Medical device registration in the UAE

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The healthcare industry in the UAE is set to boom. Dubai is in the process of setting itself up as a regional hub for medical tourism, and there is a drive towards improving the standard of healthcare throughout the country. This article briefly outlines the regulatory approval process for medical devices in the UAE.

General Background
The Ministry of Health has issued registration guidelines for medical devices. The Registration Guidelines set out the requirements for an application for regulatory approval. The registration system is intended to prevent unsafe or ineffective medical devices from entering the local market, while allowing patients access to medical devices that may help them.

The Ministry has aimed for international standards in developing the criteria for medical device registration. The Registration Guidelines themselves acknowledge that the various requirements for registration largely simulate internationally recognized rules and regulations such as the EU Medical Device Directive (93/42/EEC) and US Food and Drug Administration Guidelines. By way of example, the Registration Guidelines define various terms using the definitions that closely resemble those provided in the EU Medical Device Directive.

Application requirements
An application to register a medical device in the UAE must be made by the device manufacturer or its local representative. The local representative must be formally authorized by the manufacturer to handle the application process and the manufacturer's legal obligations and responsibilities with regard to putting the medical device on the market in the UAE.

The Registration Guidelines provide four classes of medical device for the purposes of registration. The classification system takes into account aspects such as the period of time for which the medical device is intended for use, and the degree of invasiveness on the body.

Depending on the classification of the medical device in question, and the information available with regard to approvals by regulatory bodies elsewhere, the Ministry's Committee on Medical Device Registration will consider an application for registration through either a one stage or a two stage process. Upon application, the Committee will review the medical device and decide whether or not it is able to issue a certificate of registration on the basis of the material submitted with the application, or whether further evidence relating to safety and effectiveness needs to be considered before a formal determination can be made.

The application must be supported by the submission of objective evidence relating to the safety and effectiveness of the medical device. As in other jurisdictions, the preparation and submission of such advice is a significant undertaking. The Registration Guidelines list the information that it is necessary to file in order to be considered for registration. As well as the formally executed official application form, and depending on the classification of the device, the necessary documents can include:

- Authenticated copies of certificates relating to governmental approval of the device's manufacturing facility in the country of origin.
- Copies of all certificates, documentation and letters of regulatory approval/clearance to manufacture, sell, import and export the medical device.
- Evidence of established procedures and systems for distribution records, complaint handling, adverse incident reporting and recall.
- Product and production information, such as manufacturing process and facilities information, device

description, specifications of materials used in manufacturing and packaging, intended use and instructions for use, indications and contraindications, warnings and precautions, potential adverse events, alternative therapy, device labeling, shelf-life stability, animal/human tissue content.
- Copies of certification and documentation certifying conformity to product standards, safety and effectiveness requirements, and quality systems in design and manufacturing.
- Date of first introduction and use, list of countries where device is marketed and details of corresponding regulatory status, and a summary of reported problems with the device since introduction.
- Risk assessment comprising of risk analysis, evaluation and reduction measures, and detailed information on safety and effectiveness studies, including pre-clinical and clinical studies, process validation studies, software validation studies where appropriate, and literature studies, with summary of studies, conclusions drawn from those studies and bibliography of published reports dealing with the device.
- Objective evidence on the biological safety of the device.
- Peer-reviewed scientific literature dealing with the device.
- Price information, including ex-factory price, wholesale price in the country of origin, and retail price in the country of origin.

As well as the documents and information listed above, it is also necessary for the applicant to submit a declaration confirming that the submitted material is true and that the applicant will be fully responsible for the medical device and its post market plan, and that the applicant will comply with the requirements of the Ministry's Drug Control Department (the "DCD") after the medical device has been placed on the market.

As far as formalities are concerned, it should be noted that the Registration Guidelines are somewhat prescriptive when it comes to the way in which the materials are prepared and submitted, and all documents, including certificates should be in English or Arabic.

Registration
If the safety and effectiveness of the medical device is established and the Committee approves the registration, a certificate of registration is granted, and the importation and sale of the registered medical device is permitted. The registration is valid for 5 years, although if there are material changes to the product data submitted in support of the application, then the certification may become invalid. The DCD is also entitled to cancel the registration of a medical device if the registrant so requests, or if circumstances warrant cancelling the registration. We anticipate circumstances warranting cancellation to include, for example, where post-market obligations have not been met, where the product proves to be unsafe or the quality of the product becomes lower than at the time of the application for regulatory approval, where unapproved labeling is adopted, and where the medical device infringes a third party's intellectual property rights.

Post-market obligations
As the key purpose of registering medical devices is to ensure safety, the Registration Guidelines provide for post-market obligations with regard to monitoring, and preparing for, safety issues that may arise in the market place. As noted above, failure to comply with these obligations is a basis upon which the DCD can cancel the registration of a medical device.

The post-market obligations include the obligation to maintain distribution records (to facilitate traceability), to maintain complaint handling procedures and records, to maintain adverse incident reporting procedures and records, and to have procedures in place that will allow the registrant to promptly and effective execute investigations and recalls in respect of defective or potentially defective medical devices.

If post market procedures have already been established by a registrant for one type of registered medical device, it is not necessary to resubmit the post-market procedures for other medical device registration applications, unless the procedures previously outlined have changed or need to be varied due to the

nature of the subsequent medical device. If procedures have been submitted in respect of a previous application, it will be sufficient to refer the authorities to that material.

General

It can sometimes be difficult for foreign applicants to meet regulatory requirements for medical devices. One example of the type of problem that might be encountered is where the subject medical device is not something that would require regulatory approval in the country of origin, and thus not something for which country of origin approval documentation can be provided.

Al Tamimi & Company is able to assist with all aspects of medical device regulatory approval, particularly in respect of advocacy relating to the acceptance of supporting documentation. Although we hope it will not be required, we are also able to assist with recalls and product liability issues.