ACTUALIZATION OF QUALITY MANAGEMENT SYSTEMS AT STATE LABORATORIES FOR THE CONTROL OF MEDICINES

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Introduction. Effective quality control of medicines is an obligatory component of the national security system of the state. Laboratories for the quality control of pharmaceutical products bear a major responsibility for the results obtained and conclusions made on their basis on the conformity of the tested samples with the requirements of the specifications, because the success of the treatment of patients or even their life depends on the results of such studies. ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*, is the international reference for laboratories carrying out calibration and testing activities around the world. Producing valid results that are widely trusted is at the heart of laboratory activities. ISO/IEC 17025:2017 allows laboratories to implement a sound quality system and demonstrate that they are technically competent and able to produce valid and reliable results.

Aim. The purpose of our work is to analyze the main changes in the new standard ISO/IEC 17025:2017 for determining the methods for updating the work at state laboratories for the control of medicines.

Materials and methods. The theoretical and methodological basis of the work are provisions on the formation of quality management system on the basis of modern concepts of standardization and quality management.

Results and discussion. ISO/IEC 17025 takes into consideration the new ways of working of laboratories today. The most substantive changes are as follows:

- The scope has been revised to cover all laboratory activities, including testing, calibration and the sampling associated with subsequent calibration and testing.
- A new structure has been adopted to align the standard with the other existing ISO/IEC conformity assessment standards such as the ISO/IEC 17000 series on conformity assessment. The process approach now matches that of newer standards such as ISO 9001 (quality management), ISO 15189 (quality of medical laboratories) and the ISO/IEC 17000 series (standards for conformity assessment activities), putting the emphasis on the results of a process instead of the detailed description of its tasks and steps.
- The standard has a stronger focus on information technologies. In recognition of the fact that hard-copy manuals, records and reports are slowly being phased out in favour of electronic versions, it incorporates the use of computer systems, electronic records and the production of electronic results and reports.
- A new section has been added introducing the concept of risk-based thinking and describes the commonalities with the new version of ISO 9001:2015, Quality management systems – Requirements.

Conclusions. The construction of effective quality management system in state laboratories for quality control of medicines will help reduce the number and significance of inconsistencies and errors increase the probability of reliable results, increase the awareness of staff. These measures should definitely be considered progressive both for the national quality control system for medicines and for the entire domestic pharmaceutical market.