



The Institute of
Chartered Accountants
of Pakistan

CA
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Pharmaceutical Industry

April, 2018

111-000-422



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**The Institute of
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Introduction

This is the first industry-specific guideline issued by the Professional Accountants in Business (PAIB) Committee of ICAP for the benefit of members, currently working in or aspiring to join Pharma industry.

Objective

This guideline captures a typical Pharmaceutical company; covering brief description of its main functions as well as their interaction with the finance function. It also includes references to relevant laws and regulations. The guideline aims to help Finance Executives develop broad understanding of business dynamics and industry challenges of pharma sector, thereby enabling them to perform more effectively and efficiently.

An Overview of Pharmaceutical Industry

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1 Pharmaceutical Market in Pakistan

The Pharmaceutical market in Pakistan is estimated by IMS (MAT June 2017) at Rs.300 billion, growing at a rate of 12% (5 year CAGR). The industry is dominated by local / national companies which account for 2/3rd of market share whereas multinationals enjoy the remaining 1/3rd. Top ten companies constitute approximately 46% of the market whereas top 50 share approximately 90% of the market.

Top 10 pharma companies in Pakistan

Name	Ranking	National / Multinational	Listed
GlaxoSmithKline Pakistan Limited	1	Multinational	Listed
Getz Pharma (Private) Limited	2	National	Unlisted
Sami Pharmaceutical (Private) Limited	3	National	Unlisted
Abbott Laboratories Pakistan Limited	4	Multinational	Listed
Martin Dow Pharmaceuticals (Pakistan) Limited	5	National	Unlisted
The Searle Company Limited	6	National	Listed
Sanofi Aventis Pakistan Limited	7	Multinational	Listed
OBS Pakistan (Private) Limited	8	National	Unlisted
GSK Consumer Healthcare Pakistan Ltd	9	Multinational	Unlisted
Hilton Pharma (Private) Limited	10	National	Unlisted

Source: IMS MAT June 2017

Growth in sales of national companies has been higher than the multinationals. It is essentially a low-cost generic market with large number of new generic medicine launched at higher unit price.

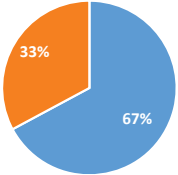
There are approximately 650 companies operating in the Pakistani Pharmaceutical market, out of which less than 30 are multinational companies. The Pharmaceutical industry contributes approximately 1% to the GDP of Pakistan annually.





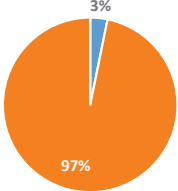
Pharmaceutical Industry

Market composition by sales value



■ MNC ■ National

Market composition by number of companies



■ MNC ■ National

There are around 9,000 actively marketed drugs in Pakistan sold at licensed pharmacies on prescription. In addition, there is a large segment of Over the Counter (OTC) products e.g., multivitamins; pain, cold and flu relief.

Pharmaceutical sector in Pakistan is strictly regulated by the government. The Drug Regulatory Authority of Pakistan (DRAP) controls the registration of new medicines and new manufacturing sites. It also determines the Maximum Retail Price (MRP) of all medicines marketed in Pakistan.

The Pakistani Pharmaceutical market is largely an out-of-pocket market (healthcare spending mainly coming from individuals' personal savings), however government provides free or low cost treatment at government hospitals and clinics. Although Pakistan does not have a national health insurance cover, the Health Insurance industry is gradually evolving to provide hospitalization coverage for the citizens.

Public Private Partnership in health sector has also increased with several Pharmaceutical companies working with government and NGOs to provide necessary access to medicines.



2 Finance

The Finance Executives within a Pharmaceutical industry have similar roles and responsibilities as in any other industry; including:

- General Accounting
- Financial Planning
- Decision Support
- Controlling
- Internal and External Financial Reporting
- Tax Compliance
- Insurance and Risk Management
- Financing and Treasury Operations
- Working Capital Management
- Other Regulatory Compliance e.g. SECP filings.

However, owing to some peculiar requirements of the Pharmaceutical industry, there are certain additional requirements.



Following are the broad areas, which may be included in the job description of a Finance Executive:

2.1 Internal Management Reporting

A company's management generally requests information on the profitability of the products on a regular basis as well as actual achievement versus budgets/targets. It is very important that sound internal reporting mechanisms are in place which provide regular and timely update to the relevant stakeholders. Since Finance Executives have access to various sales and costs information from the ERP, they can develop suitable internal management reports (e.g. MIS/dashboards) that convey useful information in a timely manner for effective decision making.

2.2 Decision Support in Resource Allocation

Finance plays a pivotal role in allocation of resources within a Pharmaceutical company. Resource allocation decisions result in investing company resources (for instance, sales force time and promotion budgets) on certain products while withdrawing/reducing resources from others.

New product launch, for example, need significant investment to ensure that the product/brand achieves a critical mass for take-off in the market. Similarly, high margin products need adequate resources to sustain company's profitability and growth. Finance Executives are required to perform profitability analysis of product portfolio for best allocation of available resources in the company.

2.3 Sales Incentives

Medical Representatives are given a fixed salary and a variable incentive pay. They call on doctors to communicate scientific product and disease information, treatment efficacy, results of clinical studies etc. They are given targets in terms of number of calls that they make to doctors in their respective assigned territories, number of scientific and promotional activities carried out as well as sales.

Finance Executives must ensure that the entity has an adequate system to capture Medical Representatives activities, so that these can be presented to management whenever requested. Generally, a Customer Relation Management (CRM) system is used for this purpose. Incentives scheme can be capped or open-ended. An open-ended scheme can result in unusually high payouts from a large sales order. Generally, tender and institutional sales orders are excluded from incentive calculation. Finance Executive should be able to check the accuracy of sales incentive provisions being recorded in the books of account.

2.4 Payments to Drug Regulatory Authority of Pakistan (DRAP)

There are certain special payments made to DRAP for various purposes including:

- i. Central Research Fund: Annual levy of 1% of Profit Before Tax
- ii. New Drug Registration Fees
- iii. Drug Registration Renewal Fees
- iv. Drug Manufacturing License Fees

2.5 Custom Duties

Active Pharma Ingredients (API) and Excipients attract custom duties ranging from 5% to 25%. Where custom duty is 25%, additional sales tax is also levied despite no sales tax on sale of medicines.

Advance income tax levied on import stage is currently at 5.5% on import value.

Import duty on medicines range from 0% to 10%. Cancer, transplant and heart related medicines have 0% custom duty; however, they attract advance tax at 5.5% on import value.

2.6 Taxation

Sale of locally manufactured medicines falls under the Normal Tax Regime (NTR) whereas, Income Tax levied on import of finished medicines fall under Final Tax Regime (FTR). In case of exports, the entire export proceeds, whether of locally manufactured medicine or imported ones, also fall under FTR.

Promotional Spend: Federal Board of Revenue (FBR) also reviews sales promotional spending by the Pharmaceutical companies. As per the Drug Act, sales promotional expenditure is restricted to 5% of turnover. The Finance Executive should ensure regular monitoring of promotional spend to ensure that it remains within defined limits.

Transfer Pricing: This issue is particularly relevant for Pharmaceutical MNCs; where local affiliate purchases API from group companies worldwide.

FBR has issued notices to many Pharmaceutical MNCs to assess whether the transfer prices of API are at arm's length. FBR is generally interested in the pricing of APIs and excipients that are used to manufacture products in Pakistan and whose income is consequently taxed under the NTR.

Due to the importance of this matter, Finance Executives should ensure that the company has adequate documentation in place to establish the purchase of products from group companies at arm's length.

Sales Tax: Pharmaceutical industry has exempt status in GST; there is no output sales tax in respect of sales of Pharmaceutical products. The GST returns are generally straightforward covering some output tax with respect to disposal of fixed assets and scrap sales.

2.7 Payments to Healthcare Professionals (HCPs)

Pharmaceutical companies make various kinds of payments to Healthcare Professionals (HCPs)/Healthcare Organizations (HCOs) with respect to services obtained from them. These payments include honoraria for delivering lectures in conferences and symposia, Local Speaker Programs (LSPs) and Round-Table Discussions (RTDs) covering topics based on latest research in various areas of medicine, awareness programs for HCPs as well as general public.

Finance Executives should carefully review all payments to HCPs. Purpose of such payments should be clear to ensure that these payments are within the confines of ethical marketing practices. Payments to HCPs cannot be made to oblige or induce them to prescribe company's medicines and thereby increase sales. There have been several instances where regulatory authorities have imposed fines on Pharmaceutical companies alleging unethical practices as well as bribing the HCPs.

Finance Executives should strengthen the process of approval of such promotional expenses spent in consultation with the compliance and medical departments to ensure compliance with applicable laws and regulations.

2.8 Sales Invoicing, Delivery and Receipt of Collection

Pharmaceutical companies generally sell their medicines on advance payment to their distributors. Distributors send cheques, pay orders with their orders; Finance Executive confirms amount credited in the company's bank account; Sales Orders are processed and Delivery Challan and Sales invoices are made in the ERP systems and revenue is recorded. Due to prevalent advance cash model, the Days Sales Outstanding (DSO) in Pharma Industry is generally nil.

Finance Executive needs to ensure that the revenue recognition policy of the company is aligned with IFRS where the risk and rewards of goods are transferred to the distributors once they take the goods in their possession.

In case of centralized distribution model (explained later in serial 14), a Pharmaceutical company recognizes revenue as soon as the medicines are delivered to the national distributor, being the point where significant risks and rewards are transferred to the distributor.

However, in a decentralized distribution model, the Pharmaceutical company cannot recognize revenue until medicines are delivered to regional distributors in their respective hometowns and when risk and rewards are transferred.

Finance Executives should remain vigilant to the fact that revenue recognition criteria are met in order to report the revenue. If the medicines have not been delivered to the distributor at the period end reporting cut-off date; appropriate adjustments need to be made in the books to comply with the IFRS.

Revenue recognition process

Revenue recognition point



Seller

Goods in transit

Buyer

3 Marketing

Under the Drugs Act 1976, Pharmaceutical companies are prohibited from reaching out directly to patients with respect to their prescription based products/brands through mass advertising (electronic, print or social media) and bill boards.

However, for the 'Over-the-Counter (OTC)' product category, which do not require prescription and are purchased directly by the patients from pharmacies; Pharma companies are allowed to advertise on print/electronic/social media. Examples of OTC brands include Panadol and Disprin (Aspirin) that are widely seen in commercial advertisements.

Top 5 selling brands			
Brand name	Manufacturer	Approximate annual sales (Rs. In million)	Launch year
Augmentin	GlaxoSmithKline Pakistan Limited	4,500	1986
Risek	Getz Pharma (Private) Limited	3,300	1996
Panadol	GSK Consumer Healthcare Limited	3,200	1976
Brufen	Abbott Laboratories Pakistan Limited	2,600	1979
Novidat	Sami Pharma (Private) Limited	2,500	1992

Source: IMS MAT June 2017

Notwithstanding aforesaid restriction on advertising, public awareness on diseases or their treatment can still be spread through various activities including mass media campaigns without mentioning any product/brand name.

Marketing function is primarily focused on creating awareness amongst HCPs about the latest medical/clinical research on the efficacy of their drugs. These awareness sessions are carried via range of scientific and promotional activities such as:

- Round table discussions with doctors
- Symposia and workshops
- Local and foreign scientific conferences sponsorship
- Local speaker programs

Other promotional spend include modest expenditure related to patient welfare, such as providing weighing machines, BP apparatus, glucometers etc. to HCPs.

Pharmaceutical companies that abide by a code of ethics, operate sound internal control processes to ensure that promotional expenses remain within the ethical and legal guidelines. Any promotional expenditure on HCPs without documentation of purpose may lead to fines and penalties by the regulatory authorities, both domestic as well as abroad.

Finance Executives should ensure that proper internal approval process is in place for all marketing expenditure supported by proper underlying documentation. These controls should be integrated with ERP payment systems to track all payments to HCPs to raise flag for any breach of limit or SOP violations. Internal Audit function should also include review of promotional expenditure in their audit scope to ensure compliance with local laws as well as code of ethics.

Pharmaceutical companies also provide physician samples to HCPs who can dispense those to patients in order to see their effects.

Finance Executives should ensure effective controls over internal processes to ensure that these samples are used judiciously with HCPs acknowledgement and are clearly marked as 'not-for-sale'.

4.1 Market Intelligence

This function is responsible for gathering market / business intelligence via different sources available publicly. Most notably among them is the IMS Health. IMS Health is an American company that provides information, services and technology for healthcare industry including prescription data and medical records. It is the largest vendor of physician prescribing data in the US.

Pharmaceutical companies make use of data/reports provided by IMS to develop their commercial plans and portfolio strategies.

IMS in Pakistan compiles data on sales made by distributors to chemists/pharmacies. It compiles information on a monthly basis and the data is made available to subscribers on payment of a prescribed fee.

Reports provided by IMS are very useful for Pharmaceutical industry. These reports include:

- Ranking of Pharmaceutical companies by size and growth rate.
- Market share of the relevant product line versus the competition.
- Specific sales information by molecule, city, brand etc.

Finance Executives responsible for business planning and performance management should use IMS data to benchmark performance in terms of growth, market share and ranking in relevant therapeutic segments.

4.2

Business Excellence / Sales Force Excellence

Business Excellence function is responsible for monitoring of Key Performance Indicators (KPIs) related to the sales force. Some of these KPIs include number of calls, Call Plan Adherence (CPA), coaching days etc. The Business Excellence function works closely with sales function to ensure that the agreed KPIs are met on a regular basis.

Finance Executives must ensure that the entity has an adequate system to capture Medical Representatives activities. Generally, a Customer Relation Management (CRM) system is used for this purpose.

5 Sales Management

The structure of sales force in a typical Pharmaceutical company is as follows:

- National sales manager(s)
- Regional sales manager(s)
- District sales manager(s)
- Sales representative(s)

Sales targets are assigned to all in the sales organization hierarchy. Sales target to sales force is based on achievement of 'secondary sales' or 'sales out' (distributors' sales to retail pharmacies, hospitals and wholesalers).

Pushing 'primary sales' or 'sales in' i.e. sales from company to its distributors and overstocking of products at the distributor level has no effect while calculating the sales force achievement.



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Each person in the sales organization from national sales manager to medical representative is assigned sales targets for the year. The incentive/bonus of the sales force is dependent upon the achievement of these targets. Sales force incentive are generally paid on quarterly achievements.

Drugs Act 1976 restricts promotion of prescription medicines directly to the public through mass media. However, the Act allows companies to communicate to HCPs the benefits of using a particular medicine based on published research. This communication is a process, referred to as 'medical detailing' which is conducted by medical representatives with HCPs at their clinics or hospitals.

After cost of products sold, Sales Field Force cost is one the most significant cost. Depending upon internal structure, it is the Finance Executive's job to ensure that the Field Force time allocation to a particular product line is aligned with company's growth strategy, its portfolio contribution and product life cycle.

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6 Medical Affairs Department



6.1 Scientific Information

Medical Affairs Department plays an increasingly important role in communicating scientific information to HCPs in an objective and ethical manner. It provides medical education on latest clinical research, treatment guidelines, new medicines, their medical benefits to patients and any risks of side effect.

The Department focuses on developing customer and patient insights about disease prevalence, their prevention and cure; translating evidence into meaningful information as well as communicating it to the doctors. Scientific information on the appropriate use of medicines and vaccines are also provided.

6.2 Clinical Trials

Clinical trials are undertaken to develop medical research evidence to understand efficacy of new medicines in treating diseases. Clinical trials are research studies that test how well new medical approaches work on people. Each study answers specific scientific questions and tries to find better ways for prevention, screening, diagnosis, or treatment of a disease. Clinical trials may also compare a new treatment to the one that is already available in the market.

Pharmaceutical companies engage leading hospitals and approved Clinical Research Organizations for clinical studies/trials on a specific medicine's efficacy in treatment of diseases. Hospitals enroll volunteers and/or patients into small study groups depending on medicine's type and their development stage.

Clinical trials can vary in size and cost, and they can involve a single research center or multiple centers, in various cities. Clinical trial/study design aims to ensure the scientific validity and reproducibility of the results. Once results of these studies are finalized, these clinical studies are presented at medical conferences and published in medical journals.

Finance Executives should ensure that the cost of these clinical trials/studies are recorded in the relevant accounting period. Since these trials/studies can span over a period longer than a year, it is important that their costs are recorded in correct accounting period.

Generally, clinical trials/studies comprise of fixed costs, which are payable by the company to the HCOs conducting the trials. The other portion, which is variable in nature comprises of amounts payable to such HCOs based on the number of patients enrolled in the study/trial. The fixed portion is recognized on a straight-line basis over the duration of the trial whereas variable portion is recognized based on actual number of patients tested. Where the trial costs are not significant, both fixed and variable cost is recognized on a straight-line basis.

Finance Executives should ensure that internal mechanisms are in place to collect the underlying information of fixed/variable cost analysis of all clinical trials/studies for each reporting period.



6.3 Pharmacovigilance (PV)

Pharmacovigilance (PV) is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with Pharmaceutical products, i.e. drugs. It is concerned with identifying any risks associated with company's medicines and minimizing the risk of any harm to patients.

Pharmaceutical companies place great emphasis on PV. There is dedicated staff that collects information on any Adverse Drug Reaction (ADR) reported by any doctor, staff or patient. All employees across organization receive training on periodic basis to be cognizant with the importance of timely ADR reporting (24hrs). In order to ensure timely reporting of ADRs, these companies have dedicated telephone lines, email addresses and social media presence linked to the PV staff.

6.4 Medical Information

Medical function also performs a value added service to HCPs by providing them answers to queries related to products, their dosage, side effects as well as results from the latest research. Even general public including patients can call in to get specific information about medicines and their usage.

6.5 Medical Governance

Medical Department is also entrusted with the responsibility to ensure that all promotional literature provided to sales representatives for HCPs dissemination is factually correct and supported by research and clinical trials. Generally, there is an expiry period for promotional literature to ensure that all medical information is updated on a regular basis. All expired promotional literature are destroyed to ensure that no outdated information is passed on to the HCPs.

The Medical Affairs Department also monitors promotional expenditure spent on HCPs as well as HCOs. They make sure that the spending remains within the ethical boundaries.



7 Regulatory Affairs

The Pharmaceutical industry is highly regulated in Pakistan. It is regulated both, by Ministry of National Health Services Regulations & Coordination (NHSR&C) and the Drug Regulatory Authority of Pakistan (DRAP).

Regulatory Affairs perform following key functions:

Registration and renewal of license for manufacturing and sale of Pharmaceutical products

All Pharmaceutical companies importing, manufacturing and selling drugs in Pakistan require license from the government. These licenses are renewed every five years. Regulatory Affairs coordinates with all relevant stakeholders in the company for application and renewal of licenses.

Registration of newly launched drugs and application for pricing

New drugs launched by a Pharmaceutical company cannot be marketed until they are registered under the Drugs Act and their prices are determined by DRAP.

Regulatory Affairs function ensures that the new products are timely registered and most favorable pricing is obtained from DRAP based on underlying market and cost data.



Pricing and inflationary indexation

In Pakistan, prices of all Pharmaceutical products are fixed by DRAP and cannot be changed unilaterally by the Pharmaceutical companies. Any new price or increase requires approval from the DRAP.

Hardship cases

In certain cases, where cost of manufacturing of a medicine increases to the extent that it becomes non-viable for the Company to continue to produce and market those medicines, it can apply to DRAP to increase the price of the product. These hardship cases are reviewed by DRAP and decision is taken whether to accept or reject the application.

Post registration variations and approvals of Pharmaceutical products

After the launch of products, Pharmaceutical companies are required to renew their licenses every five years. In some cases, where there is any change in the particulars, such as brand name, company name, source of import etc. the company can apply to DRAP for the change in the registration documents.



Pharmaceutical Industry

8 Human Resources (HR) and Training & Development

Key functions of HR are similar to other industries i.e. to develop and manage all HR processes ensuring effective employee selection, motivation, development and staffing, through effective coordination with other senior leadership.

Major accountabilities include:

- To shape HR strategies and practices that maximize human capital.
- To deliver HR initiatives including talent development, change management, diversity and inclusion.
- To manage headcount and workforce costs.
- To lead the performance management process.
- To ensure adherence to relevant labour and employment laws and, when necessary, manage labour relations, including relations with external labour organizations.
- Manage communication, especially around HR-sensitive issues.

In Pharmaceutical industry, there is generally a high turnover at medical representative level who are critical to business success. They generally switch jobs due to higher salary offered or next level placements. Retention of strong talent has to be managed via engagement, learning and development programs; career progression, promotions and market competitive remuneration and other benefits.

Talent is critical to organizational success; Finance Executives should liaise with HR leaders for future organizational changes, key talent requirements, investment requirement in capacity building so as to accurately forecast personnel costs.

8.1 Training and Development

Training is a full time function in any Pharmaceutical company. Most companies have dedicated training departments focusing on training for medical sales representatives, imparting technical and soft skills to ensure better in-clinic performance while communicating with the doctors. The training of medical sales representatives is focused on the quality of medical detailing to the HCPs.

Due to high turnover in the sales force, training function plays an important role in training new sales representatives, so that they are quickly trained on the scientific content of assigned therapeutic area and are aligned with the company's strategies and start contributing towards sales target achievement.

Sales force are trained about the scientific and technical products information supported by research and clinical data, whereas supervisors are trained with respect to coaching and mentoring skills to ensure maximum productivity of their sales teams.

Finance Executive can correlate the spending on training and development with the turnover in sales force. A high sales force turnover require spending higher amounts on training and development. A retention and capability building investment would yield high ROI in terms of lower expenditure and high sales productivity.

9 Supply Chain

The key responsibility of the supply chain function in a Pharmaceutical company is to ensure that all medicines remain available to the patients at retail pharmacies and hospitals on a consistent basis. In order to fulfil these responsibilities, the companies follow process of 'Sales & Operational Planning (S&OP)' and use relevant functionalities of their ERP systems.

9.1 Sales & Operations Planning (S&OP) process

S&OP is an integrated cross-functional planning approach, which starts with the demand planning by individual Stock Keeping Unit (SKU). The planning horizon varies among companies depending upon the complexity of business, number of product lines etc. Generally, a 12-36 months' horizon is used. Following step-by-step approach is usually undertaken:

- i. Demand is finalized by sales and marketing functions assuming that there are no constraints with respect to product availability. This is referred to as the 'unrestricted/unconstrained demand'.
- ii. Supply chain team coordinates with the production / procurement functions to see what can be achieved in reality considering production and supply constraints. Once all factors such as production plans, import quotas, lead times are considered, a 'restricted / constrained demand' emerges.
- iii. This restricted/constrained demand is signed off by all relevant stakeholders depending upon an organization's internal Standard Operating Procedures (SOPs).

From a finance perspective, the constraint demand forms the basis of the company's financial forecasts for the planning periods.

- iv. Once the demand is finalized, MRP program in the ERP is run to generate purchase requisitions (PRs) for APIs, excipients, packaging materials, and finished medicines. The purchase order issuance is handled either by the procurement function or jointly by procurement and supply chain functions.

In case of MNCs, where sourcing is from within group, generally an inter-company ordering system is used by ordering and supplying entities globally to match the quantities and supply dates.



10 Procurement

10.1 Sourcing of APIs and Excipients

Pharmaceutical raw materials comprise of Active Pharmaceutical Ingredient (API), and excipients. Most of the basic research in Pharmaceutical industry is undertaken in developed countries such as UK, Germany, Switzerland, France, Japan and the US. The Pharmaceutical imports in Pakistan takes all forms, ranging from APIs, excipients, to drugs in semi-finished and finished forms.

Name of molecule	Estimated annual sales (Rs. millions)
Ceftriaxone	9,000
Cefixime	8,300
Omeprazole	7,200
Amoxicillin + Clavulanic acid	7,000
Ciprofloxacin	7,000

IMS, MAT June 2017

10.2 Regulatory Approvals

All imports are subject to No Objection Certificate (NOC) from DRAP which means that every material imported in Pakistan requires attestation from ADC / DRAP as per local laws.

The government has granted various reliefs to Pharmaceutical sector on import of raw material e.g. reduction in custom duties under the 5th Schedule of the Customs Act, 1969 and exemption from GST under the 6th Schedule of the Sales Tax Act, 1990.

10.3 Quota Products

There are certain raw materials that are on fixed quota by the Government of Pakistan as they are classified as narcotic products. Import of these products require award of a quota from the DRAP which strictly monitors import, consumption, destruction and stock levels of such restricted items. Companies import only up to the extent of their allocated quota which has to be renewed from DRAP on an annual basis.

10.4 Quality

The quality of the APIs is important in the efficacy of the final medicines. Most Pharmaceutical MNCs purchase APIs and finished products from their parent or group companies. Local companies, on the other hand, find reliable and cost effective sources to buy the molecules.

The role of the procurement function is very critical to protect the gross margins of a Pharmaceutical company. To counterbalance the effects of inflation and PKR devaluation, the API and excipients have to remain cost effective. Therefore, a continuous cost saving effort from procurement function is required to identify and secure cheaper source of reliable raw material from across the world. The goals assigned to a procurement function include relevant KPIs in this regards.

Today more focus is on process improvements, efficiency improvements and strategic partnership with vendors with long-term service contracts based on agreed price and service levels.

Finance Executives need to work closely with procurement team and monitor rejections of Pharmaceutical inputs and take necessary action to safeguard company's financial interests.

11 Production

Pharmaceutical products generally comprise of:



A particular product can be in multiple forms. For example, the molecule, Ibuprofen is available in the market as tablets, syrup and cream under different brand names whereas another molecule, Metronidazole is being produced and sold in the form of tablets, syrups and injectables (IV).

Each product manufactured locally or imported from abroad needs to be tracked with a batch number. The batch numbers are useful in tracking of the medicines from the manufacturing plants to their final consumption. In case of quality issues resulting in product recall, batch numbers play a crucial role.

The production areas are special places where only authorized personnel with proper gear can enter. These areas have advance Heating, Ventilation & Air Condition (HVAC) systems with separate zoning. These are usually dust proof, temperature, and humidity controlled. The manufacturing personnel and visitors have to wear lab coats, caps and face mask to cover their hair, beards, and foot covers for shoes. These stringent hygiene requirements are to ensure reliable and consistent product quality free from impurities.

Cost of manufacturing plant depends upon the products format, capacity, technology and source of plant and equipment. Pharma MNCs usually use machines approved by their head offices to meet quality and reliability standards. Local companies prefer sourcing their manufacturing equipment from China, Korea or Taiwan etc. being cheaper and cost effective.

Finance Executive needs to work with plant engineering team to ensure optimal sourcing of equipment taking into consideration cost, capacity, reliability, maintenance and their replacement life.

In case of a green field (fresh) investment, plant location strategy is critical. In addition, access to trained work force, engineering suppliers, continuity of power, supply of water, connectivity with road network and cost of land needs to be taken into consideration.

12 Quality Assurance

Pharmaceutical companies place high importance on the product quality as it directly affects the lives of patients. Typical problems with quality of a product can be:

- Discoloration
- Broken or missing tablets
- Melted capsules
- Particles in solutions
- Cracked vials/bottles
- Mislabeling (misprinted text, incorrect batch number or expiry date)

All manufactured batch undergo quality assurance check for each batch. Quality department draws sample, checks it against the quality parameters, and ensure that it is fit for sale/consumption.

All deviations are thoroughly investigated and the batch is rejected if deviations are significant. Sometimes, quality problem may not be noticed based on the sample and may surface later when the product has already reached the market. In cases, where an Adverse Drug Reaction (ADR), any issue related to quality or any other observable anomaly is reported by a patient or a Healthcare Professional (HCP), the companies are required to take immediate action and recall the product from the market. In such cases, DRAP, HCPs, pharmacies and public has to be informed about particular batch for recall.

Adverse Drug Reaction (ADR) is a critical process to ensure product safety. Pharmaceutical companies provide telephone contact details and websites where anyone can lodge a product complaint or report a quality issue.

Furthermore, a Root Cause Analysis (RCA) is carried out to investigate the issue and take corrective measures.

In some cases, the government regulatory body, i.e. the Drug Regulatory Authority of Pakistan (DRAP), may also notice significant issues related to quality and may initiate its own inquiry to check, whether any malpractices are involved.

Finance Executives should ensure adequate investment in QA systems and equipment to ensure reliability of product quality. They need to have a regular interface with QA and Pharmacovigilance teams to ensure that potential sales return from ADRs reported are recorded as an estimated provision against sales return as soon as ADR is reported for any specific batch of the product.

13 Health, Safety & Environment (HSE)

As in other industries, Pharmaceutical companies also place paramount importance to Health, Safety and Environment (HSE) aspects of business.

The objective is to minimize the Lost Time Injury (LTI). An LTI is an injury sustained by an employee that will ultimately lead to the loss of productive work time in the form of worker delays or absenteeism.

HSE function is also entrusted with the responsibility to promote the culture of safety in operations in production and other functions of the organization. In a manufacturing plant, hazardous working areas include using chemicals or working at heights. Therefore, use of proper gear equipped with safety features is mandatory.

Other areas in which HSE creates awareness include, safe driving, earthquake drills, use of fire extinguishers, as well as safety precautions during an epidemic.

Finance Executives can expect to receive unplanned expenditure requests related to HSE issues which, depending upon the nature, may take precedence. Any delay in investment on HSE may become far more expensive in terms of accidents/incidents on site as well as fines and penalties from the Government. Finance Executives should consider that the Return On Investment (ROI) in these areas may not always be calculated and the expenditure cannot be justified solely on financial grounds.

14 Logistics

To ensure that the medicine is always available in the market, Pharmaceutical companies make sure that their distributors who are primary suppliers of products to chemists/pharmacies, carry a certain level of inventory of all the products at all times.

The level of inventory, which is required to be carried by distributors, is based on the historical/forecast sales of the products and is measured in number of days/weeks of stock cover. The industry generally requires its distributors to carry 6 weeks of inventory on average to ensure adequate supply of all the drugs to patients.

Supply chain ensures that the stock levels are maintained at the distributors' locations and that the invoicing is done in a timely manner to replenish stocks.

In Pharmaceutical market, both centralized (national) and decentralized (regional) distribution models exist. In a centralized model, companies appoint a national distributor who is responsible for the nation-wide distribution of products using its own network of warehouses and delivery teams.

In a decentralized model, companies appoint several distributors in different geographical locations. They deliver goods to distributors in their hometowns at its own cost who in return ensure that products are made available at local pharmacies. In Pakistan majority of Pharmaceutical companies are operating through decentralized distribution model.

Majority of products are temperature sensitive; therefore, require controlled environment during transportation and storage.



Recently the provincial government of Punjab introduced a legislation whereby Pharmaceutical products are to be transported in temperature-controlled vehicles. Due to this requirement, the cost of transportation as a whole has increased significantly.

The Finance Executive should work closely with supply chain to ensure that both inbound and outbound logistics cost are minimized by optimizing warehouse network, truckloads and frequency of dispatches.

15 Anti-counterfeit Drugs

Pakistani Pharmaceutical market is significantly infested with counterfeit drugs. A counterfeit drug is one whose label or outer-packing resembles the outer-packing of a drug of another manufacturer in order to deceive the end consumer. Although counterfeit products can be found even in the developed countries, it has reached alarming proportions in Pakistan due to poor law enforcement. The menace of counterfeit poses serious threat to public health. In January 2012, around 100 patients lost their lives in Lahore due to a substandard cardiology medicine provided to patients at one of the government-run health institutions.

Although it is the responsibility of the government and law enforcement agencies to catch the manufacturers of counterfeit drugs, it is also in the best interest of the Pharmaceutical companies to identify such networks and coordinate with relevant agencies to bring the culprits to task.

If, due to effective coordination between the law enforcement agencies and the Pharmaceutical industry, the infiltration of counterfeit drugs is minimized, it will help the companies:

- To avoid negative publicity in the market place, in case, any ADR is reported in a counterfeit drug imitating their genuine brand.
- To avoid loss of sales of their own products.
- To avoid possible investigations from DRAP and other agencies.

From a finance viewpoint, the budget allocated to anti-counterfeit department/function may not be justified solely on financial grounds. For their own good, it is very important for the companies to remain vigilant for the presence of counterfeits and also coordinate effectively with law enforcement agencies to root out the menace.

16 Corporate Social Responsibility (CSR)

Pharmaceutical companies invest in CSR activities as part of socially responsible corporate image. These activities keep society and patient welfare at its core. These activities may include the following:

- Funding NGOs to set up clinics in low income areas.
- Blood pressure and sugar testing camps.
- Tree plantation drive.
- Blood donation drive.
- Providing books and uniforms for schools in under privileged areas.
- Disease awareness campaigns for general public.

Finance Executives should ensure that the CSR expenses are incurred in a transparent and ethical manner, so as to differentiate these from marketing activities.

17 Ethics and Compliance

The integrity of a Pharmaceutical company is based on decisions taken by its employees at each level of the organization on a daily basis. These decisions are primarily based on the values and ethics of the company, as well as compliance with local laws.

Companies generally have a documented Code of Ethics that serves as a guidance document for all employees. They make it mandatory for all their employees to get training on compliance and ethics and refresh it on a periodic basis.



In case of non-compliance by any employee, customer or vendor of the company, any whistleblower can report the same to dedicated compliance officer, who normally report to the highest level in the organization.

Some companies also follow a process of due diligence while inducting any distributor, an institutional customer, vendor or a clearing agent to see whether it would be ethically correct for the company to conduct business with them.

A representative from finance is generally included in the team which performs such due diligence activities. Therefore, it is very important for the Finance Executive to be aware of the company's Code of Ethics and also take steps to ensure that finance staff is fully trained in company's Code of Ethics, values and due diligence process.



Acronyms & Abbreviations

DRAP	Drug Regulatory Authority of Pakistan
API	Active Pharmaceutical Ingredient
MAT	Moving Annual Turnover
ADR	Adverse Drug Reaction
S&OP	Sales & Operational Planning
ERP	Enterprise Resource Planning
KPI	Key Performance Indicator
CPA	Call Plan Adherence
LTI	Lost Time Injury
HSE	Health, Safety & Environment
HCP	Healthcare Professional
HCO	Healthcare Organization
CSR	Corporate Social Responsibility
NHSR&C	National Health Services Regulations & Coordination
OTC	Over-the-Counter
PV	Pharmacovigilance
CAGR	Cumulative Average Growth Rate



Author

Saad Usman, FCA

Head of Accounts & Company Secretary
Sanofi-Aventis Pakistan Limited

Reviewed by

ICAP Professional Accountants In Business (PAIB) Committee

Disclaimer

The information contained in the guideline is based on the professional experience of the authors as well as information collected from other non-finance professionals in their respective areas of expertise within the Pharmaceutical industry. Although due diligence has been exercised in compiling this information, the practices may vary between companies operating in the Pharmaceutical sector.

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