Turkish Medicines and Medical Device Agency Publishes a Circular on Emergency Licensing for Biocidal Products

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In order to prevent the spread of COVID-19 pandemic, maintaining the fast and uninterrupted supply of biocidal products that are in direct contact with the human body becomes crucial. As a response to this need, the Turkish Medicines and Medical Device Agency ("**Agency**") took precautions to prevent the shortage of these essential supplies while upholding safety and quality standards.

A license is required to release biocidal products to the market and license conditions are regulated by the Regulation on Biocidal Products ("**Regulation**"). The article 15 of the Regulation refers to an "emergency licensing and registration" and regulates the following *"The Ministry may temporarily license or register a biocidal product, which must be used in emergency situations, where an unforeseen danger occurs due to harmful organisms that cannot be controlled by other means, for limited and controlled use."* This is an exceptional provision limited to emergency situations such as the COVID-19 pandemic. On 19 March 2020, the Agency published a new circular ("**Circular**") numbered 70938 based on the referred article 15 of the Regulation to address the concerns of fast and efficient supplies of biocidal products that are in direct contact with the human body. The Circular outlines procedures and principles regarding the biocidal products type-1 and type-19. As per the Circular, a three- month temporary license can be issued for the cited biocidal products, except their use in health institutions and organizations. Accordingly, providing the physical and chemical analysis of the biocidal product in addition to the information and documents specified in article 15 of the Regulation are required and sufficient to grant a license. The application of a temporary license is filed through the Agency's electronic application system by submitting the necessary documents to the Cosmetic Products Department. Following the payment of application fees, the physical documents must be provided to the Agency within 30 days, otherwise, the application shall be canceled.

Moreover, following the application for a temporary license, companies must submit the results of the required efficiency test, accelerated stability test and irritation test within one month to the Agency. However, the accreditation / GLP condition is not required in the test method considering the difficulty to access the laboratory with the conditions specified in the legislation.

The licenses of the products that do not meet all the specified conditions shall be canceled.

The Specification of the Concerned Goods

The Regulation defines biocidal products as *"Containing one or more active ingredients as presented to the user, not only with physical or mechanical effects, but also for the purpose of destroying, removing, making harmless or preventing the effect of the harmful organism, and for controlling any harmful organism. any substance or mixture containing or formed from their composition, or any substance or mixture produced on-site from the substance or mixtures"*

As per to the Regulation, biocidal products related to human hygiene fall within the scope of "Type-1". Disinfectants, antibacterial products used for humans are covered under this type. "Type-19", on the other hand, are described as: biocidal products used for controlling invertebrates such as fleas or vertebrates such as birds but their most important feature is the control of harmful organisms. They control harmful organisms in the form of pulling or expelling. Because of these properties, they are used for providing human hygiene directly or indirectly.

In conclusion, the Agency aims to ensure the necessary biocidal products to be widely accessible by easing the process to grant marketing authorization for all interested companies.

Please see this link for the Agency's announcement regarding the Circular (only available in Turkish).