Views On News
رأي في أزمة
VIEWS ON CRISIS
ECES
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Views on the Crisis

Manufacturing Industries (cont'd)

Industries that Benefited from the crisis:

Pharmaceutical Industries

Introduction

Further to the first report on the impact of the current crisis on manufacturing industries as a whole, detailed reports aim to provide an in-depth analysis of the various types of industries. Accordingly, the manufacturing sector was divided into three sections according to the impact of the crisis on it in its early stages, as follows:

1- Industries that benefited from the crisis

2- Industries that moved out of the spotlight

3- Industries that are struggling to survive

For each group of industries, the report will provide an assessment of the situation, based on a detailed economic analysis of the current situation in an example from each group that answers the following questions:

1- What are the details of the sudden change in the value chain?

2- How is the industry affected during the crisis cycle by external and internal supply and demand shocks?

3- What are the measures required to reduce the negative impact or to increase the comparative advantage during the time of the crisis?

“The first priority for our excellent pharmaceutical sector affiliates is to build the knowledge to find treatments, vaccines and a cure for this terrible virus. But then the industry will need to have a serious introspection, about global supply chains, about the role of the state, and about how to ensure stronger health systems.”

Kemal Özkan

IndustriALL assistant general secretary

First: Brief description on the issue of the report

The pharmaceutical sector is one of the most critical sectors that acquires special importance among the rest of the manufacturing industries for several reasons, including:

- It is one of the necessary industries that affects human health and is closely related to the health care sector.[1]
- It is a large manufacturing industry with high added value and a different profitability rate.
- Drugs are inelastic goods, on which demand continues even with higher prices, as it is a necessary commodity whose lack affects human health. Even if there are some available substitutes sometimes, the demand for them remains inelastic, but with a different degree of elasticity.[2] The demand for drugs is also

[1] The percentage of Health care spending to the GDP is considered very low (4.2%) compared to the global average (9.9%), or even to the average prevalent in the Arab countries (5.3%) or in the MENA region (5.2%). The private sector finances 68% of health care expenditures, while the government spends only 32% of it (Shuaa Securities Research, "The Egyptian Pharmaceutical Industry: A Sectoral Vision," January 2020). See the Egyptian Center for Economic Studies, Views on the crisis: Health Sector, No. (10), http://www.eces.org.eg/cms/NewsUploads/Pdf/2020_4_13-7_31_13%D8%A7%D9%84%D8%B5%D8%AD%D8%A9%20.pdf

[2] Price elasticity of demand is an economic measure of the response of quantity demanded or purchased of a product to its price change. Expressed mathematically as: Price Elasticity of Demand = % Change in Quantity Demanded / % Change in Price. A commodity is considered elastic if the change in the quantity demanded is greater than it in the price as its value is greater than one such as luxuries, and vice versa if the change in the quantity demanded is less than it in the price, then the commodity is considered inelastic good and its value is less than one, such as necessities and essential commodities like pharmaceuticals, some food products, etc.

derived from high rates of disease prevalence, especially chronic diseases.

- Being an inelastic commodity makes it not much affected by periods of depression or economic recession, especially with the high prevalence of diseases. It is also not very affected by imposing precautionary measures, such as curfews, etc. As pharmacies and clinics are always excepted from these measures.
- The pharmaceutical industry is also characterized by an inelastic supply; as it is an industry with intensive research and development. Especially in Egypt, where the activity of scientific research is very low and the active pharmaceutical ingredients (APIs) are imported from abroad.
- The nature of the pharmaceutical products market varies; as it is oligopolistic by nature, where few companies dominated large proportions of the market, especially in Egypt, where this proportion is under the control of multinational companies.
- Lack of studies that dealt with the pharmaceutical industry in Egypt, especially recently.
- Its role as an industry has clearly emerged with the current Covid-19 crisis, especially with the majority of opinions turning to classifying it as an industry that benefited from the crisis, but the

real impact of this will arise through assessing the situation in this report based on a detailed economic analysis of the current situation.

Below is a description of the structure of the pharmaceutical industry, starting with a global picture of pharmaceuticals production, then a description of the value chain and an analysis of the main features of the pharmaceutical industry in Egypt.

1- The Global Picture of the Pharmaceutical Market

The global pharmaceutical market is estimated at $1.25 trillion in 2019.[3] The pharmaceutical industry is characterized by an oligopolistic nature, its market is subject to what is known as “oligopoly power. “It means the control of few companies over the market share of pharmaceutical products. Figure 1 below shows the market cap of the top ten pharmaceutical companies in the world in November, 2019, noting the following:

- The huge market cap of these companies in a noticeable way, so that the market share of the smallest company reached $108.6 billion.

[3] https://www.statista.com/statistics/263102/pharmaceutical-market-worldwide-revenue-since-2001/

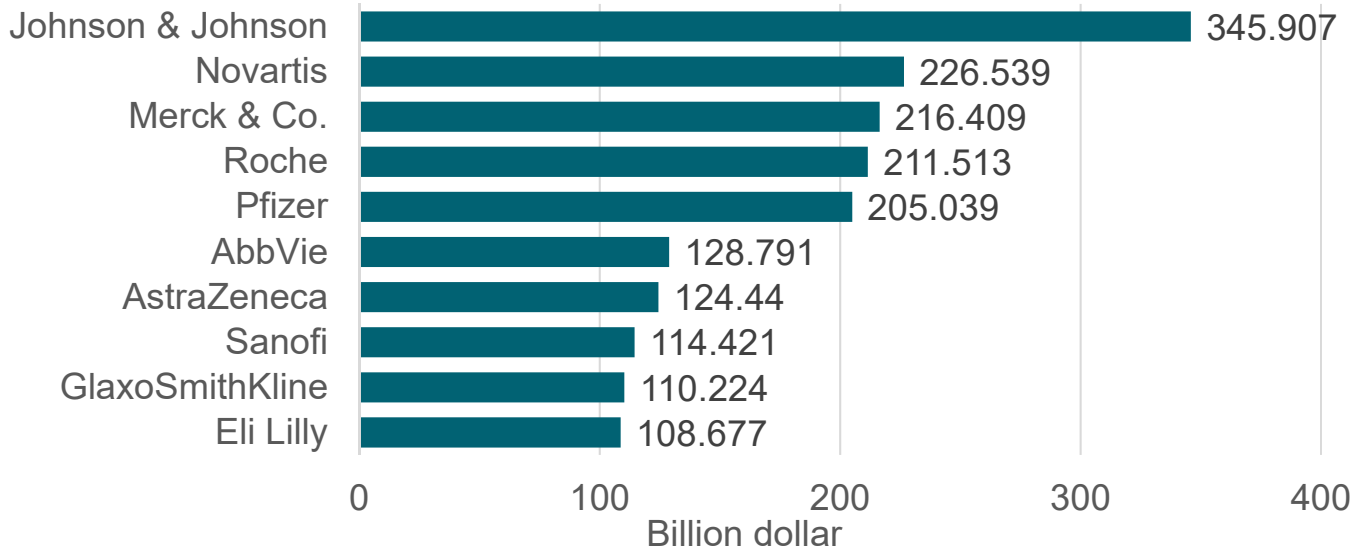
- Johnson & Johnson tops the list with a market cap of about $346 billion,[4] classified as the single company with a market cap of over $300 billion, followed by Novartis, with a difference of about 35%.
- The rest of companies are divided into two groups, the first group includes companies with a market share that exceeds $200 billion, starting with Novartis and ending with Pfizer in the fifth place, with a difference of 37 percent from the next company, which is AbbVie representing the first company in the second group, the group of $100 billion, which includes four other companies.

But the matter differs with regard to the share of countries in pharmaceutical exports. Globally, in 2019, Germany is the top country exporting pharmaceutical products, followed by Switzerland and the Netherlands, while the United States is ranked seventh, followed by the United Kingdom. India is also ranked 11th, and China is ranked 19th, probably because they have a wide market for the production and export of active pharmaceutical ingredients (API).[5]

[4] Johnson & Johnson's high market share is likely due to its large-scale cosmetic products line, especially for children. This means that pharmaceutical companies do not necessarily produce pharmaceutical products only.

[5] The market for producing or exporting APIs is a very competitive market, concentrated in the United States and the European Union, and throughout Asia, specifically in India and China http://www.worldstopexports.com/drugs-medicine-exports-country/

Figure 1. Market share* of the top ten pharmaceutical companies worldwide in November 2019



Source: https://www.genengnews.com/a-lists/top-10-pharma-companies-of-2019/

* Based on Market CAP.

The pharmaceutical sector, of course, is more dependent than any other industry on research and development (R&D). This is due to the continuous need and importance of inventing new drugs, for public health and/or for manufacturers. As the latter retains the patent for a period of 20 years, after which other companies have the right to offer similar (generic) medicines, which forces companies to move to a new invention to preserves their market share. Therefore, the pharmaceutical sector accounts for the largest share of research

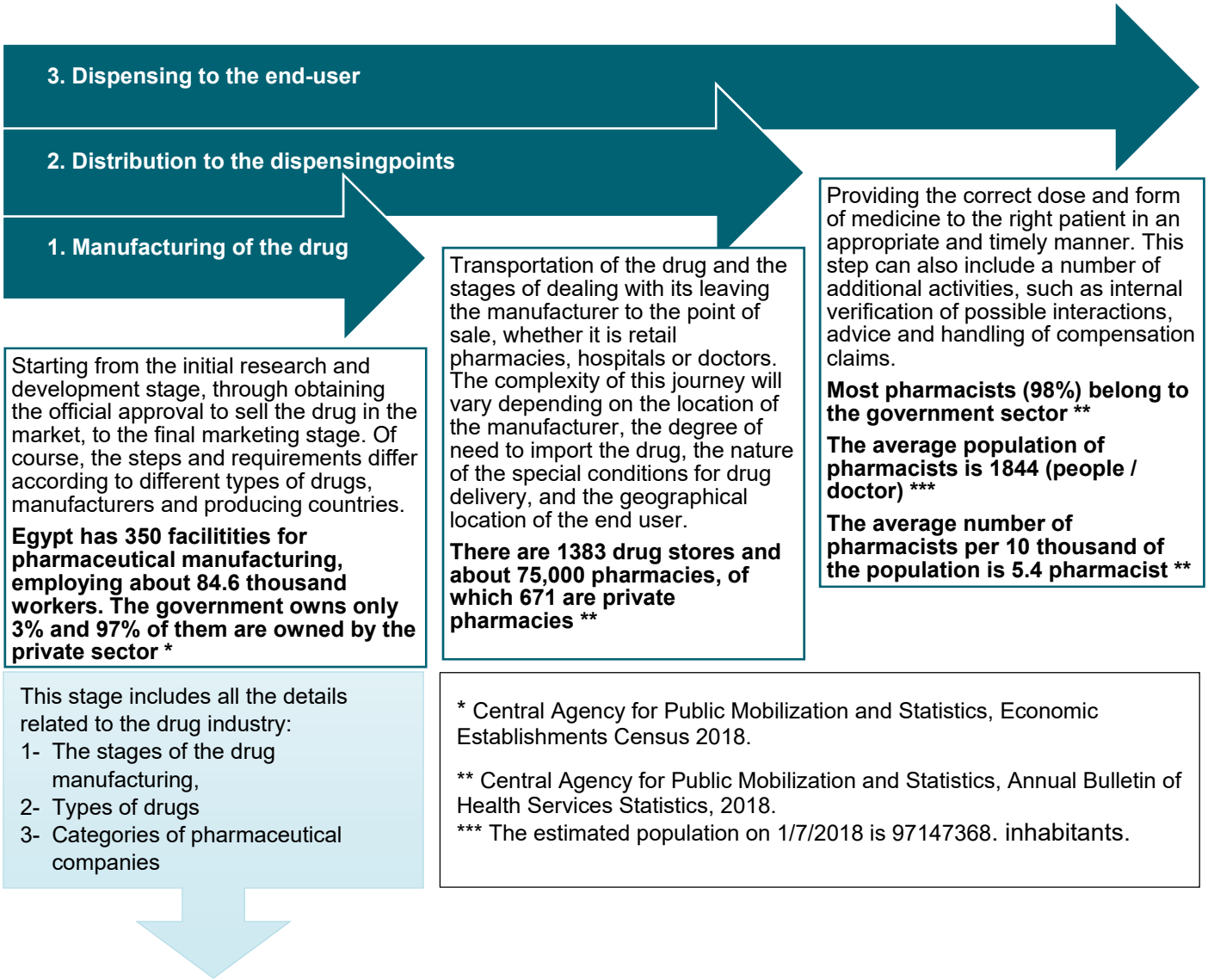
and development activities[6] (15 percent compared to 10.6 percent in the information technology sector and 5.9 percent in the automotive and engine industries), according to the latest available data.[7] The United States contributes with the largest share of spending on research and development in the pharmaceutical field reaching 58 percent of total spending on research and development in this field worldwide, followed by Japan with 13 percent, then Switzerland and the United Kingdom at 7 percent, then Germany (6 percent) and France (5 percent) in 2016[8].

2- The value chain of the pharmaceutical industry in Egypt

The following figure shows the value chain associated with drug production[9] in general, which includes three main components: drug manufacturing,[10] distribution and end-user access. The figure shows the details of each stage[11] and the status of Egypt in each of them.

[6] The industry's R&D weight represents R&D spending as a percentage of net sales in 2016.
[7] European Federation of Pharmaceutical Industries and Associations (EFPIA).
[8] https://www.abpi.org.uk/facts-and-figures/science-and-innovation/worldwide-pharmaceutical-company-rd-expenditure-by-country/
[9] https://www.ifpma.org/wp-content/uploads/2016/02/IIHI_Report_Pharma_Value.pdf
[10] For a detailed description of components of the drug industry, see Appendix No. 1.
[11] International Modernization Centre (IMC), 2004, Egypt's Pharmaceutical Sector Survival and Development Strategy Report Incorporating Results and Conclusions of Review Activity.

Figure 2. The value chain of drugs products



2-1. Stages of drug manufacturing:

The manufacture of all pharmaceutical products goes through three stages. The first and main stage includes the production of bulk pharmaceutical chemicals (BPCs) and active pharmaceutical ingredients (APIs). The second stage involves converting BPCs, and APIs, into a dosage form of tablets and capsules, topical creams,

ointments and powders, injections, and others. As for the third stage, it includes packing products in their final form, storage and distribution at points of sale. For most Egyptian pharmaceutical companies, the pharmaceutical industry falls only in the second and third phases due to the almost total dependence on imported APIs (the number of pharmaceutical factories in Egypt reaches 158, while those that manufacture the raw materials do not exceed two factories[12]), as will be shown later.

2-2 Types of pharmaceutical products:

Medicines are divided into the following four main types: **Innovative drugs**, which are the ones that were invented as a new chemical product, and thus are patent-protected from imitation or reproduction; **generic drugs**, which are copies of innovative products that are out of protection, i.e., past their patent protection period, with different types and periods of protection; medicines with **"Added-Value Generics**," where products rely mainly on copied molecules, but have been changed to give original added product properties; **branded drugs** with international pharmaceutical companies experiencing increasing proportions of their product

[12] The Egyptian Center for Economic Studies, what does localization of industry means in the Egyptian case, May 2020 http://www.eces.org.eg/cms/NewsUploads/Pdf/2020_5_8-9_20_21PR%2020200506%20Industry%20Localization.pdf

portfolios being off-protection, significant efforts are applied to build-up brand loyalty to a product before it reaches this status. Due to the regulatory framework and practices in place in Egypt, only a few of the first type are available in the local market, and thus this group of products will not be covered in detail in this report. Pharmaceutical manufacturers in Egypt mainly produce the first and last types of drugs, which are "generic drugs" and "branded drugs," due to the weak capabilities of research and development to create new or high value added medicines, in addition to the control of multinationals, which hold patents for many drugs for long periods; controlling over two-thirds of the market. Thus, the previous two types become the cheapest accessible alternative for them in light of the Ministry of Health pricing ceiling and the high cost of obtaining APIs, as will be shown later.

2-3 Categories of drug manufacturers:

There are five categories of drug manufacturers: **Pharmaceutical Innovator and Manufacturing Companies** (PIMCs), which includes research and development activities to launch new dose products in the global market under international patent protection; p**harmaceutical innovator companies** (PICs), which focus on introducing new products to PIMCs, referring to the most important field in this activity as biotechnology; **pharmaceutical development**

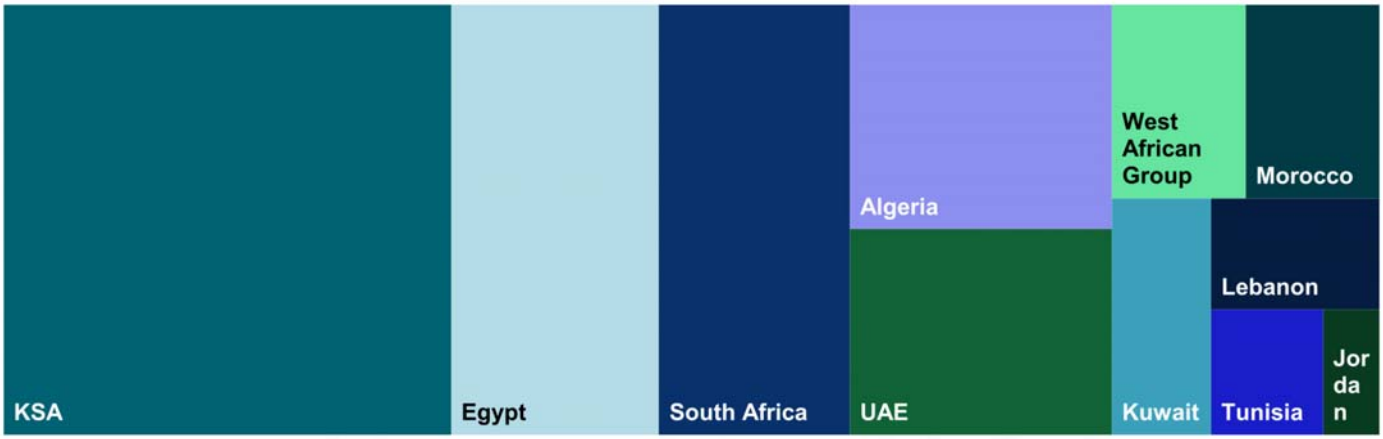
support companies (PDSCs), which take over the elements of the research and development process for new products by assigning third parties or so-called outsourcing services on behalf of PIMCs; **pharmaceutical manufacturing companies** (PMCs) that do not attempt to launch "innovative" products and focus on the manufacture of license-expired (generics and others) products; **pharmaceutical sales companies** (**PSCs)**, which conduct sales on behalf of PIMCs, and PMCs. For Egypt, the drug is manufactured through the last two categories of companies: producing generic and marketing and selling drugs, due to the low costs and production capabilities compared to other companies.

3. Main features of the pharmaceutical industries in Egypt

3-1. Egypt's regional status

Egypt achieved the highest growth rate in the Middle East for drug consumption (sales) in 2018, according to the IMS. As Figure 2 shows, Egypt ranks second in the region after Saudi Arabia in terms of its share in the region's total market value of drug sales, followed by South Africa and Algeria, while the United Arab Emirates comes in fifth, and Jordan lags behind with a small share.

Figure 3. Countries' share in the total MENA region in terms of drug market sales volume, 2018[13]



Source: IQVIA, Middle East & Africa Pharmaceutical Market Insights, June 2019

While the picture changes when Arab countries are ranked in terms of pharmaceutical exports, so that Jordan comes second after Saudi Arabia, which ranks 44th globally, followed by Morocco (65) and then the United Arab Emirates (67), while Egypt comes in 69th among pharmaceutical global exporters,[14] in 2019.

3-2. Drugs Foreign trade

Despite the huge market value of Egypt's drug sales in the Middle East, it is not the most advanced in its industry, as Egypt's increasing production of pharmaceuticals has not been coupled with the

[13] IMS is now IQVIA https://www.iqvia.com/
[14] Last quarter of 2018.

promotion of research and development nor successful attempts to manufacture the active ingredient instead of importing foreign[15] active pharmaceutical ingredients (API).[16] Egypt imports[17] the largest part of its inputs of active materials, packaging requirements, etc., or final products of medicines and medical supplies from abroad; more than 90 percent of raw materials used in local production are imported, which covers 93 percent of domestic consumption.

Egypt's imports of pharmaceutical products amounted to about $2.61 billion, compared to only $271.85 million for exports during 2019, according to the UN COMTRADE database. Consequently, our imports of pharmaceutical products exceed our exports by about 9 times (Figure 8).

3-3. The regulatory framework for the pharmaceutical industry in Egypt

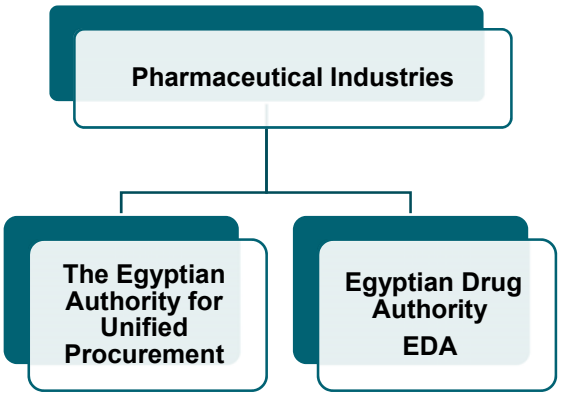
The regulatory framework governing the drug industry in Egypt has been completely restructured with the issuance of Law No. (151/2019),[18] which states for the establishment of the Egyptian Drug

[15] http://www.worldstopexports.com/drugs-medicine-exports-country/
[16] https://www.ngage-consulting.com/downloads/Pharmaceutical_PDF_Final_Version_K_and_A.pdf
[17] Health Care Issues, with application the pharmaceutical sector in Egypt, Central Agency for Public Mobilization and Statistics, May 2015.
[18] Law provisions: https://manshurat.org/node/61255

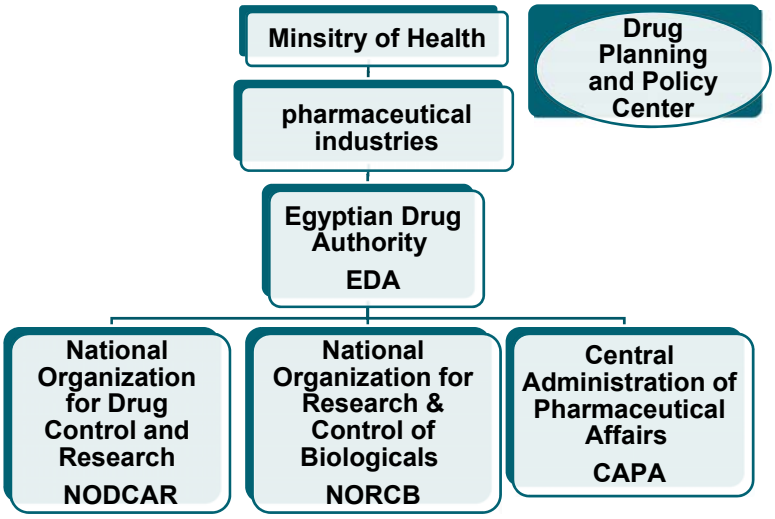
Authority (“EDA”) and the Unified Medical Procurement Authority (“UMPA”), with the aim of developing the health system, providing medicine on a regular basis, and facing monopolistic practices in the sector and the development of the medical industry, in addition to countering the phenomenon of counterfeit medicines. This is provided that these two bodies assume all responsibilities of managing the entire system replacing the Ministry of Health,all previous supervisory and research bodies and other administrative units and entities concerned with pharmaceutical, medical cosmetics and medical requirements. Details of the powers of each of the two bodies are given according to the law in Appendix No. (2). The following figure and table illustrate the difference between the previous and current organizational structure for managing the pharmaceutical sector.

Figure 3. The previous and current organizational structure managing the pharmaceutical industry in Egypt

Current System (April 2020)



Previous System (1955- March 2020)



Source: Prepared by the Egyptian Center for Economic Studies based on information of the Egyptian Drug Authority, and provisions of Law No. (151/2019).

Table 1. Previous and current regulatory framework for the pharmaceutical sector affairs in Egypt

Previous (1955 - March 2020)	Current (from April 2020)
Egyptian Drug Authority (EDA) *Law (1955/127)* Reports to the Ministry of Health and supervises three regulatory bodies:	**1- The Egyptian Drug Authority (EDA),** *Law (151/2019)* An independent body whose president has the rank of minister

1- **Central Administration for Pharmaceutical Affairs (CAPA):** It is responsible for approving the marketing of products in Egypt, licensing factories and implementing GMP standards for pharmacies.	• It replaces the Ministry of Health and Population with regard to this sector, and the Chairman of its Board of Directors replaces the Minister of Health and Population in all the authorities stipulated in Law No. 127 of 1955, so that it exclusively takes over the competencies prescribed for the Ministry of Health and Population, public bodies, and government departments in regulating registration, pricing, circulation and control of medical cosmetics and medical supplies subject to the provisions of the law and raw materials used in their manufacture. • The authority exclusively undertakes all the organizational, executive and oversight authorities necessary to achieve the objectives entrusted to it and the objectives to be achieved in accordance with the international standards of the regulatory bodies. The Drug Control and Research Authority Fund (Republican Decree 404/1983) and the Drug Planning and Policy Fund devolve to it.
2- **The National Authority for Drug Control and Research (NODCAR),** *established by Republican Decree 382/1976*: It is responsible for ensuring the quality of the pharmaceutical products available in Egypt. It is concerned with granting approvals for the quality of each batch produced inside Egypt, whether intended for sale locally or for export.	
3- **The National Authority for Research and Control of Biological Products (NORCB),** *established by Republican Decree (398/1995)*: It is responsible for ensuring that all vital biologicals and vaccines used meet the required quality, in accordance with international approved indicative standards. It is also responsible for licensing the registration and marketing of products, monitoring and control of marketing processes, access to laboratories and	

tests, and supervision of clinical trials.	
In addition to the Center for Drug Planning and Policy of the Ministry of Health under Law (127/1955), which coordinates the registration and pricing of food and drug products.	**2- The Egyptian Authority for Unified Procurement, Medical Supply and Technology Management (AUPP)** An independent body whose president has the rank of minister • It exclusively undertakes the procurement of human medical supplies and supplies for all government agencies and bodies, in return for paying a purchase fee that does not exceed 7 percent of the net value of what the authority purchases for the authorities, bodies and companies referred to in the law, without adding customs or the value added tax or other costs. • It coordinates with pharmaceutical and medical supplies companies, whether government, private, foreign, local or international, subject to the provisions of this law, to enhance the state's strategic medical stock to meet any exceptional circumstances that need urgent intervention and requires providing capabilities that exceed normal needs in stable conditions.

By analyzing the main differences between the previous and current systems, compiling the opinions of some of the concerned drug companies, it is clear that one of the most important advantages of the new system is dealing with only one entity, which shortens

measures, as well as achieves economies of scale in purchasing that allow for lower prices and better benefits. However, with these advantages of centralization, there are disadvantages represented in the monopoly of activity and the absence of a detailed executive regulations. The disadvantages extend to the focus on purchasing at low prices as the sole objective in purchasing medicines and medical supplies. The result of this may be the exclusion/escape of local investments as a result of their inability to fulfill the needed requirements and thus depending more on international companies and imports. This is detrimental to the sector in the long term and is already felt in medical supplies.[19] This is in addition to the overlapping roles and tasks between the previous and current systems so far.

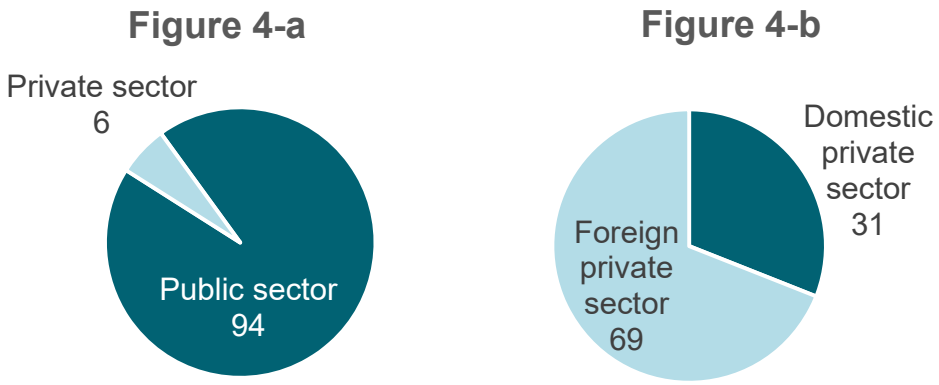
3-4. Structure of pharmaceutical production in Egypt

The public sector contributes to the pharmaceutical industry in Egypt by a very small percentage, amounting to only 6 percent, through 11 companies working in the manufacture, export and import of medicines and medical supplies, and it is affiliated to the Holding

[19] It is noted that the medical supplies are not the subject of this report, but they are mentioned because of their direct relationship with the method of dealing with the unified procurement authority.

Company for Medicines, Chemicals and Medical Supplies. while 94 percent of the market share belongs to the private sector. Consequently, the government sector's production of medicines does not exceed 20 percent of total production, while the private sector produces about 80 percent of the medicines in Egypt. Hence, the dominance of the drug market by private sector companies, whether local or multinational, becomes evident, with the second accounting for 69 percent, while the first accounting for 31 percent of the drug's market share in 2018[20] (Figure 4).

Figure 4. The sectoral structure of the pharmaceutical industries in Egypt in 2018

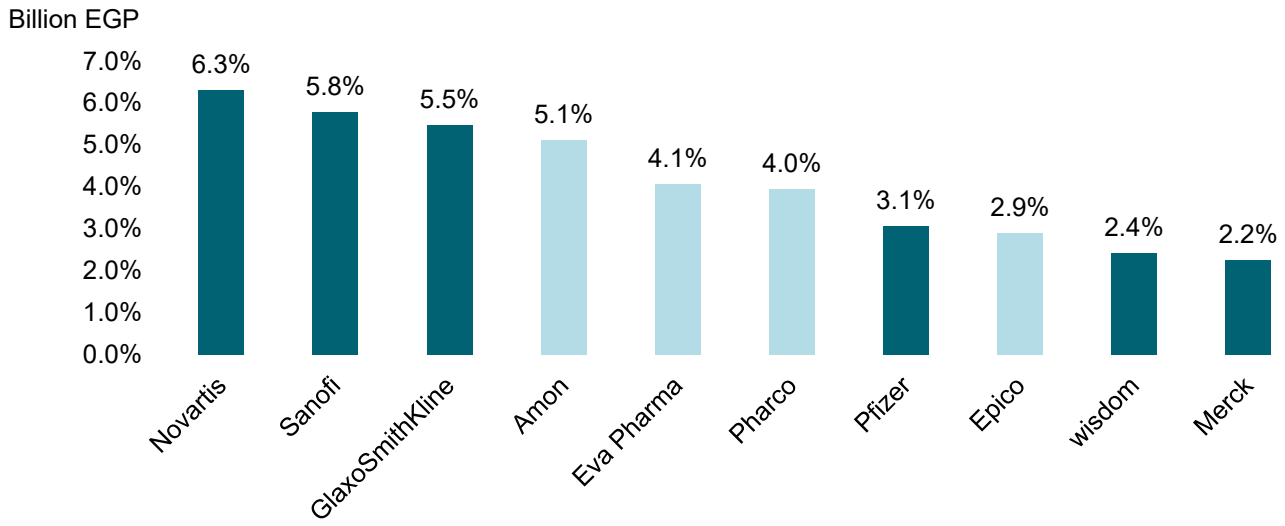


Source: SHUAA Securities Research, "The Egyptian Pharmaceutical Industry: A Sectoral Vision", January 2020.

[20] SHUAA Securities Research, "The Egyptian Pharmaceutical Industry: A Sectoral Vision", January 2020.

Regarding pharmaceutical companies in Egypt, the three companies, Novartis, Sanofi and GlaxoSmithKline, top the list of largest multinational companies in terms of the relative weight of their sales in the Egyptian market in the first quarter of 2020. While Amon, Eva and Pharco are at the forefront of the local pharmaceutical companies, as shown in Figure 5 below.

Figure 5. The relative weight of the sales of the top 10 pharmaceutical companies in Egypt in the first quarter of 2020



Source: Egyptian Center for Economic Studies calculations based on data from Al-Borsa newspaper (quoted by IMS).[21]

[21] https://alborsaanews.com/2020/04/29/1329259

3-5. Volume of drug production in Egypt

The size of the drug market in Egypt is estimated at 400 billion Egyptian pounds.[22] Pharmaceutical production contributed to the GDP by 1.3 percent during 2016/2017 .[23] The volume of investments in the pharmaceutical industry in Egypt is estimated at EGP 80 billion (8.6 percent of total investments in 2018/2019), equivalent to annual production of 2.5 billion medicine packages.[24] In terms of volume, Generic drugs represent the largest percentage, equivalent to 69.3 percent of the total pharmaceutical produced packages. In terms of value, Generic drug sales account for nearly two-thirds of the market, which represents 1.5 times the value of sales of patented drugs and generic drugs of foreign companies combined, whose total number is 89 companies that produce 1566 pharmaceutical types compared to 209 companies producing generic drugs and producing 4184 pharmaceutical types; in the private sector. This is in addition to 1400 companies working in manufacturing for third parties.[25] Figure 6 below shows the top ten Egyptian companies producing generic drugs in 2017. Pharco tops the list with a market share of 7 percent

[22] https://www.almasryalyoum.com/news/details/1471794

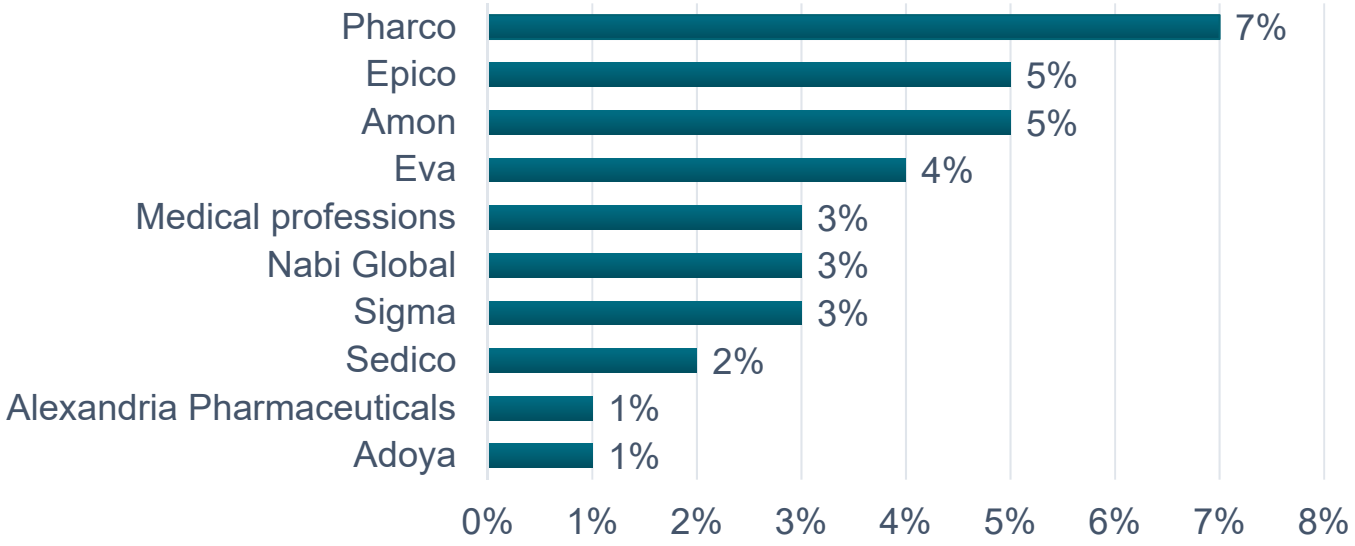
[23] ECES calculations based on the Ministry of Planning and Economic Development data of GDP.

[24] The Egyptian Center for Economic Studies, what does the localization of industry mean in the Egyptian case, May 2020 http://www.eces.org.eg/cms/NewsUploads/Pdf/2020_5_8-9_20_21PR%2020200506%20Industry%20Localization.pdf

[25] Personal interviews with experts in the field of pharmaceutical industries, Dr. Jaber Awad, former president of the Pharmaceutical Export Council.

compared to 5 percent for both Eipico and Amon in second place, while the two companies of Alexandria—affiliated to the Holding Company for Medicines—and Adoya lag behind with a very small market share of 1 percent.

Figure 6. Top ten companies in the production of generic drugs in Egypt according to market share in 2017



Source: pharmaboardroom.com.

3-6. Pricing the Pharmaceutical Products

Drug pricing is one of the most important problems facing the pharmaceutical industry in Egypt, as it represents a constant point of contention between the three heads of the pharmaceutical industry triangle: state regulatory authorities, pharmaceutical factories and

the final consumer. This is due to several factors that overlap, forming the drug pricing problem in Egypt, the most important of which are:

3-6-1. The compulsory pricing system of the medicine: Pricing medicine in Egypt was usually conducted according to the system approved in August 1988 as per Resolution No. 314/1991. It adopts the (cost +) method or what is known as the Cost Plus Formula, whereby a profit margin is determined for the producing company within 25 percent of the total cost, with the exception of the list of essential medicines that get a profit margin of 15 percent on their production, with an 8 percent profit margin for the distributor and 20 percent for the pharmacist.[26] By 2009, this pricing methodology was changed and replaced, as per Decision No. 373/2009, with a reference system based on comparison with other countries' prices through a basket of 36 countries that includes Canada, European countries and the Gulf states, with these prices reviewed every three years.[27] In 2012, it was amended by Resolution No. 499/2012,

[26] Healthcare issues with application to the pharmaceutical sector in Egypt, Central Agency for Public Mobilization and Statistics, May 2015.

[27] SHUAA Securities Research, “The Egyptian Pharmaceutical Industry: A Sectoral Vision,” January 2020.

whereby the profit margins of pharmacies were increased, and the margins of drug-producing companies reduced.

3-6-2. Exchange rate floating decisions, that directly raise the prices of raw materials and intermediate inputs needed for drug production, which are 90 percent imported from abroad, in addition to imports of final pharmaceutical products. Consequently, producers with the fixed price ceiling of the Ministry of Health suffer from greatly increasing production costs, which put pressure on their profit margins, hence stopping their production of some important medicines. State-owned companies do not have this option, which causes a bigger problem. This prompted the government to raise the prices of some medicines after floating the exchange rate in 2016 as a first round (20 percent with a minimum of 20 EGP per package), and then in early 2017 as a second round (30-50 percent according to different price groups).[28]

3-6-3. High oil prices, as the prices of some types of active ingredients are linked to oil prices due to its direct entry into their manufacture, for example petrochemical products that are chemically extracted from petroleum products.

[28] EN Cage Consulting, Public Strategy and Government Relations Specialists, 2017, “Egypt’s Pharmaceutical Sector Following Bold Economic Reforms: Challenges and Reports”.

3-6-4. Agreement on Intellectual Property Rights - TRIPS: The main challenge in signing the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is to tighten the siege on local drug producers due to the commitment to the right to invent the drug, which resulted in a decline in research and development opportunities due to its high cost, lengthy validity of the license, the exit of some local manufacturers as a result of the high cost of drug licenses, the high cost of the final medicine and the raw materials, and hence the effect on the trade balance, with a decline in the share of the local industry in the market, and the control of multinational companies and their penetration in the local market. These consequences were exacerbated by Egypt's failure to fully exploit the ten years preceding the implementation of this agreement in preparing for it through adopting effective policies instead of continuing to adopt intensive defensive policies that led to a decline in the performance of the sector as a whole.

3-6-5. Monopolizing the pharmaceutical industry: This is due to the decline in the role of the government sector in the production of medicine and the erosion of its share from 60 percent two decades ago to only 6 percent compared to the private sector companies, especially international ones. They control two-thirds of the market.

3-6-6. The repeated mergers and acquisitions, whether between international companies or between them and local companies in developing countries, which led to the ease of monopolizing market and its polarization by a small number of companies.

3-6-7. Circumvention of drug companies to adjust prices, meaning effecting a cosmetic change to pharmaceutical products or updating the package so that the drug is re-priced. This made it easier for multinational companies to manipulate the prices of their products in light of the lack of control, which negatively affected local producers.[29]

3-6-8. Other factors related to raw materials pricing mechanisms, which may be subject at times to the exaggeration of major investment companies in agreement with the approved suppliers. Also, the lack of a mechanism for adjusting prices has resulted in unfair individual differences in adjusting prices between companies, which necessitates adopting transparency principles in dealing with the pricing process.[30]

Figure 7 below shows the development of growth rates of drug sales in real terms in Egypt for the period 2011-2019, noting the following:

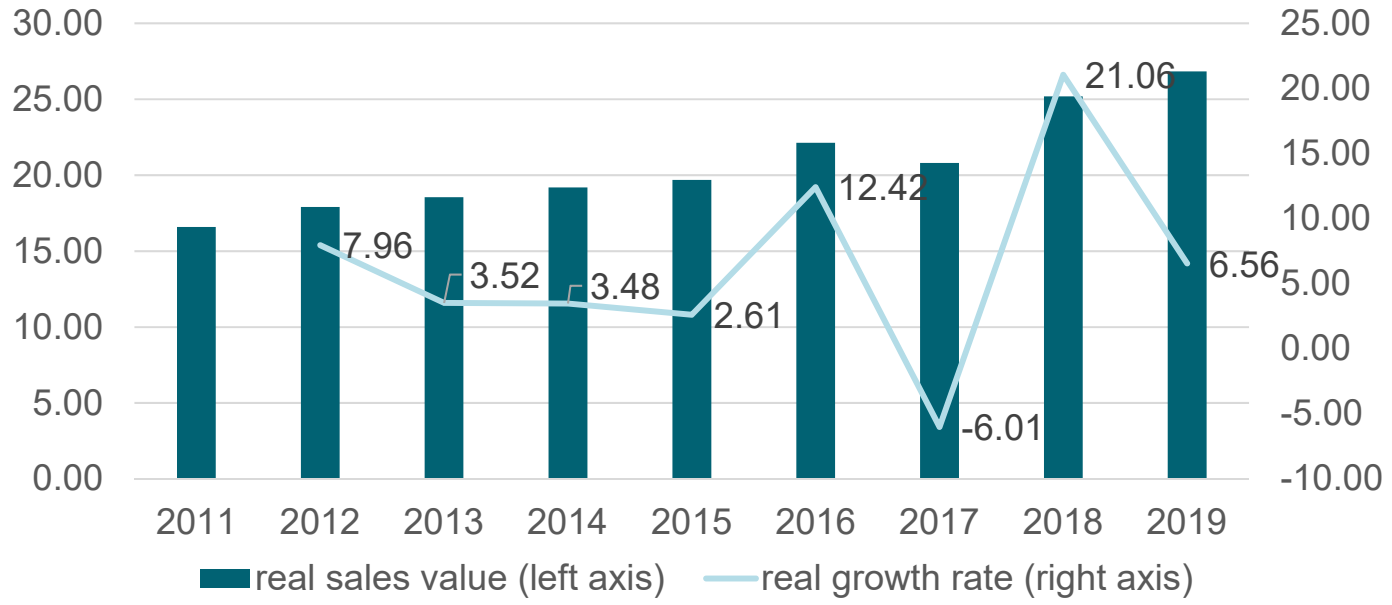
[29] Healthcare issues with application to the pharmaceutical sector in Egypt, Central Agency for Public Mobilization and Statistics, May 2015.
[30] IBID.

- Drug sales witnessed fluctuating growth over the past decade, reaching their first peak in 2016, with a marked increase compared to 2015, possibly due to the wave of price hikes approved by the Cabinet in May 2016 by 20 percent for medicines less than EGP 30, as a direct result of the shortage of about 4000 items.[31]
- The growth rate fell to its lowest level in 2017 due to the float of the local currency exchange rate in November 2016. This caused a sharp decline in the growth rate of pharmaceutical sales to -6 percent, cutting short the temporary recovery between 2015 and 2016.
- Sales recovered to their second peak in 2018, due to two factors: The first is the second wave of price hikes in 2017, according to the decision of the Minister of Health in January 2017 to raise the prices of 3010 drug types by 30-50 percent within a new pricing system,[32] in an attempt to correct the effects of floating the Egyptian pound. The second reason lies in the negative base of the growth rate in 2017, which contributed to the high growth rate.

[31] EN Cage Consulting, Public Strategy and Government Relations Specialists, 2017, “Egypt’s Pharmaceutical Sector Following Bold Economic Reforms: Challenges and Reports”.
[32] IBID.

- This strong return to the growth rate in 2018 did not last for long, as there are still complaints of high import costs and foreign companies' monopoly on the market, it declined to 7 percent, which was the prevailing rate at the beginning of the series.

Figure 7. Evolution of real values* of sales of pharmaceutical products and their growth rates in Egypt for the period 2011-2019



Source: Egyptian Center for Economic Studies calculations based on Pharma Boardroom data, and the Central Agency for Public Mobilization and Statistics.

* The CPI series adopts 2010 as a base year.

Second: The impact of previous crises

The analysis in the previous sectors has been linked to two major crises: the global financial crisis of 2007/08 and the repercussions of the 25-January Revolution in 2010/2011. As for the pharmaceutical sector, the market has been clearly affected by two additional crises over the past decade. The health crisis as a result of the spread of the bird-flu virus in 2006 and swine flu in 2010, and the repercussions of the decision to float the Egyptian pound exchange rate in 2016. The following are some details of each of the four crises in their chronological order:

1. **The spread of influenza epidemics (Bird flu 2006 – swine flu 2010)**

   The direct impact of the bird and swine flu epidemics on the drug market in Egypt is divided into two phases:

   - **The first phase** includes the spread of the virus, which slightly puts pressure on antibiotics, antipyretic and preventive vaccines, because it coincided with the winter season, in which seasonal influenza infection is mainly high, thus the demand for the same types of drugs is accordingly high.

     In the case of swine flu, the Tamiflu vaccine was introduced by foreign companies and imported from abroad at a cost of EGP

60 million for 1.9 million doses. the Nile Drug Company registered it and put it on the market 6 months after its appearance[33]. In other words, local firms did not benefit in the first six months.

- **The second phase**, which is the stage of the virus receding, whose effect was to reduce the profits of some companies as a result of the decline in sales of antibiotics and vaccines. In the case of swine flu, only a few companies (such as GlaxoSmithKline, the Nile Company, being the only local company that recorded Tamiflu vaccine) achieved a significant decrease in profits as the disease subsided.

2. **The global financial crisis (2007/08) and the 25-January revolution (2010/2011)**

   Figure 7 shows that imports have increased significantly in the two periods between 2007 and 2008, and between 2010 and 2011, that is, after the global financial crisis and the January 25 revolution.

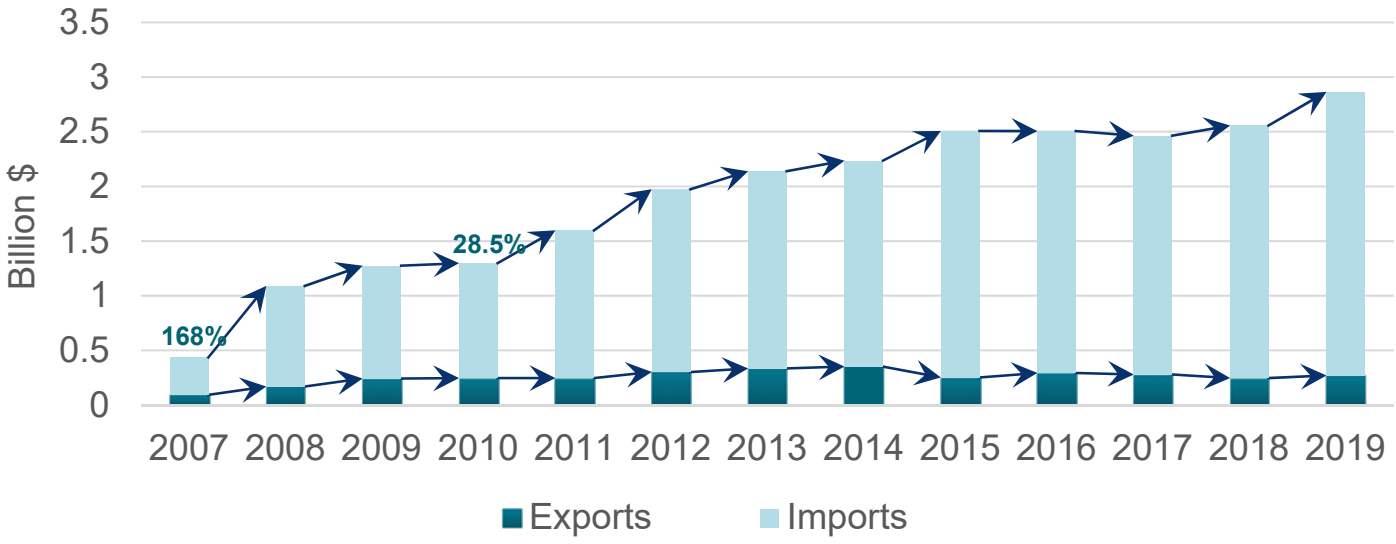
3. **Repercussions of floating the Egyptian pound (November 2016)**

[33] Al-Mal newspaper, "The decline in swine flu deprives pharmaceutical companies of antibiotic sales growth," February 2010.

The Egyptian government's decision to float the exchange rate in November 2016 greatly affected the performance of the pharmaceutical industry. This was clearly evident in high production costs due to the high cost of importing intermediate inputs. As shown in Figure 8 below, exports have fluctuated clearly, up and down, around the same rate over the past decade, while imports continued to grow over the years, except for 2016-2017, especially due to the floatation of the Egyptian pound, which doubled the cost of production inputs, with a dual effect on the trade balance of the pharmaceutical industries:

- Producers were unable to reduce the prices of their products in foreign markets.
- The import proceeds decreased as a direct result of the almost total dependence of the pharmaceutical industry on imported active ingredients.

Figure 8. Development of Egypt's exports and imports of pharmaceutical products for the period 2007-2019



Source: UN COMTRADE International Trade Database.

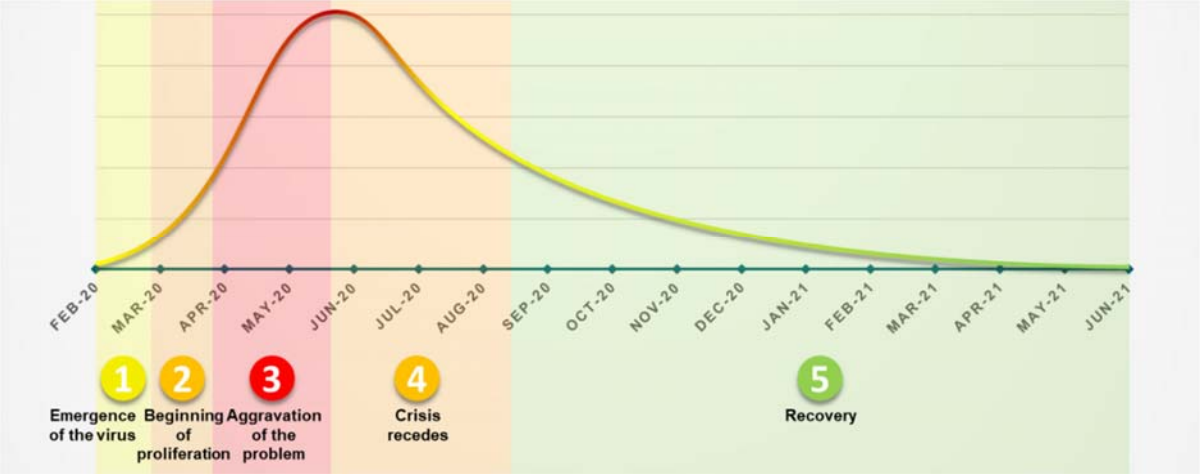
Third: Demand and Supply Shocks in the context of the Crisis Cycle

In this section, we analyze the impact of Covid-19 on the Egyptian drug market according to supply and demand shocks during the stages of the crisis cycle illustrated in Figure 9. The following is a definition of the supply and demand shocks of pharmaceutical products.

Demand shock: The huge increase in demand for pharmaceutical products and disinfection and sterilization supplies more than usual.

Supply shock: Inability of the pharmaceutical sector to meet the needed medicines, disinfection and sterilization supplies.

Figure 9. The stages of the crisis



Source: The Egyptian Center for Economic Studies.

Below is a brief description of each stage:

The first stage: Emergence of the virus

The crisis began and aggravated in China only. The rest of the world, including Arab and European countries, were not yet affected by the crisis.

The second stage: Beginning of proliferation

The spread of the virus globally. Arab countries began to be affected at the end of February and initiated precautionary measures to prevent the spread of the virus. European countries are greatly affected.

The third stage: Aggravation of the problem

The situation in the world has worsened, tougher measures in Arab countries, especially Saudi Arabia, and in European countries, a major worsening of the crisis in Italy, beginning of the virus's receding in China, and beginning of its spread in the United States.

The fourth stage: Crisis recedes

The beginning of recovery from the virus globally, starting from China, which is expected to be followed by European countries, and finally, Arab countries and the United States.

The fifth stage: Recovery

Gradual recovery in all countries, including Arab countries, although the latter's recovery is expected to be delayed due to being strongly impacted by the global economy and its weak impact on it.

Table 2 below presents the impact on the pharmaceutical sector during the crisis cycle, by analyzing what has already been achieved on the ground in the previous period, providing a descriptive analysis of the current situation, as well as presenting possible future scenarios starting from August 2020[34] in light of the following concepts and assumptions:

[34] These estimates should be read with caution, as forecasts may require further reviews due to day-to-day development of the virus outbreak, and its duration and scope are still unknown.

- Egypt depends almost entirely on importing active ingredients and production requirements.
- Both the supply and demand of drugs are derived from the development of the health status (degree of disease prevalence), which is directly related to reaching a vaccine.
- The method of managing the disease treatment system by the Ministry of Health directly affects the drug market.
- The prevailing uncertainty controls the health situation regarding the development of the virus and its repercussions on the pharmaceutical sector, as it is a new strain with a possible new mutation (as happened in China), and therefore it is not expected that a vaccine will be reached soon.
- The pharmaceutical sector is largely unorganized, causing monopolies and price speculation.
- Workers in the pharmaceutical sector are more susceptible to disease, just as doctors, as a result of their interaction with patients or potential patients.
- The analysis focuses on pharmaceutical products and prevention and disinfection supplies, given their direct relationship to the COVID-19 crisis.

- Due to the weak health insurance system,[35] the Egyptian citizen pays for his treatment from personal expenses.

Table 2. The stages of the crisis cycle due to supply and demand side shocks and the expected effects on the pharmaceutical market

Stage	Demand and/ or supply shock	Analysis	Impact on the Pharmaceutical market[36]
The first stage: Emergence of the virus (December 2019-January 2020)	Limited supply shock in active ingredients (API) imports from China. There is no demand shock.	The beginning of disruption of global supply chains with the stoppage of companies in China (the production of 10-20% of APIs stopped with the onset of the outbreak[37]) and the stopping of supply, and thus	The drug market is not affected due to the sufficient stock of active ingredients and production requirements for a period of six months (varies from company to company)

[35] Direct payments represent about 62 percent of total healthcare spending in Egypt, while this percentage reaches 38 percent for insured patients, according to the latest data available in 2016 for the World Health Organization database. The number of insured persons in 2018 reached about 55.6 million citizens, half of them are school students and nearly a quarter of them are currently in the workforce (12 million). This means that only about half of the employed (22.5 million in 2018) are covered by health insurance (Views on the Crisis: The health sector, issue # 10, Egyptian Center for Economic Studies).

[36] All data on exports and imports of medicines and pharmaceuticals are sourced from the monthly foreign trade bulletin, the Central Agency for Public Mobilization and Statistics, various issues, unless otherwise mentioned.

[37] https://www.scienceboard.net/index.aspx?sec=sup&sub=cell&pag=dis&ItemID=700

		the beginning of the shortage of imports of active ingredients, medical supplies and imported drugs. And relying mainly on existing stock.	
The second stage: the beginning of the virus spreading (February – mid-March 2020)	Continued supply shock in China Supply shock extends to India	A complete paralysis in the supply chains between China and India, and India stopped supplying other countries (the US and others) with ready-made medicines as a result of this inability to supply the raw material imported from China, with the increase in the prices of active ingredients by about 30%.[38] India's decision to halt the export of	Imports of medicines and pharmaceuticals decreased during the first quarter of 2020 by 29% compared to the corresponding quarter of last year.

[38] https://www.almasryalyoum.com/news/details/1471794

		26 active ingredients (APIs) in early March.[39]	
	The beginning of a slight shock in domestic supply		Lack of stocks of some pharmaceutical companies
The third stage: Crisis worsening (mid-March-mid-May 2020)	Strong supply shock from abroad.	Paralysis of global supply chains of pharmaceutical products and raw materials, and a shortage of raw materials for the manufacture of protective supplies (Egypt imports 95% of raw materials, packaging materials and medical supplies—55% from China and 45% from India)[40].	- Imports of medicines and pharmaceuticals decreased by 10.4% during April 2020 compared to April 2019. - Exports of medicines and pharmaceuticals decreased by about 20% during March 2020 compared to March 2019, and the percentage increased to 30% during April 2020 compared to April 2019.

[39] https://www.outsourcing-pharma.com/Article/2020/03/03/India-stops-export-of-certain-APIs
[40] https://www.almasryalyoum.com/news/details/1471794

	Severe demand shock	The beginning of rising demand and the rush for certain types of medicines and disinfection and sterilization requirements.	- Sales increased by 12% during the first quarter of 2020 compared to the same quarter of 2019.[41]
	Severe domestic supply shock	- As a result of increased pressure on stocks with the increase in the number of infections and the attempt to control the outbreak more quickly. - The spread of panic among citizens and high demand for medicines and vitamins announced in the treatment protocol, and high demand for prevention supplies and	- A shortage of certain types of medicines and vitamins and complete disappearance of some of them, which led to a notable increase in their prices. - Protective supplies such as medical masks, gloves, and sterilization cosmetics such as alcohol and others became scarce, which led to a doubling of their prices. - Decisions by the Ministry of Trade and Industry to stop the export of alcohol of all kinds and derivatives and surgical mask. - Requiring companies to supply their stock and production to the Unified Procurement and Medical Supply Authority, for which the cabinet has

[41] https://amwalalghad.com/2020/05/19/%D8%A3%D8%B2%D9%85%D8%A9-%D9%83%D9%88%D8%B1%D9%88%D9%86%D8%A7-%D8%AA%D8%B1%D9%81%D8%B9-%D9%85%D8%A8%D9%8A%D8%B9%D8%A7%D8%AA-%D8%B4%D8%B1%D9%83%D8%A7%D8%AA-%D8%A7%D9%84%D8%A3%D8%AF%D9%88%D9%8A%D8%A9/

		sterilization medical cosmetics, in addition to the crisis reaching its peak and the inability of the health system to absorb more cases, forcing many cases to stay home and follow the self-treatment protocol.	expedited the issuance of executive regulations specifically to fulfill this role and face up to the crisis. - Cancellation of all conferences and business related to medicines and medical cosmetics, suspending research work in relation to other diseases and the dedication of scientific research to reach a vaccine for the corona virus (there are currently more than 155 drugs and 70 vaccines for the Corona virus under development worldwide.)[42]
The fourth stage: the crisis recedes (mid-May-Aug 2020)	This period is divided into two phases, Phase I (mid-May - end of June 2020). It witnessed a continued severe shock in	The peak of the crisis, in terms of the speed of the disease spreading and the performance of the pharmaceutical sector. With the return of companies in China and India to production and gradual reopening of markets, supply	- Pressure on medicines and sterilization supplies has increased, and certain types of medicines and vitamins have disappeared from the market. - A sharp decline in the value of exports of medicines and medical cosmetics, which reached 98 percent in June 2020 compared to June 2019, and 53 percent in the second quarter of 2020 compared to the corresponding quarter of 2019.

[42] https://www.scienceboard.net/index.aspx?sec=sup&sub=cell&pag=dis&ItemID=700

	supply and demand.	chains of active ingredients are back to operation.	- Reimport and re-provision of medicines, but at a higher cost, and thus an increase in the import bill during the month of May 2020 only by 115.6 percent compared to the same month of the previous year. In June 2020 these percentages decreased to only 36% compared to the same period. The average increase in the import bill during the second quarter of 2020 has reached 27% compared to the corresponding quarter of 2019.
	Phase 2 (early July - end of August 2020): A gradual decline in the intensity of the supply and demand shocks	Pharmaceutical companies in Egypt started production. A gradual easing of precautionary measures and a gradual opening up of the economy. The beginning of government measures to prepare for the manufacture of the vaccine in Egypt, in agreement with the Chinese	- Limited availability of disinfectants and masks, while missing items of medicines are still under production (inline period between production of the drug and its availability in pharmacies). - The number of infected cases decreased, and so the demand for medicines, with continued demand on masks and sterilization requirements. Accordingly, possible scenarios can be constructed for the pharmaceutical sector, beginning in August, as follows:

		government, with Egypt being the center of its manufacture in the African continent and its export to African countries.	Optimistic scenario	The intensity of the crisis continues to slow and the sector gradually recovers
			Availability of medicine	The import bill will continue to rise, assuming the same rate of change between June 2020 and June 2019.
			Percentage increase in import bill	36%
			The pessimistic scenario	relapse
			Shortage of medication	The continuation of the situation in May, including strict preventive measures and a shortage of available medicines, vitamins, and preventive and

<table>
<tr><td></td><td></td><td></td><td><table><tr><td></td><td>sterilization supplies</td></tr><tr><td>Percentage increase in import bill</td><td>115%</td></tr></table></td></tr>
<tr><td>The fifth stage: Recovery (September 2020 - June 2021)</td><td></td><td>Recovery at this stage relates to possible scenarios above.</td><td>Based on the two previous scenarios, two scenarios for this stage can be constructed, as follows:<table><tr><td rowspan="4">Optimistic scenario</td><td>The arrival of a vaccine for the disease</td></tr><tr><td>No new strains of the virus appear</td></tr><tr><td>Cautious return of the sector as the spread of the disease slows</td></tr><tr><td>Increase in the value of sales and exports and gradual return of imports to normality</td></tr><tr><td rowspan="2">Pessimistic scenario</td><td>Failure to find a vaccine</td></tr><tr><td>New strains of the virus emerge</td></tr></table></td></tr>
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				Relapse to the previous pressures
				Higher prices and lack of stocks of medicines once again, with disruption of production.
				Decline in sales and exports while imports continue normally.

Fourth: Institutional weaknesses revealed by the crisis and the required interventions to mitigate the effects of the crisis

Unlike previous industrial sectors, the measures needed to mitigate the crisis are clearly linked to the institutional weaknesses of the pharmaceutical industries. The following table divides the institutional weaknesses of the pharmaceutical sector into two types, institutional weakness that has already emerged with the change of the institutional framework of the administrative and supervisory system, and chronic institutional weakness represented by the "lack

of pricing" which has existed for many years, the main dependence on imports and the irregularity of the pharmaceutical market in Egypt.

Table 3. Required procedures to address the institutional weaknesses of the pharmaceutical industries

First: Urgent measures needed to address recent institutional weakness	
Institutional weakness as a result of changing the regulatory framework,	**Urgent Actions**
A terrible overlap between the specializations and roles of each of the two bodies	- Despite the importance of dealing with one party provided by the new organizational structure, it may be desirable to make a complete separation between the responsibility of the commercial part (in relation to pricing, export, etc.) and the technical part (in terms of research, control, etc.)). - The new institutional form assigns the responsibility of drug distribution to the drug manufacturing management system as well, which is considered impractical for the distribution at the level of the Republic, as with the presence of about 75 thousand pharmacies nationwide, it is difficult to achieve this through Single Purchase Authority. Hence, there is an urgent need to deal with the known distribution companies to fulfill this role, as they perform it through a special financial mechanism in dealing with pharmacies using different financial method that is difficult to implement directly through

	dealing with the Ministry of Health or the consolidated procurement authority. - One of the important urgent procedures is to review the method of the Unified Procurement Authority with medical devices and supplies[43], which it has been working with for two years, as the main focus is purchasing at reduced prices as the sole objective of procurement, which causes the exit of local investments as a result of its inability to achieve the required requirements[44], and thus the problem must be quickly remedied so that the same type of problems do not recur with medicines. - To expedite the preparation of detailed executive regulations for the new regulatory bodies to start working regularly, with specific performance standards to avoid monopolizing the decision and causing future losses to investors, and with a clear monitoring system on the performance of the two bodies, taking into account the opinions of producers in this regard (both local and international), whether companies producing medicines or medical supplies. - Organizing the relationship between the Ministry of Health and other concerned authorities. With clarification of the tasks and roles of the ministry.

[43] Although medical supplies are not covered in detail throughout this report due to their not being directly related to drugs, it is important to refer to them as an urgent measure that has a potential impact on the drug system.

[44] This is in addition to the merging of the executive regulations of the new pharmaceutical system pharmaceuticals with medical devices and supplies.

Second: The necessary measures to address chronic institutional weaknesses	
Chronic institutional weaknesses	**Required Actions**
Mystery of drug pricing	- Despite the social goal behind reducing drug prices, the method of managing the drug pricing system has led to the distortion in the Egyptian pharmaceutical sector, and the reluctance of pharmaceutical companies to invest in Egypt, especially after the Egyptian pound floated, and even after raising drug prices to more than once in less than a year. Consequently, it is required to **review the pricing system,** benchmarking the experiences of other countries in this regard, so that certain categories (such as certain hospitals) are determined at reduced prices, but without generalizing these prices at the level of the Republic, because this causes a decline in the role of export in the field of medicines due to the strong correlation between the export price and the domestic price in the country of origin, which calls for multinational companies to escape from the Egyptian export market dragging research and development with it, while it is necessary to encourage them and encourage the entry of research and development into the local market. - Reviewing the local companies 'positions and identifying their problems, whether in relation to pricing, import, export or production.

The main dependence on imports, especially the import of active ingredients and intermediate materials required for drug production.	- Gradual reduction of this dependence on imports by creating Egyptian excellence through more research and development in the field of medicines based on Egyptian medicinal and natural plants, especially with the global interest in this type.
Market irregularity and it mainly appears in: 1- The shortage of medicines and the disappearance of important items, especially in times of crisis, as 50% of the registered items are not available, and there are 4 thousand items that were not produced despite their registration[45]. 2- The spread of counterfeit or smuggled medicines, where the trade of fake medicines represents about 10% of drug sales in Egypt, which amounted to about 60 billion EGP pounds in 2018, surpassing the global percentage estimated at 6%[46].	Undertaking rapid gradual measures in a phased manner to regulate the pharmaceutical market in Egypt to eliminate the phenomena of drug shortages and the spread of counterfeit medicines. Especially the disappearance of medicines in times of crises as a result of the demand for certain items and the increase in their prices.

[45] Egyptian Initiative for Egyptian Rights, Drug Policy Assessment in Egypt, July 2019.
[46] http://alahalygate.com/?p=87444

Appendix 1[47]

Stages of pharmaceutical production: The manufacture of pharmaceutical products goes through three stages:

Primary, involving the production of basic Bulk Pharmaceutical Chemicals (BPCs), and Active Pharmaceutical Ingredients (APIs), also including Intermediates as late stage material inputs for the manufacture of APIs. Manufacturing processes represent a series of chemical engineering unit operations, requiring equipment for: batch reaction; solid / liquid separation; milling and drying equipment; vacuum plants; nitrogen distribution; refrigeration systems; gas scrubber systems; solvent recovery; water and effluent treatment. BPCs are derived from two main sources:

- synthetics, based on petro-chemical derived chemical building blocks to produce complex organic chemicals, using techniques such as chemical synthesis, fermentation, enzymatic reactions and recombinant DNA technology;
- extraction of plant materials.

[47] International Modernization Centre (IMC), 2004, Egypt's Pharmaceutical Sector Survival and Development Strategy Report Incorporating Results and Conclusions of Review Activity.

APIs are usually manufactured synthetically, or apply extensive purification of plant extracts and include excipients and additives used in final product formulations.

Secondary, involves converting the BPCs and APIs into one of six dosage forms: tablets and capsules; topicals / creams, ointments and powders; parenterals / injectables; inhalers; suppositories; and syrups. Manufacturing processes include milling, drying and / or granulation to achieve the required solid particle size and blending together with the selected APIs, excipients and additives to achieve the final formulation. Secondary manufacturing typically requires relatively simple manufacturing processes, but these have to be undertaken in purpose built factories with controlled environments, often requiring sterile or aseptic conditions. In some cases, sterile products can be achieved through heat treatment when the product is in its final packaging. If this is not possible aseptic processing areas must be constructed where highly demanding design requirements must be met to achieve having a sterile environment. Critical process steps are those where the sterilized product and its container, or packaging, is exposed to the atmosphere or a surface. Manufacturers must consider product characteristics, equipment selection and facility design in order to meet product specifications, within the context of the identified critical process steps.

Tertiary, involves packing the products into their final form, storage and distribution the point of sale, or point of application. Only the PIMCs have fully integrated production systems covering each of the three stages, and therefore have the advantages of: economies of scale at the primary level; significant flexibilities at the second stage due to the range of production facilities in different countries; and vast and effective international distribution, marketing and sales networks to maximize market exposure of their product ranges.

Types of pharmaceutical products: Medicines are divided into four main types:

Innovative products, which have been developed as a new chemical entity and achieve protection from being copied. Due to the regulatory framework and practices that apply in Egypt, few of these products are available in the domestic market in significant volumes.

Generic products are copies of innovative products that are out of protection, with the different types and durations of protection. The aim of generic manufacturers is to be first into the market with a copied product, as soon as possible after protection expiry. Generic products have much lower prices, and profit margins, than innovative products, and there is a greater emphasis on out-sourcing

manufacturing, with some companies only operating marketing and sales activities.

Added-Value Generic where the products are mainly based on copied molecules, but they have been changed to give the original product added properties. Depending on the extent of the added properties and the regulatory requirements in which these products are to be sold, there may need to be trials of such products before they can be approved.

Branded Products with international pharmaceutical companies experiencing increasing proportions of their product portfolios being off-protection, significant efforts are applied to build-up brand loyalty to a product before it reaches this status. This is usually based on an approach of developing the generic product label into a market oriented brand name, where the market development activity is undertaken during the period of protection. If this approach is successful it makes it more difficult for generic product manufacturers to develop competing brands. Under these circumstances the generic manufacturer will compete more on price under the overall generic label.

Categories of drug manufacturers: There are five categories of drug manufacturers:

Pharmaceutical Innovator and Manufacturing Companies (PIMCs), which incorporate research and development activities to launch new dosage products into the global market under international patent protection. The global distribution of such products depends to a significant extent on the pricing regime that applies in each country and the extent to which manufacturers can achieve their target profit margins to recover product development costs.

Pharmaceutical Manufacturing Companies (PMCs), which do not attempt to launch new “innovative” synthetic products and concentrate on manufacturing products that are off-protection. The products can either be the original innovative product, or a generic copy, or version.

Pharmaceutical Innovator Companies (PICs) that concentrate on introducing new products to the PIMCs, with the most significant area of this activity referred to as biotechnology.

Pharmaceutical Sales Companies (PSCs), which undertake sales on behalf of the PIMCs and the PMCs on an out-sourcing basis.

Pharmaceutical Development Support Companies (PDSCs) that undertake elements of the research and development process for new products on an outsourcing basis on behalf of the PIMCs. Companies in each of the above categories are operating on an increasingly global scale, which is also resulting in increasing specialization within each category. The growth of the PIC, PSC and PDSC sub-sectors have been as a result of the PIMCs

Outsourcing activities to control costs.

Only **PIMCs** have fully integrated production systems that cover each of the previous three stages of production, thus enjoying the advantages of economies of scale at the most basic level; great flexibility in the second phase due to the range of production facilities in different countries; and extensive, efficient international sales and distribution networks. The primary manufacturing costs are increasing due to several factors, the most important of which is the increase in public health, safety and occupational standards; the increase in environmental standards and product quality; tighter regulations for manufacturing practices; and increased labor costs.

Appendix 2[48]

The specializations of the Egyptian Authority for Unified Procurement, Medical Supply and Technology Management include the following:

I. Executing plans and policies for medicines and medical technology, and taking the necessary measures to activate and implement them and include them in the state's plan, and follow up on their implementation in accordance with applicable laws and local and international health systems.

II. Setting specifications and guiding standards for requesting bodies in preparing their needs of medical cosmetics and supplies subject to the provisions of this law.

III. Coordination with medical products and supplies companies subject to the provisions of this law (governmental, private and foreign, and governmental, local and international agencies) to enhance the country's strategic medical stock to meet any exceptional circumstances that require urgent intervention and entail the provision of capabilities that exceed the normal needs in stable conditions.

[48] Law provisions: https://manshurat.org/node/61255

IV. Setting up inventory and collection systems for the annual needs of parties requesting medical cosmetics and supplies subject to the provisions of this law.

V. Contracting with all companies, bodies and private medical institutions, inside or outside the Arab Republic of Egypt, to purchase medical cosmetics and supplies subject to the provisions of this law, for the benefit of the requesting parties.

VI. Setting the rules for customs clearance of medical cosmetics and supplies to face emergency situations after coordination with the Minister of Finance.

VII. Establishing a system for evaluating medical technology according to the latest global systems to take advantage of modern technology, in coordination with the requesting parties.

VIII. Periodic review of the stock of medical cosmetics and supplies.

IX. Establish programs and electronic registration systems for local or foreign companies operating in the field of cosmetics subject to the provisions of this law and medical services in accordance with the rules and procedures established by the Board of Directors.

X. Establishing an integrated database for medical technology in centers, hospitals, warehouses and all public health facilities to follow up on needs, use, maintenance and training.

XI. Managing the storage, transportation and distribution system for medical cosmetics and supplies, inspecting the stores of the concerned authorities, managing and following up on the inspection and receipt processes and applying the highest international standards, without prejudice to the right of those authorities to establish and manage stores of medical cosmetics and supplies subject to the provisions of this law pertaining to them.

XII. Managing the unified maintenance system for medical devices to improve after-sales services.

XIII. Subject to the provisions of this law, acceptance of medical cosmetics and supplies received from abroad in the form of grants or donations in accordance with the rules regulating this.

XIV. Determine the needs of workers in the aforementioned areas in terms of continuous development and training for cadres working in this field.

The Egyptian Drug Authority's responsibilities include the following:

I. Establishing policies, rules and regulations for everything related to organizing, implementing and controlling the production and circulation of medical cosmetics, medical supplies and raw materials, and verifying their quality, effectiveness and safety inside and outside the republic within the framework of controlling Egyptian products, in coordination with the relevant ministries and bodies, in accordance with applicable international standards.

II. Developing and ensuring the quality, effectiveness and safety of medical cosmetics, supplies and raw materials for scientific innovations that are used in diagnosis, treatment or prevention in accordance with the latest developments in science.

III. Establish accurate and constantly updated databases for everything related to medical cosmetics, medical supplies and raw materials.

IV. Drug awareness and education to the community, and the delivery of health messages and documented information about the drug to professionals and to the public.

V. Regulating and controlling the production and circulation of medical cosmetics, medical supplies and raw materials, and verifying their quality, effectiveness and safety inside and outside the republic within the framework of control over Egyptian products and representation abroad.

VI. To propose and express opinion on draft laws, regulations, and decisions related to medical cosmetics, medical supplies and raw materials, as well as related regulatory matters.

VII. Cooperating and coordinating with national and international organizations and bodies concerned with cosmetics and public health and those concerned with issuing the relevant standards, within the scope of achieving the objectives of the authority, and participating in local and international conferences and organizing them when necessary.