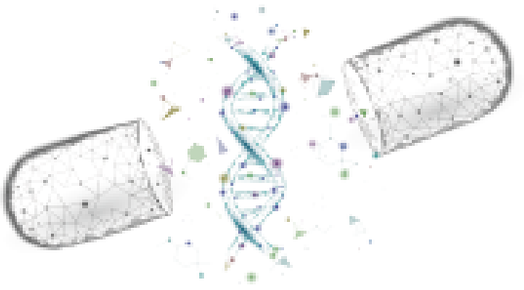
A Guide to Distribution of Pharmaceutical Products in Kuwait

2019-2020

PHARMACEUTICAL

Contents



A GUIDE TO DISTRIBUTION OF PHARMACEUTICAL PRODUCTS IN KUWAIT

1. Introduction

The area of the Gulf Cooperation Council (GCC) is regarded as an "emerging market" for pharmaceutical exports and bilateral trade. Learning this region's regulatory requirements can be beneficial for pharmaceutical exports. The Gulf countries ' regulations promote the importation of quality generic products, which facilitates a boost in the trade and economy.

In GCC countries, the drug industry reaches USD 6 billion approximately. This demand is rapidly growing and is expected to reach around USD 10 billion by 2020. Given this market's rise, local manufacturing is unable to meet the growing demand, and GCC countries continue to import most (90%) of their drug needs from abroad. Therefore, there are substantial opportunities for growth and development of this sector in GCC Besides, expanding growth in this industry will help achieve the region's strategic objectives in terms of industrial diversification into knowledge-based sectors.

The emerging sector aims at achieving the following objectives:

i. Establish a forum for the exchange of ideas and dialogue between pharmaceutical companies in the GCC

ii. Propose a multi-client study to address the needs of the region's pharmaceutical industry

iii. Identify the need for GCC producers to create a pharmaceutical trade association.

With Kuwait accelerating its plan for healthy growth as part of Kuwait's 2035 dream, the Ministry of Health (MoH) is also focusing on expanding their projects. Both the pharmaceutical and healthcare industries in Kuwait have been identified as high-priority sectors, with many initiatives under public-private partnerships (PPPs) are being carried out.

2. Kuwait Pharmaceauticals Market Overview

With the boost from the government's healthcare initiatives, the pharmaceuticals market in Kuwait is currently at a growing stage. Initially, the domestic manufacturing of medicines in the country was low due to the focus inclining towards the booming oil and gas industry coupled with limited diversification into various other sectors. It is pertinent to note that the pharmaceutical industry is closely monitored by the government, and the demand for branded and patented products has stretched the government's budget for the same. The growing trend of preventive healthcare such as the demand for pseudo pharmaceutical products like supplements and vitamins, smoking cessation aids, weight loss formulations, etc, have supported the expansion of healthcare awareness, thereby witnessing the inception of government initiatives for driving pharmaceuticals to build factories which are in line and in collaboration with the Public Authority for Industry.

3. The Regulation Process

Medicines in Kuwait are regulated on the basis of standards of quality, safety and efficacy, price control and patent protection. The nation has 40 years of regulatory framework experience and plays a leading role in the regulatory environment of the GCC.

The pharmaceutical sector of Kuwait entertains various multi-source products which are imported from multiple countries and regions. The regulatory framework set in place attempts to ensure the following objectives:

i. The product has been licensed and sold for at least twelve months in countries with recognized and

competent regulatory authorities

ii. That the product follows the desired quality standards, globally accepted, to ensure that the product is manufactured for its intended use

iii. That the product remains stable throughout the projected shelf life

iv. For local patients, the price of the product must be reasonable and affordable.

The regulation framework consists of different phases to ensure that the pharmaceuticals products that help ensure that the products are of the best quality to provide steady growth and development; the stages are as follows:

3.1 The Submission Phase

The review process begins with the local agent (or sponsor) sending the registration dossier together with a covering letter to the ***Kuwait Drug and Food Control Manager (KDFC)*** formally demanding the pharmaceutical material registration.

3.2 The Evaluation Phase

In this phase, the reviewer will evaluate the *Chemical and Manufacturing Control (CMC)* data after entering the scientific review stage, focusing on the following data:

i. Material descriptions and detailed analytical methods for finished products

ii. Total stability analyses of the expected consumer shelf life

iii. Specifications of raw materials and their procedures of analysis

3.3 The Authorization Phase

Upon completion of the full evaluation, the final approval decision is taken by the DRRS, which is officially endorsed by the authority's director.

4. The Data Required for Registration of Pharmaceutical Products

In accordance with Ministerial Decree 302/8, the Kuwait Food and Drug Authority (KuFDA) is the head regulatory agent to register pharmaceutical products.

"The pricing of a pharmaceutical product is opaque and frustrating, especially for patients."
- Heather Bresch

In order to initiate the trade and supply of any pharmaceutical product, the product must be registered in order to ensure that proper regulation can take place, the various documents and requirements needed to register the product are listed below:

I. Preview of the finished product

II. Legalized certificate of free sale issued by health authorities to COO, showing the brand register & sell with the same name & composition

III. Legalized price certificate issued by COO authority, including ex-factory price, COO wholesale price

IV. Storage conditions

V. Name of developed countries where the commodity is licensed, the foreign company's license and the foreign company's business establishment.

VI. A leaflet containing all the details (English and Arabic) such as:

i. Description: product name, strength, active substance, list of excipients, dosage, warning about certain excipients for example lactose

ii. Indication, use and clinical pharmacology

iii. Dosage and method of administration

iv. Warnings and Precautions

VII. Product supply origin and inactive components

VIII. Specifications of raw materials

IX. Specifications of finished products and methods of quality control

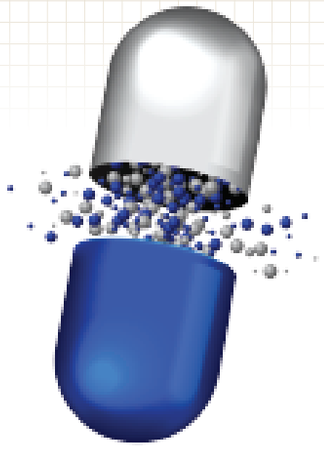
X. Stability data

XI. Accelerated studies: six months, three times the same batch, used for long-term research

5. Company Registration

To be able to distribute their pharmaceutical products in Kuwait, one must either create a legal entity or appoint a local agent.

The conventional way is to set up a legal entity to import pharmaceuticals into the country; a company can be set



"I keep encouraging the pharmaceutical companies to put more money into R&D"

– Harold E. Varmus

up through submitting the following documents along with the application form to Ministry of Commerce and Industry (MOCI):

I. Legalized letter of appointment from the company, establishing that the agent is the only exclusive agent within Kuwait

II. Original notarized Manufacturing License from country of origin for each manufacturing site issued from the Ministry of Health in the country of Origin

III. Original legalized "Good Manufacturing Practise" (GMP) from the country of origin which should not be older than two years

IV. Site Master file which must include the following:

i. General information and history of the company

ii. Capital and turnover of the past 3 years

iii. Layout and diagrams of manufacturing sites

iv. Quality control unit memo and quality management

v. Personnel Information including the number of employees, the departments and their qualifications

vi. Premises and equipment which include manufacturing sites owned by the company, manufacturing lines and equipment

vii. List of products manufactured by the company as well as exporting countries

viii. Contract manufacturing information

ix. FDA, GCC, EMEA or any recognized global approvals for the company

However, international pharmaceutical firms may opt to sell their goods through an agent with a well-established local market presence, hoping their regional contacts and know-how would propel the popularity of their products in the territory. The most prominent pharma companies in Kuwait presently are:

I. Sanofi Aventis

II. Yiaco Pharmaceuticals

III. Al Mojil Drugs Company

If a foreign pharmaceutical company decides to engage a local agent by entering into a distribution agreement, Law Number 13 governing Kuwaiti Commercial Agencies ('Department Law') allows the local agent to register the contract with the MOCI with the department. According to the law, a commercial agency means any agreement whereby the party holding the legal right entrusts a merchant or corporation in the State of Kuwait, with the duty of selling, promoting or distributing goods or items or providing services as an agent, distributor, franchisee or licensee of the product or the original supplier for a profit or fee.

The following details should be submitted along with the application form:

I. Name of the agent or distributor along with the name of the principal and his/her nationality

II. The goods, services and products covered by the agreement or contract

III. The rights and duties of each principal and agent or supplier and the extent to which the principal is responsible for the duties of the agent in respect to his representation

IV. Working area or territory of the agent or distributor

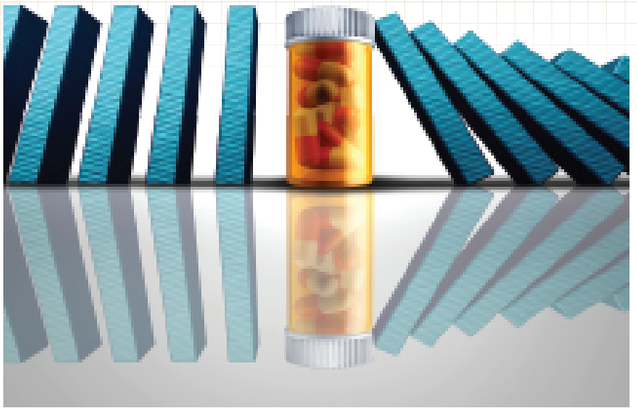
V. Time period and method of renewal of the agency

VI. Agency's termination and expiry process

VII. Any other terms negotiated between the agent or supplier and the principal

6. Protective Measures and Dispute Rules and Regulations

As mentioned above, the most popular route for international pharmaceutical companies to distribute their goods in Kuwait is an agency arrangement. In entering into such agreements, many main local law requirements for such arrangements should be taken into account by the international principal.



Initially, it should be noted that the local agent/distributor must be approved to import and distribute pharmaceutical products in Kuwait. The foreign principal must apply, and such licenses should be issued by the local agent/distributor so that the foreign principal can verify the capacity of the local agent to enter into the Agent / Distributor Agreement from a licensing perspective.

A common concern for international pharmaceutical companies is the necessity for MOH pharmaceutical registration, which allows the foreign principal to produce a certified letter granting exclusivity to the local agent. A letter of the authorisation indicating that the agent is exclusive is a necessary document for the registration of a pharmaceutical product from the MOH point of view, pursuant to Decree 302/80. Such a provision is in place to comply with the requirements for drug safety, for example, in order to be able to keep one agent responsible for MOH data management, pharmacovigilance, and to manage product recalls if necessary. While there is no provision for the agency relationship to be exclusive, the local agent will be given various rights under local law from the point of view of the MOCI and agency rule, provided that such relationship is either expressly exclusive or de facto exclusive.

These protections provide payment if the company contract is not extended. ny Unfortunately, there is no exception to the MOH provision that the local agent/distributor be named on an exclusive basis. Still, other steps can be taken to minimize the implications of a local agent being appointed exclusively.

Due to the various protections afforded to the local agent under Kuwait law, the international principal/manufacturer does not need to shy away from the company partnership. To minimize the same, the company agreement must be appropriately written. Whereas Kuwait law provides that Kuwaiti courts will have jurisdiction over any dispute resulting from the agency agreement, if the agreement's specified territory is in Kuwait, it may be agreed to refer the dispute to arbitration.

"It is clear that the pharmaceutical industry is not, by any stretch of the imagination, doing enough to ensure that the poor have access to adequate medical care"

- Herman Wouk

In addition, parties are generally free to choose any foreign law to apply to a contract under law, and any such chosen foreign law will be accepted and enforced by Kuwaiti courts, provided that the international law rules do not breach Kuwaiti's public order or morality (otherwise Kuwaiti law will apply).

As such, they generally recommend that foreign directors choose a pro principal or international governing law that is neutral, as Kuwaiti law favours the local agent/distributor. In addition, they generally recommend the inclusion in settlement of a reputable international arbitration dispute resolution process.

Depending on the experience of the Kuwaiti courts and the commitment of Kuwait to the New York Convention on the Recognition and Compliance of International Arbitral Awards, where there is a binding international arbitration clause, the Kuwaiti courts must ignore all cases brought before them due to the arbitration clause's lack of jurisdiction.

The international arbitration tribunal should then follow the foreign law chosen and should therefore not extend the statutory compensation requirements of Kuwaiti under the law of the company, as discussed above so that the law adopted does not have a specific compensation regime.

7. Intellectual Property

Pursuant to **Law Number 4 of 1962** on Patents, Designs and Industrial Models in Kuwait, *"an invention patent shall not be granted ... for pharmaceutical compositions unless such substances are manufactured by special chemical methods or procedures, in which case the patent shall not apply to the products themselves, but to the manufacturing process."*

In 1998, in response to a lack of tangible progress on intellectual property rights, including technology, videos, and sufficient and efficient patent protection for pharmaceutical products, Kuwait was elevated to *"Priority Watch"* on the *"Special 301."* Therefore, no effective

"We've had a long wrangle with the pharmaceutical industry about parallel imports, and what we were saying is we want to make medicines and drugs as affordable as a possible to what is largely a poor population."

– Thabo Mbeki

legal protection for pharmaceutical product patents is offered by the state.

8. Sale of Medicine in Private Pharmacies

It is pertinent to note that there are restrictions for selling medicines and other pharmaceutical products in private pharmacies wherein the following details must essentially be noted down by the doctor before providing a written prescription for medicines to be bought from private pharmacies:

I. Information about medicine;

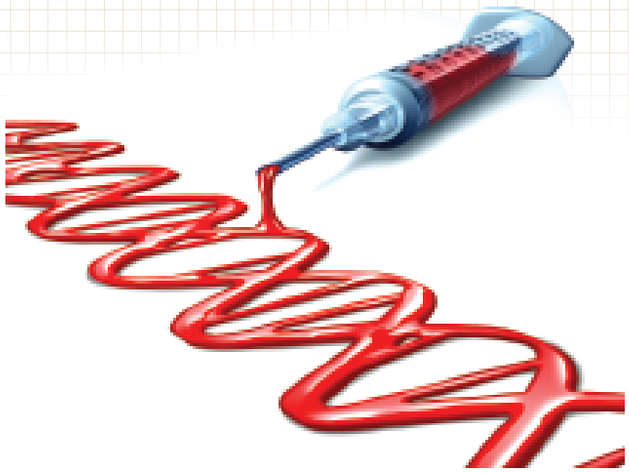
II. Patients' full names;

III. Civil ID number;

IV. Passport number in case patient is a visitor;

V. Other relevant information.

Without the abovementioned information, the sale of pharmaceutical products in private pharmacies cannot be facilitated.



9. Future Stance

It is safe to say that the industry shall have positive growth considering the manufacturing capabilities wherein the opportunity for growth for regional as well as multinational pharmaceutical companies to enter the market in Kuwait is immense. Additionally, the availability of generic products in the market is expected to increase due to Kuwait' healthcare development scheme. In light of Kuwait Vision 2035, the healthcare and pharmaceutical markets have been considered as high priority sectors.

10. Conclusion

Indubitably, in Kuwait, there has been the gradual mobilization of pharmacies and pharmacists to essentially offer direct patient care. However, the expansion of the same requires improved partnership with various physicians, adequate resources and leadership, up to date legislation from the Ministry of Health enforcing the circle of care whilst being guided by formal and uniform standards of practice. Further, there has been positive momentum and demand for skilled clinical pharmacists boosting the successful implementation of pharmacies in Kuwait.

"Our industry has massively shot itself in the foot by not done enough to communicate with consumers about drug costs."

- Shire CEO Angus Russell

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