

# Contemporary Transformations in the Global Pharmaceuticals Industry and Strategic Imperatives for Bangladesh Enterprises

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**Abstract:** Global pharmaceuticals industry is expected to reach \$1.5 trillion by 2021 with a moderate growth of 4%-7% although it was almost 9% in the recent past (IMS, 2016). This changes in the regular growth projection is due to some basic transformation in this sector among which gradual reduction of blockbuster era, innovation crisis, requirement of high R&D investment, reduced health budget by many governments, emergence of biosimilars and traditional medicines, uneven price competition, drug approval stagnation, institutional buying, strict regulatory guidelines are important. Nevertheless, Bangladesh pharmaceuticals industry is now a promising global player with a domestic market size of \$2 billion (BAPI, 2017). This sector is exporting medicines to 127 countries including USA, UK and other regulated countries with a global market capitalization of almost \$ 82.11 million after meeting 98% of the local demands. The average growth in domestic and export markets are 15% and 24% respectively (The Daily Star, 2017 & BAPI, 2017). Although this industry seems to be very flourishing both in domestic and global market but it is highly dependent on other countries considering researches and technologies that would be major setbacks in the upcoming days. Therefore, this study illustrates the contemporary transforming in global pharmaceuticals industry & suggests some strategic imperatives for Bangladesh enterprises.

**Key words:** global pharmaceuticals industry; transformation; strategic imperatives; Bangladesh etc. **JEL codes:** L

# 1. Introduction

#### **1.1 Top Market Places for Pharmaceuticals**

The global pharmaceutical industry is an imperative driver of the world economy today, generating more than 1 trillion US dollars in revenues annually (IFPMA, 2017). The American pharmaceutical industry accounts for about 40% of these revenues. However, China is fast catching up as having the fastest growth in the industry. European pharmaceuticals have also shown high revenues in prescription sales. Top ten countries considering pharmaceutical consumption is contributing 72.3% of the total market (Rolando Y. Wee, 2017). Table 1 shows top ten market places of pharmaceutical products with their share percentage.

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|--------------|--|
|              | Imperatives for Bangladesh Enterprises                               |

|    | Table 1 Top Ten Pharmaceuticais Market Places in the world by values Sales 2010 |                 |            |              |  |  |  |  |
|----|---|-----------------|------------|--------------|--|--|--|--|
| Sl | Country   | Value in mln \$ | % of Total | Cumulative % |  |  |  |  |
| 1  | USA   | 339,694         | 33.9       | 33.9         |  |  |  |  |
| 2  | Japan   | 94,025          | 9.4        | 43.3         |  |  |  |  |
| 3  | China   | 86,774          | 8.6        | 51.9         |  |  |  |  |
| 4  | Germany   | 45,828          | 4.5        | 56.4         |  |  |  |  |
| 5  | France  | 37,156          | 3.7        | 60.1         |  |  |  |  |
| 6  | Brazil  | 30,670          | 3          | 63.1         |  |  |  |  |
| 7  | Italy   | 27,930          | 2.7        | 65.8         |  |  |  |  |
| 8  | UK  | 24,513          | 2.4        | 68.2         |  |  |  |  |
| 9  | Canada  | 21,353          | 2.1        | 70.3         |  |  |  |  |
| 10 | Spain   | 20,741          | 2          | 72.3         |  |  |  |  |

 Table 1
 Top Ten Pharmaceuticals Market Places in the World by Values Sales' 2016

Source: Rolando Y. Wee, 2017, Arjun Datta, 2016 and Authors' compilation

## **1.2 Leading Pharmaceuticals Exporting Countries**

Global sales from exported drugs and medicines by country in 2016 totaled US\$ 318.6 billion. On the whole, the value of drugs and medicine exports were up by an average 0.4% for all exporting countries since 2012 when drugs and medicines shipments were valued at \$317.3 billion. Year over year, there was a -1.5% decline from 2015 to 2016. Among continents, European countries accounted for the highest dollar value worth of drugs and medicine exports during 2016 with shipments amounting to \$251.9 billion or 79% of the global total. In second place were North American exporters at 9.8% while 9.4% of worldwide drugs and medicine shipments originated from Asia (Daniel Workman, 2017).

| S1 # | Country     | Value in billion \$ | % of Total | Cumulative % |
|------|-------------|---------------------|------------|--------------|
| 1    | Germany     | 48.6                | 15.3       | 15.3         |
| 2    | Switzerland | 39.9                | 12.5       | 27.8         |
| 3    | Belgium     | 26.5                | 8.3        | 36.1         |
| 4    | France      | 22.8                | 7.1        | 43.2         |
| 5    | USA         | 22.5                | 7.1        | 50.3         |
| 6    | UK          | 22                  | 6.9        | 57.2         |
| 7    | Ireland     | 19.8                | 6.2        | 63.4         |
| 8    | Italy       | 16.6                | 4.9        | 68.3         |
| 9    | Netherlands | 15.5                | 4.9        | 73.2         |
| 10   | India       | 11.6                | 3.6        | 76.8         |

 Table 2
 Top-10 Pharmaceutical Product Exporters with Their Share Percentage

Source: Daniel Workman, 2017 and Authors' compilation

Among the above and other countries, the fastest-growing drugs and medicine exporters since 2012 were as follows:

#### **1.3 Top Pharmaceutical Product Importers**

The pharma market is radically changing position, with traditional strongholds, such as Japan and Europe, flipping over and emerging markets, such as China, becoming the head. The consequence is that healthcare investors need a fresh strategy; they need a way to keep an eye on emerging markets so they aren't left in the pitch

because they don't understand the true engines for growth in their holdings (Cheryl Swanson, 2017). The following table shows top Pharmaceutical product importers of 2016 by value sales.

|      | Table       | <b>3</b> The Fastest Growing (Up/D | own) Drug E | xporting Countries |          |
|------|-------------|------------------------------------|-------------|--------------------|----------|
| S1 # | Country     | Growth %                           | S1 #        | Country            | Growth % |
| 01   | Canada      | 84.5                               | 05          | France             | -17.0    |
| 02   | India       | 38.2                               | 06          | Spain              | -16.2    |
| 03   | Switzerland | 27.0                               | 07          | Israel             | -11.8    |
| 04   | Netherlands | 17.5                               | 08          | Belgium            | -10.9    |

Source: Daniel Workman, 2017

|      | Table 4     | 4 Top Pharmaceutical Product Importers 2016 by Value Sales |                                  |      |  |
|------|-------------|--|----------------------------------|------|--|
| Sl # | Country     | Value in \$ billion  | Value in \$ billion % of total C |      |  |
| 1    | USA         | 92.5   | 17.4                             | 17.4 |  |
| 2    | Germany     | 49.1   | 9.2                              | 26.6 |  |
| 3    | Belgium     | 34.9   | 6.6                              | 33.2 |  |
| 4    | UK          | 32.7   | 6.1                              | 39.3 |  |
| 5    | Switzerland | 24.7   | 4.6                              | 43.9 |  |
| 6    | Japan       | 24.4   | 4.6                              | 48.5 |  |
| 7    | France      | 22.1   | 4.1                              | 52.6 |  |
| 8    | Netherlands | 22.1   | 4.1                              | 56.7 |  |
| 9    | Italy       | 21.3   | 4                                | 60.7 |  |
| 10   | China       | 20.7   | 3.9                              | 64.6 |  |

Source: Cheryl Swanson, 2017& Authors' compilation

#### 1.4 Top Pharmaceutical Companies Considering Yearly Revenue

The ten largest pharmaceutical companies in the world account for more than a third of the industry's total market share according to the World Health Organization (WHO). Here we look at who the current top ten companies are and some of their highlights.

| Sl | Company  | Origin      | Revenue | Remarks  |
|----|----------|-------------|---------|--|
| 1  | J&J      | USA         | 71.89   | Revenue has increased, in part, due to a 6.5% rise in pharma sales.  |
| 2  | Pfizer   | USA         | 52.82   | The company focuses on a wide range of areas including oncology, neuroscience and metabolic diseases.            |
| 3  | Roche    | Switzerland | 50.1    | This year's success is owed to growing sales of best-selling drugs, Herceptin and Perjeta.                       |
| 4  | Novartis | Switzerland | 48.52   | Split their pharma unit in two, one being exclusively focused on oncology-which they hope to go forwards.        |
| 5  | Merck    | USA         | 39.8    | Their anticancer drug Keytruda gained approval from the FDA and EMA and is expected to be a "game-changer"       |
| 6  | Sanofi   | France      | 36.57   | Gained FDA approval for once-daily insulin Soliqua, while blockbuster drug Lantus experienced a dip in sales     |
| 7  | GSK      | UK          | 34.79   | Their increased sales can be attributed to the excellent performance of HIV drugs and strong vaccine sales       |
| 8  | Gilead   | USA         | 30.39   | Antiviral drug sales accounted for 90% of total revenue, the amount accumulated from others has risen by 13.6%   |
| 9  | AbbVie   | USA         | 25.56   | Owes much of its success this year to the usual range of global top selling drugs, such as Humira and Imbruvica. |
| 10 | Bayer    | Germany     | 25.27   | Joins the 2017 list of top 10 pharma companies due to a surge of sales from drug Xarelto (anticoagulant)         |

 Table 5
 Top Ten Pharmacy Companies Considering Yearly Value Sales of 2016

\*Revenue figures are in \$ billion. Source: Monique Ellis, 2017

## 1.5 Bangladesh Pharmaceuticals Industry

The pharmaceutical industry is one of the most dynamic and powerful sectors in Bangladesh. It is one of the most developed manufacturing industries and currently contributes about 1% to total GDP with great potential for expansion. Total domestic healthcare expenditures are currently approximately 3% of GDP, offering substantial opportunity for domestic pharmaceutical sales in addition to exports (Tashnim, 2017 & BAPI, 2017). Increased education levels, enhanced awareness of healthcare, growing per capita incomes, the emergence of private healthcare services and the government's expanding public expenditures in this sector continue to stimulate a rise in demand. There are currently around 200 Bangladeshi pharmaceutical companies in operation. The industry is highly concentrated as the top 20 companies generate 85 percent of the revenue (BAPI, 2016).

|                    | 2015        | 2016        | 2017        |
|--------------------|-------------|-------------|-------------|
| Market Size        | \$1,505,860 | \$1,686,563 | \$1,897,000 |
| Local * Production | \$1,460,684 | \$1,635,966 | \$1,843,500 |
| Exports            | \$11,278    | \$14,097    | \$17,540    |

 Table 6
 Market Size in \$ U.S. Thousands of Bangladesh Pharmaceutical

(Local Production\*: 97% of requirement). Source: BAPI, 2016

## 1.6 Objectives

To identify the contemporary transformations in global pharmaceuticals industry and proposing strategic imperatives for Bangladesh Enterprises based on the above transformations.

## 1.7 Methodology

This is a descriptive research based on secondary data. We have mostly relied on reputed academic journals, reports from the professional bodies, relevant articles from the experts and official website of the respective associations for our data source. Since our area of concentration was marketing and management related issues; so, we have reviewed the articles pertinent to these. The articles that describe any change in pharmaceutical marketing & management related issues were our basic target and we have considered last 12 years as transformation time for our study. For statistical figures IMS data was the basic source and we have compiled the original data in our own way.

# 2. Literature Review

# 2.1 Increasing Share of Generics

The generics industry quickly put this setback behind it. In 1984, generic drugs were just 19% of prescriptions in the US; according to the market research firm IMS. By 2013, they had reached 86% (Ann M. Thayer, 2014). Over the last few years, generic drugs have been gaining in volume and market share. Typically priced at significant discounts (50%-70%) to their branded counterparts, health plans and governments around the world, which are dealing with rapidly increasing costs and aging populations, have actively encouraged and promoted their use. Today in the US, generic drugs account for 88% of all prescriptions filled and according to latest IMS report, generics may account for 91%-92% of prescription volumes by 2020 (IMS, 2014 & Indxx, 2016).



Source: IMS, 2014

# 2.2 Generic Companies Are Performing Well

Common drugs going off patent have seen the generics industry push major companies such as Novartis and Pfizer for their market share. Pharmaceutical-technology.com lists the world's biggest generic pharmaceutical companies based on 2015 revenues (Timeline, 2016).

|      |                | Table / | Performances of top 10 Generic Companies   |
|------|----------------|---------|--|
| S1 # | Company        | Revenue | Remarks  |
| 1    | Teva           | 9.5     | Generic medicines segment generated 49% of the company's total revenue in 2015   |
| 2    | Sandoz         | 9.2     | Operates under three segments: Retail Generics, Biopharma and Oncology.<br>Europe accounted for 43% of Sandoz's sales in 2015        |
| 3    | Mylan          | 8.17    | Generics segment markets 1,400 products and generated 48% of its 2015 sales in North America, 27% in Europe                          |
| 4    | Fresenius Kabi | 5.19    | Witnessed a 16% increase in sales year-on-year in 2015. The subsidiary specializes in IV generic drugs and clinical nutrition.       |
| 5    | Hospira        | 4.7     | Global supplier of Injectables technologies and leader in biosimilars. Acquired by Pfizer in September'15 for \$17 bln.              |
| 6    | Sun            | 3.9     | The biggest pharma company in India and the 5 <sup>th</sup> biggest in the US. Witnessed high growth in 2015 by merger with Ranbaxy. |
| 7    | Aspen          | 2.3     | Generics segment continued to drive revenue growth in 2015. This was despite the divestment of certain products.                     |
| 8    | Sanofi         | 2.1     | Sales from generics segment increased by 7% in 2015. The company operates its generics business through 05 brands.                   |
| 9    | Lupin          | 1.9     | The company started the year by launching the Valsartan tablet, the generic version of Novartis' Diovan.                             |
| 10   | Cipla          | 1.8     | The year's major highlight was to acquire 100% stake in the generic businesses<br>InvaGen Pharma and Exelan Pharma.                  |

# Table 7 Performances of top 10 Generic Companies

Figures are in bln \$. Source: Timeline, 2016

# 2.3 Emerging Markets Are Becoming the Potential Destinations

Parma's growth prospects in emerging markets didn't appear out of nowhere. For years the so-called BRIC countries had been fingered as economic stars. Growth spawned middle-class consumers able to pay for their own

meds. It enabled governments to invest heavily in their neglected-or all but nonexistent healthcare systems. Meanwhile, populations were growing. And chronic diseases common in the U.S. and Europe were spreading. (Tracy Staton, 2017).

Indeed, IMS Health identified seven "pharmerging" markets expected to grow more than 7.5% per year through 2011, to become 12% of the global market. Four years later, the list expanded to 17, still led by the BRIC countries, but followed by such sudden pharma stars as Poland and Turkey. China's drug spending was growing by more than 25%. That market alone was expected to double in size by 2013; all together, those 17 countries were pegged for a \$90 billion expansion from 2009 to 2013 (IMS, 2011).



Figure 2 Pharmaemerging Countries Already Crossed EU5 in Terms of Pharma Spending (\$ bln) Source: Md. Abu Zafor Sadek, 2016

## 2.4 The Patent Cliff Is Giving Boost to Generics

According to a report by IMS Health, from 2013-2018 generic drugs are expected to account for 52% of global pharmaceutical spending growth, compared to 35% for branded drugs. Overall, sales of generic drugs are forecast to increase from \$267 billion in 2013 to \$442 billion in 2017, an annualized growth rate of 10.6%. Major factors driving this growth include popular branded drugs losing their patent protection, support for generics from governments, new complex generics coming into the market and industry consolidation (IMS, 2013).

Traditionally, pharmaceutical companies develop new branded drugs by investing huge amounts of money (often more than \$1 billion) into research and development over 10-15 years. This is the amount of time and money required to not only develop a number of potential new drugs, but go through the long, expensive and arduous approval process required by the US Food and Drug Administration (FDA) to prove a drug is safe and effective, and then markets the drug to consumers. Since this model is so expensive and time consuming, the FDA typically gives drug companies 12 years of patent protection and a total monopoly on sales during that period. This allows the drugs companies to recoup their costs, earn a profit, and start the process anew for the next wave of new and innovative drugs (VanEck, 2016).

#### 2.5 Blockbuster Era Is Reducing Gradually

Blockbuster drugs, those medicines that bring in more than \$1 billion in sales every year, are the holy grail of drug development (Laura Lorenzetti, 2016). One of the major issues confronting the pharmaceutical industry is the challenge to, and shifting focus of, the traditional business model. It is widely considered that the conventional

strategy of pursuing blockbuster medicines is in sharp decline, as patents expire on major products and the output of product pipelines diminishes. For the world's largest prescription drug manufacturers, the last few years have been a harrowing time. Recently, Pfizer's Lipitor, Glaxo Smith Kline's Advair, Astra Zeneca's Seroquel and Sanofi-Aventis and Bristol-Myers Squibb's Plavix all came off patent in the crucial U.S. market. This so-called "patent cliff" meant hundreds of billions of dollars in lost revenue and has pharmaceutical developers scrambling to create new drugs and litigating to extend current patent protections (Jie Jack Li, 2014).

Some estimate that, over the next five years, drugs currently generating \$142 bln in sales annually will lose patent protection. At a time when the world's population is getting bigger, older and more likely to take prescription drugs, it seems counter-intuitive that the \$518 bln pharmaceutical sector could be entering an era of declining revenues and profits. However, it is a real possibility; and just last week the subject was a major topic for discussion at an annual life-sciences conference in London hosted by the venture-capital investment firm Index Ventures. The sector is preoccupied with its own evolution; and, as this analysis shows, the challenges, and potential risks and rewards, are immense (Independent, 2010).

## 2.6 R&D Productivity Is Facing High Crisis

In recent years, there has been much discussion about the dearth of innovation in the pharmaceutical industry. Across the globe, regulators and international organizations such as WHO have expressed concerns about the declining output of the pharmaceutical industry pipeline. These concerns focus both on the decline of the total number of New Chemical Entities (NCEs) released into the major markets and the many real public health needs of the population that are not addressed by new medicines. Within the European Union, these concerns have been complemented by fears about deterioration in the relative competitiveness of the European pharmaceutical industry (Lygature, 2012). There were four root causes of the R&D productivity crisis in pharmaceuticals:

2.6.1 Relentless Health Economics Pressures

The ever-growing back catalog of cheap generic drugs continuously raises the bar for new medicines. It incentivizes companies to prioritize tougher medical challenges with inherently lower probabilities of success.

2.6.2 Increasing Regulatory Hurdles

Health economics pressures push pharmaceutical R&D to experiment with new bioscience technologies and innovative treatment approaches. But this in turn increases public concerns about safety and encourages regulators to increase their hurdles.

2.6.3 Immature State of Knowledge and Molecular Reductionism

Our global state of knowledge in human biology, especially as regards the complex inter-relationships that constitute biological pathways, is still far behind other scientific and technical areas.

2.6.4 Management Reductionism and Diseconomies of Scale

An overly-simplistic management paradigm led to R&D consolidation and industrialization, which in turn engendered a lack of creative diversity, a paucity of innovations and poor management decision making. Again, the industry is now playing catch-up to address these shortcomings (Robert Thong, 2015).

## 2.7 Emergence of Patient Centric Healthcare Approach

A patient-centric approach is a healthcare system that establishes a partnership among practitioners, patients and their families to align decisions with patients' wants, needs, and preferences. This also includes the delivery of specific education and support patients need to make these decisions and participate in their own care (Evariant, 2017). According to the Institute of Medicine, patient-centric care is defined as "providing care that is respectful of and responsive to individual patient preferences, needs and values, ensuring that patient values guide all clinical

decisions."

The patient-centric model is a focus across all healthcare entities, including life sciences. In fact, a collaborative study to define patient centricity and gauge the impact of patient engagement on life sciences companies identified several patient values that increase engagement. These include access and affordability of medications, and patient access to information.

2.7.1 Impact of Patient Engagement in Healthcare

The impact of the patient-centric model and patient engagement in healthcare is complex and constantly evolving, but here are five effects of the focus on patient-centric healthcare:

(1) Greater involvement of patients and family members on advisory councils as well as quality committees or boards of directors: While many institutions and physicians rely on patient surveys for feedback, more institutions are adding community representatives to committees and councils to provide the patient/family perspective.

(2) Enhanced one-on-one communication with patients via bedside rounds and programs to address potential language barriers: Although some hospitals have initiated hourly rounding by nurses as a patient safety measure, the added benefits of a nurse visiting the patient on a regular basis versus waiting for the patient to push a call button include increased patient satisfaction, improved outcomes and enhanced employee satisfaction.

(3) Use of patient-centered metrics to compensate health system leaders: Although not widespread, some health systems are integrating outcome and patient satisfaction metrics into algorithms that determine health leaders' compensation.

(4) *Redefinition of quality measurements:* As a patient-centric model of care is adopted in a healthcare organization, there is a need to revisit the metrics used to define quality. Rather than focusing on environment, technical aspects of care and patient reports of satisfaction, healthcare providers will need to define quality from the patient's perspective-do outcomes match patient's expectations and goals for quality of life.

(5) *Real-time access to patient health information:* In order to support consistent patient-centric healthcare and enhanced patient engagement, access to the longitudinal health record that includes all aspects of a patient's health and medical history is critical. Physicians and case managers who can review a physical therapist's notes to confirm that the patient is receiving the prescribed therapies are better equipped to ask a patient why they miss appointments. If it is a transportation problem, solutions that include community transportation or schedule changes that enable a family member to drive the patient can be offered (Danielle Siniscalchi, 2017; Ellen Schultz, 2017).

# 2.8 Contract Manufacturing

With few exceptions, pharmaceutical companies have moved away from the belief that they should produce products in-house by default. Today, the dominant model is a balance of in-house and contracted production, with most pharmaceutical production in-house and API outsourced. On average, a global pharma companies works with 100 to 200 contract manufacturing organizations (CMOs)-probably too many. A more proactive approach to external partnerships is a powerful way to optimize utilization and reduce risk-and it can accelerate innovation. Partners can bring new formulations to the table, along with packaging ideas or devices. As breakthrough research becomes more difficult, these can become key differentiators (David Keeling et al., 2010).

# 2.9 Emergence of Biosimilars

A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product (USFDA, 2017). A biosimilar is a biological medicine highly similar to another already approved biological medicine (the reference medicine) (EMA, 2017). By 2020, biologic medicines worth an estimated \$81 billion globally are expected to experience patent expiry, paving the way for the next generation of biologic medicine biosimilars. In 2012, the European Commission sponsored a review of the biosimilars market and determined biosimilars market share varied between 7-18 percent of the accessible market (Amgen, 2010). Twelve biological products with global sales of more than US\$67 billion will be exposed to biosimilar competition by 2020, with Enbrel (etanercept) whose US patent has been extended until 2028, scoring global sales of US\$7.3 billion by December 2011; coming in second after Humira (adalimumab) with global sales of US\$7.9 billion (Sheppard, 2012). The expiration of patents and other intellectual property rights for originator biologicals over the next decade opens up opportunities for biosimilars to enter the market and increase industry competition. Price reduction strategies should increased adoption among physicians and patients alike, spurring increases in the biosimilars market share. The biosimilars market earned revenue of approximately US\$172 million in 2010, according to Frost and Sullivan. However, despite estimates that the market will reach approximately US\$3.987 million by 2017, the biosimilars industry is not for the faint hearted. Considerable investment is required to manufacture and get a biosimilar to market, and with such complex molecules failure can occur at any stage of the development. Despite this, with a compound annual growth rate of 56.7% expected from 2010 to 2017 many companies — both originator and generics alike-are finding the sector hard to resist (GaBi, 2012).

| Sl                  | Brand                                  | Active             | Company           | Indication         | Market |  |
|---------------------|--|--------------------|-------------------|--------------------|--------|--|
| 1                   | Humira                                 | Adalimumab         | Abbvie            | Arthritis          | 10.8   |  |
| 2                   | Lantus                                 | Insulin Glargine   | Sanofi            | Diabetes           | 9.2    |  |
| 3                   | Rituxan                                | Rituximab          | Biogen            | Arthritis          | 8.6    |  |
| 4                   | Enbrel                                 | Etanercept         | Amgen             | Arthritis          | 8.3    |  |
| 5                   | Remicade                               | Infliximab         | Janssen Biotech   | Crohn's Disease    | 7.9    |  |
| 6                   | Avastin                                | Bevacizumab        | Genentech         | Ovarian Cancer     | 7.0    |  |
| 7                   | Herceptin                              | Trastuzumab        | Genentech         | Breast Cancer      | 6.8    |  |
| 8                   | Avonex                                 | Interferon Beta-1A | Biogen            | Multiple Sclerosis | 5.5    |  |
| 9                   | Copaxone                               | Glatiramer Acetate | Teva Neuroscience | Multiple Sclerosis | 4.6    |  |
| 10                  | Neulasta                               | Pegfilgrastim      | Amgen             | Neutropenia        | 4.5    |  |
| 11                  | Lucentis                               | Ranibizumab        | Genentech         | Macular Dege.      | 4.5    |  |
| 12                  | Levemir                                | Insulin Detemir    | Novo Nordisk      | Diabetes           | 2.5    |  |
| 13                  | NovoMix 30                             | Insulin Aspart     | Novo Nordisk      | Diabetes           | 1.8    |  |
| 14                  | Xolair                                 | Omalizumab         | Genentech         | Asthma             | 0.8    |  |
| 15                  | 15 Erbitux Cetuximab Eli Lilly Colored |                    | Colorectal Cancer | 0.25               |        |  |
| Total (Billion USD) |  |                    |                   |                    |        |  |

 Table 8
 Scope for Biosimilars Due to Patent Expiration

Source: Md. Abu Zafor Sadek, 2016

#### 2.10 Emergence of Herbal Medicines

In recent years, increasing numbers of people have been choosing herbal medicines or products to improve their health conditions, either alone or in combination with others. Herbs are staging a comeback and herbal "renaissance" occurs all over the world. According to the World Health Organization, 75% of the world's populations are using herbs for basic healthcare needs. Since the dawn of mankind, in fact, the use of herbs/plants

has offered an effective medicine for the treatment of illnesses. Moreover, many conventional/pharmaceutical drugs are derived directly from both nature and traditional remedies distributed around the world. Up to now, the practice of herbal medicine entails the use of more than 53,000 species, and a number of these are facing the threat of extinction due to overexploitation. This paper aims to provide a review of the history and status quo of Chinese, Indian, and Arabic herbal medicines in terms of their significant contribution to the health promotion in present-day over-populated and aging societies (Si-Yuan Pan et al., 2014).

The global herbal medicine market size was valued at USD 71.19 billion in 2016 and is expected to exhibit profitable growth over the forecast period. The increase is attributed to the increasing preference of consumers towards traditional medicines (Ayurveda, Unani and Traditional Chinese Medicine) which do not cause overdose toxicity and have fewer side effects. In addition, increasing substantial research investments and funding will support the market growth in near future.



Source: Hexa, 2014

# 2.10.1 Segmentation by Indication

Digestive disorder segment is expected to grow at a CAGR of 6.6% over the forecast period owing to increasing use of herbal medicines for conditions such as indigestion, gastroesophageal reflux disease, and dyspepsia. Easy accessibility of various products for the treatment of digestive tract disorders is expected to fuel the market over the forecast period. Blood disorder segment is projected to generate maximum revenue due to increasing prevalence of hypertension. Growing popularity of ginger, garlic and ginkgo biloba coupled with a variety of products available in the market is expected to boost growth over the forecast period (Hexa, 2014).

2.10.2 Segmentation by Region

In 2016, Europe dominated the global herbal medicine market and is expected to retain the share during the forecast period as well. Associations such as British Herbal Medicine Association and European Herbal & Traditional Medicine Practitioners Association (EHTPA) promote the use of these alternative medicines in European region by organizing various seminars and increase the awareness regarding benefits of using herbal remedies. Furthermore, high flexibility regarding the launch of these products in the European Union is a major contributing factor for the market growth in this region. Asia Pacific is expected to show the fastest growth over the projected period due to increasing awareness of these products which include drugs, dietary supplements, and skin care products. India and China being the major markets for herbal medicinal products in the region,

these countries have a strong background (Hexa, 2014).

# 2.11 Limited Number of New Molecules

Number of new molecule 2016 was a slow year for drug approvals. In this year, the FDA's Center for Drug Evaluation and Research approved 51% fewer new molecular entities (NMEs) than in the prior year. In the years leading up to 2016, NMEs were on an upswing. Although approvals were lower than average in 2016, the number of applications for approval has remained relatively stable (Emily Walter, 2017). It is difficult to pinpoint the reason for a reduction in approvals, whether it is stricter guidelines or product-specific issues, so it is difficult to predict the outcome for 2017. We must wait to see whether new drug approvals will remain low again for this year.



Figure 4 New Molecule Entity (NME) and New Biologics License Application (BLA) Filings Approvals Source: official website of USFDA, 2017

## 2.12 Technology Oriented Treatment

In the near future, physicians may receive a constant, daily stream of data from some patients. The Diovan hypertension pill, with the embedded Proteus chip, is already in trials, with stellar patient-compliance results. The chip records the time when the patient takes a pill and transmits this information from inside the body to a patch the patient wears. (The patch also captures other physiological data.) This information can be shared with a Smartphone, a laptop, and the cloud, so the patient and provider can access it. Such developments have prompted Dr. Krishna Yeshwant, general partner at Google Ventures, to conclude that "physicians need to operate in a more complex environment with an ever-growing range of tools. Physicians need a package of solutions to navigate this environment." (David Champagne, 2016).

#### 2.13 Venture Capital Flow

Venture capital flow is an important measure of any industry, and it ended on an overall weak note in 2016 as quarterly deals and dollars fell for the second quarter in a row. Pharmaceutical deals dropped by 16% and dollars dropped by 20% in 2016, and global trends within the pharma industry followed the same flow with deals declining at 10% and dollars declining at 23%. This decline may present challenges for the pharmaceutical industry as it struggles to improve or maintain growth in this year. However, new introductions and innovations,

such as biosimilars, may help entice investors in the near future (Emily Walter, 2017).

# 2.14 Laws and Regulations

Laws and regulations evolve within countries over time, but in recent years, the trend has been toward the globalization of pharmaceutical issues, which affects national legislation. This globalization, exemplified through changes in international trade, patent protection, and pricing, has resulted in a number of initiatives that must be considered by countries developing pharmaceutical regulations. The regulatory strategy for product development is essentially to be established before commencement of developmental work in order to avoid major surprises after submission of the application (Shweta Handoo et al., 2012).

## 2.15 Wholesale and Distribution Segment

The global health care wholesale and distribution market is projected to grow an average of 6.82 percent annually in 2014-2019, with revenues increasing from \$752 billion to \$1.04 trillion during the period. Key growth drivers include the rapid expansion of the pharma industry, technology advances, increased use of temperature-sensitive drugs, and growing demand for drug therapies in emerging markets. In 2014, the Americas region dominated the pharma wholesale and distribution market, followed by Asia-Pacific. Key customer segments include hospitals and clinics, patients, and specialty/traditional wholesales. AmerisourceBergen, Cardinal Health, and McKesson are the leading players in the distribution and wholesale segment, and the three collectively hold more than 50 percent of the total global market share (Deloitte, 2016)

## 2.16 Policy reform:

Any changes to healthcare with a new presidential administration will undoubtedly have an impact on the pharmaceutical industry. The future of the Patient Protection and Affordable Care Act (ACA) is currently under review with various potential scenarios that may occur to repeal and replace the healthcare act. With that, there are also legislative efforts to maintain the current policy. However, with healthcare being top priority for the current administration, we can expect some change to occur (Manostaxx, 2017).

## 2.17 Emergence of Personalized Medicines

Personalized medicine is an emerging science with the potential to improve early cancer diagnosis and enable the development of treatment based on an individual's genetic background, family history and other characteristics (Medscape, 2017). In personalized medicine, diagnostic testing is often employed for selecting appropriate and optimal therapies based on the context of a patient's genetic content or other molecular or cellular analysis. The use of genetic information has played a major role in certain aspects of personalized medicine (e.g., pharmacogenomics), and the term was first coined in the context of genetics, though it has since broadened to encompass all sorts of personalization measures (PMC, 2017).

Specific advantages that personalized medicine may offer patients and clinicians include:

- Ability to make more informed medical decisions
- Higher probability of desired outcomes thanks to better-targeted therapies
- Reduced probability of negative side effects
- Focus on prevention and prediction of disease rather than reaction to it
- Earlier disease intervention than has been possible in the past
- Reduced healthcare costs (U.S. News, 2013)

# 3. Strategic Imperatives for Bangladesh Enterprises

#### 3.1 Emphasizing on Biologics

In view of the changes in disease pattern, increasing life expectancy, changes in healthcare expenditure and other pertinent factors necessity of biologics is increasing day by day (Md. Halimuzzaman, 2017). At present roughly 20% of the global pharmaceutical sales come from biologics which will be more than 30% within next five years (Craig W. Lindsley, 2016).

However, biologic segment in Bangladesh pharmaceuticals industry is less than 5% of the total sales. If we exclude insulin then the figure will be very insignificant. Due to high investment requirement, lack of skilled human capital, inadequate disease awareness campaigns, healthy growth in conventional business model local companies were little late with biologics. Now the scenario is changing, some companies are coming with biologics but still the number is very poor, only 09 local companies among more than 200 companies are partially playing with biologics. Considering the recent upward trend of certain chronic diseases like diabetes, asthma, arthritis, stroke and huge number of patients Bangladesh will be a potential destination for biologics. Also, taking into account that Bangladeshi universities are producing trainable graduates, there are so many companies that have capacity to go for huge investment, lot of global giants are ready to come in Bangladesh with technical assistances, an industry friendly guidelines by Directorate General of Drug Administration (DGDA), enormous export possibilities, it is high time for Bangladesh to go for massive investment with biologics.

#### **3.2 Special Attention towards Emerging Countries**

An emerging market is a country that has some characteristics of a developed market, but does not meet standards to be a developed market (Kimberly, 2014). Pharmaceutical sales in BRICS (Brazil, Russia, India, China and South Africa) & MIT (Mexico, Indonesia and Turkey) countries have been doubled in last five years and many of them are highly import dependent. Between 2015-2020 pharmaceutical sales growth estimates scored higher in emerging countries than developed countries (Md. Abu Zafor Sadek, 2016). Therefore, considering the upward trend in pharmaceutical spending, present status of requirements and regulatory frameworks Brazil, Russia, Chile, Colombia, Hungary, Malaysia, Mexico, Peru, Philippines, Poland, Russia, South Africa, Thailand and Turkey may be an exceptionally impressive destination for the pharmaceuticals export from Bangladesh. Although few of the Bangladeshi companies are exporting medicine to some of the above countries in a limited scale but more attention is required by all top companies. However, due to rapid urbanization, sedentary lifestyle, changes in income level antidiabetic, cardiovascular and anticancer therapeutic segments may the target for emerging countries.

#### 3.3 Technical Collaboration with Global Giants

Pharmaceutical is highly technology oriented and research based industry but still now Bangladesh is far behind with the above issues. The country is highly dependent on other countries for technology and research. High investment requirement and lack of skilled human capital are the two basic hindrances for necessary researches. Therefore, considering the above requirement technical collaboration with global giants is highly important. Technical collaboration will give an immediate boost also a longtime opportunity to develop local human capital.

#### 3.4 Strengthening Industry Academia Relationship

In Bangladesh industry-academia relationship is diminutive to directly contribute in the growth of the pharmaceutical industry. But the good point is that they are producing trainable graduates (Muktadir, 2017). Very

few academics are personally involved with some companies as consultant. However, collaboration for basic research is still rare.

University of Dhaka and North South University have very good research facilities that can be used for basic research. Also, a consortium may be developed by Department of Pharmacy/Biotechnology & Genetic Engineering of different renowned universities, ICDDR, B, BSMMU and BCSIR for basic research where pharmaceutical companies will be the patrons.

#### 3.5 Introduction of Patient Centric Approach

In generic marketing it is very difficult to differentiate one from others but it is utmost priority. Patient centric approach may be an important tool for distinguish one from others. A patient-centric approach is a system that establishes a partnership among practitioners, patients and their families to align decisions with patients' wants, needs and preferences. Here patient records, health information, procedure costs and practitioner data are made more easily available over the Internet. It is a personalized care that values the whole person in mind, body and spirit ultimately brand loyalty develops.

# 3.6 Launching More Number of Contract Research Organizations (CROs)

CROs provide clinical trial and other research support services for the pharmaceutical, biotechnology, medical device industries and also serve government institutions. For exporting as well as to maintain high local standard there is no alternative of various clinical trials. Local pharmaceutical companies are increasingly looking to outsource for the above research which involved with high cost. Recently few companies like Khwaza Yunus Ali Medical College & Hospital, Clinical Research Organization Ltd., International Centre for Diarrhoeal Disease Research, Bangladesh, Filaria and General Hospital., Beximco Bioequivalence Center going to establish CRO which is a positive sign (Salahuddin, 2017). However, to increase product standard and to meet the global requirement almost all the top ranked companies need to have research based unit.

#### 3.7 Developing More Patient Awareness Campaigns

Disease awareness campaign is the connection between patients and manufacturers. It generates a positive perception about the company/brand. From literature we knew that specific awareness campaigns have driven more people to see their doctors' means possibility of getting more consumers. Many awareness campaigns are already lead generators.

It's an effective way to build email databases of potential patients which can be used for multiple purposes.

# **3.8 Initiation of Personalized Medicine**

Personalized Medicine is the concept that managing a patient's health should be based on the individual patient's specific characteristics, including age, gender, height/weight, diet, environment, etc. Personalized medicine aims to identify individuals at risk for common diseases such as cancer, heart disease and diabetes. One potential benefit of personalized medicine model is 100% brand loyalty. It is win-win situation for both healthcare provider and the patients. Here, patients will enjoy super specific treatment with very minimum or no side effect and pharmaceutical companies will get life-time consumers. Local companies need to work with these medicines.

## **3.9 Focus on Traditional Medicines**

WHO forecast, the global herbal market would be worth \$5 trillion by the year 2050 (Biospectrum, 2018). India is very aggressive with traditional medicines and they put their footprint in every parts of the world including Bangladesh. However, very few Bangladeshi companies are putting concentration on it. Considering better side effect profile, cost advantages, connection with nature and potential outcomes in particular disease condition, there is a substantial demand of traditional medicines in Bangladesh. It is noted that due to some low

graded manufactures perception about locally manufactured traditional medicines is not up to the mark. To avoid such negative perception as well as to explore the market potentiality more number of reputed companies needs to come up with traditional medicines.

# 3.10 Drawing Attention for Toll Manufacturing

Bangladesh have ampoule opportunity for toll manufacturing. The country has so many world class manufacturing facilities which can be used for toll manufacturing. This will help for proper capacity utilization. Considering worker wage, salary of managerial staffs, price of industrial land, office rent, income tax, geographical location, water, electricity and gas bill etc Bangladesh is ahead than Shanghai, New Delhi, Seoul and other competitors. Therefore, Bangladesh may be an impressive hub for the toll manufacturing of pharmaceuticals.

#### 3.11 Merger/Acquisition

There are more 200 pharmaceutical companies in Bangladesh which is far higher in number. Kaiser Kabir (2016) reported that 68.3% of the total sales come from top 10 companies and rest of the companies (185) are generating only 31.7% share. There are some companies who are fighting for their existence and some others are underutilized. Therefore, for the smooth running of the industry merger or acquisition is highly important. Potential therapeutic segment or special area of interest may be the basic elements that should be considered for necessary merger or acquisition.

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