PRESS RELEASE

Chisinau, 19 April 2018

THE FIFTH STEERING COMMITTEE MEETING HAS BEEN ORGANIZED

On 19th April 2018, the fifth Steering Committee meeting of the EU-funded Twinning Project "*Strengthening of the Medicines and Medical Devices Agency of the Republic of Moldova as regulatory agency in the field of medicines, medical devices and pharmaceutical activity*" was held to evaluate the results of the activities implemented within the project, as well as to set the main targets for the next quarter.

The meeting was attended by representatives from the Ministry of Health of the Republic of Lithuania, the State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products of the Republic of Poland, the Delegation of the European Union to the Republic of Moldova, the Ministry of Health, Labour and Social Protection of the Republic of Moldova, the Medicines and Medical Devices Agency of the Republic of Moldova, the National Health Insurance Fund of the Republic of Moldova, the Centralized Procurement Centre for Health of the Republic of Moldova, the National Agency for Medicines and Meical Devices of Romania.

Mr. Vladislav Zara, the General Director of the Medicines and Medical Devices Agency of the Republic of Moldova (MMDA), mentioned that the EU-funded Twinning Project is developing successfully and the MMDA staff appreciates the role and value of the cooperation process with the Polish and Lithuanian partners, which contributes to the development of the MMDA and creates favourable conditions for the establishment of a strong, prosperous and institutional trust.

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Mr. Saghin, the Beneficiary Country Project Leader, mentioned that the SCM has become a good platform for discussing all the values and ideas that the beneficiary institutions of the Twinning Project share and conveyed his sincerest gratitude and congratulations to all those involved in this project since the success of it depends on all the parties involved.

The Project Leaders from the Republic of Moldova, Lithuania and Poland reviewed the main results achieved over the past few months, the challenges the project faces and the actions of the experts for the next period.

Mr. Barcys highlighted the need to amend the Draft Law on Medicines, taking into consideration the recommendations provided by the Lithuanian and Polish Short-term experts as soon as possible as well, stressed the necessity to have a fully functioning National Agency on Public Healthcare of the Republic of Moldova as it is very important from the public point of view..

The representatives from the Ministry of Health, Labour and Social Protection of the Republic of Moldova mentioned that the Draft of the Law on Medicines will be submitted by the MoHLSP for approval to the Government within the 3rd quarter of the 2018 year. It was also mentioned that the National Agency on Public Healthcare of the Republic of Moldova is not yet functional as the Government has to approve the state staff of the mentioned Agency, and after the process of hiring will start. Thus, it is difficult to give an estimated date when the control functions attributed to the Agency will be operational.

Dr. Grzegorz Cessak, the Junior Project Leader and the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products of the Republic of Poland noted that for the Polish partner it was the pact with activities period in whole project's history. The Component 1 of the EU-funded Twinning Project, leaded by a Polish expert was successfully completed. The analysis presented in the mission reports indicates a huge effort undertaken by the Moldavian legislators to establish the pharmaceutical laws with the objective of compliance with the aquis communautaire, but still a number of deficiencies was identified and addressed in the reports. Dr. Grzegorz Cessak expressed his hope that these findings and proposals will be useful for the development of the pharmaceutical field.

The Resident Twinning Adviser Ms. Anželika Oraitė presented the most important information regarding the last quarter of the Project, which are: 8 activities implemented,

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with the involvement of 22 short-term experts from Lithuania and Poland during 38 working days mission and attended by more than 50 experts from the Beneficiary Country. In total, 5 BC institutions were involved in the EU-funded Twinning project activities. The plan for the next quarter has also been presented.

During the fifth quarter short-term experts from Lithuania and Poland provided several workshops in the fields of GVP, GMP/GDP issues, on the assessment of the quality part of the clinical trial application dossier, on Verification of conformity assessment documentation for medical devices, as well as control of conformity assessment documentation of IVD medical devices and on the assessment of clinical evaluation documentation.

Also, first GVP inspection has been conducted in Chisinau. It was jointly organised by the Short Term Experts and MMDA GVP inspectors.

Furthermore, the several SOPs for the MMDA were elaborated, namely: the Standard Operational Procedures on Approval of the Substantial Amendment of Clinical Trial, Standard Operational Procedures on Authorization of the Clinical Trials with Medicinal Products, Standard Operating Procedure for Issuing Authorization/Refusal on Starting the Clinical Investigation in the Republic of Moldova, Standard Operating Procedure for Monitoring Incidents Investigations and field Safety Corrective Actions Implementation, and Standard Operating Procedure for Issuing Authorization/Refusal on Making the Amendments to the Clinical Investigation and for Supervision Over the Clinical Investigation in the Republic of Moldova.

The next Steering Committee meeting was fixed for **19th July 2018**.

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