The Regulation on Market Control of Human Medicinal Products entered into force.

21 Jul 2023

The Regulation covers the market control activities of (i) the human medicinal products that are licensed or authorized by the Agency, (ii) the active substances used in their production, (iii) foods having special medical purposes. Magistral medicines are not included within the scope of the Regulation.

Market control activities will be organized periodically for the products and active substances that are covered by the scope of the Regulation. Active substances and products to be included in the market control program will be determined according to the risk parameters determined by the Agency. The locations where samples of these products will be taken, shall be determined in accordance with the data retrieved from Pharmaceutical Track and Trace System.

Active substance samples shall be obtained directly from the production sites. The general aspects and responsibilities concerning the acceptance and examination of samples and the preparation of analysis reports are regulated separately within the scope of the Regulation.

In addition to routine controls, market control activities can be carried out upon complaints received by the Agency or the matters identified by the Agency regarding the efficiency, safety and quality of the products that are within the scope of the Regulation.

Additionally, with the Regulation, it is also possible that the products that were found risky during the inspections of inspectors and product inspectors to be added routine market control activity program or a market control can be conducted directly with respect to these products.

The sanctions that shall be applied in case of violation are also regulated. Accordingly, the relevant sanctions referred to in the Regulation on Withdrawal and the Regulation on the Licensing of Medicinal Products for Human Use, the Regulation on the Licensing of Traditional Herbal Medicinal Products, the Regulation on the Licensing of Homeopathic Medicinal Products and the Regulation on the Licensing of Foods for Special Medical Purposes shall apply.

You can access the full text of the Regulation on Market Control of Human Medicinal Products through this link. (Only available in Turkish)

Related Practices

- R&D, Licensing and Technology Transactions

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