

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

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For companies wishing to offer therapeutic alternatives to their patients, or to expand into the Middle East market, the general trend is for these companies to start by importing into the UAE, then to look towards expanding into other markets in the region, depending on the success of their products in the UAE.

The importation of medical devices and pharmaceuticals into the UAE is controlled by the Ministry of Health. The Ministry regulates the importation of both medical devices and pharmaceuticals for all of the emirates; there are no separate, individual, local emirates departments. In this article we will look at the procedure by which a company can import medical devices or pharmaceuticals into the UAE, with the intention of then selling these products to UAE hospitals or health care clinics. The regulations that apply to hospitals wishing to import drugs and medical devices are different and will not be addressed in this article.

While federal law states that no medicine or pharmaceutical preparation should be put into circulation, except after registration of the product with the Ministry, the Ministry will consider an application to import certain unregistered drugs into the UAE. However, there are specific requirements in place for the importation of an unregistered pharmaceutical, and such importation must be in conjunction with a hospital or clinic local purchase order and a justification letter from a medical consultant. Without these, only registered pharmaceuticals or medical devices may be imported into the UAE. However, for both registered and unregistered pharmaceuticals and medical devices, the importing company must, itself, be registered with the Ministry before it will be allowed to import these products into the UAE.

The registration of an importation company and the registration of a pharmaceutical or medical device can happen simultaneously; however, the registration process for the company is a faster process than the registration of a pharmaceutical or medical device.

Importation Options

In order to import pharmaceuticals or medical devices into the UAE, the importing company must be an entity established in the UAE, although a UAE national may also apply to be a registered importer of pharmaceuticals and medical devices. While in the past there was a requirement that only companies wholly owned by UAE nationals could apply for registration, it is now possible for companies owned by both a UAE shareholder and a foreign shareholder to apply for registration. Therefore, for companies wishing to import pharmaceuticals or medical devices into the UAE, there are two options: 1) incorporate a company in which they are a shareholder, and undertake the registration process with the Ministry (outlined below); or 2) engage a distributor or agent which is already registered with the Ministry.

If the intention is for the company to incorporate their own entity in the UAE, then they must ensure that the company's UAE trade license permits them to perform the activities associated with pharmaceutical and medical device importation. Without the proper activities listed on the trade license, the company will

not be successful in their registration with the Ministry.

In the remainder of this article, we will address only the process to register the company that will import registered medical devices and pharmaceuticals. In a later article, we will address the process of registering medical devices and pharmaceuticals themselves, and the process for the importation of non-registered pharmaceuticals.

Registration of Importation Company

The first step in the process to become registered as a pharmaceutical or medical device importer in the UAE is to obtain a medical warehouse licence. The Ministry of Health has in place certain requirements for these warehouses, such as they must be of a certain size, they must be in a certain location, they must have specific equipment in place for the storage of the pharmaceuticals and medical devices and a licenced pharmacist must be employed to oversee the pharmaceuticals and medical devices imported. Prior to the Ministry of Health granting the medical warehouse licence, it will inspect the warehouse to ensure that it meets these requirements. Only if all of the requirements have been met, will a medical warehouse licence be granted. The Ministry provides a service where it will, with a representative of the company, attend at the warehouse site, prior to the lease being signed, and undertake an initial inspection of the warehouse to give its approval of the site. This allows the company to wait to sign a lease agreement until it knows that the proposed space is suitable in the eyes of the Ministry.

Once the warehouse has been inspected, and the site approved by the Ministry of Health inspectors, the entity must then submit a file, along with all of the necessary supporting documents, containing proof of the inspection having been passed, information relating to the licensed pharmacist and information about the pharmaceuticals and medical devices that the company intends to import. This file is reviewed, at an initial level, by the Ministry and either rejected or accepted.

If the Ministry accepts the file, it is then passed to a final committee at the Ministry. The committee meets four times a year to review all of the applications filed and determines, on a case by case basis, which companies should be granted a medical warehouse licence and be registered with the Ministry as approved importers of pharmaceuticals and medical devices. Once these companies have been registered, they are then eligible to obtain import permits for pharmaceuticals and medical devices to be sold in the UAE. If for any reason the file is rejected, the committee will provide reasons as to why. This permits the company to make necessary adjustment and make a new application once compliance has been achieved.

Conclusion

In order for a company to import pharmaceuticals and medical devices into the UAE, they must both incorporate a company in the UAE and apply for this company to be registered with the Ministry of Health, or engage a local agent or distributor, who is already registered with the Ministry, to import the pharmaceuticals and medical devices on their behalf. While the process to register a company or engage a local company may seem daunting, we are able to provide guidance and assistance throughout the entire process.