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Product Development & Commercialization in Pharmaceutical Industry

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Abstract

This study examines the importance & imperative parameters in order to bring a new product in a Pakistani pharmaceutical Industry/market. Although, there is good quality international literature available for the under examine topic, but it carries the perspective of developed countries, where things are very different from a developing country like Pakistan. The study identified that Pharmaceutical products can be classified under two main categories: Prescription products and OTC products. The study concluded that a company's product mix has four important dimensions: width, length, depth and consistency. Product mix *width* refers to the different product lines a company carries; Product mix *length* refers to the number of items a company carries in its product lines. Product mix *depth* refers to the number of versions each product offers. The new product development process in Pakistan's pharmaceutical industry can be outlined as 1) Molecule identification, 2) Molecule screening, 3) Sourcing of raw material, 4) Pilot batch manufacturing, 5) Marketing strategy development, 6) Test marketing/Clinical trial/user trial, and 7) Commercialization. We can attempt to develop a concept on similar lines for pharmaceutical products in different characteristics like 1) Quality Level, 2) Feature of a product, 3) Dosage forms 4) A brand name and 5) Packaging of products.

Keywords: Products Mix Depth; Product Mix Length; Product Mix Width; Molecule Screening; Molecule Identification; Pilot Batch.

1. Introduction

Pharmaceutical industry is one of the most organized industries in Pakistan, employing a large number of professionals in all areas of operations. The industry currently comprise of more than 900 companies, out of which around 500 or so can be termed as "Active Companies" involved in manufacturing & marketing of pharmaceutical products ^[1].

1.1 Defining Product

From the point of view of pharmaceutical marketing, a product is any tangible thing, which can be used to treat a medical ailment diagnosed in a human body. Once we have defined the product, we can clearly see a difference. In general marketing terms, a product can even be for satisfying a psychological need with no tangible benefit whatsoever. However, in pharmaceutical terms, a product will only be termed as one if it helps in curing a disease or at least help in curing or improving the condition of a patient ^[2].

1.2 Levels of Product

As in general marketing terms, a pharmaceutical product can also be thought of at three levels:

- a) Core product
- b) Actual product
- c) Augmented product

In general marketing, the core product is the basic benefit that the consumers seek when they buy a product ^[3]. In pharmaceutical scenario, this will be the disease treating characteristics of a product, which will be considered the core product. The actual product in general marketing terms suggests five characteristics that a product can have; a quality level, features, design, a brand name, and packaging ^[4]. We can attempt to develop a concept on similar lines for pharmaceutical products in the following manner:

1.3 A quality level

The level to which a product conforms to the required standard not only in terms of its profile, but also in terms of its ability to cure a disease, and to remain effective for the stipulated period of time which is also called shelf-life of a product.

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1.4 Features

For pharmaceutical product, this will mean the pharmacological profile of a product; what it does when it goes into a human body. This includes the rate of absorption of drug into the blood stream, when the action actually starts; its action against the disease cause, its side effects, and finally its elimination from the body. All drugs have their standard profile, which act as a standard when a product is evaluated in terms of its quality level^[5]. This effectively means that unlike general products, the quality levels in pharmaceutical products are very objective and are not dependent on individual perceptions.

1.5 Dosage Form

Dosage Form will replace design in case of pharmaceutical products. A product can be in the form of capsules, tablets, syrup, injection or ointment. This is a major determinant factor when a product is chosen for use in treating a patient^[6]. For example, a tablet might be preferred for an adult patient, syrup for children, an injection when quick action is required, and an ointment for skin diseases or localized pain.

1.6 A brand name

Unlike consumer products, where every product invariably carries a brand name, pharmaceutical may or may not be branded. Some companies may decide to market their products as under a generic name, instead of giving it a brand name. This often happens when the company adopts a marketing strategy under which the product will not be promoted actively, and instead be sold to institutions, which purchase products by generics and not brands^[7, 8]. For example, a hospital may call for offers for supply of paracetamol tablets, which are available both under generic name and brand names like Panadol and Calpol.

Most of marketing oriented companies, though prefer to market their products under brand names, which only allows them to position and promote their products effectively^[9]. It is interesting to note that over the period of time, products do become synonymous with their generic names like Brufen for Ibuprofen, Voltaren for Diclofenac Sodium, Panadol for Paracetamol and so on and so forth. Each of these generics has dozens of brands available, but not all become readily recognizable with their respective generics.

1.7 Packaging

Perhaps in no other product category does the packaging play as significant a role as it does in pharmaceutical products. It goes beyond just acting as outer container, and it has to ensure the conditions required for stability of the medicine inside. A company cannot just select the packaging material arbitrarily, but it has to consider if the packaging selected conforms to the standards required for a particular product profile or not^[10]. For example, there are products, which can be kept stable inside simple aluminum foil, but some need specialized double-sided aluminum foil, or PVC, or PVDC, or even airtight bottle. The efficacy of a product is dependent on its stability inside the packaging. Any negligence can result in deterioration in product quality and efficacy^[11].

The second most important function performed by packaging is to contain required information regarding the product profile as prescribed by the regulatory bodies. It does not only carry brief instruction on outer & inner containers, but also carries a leaflet, which contains detailed prescribing information for the products^[12]. Besides that, pharmaceutical products are

required to carry dates of manufacturing & expiry and batch numbers for future reference, which are also mentioned on the outer carton as well as inner container like a strip, blister, bottle, ampoule or tube. There are also some special requirements for labeling like the brand name and generic name should be equally prominent, which has to be strictly adhered to^[13]. However, once a company conforms to all these requirements, they can use the packaging for product differentiation through color schemes and graphics if they want.

In a third world country like Pakistan, a patient seldom buys a full pack of a product. Retailers normally sell individual tablets, capsules, and ampoules due to affordability issue. Though, this is not applicable in case of liquids, injections and ointments where a patient obviously has to buy a full pack, companies pay less attention to beautifying their packaging and find it just enough to fulfill the regulatory and product stability requirements as there is nothing like off-the-shelf impulse buying in medicines^[14, 15].

Product augmentation has emerging as the latest trend in pharmaceutical marketing. Companies support their products through different methods^[16]. Some companies like MSD and Novartis have also started free home-delivery and discounts on repeat purchases of medicines^[17].

2. Materials and Method

2.1 Product Classifications

Pharmaceutical products can be classified under two main categories. The criterion for division is whether a product is marketed to the medical profession or directly to the consumers? The first category products are called "Prescription Products", and those marketed directly to consumers is called "Over-The-Counter", or OTC products as they are commonly referred to^[18].

2.1.1 Prescription Products

Selecting a medicine involves host of factors to be considered like patient profile, disease history, drug tolerance, possibility of allergic reactions, duration of therapy, side-effects profile, and of course quality and price of the product. Obviously, a common person in no way can arrive at a right decision as he lacks the technical knowledge. A wrong decision is not affordable as the stakes are as high as the life of the patient. For this reason, most of the medicines are categorized under prescription products, and can be sold only through prescription of a registered medical practitioner^[19].

However, in reality things are different in developing countries like Pakistan. Here, one can buy any medicine directly from a chemist without a prescription quite conveniently. The irony is that a country where literacy rate is amongst the lowest in the world, this law of prescription drugs is not being applied in spirit^[20]. This results in continuous danger of deaths and disease complications due to self-medication, which people usually indulge into in order to save the consultation fee of the doctors.

2.1.2 OTC Products

These may be termed as low-risk medicines and so consumers are allowed to purchase them over-the-counter. Vitamins, nutritional products, cough syrups and simple painkillers all fall under this category.

In developed countries, pharmaceutical companies are even allowed to promote their OTC formulations directly to public using mass media, but not in Pakistan. The Ministry of Health,

under the pretext of low literacy rate, which may lead to consumption of wrong medicine, or in a wrong manner, keeps a ban on promotion of OTC medicines directly to masses [21]. However, some products like Panadol, Volteran, Ponstan, Actifed, etc. have eventually become OTC drugs in Pakistan by virtue of their long standing in the markets and mass awareness about their actions.

It must be clear from the above discussion, that the differentiation between prescriptions and OTC medicines in Pakistan is a gray area. Unless the regulatory bodies come up with a viable plan to strictly enforce the drug laws, we may continue to have this confused state of affairs [4].

2.2 Product Line Decisions

A product line in context of pharmaceutical marketing is a group of products, which deal with the same disease category, or is promoted to the same segment of the medical profession. Merck Sharp and Dhome (MSD) have a range of antihypertensive drugs, with some differences in their profile, action and prices. They have brands called Renitec, Cozaar & Hizaar, all performing the same function, i.e. lowering the blood pressure through different modes of action and are priced at different levels [22].

As in general products categories, product line decisions are also critical in pharmaceutical marketing, and the most critical one is deciding upon the length of product line. A company has to decide on having a certain number of products in one product line. The aim is to have a product line, which offers enough choices for the doctors while keeping the length of product line manageable and profitable [23]. A company may increase the product line length either by stretching it upwards and/or downwards, or through product line filling.

Suppose, a company has a drug indicated in hypertension, which is an old molecule and is priced at a low level. The company may decide to launch a newer version of the same drug category at a higher price, which will be termed as upward line stretching. On the other hand, a company might be having a high-end product and may decide to take the share of the low-end market as well by launching a basic low price molecule, which will be termed as downwards line stretching. A company may even go for a both-side stretching if it feels appropriate to have a long product line. Putting products in between low and high-end products is termed as product line filling [4, 5].

2.3 Product Mix Decisions

A product mix or product assortment consists of all the product lines and items that a company has to offer. A company may have a range of antibiotics, a number of painkillers, a few cough syrups and some other medicines in different categories. All of these put together will be called a product mix.

A company's product mix has four important dimensions: width, length, depth and consistency. Product mix *width* refers to the different product lines a company carries; e.g. SmithKline & Beecham has a wide product mix comprising antibiotics, painkillers, multivitamins, skin treatments, and antiulcerants [24]. Product mix *length* refers to the number of items a company carries in its product lines. SKB has Fortum, Augmentin, Ampiclox & Ampicillin in its antibiotics category. Product mix *depth* refers to the number of versions each product offers. SKB's antibiotic brand Fortum comes in 250 mg, 500 mg and 1 gram, and similarly the other brands are also available in different strengths.

Finally, the consistency of the product mix refers to how

closely related different product lines are. In case of SKB, it is an inconsistent product line, but the company successfully manages it due to immense resources and elaborate infrastructure. However, a company lacking in these two areas better keep a consistent product mix to ensure effective management [25].

3. Discussions

3.1 New-Product Development

New product development in pharmaceutical industry is a much more complex process as compared to other industries. The cost of development, the R&D capability, registration with the ministry of health, sourcing of raw material, all make this a daunting task for any marketing team.

One of the most widely used methods of acquiring new products, acquisition, is not applicable to local pharmaceutical companies in developing countries. The reason is that all multinational companies of some stature already have their local offices in almost every developing country, and they prefer to market their products through them instead of joining hands with local partners. There are some examples of an arrangement between a local company and an international company, but they comprise a very minute portion of the total industry turnover [4, 29]. This leaves the companies with no other option but to develop branded generics for marketing. At present, there is no possibility of development of original products given the size and resources available to local industry. The new product development process in Pakistan's pharmaceutical industry can be outlined as follows:

- Molecule identification.
- Molecule screening.
- Sourcing of raw material.
- Pilot batch manufacturing.
- Marketing strategy development.
- Test marketing/Clinical trial/user trial.
- Commercialization.

Now we will go through each step to develop a clear understanding of the new product development process.

3.1.1 Molecule Identification

Pharmaceutical products are basically a dosage form (tablet, capsule, syrup, injection or ointment) containing an active ingredient, which is responsible for the therapeutic effect, or the core benefit expected from the product.

The first and foremost step in new product development is the identification of molecules; i.e. the active ingredient that a company wishes to brand and launch [26]. Keeping under consideration the marketing focus of the company, resources and profile, several molecules can be of interest, which are short-listed, and then the real game begins of screening the molecules to arrive at the final one or more.

3.1.2 Molecule Screening

This is the most important step a marketing team has to go through while deciding upon a new product. There are several factors to be taken into account while screening a molecule to find its merits and demerits. We will discuss some important ones here:

a. Company's Objectives

Lot depends on what a company needs and wants to achieve. Is it aiming for entering into a new product category? Is it aiming to strengthen an existing product line? Is it aiming for

maximizing market share? Is it aiming to build volumes? Is it focusing on high profitability? Whatever a company decides, will affect directly on a new product decision. A company wishing to enter a new product category may wish to select a comparatively newer molecule in order to make a positive impact on the medical profession, which otherwise doesn't give much importance to the companies who come in with brands with a molecule which several other companies are marketing. However, in case a company wants to strengthen one of its existing portfolios, even an older molecule may very well compliment the existing range [27].

b. Patent Status

Pharmaceutical raw material, unlike other industries has to be procured very carefully. Whereas, in other industries the concerns might revolve around quality, price and availability, in pharmaceutical products, there are a host of other factors to be analyzed. One of the top issues to address is the "Patent Status" of the molecule. Patent is the protection granted to a company for a certain period of time, during which it can recover the heavy expenditure incurred in R&D. Patents are normally granted for a period of 16 years from the date of application [28].

Patent is one of the most crucial matters for a third world country like Pakistan. Multinational companies try to keep the price of the products in line with International markets, which make those products almost unaffordable for the local masses. However, on the other hand, the patent law prevents other local companies to brand that molecule. Until recently, the patent law was not being implemented in Pakistan in letter & spirit, but now with implementation of WTO & TRIPS approaching, the stance of regulatory bodies is becoming more & more firm in protecting the interest of patent holder [27, 28].

However, realistically speaking, a company in a country like Pakistan must not rule out patented products just because of their legal status. They should consider if the company holding the patent is actively represented in Pakistan? Has that company ever taken a legal action against any other company? What is the validity period left for the patent? This makes any gray areas identified and a company might still have the opportunity to launch a product and taking a calculated risk, which may pay big dividends if it can get away with it [4, 29].

c. Special Requirements

Once, the company is clear about the patent, it has looked into manufacturing requirements, and if the facilities are available or not. Pharmaceutical ingredients may require special facilities like control humidity/temperature/moisture, storage conditions, manufacturing processes, packaging material etc. This might either not being currently used by the company, or may prove to be too costly if arranged for just one product.

d. Market Size

Pharmaceutical marketers have one major advantage; and that is availability of authentic market data, compiled and distributed at cost by International Marketing Statistics (IMS), a Swiss company. This allows them to know accurately the market size, growth rates and product performances. This becomes the foundation stone for preparing a reliable market forecast, and to judge the attractiveness of target segment(s).

e. Competitive position

The company then looks into the competitive environment, and chances of success in view of the strengths & weaknesses, which it possesses. The number of brands of the same molecule

in the market, number of players, acceptance of the molecule amongst the medical practitioners, the future prospects and so on

3.1.3 Sourcing of raw material

One unique characteristic of pharmaceutical product is the need to conform to standard parameters all the time. Every drug has its standard characteristics like dissolution time, shelf life, physical appearance, and stability in form etc. In order to maintain all these, a company tends not to switch sources without performing a pilot batch study, for a certain period of time (usually 3-6 months) in order to make sure that the quality of product is up to the mark. This is an important matter, as a company needs to be extra careful to ensure that the company they are planning to buy the raw material will ensure consistency of quality, and meets their demand regularly. Besides conducting pilot batch testing, most of the companies also have an elaborate vendor evaluation program [30].

3.1.4 Pilot Batch Manufacturing

Pilot batch manufacturing or stability study is a sort of simulation exercise in which a trial batch is manufactured while maintaining the real life conditions. The raw material & packaging material, as well as the manufacturing equipment are the same, which will be then used in commercial production.

Once the batch is manufactured, it is kept under different conditions like room temperature, high temperature, high humidity, sunlight etc. for 3-6 months, and a test is performed each month to see the stability of a product. If the outcome matches with what the standard profile suggests, the product is approved for manufacturing [31].

3.1.5 Marketing Strategy Development

Parallel to trial batch testing, the company starts working on its marketing plan. A typical marketing plan covers the following areas with reference to pharmaceutical products:

- a. **Market overview:** Size of the segment, profile of the segment, growth rates, prospects.
- b. **SWOT Analysis:** Company's strength & weaknesses, environmental threats & opportunities.
- c. **Competition analysis:** Number of players, market shares, growth rates, SWOT.
- d. **Product profile:** Classification, molecule structure, mode of action, advantages/disadvantages with respect to segment, dosage form, dosage regimen.
- e. **Clinical Profile:** Indications, efficacy, side effects, precautions, other pharmacological aspects, clinical reports etc.
- f. **Product positioning:** The basic stance of the product. Usually based on a USP.
- g. **Marketing/Sales Objectives:** Qualitative & quantitative objectives.
- h. **Promotional Strategy:** Message(s) to be communicated, material to be used, sampling to be done, other activities like clinical trials, user studies, seminars, symposia, advertisements etc.

- i. Sales Strategy:** Areas/segments to be covered, doctors to be visited, indications/diseases to be focused according to different target segments etc. Distribution strategy also comes under this head.

The above, coupled with financial become the basic control document for the marketing team.

3.1.6 Test marketing/Clinical trial/User trial

Depending upon the nature of product, a company may decide to go for a clinical trial or user study to enhance confidence of the medical profession on the efficacy and/or safety of the product. It can be fully protocol-controlled trial, or just a user study where doctor can judge the results obtained through the product by using the free samples provided to him/her. The results, if come out to be positive, become a very important promotional tool for the company. The trial can be either pre-launch or post-launch depending upon the situation and nature of product [32].

3.1.7 Commercialization

Commercialization starts with sending the stock to distributors. The sales team plans the promotional activities in view of the availability of the product, and start visiting the doctors, in whose vicinity the product has reached the chemist shelves.

3.2 Product Life-Cycle Strategies

Product life cycle is the course of product’s sales and profits over its lifetime. It involves five distinct stages:

i) Product Development: The process of finding & developing a new product.

ii) Introduction: Period of slow sales growth as the product is just being introduced to the doctors.

iii) Growth: Period of rapid market acceptance and increasing profits.

iv) Maturity: Slowdown in growth, because a product is already being prescribed by most of the target audience.

v) Decline: Period when sales fall off and profit drops. The basic characteristics of all these stages are similar to other products. However, there are marked differences in reason of shifting from one stage to another, and strategies that can be used to manage the product through its life cycle [33].

Following is a chart showing strategies during different stages:

Table 1: Product Life Cycle in Pharmaceutical Industry

Strategies/Stages	Introduction	Growth	Maturity	Decline
Product	Depending on the category, a company may decide to start with one or more strength/dosage forms.	Try to come up with new dosage forms/strengths/features like flavors or packaging.	Maintain the complete range and try to focus on the most profitable one to gain maximum advantage. Also identify and explore new indication/segments.	Wait as long as the product is beneficial commercially and then withdraw.
Price	Whatever approved by the regulatory bodies. A company may choose to launch the product at lower than approved price, but then that priced cannot be increased.	Same as fixed at the time of launch.	Same as fixed at launch. Some companies may choose to reduce prices to gain/maintain market-share.	Same as fixed at launch. Some companies may choose to reduce prices to counter erosion of market-share.
Place	Selective	Selective (for prescription products) Extensive (for OTC products)	Selective (for prescription products) Extensive (for OTC products)	Selective
Promotion	Heavy sampling for trial generation, focus on opinion leaders/consultants, elaborate literatures/brochures, user/clinical trials, seminars/symposia/panel discussions, advertising in medical press, expensive gifts, sponsorships. Direct mailers and teasers may also be used at this stage.	Moderate sampling, focus on coverage and call-rate, shift from consultants to general physicians, moderate advertising, reminder brochures, reminder gifts, sponsorships.	Sampling mostly on demand, focus on loyal prescribers, reminder brochures, and reminder gifts.	Selective and focused promotion to retain market share as long as possible.

Source: Adopted from Kotler & Armstrong [34]

4. Conclusion

This study concluded that things are changing at lightening pace in pharmaceutical marketing, as in all other disciplines. The scenario in Pakistan is very dynamic and evolving rapidly. Things have really changed if we considered the local pharmaceutical industry. The study identified that Pharmaceutical products can be classified under two main

categories: Prescription products and OTC products. The criterion for division is whether a product is marketed to the medical profession or directly to the consumers in Pakistan. The study further concluded that a company’s product mix has four important dimensions: width, length, depth and consistency. Product mix *width* refers to the different product lines a company carries; Product mix *length* refers to the

number of items a company carries in its product lines. Product mix *depth* refers to the number of versions each product offers. The new product development process in Pakistan's pharmaceutical industry can be outlined as 1) Molecule identification, 2) Molecule screening, 3) Sourcing of raw material, 4) Pilot batch manufacturing, 5) Marketing strategy development, 6) Test marketing/Clinical trial/user trial, and 7) Commercialization. We can attempt to develop a concept on similar lines for pharmaceutical products in different characteristics like 1) Quality Level, 2) Feature of a product, 3) Dosage forms 4) A brand name and 5) Packaging of products.

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