Distributing herbal medicine and teas in Kuwait

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Kuwait's Pharmaceutical and Herbal Medicines Registration and Control Admission at the Ministry of Health ('MOH') issued a Ministerial Decree this past July for the registration of herbal medicines and herbal preparations No.101 for the year 2020 ('Decree 101/2020').

Previously, Kuwait lacked a classification system for herbal medicines, relying mainly on the classification of the product in the country of origin, which led to many herbal medicines being classified as dietary supplements and thereby escaping rigorous assessment. The classifications and definitions put into place under Decree 101/2020 provide a clearer pathway for determining the level of regulatory control that is most appropriate for evaluating quality, safety and efficacy.

Decree 101/2020 addresses the following:

1. local agent, market authorisation holder ('MAH'), and manufacturing company registration requirements;
2. herbal products and herbal teas classification and registration requirements; and
3. variations, transfer of agency, suspension and cancellation of a herbal product/herbal tea registrations.

1. Local agent, MAH, and manufacturing company registration requirements

In line with the relevant regulations of the State of Kuwait, pharmaceutical products, including herbal products and teas, may only be brought into the local market via a local appropriately licensed agent and following registration with the Kuwait Drug and Food Control and Administration ('KDFC') at the MOH. The burden of such registration requirements rests with the local licensed agent.

Both the locally licensed agent, as well as the MAH (defined under Decree 101/2020 as the pharmaceutical company that legally holds the right and responsibility of marketing the product in Kuwait), must be registered with the MOH. If the manufacturer is different to the MAH, then the manufacturing site will also need to be separately registered with the MOH.

1. copy of valid licence from the Ministry of Commerce and Industry, which includes the activity of "sales of medicine";
2. copy of valid store licence issued by the Drug Inspection Authority; and
3. copy of authorised personal signatures.

When registering a MAH, documents to be submitted would include, but are not limited to the following:

1. legalised letter of appointment ('LOA') from the MAH stating that the local agent is the sole and/or exclusive agent in the State of Kuwait;
2. original legalised manufacturing licenses from the country of origin for each manufacturing site, issued by the MOH or concerned regulatory authority in the country of origin;
3. original legalised Good Manufacturing Practice Certificate from the country of origin;

4. list of herbal products/teas manufactured by the company; and
5. site master file, for herbal products other than herbal teas.

2. Herbal products and teas

As per Decree 101/2020, an herbal product is defined as "any medicinal product, exclusively containing active ingredients consisting of one or more herbal substances or herbal preparations or such herbal substances, in combination with such herbal preparations that are intended for prophylactic, therapeutic, or other human health benefits". Herbal teas are also considered herbal products, with the distinction being that they are "packed into paper or cloth bags or sachets, each containing ground herbal materials sufficient for one dose for making an infusion . . . [and] . . . including a clear medical/therapeutic indication explaining its purpose".

Herbal products, excluding herbal teas, are classified as either herbal medicine ('HM') or traditional herbal medicine ('THM'). HM can be seen as products that have been tried and tested, the efficacy of which has been demonstrated via clinical data whereas, THM relates more to the knowledge, skills, and theories native to different cultures, such as Ayurvedic Medicine, which in contrast is not supported by traditional clinical evidence.

Applications for HM registrations are required to be supported by scientific references supporting the pharmacological claims and a study showing the pharmacological action of the product, amongst others. On the other hand, THM registration applications are required to demonstrate that the product has had a period of at least 30 consecutive years of traditional use.

Amongst other requirements, applications for the registration of herbal teas are required to be submitted with a certificate of analysis of the finished product, which must include total ash, acid, insoluble ash, moisture content at 110 °C, microbiology and, in the case of fresh herbal substances, heavy metals. Further, safety and efficacy studies from competent international authorities (and/or evidence of tradition use or clinical studies, in line with those required for HM and THM herbal medicines) must be submitted. The registration for herbal products, including herbal teas, must be renewed every five years.

3. Variation, transfer of agency, suspension and cancellation of an herbal product/herbal tea

It is important to keep the MOH informed of any changes to the agency relationship and the product, whether it be a transfer of an agency, cancellation of a product's registration, or changes/additions made to the registered product. In each case, the MOH's approval must be obtained of such changes or additions.

Should the MAH opt to operate in Kuwait via a different agent, then a legalised LOA for the new local agent issued from the MAH, termination letter issued from the MAH specifying the date of termination of the local agent, and list of products affected by the transfer must be submitted.

The MOH has the discretion to cancel the registration of herbal products or teas for non-compliance with Decree 101/2020 and in certain other situations, such as: (i) the herbal product or tea is banned or suspended in the country of origin or any other country for safety reasons; (ii) documents submitted are false; or (iii) two years have passed without the registered product having been imported.

Both the local agent and the MAH should ensure compliance with local law requirements, specifically with

respect to banned ingredients. Such ingredients are annexed in Decree 101/2020 under two main umbrellas: (i) narcotic and poisonous herbs, which cannot be included in herbal products or tea submitted for registration; and (ii) herbal ingredients subject to specific restrictions (i.e. acceptable limits). In addition, the MOH has the right to restrict any herb or plant that is proven harmful for human use.

4. Additional considerations

The local agent, MAH, and manufacturer should also take into account the requirements set forth under Law No. 13 regulating Commercial Agencies in Kuwait ('Agency Law') and Law No. 68 of 1980 promulgating the Commercial Law (the 'Commercial Law'), alongside the health regulatory considerations specified above.

Aspects such as exclusivity versus non-exclusivity, agency registration requirements, and governing law and dispute resolution clauses are paramount when drafting commercial agency agreements (such as distribution agreements) and must be analysed based on the specific case at hand. For instance, the Commercial Law allows the principal (such as the MAH) to utilise the services of more than one agent or distributor in the same area and for the same branch of activity. Similarly, the Agency Law provides that the principal may have more than one agent or distributor. Yet these are contrary to Decree 101/2020 and various other health regulations which require a LOA stipulating that the local agent is the sole, exclusive agent for the pharmaceutical product and/or herbal products or tea.

Parties should not turn a blind eye to engaging in a legal review prior to execution of their distribution agreements in order to minimise the risks of disputes ending up in court battles and subjecting the foreign principal to local laws that were perhaps not originally contemplated in the drafting of the distribution agreement.

For further information, please contact healthcare@tamimi.com.