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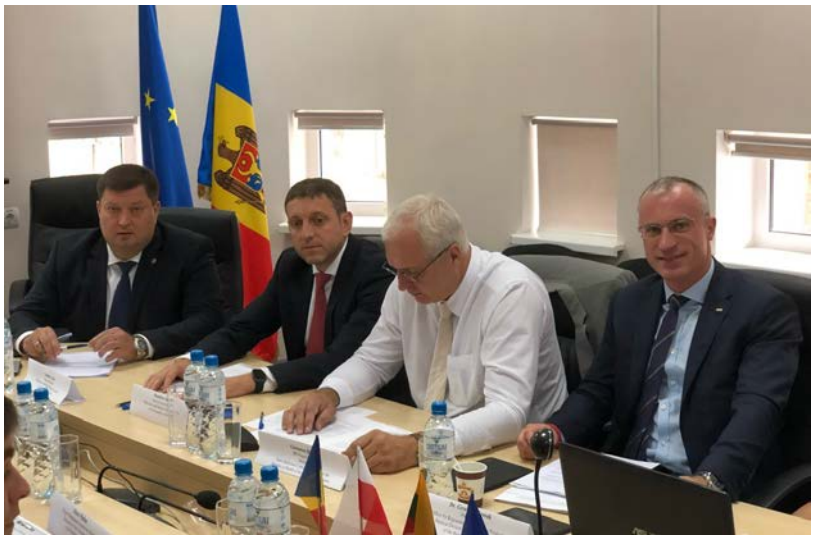
*Chisinau, 19 July 2018*

## THE SIXTH STEERING COMMITTEE MEETING HAS BEEN ORGANIZED



The sixth meeting of the Steering Committee of the EU-funded Twinning Project "Strengthening the Medicines and Medical Devices Agency of the Republic of Moldova as a regulatory agency in the field of medicines, medical devices and pharmaceutical activity" was held on the 19 of July 2018.

The Meeting was organized within the premises of the Medicines and Medical Devices Agency of the Republic of Moldova (MMDA), with the participation of Project Leaders from the Republic of Lithuania, Republic of Poland and the Republic of Moldova, the Resident Twinning Adviser, representatives of the European Union Delegation to the Republic of Moldova, the Ministry of Health, Labour and Social Protection of the Republic of Moldova, the National Health Insurance Company of the Republic of Moldova, Centralized Procurement Centre for Health of the Republic of Moldova and the specialists from MMDA as well as Polish Competent Authority.

In his greeting message, the General Director of the MMDA, Mr. Vladislav Zara mentioned that the results of the project are already palpable. Thereby, one of the successes is the attestation of the MMDA Medicines Quality Control Laboratory by the European directorate for the Quality of Medicines and HealthCare, which declares that it has satisfactorily implemented a Quality Management System in accordance with ISO/IEC 17025, with the relevant texts of the European Pharmacopeia, with the Quality Management Guidelines and the Terms of Reference of the General European OMCL Network. The confirmation of the Quality Control Laboratory of Medicines as a full member of the General European OMLC Network (GEON) was taken after a group of expert members of the European Medicines Control Board (EDQM) conducted an audit to evaluate the work and organization of the laboratory in October 2017.

This project is funded by the European Union

The European Union is made up of 28 Member States who have decided to gradually link together their know-how, resources and destinies. Together, during a period of enlargement of more than 50 years, they have built a zone of stability, democracy and sustainable development whilst maintaining cultural diversity, tolerance and individual freedoms. The European Union is committed to sharing its achievements and its values with countries and peoples beyond its borders.

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"This is not the only achievement during the last period. Major progress and visible results are attested by the Medicines Authorization Department, where the Standard Operating Procedure for post-authorization variations of the medicinal products and Standard Operating Procedure for initial marketing authorization and renewal of the medicinal products have been approved and are already implemented. The Standard Operational Procedures for the Clinical Trials and Pharmacovigilance Department will enter in force soon" said Mr. Vladislav Zara.

Project Leaders of the Member States, Mr. Gintautas Barcys, Director of the State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania and Dr, Grzegorz Cessak, President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products of the Republic of Poland, noticed that the project is successfully developing, and the number of results achieved is increasing. At the same time, the officials noted the effort made by the MMDA's experts in order to support the successful implementation of the project activities. "Despite challenges raising from the broad scope of knowledge and complexity of the topics, Moldovan colleagues tirelessly put any possible effort to benefit from the project and to achieve assumed goals," said Dr. Grzegorz Cessak.

At the same time, Mr. Gintautas Barcys has repeatedly mentioned that the Republic of Moldova needs to approve a new Law on Medicines, the draft of which has already been published for public consultation. In this context, the Project Leader reminded that within the EU funded Twinning project, several missions were organized with the participation of European experts, whom analysed and made recommendations on the draft Law on Medicines.

In turn, the Project Leader of the Beneficiary Country, Mr. Dumitru Saghin, General Deputy Director of the MMDA, pointed out the success of implementing all project activities, the most recent ones being in the field of pharmacovigilance, good clinical practice, good manufacturing practice and good distribution practices.

The Project Leader also noticed that "the Republic of Moldova, as a Beneficiary Country, requests the extension of the EU funded Twinning Project with three additional months to the implementation period, because the realization of some project activities has been delayed due to the restructuring of the government institutions and the reallocation of some functions to other institutions."

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The request is to be examined by the European Commission.

The EU funded Twinning Project "Strengthening the Medicines and Medical Devices Agency of the Republic of Moldova as a regulatory agency in the field of medicines, medical devices and pharmaceutical activity" was launched in January 2017, with a duration of 24 months and a budget of 1.1 million Euro.

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