Transfer of Marketing Authorisations for Medicinal Products

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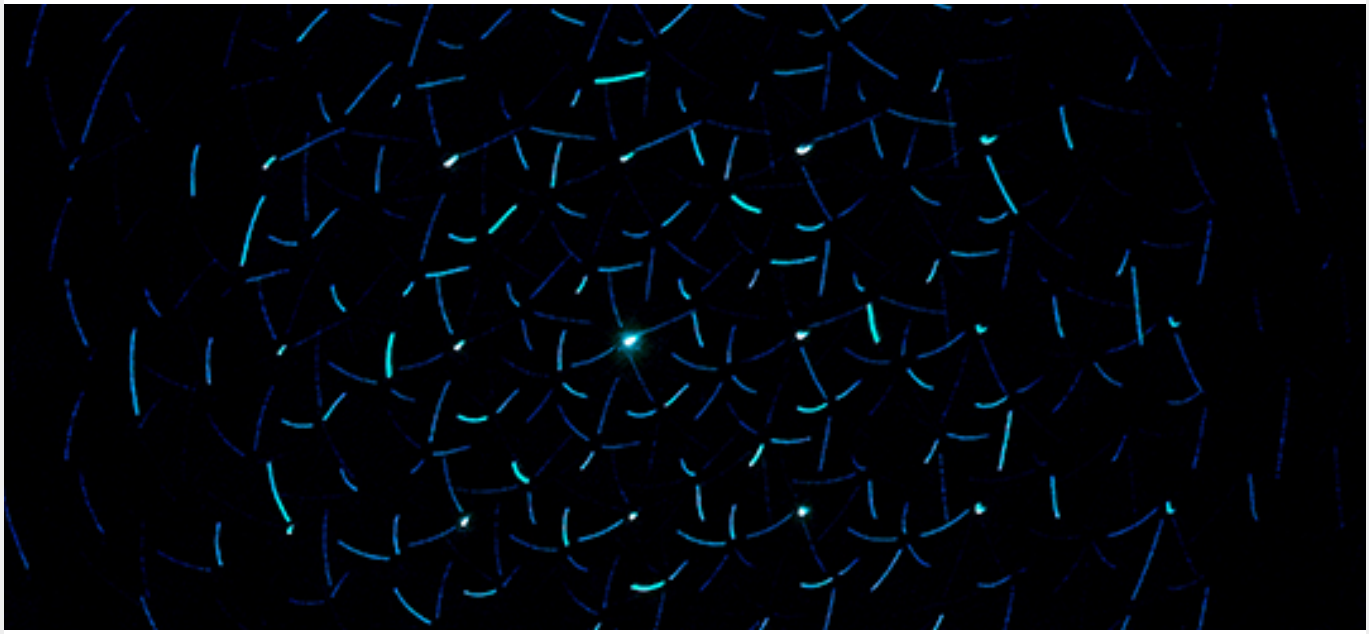

Under Turkish law, only entities registered in Türkiye are eligible to obtain a marketing authorization ("**MA**") for medicinal products for human use. This requirement compels global pharmaceutical companies intending to engage in business in Türkiye to establish local presence either through forming a subsidiary or teaming up with a local partner such as a distributor. In case of a partnership (e.g., established through a distributorship relationship), transfer of MA will be one of the main topics to be discussed if and when such partnership comes to an end. This article provides an overview of the regulatory framework governing the transfer of MAs in Türkiye, with a particular focus on transfers where there may potentially be a disagreement between the transferor and the transferee.

According to the Regulation on the Licensing of Medicinal Products for Human Use ("**Regulation**") and the Guidelines on Conditions Requiring Re-authorisation for Licensed Medicinal Products for Human Use, in order to transfer an MA, certain documents must be submitted to the Turkish Medicine and Medical Device Agency ("**TMMDA**"), and the relevant procedures must be completed. Transfer process has two main aspects: (i) submission of the transfer application to the TMMDA and (ii) cooperation of the transferor.

In the application for the transfer, the transferee must submit to the TMMDA: (i) a court decision stating that the transfer of MA has been fulfilled, (ii) an execution office decision stating that the license has been sold through forced execution proceedings, or (iii) a transfer agreement executed between the transferee and the transferor before a notary public.

As for the cooperation of the transferor, this holds great significance in an amicable transfer process. In cases where the transferor (e.g., the former local distributor who is the holder of MA in Türkiye for the relevant products) cooperates, the transfer merely involves execution of a transfer agreement before notary public and sub-

mission of the same to the TMMDA along with the other necessary documents. However, if the transferor does not cooperate, which may be the case in the event of an unamicable termination of a distribution relationship, as per the Regulation, *inter alia*, a court decision can be submitted attesting that the MA has been transferred by the court. In circumstances where the process involves a court decision, it is essential for such decision to resolve on the transfer of MA, and not merely the termination of the relationship between the transferor and the former MA holder in Türkiye. In fact, according to a precedent of the District Court of Appeal, actions seeking solely declaratory relief on the termination of the relationship shall be dismissed due to lack of legal interest. (*Istanbul 13th District Court of Appeal, decision numbered 2019/2544 E., 2020/675 K.*)

Upon submission of the required documentation and payment of the application fees, the review process will commence where the TMMDA shall look into the application to confirm that all regulatory requirements are met, with a particular focus on whether the transferee is well equipped to manage the respective medicinal product in a responsible manner. The TMMDA shall make an assessment on the application within thirty days of the application date, and can request further information or documents, which would re-start the review period. Once the review process is completed, approval will be granted and the MA registry will be updated to reflect the change in the ownership, and the new holder will assume all rights and responsibilities associated with the authorisation.

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