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Turkish Medicines and Medical Devices Agency Published the Guideline on Triggers for Routine and/or for “Specific Reason” Inspections and the Guideline on Triggers for Inspections of Bioavailability / Bioequivalence Studies

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The Guideline on Triggers for Routine and/or for "Specific Reason" Inspections and the Guideline on Triggers for Inspections of Bioavailability / Bioequivalence ("**BY / BE**") Studies have been published by the Turkish Medicines and Medical Devices Agency ("**Agency**"). The Guidelines identify potential triggers that could be used to initiate inspections and provide an overview of the triggers.

Notable provisions of the guidelines are as follows:

- The checklist provided in the annex of the Guideline on Triggers for Inspections of BY / BE Studies includes examples of triggers that evaluators can use during the examination of BY / BE studies, which are presented as a basis for the registration of generic drugs. However, the checklist is not exhaustive and other triggers may also be defined.
- The triggers provided in the checklist can be summarized as follows:
    - Whether the study or the center where the study was carried out was inspected by the Agency previously,
    - Whether it has been more than 3 years since the last inspection,
    - Whether the product is of a specific character,
    - Whether the responses submitted regarding the missing information raise doubts regarding compliance with current requirements and guidelines.
- Whether there are any observations that raise concerns about the validity or quality of reported study data, statistical analysis, analytical method validation, subject-related data and subject samples, or sample processing.
- It is also regulated the compliance of the study with the current requirements shall checked before an inspection is requested in case the BY / BE study is an old study —for example, 5 years or older.
- The Guideline on Triggers for Routine and/or for "Specific Reason" Inspections envisages the factors to be considered for performing routine inspections and inspections based on a "specific reason".
- Regarding routine inspections, it has been regulated that factor such as deficiencies and inconsistencies present in the license application file, audit history and commercial considerations will be taken into account. Furthermore, factors such as the size and complexity of the organization of the study, the country in which the study was conducted, the patient/volunteer recruitment rate of the center will also be considered.
- Within the scope of "inspections based on a specific reason"; ethics, administrative structure of the study, considerations regarding the protocol, volunteers, efficacy and safety evaluation criteria and data will be taken into consideration.

You may access to the full text of the Guidelines through this link. (Only available in Turkish)

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