PROJECT FACTSHEET

Funded by the European Union

Strengthening regulatory and institutional capacities for EU alignment in medicines and medical devices in Moldova

Duration: 01.02.2026 - 31.07.2027

Countries:
Moldova

EU contribution: € 200 000

Total budget: € 200 000

Implementer:
World Health Organization, Country Office in the Republic of Moldova

Project description:
The proposed intervention seeks to advance Moldova's progress toward EU accession under Chapter 28 – Consumer and Health Protection. Its aim is to strengthen the institutional and technical capacity of the Medicines and Medical Devices Agency (MMDA) of the Republic of Moldova to align with and implement the EU acquis on medicines and medical devices. Implemented through a contribution agreement with WHO under indirect management, the 18-month project will adopt a phased capacity-building and EU alignment approach. Activities include staff training, development of EU-aligned guidance and Standard Operating Procedures (SOPs), interoperability assessment and conceptualisation of interoperable digital tools for post-market surveillance. Close collaboration and peer exchanges with EU regulatory authorities and relevant EU institutions will ensure practical knowledge transfer and long-term sustainability. The Action will contribute to stronger public health protection and Moldova's progressive integration into the European regulatory framework, with the ultimate goal of achieving equitable access to safe, effective, and quality-assured medicines and medical devices for all Moldovans.

Expected results:
SO/Outcome 1: MMDA progresses with alignment and implementation of EU acquis on medicine and medical devices.
Output 1: The MMDA has improved alignment with EU acquis on medicines and medical devices and introduced SOPs for core regulatory processes.
Output 2: The staff of MMDA have improved knowledge and skills in authorisation of medicines, quality control of medicines, clinical trials, pharmaceutical inspections, and post-market surveillance of medicines and medical devices in line with EU standards, procedures and good practices.
Output 3: The MMDA has improved preparedness to introduce tools and procedures interoperable with EU systems EudraVigilance and EUDAMED.