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Certain Amendments are Introduced to the Regulation on the Safety of Medicines

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Regulation Amending the Regulation on the Safety of Medicines ("**Amendment Regulation**") was published in the Official Gazette dated 21 July 2022 and numbered 31899 and entered into force on the same date. Accordingly, the definition of the "medicine" has been broadened and new regulations have been introduced regarding administrative sanctions to be applied by the Turkish Medicines and Medical Devices Agency ("**Agency**") and the reporting procedures of suspected adverse reactions, periodic benefit / risk assessments and risk management plans.

The main amendments are as follows:

- Substances used or applied for medical diagnosis have been include to the definition of "medicine".
- Serial numbers of the biological and biotechnological products shall be included to the suspected adverse reaction reports.
- Paragraph 8 of article 22 of the Amendment Regulation states that the periodic benefit / risk assessment reports will be prepared in accordance with the European Union reference date and presentation frequency list as of the license date of the medicine. In case the active substance of the drug is not included in this list, a report will be prepared every six months for the first two years, once a year for the next two years, and every three years following the extension of the license validity period and the reports will be submitted immediately upon the request of the Agency.
- The Regulation has paved the way for the imposition of administrative sanctions on contracted pharmacovigilance service providers which do not act in compliance with the provisions of the Regulation. In this context, license holders and contracted pharmacovigilance service providers will be granted a period to ensure compliance, and if the violation is not remedied in due time, contracted pharmacovigilance service providers may face sanctions such as restriction of activities, suspension or cancellation of the license, depending on the nature of the violation. Administrative sanctions for license holders are envisaged as preventing the notification of the medicine tracking system, stopping product movements, suspending or canceling the license of the medicine, depending on the nature of the violation.

Please see this link for the full text of the Regulation published in Official Gazette dated 21 July 2022 and numbered 31899 (only available in Turkish).

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