Distribution of Pharmaceutical Products in the GCC

Christina Sochacki - Senior Associate - Corporate / Mergers and Acquisitions
c.sochacki@tamimi.com - Jeddah

Robert Roberts - Senior Associate - Corporate / Mergers and Acquisitions / Commercial
- Dubai Maze Tower

In order to legitimately commercialise pharmaceutical products in the GCC, a foreign manufacture would need to either (i) establish a local presence in the relevant country, or (ii) appoint a local agent for that country. In our experience, most foreign pharmaceutical companies will not have a legal presence in the territory that is authorised to undertake distribution. There are obviously separate considerations to be born in mind in the event that a foreign manufacturer does wish to establish a local presence, such as foreign ownership restrictions and sponsorship arrangements, but these fall outside the scope of this article.

Consequently, where a foreign manufacturer does not have a local presence, it cannot directly obtain the product registration required in the country, or any other of the necessary approvals for importing, distributing, or advertising its pharmaceutical products without the use of a local partner. As a result, many pharmaceutical companies will call upon the services of a local (appropriately licensed) agent as an alternate means to procure all necessary approvals and distribute its pharmaceutical products in the country. This is a very popular, and relatively simple, method of facilitating the distribution of pharmaceutical products throughout the GCC and can provide a foreign manufacturer with valuable local knowledge and resource, allowing it to benefit from associations and sale channels that an agent may have forged over a number of years.

Nevertheless, whilst these types of arrangement can be very beneficial to a foreign manufacturer it is important that a foreign manufacturer considers the local regulatory and local law issues that could affect the pharmaceutical products on route to market. What follows is a brief overview of such considerations, but specific advice should, of course, be sought before entering a new market to ensure compliance with local laws and regulations and to obtain further insight into local law considerations that could impact on the proposed arrangement. This is certainly the case in respect of the distribution of pharmaceutical products in the GCC.

Regulatory Background – UAE Pharmaceuticals

Under United Arab Emirates ("**UAE**") federal law, no medicine or pharmaceutical preparation may be put into circulation except after registration of the product with the Ministry of Health and Prevention ("**Ministry**"). In order to register a pharmaceutical with the Ministry, a new drug application must be submitted, accompanied by various supporting documents. Specifically, the application must be made by the market authorisation holder from the country of origin, jointly with the local authorised representative. The local authorised representative must be explicitly designated by the foreign manufacturer to act in the UAE, on behalf of the manufacturer, with regard to the manufacturer's legal obligations and responsibilities.

The local authorised representative may be the licensed distributor of the product or a separate authorised representative. If the local distributor is to act as the local authorised representative as well, the distributor must show evidence of its ability to effectively fulfil the regulatory responsibilities required by the Ministry. For example, the local authorised representative is fully responsible for the product and the post-market plan for handling complaints or recall. Further, the local authorised representative is responsible for fully complying with the requirements of the Ministry after placing the product on the market.

Regarding the local agent, in order to import pharmaceuticals (and this also applies to medical devices) into the UAE, the importing company must be an individual or entity established in the UAE and licensed to import medical products. With regards to an individual, only UAE nationals may apply in their individual capacity to be a registered importer of pharmaceuticals. While in the past only companies wholly owned by UAE nationals could apply for a licence to import medical products, currently companies owned by both a UAE shareholder and a foreign shareholder may also apply for such a licence, subject to foreign ownership restrictions. However, companies with 100% foreign ownership cannot yet apply for a pharmaceutical importation licence. Therefore, for companies wishing to import pharmaceuticals into the UAE, there are two options: 1) incorporate a UAE entity in which they are a shareholder jointly with a UAE national, and undertake the licensing process with the Ministry or 2) engage a distributor agent which is already licensed through the Ministry.

UAE Commercial Agency

Typically, pharmaceutical companies will call upon the services of a locally licensed agent to distribute its pharmaceutical products in the country. Consequently, a foreign pharmaceutical company should be aware of local laws that could have application to the distribution arrangement.

In respect of the UAE, the registration of a distribution agreement at the Ministry of Economy ("**MOE**") (more specifically the commercial agencies register) under Federal Law No. 18 of 1981 Concerning the Organisation of Trade Agencies, as amended ("**Agency Law**")) has been covered numerous times in previous Law Update articles, and is an important consideration for a foreign manufacturer to consider.

In order to qualify for registration at the MOE, the local agent must meet certain qualification criteria, which can be briefly summarised as follows:

- the agent must be a UAE national or a UAE entity 100% owned by UAE nationals;
- exclusivity must be granted for one or more of the emirates; and
- technically, an agreement also must be notarized and in Arabic (and recently the MOE has been requiring a letter, from the foreign manufacturer, confirming it has no objection to registration), though we are aware that in circumstances where these formalities have not been carried out (i.e. no Arabic version/letter of consent not provided) it is possible for an agent to approach the MOE or local courts to seek an order for registration (provided they can show that they meet the prerequisite registration criteria).

There is sometimes a misunderstanding between the requirement for a local agent to be registered as the local authorised distributor with the Ministry, as referred to above, and a requirement for the local agent to be registered with the MOE.

In practical terms, the Ministry will only allow one distributor of pharmaceutical products in the UAE as a result of local pharmacovigilance and drug safety requirements (e.g. it is much easier to deal with one local agent who is recognised as the distributor for the pharmaceutical product in respect of, say, a recall). Generally speaking, we find that it is not unusual for a local agent to insist on being granted express "exclusivity" in the distribution agreement as a result of the fact that it will be ultimately responsible for the product in UAE (i.e. given this responsibility, it would want to control the distribution of the products itself and would not want to be responsible for the acts of other agents, notwithstanding, as mentioned above, that the Ministry will technically only permit one distributor for a pharmaceutical product to be registered with it).

Notwithstanding the commercial benefits to the local agent of exclusivity, a primary motive for an agent wanting an express grant of exclusivity under the relevant distribution agreement may be, as highlighted above, that it is one of the prerequisite criteria to effecting registration at the MOE. In the event the local agent is a UAE national or an entity wholly owned by UAE nationals, then the two principle requirements to achieve registration at the MOE would be satisfied and, in such circumstances, it would be unusual if a local agent did not try to register the agreement at the MOE given the significant protections it could

benefit from under the Agency Law. Therefore, the ownership structure of the local agent is also a consideration in the event that exclusivity is being insisted upon by a local agent.

In the event that the local agent did obtain registered agent status at the MOE in respect of the pharmaceutical products listed under its relevant distribution agreement, then the local agent would be able to avail itself of the benefits afforded to registered agents under the Agency Law including:

the agent will have exclusivity to import and distribute the relevant pharmaceutical products in the agent's registered territory (either part or the whole of the UAE subject to the definition of territory under the relevant distribution agreement);

- the agent can block third parties from importing the relevant products into its registered territory, whilst it remains the registered agent of those products at the MOE;
- the agent will be entitled to commission on every sale of the relevant products made in the agents territory, notwithstanding the fact that they may not have had any involvement in the transaction;
- the agent will be in a strong position to seek compensation upon termination; and
- the agent can only be terminated by the foreign principal by either (i) mutual consent of the parties or (ii) for "material reasons", which are not further defined under the Agency Law and which the applicable local judicial bodies have interpreted narrowly (the result being that, notwithstanding any express right to terminate the agent under the relevant distribution agreement, the foreign principal may be unable to unilaterally terminate the local agent; essentially meaning that the local agent and foreign principal remain bound, regardless of the terms of the distribution agreement, until such time as the local agent is deregistered at the MOE).

Whilst the above are all significant consideration for a foreign manufacturer to bear in mind, the two key consequences of registration that predominantly concern a foreign manufacturer are (i) the right of the local agent to claim compensation upon termination of the arrangement and (ii) the ability of the local agent to block the pharmaceutical products for which it is a registered commercial agent at the MOE. The latter especially could have a significant impact on the foreign manufacturer's ability to exploit the UAE as a market.

GCC Commercial Agency

Similarly, there are commercial agency regimes in place throughout the GCC countries that extend similar rights to the local agents, though not all afford the local agent the right to block imports of the pharmaceutical products or, where such a right to request a block on importation exists, the relevant authorities may not be as willing to grant such a request. For example, in Qatar, a registered commercial agent is entitled to submit, without notice to the foreign manufacturer, a request to the Ministry of Economy and Commerce ("**MEC**") to ban the importation of the products as a result of the termination or non-renewal of an agency agreement. However, it is our current understanding that such applications are usually declined by the MEC and we are not aware of such a ban being imposed on the importation of goods in Qatar since 2007. Notwithstanding this, there is obviously no guarantee that such an importation ban request, if submitted, would be denied by the MEC, so it is important that a foreign manufacturer take local law advice in order to minimise the potential post termination or non-renewal consequences that it could face. This again highlights the need for a foreign manufacturer to obtain local law advice in order to familiarise itself with local laws considerations and the potential impact of such on the ability to distribute its products in the region.

The above represents a general overview of the impact that commercial agency laws can have on these types of agency arrangements in respect of pharmaceutical products in the GCC and hopefully highlights the importance of obtaining local law advice in order to obtain knowledge of (i) local market practices and applicable regulatory regime, (ii) the benefits and pitfalls that a party may face upon termination or non-renewal of a commercial agency relationship, and (iii) the impact of any local laws -before any issues arise.