Turkish Medicines and Medical Device Agency Grants an Extension of Time for Emergency Licensing on Biocidal Products

22 May 2020

In order to prevent the spread of COVID-19 pandemic and ensure the fast and uninterrupted supply of biocidal products which are in direct contact with the human body, the Turkish Medicines and Medical Device Agency ("**Agency**") granted a three-month temporary license for the cited biocidal products with the Circular ("**Circular**") stated in our previous article.

As per the Agency's announcement ("**Announcement**") dated 15 May 2020, the application deadline for the temporary license has been determined as 31 May 2020. After this date, temporary license applications shall not be accepted.

Moreover, any missing document or information required for the temporary license application should be submitted by 15 July 2020. The Agency will not take documents submitted or license fees paid after the stipulated date into consideration.

According to the Circular, following the application for a temporary license, companies were obliged to submit the results of required efficiency, accelerated stability, and irritation tests within one month to the Agency. Agency extended this period to a total of two months, with the Announcement. The temporary licenses of applicants who fail to submit these within given time shall be revoked. Likewise, submissions not meeting the specified criteria shall be canceled.

The temporary licenses for the biocidal products are valid only for three months and such licenses will be expired at the end of this period, and biocidal products shall not be allowed to be placed on the market.

Within the temporary license period, companies shall file an application and follow the ordinary license procedures regulated by the Regulation on Biocidal Products in order to maintain the marketing authorization for the supply of these biocidal products. In this case, the license fee will not be requested again, the license will be simply renewed, and the license number will remain the same. For those who do not follow the licensing procedure within the temporary license period, the licensing procedure will start over again and will not be considered as a continuation of the temporary license.

In conclusion, the Agency clarifies the deadlines for the temporary licensing process of relevant biocidal products and aims not to impose any additional burden on companies during the ordinary license procedure.

Please see this link for the Announcement (only available in Turkish).