New Regulation on the Licensing of Medicinal Products for Human Use

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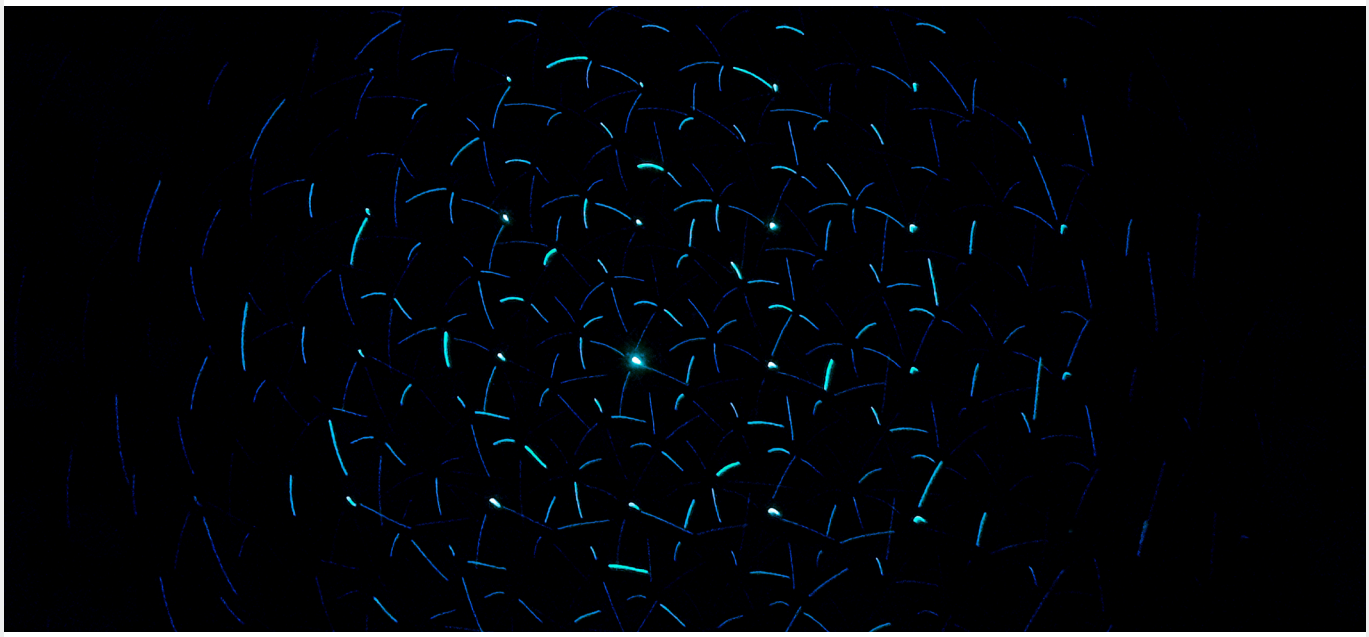

Dear Clients, Colleagues and Friends,

The New Regulation on the Licensing of Medicinal Products for Human Use ("**Regulation**") was published in the Turkish Official Gazette on 11 December 2021. This has been awaited as expected since 8 November 2018 when the Turkish Pharmaceutical and Medical Device Institution ("**Institution**") published the draft Regulation. The Regulation brings changes and introduces new concepts with a view to harmonizing with the EU directive numbered 2001/83/EC and keeping up with the necessities and needs of the time.

The changes brought by the Regulation mainly aims to clarify certain matters relating to the licensing process, facilitate licensing procedures, ensure transparency and eliminate the difficulties commonly encountered in the licensing process. There have been slight changes on the draft Regulation which was published on 8 November 2018 for the purpose of addressing the current needs of the sector.

Below are some significant changes offered by the Regulation:

New Scope. Traditional herbal medicinal products, homeopathic medicinal products, supplements for special medical purposes and advanced therapy medicinal products, which were covered by the previous regulation are not within the scope of the Regulation. According to the announcement of the Institution dated 11 December 2021, these products will be covered under separate respective regulations to be published by the Ministry of Health. In case of doubt with respect to the identification of a product, the Regulation will be applicable.

Electronic Filings and Licensing Periods. Except for force majeure, other similar compulsory cases or where the Institution deems necessary, licence applications and all related correspondence will exclusively be made electronically. Separately, the Regulation sets out a timeframe for the licensing process. Accordingly, while an application can be filed at any time throughout the year, the related licencing process will commence in February, May, August or November, depending on the timing of the application. With this proposed timeframe, review periods of the applications are expected to be shorter in practice.

Application Review Process. The Regulation includes details regarding the review of license applications. Within the scope of review process, the applicant is granted the right to submit a maximum of three written and two verbal responses in relation to each of the following items: (i) the potential risk that the product bears under normal conditions of use is higher than the beneficial effect of the treatment, (ii) the product's therapeutic effect is insufficient or has not been adequately demonstrated, (iii) bioavailability of the product is not sufficient, or (iv) the similarity of the product to the reference biological product cannot be proven. If it is so concluded after submission of the responses by the applicant mentioned above, the license application would be rejected.

Procedural Rejection. Failure to submit the information and documents requested by the Institution within 30 days would result in the rejection of the application. In case the requested information and documentation cannot be provided within the said 30 days, explanations on the grounds of such failure along with the information as to when the requested data and documents will be submitted should be provided within the same 30-days period.

New License Types. New types of licenses are available under the Regulation. These are (i) conditional license, which can be obtained within a rather shorter period for medicinal products needed for the treatment, diagnosis or prevention of serious or contagious diseases or which shall be used in cases of emergency recognised by the World Health Organisation or European Union or accepted by the Turkish Ministry of Health. A fast-track conditional licencing process can be gone through for these products, at the end of which the Institution shall grant the licence with the condition that the licence holder shall comply with certain obligations to be determined by the Institution, (ii) exceptional license, which shall be available for medicinal products on which no sufficient details can be provided due to the unavailability of scientific data or the rarity of the therapeutic indications at hand, or if collecting such data would contradict with medical ethics. Upon obtaining an exceptional licence, the licence holder will need to meet certain safety conditions to be identified by the Institution, and the validity of the licence will be reviewed by the Institution on an annual basis, and (iii) mandatory license for which an application can be filed for the products that the President deems appropriate to manufacture under a mandatory licence due to public interest related reasons.

Hybrid Application. The Regulation introduces a new type of application in which both data obtained from a reference product and studies conducted for the new product shall be submitted together and reviewed by the Institution. Hybrid applications are rather relevant for products that do not qualify as generic products but have some of their characteristics.

Priority Assessment Board. The Regulation establishes a Priority Assessment Board within the Institution, which shall be in charge of, amongst others, (i) identifying products that bring innovations in terms of treatment and diagnosis or that have strategic importance for public health needs, and (ii) ensuring sustainability of access to or rapid delivery of the products. Upon clearance by the Priority Assessment Board, an application for licensing of a product will have priority over others.

Scientific Advice Services. Another novelty brought by the Regulation with the objective of facilitating the licensing process is the availability of scientific advice services. In this context, applicants will be able to seek, in consideration of a fee to be pre-defined under a tariff, scientific advice from the Institution prior to or during the course of a license application process.

Co-marketed Products. New concepts and rules have been introduced under the Regulation in relation to co-marketed products. Accordingly, those applying for a license for co-marketed products will need to submit to the Institution a separate undertaking stating that the products to be co-marketed are identical, all variation applications will be made simultaneously, and that no other application will be made by the licence holder for an additional production facility relating to the co-marketed products. The licensing period for co-marketed products is determined as 90 days under the Regulation.

Notification Obligations of the License Holders. Licence holders are obliged to notify the Institution 30 days in advance in the event that a licensed product will not be released to the market at a certain point in time. A licence holder is also obliged to notify the Institution within certain periods of time set forth in the Regulation in case the product licence is suspended or cancelled, or the product is recalled in any other country due to quality, effectiveness or safety issues.

The Regulation is expected to ease and expedite the licensing processes for medicinal products, while maintaining the surveillance of the pharmaceuticals market. Sector players are to observe in their license applications the provisions of the Regulation, most of which are already effective.

Please do not hesitate to contact us for any further information on this briefing.

Kind regards,

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