06/21/2018 Events

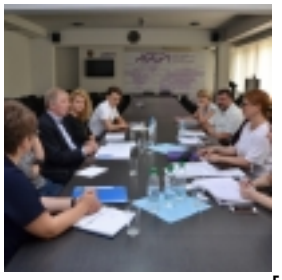
AGEPI Director General Lilia Bolocan today met with representatives of the World Health Organization (WHO) and EU Twinning Project “Strengthening of the Medicines and Medical Devices Agency as Regulatory Agency in the Field of Medicines, Medical Devices and Pharmaceutical Activity”.

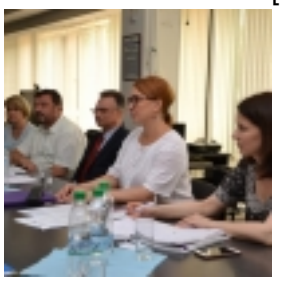
During the meeting were discussed recent amendments to the National Law on the Protection and Ensuring of the Confidentiality of Data in the Process of Registration, Testing and Approval Pharmaceutical, Agrochemical and Phytosanitary Products. Through the new amendments is instituted a new mechanism for the protection of data on the testing of pharmaceutical products for a fixed period of time. Thus, the innovatory company registering such a product will have the sole right to test data and the state authority empowered to authorize the product will refuse to authorize generic medicines or identical chemicals in the protection period without the consent of the authorization holder.

As a measure to provide the internal market with medicinal products, from 1 January 2020, holders of the original medicinal products for which marketing authorization is requested will benefit from a 5-year test data protection period and an additional 2-year market exclusivity period. In this way, producers of new/innovative medicines are stimulated to enter the Moldovan market as soon as possible in order to benefit from this system.

Also, during the meeting was brought up for discussion the subject regarding the draft Law amending and supplementing the Law No. 50-XVI of 07.03.2008 on the Protection of Inventions, developed by AGEPI, for the effective application of the flexibility offered by the TRIPS Agreement, especially those related to the procedure for grant of compulsory licenses. Thus, according to the proposed amendments, the compulsory license will be granted not only by the court but also by the competent authority designated by the Government, in case of exceptional situations. This amendment was welcomed by WHO representatives.

At the end of the meeting, the AGEPI General Director confirmed the opening of the Agency to cooperation in the implementation of reforms in the healthcare system of the Republic of Moldova.


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