

Guideline on Communication, Organization and Responsibilities of Stakeholders in Market Control Programs has been Published

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Guideline on Communication, Organization and Responsibilities of Stakeholders in Market Control Programs ("**Guideline**"), prepared by Turkish Medicines and Medical Devices Agency ("**Agency**") Medicine Inspection Department, has been published on 22 April 2022.

The Guideline aims to define and navigate the communication, organization, and responsibilities of internal and external stakeholders and to guide the relevant parties in planning, execution, and finalization of market control activities of human medicinal products, active material and special medical purpose diet foods carried out by the Authority.

The most remarkable matters within the scope of the Guideline are as follows:

- In the Guideline, the determination process of the medical products and active ingredients to be included to the program the principles regarding the initiation, execution and conclusion of the program and the responsibilities of the stakeholders have been listed.
- Pursuant to the Guideline, Provincial Health Directorates obtains samples from the products included in the list which are determined by the Pharmaceutical Market Control and Consumer Issues Unit ("**Unit**") and transmit them to the Unit. After the Unit will record the samples in the New Documentation System and carry out the necessary investigations.
- After the Unit determines that the laboratory and analysis results are appropriate, a letter of confirmation will be written to the Provincial Health Directorate. In case the laboratory and analysis results are not appropriate, the procedures will be initiated to withdraw the products from the market.
- The Guideline determines the duties and responsibilities of administrative departments, namely, the Unit, Department of Analysis and Control Laboratories, Department of Economic Evaluations and Drug Supply Management, and Provincial Health Directorates, which will be co-working through the process.
- The Guideline also lists the internal and external stakeholder communication list of the market control program, the workflow chart and the stakeholder chart.

Please see this [link](#) for the full text of the Guideline published by the Ministry of Health on the date of 22 April 2022 (only available in Turkish).

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