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# Client Alert

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## UAE overhauls legal framework for medicines, medical devices and health consumer products, and opens an avenue for direct trading on an exceptional basis

On 19 December 2019, the UAE government adopted a new federal law which replaces Law No. 4 of 1983 on the Pharmacy Professional and Pharmaceutical Establishments and Law No. 20 of 1995 on the Drugs and Products. **Law No. 8 of 2019 on Medical Products, Pharmacy Profession and Pharmaceutical Establishments (the new Law)** aims to consolidate and modernise the legal framework under which medical products are placed on the UAE market. The new Law applies to ***medicines (both human and veterinary), medical devices and health related consumer goods***. The scope of the new Law is wide ranging and covers the following areas:

- product registration and status of marketing authorisation holder/applicant;
- pricing;
- import, export, distribution,warehousing and manufacturing;
- post-market surveillance, safety reporting and recalls;
- promotion;
- licensing requirements for manufacturers, importers, distributors, wholesalers, marketing offices and consulting firms, pharmacies, laboratories and research centers;
- product availability measures;
- clinical trials;
- (semi-) controlled substances and precursors; and
- generics

Some of the key highlights are:

- The **concept of marketing authorisation holder** is defined and reinforced. The terms of "marketing authorisation" and "marketing authorisation holder" are defined under the new Law and clear obligations on the applicant/marketing authorisation holder are laid down. The rules, conditions and procedures for obtaining a marketing authorisation will be laid down in a new ministerial resolution. The practical impact on the current process for obtaining a marketing authorisation will depend on the terms laid down in such resolution.

  However, it appears that there is a move away from agent/distributor led interventions towards more direct contact and accountability for pharmaceutical, device and consumer companies. Such accountability is also translated in the requirement for an **applicant/marketing authorisation holder to appoint one or more qualified persons residing in the UAE**: Such person(s) must have pharmaceutical or medical qualifications and be licensed in the UAE. They will be **jointly liable with the marketing authorisation holder for compliance with the new Law.** The liability is both civil and criminal in nature. The exact impact of these provisions for the concepts of legal manufacturers of medical devices and their legal representative (in case of a foreign manufacturer) is to be further assessed.

- The new Law suggests that a marketing authorisation holder **must appoint one pharmaceutical establishment as an importer** but **can appoint one or more distributors to distribute the products within the UAE.** This may be viewed as a departure from the past where import and distribution were entrusted to one single agent/distributor per product and underlines the government's support to liberalisation and competition. To ensure oversight and security of supply chains, any such importers and distributors must be duly licensed by the UAE Ministry of Health and their appointment by the marketing authorisation holder must also be approved by the ministry.

- The new Law explicitly provides that **no person may start up a pharmaceutical establishment** (such as for import, distribution and storage purposes) **unless he is a UAE citizen**. However, exceptions can be granted by a cabinet resolution, which would **exempt foreign owned companies from the UAE citizenship requirements**. Also, companies set up in the free zone are not subject to the ownership restriction. The new Law does not provide any specific criteria under

which such exemption may be granted.

- The new Law has **not retained the concept of a scientific office.** The law of 1983 which is now repealed, had established the concept of a scientific office which was further developed in Minsterial Resolution 1110 of 2016 on Scientific Offices. As a consquence, many global pharmaceutical and medical devices companies have established a scientific office onshore or in a free zone to support scientific, medical, regulatory, safety and marketing activities under the supervision of a licensed pharmacist.

  The new Law has introduced the **new function of a qualified person appointed by the marketing authorisation holder** with similar obligations and a **more limited concept of a marketing office** which is responsible for promoting medical products and following up on the circulation of the products in the UAE. However, the qualified person is a natural person and needs to reside in the UAE. A key point is whether from a compliance and governance perspective the qualified person can be on the payroll of a marketing office going forward. It is also noted that a marketing office falls under the definition of Pharmaceutical Establishments and this could imply that the UAE ownership applies to a marketing office. This should be clarified by the legislator/regulator as marketing offices are usually extensions to foreign pharmaceutical companies or foreign manufacturers.

- The new Law includes **provisions on the conduct of clinical trials largely codifying existing practices**. The UAE Ministry of Health will set up a supreme committee for clinical study ethics. While the day to day ethics oversight seems to remain with the local health regulators and local ethics committees, the supreme committee will be responsible for national ethics policies and coordination to ensure a harmonised approach.

- Medical device companies will need **to monitor if** under a minsterial resolution **medical devices can remain outside the scope of products for which price controls are imposed,** as the general rule laid down in the new Law mandates a price for medical products as part of the marketing authorisation procedure.

- Medical products subject to price controls cannot be sold at higher prices and **no discounts** may be granted. It needs to be clarified if this provision implies a departure from the rule adopted under the UAE Ministry of Health's Promotional Code of 2017 which provides that for price controlled products a maximum of 15 % of the total

invoice value can be offered as free of charge products.

- **Regulatory data protection for innovative medicines** has not been introduced. Instead, the new Law confirms the UAE's commitment to the international agreements and the law on patent protection. The new provisions read as a confirmation of the patent linkage mechanism currently in place.

- The new Law provides a **prohibition for the pharmacist to substitute or replace items that are prescribed unless the issuing person is consulted**. However, the new Law provides an exception for generic substitution based on implementing regulations, hence providing a basis for further expanding the generics policies.

- **Sanctions** are substantially increased. In a serious step up compared to the old regulations, the new Law introduces administrative sanctions without prejudice to additional civil and criminal liability. Administrative sanctions range from warnings, to temporary suspensions of licenses and administratives fines between AED 1,000 and 1,000,000 for pharmaceutical establishments. Criminal sanctions can be added for breach of specific provisions of the new Law ranging from six months to five years and/or criminal fines from AED 50,000 to 500,000. However, counterfeit related violations will trigger fines up to AED 1,000,000.

The new Law was published in the Official Gazette on 31 December 2019 and **entered into force on 30 January 2020**. However, until new implementing regulations are issued, the implementing regulations under the repealed laws of 1983 and 1995 will remain in effect to the extent that such implementing regulations do not contradict the provisions of the new Law. The timeline set for adopting the implementing regulations is 6 months. The law provides for a **transitional period of 1 year** which may be extended by the UAE Ministry of Health for up to 5 years.

Companies are advised to familiarise themselves with the provisions of this new Law and to assess the impact on their business as well as the opportunities. The full impact of the new Law will become clearer over time as the executive and other implementing regulations are being adopted. We will continue to monitor and clarify various aspects of the new Law.

For further information, please feel free to contact one of the lawyers below or your usual Baker McKenzie contact.

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