Practical Conditions for the Advertisement of Non-Prescription Pharmaceutical Products in Egypt

Rana Hegazi - Senior Associate - Corporate / Mergers and Acquisitions / Commercial / Competition
r.hegazi@tamimi.com - Kuwait City

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In 2016, several laws and decrees have been issued regarding the regulation of pharmaceutical related products and activities. However, to date, there is limited legislative text governing the advertisement of non-prescription pharmaceutical products. Existing laws do not cover all parameters and the implementation of the rules are left to practice and interpretation of the competent authority.

Advertising of non-prescription pharmaceuticals is generally regulated the Ministry of Health and Population ('Ministry'). The competent administration within the Ministry is the Central Administration for Pharmaceutical Affairs ('CAPA'), which regulates the advertisement of pharmaceutical products and grants approvals for promotional activities related to non-prescription pharmaceuticals. In addition, CAPA undertakes assessment and monitoring activities for human and veterinary medicines, food supplements, insecticides, medical devices, and cosmetics to evaluate their compliance with the applicable standards in order to ensure safe, effective, affordable, and secure access to the consumer.

The marketing and advertisement of medical products and supplies are regulated under numerous pieces of legislation in Egypt. The most notable legislation of which is the Pharmacy Law No. 127 of 1955) (the 'Pharmacy Law'), and its executive decrees.

I- The Technical Committee's approval: a crucial prior condition

The Pharmacy Law prohibits any advertisement of prescription pharmaceutical products (excluding authorised vaccines). However, a non-prescription pharmaceutical product is excluded from such prohibition if it has a valid marketing authorisation licence (registration licence) granted by CAPA. The advertisement of non-prescription pharmaceuticals must comply with article 63 of the Pharmacy Law, which states:

The data mentioned on the pharmaceutical products' cards and any bulletin or advertisement distributed therefore shall be consistent with the material these products actually contain as well as their remedial characteristics. These data shall not contain any phrases that contradict with the public morals or mislead the public. The approval of the Technical Committee for Medicines Supervision on the text of such data, bulletins or advertisements must be obtained prior to their publication. (emphasis added)

On the basis of the aforementioned article, numerous ministerial decrees regulating the registration and advertising of pharmaceutical products have been issued, the most important and significant of which is Decree No. 76 of 2000 regulating the Advertisement of Drugs Pharmaceutical Products and Dietary Supplements (the 'Decree'). The Decree confirms that pharmaceutical companies wishing to advertise any non-prescription pharmaceuticals, whether in newspapers, magazines, or any other advertising medium, must obtain the approval of the Technical Committee at the Ministry in advance of publication. The Technical Committee proceeded to issue Decree No. 106, dated 20 November 2008, as one of the complementary decrees implementing article 63 of the Pharmacy Law. This decree stipulates that:

A company may not publish or issue any advertising materials for any products without the approval of the Central Administration for Pharmaceutical Affairs, and all data submitted shall be in conformity with the certified data of the product's registration as reflected in the Administration's records.

Accordingly, the approval of CAPA to proceed with the advertisement must be secured before undertaking the advertisement.

The Decree further provides for the applicable penalties in the event of breach of its provisions. Under such provisions, if a breach of the Decree occurs, a written notice will be sent by CAPA and addressed to the breaching entity ordering the ceasing of the advertisement or rectifying of the falsified data. Penalties for such breach may include the withdrawal of the product from the market and the cancellation of its registration. Such withdrawn products may not be re-registered prior to the lapse of at least one year from the date of cancellation of the registration.

II- Scientific Office requirements: additional prerequisite

The aforementioned article 63 of the Pharmacy Law stipulates that obtaining the Technical Committee's approval is the sole prerequisite to lawfully advertise non-prescription pharmaceuticals. However, in practice, the Technical Committee only provides advertisement permits to pharmaceutical companies having or contracting with a Scientific Office (as defined herein), despite there being no legal basis for this restriction.

Scientific offices are regulated in accordance with Decree No. 429 of 1976, issued by the Ministry. The main objective of a scientific office ('Scientific Office') is to market pharmaceutical products, medical supplies, and pharmaceutical chemicals. Each Scientific Office must obtain a licence from the Ministry. A Scientific Office may keep product samples but is not permitted to sell pharmaceutical products directly. A Scientific Office is required to preserve pharmaceutical samples in accordance with the technical specifications provided in the Pharmacy Law and its executive decrees, hold registered samples as sealed by CAPA, provide CAPA with a monthly report on its distribution of samples, and release samples only to persons authorised to be granted samples according to the Pharmacy Law.

III- Rules governing the advertisement of a pharmaceutical product

CAPA has outlined a set of general guidelines for the advertising of pharmaceutical products. For example, CAPA requires promotional materials to comply with the locally accepted customary practices, ethical rules, and religious directions, and that such materials should not be misleading or unrealistic. Most importantly, CAPA declares that promotional materials must represent a 'fair balance' between claims regarding the efficacy of the product and its safety so that healthcare professionals and consumers receive complete and accurate information in order to properly evaluate the appropriateness of the product for a particular patient's care.

Conclusion

Pharmaceutical promotion may lead to misinformed treatment choices that may damage public health and increase health care costs. Egyptian authorities continue to exert their endless efforts to strictly regulate and supervise the diverse parameters of the Egyptian pharmaceutical market. Consequently, those wishing to advertise pharmaceutical products should take a careful look at the applicable regulations and ensure full compliance with the same.