Turkish Medicine and Medical Device Agency Announces New Rules for Using the Phrase “Apyrogenic” on Pharmaceuticals

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The Turkish Medicines and Medical Devices Agency ("**Agency**") has announced new conditions for using the phrase "apyrogenic" on pharmaceuticals, along with transitional procedures ("**Announcement**"). The transitional procedures must be completed by 30 June 2018, or else pharmaceutical companies must remove the phrase "apyrogenic" from product packaging and patient leaflets manufactured after this date.

The Agency published the Guideline Regarding Pharmaceuticals' Packaging Information and Patient Leaflets, based on the Regulation for Pharmaceuticals' Packaging Information, Patient Leaflet and Tracking of These published in Official Gazette number 30048 on 25 April 2017.

According to the Guideline, apyrogenic products must have the phrase "apyrogenic" on the inner and outer packaging, as well as patient leaflets. However, as per the Agency's recent Announcement, the "rabbit pyrogen test" becomes to only acceptable registered testing method within finalized product specifications for pharmaceutical preparations to qualify to use the phrase "apyrogenic".

Pharmaceutical companies which wish to use the phrase "apyrogen" on pharmaceutical preparations, but do not use the "rabbit pyrogen test" as the registered testing method in finalized product specifications, must apply to either of the following bodies (depending on the pharmaceutical's type), submitting up-to-date information and data:

- Licensed Medicine Technological Evaluation Unit for Type IA or Type IB
- Biologic and Biotechnological Products Unit for Type II variations.

The application requirement above includes companies which already have Agency approval to use the phrase "*apyroge*n".

For pharmaceutical companies to continue to use the phrase "*apyrogen*" on products which adopt the "*rabbit pyrogen tes*t" as the registered testing method in the finalized product specifications, these companies must apply to the Licensed Medicine Technological Evaluation Unit for authorized pharmaceuticals or the Biologic and Biotechnological Products Unit depending on the pharmaceutical, with up-to-date information and data.

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

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