Circular regarding drug tracking system notifications

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On 25 December 2019, the Turkish Medicines and Medical Devices Agency published *Circular No 2019/3* (Turkish language), regulating the terms for notifications to be made on the Pharmaceutical Tracking System (ITS) for manufactured and imported products.

In accordance with to the circular, notifications for manufactured pharmaceuticals shall be made within 60 days after the date of production. In terms of imported pharmaceuticals, notifications shall be made within 45 days after the date of last customs entry, while customs entry and billing samples shall be submitted to the agency within 15 days after the import. Notifications made after the specified terms shall not be accepted.

The circular also refers to the article on the suspension of market authorisations (MAs) in the Regulation on Licensing of the Human Medicinal Products, stating that in case of any non-compliance with the notification terms, the MA of the relevant pharmaceutical shall be suspended.

The requirements will be in force from 1 February 2020. However, the notifications for already produced products and products for which customs entry transactions are completed shall be taken to have been finalised.