PRESS RELEASE

Chisinau, 11 October 2018

THE SEVENTH STEERING COMMITTEE MEETING HAS BEEN ORGANIZED

The seventh 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 11 of October 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 and the Republic of Moldova, the Resident Twinning Adviser, representatives of the European Union Delegation to the Republic of Moldova, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products of the Republic of Poland, 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, the Ministry of Finance of the Republic of Moldova as well as the specialists from the MMDA.

The General Director of the MMDA, Mr. Vladislav Zara mentioned that that being closer to the ending period of implementation of the EU-funded Twining project, the cooperation among the partner agencies as well as among the beneficiary institutions is at its highest level.

Additionally, all the activities planned were accomplished due to the team spirit of all the involved experts. “This is even more evident after the Benchmarking of European Medicines Agencies (BEMA) assessment carried out during the first week of October by the Lithuanian and Polish team of experts. As a result of the assessment of the systems and processes within the MMDA, based on a set of indicators in the fields of management systems, assessment of marketing authorization criteria, pharmacovigilance activities, and inspections, the audit team appreciated the MMDA's level with a high score“ pointed Mr. Zara.

This project is funded by the European Union

PRESS RELEASE

Project Leader, Mr. Gintautas Barcys, the Director of the State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania, highlighted that all the activities were implemented according to the planned schedule and mentioned that the BEMA self-assessment and the following audit by the BEMA auditors showed that MMDA is well governed and appropriately prepared in terms of scientific and regulatory knowledge to carry out activities as a EU National Competent Authority for medicinal products.

Mr. Marcin Kolakowski, the Vice President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products of the Republic of Poland (URPLWMiPB) stressed that the Polish partner is doing its best for facing the heavy Twinning project schedule. “During the last quarter, the polish experts were involved in the BEMA self-assessment and audit as well as in several missions were the Polish experts organized trainings and shared their best practices in pharmacovigilance, safety risk communication, educational campaigns as well as GCP inspection planning“ pointed Mr. Kolakowski.

In turn, the Project Leader of the Beneficiary Country, Mr. Dumitru Saghin, General Deputy Director of the MMDA, highlighted that the involvement and cooperation of all parties is going very intensively. The MMDA as the main beneficiary institution of the project, is on time with the implementation of all the planed activities and facing the program changes required by the other parties. “The MMDA staff benefit from the support provided by the EU experts and involved in all the activities organized within the project, most recent study visits in the Republic of Poland, as well as joint observed GDP inspection, GMP inspection, GCP inspection and GPP inspection in the Republic of Moldova“ stressed Mr. Saghin.

The Resident Twinning Adviser Ms. Anželika Oraitė presented the most important information regarding the seventh quarter of the EU funded Twinning Project, which are: 5 implemented activities, with the involvement of 25 experts from the Republic of Lithuania and the Republic of Poland during 33 working days and attended by more than 30 experts from the Beneficiary Country.

During the seventh quarter Good Manufacturing Practice /Good Distribution Practice (GMP/GDP) inspectors, Clinical Practice (GCP) inspectors, as well as Good Pharmacovigilance Practice (GVP) inspectors from the Beneficiary Country were trained to the level of the EU standards.

This project is funded by the European Union

Aditionally, trainings on supervision of pharmacies and enforcement of GPP with the recommendations for improvement of legal framework for GPP inspectors, as well as theoretical trainings in the field of regulation of pharmacy activities in Lithuania were conducted.

The next Steering Committee Meeting was fixed for 18 December 2018.

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.

This project is funded by the European Union