

April 11, 2018

LEGAL ALERT

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## UKRAINE'S NEW ACTION PLAN ON IMPLEMENTATION OF EU-UA ASSOCIATION AGREEMENT: HEALTHCARE HIGHLIGHTS

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On March 17, 2018 new Governmental Action Plan On Implementation of the EU-Ukraine Association Agreement became effective.

The plan contains ambitious goals on harmonization of the Ukrainian legislation with its European counterpart: almost 2,000 tasks in such diverse spheres as public procurement, labor, agriculture, entrepreneurship, **healthcare**, consumer protection, trade, energy efficiency, etc.

Below we briefly look through the Action Plan tasks concerning **healthcare**.

### (1) GDPR

Ukraine has officially declared its intention to update data protection legislation in line with the EU GDPR. The Government set **May 25, 2018** as its own very ambitious deadline for aligning. Since it is up to the Parliament to finally decide on amendments to the legislation, this deadline does not practically mean actual implementation of the amendments, but rather the Government's commitment to make it possible, provided the Parliament cooperates. While the deadline seems pretty unrealistic, the Government's intention sends a clear message that the Ukrainian data protection legislation will be harmonized with the EU law relatively soon.

### (2) Healthcare Funding Reform

Ukraine reaffirms its intent to reform the Ukrainian healthcare financing system (as laid down in the recently adopted laws launching the healthcare reform in Ukraine) by the end of 2020. So far the Government demonstrated visible progress in implementing the reform with the leading role of the Ministry of Health.

The reform is a far-reaching endeavor, with the goal of achieving a transparent and efficient healthcare financing through introducing the state guaranteed healthcare benefits package and funding of healthcare services providers (both public and private) under the "money follows the patient" principle. The reform also involves further

extension of medicines reimbursement programs and full-scale implementation of e-health.

The healthcare funding reform is to be implemented gradually. Transformation of the primary care has already been launched in 2018, with next levels to follow in subsequent years.

### **(3) Registration and Circulation of Medicines**

Ukraine plans to adapt the Ukrainian legislation on registration and circulation of medicines to the relevant EU laws, with the task of adopting a relevant roadmap being the introductory step in this direction.

Sponsored by EBRD assessment report on conformity of the state registration of medicines in Ukraine with the EU law as of end 2016 may be found [here](#). We were happy to significantly contribute to drafting of the report in question. Currently a lot of work is being done, with support of business associations and experts in the field (also from the EU), to develop amendments to the legislation on registration procedures, quality, GxP, clinical trials, in order to help the Government with the harmonization efforts. We are actively engaged in these activities and would be happy to share further updates.

### **(4) Intellectual Property (incl. data exclusivity)**

Ukraine has declared its intent to adopt the EU model of **protection of regulatory data** by **December 31, 2023**. Since amendments adopted back in 2011, Ukraine offers R&D pharma only 5+1 years of market exclusivity, without any specific incentives covering pediatric indications and orphan medicines. These provisions are going to be revised within the next few years.

Ukraine also plans to harmonize legal terminology in the area of protecting rights to **inventions and utility models** by the same date.

### **(5) Other Healthcare Goals**

Among other important tasks, Ukraine also:

- confirmed its intention to implement the **Strategic Concept of Public Health** (already adopted in 2016) by October 31, 2024;
- undertook quite a number of tasks in the areas of **transplantation of human tissues and cells and blood donation**, e. g. harmonizing relevant licensing conditions and procedures, determining a state body/-ies responsible for quality and safety of human cells, tissues transplantation and blood donation, ensuring effective state monitoring, ensuring traceability of cells/tissues/blood, strengthening sanctions for violating relevant legislation, etc.;

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- declared intent to introduce **comprehensive approach to cancer diagnostics** in line with best practices of EU member states;
- undertook to bring its **GMO legislation** in line with the EU laws by December 31, 2019.

We will carefully monitor the developments in the harmonization of healthcare-related regulations with the EU laws and will update you in case of any news.

If you have any questions, please contact:

**Borys Danevych**

Partner

[borys.danevych@marchenkodanevych.com](mailto:borys.danevych@marchenkodanevych.com)

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