PROCEDURE FOR WITHDRAWAL OF MEDICINES FROM PHARMACIES

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Introduction. In accordance with the standard ICO 9001: 2015, quality assurance is the main task of the management and requires the participation and responsibility of the company's personnel at all levels. The correct solution for fulfilling the tasks is the implementation of the rules of GMP and GSP, which take into account all components of the quality system, including risk management, and factors that may affect the quality of the drug during the delivery to the destination.

Aim. An important component of the quality of the drug is an effective quality management system, in which there should be a procedure for recalling medicines from the market.

Materials and methods. The effectiveness of the drug recall procedure from the pharmaceutical market depends on: 1. A clear distribution of powers of the responsible person; 2. A clear and complete description of the sequence of procedures; 3. Complete interaction with regulatory authorities; 4. Interrelationships with suppliers; 5. A clear and regular documentation review procedures.

When the distributor interacts with a pharmaceutical company that deals with the retail sale of medicines, it is a prerequisite to conclude a contract on the basis of individual contract terms.

Results and discussion. The fate of the medicinal product and the reasons for the refunds:

1. Drugs according to the recall of the distributor.
2. Medicament according to the manufacturer's recall.
3. Medicinal product according to the order of the regulatory authority (rejection of the medicinal product - marking, impurities, termination of registration in the territory of Ukraine).
4. Medicinal product according to the order of the regulatory authority (suspicion of falsification according to consumer complaints).
5. When the falsification of a medicinal product is confirmed, this series, according to a written notification from the regulatory authority, withdraws from the pharmaceutical market.
6. When refuting the falsification of a medicinal product, according to a written notification from the regulatory authority.

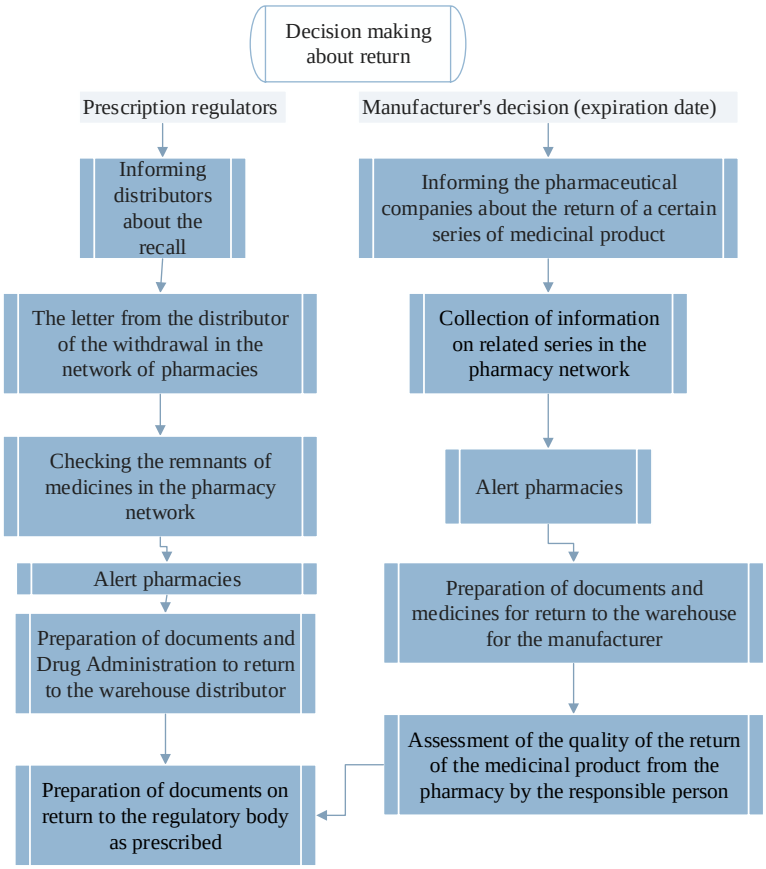
For proper and strict management procedures Review of medicines, appointed by the person in charge of the pharmacy, which is responsible for the review

procedure with the pharmaceutical market. The key procedure is implemented by the process manager in the pharmacy network of the pharmaceutical company.

The drug is subject to return from the pharmacy network in accordance with the terms of the supply agreement with the distributor or manufacturer, and the terms of the contract, regardless of the import or domestic production of the medicinal product. Obligatory is the preparation and signing of documents, the procedure for possible refunds (reviews) is preliminarily announced.

The effectiveness of the recall procedure is possible when displaying all the conditions for the return of the medicinal product to the distributor:

- information about the responsible persons (surname, name and patronymic, telephone);
- document flow during recall;
- methods of communication for urgent interaction;
- method, conditions, terms of repayment;
- obligations to the distributor (ensuring the full interaction of the return of the recalled products).



Conclusions. We have developed a return procedure in the form of a flowchart of return procedures taking into account the areas of responsibility. Formation of the withdrawal procedure will ensure compliance with the requirements of GDP, GSP, GPP, and will be one of the components of the guarantee for the end user.