PHARMACEUTICAL INDUSTRY - *For the journey that is life*

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CHARTERED ACCOUNTANTS

Background

The modern pharmaceutical industry can be traced back to the discoveries of insulin and penicillin in the early 20th century. These products began to be mass manufactured, particularly in European countries, with other developed countries following close behind. The implementation of scientific processes to the research and discovery of new medicines has led to the industry that exists today, with companies constantly searching for new products that heal, prevent, and cure consumers.

Back in 2014, the total pharmaceutical revenues worldwide had exceeded one trillion U.S. dollars for the first time. Increased competition owing to the growing size of the industry has noticeably increased the complexities of operations, sales and marketing, which in turn have led to an alarming spike in malpractices by stakeholders involved at various levels in the industry.

The pharmaceuticals industry consists of drug manufacturers, biotechnology companies and the distribution and wholesale companies that handle the products produced. Most of the revenues in the industry come from drug companies who make prescription, generic, and over-the-counter drugs for medical or veterinary use. The major challenge faced by pharmaceutical industry is in generic drug exports which is a major source of their revenue.

Pharmaceutical companies may deal in generic or brand medications and medical devices. They are subject to a variety of laws and regulations that govern the patenting, testing, safety, efficacy and marketing of drugs.

Operational and strategic risks are central and inherent in pharmaceutical companies which are to great extent 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.

Strategic and Marketing risks on one side, compliance risks such as adherence to regulations, GMP, cGMP and other norms is again the most important and a whole different story where a small mistake or ignorance even at the minutest level of operation can cost a fortune to the businesses.

Indian pharmaceutical industry has grown at a high pace during the last few decades.

- The Indian pharmaceuticals market witnessed growth at a CAGR of 5.64 per cent, during FY11-16, with the market increasing from US$ 20.95 billion in FY11 to US$ 27.57 billion in FY16. The industry's revenues are estimated to have grown by 7.4 per cent in FY17.
- Indian pharmaceutical market grew 5.5 per cent in CY2017 in terms of moving annual turnover. In March 2018, the market grew at 9.5 per cent year-on-year with sales of Rs 10,029 crore (US$ 1.56 billion).
- By 2020, India is likely to be among the top three pharmaceutical markets by incremental growth and 6th largest market globally in absolute size.
- Increase in the size of middle class households coupled with the improvement in medical infrastructure and increase in the penetration of health insurance in the country will also influence in the growth of pharmaceuticals sector.
- The steady decline in the Indian rupee is expected big bonanza for export-oriented businesses. Pharmaceutical firms which earn a large part of its revenues in dollars are likely to see increase in margin.

- EBITDA (earnings before interest, taxes, depreciation and amortization) margins and revenue of pharma companies will get a boost depending on the net of foreign debt exposure, hedged portion and how the rupee moves further from here. The debt exposure will increase interest payments.

THE GOVERNMENT NEEDS TO PLAY A CRUCIAL ROLE

- The government needs to play a direct role in driving access to healthcare through long range initiatives.
- Raise healthcare spending to stated 3 per cent of GDP.
- Invest in healthcare infrastructure, particularly in Tier-II and rural markets.
- Adopt a broader set of measures to contain healthcare costs.
- Reduce the shortage of physicians.

Key drivers of Pharma Industry

(i) Low Manufacturing cost

India is capable of manufacturing low cost generic alternatives due to several economic factors favoring the industry. Some of these include:

- cheap land rates;
- cheap labour available
- low resource costs like water, electricity
- lower cost of production machinery

(ii) Research & Development

India has a large branded generics market which enables most companies to launch their version of a generic drug in the market place. there are Indian companies who are investing in their R&D centres and are offering early stage discovery services as well as promising molecules.

(iii) Experience in International Servicing

Many of the Indian pharmaceutical companies are experienced in servicing top multinational companies for their highly regulated markets, meeting their stringent quality expectations

Illustrative list of regulatory frameworks applicable to Pharma Companies:

- National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012)
- Guidelines for Blood Banks
- Good Clinical Practice Guidelines
- Narcotic Drugs and Psychotropic Substances (Regulation of Controlled Substances) Order, 1993
- 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)
- Guidelines for import and manufacture of medical devices
- Guidelines on Recall and Rapid Alert System for Drugs

Significance of quality in Pharma industry

The pharmaceutical industry is a vital segment of the Healthcare cycle conducting research and manufacturing products which are life-saving, life maintaining and life restoring. Quality directly affects the purity, safety, effectiveness and reliability of the drugs produced. The stringent, scientific, systematic and sustainable approach to commercial drug production ensures protection of patients health.

The main functions of quality assurance systems in pharmaceutical companies are:

- To be the caretaker of the Pharmaceutical Quality System
- Preparing the groundwork for certification by the qualified Person
- Quality on floor
- Product and safety liability

Some of the key regulatory authorities in pharma include

Australia – Therapeutic Goods Administration (TGA)

Canada – Health Canada

Germany – Federal Institute for Drugs and Medical devices

India – Central Drug Standard Control Organization (CDSCO)

USA – Food and Drug Administration (FDA)

UK – Medicines and Healthcare Products Regulatory Agency (MHRA)

Impact of GST in Pharmaceutical Industry

Goods and Service Tax is having a constructive impact on the Indian Pharmaceutical Industries as it has increased the manufacturing cost. Most drugs mentioned in 5% tax bracket under GST were previously covered in 4% tax bracket under VAT. It will eliminate the cascading effect of multiple taxes applied on One Product. Under GST, Ayurvedic medicines could get costlier as they would be taxed at the rate of 12% which were earlier covered by 4% tax bracket under VAT regime. Because of this hike in the tax rates, MRP has to be revised to absorb overall effect.

As GST is applicable on phases of the supply chain, it will have a negative impact on Free-drugs samples, Bonus/Discount Schemes, Inter-state stock transfer, etc.

Beside negative impact, there are some negative positive impacts also. Traditional Cost and Distribution Model will get replaced by supply chain efficiencies due to discontinuance of the Central Sales tax and interstate transactions between two dealers will become tax neutral. Pharmaceutical companies will experience improved operational efficiency and improved compliance. It will also benefit warehousing strategy. As of now, companies kept their warehouses in different States to avoid Central Sales tax of different States. Now, they can consolidate warehouses at strategic locations as they will only have to pay Integrated GST (IGST) on inter-state supplies of Goods and Services. GST will surely benefit pharma sector by way of reduced complexities and the consolidation of multiple taxes into a single rate.

Now under GST, various distribution channels will now be required to obtain registration and file returns. Earlier they were not required to obtain registration since they were not involved in the payment of taxes and filing of returns. This will increase compliance and would curb practices of non-issuance of invoice.

AUDIT OF PHARMACEUTICAL INDUSTRY

Internal Audit and process

Internal Audit Definition:

According to the Definition of Internal Auditing in The IIA's International Professional Practices Framework (IPPF), internal auditing is an independent, objective assurance and consulting activity designed to add value and improve an organization's operations. It helps an organization accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes.

Performed by professionals with an in-depth understanding of the business culture, systems, and processes, the internal audit activity provides assurance that internal controls in place are adequate to mitigate the risks, governance processes are effective and efficient, and organizational goals and objectives are met.

Emerging trends in internal audit leverage on machine learning, predictive analytics and other data science techniques are also capable of identifying potential future threats and non-compliances through trend and process analysis allowing the organizations to have adequate controls and precautions to be future ready.

Internal Audit process

Internal audit revolves around the following key steps as a part of providing assurance and value add to the entire process

The audit process starts with the preparation of an audit universe which lists all the auditable units within an organization. Every year the first step that is undertaken is to update the audit universe and bring it in line with the organizational current state.

Then the Chief Audit Executive (CAE) would prepare a detailed audit plan taking into consideration the key risks as per the Enterprise Risk Management (ERM); including any other emerging risks; periodicity of coverage of the auditable units; perceived sensitivity; change in people, process and technology; understanding the business strategy and goals of the organization, and finally considering the inputs from the various stakeholders. These would include the various functional heads, business heads, CEO, CXOs and the second line of defense viz. financial controlling, security, risk management, quality, inspection and compliance. The final plan is then presented to the Board of Directors (BOD) for approval.

Few of the key areas to be reviewed for Internal Audit.

(i) Procurement to Pay
(ii) Statutory compliances
(iii) Production
(iv) Inventory Management

Brief description of various activities, control objectives and key controls relating to procurement to pay cycle and Inventory Management:

I. Procurement to Pay

1. Activity – Creation and Maintenance of Vendor Master

Control Objective -

Complete, accurate and updated data should exist in the vendor master. All changes to the vendor master should be duly authorized and accurately captured and no duplicate/redundant data should exist in the vendor master

Key Control

Review of the vendor master including documentation requirements.

Monitor all changes to the master file, i.e., review log of changes to the vendor master**.**

2. **Activity - Creation and Maintenance of item master**

Control Objective –

Complete, accurate and updated data should exist in the item master and All changes to the item master should be duly authorized and accurately captured and no duplicate/redundant data should exist in the item master.

Key Control

Review of the item master including documentation requirements.

Monitor all changes to the master file, i.e., review log of changes to the item master.

3. **Activity - Purchase of Raw Material for production, purchase of engineering spares.**

Control Objective -

All purchases should be supported by valid business needs and should be duly authorized.

Key Control

Review of monthly procurements and annual budgets for purchases along with approval.

4. **Activity – Material Inwards at Warehouse**

Control Objective –

All receipts should be duly approved and correctly accounted for in a timely manner.

Key Control

Review of processes at the time of receipt of goods at the factory including physical count of goods received

Review of Material Receipt Note (MRN)

5. **Activity – Processing of Vendor Invoices**

Control Objective –

Rates of goods/ services should be consistent with PO/ contract, should matching with receipts of goods/ services and no duplicate payments should be made. Liability should be correctly and completely recorded for invoices that have been processed.

Key Control

Review of invoices and comparison with PO and MRN including the approval process for payments.

Review of reconciliation of Purchase bills to be received with general ledger.

II. **Inventory Management:**

1. **Activity - Physical verification of inventory items**

Control Objective

Balance of inventories as per books of accounts should agree with the physical balance of inventories.

Key Control

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 reviewed properly.

2. **Activity - Updating Bill of Material (BoM)**

Control Objective

BoM shall be updated in a timely manner

Key Control

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. **Activity - Updating Item Master**

Control Objective

Complete, accurate and updated data should exist in the item master and all changes to the item master are duly authorized and accurately captured.

Key control: To ensure that each new item code of FG and WIP is created on the basis of request received from concerned plant and item codes are created after receiving approval from the authorized personnel as per Organisation DOA matrix.

4. **Activity - sale of scrap**

Control objective

All sale of scrap should be duly approved and correctly accounted for in books of accounts on a timely basis.

Key Control

To ensure that all scrap sales are based on the invitation of the quotation and sale is awarded to the best approved rates.

To ensure that quantity of scrap is matched with invoice generated for scrap before dispatch

5. **Activity - Obsolete Inventory**

Control Objective

All obsolete inventories should be identified and accounted completely and accurately.

Key Control

To ensure that all obsolete inventories are identified, stock adjustment note is prepared for obsolete inventories identified during physical verification and approval is obtained from authorized personnel

Red flags in Pharmaceutical Industry

Globally, regulatory authorities have developed a keen interest in the pharmaceutical industry, few of the Pharma giants have paved the way for regulatory agencies to dig deeper into the malpractices prevalent in the pharmaceutical industry. With the growth of the pharmaceutical industry and the unavoidable by-products that result from it, the industry is currently faced with several schemes that have been tailored to manipulate and defraud enforcement agencies and the public at large

Red Flags and Fraudulent Schemes

The Indian pharmaceutical industry is faced with several challenges from a compliance point of view. The most prevalent fraudulent schemes in the industry relate to year-end targets, sales returns, etc., which are used as a veil to effectuate concerns around channel stuffing, free of cost products, free samples, fraud. These schemes are deeply entrenched into the system and are mingled into the day-to-day operations and accounting practices employed in the industry. Owing to the complex way these schemes operate, they remain concealed unless the substance of the activity is specifically analyzed.

Fictitious Sales

Modification of invoice number and other invoice details may enable distributor to claim incentives from the Companies by reporting bogus sales. Shell companies are also set up by distributors to claim more incentive from companies by showing false sales.

Free samples

Many a time, samples are provided free of cost to the distributors for distribution to end customers. However, these samples, if not specifically marked as "Free sample" are sold to the end customers at regular prices. Thus, the distributor records a profit of complete sale value violating the agency conditions with the company.

Expired Inventory

The expired inventory of daily-use drugs of low value lying with distributors is recorded as sales in the companies' accounts without them being sold. The inventory is essentially not taken back from the distributors citing the higher administration costs involved in retrieving these medicines.

Distributor Channel Stuffing

Most of the companies engage in channel stuffing to inflate sales and earnings figures by deliberately sending distributors along its distribution channel more medications than they can sell to the public. The companies pay extra incentives to the distributors to hold up the inventory and not return it for a refund. Subsequently, the companies purchase back the inventory through shell companies created for this purpose at substantially lesser prices. This is generally done at the end of the financial year to inflate the revenue figures in the financial statements for investors.

Grey Market

A huge racket perpetrated by distributors in the pharmaceutical industry involves selling of grey market or generic drugs after illegally labelling and branding them. This issue recently caused much hue and cry in the US with consequences not only limited to civil liabilities but also criminal proceedings against the accused.

Institutional Dealings

Companies that supply medication and drugs to government hospitals and institutions also indulge in bribery of government officials to obtain or retain contracts associated with government hospitals. Commercial bribery in the form of giving kickbacks to vendors or offering unethical incentives to doctors or hospitals to promote specific pharmaceutical products is very common across the pharmaceutical industry.

Companies offer discounts to different categories of institutional buyers such as hospitals, corporates, research agencies and others. The discounts are mostly passed on in the form of credit notes, which are subsequently misappropriated in collusion with the buyers.

Under the present Indian legal framework, the Uniform Code of Pharmaceutical Marketing Practices (**UCPMP** or **Code**) regulates various marketing practices prevalent in the pharmaceutical industry. There are talks of making the said Code mandatory for all pharmaceutical companies, but now, the said Code is voluntarily implemented.

Conclusion:

Internal audit provides an independent and unbiased view on the organizational processes and activities thereby adding value to the organization. It greatly contributes in improving operational efficiency by objectively reviewing the organization's policies and procedures, providing assurance that the organization is doing what the policies and procedures say they are doing, and that the processes are adequate in mitigating unique risks, continuously monitoring and reviewing the processes, identifying control recommendations to improve the efficiency and effectiveness of the processes in turn, allowing your organization to be dependent on process, rather than people.