

New guidelines for off-label use of drugs published

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On 8 February 2019, the Turkish Medicines and Medical Devices Agency published new [Guidelines for the Off-Label Use of Drugs](#) (Turkish language) and abrogated the previous version of the Guidelines, dated 18 July 2014. The new Guidelines entered into force upon publication.

The Guidelines reference a new system for applications for the off-label use of drugs. The system is named as the "System on Administration of Unauthorized and Off-Label Drugs" (abbreviated in Turkish as "REIYS"). Pursuant to Article 4/6 of the Guidelines, any applications for off-label use of drugs must be made via the REIYS online or via post to the address of the Agency.

The Guidelines do not change the provision regarding retrospective applications, that is, where the off-label use of a drug has been initiated without the Agency's prior authorisation, an application made by the physician after such use shall continue to not be evaluated. However, the Guidelines introduce an exception for the acceptance of such applications in cases where it is determined that the drug was used off-label for a medical emergency.

The Agency requires applications to be re-submitted for drugs that were approved for off-label use before the new Guidelines entered into force. Therefore, physicians must apply to the Agency for the authorisation of off-label use of drugs that were previously approved.