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Review Article

Problems Facing the Arab Pharmaceutical Industry: A Case Study from Yemen

Mohammed Al-Shakka*¹, Ebtesam Abood¹, Adel Al-Dhubhany², Sami Abdo Radman Aldubai³, Khaled Said⁴, Nisha Jha⁵, P Ravi Shankar⁶

¹Department of Clinical Pharmacy, Faculty of Pharmacy, Aden University, Yemen

²Ministry of Health and Population, Sana'a, Yemen

³Faculty of Medicine, SEGi University, Selangor, Malaysia

⁴Department of Biology, Faculty of Education, University of Aden, Yemen

⁵Department of Clinical Pharmacology and Therapeutics, KIST Medical College, Imadol, Nepal

⁶Department of Pharmacology, Xavier University School of Medicine, Aruba, Kingdom of the

Netherlands

ABSTRACT

Because of the almost-instant connection with the welfare and well-being of individuals, pharmaceutical industry stands prominently as a very important factor for the improvement and progress of a healthy productive nation. These days, pharmaceutical industry thrives as one of the largest and exponentially expanding global industries. Nonetheless, millions of people in low income developing countries, have to suffer from the fatal consequences of the inaccessibility and non-availability of essential drugs. This is also happening in Yemen, where the pharmaceutical manufacturers sector have to face up to many challenges.

The Yemen Drug Company (YEDCO) was founded in 1964 by the Yemeni government as it collaborated with private investors. It was endorsed as a company with the expertise in the medicinal drug marketing. YEDCO started its work by taking in drugs from foreign companies and then locally marketing and distributing them. In 1982, YEDCO built the first medicinal factory for drugs in Sana'a. Since then, seven companies were set up to manufacture medicines in Yemen.

The expanding population has led to the need to have more pharmaceutical products. It may be understandable that pharmaceutical manufacturer companies are also hit by the political crisis in the country. Inadequate amount of fuel and raw material as well as low security status were some of the underlying factors behind these ill-effects in Yemen.

Imported drugs make up about nearly 90% % of the pharmaceutical market compared to 10% drugs from the domestic market. This situation has led to an additional burden being shouldered by the national economy, where Yemen spends about US\$263 million annually on pharmaceutical drugs, in reference to the national Supreme Drugs Authority.

Although there is a very quick growth in the population and drugs consumption, the pharmaceutical industry has not been very active, where global pharmaceutical products play their role dominantly on the domestic market. The pharmaceutical production necessitates skilled human resources like university graduates. By contrast, the government and the private sector should also motivate the pharmaceutical industry and make use of the local employment.

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*Correspondence to:

Dr. Mohammed Al-Shakka, Email: alshakka400@gmail.com

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INTRODUCTION:

Nowadays, the pharmaceutical industry, a vital source of employment generation and foreign exchange

earnings for many countries all over the world, is regarded as one of the largest and rapidly expanding

global industries. It is never arguable that pharmaceuticals have become a vital part of health care system to the world today. Broadly speaking, pharmaceuticals are integral to the human development as they enhance personal satisfaction and reduce the time spent in the healing facilities.

Most of the pandemics and constant infections can be treated these days, today, which are unachievable without the inventive pharmaceutical industry today. Citing the World Health Organization (WHO), 30% of the world population do not have access to life-saving medicines: and it exacerbates in some countries (such as Asia & Africa), with the average increases as high as 50%. A part of this problem is associated with the lack of pharmaceutical industry. Poor manufacturing capacities in this industry proves to be a serious issue among the developing countries, where the local industry attempts to meet a tiny fraction of domestic pharmaceutical demand, and it depends a great deal on imports and medicinal aid. To add, the share of medicines in the "Out-of-pocket" health payments (i.e. paid by the patient) ranges between 40-60% in developing countries. Consequently, medicines are neither available nor accessible to so many people in many countries and unfortunately, as the result, they die from preventable and treatable diseases.

Following the Union of Arab Manufacturers data, the Arab pharmaceutical market is worth US\$ 6.20 billion which make up 1.25 per cent of the global pharmaceutical market in the year 2003[1].

Local drugs production, as reported in Arab countries make up various percentages of national drug market, ranging from zero to more than 90 percent. On average, the local Arab drug industry covers 50 per cent of the total Arab drug market as the Arab drug market is estimated to be worth US\$ 10 billion in 2007, (we have to remember that Saudi Arabia and Egypt are the two major markets in the region with a market size of more than US\$ 1.2 billion each). In some studies, the Egyptian market is estimated to be around US\$ 1.7 billion and most locally produced products are formulations. In other countries, about 40 per cent of drugs are licensed or yielded in subsidiary plants of multinational companies, and more than 90 per cent of the raw materials needed for local production are brought in from other countries. [2]

In some of the Arab countries (except Kuwait, Qatar, Mauritania, Somalia and Djibouti) pharmaceutical industries' contributions cover domestic consumption requirements ranging between 12% in Lebanon and 15% in Yemen while the rise of these contributions is up to 85% in Morocco and about 95% in Egypt. In

terms of exported products, according to the statistics in 2000, only five of the Arab countries are exporting their drugs.

Another fascinating finding is that 327 pharmaceutical manufacturers mainly produce branded generics in different dosage forms and therapeutic categories. Antibiotics are the leading therapeutic class followed by NSAID's —they are mostly taken orally, in solid form. The demand for pharmaceuticals is largely met by imported drugs, with the government being the main health care provider.

The situation of the Arab pharmaceutical industry is analysed and some findings have been established:

- A- The volume of coverage of the drug for the domestic Arab industries has been set to about, 44-47% from 1975 until 1999, and 230 factories have been built after 1975.
- B- While the national production of medicines has doubled the value of about nine times over the last quarter century, however, the interest in the production of raw materials is restricted, as about 90% of the needs of raw materials are imported.
- C- Jordan is one of the exporting countries, even though its inception was in the late seventies of the last century, And later followed by Egypt.
- D- There has been a horizontal, rather than vertical, growth for the Arab pharmaceutical industry. This means that they are growing in a number of similar factories in technological capability.
- E- The research and development is still lagging behind. Even worse, research and development activities in the Arab pharmaceutical industry data are simply absent.
- The research and development activities in the Arab drug industry are primarily quality control activities.
- 2- The total cost for the research and development activities for the sales in the Egyptian companies ranges between 0.846% and 2.389%. Thus, while most of these companies come from the public sector companies which carried a great responsibility in domestic consumption coverage in Egypt before the nineties of the last century, they also contributed to the number of Egyptian private sector companies as well as a large number of Arab companies and technical cadres.
- 3- About 50 to 75% of the cost of research and development activities carried out in the

- Egyptian companies is consumed in the cover wages item.
- 4- There may be a good start in the Nile Pharmaceutical Company in Egypt and recently doing the transfer of biotechnology for the production of interferon and doing research for the development of the drugs by pharmacists. The last glimmer of hope may rise in the developmental research activities carried out by the Jordanian company for the production of medicines in Jordan to pursue the development of existing products as well as entering into the production of diagnostic tools laboratory via biotechnology.
- 5- The Arab pharmaceutical industry did not take heed to the crucial role of the new global mechanisms in the development of its business, despite the scarce companies (especially in Jordan, Saudi Arabia) and their modest activities that have begun in similar

- directions.
- F- The scarcity or absence of orientation towards biodiversity investment in the Arab region (on land and in the sea) is seen as welcoming, as it renders the development of pharmacological long-term possible.
- G- There has been no active role for governments on the development of Arabic medicine industries. various governments have executed procedures and specific arrangements in the pharmaceutical fields such as encouraging the communication between research industrial enterprises, and stimulating the establishment of strategic alliances both locally and internationally, to name but a few, the Arab governments do not generally exercise an active role in the preparation and stimulation, guidance and adjustment of the orientations of the pharmaceutical industry [2,3].

Table No 1: Arab Producers Union data

Country	Total Market	Share of Local	Number of
	(US\$)	companies %	Manufacturers
KSA	3,130,000,000	25.00%	17
Egypt	2,550,000,000	94.00%	85
Iraq	1,400,000,000	10.00%	10
UAE	762,000,000	20.00%	7
Algeria	1,345,000,000	48.00%	34
Morocco	1,174,000,000	93.00%	31
Syria	930,000,000	93.00%	62
Tunisia	655,000,000	48.00%	27
Yemen	626,000,000	15.00%	7
Libya	563,000,000	3.66%	1
Lebanon	470,000,000	12.00%	6
Sudan	386,000,000	49.00%	16
Jordan	406,000,000	29.00%	16
Kuwait	315,000,000	0.0%	1
Oman	170,000,000	10.50%	2
Qatar	170,000,000	0.0%	0
Bahrain	95,000,000	0.0%	0
Palestine	235,000,000	21.00%	5
Total	15,382,000,000		327

Source: The Jordanian Association of Pharmaceutical Manufacturers [4]

The Yemeni pharmaceutical industry

The pharmaceutical market in Yemen is an open market with a very large growth in comparison to the annual population growth (3.1%), evident from the records of the Ministry of Health, and the supreme administrative and drugs medical devices. The growth of the Yemeni pharmaceutical market during the last decade is specifically recorded as follows:

- A clear increase in local manufacturers of pharmaceuticals 1-9 (growth rate 4900%).
- There is also an increase to 243-490 (growth rate¹/₄101%) the number of registered foreign pharmaceutical companies, from 69 countries.
- The pharmaceutical market will be worth \$ 297 million in 2010 compared to US \$ 70 million in 2000) rate¹/₄ growth of 324%).

 About 95% of the market is made up of imported drugs. Endangered prescription drugs make up 78% of the market. However, the number of drugs without Official registration?12.596 trademark exists in the medicine market following cases of smuggling and counterfeiting. [5]

Because of the increasing need for such drugs in Yemen, the pace of import of various pharmaceutical products from abroad has accelerated and due to this, drug safety has become an increasingly important issue. While there is competition to cater for the medicine demand for the community, pharmaceutical industry in Yemen, has thrived as a promising sector.

So far and through more than ten years, seven national factories were built alongside the Yemen Company to manufacture drugs, which yields thousands of pharmaceutical quality items tried and tested by international organizations. Although there are many obstacles and problems impeding the pharmaceutical industry in Yemen, there is still a stress on the development and expansion of this sector, to accomplish the pharmacological security.

The pharmaceutical market in Yemen and Gulf Cooperation Countries (GCC) exceeds 6 billion USD. This market is rapidly expanding and it is expected to reach around 10 billion USD by 2020. In spite of the growth of this market, local manufacturing is not able to cater for the growing demand, and these countries continue to import most medicines from foreign countries [6].

In Yemen, responding to the high needs of the drug market and the fast-paced import of pharmaceutical products, greater efforts exerted toward pharmaceutical security and safety become crucial.

Although excellent quality results were noted of the locally manufactured products tested, trends of local pharmaceutical industry in Yemen require tremendous attention and improvement in different areas to raise their awareness about medicinal use to improve the nation's health status [7].

There are 10 licensed pharmaceutical manufacturers in Yemen. The capabilities of these local manufacturers are:as follows:

Production of pharmaceutical raw materials production of formulations from pharmaceutical raw material repackaging of finished dosage forms

The first local pharmaceutical manufacturer was established in Sana'a the capital city, in 1982. In the next four decades several pharmaceutical manufacturers

had built factories and many pharmaceutical products had become available locally [8].

In 2010, the domestic manufacturers were in control of 9.40 % of the market share by value produced. Locally multinational pharmaceutical products were unavailable. Good Manufacturing Practice (GMP) certificates were conferred to these ten manufacturers or companies. Thousands of pharmaceutical products of these local companies have carved their names in the local markets. The international organizations for different types of local pharmaceutical products were recognised. Additional to the local pharmaceutical products, there are more than 306 medical importers in Yemen due to the inability of local manufacturers to tailor to all the needs for the pharmaceutical products [7.8]

There is an ongoing expansion of the local pharmaceutical products despite the varying difficulties that have dampened the development in this sector. These challenges and obstacles must be overcome by allowing more public and private efforts and solutions to be executed [7-11].

Yemeni pharmaceutical product manufacturers increased and developed despite the emerging issues. Unfortunately, due to the persisting political crisis in the country, some pharmaceutical manufacturers had terminated their activity for a while. Fuel deficiency and unavailability as well as unsafe condition were some factors behind this [13].

The main factor that we must have for continuous improvement and fast growth in the pharmaceutical product sector is political stability and economic improvement in any country. Accordingly, and referring to that important factor, the future of pharmaceutical products Yemen may continue to be doomed unless something is done to raise the awareness.

Investment in pharmaceutical products sector by international manufacturers or companies should be highly prioritized to encompass the market needs and to better the quality of medical services in Yemen. Therefore, a significant opportunity for foreign pharmaceutical companies should be given and seized [13].

Recently, the pharmaceutical industry has been progressing very well in Yemen. It is noteworthy that the starting level of this industry is already a modern level, according to the standard specifications. Nowadays, these local factories generate at least 15 to 20% of the local market needs, while in the past years,

it did not even surpass more than 5%, because the manufacturing production volume and the volume of consumption in the market, according to our studies were 15 to 20%.

Yemeni pharmaceutical producers have tried to visualise the future to develop the pharmaceutical industry, which is unfortunately, not shared in the Ministry of Health Vision. It is assumed that, the industry up after five years to cover 40%, after ten years to cover about 70%. Actually, these will have a great impact, to improve the development, to expand the industries and the production process as a whole, which can subsequently support the national economy. Moreover, in the presence of institutes and universities, especially as Yemenis are consumers of the drug, the chances to import from countries such as Saudi Arabia and the Gulf states are slim.

In fact, the pharmaceutical industry in Yemen has a good quality and viable development even in rural areas, which reached about 35% in some local varieties although it is still at its infancy—the medicines are always available at a reasonable price, with high quality, according to the standard specifications and measurements. There are a lot of drug companies in Yemen, with international standards and specifications, and they are considered some of the most successful manufacturers and producers of drugs, which earned the testimony of international organizations as well as the Ministry of Health.

Some historical studies are deemed significant; the beginning was in 1964, where the Yemeni industry and the trade of drugs were established as the first Yemeni pharmaceutical company which exercised its official exclusive agent and distributor of corporate drug world and which enabled the necessary processing of raw materials. This is beginning in 1983 after the construction of the first plant in the altar area of the capital Sanaa, evolution it in 1994 by adding intravenous fluids plant and the situation continues until 2006, where added production line modern solutions venous to keep pace with increased demand in the domestic market.

Later on, in 1993, the first private company "Saba Pharmaceutical Industries and companies" was established, automatically making the total number of companies (7), of which six (6) were reputed to have quality medicines.

These companies are:

- 1- Saba Pharma.
- 2- Shephaco Company.
- 3- International Company for Pharmaceutical

- Industry.
- 4- modern pharmaceutical company.
- 5- global company for the pharmaceutical industry.
- 6- BioPharmaInc.
- 7- Yemeni-Egyptian Company.

In its report, by the end of 2010, the Supreme Board of Drugs and Appliances, illustrated that the value of the drugs consumption in the domestic market had cost \$ 297 million, where \$ 265 million imported drugs and the local pharmaceutical industry ratio remained to be almost 11% of this value.

The challenges facing the Arab Pharmaceutical Industries

Previously, we have dwelt into the challenges facing Yemeni pharmaceutical industry, bearing in mind that these challenges are not only facing Yemen but more specifically the Arab pharmaceutical industry. These challenges could be divided into three categories; main challenges, external challenges, and self-challenges. We will next discuss each category and the link between these categories.

A- The Main Challenges:

The challenges that surface are mainly due to trade agreements, either at a national or international level. It has a forceful impact on the market all in all evident from the increasing cost pressure; higher manufacturing costs, with a higher regulatory requirements (*such as, BE,GMP,PV*). These challenges are common for any kind of industry which in turn will lead to in the increased cost of compliance & marketing. Furthermore, the Changes in Business Trends are also one of the main challenges facing the Arab pharmaceutical industry, and the challenge of Originators into Generics, is another challenges that cannot be taken lightly.

To tackle these challenges, we now come to a summary of the challenges that Arab countries are facing in regard of medicine production:

- Encouraging innovations and development of new medicines and ensure universal access and affordability all around the world.
- Complying with the national and global codes of ethics to promote safe medicine.
- Complying with the WTO and bilateral free trade agreements and making sure that the interest of public health is safeguarded.
- Combating the serious issue of counterfeit medicines nationally and

- globally.
- Using traditional medicines in a proper way.
- B- The External Challenges: External challenges include multiple dimensions; and they can be seen from two angles. One emphasizes both the administrative and technological dimension and the other is concerned with dimensions that have to do with global trade agreements, particularly, the Convention on intellectual property rights. What we have below is a discussion about the significance of each one of them.

1- Challenges related to administrative and technological dimensions:

The small size of the Pharmaceutical market calls for a higher degree of coherence and coordination among the members of this market, so that there will be a positive impact in the course of pharmaceutical matters (like the issues of pricing and transfer technology.

 There is a relative backwardness in the Arab Pharmaceutical market compared to some developing countries namely India, Brazil and China.

The development of management officers for the pharmaceutical industry mechanisms in the international environment, as far as the Arab pharmaceutical industry is concerned, did not strive for the prosecution or development.

- b) The existence of a great deal of negative practices in the international environment for the pharmaceutical industry calls for a cautious and collective Arab intelligence on these practices.
- c) Fast-paced changes in the research and development activities, in the specification and in the pharmacy systems, necessitate intensive and sustained efforts for the organization, coordination and harmonization.

2- Challenges of global trade agreements

These challenges arise through three main mechanisms, a) Availability of Permeability market

- b) Commitment to Universally accepted specifications.
 - C) The protection of intellectual property rights.

C. Self-Challenging

1- As a member in the Arab countries Yemen has a lack of strategic vision, for the development of the pharmaceutical industry. The lack of such vision has led to some fundamental mistakes such as:

- Continuing to evaluate the progress of the pharmaceutical industry standard covering domestic consumption,
- The establishment of a national pharmaceutical company with the participation of consortium US dollars in the establishment of a research and drug development company without any sound policies or blocs or alliances and national research*.
- 2- The lack of potential especially after 2005 (the date of the start of implementation of the TRIPS Agreement). It is worth mentioning here that the heads of national companies in Egypt (from the public and private sectors), had assembled twice in 2001. Once taught to fulfill the request of foreign companies, to terminate the production of two hundred Egyptian medicine (in May). Again, another taught for an American company on the right investment marketing for one of their drugs (in September). However, the gathering was never at the same speed and seriousness and diet adequate to confront the post-transition period for TRIPS Agreement implementation and the procedures, which came to a close at the end of December 2004.
- 3- Delayed growth of the pharmaceutical raw materials industry, as well as the delay in the organization of the pharmaceutical industry.
- 4- Satisfaction of local competitiveness within the restricted scope of consumer.
- 5- Absence of coordination on plans and directions of a production, leading to the similarity of the products.
- 6- Absence of an Arab strategy from the domestic and foreign marketing.
- 7- Poor quality (considering the global competitiveness).
- 8- Entry of international companies as they purchase national companies and its success in this a few times (in Egypt in particular).

D- The link between the external and subjective challenges:

It is conclusive that this common factor deteriorates the Arab stability regarding future prospects in the domain of pharmaceutical industry. Without a sense of the urgent need for collaborative action, there is the lack of transparency in information and low level of commitment among some leaders. The failure to envisage the future tends to cause more failures and they become more and more unable to deal with issues surrounding intellectual property rights.

The requirements for the future, the way forward:

The basis of the pharmaceutical industry is mainly the scientific research and development activities, and yet, in the Arab region, the scarcity of the research and development of effective activities has been well acknowledged, despite the growing number of qualified researchers in the areas or fields of drug. Graduates from the faculties of science, pharmacy, agriculture, medicine, and even engineering, are deployed in units of scientific research in Egypt and other Arab countries. In addition, systematic doubt these claims exaggerated to a very large extent, as we have made clear before we attract attention to developments in the international environment for the pharmaceutical industry believe that a positive deal with it absorb higher enablers and requirements for the future. The most important of these developments point briefly - to the following:

- a) The alliance of big companies do not necessarily and automatically lead to improved sales and research capabilities. [14]. However, the companies involved might be exposed to the decrease in the productivity speed, jumps and hops stemming from research and development. Compared quickly similar jumps in these companies by the union, which made analysts think that big companies resort to the Union (or gigantism) from the perspective of the fear of a union between competitors [14]
- b) The greatness of major companies in the world of medicine does not deprive small and medium-sized companies of producing value capabilities or Value Creation Potential, especially when the efficiency of small and medium-sized companies tend to be higher [14].
- c) it is hard in practice that a small or mediumsized companies have been able benign management and budgets of research is relatively low (less than \$ 30 million) to continue to new drug substances and to achieve an alliances have a presence on the global level, references
- d) That the major research achievements of the giant pharmaceutical companies are evident through vital collaborations between these major companies and other small research companies, and small private companies and research (in the field of medicines produced by biotechnologies) boasted off rapid and sustained global triumphs.
- e) The task of pharmaceutical developments and producing a great added value not only yields a new drug materials research (which may override the degree of financial risk), but also

the work and activities of research on the development of pharmaceutical dosage forms which activities are less expensive and tender faster.

Having achieved that, perhaps it can be briefly be referred to the following as the most important requirements on the Arab pharmaceutical industry in a positive interaction with the challenges that surface.

- 1- Coordination and harmonization within the Arab pharmaceutical market so that they become a big market especially when as it deals with issues of raw materials also the transfer and development of technology.
- 2- Arab pharmaceutical industry ranking list (the national and regional levels) into two types:
- industry of Generics or quality, so-called generics.
- Pharmaceutical industry Research. By means of making the necessary arrangements and requirements and alliances so that growth can be achieved for both industrial cities.
- 3- Revaluation of the exchange rate on the research and development activities and the rationalization of operations management of these activities spurred by governments' positive roles in this regard, aided by efforts of governments of other countries (in Spain, England, Portugal, Singapore and India, for example).
- 4- Sponsors for the pharmaceutical industry Arab civil systems, on the national and regional levels (such as the Arab Union of Producers of medicines, and the Federation of Egyptian Industries), working together to reach a strategic vision on the development of the Arab pharmaceutical industry, aided by details and experiences of other countries (such as India, Spain and Brazil).
- 5- Alliance between pharmaceutical Arab companies and Arab banks and Arab investors to create and develop the BS Arab Research Centre aiming at creating work breakthroughs and at creating the coordination of Arab Research and development activities and the establishment of research alliances —Saudi Arabia and its Arab counterparts.
- 6- Productive and marketing coordination between Arab members of the pharmaceutical industry.
- 7- Solidarity at the Arab level (the pharmaceutical industry NGOs governments) for the introduction of changes to the Convention on the intellectual property rights to be in line with the general

humanitarian interests and the Southerners in particular. [14]

Recommended solutions:

- ➤ To have a better organised data collection on the consumption patterns, needs, local markets and local production of medicines and vaccines with a particular stress on the coverage of essential medicine needs
- ➤ Build policies to boost the production of essential medicines and vaccines with good quality and which support the quality assurance (GMP and ISO 9000) and environment management (ISO 14000) systems
- Develop holding companies bationally and regionally with three main responsibilities, coordinating the drug production, empowering the quality assurance and promoting research and development
- ➤ Improve the capacity of the national regulatory authority to enforce GMP requirements, and cater for WHO prequalification requirements
- Work on and carry out new strategies (generic medicine policies, hospital formularies etc.) to keep an ongoing supply of essential medicines and good quality vaccines at reasonable prices
- ➤ Motivate academic and research institutions to steer their research activities towards developing new medicines for diseases prioritised by the government [1]

Conclusion

In spite of the exponential growth in the population and in the consumption of drugs, the pharmaceutical industry has been very weak, where global pharmaceutical products appear to take over the domestic market. The pharmaceutical production is in need of skilled human resources like university graduates like pharmacists, biologists, chemists and laboratory technicians. By contrast, the government and the private sector should also boost the pharmaceutical industry and manipulate the local employment.

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