Part II: Importation of Medical Devices and Drugs into the UAE

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To recap, the importation of medical devices and pharmaceuticals into any of the emirates of the UAE is controlled by the Ministry. As we discussed in our Part I article, in order to import pharmaceuticals or medical devices into the UAE, the importing company must be an individual or entity established in the UAE and licensed to import medical products into the UAE. With regard to an individual, only UAE nationals may apply in their individual capacity to be a registered importer of pharmaceuticals and medical devices. 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. Companies with 100% foreign ownership cannot yet apply for a medical product importation licence. Therefore, for companies wishing to import pharmaceuticals or medical devices 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 or agent which is already licensed through the Ministry. Our Part I article further discusses these options.

In this article, we will look at the registration of medical devices and pharmaceutical products, in order to permit their importation into and sale within the UAE.

Registration of Medical Devices and Pharmaceuticals

Under federal law, no medical device, medicine or pharmaceutical preparation may be put into circulation except after registration of the product with the Ministry. Thus, even if a company is licensed to import medical products, it will not be permitted to import a medical device or pharmaceutical unless that specific product is registered with the Ministry. There are certain exemptions from this requirement, which will be discussed in this article.

In order to register a medical device or pharmaceutical with the Ministry, an application for medical device or new drug application, as appropriate, must be submitted to the Ministry for review and approval. The application must be made by the manufacturer from the country of origin (the market authorisation holder in case of pharmaceutical products) 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 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. The local authorised representative is entirely 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.

The application to be submitted to the Ministry must contain information about the pharmaceutical or

device as well as the details of the manufacturer, local authorised representative, and local distributor of the product. A medical device will be classified as Class I, II, III, or IV, depending on its intended use; the required documentation will vary depending on the classification of the device. However, all applications must include a legalised free sale certificate or letters of regulatory approval, clearance to manufacture, sell, import and export the product, from the competent authority in the export country. The Ministry will accept accreditation of conformity assessment bodies from the European Union, Australia, Canada, the United States of America, Japan and Singapore, and will also consider any approval obtained for a product from other competent authorities.

Further, the applicant must submit provisions for an audit plan, details of the manufacturing site, a general post-marketing surveillance plan, as well as details concerning the product's intended use, indications, precautions, instructions for use, safety and effectiveness data, and labelling. Once submitted, the application will be evaluated and the Ministry may request additional data or samples of the product.

Importation of Unregistered Pharmaceuticals

There is an exception to the general position under Federal law, which provides specific approvals for the importation of an unregistered medical product. The intention behind the exception is to allow for emergency medicines or medicines to treat rare conditions, which may not be registered due to the cost-prohibitive nature of registering a rarely consumed medicine. This system allows providers and patients to access treatments despite the lack of registration.

The importation of an unregistered medical product must be performed in conjunction with a hospital or clinic local purchase order and a justification letter from a medical consultant. The letter should include the clinical reasons for using an unregistered medicine instead of a registered alternative. Even so, the importation of unregistered medicines is still permitted only by a licensed UAE medical store. In order to obtain Ministry approval for the importation of an unregistered medicine, as a minimum, the following documents are required:

- Ministry licence of the importer
- Valid trade licence
- Local purchase order from the hospital or clinic
- Declaration letter from the hospital or clinic
- Justification letter from the medical consultant.

If the consignment exceeds the equivalent of a one-year supply for one patient, or if the total value for any single item exceeds $2,500, a 'Certificate of Pharmaceutical Product' must be provided before the consignment can be released. Additionally, the medicine should be registered with the competent drug regulatory authority in the country of origin. Further, the medicine may not contain a substance that is banned in the UAE and the product must be labelled in English, at a minimum.

Once in the UAE, unregistered medicines must be stored in a separate area within the medical store and clearly marked as unregistered medicines. Each medical store must keep a register of unregistered medicines to enable their recall if necessary. Hospitals and clinics must also keep a register of the unregistered medicines that they use and the patients who receive these medicines, to enable recall.

Conclusion

In order for a company to import pharmaceuticals and medical devices into the UAE, a company must: 1) both, incorporate in the UAE and obtain a medical importation and distribution licence from the Ministry, or 2) engage a local agent or distributor, who is already registered with the Ministry, to import the pharmaceuticals and medical devices on their behalf.

Unless the medical product has been specifically ordered by a hospital or clinic and approved as a permissible unregistered medicine by the Ministry, it also is necessary for the medical product itself to be

registered with the Ministry. While registration of a pharmaceutical or medical device takes longer than the registration of a company, they can be done simultaneously. We are able to provide guidance on each element of bringing a pharmaceutical product or medical device to market in the UAE, from establishing a local entity and providing contract drafting and review, to registering the medical products themselves.