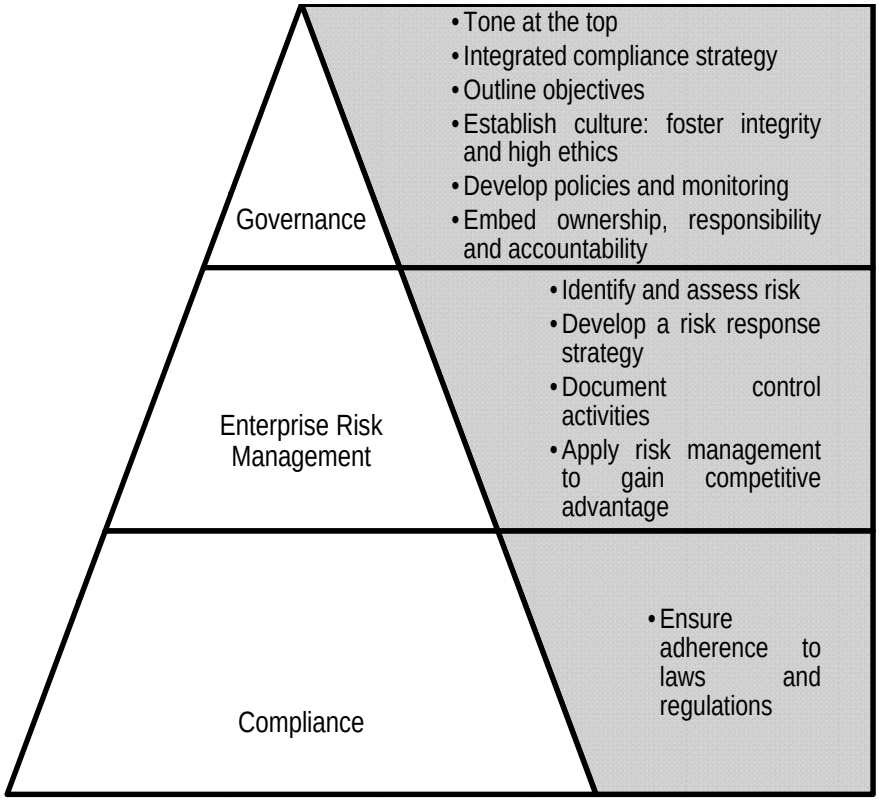
(b) an integrated risk management strategy that takes a holistic view of all types of risk within the organization and

(c) integration of risk management into business processes

It is not easy to accomplish these stated objectives. The method and processes for execution may vary significantly based on the size, structure, and culture of the organization. Each company must determine the most practical method of implementation. However, this integrated approach will allow risk management to become an offensive weapon for management rather than the more common defensive reaction to incident occurrence.

10.11 Organizations should take a proactive approach to optimizing their risk profiles. Minimal investment in risk assessment and subsequent risk management program development and implementation can improve efficiency and reduce losses.

Organisation view



Organisation View of Risk Management

10.12 Each entity should seek to build its organizational structure to support a top-down approach that beings with consideration of overall corporate governance, progresses to risk management and assessment and ultimately considers the achievement of all compliance requirements.

Executive management along with the board of directors should develop and document a strategy that outlines what the organization expects to accomplish: its goals as well as the objectives it must achieve in order to realize the desired results. A clearly documented strategy and associated objectives are critical to the development of an effective ERM program.

10.13 An outline in these areas allows the organization to focus on opportunities presented in the strategic plan as well as to minimize the potential impact of threats. From a practical prospective, this may be a single-page document that outlines organization goals in terms of areas such as the customer, financial expectations, and products/services. The strategic plan, at the highest level, will aid in the facilitation of all future discussions regarding risk and risk mitigation. The organization should consider the strategy from a financial and an operational perspective. The absence of a documented strategy and objectives, including related policies and job descriptions that outline overall expectations and define roles and responsibilities, significantly impairs an entity's ability to design and implement an effective ERM program.

10.14 Once the entity has documented and can articulate its strategy and related objectives, it can then develop and implement an ERM program. Doing this includes performance of a risk assessment, which includes considering what could go wrong that might prohibit the entity from achieving its objectives. Part of the risk assessment process should include consideration of entity compliance with all applicable laws and regulations. Ultimately the entity will seek to mitigate identified risks through numerous forms of control activities.

ERM Today

10.15 Less than a decade ago, ERM was not a major focus for most organizations. Today, it is quickly ascending to the top of the agendas of senior executives and shareholders alike as corporate scandals and globalization challenge the status quo and regulators publish new or updated requirements.

10.16 ERM is a structured approach to aligning strategy, processes, people, technology, and knowledge to identify and manage uncertainties and

risk. Providing a comprehensive, integrated framework that enables organizations to proactively manage business risk, ERM aids in the achievement of balance between business needs and risk thresholds to increase competitive advantage and shareholder value.

ERM definitions tend to vary from source to source, but all contain common themes: a standard risk management process, an integrated view of risks and a focus on relating risks to business objectives.

Despite the plethora of internal and/or external events that could expose an organization to serious risks, companies focus much more on measuring and monitoring financial performance than on proactively measuring, analyzing, and responding to and mitigating risks: threats that could negatively impact financial performance.

10.17 Risk management is rapidly becoming a major area of focus, and risk areas within each organization should be analyzed. A number of major drivers prompt the development of a formal enterprise risk framework, including:

(a) Regulatory guidance

(b) Evolving roles of the audit committee and board of directors

(c) Risk assessment standards

Benefits of ERM

10.18 The following are major benefits of ERM:

- Minimise surprises through better anticipation and evaluations
- Align strategy with the risk appetite (acceptable level of risk) that allows management to draw the line in a more informed and pre-established manner
- Better decision making through comprehensive evaluation of various options & their consequences
- Improve management accountability by comparing planned outcomes through ERM with actual results
- Problem anticipation, better preparedness & response to uncertainty
- Greater alignment and improvement to business objective achievement

- Better business understanding of various inter-related events and response actions
- Increased profitability and return on assets through cost/loss reduction and revenue/profit enhancement
- Better portfolio management and allocation of scarce resources
- Risk awareness by using a formal ERM system, one can improve the 'risk awareness' of an organisation
- Promote risk taking in a more 'risk intelligent' manner

Limitations of ERM

10.19 The following are major limitations of ERM:

- *Inherent uncertainty*: With the dynamic business environment, it is hard to anticipate events with any degree of certainty
- *Data integrity*: The information may be lacking due to unique nature of the risk with limited past experience in that particular area.
- *Subjectivity*: Risk is perceived by individuals and is, therefore, exposed to the subjectivity of the perceiver due to their personal understanding and expertise.
- *Time limitations*: Most risks require to be researched reasonably quickly and extensively to be able to evaluate them in an accurate manner.
- *Cost and resource limitations*: The cost of implementing an ERM system may outshine the benefits that would reap out it.

ERM in Pharmaceuticals Industry *(based on risks associated under select businesses)*

10.20 The following arfe external risks related to ERM in Pharmaceuticals Industry:

(a) Volatility in input prices

Risk	Risk of constant and rising input prices coupled with rising cost of doing business in inflationary market condition may significantly impair company's ability to generate adequate positive margins to fund long-term business growth and maintain leadership position.

	Increasing prices of inputs cannot be passed due to competitive prices prevailing in market.
Contributing factors	• The current in house production of input not sufficient to meet the requirement • Volatility in the prices of inputs • Major competitors are based in countries where the inputs are available at very low prices
Mitigation plan	Supply chain should assure the supply at budgeted price and R&D should look at innovative ways to significantly reduce consumptions of key raw material or develop substitute

(b) Input cost/ availability

Risk	Risk of constant and rising input prices coupled with rising cost of doing business in inflationary market condition may significantly impair the organisation's ability to generate adequate positive margins to fund long term business growth and maintain leadership position. Increasing prices of acetic acid and alcohol cannot be passed on to the customers due to competitive prices prevailing in market. Risk of inability to procure the planned quantities of feedstock at planned prices may lead to significant impact on margins. Alcohol: Supplies to chemical industries is limited due to alternative uses, government mandate to use alcohol for petroleum blending and use of a significant percentage of available alcohol for portable use. Acetic Acid: Supplies of acetic acid are completely import dependent and the prices are very volatile With the requirement of feedstock expected to increase significantly with a significant growth expected in Acetyls revenue, any lack of availability of its required quantity or failure of the supplier to supply the desired quantities coupled with non-availability of in-house capacity could have a significant adverse impact on the realisation of business objectives. The risk would increase further if different feedstock technologies are being used by the organisation and its

	competitors (wherein the organisation uses alcohol and acetic acid). Shortage of alcohol or acetic acid would lead to increase in prices for the organisation, but input prices for its competitor would not be affected. Thus, the organisation would be unable to pass on the price rise fully to its customers.
Contributing factors	• Cyclical nature of sugar production impacting the availability and prices of molasses and, thus, impacting the price of alcohol and acetic acid, the raw materials for the acetyls business • Alternative uses of Alcohol (portable and blending) limiting the supplies resulting in price increase • Increasing instances of forward integration in sugar industries/ entry of sugar companies in manufacture of alcohol/ acetyls • Alcohol is one of the most difficult commodities to import • The contracted suppliers for acetic acid are also competitors in the final products segment • No production facility available for acetic acid
Mitigation plan	Organisation should develop new acetic acid suppliers from other countries, e.g., China and Taiwan. It should buy molasses and store in lean season. Micro level planning of inventory should be done. Also, long-term contracts should be entered with alcohol suppliers for ensuring required quantities.

(c) Competition

Risk	Risk that action of competitor's or new entrants to the market may impair company's competitive advantage and lead to erosion of margins. Highly competitive prices offered by competitors leading to pressure on margins.
Contributing factors	• Liberal grant of credit by competitors • Export incentives/ subsidy by competitor's government • Labour cost advantage • Capacity advantage • Availability of raw material at low rates in

	competitor's country • Willingness of competitors to operate at low margins
Mitigation plan	Cost improvement initiatives and manufacturing efficiency improvement plans should be introduced at plant. For major raw materials, significant improvement in norm should be planned. Initiatives should be taken to increase manufacturing efficiencies. From customer front, company should get closer to customers, offer unmatched services and aim for long term contract with them.

(d) Customer

Risk	Risks that change in customer's organisation, behaviour, needs and/ or expectations lead to decrease in market attractiveness and/ or adverse competitive position. Over-dependence on few customers may lead to significant loss to business in case of loss of customer.
Contributing factors	• Acquisition of competitor by the key customer or vice versa • Natural/ unnatural calamity affecting any key customer • Poor quality performance of products
Mitigation plan	Company may diversify risks by forward integration of businesses. In that case, project, technology, R&D and manufacturing plan should be in place. Company should spread the market place so that dependency over individual customers is decreased.

(e) Technological innovation

Risk	Risk that company's cost advantage is under threat due to emergence of: • new cost effective technology to produce end product or • substitute of end product
Contributing factors	• Inability to identify new trends/ developments in the market • Target based development in process by the competitors

	• Innovation by competitor's from completely different field • No current focus on creation of a new technology/substitute for manufacturing end product
Mitigation plan	There should be a continuous review of patents and company should strive to be at the forefront of end product's technology. R&D initiatives should be taken up.

(f) Margin protection

Risk	Foreign currency fluctuations leading to risk of failure to pass on increased input prices to customers puts margin pressure on the organisation to create reserves for future expansion and execute strategies.
Contributing factors	• Instability in the world market will lead to volatility in the foreign exchange • High foreign exchange exposure due to high dependence on international market for procurement
Mitigation plan	Rupee depreciation will also result in higher revenues through exports. Hedging should be done to mitigate the forex risk.

(g) Disaster/ business interruption

Risk	Risk that any disaster or other upheavals threatens the organisation's ability to sustain operations. Occurrence of natural/unnatural event at any manufacturing plant without any Disaster Recovery Plan (DRP)/ Business Continuity Plan (BCP) may impact continuity of operation
Contributing factors	• Complete dependency on a specific manufacturing plants subject to disaster such as earthquake, cyclone, typhoon, bad monsoon, etc., and business interruptions such as an act of terrorism. • Disasters beyond company's control • Absence of a conscious efforts by top management to draft a BCP/ DRP to handle crisis situations created by natural/ unnatural disasters • Uninsured company's assets

Mitigation plan	Company should have Defined Business Continuity Plan (BCP)/ Disaster Recovery Plan (DRP)including but not limited to clearly defined roles and responsibilities, etc. Also, company should insure the assets held.

(h) Suppliers relations and resource availability

Risk	Risks that high dependency on important suppliers threatens the organisation's ability to produce and deliver quality products/services to competitive prices on a timely basis. Dependency on few suppliers without developing alternate vendors may lead to stock-outs and delayed deliveries.
Contributing factors	• Incorrect Sales forecast • Supplier performance • Suppliers also act as competitors
Mitigation plan	Atleast two-three vendors should be developed for key molecules. A single supplier should be de-risked by having local contract manufacturing options as alternate sources and continue buying from most competitive source. For suppliers of intermediates who also act as competitors for the API, company should enter into medium term contracts to ensure timely supplies.

(i) Market dynamics and changing trends

Risk	Changes in guard from one to another political party may lead to changes in the governance of the industries, government policies, etc., impacting business operations. Promotional subsidy schemes introduced by different political parties may impact the margins.
Contributing factors	• Lack of stability of the Indian political environment and difference in ideologies of political parties • Lack of effective lobby/ ability to pre-empty the changes in the policy
Mitigation plan	Management should develop portfolio of pre-mixes, specialty products and trading of niche products, thereby reducing the dependency on a specific promotional subsidy scheme introduced by the political party in government.

(j) Increase in logistic cost

Risk	Increase in logistic cost may adversely impact margin of the products. Failure of the company to minimize the logistics costs, both internationally and domestically, would add to the margin pressures. Ocean freight has been increasing significantly.
Contributing factors	• Increased share of logistics cost in overall cost necessitated by the plan to increase export sales • Increase in fuel prices • Distance from ports results in additional cost pressures
Mitigation plan	Supply chain should ensure that the logistics are managed in most cost effective manner.

(k) Environment

Risk	The risk that activities harmful to the environment expose the organisation to liabilities for bodily injury, property damage, cost of removal and punitive damages. Possibility of damage to health and environment, prolonged exposure to chemicals, inadequate mechanism to identify pollutants, hazardous emissions, etc., leading to regulatory action or litigation against the company which could adversely impact the reputation of the company and a possibility of plant closure / imposition of heavy penalties. In the course of manufacturing operations, the company may generate wastes, effluents and emissions which are hazardous in nature. Prolonged / repeated exposure to chemicals at the shop floor, production facility, etc., could adversely impact the health of susceptible workers and neighbours over a period of time. Such health hazards could lead to claims against the company, fall in employee morale and also a loss of reputation for the company. Further, inadequate mechanisms to identify pollutants or limit their discharge to the environment could lead to environmental damage. With some of the manufacturing operations of the company being located in the vicinity of residential areas, the threat of community

	action / PIL's gets prominent and there could be a demand to relocate such plants.
Contributing factors	• Stringent environment regulations and principle of absolute liability, i.e., punishability despite having taken complete care • Lack of adequate training on/ deployment of safety guidelines • Inadequate Environment, Health and Safety (EHS) measures • Factory establishment in vicinity of residential area
Mitigation plan	Company should install waste disposal plants. PPE (Personal Protective Equipment) should be made compulsory for use by workers at shop floor level. To mitigate these risks the company may follow the Hazard Identification & Control system through Hazard and Operability(HAZOP) or similar tool to identify the Safety aspects related to manufacturing activities for new projects/ expansion of existing plants and management plan for the same. The company should also maintain an industrial all-risk insurance policy for its primary manufacturing facility, as well as property and casualty insurance at other manufacturing facilities and it should be in accordance with customary industry practices in India and abroad. The company may engage with community around as well as employees of the plant through various programs implemented for local community in the field livelihood, education and health for the upliftment of society.

(l) Regulatory

Risk	Risk that any delay from customer's side in obtaining the approval for the product would adversely affect the business. Delay in regulatory approval due to poor documentation or delayed response to regulatory bodies may result in loss of business, e.g., customer decides not to launch the product due to failure to obtain approval or delay in getting the approval.
Contributing factors	• Delay is inherent to the nature of business

	• Delay in submitting the data or responding to the query by the customer
Mitigation plan	Regulatory approvals should be adequately prepared to answer deficiencies received from regulatory bodies. Drug Master File (DMF) amendments and frequent change in process should be minimised. However, very little can be done if customer approval gets delayed for reasons beyond the organisation's control.

Internal risks

The Internal Risks related to Pharmaceutical Industry are as follows:

(a) Production capacity

Risk	Risks that insufficient capacity threatens organisation's ability to meet customer demands and to be competitive and excess capacity threatens the organisation's ability to generate competitive profit margins. Delay in execution of capital projects or inability to create sufficient capacity to cater future demands of customers would lead to loss of potential business or permanent loss of customer.
Contributing factors	• Failure to identify opportunity in time • High lead time between market assessment, capex decision and actual upgrade of production capacity • Non availability of fund • Time-consuming capex approval process in general • Lack of adequate project monitoring • Unrealistic expectations on lead time • Absence of a robust mechanism to monitor the project
Mitigation plan	There should be a systematic planning for undertaking any capacity expansion project and continuous monitoring of on-going capital projects for their timely completion.

(b) Resource availability

Risk	Risks that limited availability of resources (labour, capacities, energy, raw materials, component parts, etc.)

	threatens the organisation's ability to produce quality products at competitive prices on a timely basis. Unutilised capacity for short time due to reasons like power breakdown, unavailable labour, transport strike, etc. may lead to not meeting production targets and not fulfilling customer orders on time.
Contributing factors	• Frequent stalling of production • Region specific factors such as strikes, kawaria movements, etc., which impact the transportation system of the country and, thus, impacting deliveries • Transporters Strike • Defaults in design of plants • Inefficient plant maintenance • Aggressive plant up-time considerations in business plans
Mitigation plan	Any problems in supply chain should be resolved so as to ensure availability of the raw material on timely basis to the plants. Business plans should be improved. There should be regular maintenance of plants and machineries.

(c) Production efficiency

Risk	High down time due to technology under optimisation leading greater than desired plant outage, wastage and yield losses may impact the competitiveness of the business.
Contributing factors	• Aggressive plant up-time considerations in business plans • Chemical process makes plants more vulnerable
Mitigation plan	Plant operating capacity should continuously being improved at regular intervals. All required modifications should be done so as to achieve the required capacity.

(d) Increase in overhead costs

Risk	Increase in overhead cost leading to adverse impact on margins. Overhead costs comprise a major cost to the business in comparison to the unorganized companies. Due to the rising costs (both fixed and variable, e.g., Utilities and Power), maintaining cost competitiveness is

	a challenge for the Company. Inability to control/reduce the variable cost (e.g., raw materials, power and utilities) and the necessity to invest in human capital especially compared to unorganized players may lead to reduced bottom-line.
Contributing factors	• Rise in production costs due to inflation and other factors such as necessity to invest in human capital unlike other domestic unorganized players
Mitigation plan	Projects on lean six-sigma may be taken to identify least cost matrix. This may be done in collaboration with the manufacturing team at various plants. Business should also do the benchmark analysis with respect to cost and price with key-competitors.

(e) Product portfolio

Risk	Risk that product portfolio is not optimally aligned to deliver on desired margins due to structural challenges or non availability of information for decision making. Over-dependence on single product (e.g., choline chloride) may adversely impact the realization of long-term business objectives. Risk that any failure on the organisation's part to de-risk the portfolio either by including new products/ innovative products or by increasing the share of other businesses could result in significant losses, in the event of decrease in demand/ poor business for the key product. The product portfolio/ mix of the organisation in this business is such that a single product (e.g., choline chloride) contributes to major part of the business, e.g., over 70% of the business, and another (pre-mixes) to over 30%.
Contributing factors	• Disruption in supplies of raw materials for the key product • Availability of more economical substitutes
Mitigation plan	The company should seek the right balance between high margin-low volume products and low margin-high volume products. Low margin products provide the company with necessary cash flows, however, they block available capacities which could be used to produce high margin products, thus resulting in reduced profitability. Research

	and development team should continuously work upon development of new products and niche specialty products.

(f) Business portfolio

Risk	Risk that relevant and reliable information that enables management to set product/ customer priority are missing or that the strategic balance of Business Units is insufficient. Organisation Structure is not aligned to cope with exponential growth of business adversely impacting long-term business objectives. This may result in reduced effectiveness (e.g., reduced service levels, use of re-active approach rather than pro-active approach) and loss of potential business. This may also preclude organisation from optimizing its overall performance.
Contributing factors	• Lean/ inflexible organisation structure • Employees at key positions are resistant to change
Mitigation plan	Since it is difficult to change mind set of employees, one possible solution could be to do away with the matrix structure.

(g) Research and development

Risk	Risk that the insufficient focus on research and development or failure of research & development to create the necessary differentiations, or innovate to reduce cost could result in significant loss of revenue. Failure to innovate new and cost effective products may pose a threat to the organisation's competitive position. Nutrients business is primarily research driven and, hence, the success of research and development is proportionate to the success of the business. In order to increase the profitability of the business and to add sustainability to the business, it is imperative to have a strong and effective research and development department (especially to meet the Company's strategy of increasing its share in pre-mixes business).
Contributing factors	• Insufficient investment in research and development
Mitigation plan	There should be sufficient investment in research and development activities.

(h) Inventory obsolescence and loss

Risk	Risks that the inventory obsolescence (e.g., bypass of expiration dates on strategic raw materials) or inventory shrinkage exposes the organisation to financial losses. Considering the nature of substance, materials are required to be stored at specific temperatures. Poor handling/ mishandling of material may lead to damages and inventory loss.
Contributing factors	• Unskilled labour employed • Storage facility out-sourced • Nature of products is such that they are required to be stored at specific temperature or conditions
Mitigation plan	First in first out method should be used as priority principal to be followed at plant. Inventory planning analysis should be done to locate obsolete items.

(i) Human resource: Recruitment and Retention

Risk	Risks that an insufficient focus on human resources processes (e.g., recruiting, talent management, labour management, development and training) threatens the possibility for the organisation to recruit and/or hold the qualified personnel required to maintain desired operational standards. Inability to retain and motivate existing talents may lead to operational inefficiency and knowledge drain. Risk that leadership does not live up to group value scorecard and, therefore, leads to de-motivation and unwanted turnover of employees.
Contributing factors	• High attrition rate • Non-competitive compensation structure • Non creation of an image of a great employer • Inadequate training and development
Mitigation plan	Company should opt for reward and recognition plan across the functions. Particularly for sales team, there should be a provision of attractive sales incentive. HR efforts may help on to engage the campus talent from right and premier knowledge centres.

(j) Human resources: Succession planning

Risk	Risks that an insufficient focus on human resources processes (e.g., recruitment, talent management, labour management, development and training) threatens the possibility for organisation to recruit and/or hold the qualified personnel required to maintain desired operational standards. Lack of succession planning may lead to adverse impact on operational efficiency in case of sudden exit of any key personnel.
Contributing factors	• Significantly high dependence on top management for providing leadership and guidance to the organization
Mitigation plan	Plan should be in place for developing second line talent and recruiting accordingly.

(k) Human resources: Confidentially of information

Risk	Risk that the actions of the existing or former employees are prejudicial to the interest of the company, its assets, its people, its reputation, etc.
Contributing factors	• Absence of framework to protect the information of the company • Unresolved employees' grievances • Employee dissatisfaction resulting from efforts and reward mismatch, etc.
Mitigation plan	Under the framework to protect the information of the company, every employee should sign a confidentiality and non-disclosure agreement at the time of joining. Company may conduct employee engagement survey at regular intervals to gauge the organization's health. Good feedback system should be implemented in the organisation to get feedback from employees on different aspects of work and work culture.

(l) Information technology (IT) access

Risk	Risks that inappropriate or unauthorized access to critical business information such as formulas is possible, leading to potential Intellectual Property loss and/or customer relationship deterioration. Loss of trade secrets

	which may be used against the interest of the company. Risk of leakage/ loss of intellectual property/ trade secrets or other confidential information (formulae/know how, etc.) which may be used against the company's interest and cause a loss of market share (and associated margins). Sensitive information (e.g. formulas, ingredients, product-customer links, etc.) are valuable to competitors, regulators, customer and external stakeholders.
Contributing factors	• Poor knowledge harvesting/ data archiving • Inadequate access controls, privilege management policy and procedures
Mitigation plan	Formation of groups at IT servers should be based on information need to ensure the appropriate circulation of data and information among different levels in the organisation.