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## Challenges Faced by MNCs in Pakistan Due to Unethical Practice of National Pharmaceuticals Industry

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### Review Article

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#### ABSTRACT

The aim of this study is to give a broad overview of the main challenges faces by Multinational companies (MNCs) of pharmaceuticals in Pakistan. The aim of study is also to investigate ethical Challenges facing by pharmaceuticals companies in Pakistan. In Pakistan market pharmaceutical companies influence the physicians' or professionals and sometime force them to prescribe their products by all means. In Pakistan, there is no strong mechanism to monitor the drug promotional movement by pharmaceutical industry although the fact is that there is sufficient evidence that irrational pharmacotherapy is gradually more encountered even in the urban countries due to unethical practices of pharmaceutical promotion. These papers focuses on the Multinational Pharmaceutical industry and have discussed the changes of last 10 years because of decreased economic status, costly healthcare facilities, illegal and un-ethical practices and off course because of low quality products. Some major challenges facing by complex MNCs Pharmaceutical business are focused and discussed in this article. This include the unethical practice of general physicians, decline in the discovery, approval and marketing of new chemical entities (NCE) or drugs, competition from generics drugs, low quality products, overburden on regulatory authorities in Pakistan, regulatory pressures, political influence on regulatory authorities, counterfeit drugs and raw material source. We have also discussed in this article some local and MNCs brand quality, and we found that MNCs are meeting quality parameters. There is strong proof that associations between local industry and physicians influence the prescribing behaviour along with clinical decision making.

#### INTRODUCTION

Pakistan's economy; from few years have suffered more because of the terrorist attacks and also due to the terrible economic conditions. Furthermore, domestic inflation, decrease Pakistani currency rate also contribute towards the terrific Pakistani economic situation. Government is trying to improve the current situation but it requires broad management and skills to come out of this phase. In order to review the Pakistan Pharmaceutical market we must look at the Pharmaceutical market on global level. In 2008-2009 the Pharmaceutical market of entire world is about 650 billion US\$, with annual growth rate of 8%. In this manner, the growth rate may increase up to 1.1 trillion US\$ up to 2015. Japan, USA and EU thus governed the value of 12%, 48% and 28% respectively while 20% of pharmaceutical market is governed by rest of the world.

However Pakistan Pharmaceutical market is very uniform and challenging. In Pakistan 400 manufacturing companies are there from total of 750 Pharmaceutical companies. But still Pakistan Pharmaceutical companies are facing tough time because of inflation and devaluation of Pakistan rupees. However today picture has been changed totally. Pakistan Pharmaceutical manufacturing was under MNCs in early nineties and products according to GMP and quality control standards were produced. But now criteria have been changed totally. During the last 16-years only 25 MNCs units are producing the quality drugs but even with challenges. Today, the ratio of MNCs and national/local companies is 2:3. Pakistan Pharmaceutical market is earning 1.64 billion US\$ annually with 10% growth rate greater than the global growth rate. Today 25% need is fulfilled by import while 75% need is

fulfilled by local companies. China, Europe, North America and India are the major countries from which raw material are being imported. But almost all the raw materials are imported from China, India, Europe, North America and other countries, but most of the local companies import their raw material from India which is not according to specification. Because Indian raw material has low cost due to these local investors prefer Indian raw material. However 20% import is from Switzerland according to the data of 2010-015 <sup>[1-3]</sup>.

In Pakistan, GlaxoSmithKline (GSK) comes first in the list of MNCs, with 8.92% growth rate and 11.60% market share. Getz Pharmaceutical (Pvt.) Ltd comes first in national pharmaceutical list with 3.75% market share and >70% growth rate. Another national pharmaceutical company Sami Pharmaceutical (Pvt.) Ltd is also at the top of the list with 2.78% market share. But some national industries don't follow ethics, they provide personalized gifts, family foreign tours and many other things, due to this physician always prescribe their medicine

In Pakistan, the regulatory and representative body for multinational companies (MNCs) is Pharma Bureau which undergoes drugs registration and clears increasing backlog. In the medicinal market a gap of \$20 million will be created if any member of Pharma Bureau exits the Pakistan along with 1,000 households will be affected and also quality products will be compromised. Johnson & Johnson exits Pakistan as their sutures manufacturing unit was shut down and now the products are being imported at increased price rate from Dubai. All of these cause unemployment, investment loss and off course increase in the import charges.

MNC's invest \$0.5b during previous eight years to maintain Current Good Manufacturing Practices (CGMP) standards. This is very difficult to maintain cGMP for pharmaceutical industries. Today MNCs invests about \$3.5 million per year to maintain CGMP practices <sup>[4-7]</sup>. In Pakistan the largest employer of graduate students is MNCs as these industries provide livelihoods to 30,000 people directly and 300,000 people indirectly approximately.

In 2015, Revenue generated by MNCs was \$1.2 billion and tax of \$160 million. Many innovative and novel therapies for non-communicable diseases (cancer and kidney failure) were introduced by MNCs. Although MNCs in Pakistani market faces problems and tough circumstances but still they ensures the availability of quality control products at low price e.g., in Pakistan Augmentin 625 mg is available for PKR.20 against £1.51 in UK and PKR.66 in India, while Humulin insulin 70/30 is available for PKR.498 in Pakistan against PKR.877 in Bangladesh and PKR.617 in India. MNCs always delivered quality drugs which totally meet all pharmacopeial test not only few one. National pharmaceutical industries do not produce biological products still. MNCs are here to provide these lifesaving products.

Many MNC's are winding up their business from Pakistan like MSD (Merck Sharp & Dohme) has sold the company to a local pharmaceutical OBS (Organon Biosciences) <sup>[8]</sup>. The reason behind this scenario is the same discussed before like devaluation of Pakistani rupees etc. and thus now there are only 7 MNCs in Pakistan as compared to ten years before as they were 38.

### **Challenges to the MNCs pharmaceutical industry**

Although Pakistan pharmaceutical market is growing at a steady rate but still MNCs are facing certain challenges which are summarized as follows:

- In Pakistan, there is total control of government on product prices
- Increase budget by importing raw material
- Following the cGMP and produce quality products, majorly involve all quality control test.
- Use of quality inactive ingredients, not only active raw material.
- Devaluation of the Pakistani currency in the world.
- Less profit rate.
- Increasing manpower and energy cost.
- High expenditure on research and development but still no research was conducted on newly emerging diseases

### **Limited approval of new chemical entities**

During the process of drug discovery the discovered compounds are known as New Chemical Entities (NCEs). MNCs spend lot of money on research and produce new dosage form which is available in other countries, but Pakistani regulatory departments are not willing to register these new dosage form.

## Increased generic competition

For the multinational Pharmaceutical companies generic drugs are the big challenge. It requires huge investment and years by Large Pharmaceutical industries in order to launch a product. According to Congressional Budget Office (CBO) the estimated cost was \$137 million dollars which has been increased to \$446 million dollars in 1990. The benefits were taken by MNCs but by affecting their patent and then they were expired. The generic drug manufacturers are able to lower the Pharma profit margin within 6 months by producing lower cost products and also by producing their alternatives. In Pakistan national pharmaceuticals companies do not spend any penny for research and development even there is no data of bioequivalence is available from Pakistani national pharmaceutical companies.

## Regulatory changes and political impact

There is need of proper regulation and improvement in regulatory processes of Pakistan Pharmaceutical industry as observed from the current economic slump of 2010–2015 in order to satisfy the stakeholders and to ensure the investments and profit ratio i.e. the profit is in accordance with the cost of products, services and insurance. This strategy actually forces the Pharmaceutical companies to reconstruct their cost structure policy because government, insurance companies and public want less expenditure on healthcare. Institution order for medicine is much politicized, there is no concern with patients' health and people want to make money by all illegal means. This is very difficult to get new registration of product in Pakistan; in some cases lifesaving products is not easily available or available in high cost. Sofosbuvir is new miracle product, but that was available at very high cost in Pakistan, only few national companies have charge to deal this.

## Major difference of quality between national companies and MNCs

We have taken Diclofenac sodium injection five different companies. One brand of MNC and other four were local. We have performed all B.P tests, but found only MNCs brand according to B.P specifications. Quality does not mean assay of the products, it also involves other test like impurities found in products. There is no any data available in national companies regarding Pharmacovigilance and R&D.

## Drug promotion with qualified persons

All employees in MNCs which involved in drug promotion are qualified and pharmacists, so they are getting more pay. Budget of MNCs increase due to several quality works. These companies also generating data concerning Pharmacovigilance in Pakistan.

## Counterfeit drugs

Intellectual Property (IP) Laws protect against Intellectual Property Rights (IPR) infringements. IPR violations are a serious cost to any research based pharmaceutical industry; it can also lead to issues such as counterfeiting and production of sub-standard drugs. Intellectual Property Rights of a researched molecule are protected by the patent. This patent has to be respected in order for innovative companies to keep coming up with lifesaving drugs. In Pakistan, both IPR and Data Exclusivity are relatively newer concepts but with the establishment of a robust IPR regime and the Intellectual Property Office of Pakistan, it is hoped that IPR infringements will be addressed in a more serious manner. Pfizer actively engages with the IPO and other enforcement agencies to advocate and lobby for a broader implementation of IPR laws and have entered into various industry-wide partnerships for training and capacity building of the officials (Tables 1 and 2).

**Table 1.** Comparison of growth in Pakistan and India.

Description	Pakistan	India
Total Pharma market	\$2.1b	\$21b
Growth rate	15%	20%
International Racking Value wise	45	13
Pharma companies	600	25000
FDA approved plant	none	523
Pharmaceuticals export	\$180m	\$15.5b
Raw material supply	30%	70%

**Table 2.** Top 10 Pharma companies in Pakistan.

1	GlaxoSmithKline
2	Abbott
3	Getz
4	Sami
5	Novartis Pharma
6	Sonafi-Aventis
7	Searle
8	Ferozsons
9	Servier pharma
10	Macter

No one national company is FDA approved, so in Pakistan not quality products are selling because of unethical prescription of physician. These companies don't spend money on R&D, or not form any new dosage form or even any international publication.

#### **Raw material source**

Mostly raw material purchased by national pharmaceutical companies from Asian countries, Asian countries has quality issues and material is not prepared in proper way. Excipients are inert materials which are combined with active substances to create a complete dosage form. Excipients always affect the rate of dissolution, absorption, metabolism and distribution in humans or animals. In Pakistan national pharmaceuticals companies have less concern with quality excipients. Melamine which is a toxic chemical was found in children's milk powder in 2008 and thus cause death of 6 children while about 300,000 children were hospitalized. In 2002, China and also in many other countries hundreds of people were expired due to slow reporting on outbreak of Sars. In Asian countries there are many issues regarding product safety as in one scandal Police have arrested about 37 people for sale of vaccines illegally. According to Xinhua news service current report, three pharmaceutical companies might have been involved in illegal sales of drugs, expired drugs and inappropriate storage of vaccines.

#### **Some drug makers send low-quality meds to Africa deliberately**

Two different antibiotics and tuberculosis drugs were taken that were manufactured in Asian country and then exported in Africa and other low economic countries of the world. Samples were analyzed and it was observed by the researches that these were sub-standard drugs. 17.5% rifampicin samples were substandard when these were purchased from Africa. And thus it showed that 80% active therapeutic ingredient were there in Africa <sup>[9]</sup>.

### **DISCUSSION**

In this article we emphasizes on challenges face by MNCs in Pakistan. MNCs always play important role in health life by producing quality product at low cost. National companies don't have proper system like Pharmacovigilance and R&D section on which MNCs spend high budget for better health. In Pakistan MNCs also spend money on charity. Government has to pay these companies and have to solve their problems. In Pakistan, there is no strong mechanism to monitor the drug promotional movement by pharmaceutical industry although the fact is that there is sufficient evidence that irrational pharmacotherapy is gradually more encountered even in the urban countries due to unethical practices of pharmaceutical promotion. This article focus on ethical practices which are not followed by all national companies and these companies are making money and MNCs are operate in many countries for developing different level of health. MNCs create vacancies in different units of industries and thus decrease the unemployment rate in the host countries. It also explores the managerial talent of the local population and connects the world with the host country and with the local population. MNCs provide opportunities to do work in international level and encourage overseas operation through technology and talent transfer and through entrepreneurship and thus all these efforts result in enhancing world harmony and also it ensures the availability of medicines for local consumers.

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