

Importation of Unregistered Drugs in the UAE

Ahmad Zaza - Senior Associate - Intellectual Property
a.zaza@tamimi.com - Dubai International Financial Centre

The main principle according to the above Law is to implement the registration of all medicines with the Ministry of Health (MOH) in order to be legally circulated in the UAE market. Article 65 of the Federal Law No. 4 of 1983 concerning the Profession of Pharmacy and Pharmaceutical institutions, states the following:

“No imported medicine, pharmaceutical preparation or children’s food should be put for circulation before being registered in the Ministry. Any medical company, which plans the marketing of its production in the country, should be registered in the Ministry”.

Based on the above article, it is clear that the general rule is not to allow the import of any medicine unless it is registered in the UAE. However, the question arises as to whether there are any exceptions and does the above rule apply in all situations? According to the Law there are no exceptions, as imported drugs are only permitted if they have been registered with the MOH.

However, practices by pharmaceutical companies have proven that there are indeed exceptions and in some cases, they have been able to import unregistered drugs. The MOH has enabled a process to import unregistered medicines in exceptional circumstances, namely:

- Medicines to be used in emergency situations necessary for the continuation of patients’ lives;
- Certain drugs that are not available in the local market and cannot be dispensed in hospitals, such as heart cancer treatments;
- Other pharmaceuticals which have not yet been regulated by the Ministry;
- Medicines required by health institutions affiliated to government or semi government agencies & entities, which have been imported based on purchase orders from the government or semi government hospitals which are affiliated to Abu Dhabi Health Authority or Dubai Health Authority or Ministry of Defence or Ministry of Interior;
- Registered medicines that are not available at the official deal or not available in the market;
- Drugs whereby registration has been cancelled at the request of the official agent due to lack of local market demand;
- Unregistered narcotic or psychotropic drugs, used in specialised hospitals (private & governmental).

Accordingly, some hospitals which are affiliated with Abu Dhabi Health Authority or Dubai Health Authority are allowed to import unregistered drugs into the UAE subject to approval from the MOH. The application to import unregistered drugs in such circumstances must be detailed and specific in order to gain approval. As such, the quantity of the imported medicines shall be limited to the hospital capacity and the number of existing and/or expected patients and under no circumstances are they able to supply non-registered medication outside the hospital. The MOH has the full authority to refuse an application to import unregistered drugs, amend the quantities, or issue a conditional or unconditional acceptance to such request and quantities.

The MOH have set a number of conditions with regards to the import of unregistered drugs:

- The application to import unregistered medicines shall be made by a registered agent in the UAE, or through a licensed medicine store or authorised distributor (this condition does not apply to the import of unregulated pharmaceutical products, such as chemicals used in laboratories and other medical materials used in nuclear medicine in government hospitals);

- The medicine must be registered in the country of origin or an approved country such as the USA or in Europe or the GCC. If the medicine is registered in one of the GCC countries or by the European Medicines Agency or US FDA, then the obtaining of the approval from the MOH to import such unregistered medicine in the UAE will be easier.
- The application must be made from the Medical Director of the Hospital/Head of the concerned department of the purchase order and contain:
- A Letter of Undertaking from the hospital to use the product and bear all the responsibility of such use;
- A registration certificate of the manufacturing company of chemical products; and
- A valid analysis certificate of the product from the plant.

Any hospital/entity which imports unregistered medicine is liable for such import and use of that medicine. This legal obligation is referenced by the condition above requiring a Letter of Undertaking from the hospital to use the product and bear all responsibility of such use. The sanctions stated in Law No. 4 of 1983 concerning the Profession of Pharmacy and Pharmaceutical Institutions shall be applied in case of any violation of the terms.

As with the general rule applying to all medicines, the law also prohibits importers of unregistered drugs from promoting any medicine in any way as per Article 92 of the Pharmacy Law which states: "Publication of pamphlets or books and advertising through newspapers, radio and TV for any medicine, pharmaceutical preparation or children's food to be determined by the Minister shall not be permitted". Conversely, the MOH welcomes medicine and disease awareness programs subject to their approval regardless of whether the drug is registered.

As with most rules, the above shows that whilst the law prohibits the importation of unregistered drugs, there are instances in which exceptions can be made.