The Institute of Chartered Accountants of Pakistan

CA PAKISTAN

2nd Edition

Pharmaceutical Industry

January, 2024

111-000-422

http://www.icap.org.pk/paib/

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Introduction

This is the second edition of the pharma 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 Pharmaceutical industry.

Objective

This guideline provides an overview of a typical pharmaceutical company, offering a brief description of its main functions and their interaction with the finance function. It also includes references to relevant laws and regulations. The guideline aims to assist Finance Executives in developing a broad understanding of the business dynamics and industry challenges within the pharmaceutical sector, thereby enabling them to perform their tasks more effectively and efficiently.

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1 An Overview of Pharmaceutical Industry

Modern Healthcare is dependent upon the pharmaceutical industry that **conduct research, develops, manufactures, and markets medicines, vaccines, and medical devices.** It plays a vital role in improving the health and well-being of people around the world.

The pharmaceutical industry is a complex and highly regulated industry. The process of developing a new drug can take many years and cost billions of dollars. The industry is also subject to strong regulatory, ethical, and legal compliance.

The pharmaceutical industry is a major driver of economic growth and scientific discovery. The industry employs millions of people around the world, and is constantly innovating and developing new drugs to treat a wide range of diseases by investing billions of dollars in R&D and drug discovery. The industry plays a vital role in the global healthcare system.

Rising cost of drug development, the increasing prevalence of counterfeit drugs, and the need to address the growing problem of antimicrobial resistance are major challenges of the industry.

Key activities of the pharmaceutical industry include research & development (R&D), manufacturing, marketing & sales, and regulatory compliance.

2 Pharmaceutical Products

Pharmaceutical products are generally classified under following categories:

- Tablets and Capsules
- Syrups including suspensions
- Injectables (Ampoules & vials)
- Alternative Medicines
- Unani Medicine
- Homeopathic
- Creams & Ointments
- Medical Devices
- Surgical items
- Herbal products
- Phyto products
- Health products (Food Supplements, Nutritional and Diabetic foods)

Besides above classification pharmaceutical products are also commonly classified under Prescription (Rx) and non-prescription products (or Over the Counter: OTC).

Furthermore, companies often refer product group based on Therapeutic indication or usage (e.g. Anti-epileptics, Anti-diabetics, Topical Antibacterials, Vitamins, Cardiology, Women healthcare etc.)

The related laws, regulations, taxation and custom duties differs from category to category

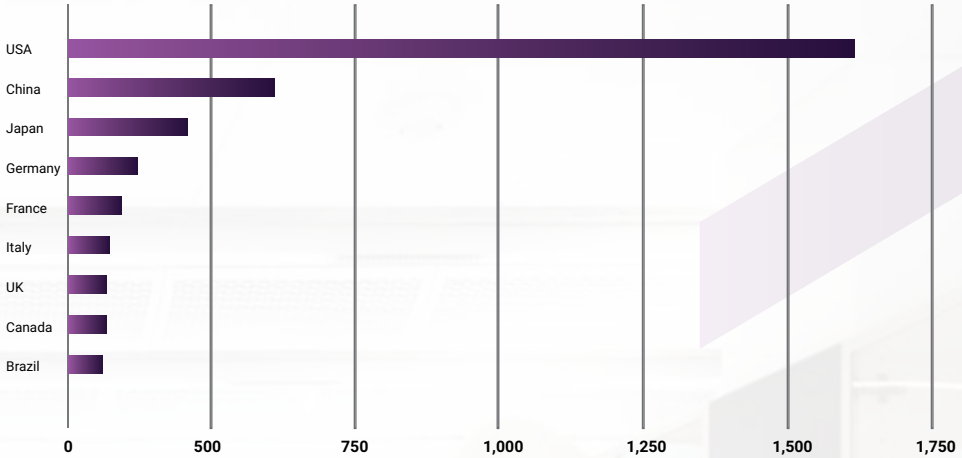
Quota Products (Controlled Substances)

There are certain raw materials that are extensively regulated by the Government of Pakistan. These are generally known as psychotropic or controlled substances. These products can only be imported through an award of import quota by Drug Regulatory Authority of Pakistan (DRAP), which strictly monitors import, consumption, destruction as well as stock levels of these substances. Companies can import only up to their allocated quota in a given year. The quota has to be renewed from DRAP on an annual basis. The quota is only increased by up to 10% per annum provided that the Company can show the consumption of the previously awarded quota during a given time period.

3 Global Pharmaceutical Industry

In 2022 the global pharmaceutical market was estimated at USD 1.5 trillion and is expected to grow to USD 1.8 trillion by 2026. Globally, the United States is leading market for pharmaceuticals, followed by China, Japan, Germany, France, Italy, United Kingdom, Canada, and Brazil. Other emerging markets include India, Russia, Colombia, and Egypt.

Pharmaceutical Market Size in USD Billion



Source: Revenue of the worldwide pharmaceutical market from 2001 to 2022

USA dominates in pharmaceutical market due to higher patient access to innovative medicines.

Top Disease burden / Therapeutic class of global pharmaceutical market

• **Oncology**	• **Diabetes**
• **Ophthalmology**	• **Endocrinology**
• **Cardiovascular Disease**	• **Central Nervous System & Neurological Disorders**
• **Gastrointestinal Disorders**	• **Nephrology**

Source:

Strategic Analysis of Global Pharmaceutical Market, Bloomberg, May 23, 2023

4 Pharmaceutical Market in Pakistan

The Pharmaceutical market in Pakistan is estimated by IQVIA (MAT June 2023) at Rs.748 billion, growing at a rate of 15.3% (5-year CAGR). The industry is dominated by local / national companies which account for more than 2/3rd of the local market share. Top 10 companies constitute approximately 48% of the market whereas top 50 share approximately 93% of the market.

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

Growth in sales of national companies has been higher than that of multinationals. Pakistani market is essentially a low-cost generic market with a large number of new generic medicine launched every year. There are approximately 650 companies operating in the Pakistani Pharmaceutical market including multinational companies. The Pharmaceutical industry contributes approximately 1% to the GDP of Pakistan annually.

There are approximately ~ 11,000 actively marketed drugs in Pakistan sold at licensed pharmacies based on prescription. In addition, there is a large segment of Over-the-Counter (OTC) products e.g., multi-vitamins; pain, cold and flu relief etc.

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 the masses necessary access to medicines.

Export Potential

Global pharmaceutical markets are in flux due to major restructuring, there is an opportunity to strategically enter the global off-patent drugs market that will be worth USD 700 billion in branded generics and USD 381 billion in generics by 2025. Pakistan's current total exports are USD 235 million with easy target to reach USD 500+ mio in a matter of few years.

Pakistan's pharmaceutical industry can offer its wide range of medicines for exports into developing countries of the world including Africa, Central Asia and Far East. These countries, where regulatory requirements are not as stringent as the developed countries, can be attractive export destinations for Pakistani pharmaceutical products.

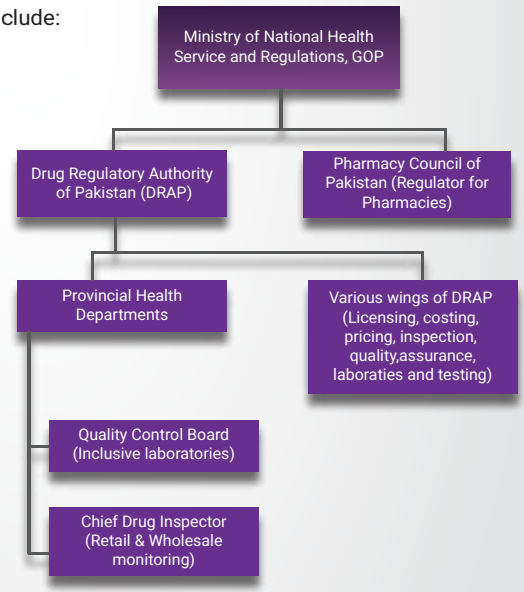
5 Pakistan's Pharmaceutical Regulatory Environment

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).

DRAP is an autonomous body of Federal Government working under the administrative control of Ministry of National Health Services, Regulations & Coordination. General direction, administration and monitoring of the Authority vests with Policy Board of DRAP. Established under DRAP Act 2012, DRAP is responsible for providing effective coordination and enforcement of The Drugs Act, 1976 (XXXI of 1976) and to bring harmony in inter-provincial trade and commerce of therapeutic goods.

Therapeutic goods regulated by the DRAP include:

- Pharmaceutical and biological drugs for human or veterinary use,
- Medical Devices and Medical Cosmetics
- Health & OTC (non-drugs) also known as alternative medicines such as:
- Ayurvedic
- Chinese
- Unani
- Homeopathy
- Nutritional products
- Food supplements for human beings, animals



The DRAP Act, 2012 and the Drugs Act 1976 sets out legal requirements for the manufacture, import, export, storage, distribution, and sale of therapeutic goods in the country. DRAP ensures that every drug, medical device or cosmetic, alternative medicine and health product must have standard of quality and is safe and effective for use.

DRAP ensures that therapeutic goods, approved and available in the market, meet prescribed standards of quality, safety, and efficacy.

Details can be viewed from https://www.dra.gov.pk

5.1 Key functions of Regulatory Affairs

The regulatory affairs function plays a vital role in the success of pharmaceutical organization. By ensuring that the company's products comply with all applicable regulations, this includes regulations governing the registration, licensing, development, manufacturing, testing, marketing, and sale of pharmaceutical products. It helps to protect patients and the company from liability. The specific roles and responsibilities of the regulatory affairs function can vary depending on the size and complexity of the organization, as well as the specific needs of the business.

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. As per the Drugs Pricing Policy 2018 (“DPP 2018”), the pharmaceutical companies can increase MRPs of their essential/biological drugs products up to 70% of the Consumer Price Index (CPI) notified by the Government (with a capping of 7%), whereas for non-essential and lower priced drugs, up to 100% of the CPI (with a capping of 10%) subject to certain mandatory filing of information with 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. DRAP may refer any particular case to the Federal Government, which will then be decided accordingly subject to certain time restrictions.

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.

Some other regulatory functions performed by DRAP include:

- Medicine registration & marketing authorization,
- Market surveillance and control,
- Drug Manufacturing licensing establishments
- Manufacturing GMP and GWD Vigilance,
- Regulatory inspection
- Laboratory testing,
- Clinical trials oversight,
- Pharma co-vigilance, and
- Lot release of biologicals etc.
- Import vigilance.

5.2 Payments to Drug Regulatory Authority of Pakistan (DRAP)

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

i. Central Research Fund
ii. New Drug Registration Fees
iii. Drug Registration Renewal Fees
iv. Drug Manufacturing License Fees

DRAP is the regulatory body which is authorized by the Government of Pakistan to register new products/brands which the pharmaceutical companies want to introduce. These products can be either innovator products (based on original research) or generic products (me too) based on research of other companies (when the underlying patents expire). Pharmaceutical companies are required to follow a detailed process which includes the following steps:

- Filing of product dossiers
- At least 6 months of product stability data
- List of intended brand names
- Drug manufacturing license
- Psychotropic license (in case of psychotropic products)

DRAP evaluates the documentation and once satisfied, it registers the brand, allocates Maximum Retail Price (MRP) and issues registration letters and marketing authorization. Once the registration letters are obtained, the Company can market the drug in the local market. For exports, the Companies need to follow the regulatory requirements of the target countries, which may be stringent (in case of developed markets) or similar to Pakistan (in case of developing markets).

6 Role of Finance Function

The finance function in a pharmaceutical organization is a complex and challenging role. However, by effectively managing the organization's finances, the finance function ensures the company's long-term success. It plays a vital role in ensuring the company's financial health and success. The specific roles and responsibilities of the finance function vary depending on the size and complexity of the organization, Key responsibilities include:

- Financial planning and analysis
- Budgeting and forecasting
- Cost accounting
- Financial reporting
- Compliance with financial regulations
- Risk management
- Investor relations
- Manage costs of drug development and manufacturing
- Managing the pricing of drugs
- Managing the reimbursement process
- Managing the risk of recalls
- Managing the intellectual property of the company

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:

6.1 Internal Management Reporting

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

6.2 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 the company's profitability and growth. Finance Executives are required to perform these profitability analyses on product portfolio for best allocation of the company's resources.

6.3 Sales Incentives

Medical Representatives (medical reps) are generally given a fixed salary as well as a variable incentive pay. The job of these medical reps is to call on healthcare professionals to communicate latest scientific product and disease information, treatment efficacy, as well as results of any relevant clinical studies etc. They are given targets in terms of:

- number of calls that they are required to make per day,
- number of scientific and promotional activities to be carried out,
- number of prescriptions generated for their products.

Finance Executives must ensure that the entity has an adequate system to assess activities of these medical reps, so that these can be presented to management whenever requested. For this purpose Finance is required to liaise with Commercial Excellence (also known as Business Excellence function).

Generally, a Customer Relationship Management (CRM) system is used for this purpose. Incentives scheme can either be capped or open-ended. An open-ended scheme is one, for instance, where the medical reps get incentive based on each pack sold in the secondary market (ex-distributor sales). These open-ended schemes can result in unusually high payouts from a large sales order. Generally, tender and institutional sales orders are excluded from the incentive calculation for the medical reps.

The provision of expense of these incentives are recorded in the books of account as soon as the sales are recorded by the Company. However, the payout is often made to medical reps after the calculation of their achievements on a quarterly basis. Finance Executive should be able to check the accuracy of sales incentive provisions being recorded in the books of account.

6.5 Custom Duties

APIs 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 is also levied at import stage u/s 148 of the Income Tax Ordinance.

Import duty on medicines range from 0 to 10%. Certain categories such as Oncology (cancer products) have 0% custom duty; however, they do attract advance tax at import stage.

6.6 Taxation

Income Tax

The sale of locally manufactured medicines falls under the Normal Tax Regime (NTR) and taxed at normal statutory rate. Super tax may be levied if the Company fulfills the criteria for the same. Income Tax levied on import of finished medicines or/and Bulk form product fall under Minimum Tax Regime (MTR). In case of exports, the entire export proceeds, whether of locally manufactured medicine or imported ones, fall under Final Tax Regime (FTR). An option to opt out FTR may be exercised.

Finance professionals as a best practice should have a Tax Expert on retainer for advice on tax planning and compliance. Avail tax incentives for **Special Economic Zones, new Start-ups, R&D, priority disease area and exports.** Timely write-offs of obsolete inventory and bad debts. They should timely claim of all withholding taxes and make timely follow up of all tax refunds.

Promotional Spend

The Federal Board of Revenue (FBR) also reviews sales promotional spending by the pharmaceutical companies. As per Drug Rules, sales promotional expenditure is restricted to 5% of turnover. However, as per the Income Tax Ordinance, any promotional expenditure in excess of 10% of turnover of pharmaceutical products shall be disallowed. The Finance Executive should ensure regular monitoring of promotional spend to ensure that it remains within defined limits. Promotional spend is the significant recurring cost of selling and distribution expense.

Promotional giveaway, Conference, symposium, and physician samples are often challenged by Tax authorities as Prizes and Winning under Section 156.

It is important to understand that whenever a new product is launched, the promotional spend in the first few years is always higher than 5% of turnover due to a smaller base and high promotional spend required to create awareness of the brand (among the sales force as well as healthcare professionals). As the product gradually matures, the promotional spend as a % of sales normalizes. The Finance Executive should ensure that the promotional spend on an overall basis is well within the threshold specified by the Drugs Law. Finance professionals should ensure that Strategic Growth Brands and New launches are well funded to achieve targets. They must monitor promotional spending to ensure that it remains within regulatory limits.

Transfer Pricing

This issue is particularly relevant for MNC or Group of pharmaceutical companies; where the local affiliate imports Active Pharmaceutical Ingredients (API) from other group companies.

The Federal Board of Revenue (FBR) has issued notices to many MNCs pharmaceutical companies to assess whether the transfer prices of APIs 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 Normal Tax Regime (NTR).

Due to the importance of the matter, Finance Executives should ensure that the company has adopted a reasonable method of Transfer Pricing and maintained the prescribed documentation to establish the purchase of products from group companies are at arm's length principle.

Prescribed documentation mainly include:

- Local File,
- Master File and
- Country by Country Report (CbCR)

Advance Income Tax

Advance income tax on pharmaceutical products (Only DRAP registered products) is collected at the time of invoicing

- @ 0.1% in case of Dealers/distributor and wholesalers, and
- @0.5% in case of Retailers/Institutions

No advance income tax implication in case pharma product to patient.

Super Tax

In addition to the corporate tax rate of 29%, an additional tax 'Super Tax' is also applicable on the income of the companies, provided the income for the tax year exceeds Rs. 150 million. Super Tax rates ranges b/w 1% to 10%. Most of the industry players are contesting Super Tax legitimacy.

Federal Sales Tax

Pharmaceutical industry has a special tax regime in GST whereby 1% sales tax is paid on sales of manufactured pharmaceutical goods or at the time of import of pharmaceutical product which is full and final discharged in the entire supply chain. No input adjustment is allowed against the above tax. Sales tax on Alternative medicine (which do not fall under Chapter 30 of Customs Act) are mostly charged at input and output stage @ 18%, which is adjustable sales tax.

Provincial Sales Tax

Provincial Sales Tax on toll manufacturing activity has been a disputed issue for some time. However, as per recent alignment in National tax council, the Sindh Revenue board has denounced the right in favour of Federal Sales tax. Now, the FBR is empowered to collect the sales tax on toll manufacturing activity.

6.7 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 honorarium 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. The 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 ensure that the Company has a well-documented policy duly endorsed by Medical and Compliance functions which regulate the permissibility of the nature as well as approval mechanism of payments to HCPs.

6.8 Sales Invoicing, Delivery and Receipt of Collection

Pharmaceutical companies generally sell their medicines to their distributors against advance cash payment. Distributors send cheques/pay orders/demand drafts along with their orders. The amount credited in the company's bank account is confirmed and Sales Orders are processed. On delivery of goods, Delivery Challan and Sales invoices are made in the ERP systems and revenue is recorded. Due to the advance cash model, the Days Sales Outstanding (DSO) in Pharma Industry is generally nil for market sales.

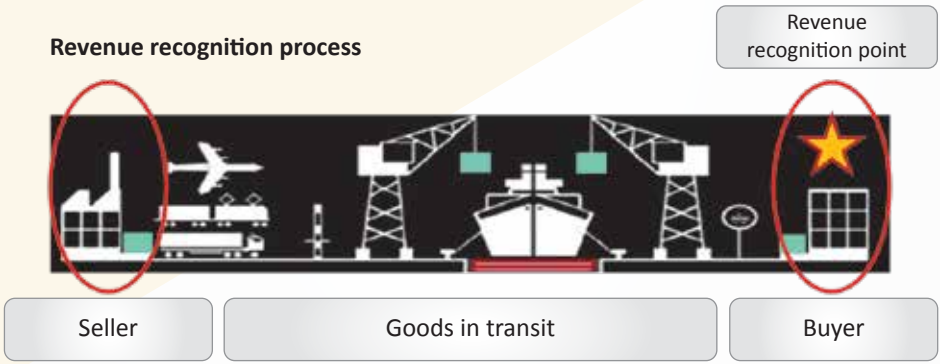
Finance Executive needs to ensure that the revenue recognition policy of the company is aligned with IFRS such that revenue is recognized only when all performance obligations on part of the Company are fulfilled as required by IFRS 15 and control of goods is transferred to the distributors.

In case of centralized distribution model (explained later in serial 16), a Pharmaceutical company recognizes revenue as soon as the medicines are delivered to the national distributor, being the point where control of the goods is 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 control of goods is actually transferred.

Finance Executives should remain vigilant to the fact that revenue recognition criteria are met in order to recognize 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



E-Pharmacies

Recently the sales through E-Pharmacies are also gaining significant importance in Pharma industry. Some companies are directly supplying while most of the companies are supplying to those E-Pharmacies via distributors. Even though sales are still lower in absolute numbers but growing exponentially every year in line with change in public's buying pattern. Few of key E-Pharmacies are; DVAGO, Sehat, Dawaai, Medonline, Tabiyat, Ehad Pharmacy, Hol, and Servaid.

The finance function also plays an important role in supporting other functions within the organization, such as **marketing, sales, supply chain, HR, IT, BD, and R&D** functions. By providing financial analysis and insights, the finance function can help these functions make better decisions that will contribute to the organization's overall success.

7 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.

Brand Name	Manufacturer	Launch year
Panadol	Haleon Pakistan Limited (GSK CH Limited)	1976
Augmentin	GlaxoSmithKline Pakistan Limited	1986
Risek	Getz Pharma (Private) Limited	1996
Brufen	Abbott Laboratories Pakistan Limited	1979
Oxidil	Sami Pharma	2000

Notwithstanding the aforesaid restriction on advertising, public awareness on diseases or their treatment can still be spread through mass media campaigns without mentioning any product/brand name. In certain cases, where a product which was out of production for some time has resumed production/sales, the Company can notify the chemists/wholesalers about its availability through advertisements in newspapers. However, the Company should ensure that advertisements do not include recommendations for the use of the product in any given situation.

In a pharmaceutical company, the Marketing function conducts activities aimed at 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 than above, there can be modest promotional 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, have 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. This expenditure should be reviewed by Medical and internal Compliance. 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'.

7.1 Trade Marketing

Recently, pharmaceutical companies have started to realize the importance of trade marketing. Trade marketing activities in a pharma company typically involves following activities:

- To ensure better access of company's products at pharmacies across the country so that there is no sales loss due to non-availability
- To ensure that the products are suitably placed in pharmacies that ensure good visibility to walk-in customers
- To ensure that trade offers announced by pharma companies (which provide incentives to chemists / retailers to buy Company's products) are executed in a good manner
- To carry out activities for the general benefit of walk-in customers such as diabetes/blood pressure check, weight check etc.
- Increasing the Product visibility and channel activations in case of new or strategic products
- Building capability of pharmacists through training programs, etc.

Trade marketing personnel are in constant coordination with distributors and key pharmacies in their respective areas to ensure that the Company's products are available at all times. Trade marketing may also involve giving out targeted incentives to pharmacies based on the KPIs which address the afore-mentioned objectives.

Finance executive may need to understand the ROI of the expenditure on these activities and should remain vigilant that these activities are conducted within ethical bounds and as permitted by the Drugs Act.

7.2 Market Intelligence and Business Excellence

Market Intelligence

This function is responsible for gathering market / business intelligence via different sources available publicly. Most notably among them is the IQVIA – IQVIA Solutions Pakistan (Pvt) Limited (formerly IMS Health). IQVIA 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 IQVIA to develop their commercial plans and portfolio strategies.

IQVIA 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 IQVIA 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 IQVIA data to benchmark performance in terms of growth, market share and ranking in relevant therapeutic segments.

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.

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.

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.

8 Medical Affairs Department

8.1 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, and 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.

8.2 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 costs 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.

8.3 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.

8.4 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.

8.5 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.

9 Human Resources

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 maximizes 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 labor and employment laws and, when necessary, manage labor relations, including relations with external labor 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.

9.1 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 supported by research and clinical data, and are aligned with the company's strategies to enable them to start contributing towards sales target achievement. Sales force 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 requires 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.

10 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.

10.1 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. It is an iterative process that is constantly being updated as new information becomes available. This ensures that the organization is always prepared to meet demand and avoid unnecessary costs.

Following step-by-step approach is usually undertaken:

- 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'.
- 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.
- 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.
- 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.

11 Procurement

11.1 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 take all forms, ranging from APIs, excipients, to drugs in semi-finished and finished forms. List of Key Molecules of Pharmaceutical industry are:

Molecule	Market Leader	Second Largest
Ceftriaxone	Oxidil (Sami)	PD-Cef (PDH Labs)
Paracetamol	Panadol (Haleon)	Calpol (GSK)
Cefixime	Cefspan (Barrett Hodgson)	Caricef (Sami)
Omeprazole	Risek (Getz)	Ruling (High-Q)
Amoxicillin + Clavulanic Acid	Augmentin (GSK)	Calamox (Bosch)

Pakistan's API [raw material] industry requires policies at the government level that could promote its expansion. Currently, 23 pharmaceutical manufacturers possess the license to manufacture APIs. These firms produce about 15pc of APIs while the remaining 85pc is imported. The global API market was over $190 billion in 2021 and projected to be over $309 billion by 2028. [Global API market]

11.2 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.

11.3 Quality of APIs

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, endeavor to find reliable and cost-effective sources to buy the APIs.

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 should remain cost effective. Therefore, a continuous cost saving effort from procurement function is required to identify and secure cheaper sources of reliable raw material from across the world. The goals assigned to a procurement function include relevant KPIs in this regard.

Today more focus is on process and efficiency improvements and strategic partnership with vendors with long-term service contracts based on agreed price and service levels. These long-term contracts can be useful in situations where there is considerable stability in global prices of raw materials. Finance executive should pay close attention to those products, where the volumes are high and gross margins are low. Even a minor reduction in the prices of raw materials may lead to a big impact in the profitability of the Company.

12 Production

Pharmaceutical products can take any of the following galanic forms such as:

- Tablets & capsules
- Liquids (syrups)
- Creams and ointments
- Injections (ampoules or vials)
- Dry Powder Inhalers etc.

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 whether manufactured locally or imported 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 product 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 Conditioning (HVAC) systems with separate zoning. These are usually dust proof, temperature, and humidity controlled. The manufacturing personnel as well as visitors are required 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 procuring their manufacturing equipment from different sources which may be reliable as well as 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 into setting up a new plant from scratch, location of manufacturing site can be 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.

13 Quality Assurance

Pharmaceutical companies place high importance on their products' 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 batches undergo quality assurance check. 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 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. These instances are technically known as 'Adverse Drug Reactions (ADRs)'. In such cases, DRAP requires that the Company informs, HCPs, pharmacies as well as general public about the details of the product 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.

14 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.

15 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 6-8 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. Whereas in a decentralized model, companies appoint several distributors in different geographical locations. They deliver goods to distributors in their hometowns at the Company's cost whereas the distributors ensure that products are made available at local pharmacies in their towns/cities. 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. 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.

16 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.

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 coordinate effectively with law enforcement agencies to root out the menace.

17 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.

18 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.

"I took a course in ethics, but everything was contradicted by the course I took in accounting."

19 Opportunities in Pharmaceutical Industry

19.1 Market Attractiveness

Pakistan is the fifth most populous country in the world. Pakistan's large population of 225 million with sub optimal access to quality medicines, highly attractive industry growth rate of ~15% (last 5 years) and high disease burden offers growth opportunities to pharma companies.

Demand patterns are also shifting, with increased life expectancy, literacy rates, incomes and better awareness of health-related issues, which unfolds a greater demand for pharmaceutical products in Pakistan.

19.2 Health care insurance in Pakistan

Pakistan's pharmaceutical market is primarily out-of-pocket market, which means that majority of the common masses spend on their medicines from their own pocket. Government and public institutions provide medical benefits to their employees and their families. In the corporate world, some organizations that provide insurance cover to their employees only offer hospitalization cover, very few organizations offer the OPD cover as well.

Pakistan has a huge potential for a national health insurance as it has a large population. Development in the healthcare insurance can result in a surge in demand for quality pharmaceutical products as well as other medical care (including hospitals, diagnostic centers, maternity homes, blood banks etc.).

20 Challenges of Pharmaceutical Industry

The industry is facing multiple challenges including intellectual property rights and uniformity in quality. Some of the key challenges pharma industry is facing currently are;

20.1 Regulatory Price Controls

Being largely import dependent, Pharma industry is negatively impacted by continuous devaluation of Pak Rupee together with high inflation and utility costs. In such an environment price control hurts margin and industry attractiveness. Low margins make certain medicines not viable to market and pharma companies stop making them leading to shortages of essential medicines and causing distress to patients. Several multinational companies have exited the country because of low margins. The introduction of CPI indexed pricing was welcomed by the industry, however, it has its own limitations such as maximum capping and no consideration of devaluation of Pakistan Rupee (PKR) which is in itself one of the major cost escalation factors.

Pricing undoubtedly is politically sensitive and most burning issue with DRAP. There is no country except Pakistan that control pricing of all drugs from essential to non-essentials. Neighboring India and China have liberalized their drug pricing and only controlled pricing for essentials drugs.

20.2 Delay in New Medicine Registration

It takes significantly longer time to obtain registration for new research-based products. Slow regulatory process causes delay in registration, adversely affecting the patient's access to more effective new treatment. Delay also impacts profitability due to Rupee erosion increasing import costs, companies sometimes do not launch those products. Patients end-up paying higher price for those medicines coming through the gray channel. Price adjustment for new medicine for increase in import cost would ensure a fair margin and incentive to introduce new research-based medicine that will be beneficial for patients.

20.3 Heavy reliance on Imports

Over 90% of the raw material used in making of drug is imported. Only 12% API are produced in Pakistan. Specialized finished dosage form and biologicals such as Vaccines, oncology etc. continue to be imported. The current practice of importing 95% of the raw material, compounding active ingredients with excipients, coating the pills, and packaging the drugs cannot continue to be the long-term goal of the sector.

Access to low-priced APIs is critical for any pharmaceutical sector based on drug formulation. The sector is weakly developed in Pakistan, with 6-7 local manufacturers producing a little over 30 APIs. Developed countries have shifted focus to large molecules, called biologics. This creates opportunities for developing countries such as Pakistan to fill the gap for production of cost-efficient small molecule therapeutics. Beside heavy import dependency, active ingredients from neighboring countries such as China and India also posted significant concentration risk. Reliance of local pharmaceutical industry on India is estimated at 50% - 60%. The government should incentivize investment in manufacturing of local material specifically API to protect industry from geopolitical impact and conserving foreign exchange. Investing in basic manufacturing of active ingredients will create employment opportunities and ensure less dependency on imports.


70%

GLOSSARY

ADR	Adverse Drug Reaction
API	Active Pharmaceutical Ingredient
BD&L	Business Development & Licensing
CAGR	Cumulative Average Growth Rate
CPA	Call Plan Adherence
CRO	Clinical Research Organization
CSR	Corporate Social Responsibility
DRAP	Drug Regulatory Authority of Pakistan
ERP	Enterprise Resource Planning
HCO	Healthcare Organizations
HCP	Healthcare Professional
HOTC	Health Over the Counter
HSE	Health, Safety & Environment
KPI	Key Performance Indicators
LTI	Lost Time Injury
MAT	Moving Annual Turnover
NHSR&C	National Health Services Regulations & Coordination
OPD	Out Patient Departs
OTC	Over the Counter
PV	Pharmacovigilance
RTD	Round Table Discussion
R&D	Research & Development
S&OP	Sales & Operational Planning
SFE	Sales Force Excellence

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Disclaimer:

This is the updated version of first industry-specific guideline issued by the Professional Accountants in Business (PAIB) Committee of the Institute of Chartered Accountants of Pakistan. The objective is to provide guidance and a head start to fresh Chartered Accountants willing to join the pharmaceutical industry. The information contained in the guideline is based on the professional experience of the author and reviewers as well as the information collected from other professionals in their respective areas of expertise within the pharmaceutical industry.

Although due diligence has been exercised in compiling information, the practices may vary across companies operating in the sector. The Institute does not accept any responsibility for any loss to any person arising out of acting on the information contained in the guideline. The readers are requested to inform the PAIB Committee of the Institute about errors/omissions, if any, in the guideline for correction in future editions.

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