

# A Guide to Distributing Pharmaceutical Products in Kuwait



In order for a foreign principal to distribute their pharmaceutical products in Kuwait, they must either set up a legal entity in Kuwait or appoint a local agent. More often than not, the foreign pharmaceutical companies will opt to distribute their products through an agent who has a well established presence in the local market, in the hopes that their local connections and knowhow will catapult their products' success in the territory.

In doing so, the foreign manufacturer must keep in mind key regulatory considerations prior to setting foot in the Kuwaiti market. Such issues are addressed in brief below.

## **Ministry of Health ('MOH') considerations**

Under Kuwait law, registration of the pharmaceutical product with the MOH is required. Registration would be carried out at the MOH's Registration Department and the applicant must provide various documents, as outlined in Ministerial Decree 302/80 regarding the Guidelines for Registration of Pharmaceutical Products ('Decree 302/80'). These documents include, but are not limited to, the following:

1. letter of authorisation issued by the manufacturer from the country of origin, duly authorised by the relevant authority in the country of origin, stating that the local agent is the exclusive agent in Kuwait;
2. original legalised "Good Manufacturing Practice", certificate duly authorised by the relevant health authority in the country of origin (such certificate must have been issued within the last two years); and
3. master file, including details of the local agent and the manufacturer, such as general information and history of the company, premises, and equipment, including manufacturing sites, quality control, FDA, EMEA GCC or any recognised global approvals.

Without such registration, a pharmaceutical product will not be permitted to be imported into the country.

## **Ministry of Commerce and Industry ('MOCI') considerations**

If a foreign pharmaceutical manufacturer decides to engage a local agent by entering into a distribution agreement, Law No. 13 regulating Commercial Agencies in Kuwait ( 'Agency Law') provides that the local agent is required to register the agency agreement with the MOCI. As per the Agency Law, a commercial agency means each agreement whereby the party holding the legal right entrusts a merchant or company in the State to sell, promote or distribute goods or products or render services in its capacity as an agent, distributor, franchisee or licensee of the product or the original supplier against a profit or commission .The following details are to be included in the application:

1. name of the agent or distributor and name of the principal and its nationality;
2. the goods, products, or services covered by the contract;
3. the rights and obligations of each of the principal and agent or distributor, and the extent of the principal's liability for the agent's obligations in the field of its representation;
4. the agent or distributor's working territory;
5. duration of the agency and its renewal method;
6. method of termination and expiry of the agency; and
7. any other conditions agreed upon between the principal and agent or distributor.
8. If the agency agreement is not registered at the MOCI, then the Kuwaiti courts will not hear any disputes arising from the agency relationship.

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## **Additional considerations**

As detailed above, to distribute their products in Kuwait the most popular route foreign pharmaceutical companies opt for is that of an agency agreement. In entering into such arrangements, the foreign principal should bear in mind several key local law considerations for such agreements.

Initially, it is worth noting that the local agent/distributor must have the requisite licences to import and distribute pharmaceuticals in Kuwait. The foreign principal should request, and the local agent/distributor should produce such licences so that the foreign principal can confirm the local agent's capacity, from a licensing perspective, to enter into the agent/distributor agreement.

A common concern for foreign pharmaceutical companies is the MOH pharmaceutical registration requirement that requires the foreign principal to produce an attested letter granting the local agent exclusivity. From the MOH standpoint, pursuant to Decree 302/80, a letter of authorisation stipulating that the agent is exclusive is a required document for registration of a pharmaceutical product. Such requirement is in place to comply with drug safety requirements, for example, in order to be able to hold one agent accountable for maintenance of information at the MOH, pharmacovigilance, and to handle product recalls, if required. Whilst there is no requirement for the agency relationship to be exclusive, from

the standpoint of the MOCI or Agency Law, the local agent will be granted various protections under local law if such relationship is either explicitly exclusive, or deemed de facto exclusive. Such protections include compensation upon non renewal of the agency agreement. Unfortunately, there is no exception to the MOH requirement to appoint the local agent/distributor on an exclusive basis however, other steps may be taken to mitigate the ramifications of an exclusive appointment of a local agent.

The foreign principal/manufacturer need not shy away from the agency relationship because of the various protections afforded to the local agent under Kuwait law. In order to mitigate the same, proper drafting of the agency agreement is paramount. Although Kuwait law provides that Kuwaiti courts will have jurisdiction for any dispute arising from the agency agreement, if the defined territory of the agreement is in Kuwait, it may be agreed to refer to arbitration to settle the disputes.

Further, in general, parties are free to choose a foreign law to apply to a contract under Kuwaiti law and any such chosen foreign law will be recognised and upheld by the courts of Kuwait, provided that the rules of the foreign law do not violate public order or morality in Kuwait (otherwise Kuwaiti law will apply).

As such, we generally recommend that foreign principals select a pro principal or neutral foreign governing law, as Kuwaiti law favours the local agent/distributor. Further, we generally recommend that a valid foreign arbitration dispute resolution mechanism is included in the agreement.

Based on the practice of the Kuwaiti courts and Kuwait's adherence to the New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards, if there is a binding foreign arbitration clause, the Kuwaiti courts should dismiss any cases brought before them for lack of jurisdiction due to the arbitration clause. Thereafter, the foreign arbitration proceedings should apply the chosen foreign law and therefore, the Kuwaiti statutory compensation provisions under the Agency Law, as discussed above, should not apply, assuming that the chosen law does not have a similar compensation regime.

## **Conclusion**

The above is a brief guide to some of the key legal considerations a foreign principal/manufacturer should consider prior to distributing their products in Kuwait. It is essential that the foreign party seek local counsel prior to entering into any agreement with a local agent in order to better understand the various legal considerations and requirements under Kuwaiti law and ultimately, to best safeguard their interests in the unfortunate event of a dispute.

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