Higher-quality medicines on market in Moldova

The Government today approved the Good Manufacturing Practice (GMP) Rules for medicines, which improve the regulations in the pharmaceutical manufacturing.

The new rules establish a clear framework for organizing and carrying out manufacturing and import activities for medicinal products for human use, including those intended for clinical trials. At the same time, they help strengthen quality control mechanisms for medicines manufactured and imported in the Republic of Moldova.

An important element is the reduction in the number of permissive documents required for economic operators. Their activity will now require only two documents, compared to the four previously needed: a manufacturing and import authorization issued by the Medicines and Medical Devices Agency (AMDM), and a certificate of compliance with Good Manufacturing Practice, issued following inspections that confirm adherence to quality and safety standards.

The document also sets out the procedures related to authorization, inspection, and certification, as well as the responsibilities of manufacturers and importers in the medicines manufacturing process.

The new rules will contribute to increased safety and quality of medicines on the market, simpler procedures for operators, and more effective control by the authorities.