Turkey Announces Transition Procedures for Adding Braille to Pharmaceutical Packaging

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In 2017, the Turkish Medicines and Medical Devices Agency ("**Agency**") announced that from 1 January 2019, human medicinal products must bear the product's name in Braille, as well on the outer packaging. The Agency has now announced transition procedures for Braille alphabet and name modifications ("**Announcement**") which must be completed by 31 December 2018.

The Regulation for Pharmaceuticals' Packaging Information, Patient Leaflet and Tracking of These ("**Regulation**") was published in Official Gazette number 30048 on 25 April 2017. The Announcement outlines transition procedures for requirements introduced by the Regulation.

According to the Announcement, license holders must make a "Braille Transition Notice" by 31 December 2018, accompanied by:

- Expert approval regarding the suitability of the information to be written in Braille on the packaging.
- An approved document showing the expert's competence in Braille.

The Agency will not issue an official letter stating it has received the notification. Therefore, license holders must monitor and ensure their own regulatory compliance for the transition.

A variation application is not necessary if the Agency requests the product name be amended, without changing the medicine's name. For example, adding the medicine strength or a pharmaceutical shape. The Announcement says such modifications can be made via an annotation request submitted with the original license or certificate.

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

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