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Turkey Updates Rules for Pharma Packaging and Patient Leaflets

13 Jun 2018

The Turkish Medicines and Medical Devices Agency ("Agency") updated the guidelines for packaging and patient leaflets related to human medicinal products. Changes primarily relate to how active ingredient should be indicated, as well as phrases which should be included on internal and external packaging.

Rules for packaging and patient leaflets for human medicinal products are contained in:

- The Guideline on Packaging Information and Patient Leaflets for Medicinal Products.
- The Guideline on Legibility of Medicinal Products' Packaging Information and Patient Leaflets.
- The Guideline on Excipients in Packaging Information and Patient Leaflets.

Notable changes to the rules include:

- All products containing polymyxin group antibiotics must now indicate the active ingredients as I.U. or U.
- The authorization number is no longer required to be included on the inner packaging of a product's first two series if production authorization was granted within the scope of localization.
- For products which have dry powder pharmaceutical form and which will be used by adding water, a notch or corresponding marking (such as a line) should be added to the inner packaging, to determine the correct amount of water to be added.

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

Related Practices

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