

UAE Issues New Code Governing the Promotion and Distribution of Medical Products

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Introduction:

In November 2017, the United Arab Emirates (“UAE”) Ministry of Health and Prevention (“MOHAP”) issued the “Code of Ethical Practices for the Promotion and Distribution of Medical Products in the UAE” (“Code”), which provides directives for the ethical promotion and distribution of medical products in the UAE. It covers the minimum standards that should govern the interaction between medical product companies or their representatives and the healthcare professionals. It aims to ensure that all interactions between such parties are intended to advance healthcare practices and to benefit patients.

Scope of Code:

The Code has been adopted and is applicable to all entities involved in the promotion of medical products in UAE, including and not limited to: marketing authorisation holders and whoever acts on their behalf, distributors, and marketing consultants, as well as individuals and entities involved in the prescription, dispensing, purchasing, enlisting, and reimbursement of medical products in the private and governmental sectors, including all medical and pharmaceutical facilities in the UAE.

The Code covers promotional practice relating to the following topics:

- Marketing authorization and approved labelling;
- Promotion and its substantiation;
- Transparency of promotional activities;
- Gifts and other items;
- Samples and/or demonstration products;
- Consultancy services;
- Grants and donations;
- Company staff obligations;
- Promotional materials and information to be made available;
- Distribution of promotional materials;
- Events and hospitality;
- Distribution and commercialisation of medical products;
- Support for education;
- Clinical research, including post marketing assessment studies;
- Improvement in patient care through educational and medical programs;
- Enforcement procedure.

Bonus Payments / Monetary and Non-Monetary Benefits:

The Code provides key points of clarity regarding certain promotional practices that have typically been a “grey area”. A matter that has been of particular contention is the provision of “bonus” payments by suppliers to pharmacies. Typically, these types of bonus payments were considered to be in violation of UAE Ministry of Health and Prevention Circular No. 171 of 2011 (“Circular 171”), which strictly prohibits the provision of bonus payments, direct discounts, to private pharmacies and private hospitals on

pharmaceuticals that are priced by the UAE Ministry of Health and Prevention. One of the rationales given for such a restriction under Circular 171 was that the approved prices take into consideration the profit of the pharmacies and the importing agent and should, thus, not be amended by the suppliers.

The Code, however, states that “[m]edical products companies and their distributors can offer a quantity of free of charge goods (bonus) up to 15% of the invoiced quantity to pharmacies.” In the same section, the Code clarifies that the “permitted quantity of free of charge goods (bonuses) indicated can be amended by increase, decrease or nullification via a decree issued by the Minister of Health and Prevention, whenever such amendment is needed”. Hence, the Code introduces a significant change to the treatment of bonus payments, superseding the blanket ban previously created under Circular 171.

Apart from this, the Code prohibits any monetary benefit, or equivalent, such as additional bonuses, discounts or any other forms of financial benefit to be offered to pharmacies or healthcare facilities. Specifically prohibited are any benefits for the execution of regular business activities, such as and not limited to: allowing medical representatives access to the facility, visits to healthcare professionals, enlisting products in formularies, and making products available on the shelves.

The standard tendering and purchasing channels for government funded institutions remain outside of the Code, permitting such institutions to negotiate orders and prices of medicines and medical products with suppliers.

Events and Hospitality

Another section of particular interest is that on events and hospitality. This section demonstrates MOHAP’s increased focus on targeting mechanisms by which healthcare professionals prescribing may be influenced in a way that is not centred solely upon the benefit of the prescription to the patient. Specifically, the Code prohibits the use of hotels that are well known as recreation locations (such as resorts, spas, golf hotels) for promotional, scientific, educational, or professional meetings, as well as congresses, conferences, symposia, and other similar events. Medical product companies are further limited to paying for reasonable and actual travel, meal, accommodation, and genuine registration expenses of healthcare professionals from the UAE, and are prohibited from extending hospitality to any spouses or guests of the healthcare professional.

Compliance with the Code

MOHAP reserves the right to audit medical product companies, pharmacies, and healthcare facilities to ensure compliance with the Code. Particularly, the Code requires that each company appoint at least one senior employee who will be responsible for supervising the company and its subsidiaries to ensure that compliance with the Code is maintained. MOHAP may request, at any time, all necessary documentation to prove compliance with the Code. Violations of the Code are considered to be violations of the ‘parent law’, Federal Law 4 of 1983, concerning “Pharmaceutical Professions and Institutions”, and will be referred to the relevant health authority’s licensing committee to take appropriate action.

The Code introduces significant clarifications and changes to the governing laws on the promotion of medical products in the UAE. Internal policies and business practices of pharmaceutical and distribution companies should be revised to reflect the changes.