



MINISTRY
OF HEALTH
OF UKRAINE

MEDICINE
HEALTH
TREATMENT
DOCTOR
SURVEY
RECIPE

STATUS OF THE IMPLEMENTATION OF EU INTEGRATION COMMITMENTS AND BENCHMARKS

Ms. Maryna SLOBODNICHENKO

Deputy Minister of Health of Ukraine for European Integration



CLOSING BENCHMARKS FOR EU ACCESSION

European Commission working documents setting out the mandatory EU acquis to be aligned with and the requirements for institutional and administrative capacity.



NATIONAL PROGRAMME FOR THE ALIGNMENT WITH THE EU ACQUIS

Resolution of the Cabinet of Ministers of Ukraine No. 438 of 1 April 2026 "On Approval of the National Programme for the Alignment of Ukrainian Legislation with the Law of the European Union (EU acquis)."

BM 28.2

Ukraine will achieve a **high level of alignment** with the EU acquis and international obligations in the field of **tobacco control**.

BM 28.3

Ukraine will align its legislation in the following areas:

- cross-border healthcare;
- substances of human origin (SoHO) and organs;
- human and veterinary medicinal products;
- cosmetic products;
- medical devices;
- public health.

- ensure adequate **administrative capacity**, integrity, and a sustainable regulatory and supervisory system;
- **ensure implementation of the EU acquis** with a view to achieving full compliance by the date of accession to the European Union.



CHAPTER 28 "CONSUMER AND HEALTH PROTECTION"



ONGOING COMPLETED

71

TOTAL TASKS FOR THE MOH

39

% COMPLETION OF THE 2026 PLANNED TASKS



MEDICAL DEVICES

Technical Regulation on Medical Devices adopted

- **CMU Resolution No. 759 of 10 June 2026**

Technical Regulation on In Vitro Diagnostic Medical Devices adopted

- **CMU Resolution No. 758 of 10 June 2026**



COSMETICAL PRODUCTS

Amendments to the Technical Regulation on Cosmetic Products adopted

- **CMU Resolution No. 737 of 4 June 2026**

European Commission confirmed a **high level of alignment** with the EU acquis in the field of cosmetics.



MEDICINAL PRODUCTS

Procedure for conducting clinical trials established

- **MOH Order No. 184 of 16 February 2026**

Procedure for Health Technology Assessment (HTA) established

- **CMU Resolution No. 358 of 25 March 2026**



SoHO



A Roadmap for the Implementation of Regulation (EU) 2024/1938 on Substances of Human Origin (SoHO) Has Been Adopted.

- **Ministry of Health of Ukraine Order No. 857 of 23 June 2026**



PUBLIC HEALTH



The Procedure for epidemiological surveillance and the procedure for conducting epidemiological investigations of epidemics have been approved.

- **Cabinet of Ministers of Ukraine Resolution No. 505 of 22 April 2026**



CROSS-BORDER HEALTHCARE



The Roadmap on Patients' Rights in Cross-Border Healthcare has been approved.

- **Ministry of Health of Ukraine Order No. 1372 of 1 September 2025**

Draft Law on the Cross-Border Provision of Healthcare Services Developed and Submitted to the Government

ESTABLISHMENT OF THE UKRAINIAN PHARMACEUTICAL AGENCY



The Ukrainian Pharmaceutical Agency Has Been Established

- **Cabinet of Ministers of Ukraine Resolution No. 739 of 4 June 2026**
- **Current Stage – Selection of the Head**

A Twinning Project to Establish a National Regulatory Authority for Medicinal Products and Medical Devices Is Under Implementation.

PROFESSIONAL TRAINING



- Training of 20 Pharmaceutical Professionals at **Uppsala University**



- Training of 12 Specialists in the Field of Substances of Human Origin (SoHO)
- Development of Laboratory Control and the Quality Management System

TAIEX



- ✓ Medical Devices



- ✓ Cosmetic Products



Planned TAIEX Projects on

- Cross-Border Healthcare



- Training for Notified Bodies



- Assessment of Marketing Authorisation Dossiers for Medicinal Products





TOBACCO CONTROL

Launch of the e-Excise traceability system	November 2026	ONGOING Consultations with the EU with the participation of the Ministry of Health and the Ministry of Digital Transformation
Adoption of the Law of Ukraine on the Ratification of the WHO Protocol to Eliminate Illicit Trade in Tobacco Products	December 2026	ONGOING Submission to the Ministry of Foreign Affairs is planned
Adoption of the Law on Amendments to Certain Laws of Ukraine on the Prohibition of the Visible Display of Tobacco Products and Other Products in Retail Stores	December 2027	ONGOING Registered in the Verkhovna Rada (Registration No. 12091 dated 04.10.2024)



CROSS-BORDER HEALTHCARE

Adoption of the Law of Ukraine “On Amendments to Certain Legislative Acts of Ukraine Regarding Cross-Border Medical Services”

December 2026

ONGOING
Submitted to the Cabinet of Ministers of Ukraine

MEDICINAL PRODUCTS

Selection for the Head of the Ukrainian Pharmaceutical Agency

October 2027

ONGOING

Continuation of the implementation of the Twinning project on establishing the State Control Authority for medicinal products and medical devices

July 2027

ONGOING
Being implemented according to the plan



SoHO

Adoption of the Law of Ukraine “On Amendments to Certain Laws of Ukraine Regarding Safety and Quality Standards of Substances of Human Origin”	December 2027	ONGOING Under approval in MoH
Support and adoption of the Law of Ukraine on Amendments to Certain Legislative Acts of Ukraine Regarding Strengthening Liability for Violations of Legislation in the Field of Blood Donation and Blood Components	December 2027	ONGOING Registered in the Verkhovna Rada (Registration No. 13630 dated 15.08.2025)



ORGAN TRANSPLANTATION

Approval of the Procedure for Reviewing Information on Serious Adverse Events, Serious Adverse Reactions, and Suspicions of Such Events or Reactions in the Field of Organ Transplantation	December 2027	ONGOING Being developed at the MoH
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CROSS-BORDER THREATS

Approval of the list of border crossing points in Ukraine that comply with the requirements of Section B of Annex 1 to the International Health Regulations	December 2026	ONGOING Strengthening bilateral cooperation with Romania and Moldova on joint border crossing points
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OTHER BENCHMARKS OF THE MINISTRY OF HEALTH



**CHAPTER 1:
PRECURSORS**



**CHAPTER 1:
GOOD LABORATORY
PRACTICE (GLP)**



**CHAPTER 1:
TRANSPARENCY OF
PRICING**



**CHAPTER 3:
EDUCATION AND
ALIGNMENT OF
TRAINING
PROGRAMMES**

ROADMAP FOR THE IMPLEMENTATION OF THE NPAA



MINISTRY
OF HEALTH
OF UKRAINE



World Health
Organization



LIST OF TASKS



**MONITORING
INDICATORS**



**TECHNICAL
ASSISTANCE
NEEDS**



**CHALLENGES
AND RISKS**

**PRESENTATION OF THE ROADMAP TO INTERNATIONAL PARTNERS
SEPTEMBER 2026**