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Chisinau, 12 October 2017

### **The Third 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 12th October 2017, the third 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 for reviewing the progress made under the project.

The event was chaired by Mr. Vladislav Zara, the General Director of the Medicines and Medical Devices Agency of the Republic of Moldova (MMDA), who welcomed the participants of the Steering Committee meeting and highlighted the importance of the ongoing project which offers a great support to the employees of the MMDA.

Mr. Dumitru Saghin, Beneficiary Country Project Leader and the Vice Director of the MMDA mentioned that the EU-funded Twinning project helped the MMDA to have access to some of the most important institutions in the field of medicines and medical devices, namely the European Directorate for the Quality of Medicines (EDQM) and the European Medicines Agency. He expressed his gratitude for the organized trainings which offered a great support in strengthening the capacities of the MMDA employees.

Mr. Gintautas Barcys, Member State Project Leader and the Director of the State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania as well as Ms. Magdalena Pajewska-Lewandowska on behalf of Dr. Grzegorz Cessak, Junior Project Leader and the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products of the Republic of Poland highlighted the fruitful cooperation and commitment among the Project partners.

Mr. Dumitru Parfentiev, General Director of the National Health Insurance Fund of the Republic of Moldova thanked for involving the experts from the institution that he is leading in the EU-funded Twinning activities, mentioning that the experience shared by the short term experts from the Member States was very useful for the implementation of reforms in the field of reimbursement of medicines.

The Resident Twinning Adviser Ms. Anželika Oraitė presented the most important information regarding the third quarter of the Project, which is: 5 activities, with the



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involvement of 12 short-term experts from Lithuania and Poland in 33 working days mission and attended by more than 60 experts from the Beneficiary Country.

During the third quarter short-term experts from Lithuania provided consultations and recommendations in respect of the pricing and reimbursement 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 will be elaborated during the next quarter of the Project.

In addition, the review of the Moldovan legislation as well as legal gap and inconsistency with the *EU acquis* analysis in respect of medicinal products regulation in the Republic of Moldova was performed.

Furthermore, 2 Standard Operating Procedures in respect of marketing authorization of medical products following the best EU procedural practice and the ISO standards were created.

Also, the assistance to the MMDA in preparation and amendment of the national legislation, medicines quality control documents and procedures for getting status of the Official Medicines Control Laboratory certified by the EDQM was provided. To this respect more than 20 documents were drafted or updated.



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