Co-Marketing of Medicinal Products in Türkiye

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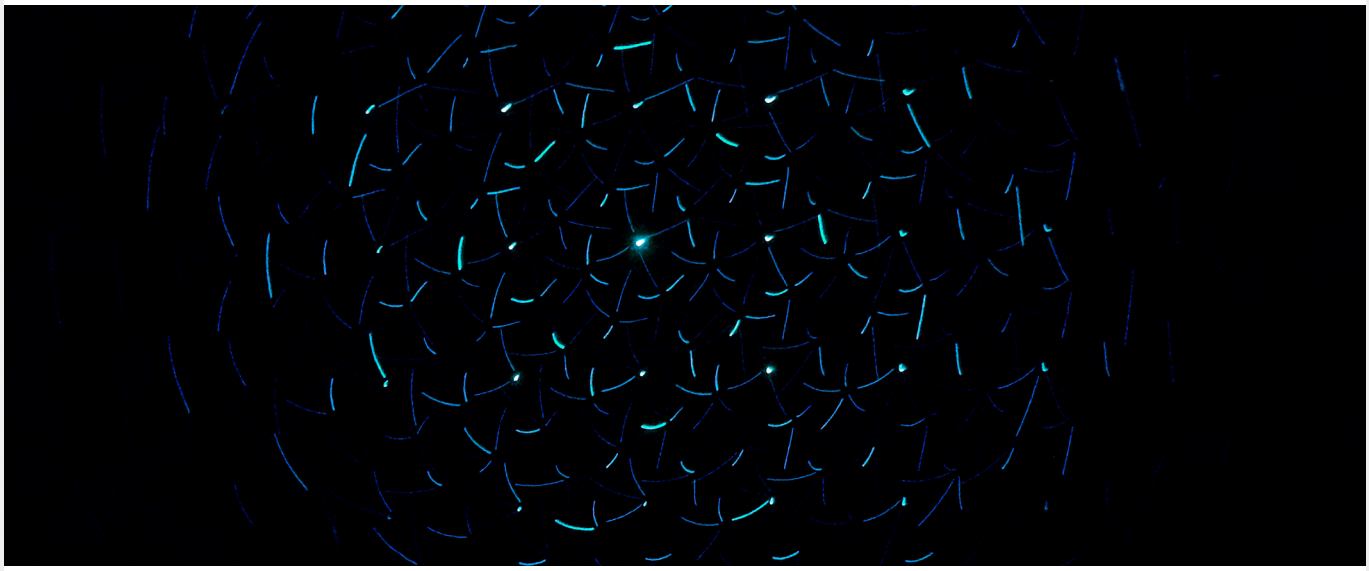

Dear Clients, Colleagues and Friends,

Co-marketing is a tool that allows sale of medicinal products with the same qualitative and quantitative composition and in the same pharmaceutical form that are manufactured at the same facility, but sold under different trade names. The aim of co-marketing is to enable the promotion of products in direct competition, and to facilitate access of patients to the relevant medicinal products.

Co-marketing is mainly regulated under (i) the Regulation on Licensing for Human Medicinal Products published on 11 December 2021 ("**Regulation**") and (ii) the Guidelines on Co-Marketed Medicinal Products for Human Use, which was issued on 17 February 2023 ("**Guidelines**") by the Turkish Medicine and Medical Devices Authority ("**Authority**"). These pieces of legislation address various aspects of a co-marketing arrangement including, amongst others, licence application, relationship with the principal product and packaging requirements.

Below are certain significant aspects of co-marketing as set forth under the above-mentioned legislation:

Co-marketing licence. Those who intend to engage in co-marketing activities should initially obtain a co-marketing licence from the Authority. The prerequisite for issuance of a co-marketing licence is the principal product having been licensed by the Authority. Although the principal product can be co-marketed more than once, the co-marketer cannot sublicense the co-marketing right to third parties. In other words, the co-marketer cannot enter into arrangements with third parties to share its co-marketing right.

Undertakings of parties involved. As part of a co-marketing licence application, certain undertakings must be given by the co-marketer, the principal licence holder and the manufacturer. Among these, the applicant (the co-marketer) should declare that the product to be co-marketed will be identical to the principal product. The principal licence holder should undertake that it will grant access of scientific documentation related to the principal product to the co-marketer. The manufacturer, on the other hand, should undertake that the principal product and the co-marketed product are same in terms of the manufacturing process, the finished product, active and inactive ingredients and the packaging material.

Packaging requirements. The packaging details of the co-marketed product must be the same as those of the principal product. Accordingly, the packaging size of the co-marketed product cannot differ from the

principal product. However, design of the packaging, licence holder's name and logo should be different from those of the principal product. Indeed, the commercial name of the co-marketed product should be distinct, and should not lead to confusion or association with the commercial name of the principal product.

Manufacturing process. The manufacturing process of the co-marketed product must be identical to those of the principal product. If there is any imprint or information/logo available on the solid dosage form of the principal product, the same imprint should also be made available on the co-marketed product. That being said, the name and/or logo of the principal licence holder or the name of the medicinal product should not be placed on the solid form of the co-marketed medicinal product to ensure distinctiveness of the co-marketed product.

Variations to the principal product. If the principal product goes through a variation process, a variation application should also be filed for the co-marketed product within 30 days following the approval of the variation of the principal product. The licence holder of the principal product must inform the co-marketer in advance of and upon approval of the variation. The Guidelines explicitly restrict simultaneous variation applications for the principal product and the co-marketed product.

Application with limited information. Application for obtaining co-marketing license can be filed with limited information, *i.e.*, administrative information listed under Module 1 of Annex 1 of the Regulation. If the application is made by submission of administrative information only, the co-marketing licence would be simultaneously suspended/cancelled upon suspension/cancellation of the principal product's licence. However, if the co-marketing licence is obtained upon submission of complete set of information based on the comprehensive CTD (common technical document) format, the co-marketing licence may be converted into an independent licence upon co-marketer's request, in case of suspension/cancellation of the principal product's license, unless there are drug safety issues involving the co-marketed product.

Due to lowering productivity and increasing manufacturing and marketing costs, co-marketing arrangements have become more prevalent lately. In practice, co-marketing arrangements lead to the parties also entering into manufacturing agreements, as per which the principal licence holder manufactures and supplies to the co-marketer the co-marketed product. When drafting the related agreements, one should pay specific attention to provisions on warranty regarding the product, confidentiality, variations to the product and intellectual property rights, given these are critical for the parties to a co-marketing arrangement. Co-marketing arrangements may also include non-compete obligations and involve exchange of commercially sensitive information between competitors. The parties should therefore ensure strict compliance with competition law rules as well.

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