



PRESS RELEASE

Chisinau, 11 January 2018

**The Fourth 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” has been held**

On 11th January 2018, the fourth 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 2018.

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 and the National Health Insurance Fund of the Republic of Moldova.

Mr. Vladislav Zara, the General Director of the Medicines and Medical Devices Agency of the Republic of Moldova (MMDA), chaired the event. In his greeting message, Mr. Zara mentioned that the EU-funded Twinning Project is developing successfully and the collaboration established between the partner countries is auspicious. Lithuania and Poland have the chance to share the valuable experience they have accumulated during the process of implementing the same reform in their countries, while Moldova has the opportunity to benefit from a high level of expertise from the Member States (MS) of the European Union.

Mr. Gintautas Barcys, the Member State Project Leader and the Director of the State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania specified that following the missions carried out in the Republic of Moldova, Lithuanian experts have already developed an Action Plan in respect of the centralized procurement system and pricing and reimbursement decision taking, which will be sent to the Beneficiary Country (BC) authorities. At the same time, Mr. Gintautas Barcys together with Mr. Jordi Rodriguez-Ruiz, the Project



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PRESS RELEASE

Manager, Delegation of the European Union to the Republic of Moldova invited the Ministry of Health, Labour and Social Protection of the Republic of Moldova to form an intern-institutional working group in order to examine the documents produced by the Twinning Partners and implement the recommendations.

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 stressed the importance of qualitative implementation of the activities foreseen within the EU-funded Twinning Project in order to implement all the outputs and achieve the objective. Simultaneously, from the broader perspective, he highlighted beneficial influence of the project on the areas of i.a.: public health, precondition for sustainable development and economic growth and approximation of Moldovan legislation to the EU acts, which all are mentioned in the Association Agreement between the European Union and the Republic of Moldova.

Mr. Dumitru Saghin, Beneficiary Country Project Leader and the Vice Director of the MMDA highlighted the fruitful cooperation and commitment among the Project partners. He mentioned that the project results are on their best way to be achieved so that at the end of the project implementation the BC institutions beneficiating from the project to be at the same level as the EU institutions.

The Resident Twinning Adviser Ms. Anželika Oraitė presented the most important information regarding the last quarter of the Project, which are: 8 activities implemented, with the involvement of 38 short-term experts from Lithuania and Poland during 48 working days mission and attended by more than 64 experts from the Beneficiary Country. In total, 9 BC institutions were involved in the EU-funded Twinning project activities. The plan for the next quarter has also been presented.

During the fourth quarter short-term experts from Lithuania provided consultations and recommendations in respect of the pricing, reimbursement and central procurement of medicinal products and medical devices. As a result, a Report on the possibilities to improve mechanisms to ensure availability and access, as well as a Plan in respect of the centralised procurement system and pricing and reimbursement decision taking was elaborated and will be submitted to the BC institutions.



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In addition, a study visit to Lithuania for 3 MMDA experts involved in medicines marketing authorisation procedures was organized. The BC experts were trained on primary evaluation and validation of the dossiers, on the assessment of the quality, safety and efficacy of MPs, as well as on the management and approval of variation procedures.

Also, several workshops were held by MS experts in Chisinau. The BC experts were trained on the classification of medical devices, on qualification and classification for IVDMD and medical devices, as well as on pricing, reimbursement and central procurement of medicinal products and medical devices.

Furthermore, the elaboration of the draft SOPs for the MMDA as well as Analysis of Moldovan legislation on advertising of medicinal products and control procedures including recommendations and action plan for improvement were started.

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



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