Supervision of quality of medicinal products

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In order to protect human health and life State Pharmaceutical Inspection supervises quality of medicinal products available on Polish market on the way of execution of market surveillance plan. Chief Pharmaceutical Inspectorate GMP and GDP Inspectors supervises the national level and pharmaceutical inspectors of voivot pharmaceutical inspectorates performer their duties on the voivot (provincial) level.

Inspection activities covers perform of following:

- controlling of the conditions of transport, handling and storage or medicinal products,
- controlling pharmacies and other entities engaged in retail sale or wholesale of medicinal products,
- controlling the marking and advertisement of medicinal products.

Medicinal products quality is directly controlled through:

- controlling the quality of magistral and officinal formulas prepared in pharmacies,
- the Pharmaceutical Inspection directing medicinal products, that obtained marketing authorisation in the Republic of Poland for the first time, for quality tests performed within specialized institutes and research laboratories
- directing medicinal products for quality testing on the basis of National Surveillance Plan In accordance with approved Schedule and scope of control - samples are taken from various stages of medicines lifecycle in all voivodships

If the controls and tests lead to any justified suspicions that a specific medicinal product does not meet the approved requirements, competent authorities of the State Pharmaceutical Inspection issue relevant decisions:

- the voivodship pharmaceutical inspector – decisions on suspending the turnover of particular batches of a medicinal product within its voivot area;
- the Chief Pharmaceutical Inspector – decisions on suspending the turnover of particular batches of a medicinal product in the entire country

After issuing such decisions, the turnover (sale) of the particular batches of a specific medicinal product is suspended in all wholesale stores and pharmacies, until laboratory test results confirming or excluding a quality defect are obtained.

If the test results confirm that a medicinal product does not meet the approved quality requirements, the Chief Pharmaceutical Inspector issues a decision to recall the medicinal product (or, if it hasn’t been marketed yet,

bans the marketing of a medicinal product).

To ensure safety of drug therapy without direct link to the quality of specific medicinal product however in case of justified suspicion that it could cause severe adverse reactions, law allows the Main Pharmaceutical Inspectorate to issue relevant decision.

The decision may be related to:

- temporary prohibition of marketing of a specific product,
- suspending the turnover of a specific product,
- recalling a specific product.

Such decisions are issued at the request of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL).

If there is a possible risk to public health caused by medicinal products, the Chief Pharmaceutical Inspector, at the request of the Minister of Health or the President of the Office (URPL), issues a decision to temporarily ban the marketing of the product, suspend its turnover or recalling it.

Supervision over vaccines

The State Pharmaceutical Inspection is responsible for supervising the quality of medicinal products on the market, including vaccines. Every reported suspicion that a given medicinal product does not meet the quality requirements is analysed and investigated to assess the quality defect and the risk to patients' health and life.

Considering the patients health and life, the Chief Pharmaceutical Inspector takes decisions within the scope of its competences to eliminate medicinal products that does not meet approved quality requirements from the market. Decisions of the Chief Pharmaceutical Inspector on recalling, withdrawing or banning medicinal products are available on the Main Pharmaceutical Inspectorate's website in Decyzje i komunikaty [Decisions and communications].

The entity responsible for provision of vaccines within the entire country under the Preventive Vaccination Plan and supervising entities responsible for storage and provision of vaccines to service providers is the Chief Sanitary Inspector. Tasks of the Chief Sanitary Inspector include also the planning of activities related to the performance of preventive vaccinations, supervising this process and executing it.

Adverse reactions

According to the Pharmaceutical Law, every patient is entitled to report adverse reactions to a medicinal product.

An adverse reaction shall be understood as every unfavourable and non-intended effect of a medicinal product.

The authority competent for monitoring adverse reactions to medicinal products, i.e. to collect reports and other information on adverse reactions is the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products . If there is a justified suspicion that the use of a medicinal product causes severe adverse reactions that change the relation of benefits and risk, the Main Pharmaceutical Inspector, at the request of the President of the Office, issues a decision to temporarily ban the marketing of the product, suspending the turnover of this product or recalling it.

Adverse reactions to medicinal products should be reported to the President of the Office or the Marketing Authorisation Holder. Patients and their statutory representatives or actual caregivers can report adverse reactions to medicinal products to medical personnel, the President of the Office or the Marketing Authorisation Holder.

Data regarding adverse post-vaccination reactions and criteria of recognition thereof are collected by the State Sanitary Inspection units.