Discrepancy between Law and Practice in Egypt’s Pharmaceutical Advertising

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Pharmaceutical companies generally have a number of registered activities including ‘marketing’. However, bureaus of the Ministry of Health are only giving marketing authorizations to ‘scientific offices’ being , stand alonethe entities with a limited scope of operation, and the Ministry is refusing to authorise marketing for issue the same to pharmaceutical companies even where they have if the latter has “marketing” among their registered activities. This article considers the issue in further detail. From a structuring standpoint and from experience, a corporation typically opts to reduce the number of legal vehicles and entities it holds, to simplify its structure, reduce its running cost, and eliminate unnecessary corporate work and day-to-day filings. Thus, such practices by the Ministry of Health increase the corporate structuring burden of pharmaceutical companies.

1. Scientific offices Under Egyptian Law:

According to the Decree no. 429 for the year 1976 of the Ministry of Health and Population, the ‘scientific office’ is regulated as follows:

Objective: The main objective of a scientific office is to market the medical drugs, products and supplies, and pharmaceutical chemicals.

Licence: The licence to establish a scientific office may only be granted to companies manufacturing drugs (local or foreign) and ratified and delegated commercial agents who hold a licence from the Central Administration for Pharmaceutical Affairs (CAPA).

Samples: Each scientific office must include a warehouse for storing the drug samples according to technical methods.

Scientific offices must adhere to the following:

- Preserve the samples in accordance with the technical specifications provided in the Pharmacy Law no. 127 for the year 1955 (“Pharmacy Law”) and its executive decrees;
- Hold samples register as sealed by CAPA;
- Provide CAPA with a monthly report on its samples’; and
- Release samples only for persons authorized to be granted samples according to the Law.

Prohibitions: Scientific offices are prohibited to undertake the following:

- Advertise products not registered at the Ministry of Health pursuant to the Pharmacy Law or products banned from being imported;
- Advertise its pharmaceutical products in fields other than the medical or specialized fields of such office’s activity.
- Subordination: Scientific offices are run administratively and financially by a sole agent – if any – who holds a licence. Otherwise, a scientific office follows the manufacturer.

It is admissible to establish one common private office for several companies or manufacturers.

2. Pharmaceutical Companies' Right to Advertise Pharmaceutical Products:

As per the Pharmacy Law, pharmaceutical companies are not prohibited from advertising pharmaceuticals on the condition that they obtain the approval of the competent authority. This is indirectly stipulated by Article 63 which sets the standards for the information that should be reflected on any bulletin or advertisement for a pharmaceutical product, without limiting the right of advertisement to a certain entity. In other words, there is no restriction in this law that limits the activity of advertising solely to scientific offices. However, certain approvals are required under Article 63, which states that the information regarding a pharmaceutical product on any pharmaceutical bulletin or advertisement must be approved by the Technical Committee for Pharmaceutical Supervision at the Ministry of Health (the "Committee") before it is published.

The Minister of Health and Population Decree no. 76 for the year 2000 provides that pharmaceutical companies wishing to advertise any pharmaceutical product, whether on newspapers, magazines, or any other different advertising medium, must obtain the approval of the Committee prior to advertising any products. This decree specifically states that pharmaceutical companies are allowed to advertise pharmaceutical products after obtaining the required approval. Further, this decree provides a penalty for any breach of its provisions. According to the said decree, a company is warned about its breach, if such company does not stop the advertisement or amended its contents within 10 days, the relevant pharmaceutical product is promptly withdrawn from the market and its registration is cancelled.

In addition to the Committee, under the Ministry of Health and Population Decree no. 91 for the year 1999, approval of the New Cure Systems Committee is required for all forms of advertising of any pharmaceutical products, drugs, or new methods of cure which are to be placed in newspapers, magazines, television, radio or any other different advertising medium. In practice, this approval is obtained in conjunction with that of the Committee. Whoever breaches this decree shall be subject to legal liability, in addition to the withdrawal of such person's pharmacist license.

3. Actual Practice:

As per CAPA's advice, the Committee does not, in practice, give advertising permits to pharmaceutical companies to advertise their products. According to CAPA, the Committee only approves advertisements of pharmaceutical products submitted by scientific offices. Thus, CAPA is applying a limitation with no legal basis which is a unconstitutional practice.

4. Argument with the Competent Offices:

While CAPA officials agree that there is no legal basis for not approving advertisements conducted by pharmaceutical companies, CAPA officials have indicated that they will not change their practice unless they receive higher orders or instructions to this effect. Thus, for the time being, a pharmaceutical company must also establish a scientific office if it wishes to carry out advertising activities.

Conclusion

From a structuring standpoint, the present approach by the Ministry of Health creates an unfortunate requirement that pharmaceutical companies have to set up a separate scientific office in order to market their products in circumstances where their existing license already caters for 'marketing'. A corporation will typically opt to reduce the number of legal vehicles and entities it holds in order to simplify its structure, reduce its running cost, and eliminate unnecessary corporate work and day-to-day filings. However, this is compromised by the current practice of the Ministry of Health which acts to increase the corporate structuring burden of pharmaceutical companies.

In our opinion, if need be, a claim before the competent administrative courts maywould overrule the

current practice given the lack of a legal basis for the approach currently being taken and thus help to rectifying the practice to simplify alleviate the existing burden uponto pharmaceutical companies in terms of their required structure and the existing requirement for increased , reduce corporate secretarial work, and decrease filings and other associated costs.