LIFE SCIENCES & HEALTHCARE IN UKRAINE

2017 in Review

KINSTELLAR

January 2018

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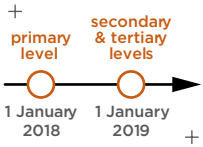
CONTENTS

HEALTHCARE REFORM

Reform of the healthcare financing system

INSTITUTIONAL CHANGES

Establishment of the National Healthcare Service of Ukraine (the "Service").



STATE GUARANTIES

Programme of state guaranties of medical treatment for the public. The list and scope of healthcare services, devices and medicinal products to be financed from the state budget and provided to patients free of charge will be adopted annually as part of the state budget.

E-HEALTH

Collection and automatisation of processing medical and financial data on healthcare services provided to the public.

AGREEMENT

Payment for healthcare services provided to patients in accordance with agreements between healthcare providers and the Service (effective from 2019).

FINANCING

Change in the model of financing the healthcare system to the "money follows the patient" principle: payment to healthcare providers for healthcare services is to be based on unified tariffs.

FREE CHOICE

The patient's right to choose a doctor.

E-Health: test mode

Collection and automatisation of processing medical and financial data on healthcare services provided to the public

FINANCING

E-Health allows for the implementation of a new model of financing the healthcare system in Ukraine to the **"money follows the patient"** principle.

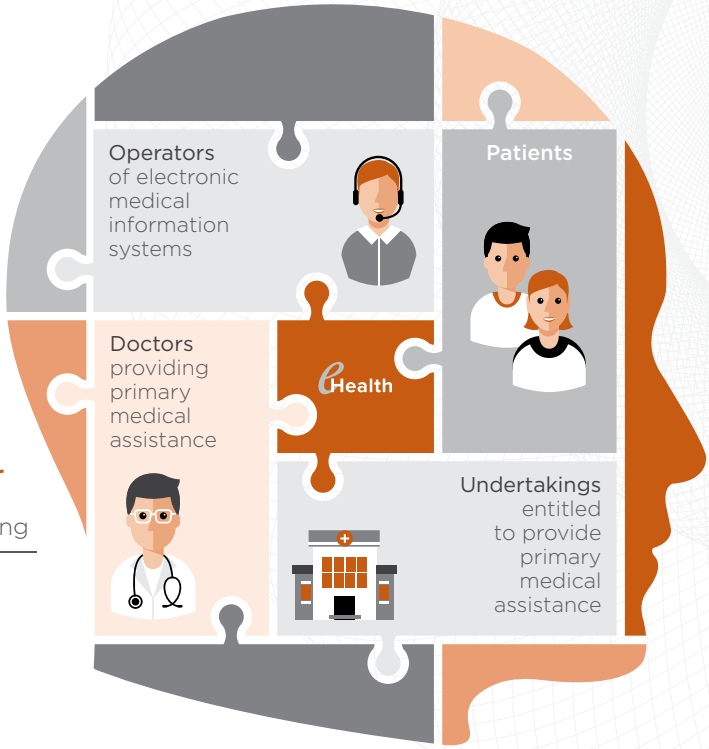
PLANNING

E-Health enables effective planning for the public procurement of healthcare services and medicinal products.

PERSONAL DATA PROTECTION

Access to patient's data subject to patient's consent UNLESS:

- there is a risk of mortality;
- consent cannot be obtained;
- pursuant to court decision.



1-year

E-Health testing

(subject to consent and free of charge)

Participation of the Ministry of Health of Ukraine ("MoH") in E-Health testing is mandatory.
Follow this link to E-Health website.

Reorganisation of state-owned and municipal healthcare providers

REORGANISATION

- State-owned institutions
- State-owned enterprises
- Municipal institutions
- Municipal non-profit enterprises

→ Administrative and financial independence

NB! Private healthcare providers are not limited in their choice of legal and organisational form. The privatisation of state-owned and municipal healthcare providers is not allowed.

SUPERVISION

Establishment of supervisory boards in state-owned and municipal healthcare providers.

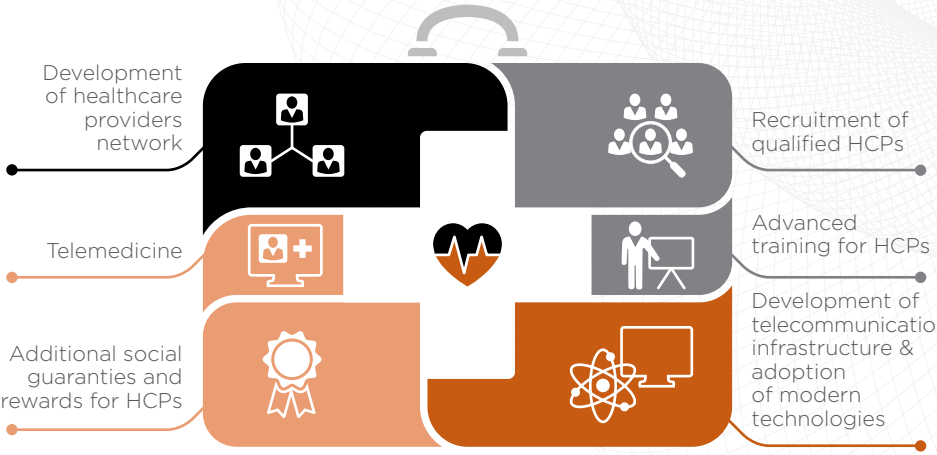
TRANSPARENCY

Transparent and competitive selection and appointment of heads of state-owned and municipal healthcare providers.

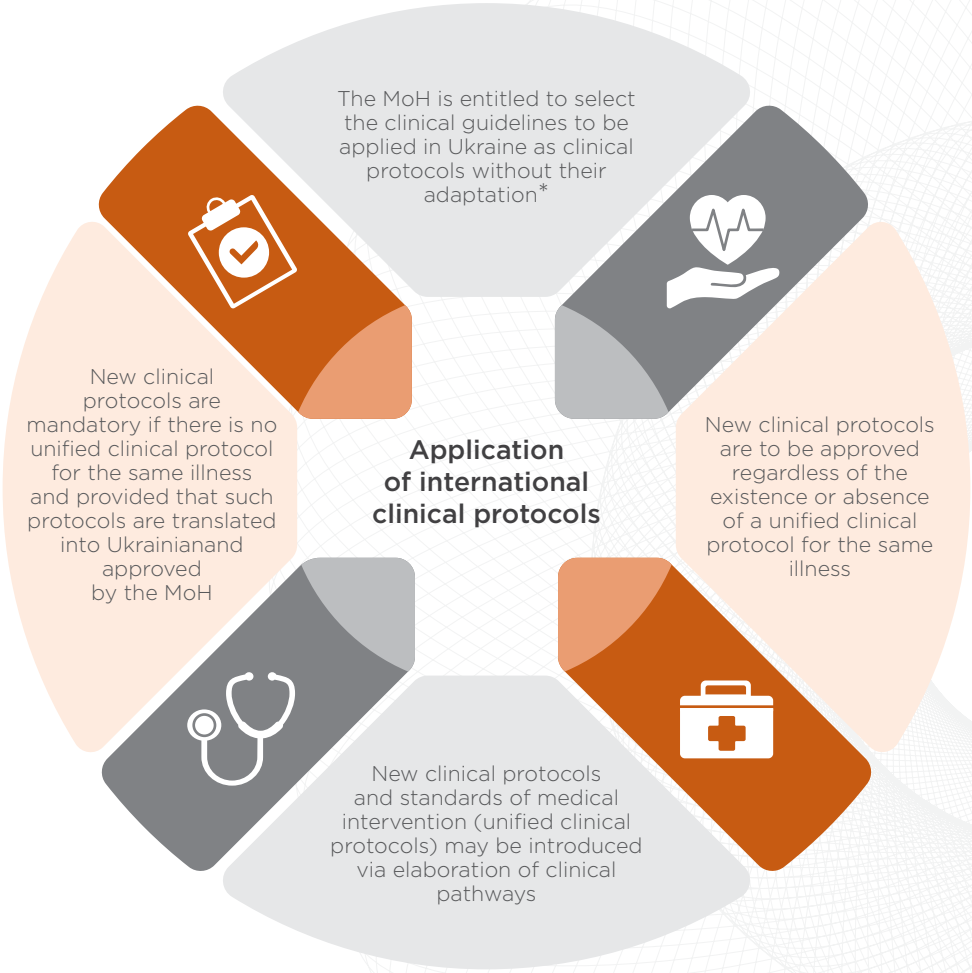
FINANCING

Healthcare services should be provided to the public under agreements between the administrators of public funds and healthcare providers. Healthcare providers may provide healthcare services beyond the scope of the above-mentioned agreements based on separate fees (effective from 1 January 2018).

Development of rural medicine



International clinical protocols & introduction of evidence-based medicine



* The approved MoH list of clinical guideline sources is available here (in Ukrainian only).

Application of new clinical protocols

1 If a new clinical protocol and a unified clinical protocol exist concurrently for the same illness

- the new clinical protocol may be applied subject to the patient's consent* and doctor's clarification as to the difference between concurrent protocols;
- the application of a new clinical protocol excludes the application of the unified clinical protocol.

2 If there are, concurrently, new clinical protocols for the same illness

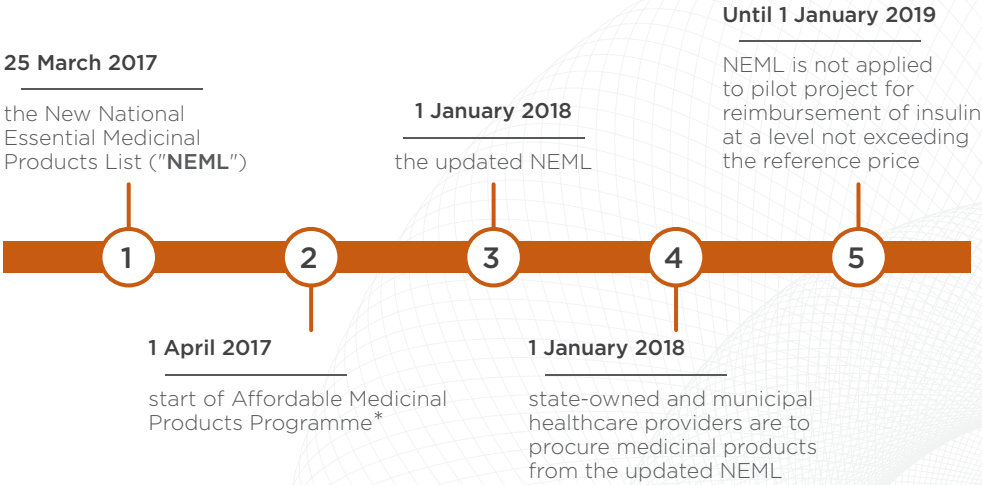
- the doctor shall choose one of the concurrent clinical protocols;
- the doctor shall notify the patient of his / her decision.

3 If full compliance with a new clinical protocol is impossible due to the unavailability of certain medicinal products, medical devices, etc.

- the doctor shall notify the patient of healthcare institutions that can provide healthcare services in full compliance with the new clinical protocol;
- the doctor shall prescribe available generics / analogous medical devices / technologies (subject to the prior consent of patient);
- the doctor shall notify the healthcare department at the local state authorities of any inability to fully comply with the new clinical protocol.

* The approved MoH form of consent is available here (in Ukrainian only).

REFERENCE PRICING & REIMBURSEMENT



* Reimbursement of medicinal products for cardiovascular diseases, type II diabetes and bronchial asthma.

Updated New National Essential Medicinal Products List

WHO

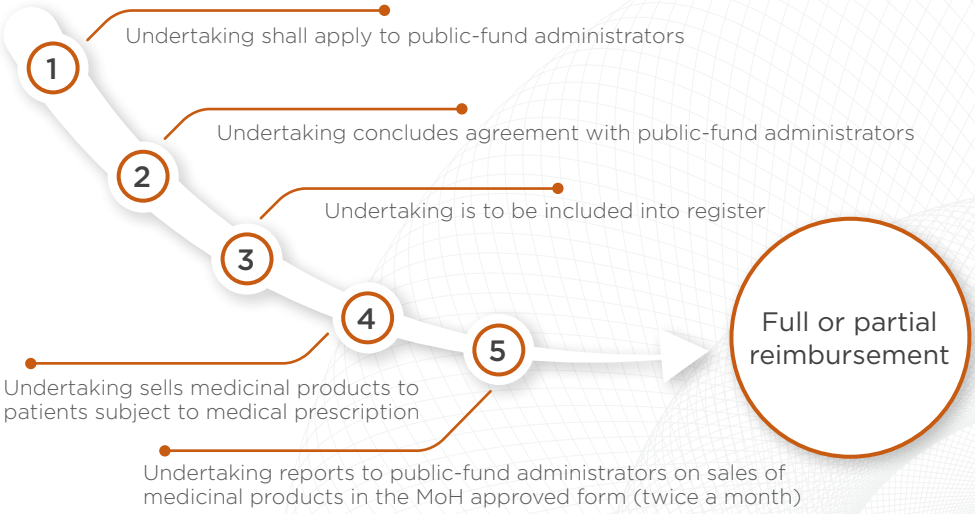
NEML is based on the WHO Model List of Essential Medicines.

Maximum wholesale prices and retail margin for the retail market are to be applied to medicinal products listed on NEML.

NEML is to be applied to public procurement / reimbursement **BUT**

- NEML is not applied to procurement through specialised procurement organisations;
- NEML is not applied to the pilot project for reimbursement of insulins;
- Medicinal products beyond NEML may also be procured if demand requirements are met;
- Resolution No 1303 for a transition period: medicinal products beyond NEML may be procured and reimbursed if such medicinal products are registered in Ukraine and used pursuant to healthcare industry best practices.

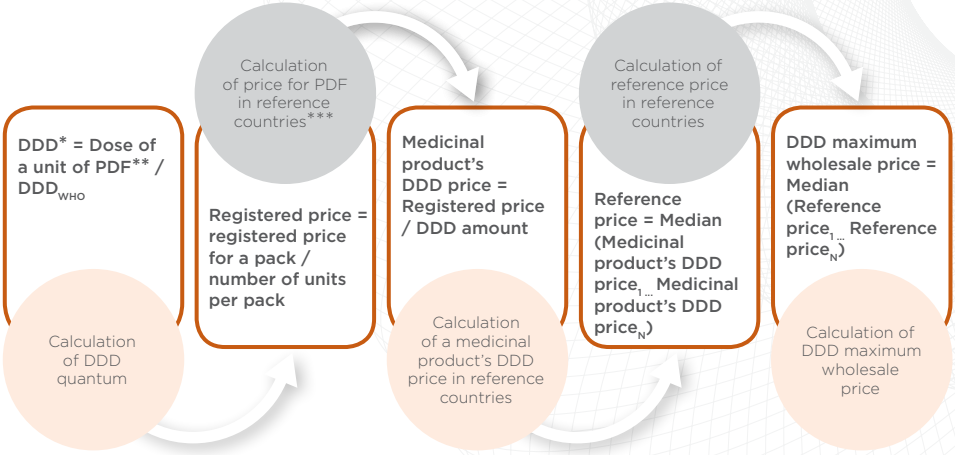
Reimbursement Mechanism



NB! The reimbursable price of a medicinal product shall not exceed the maximum wholesale price approved by the MoH.

The registry of maximum wholesale prices in Ukraine is available here (in Ukrainian only).

Maximum wholesale prices: DDD & external reference pricing



* DDD – is the assumed average maintenance dose per day for a medicinal product used for its main indication in adults.

** PDF – Pharmaceutical Dosage Form.

*** Reference countries – Poland, Hungary, Czech Republic, Latvia and Slovak Republic.

Affordable Medicinal Products Programme

On 1 April 2017, reimbursement of medicinal products for cardiovascular diseases, type II diabets and bronchial asthma started.

198 medicinal products

6,179 pharmacies

UAH 700 million of budgeted funds in 2017

Register of Reimbursable Medicinal Products is being updated

From 100,000 to 200,000 patients monthly

UAH 1 billion of budgeted funds in 2018

UPD! It is expected that starting from 1 January 2018, medicinal products for chronic diseases of the stomach and duodenum, depression and depressive syndromes, prevention and treatment of anaemia in the first trimester of pregnancy are also to be reimbursed.

Public procurement of medicinal products and medical devices

Specialised procurement organisations in 2017

United Nations International Children's Emergency Fund

United Nations Development Programme

Crown Agents Limited

The list of medicinal products and medical devices subject to procurement by international specialised organisation has been extended.

Please follow this link to download the list and amendments to it (in Ukrainian only).

A new concept for the procurement of medicinal products and medical devices has been approved

The procurement organisation will be entitled:

- to procure medicinal products and medical devices at the national, local and international levels
- to provide advisory support to customers
- if there is a need to procure from international suppliers
  - to import medicinal products and medical devices, and
  - involve other organisations for their customs clearance, storage and distribution

FAST-TRACK REGISTRATION OF MEDICINAL PRODUCTS

Fast-track registration of medicinal products already registered in the US, Switzerland, Japan, Australia, Canada, and the EU.

The State Enterprise "State Expert Centre of the Ministry of Health of Ukraine" (the "Centre") reviews registration materials.

Registration within 17 days upon submition of the required registration materials to the Centre.

17 DAYS

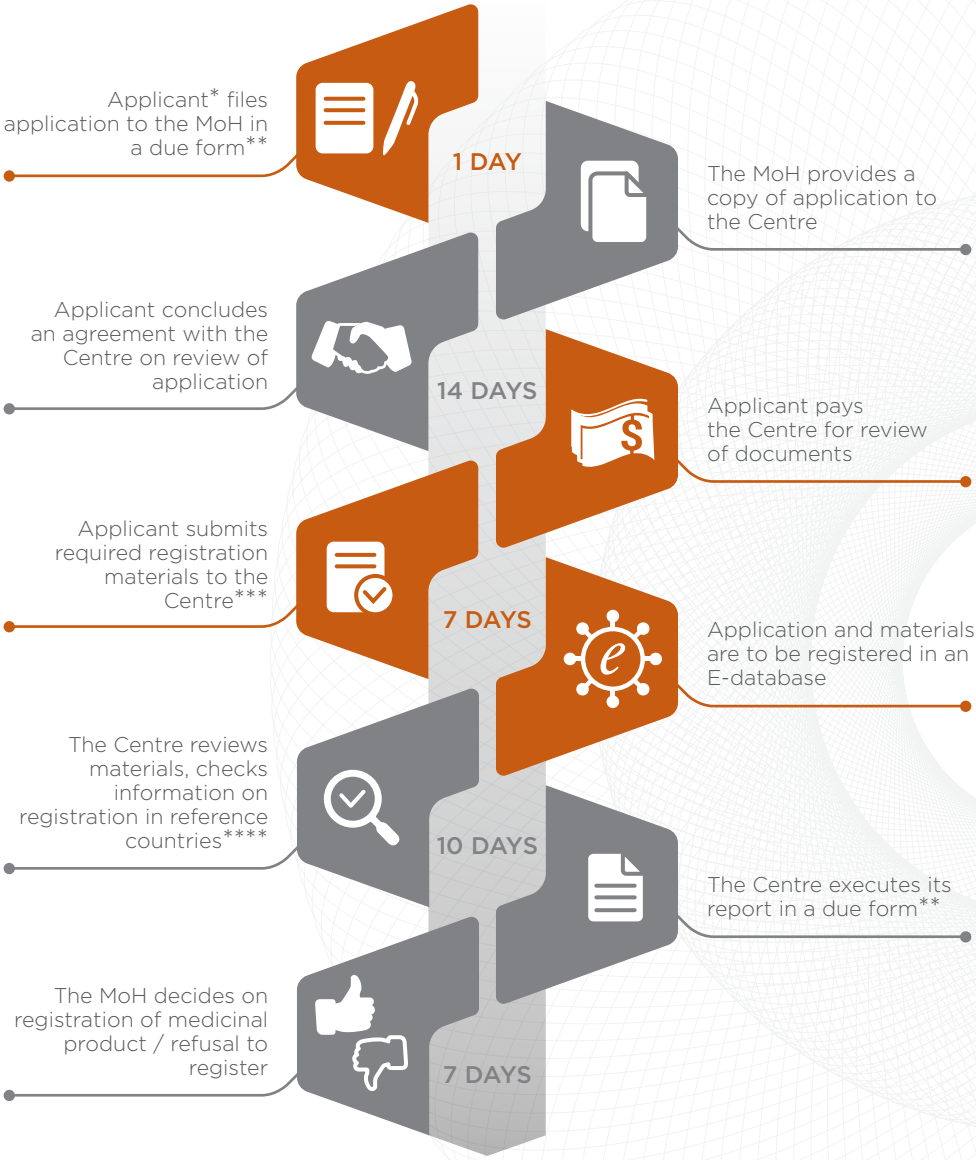
The Centre may request additional documents and information, which the applicant shall provide within 30 days.

Five years after its initial registration a medicinal product shall be re-registered. Thereafter the term for medicinal product trade is not limited, unless the MoH requires additional registration after another five years.

5 YEARS

Certain discrepancies with the reference dossier are acceptable.

Fast-track registration of medicinal products: timeline



* Applicant – owner of the registration certificate and / or its representative.

** The approved MOH form is available here (in Ukrainian only).

*** List of required documents is available here (in Ukrainian only).

**** Websites are available at the following links: U.S. Food and Drug Administration, Swissmedic, PMDA, TGA, Health Canada, European Medicines Agency.

ANTI-CORRUPTION REGULATION

Starting from 1 January 2018, public healthcare institutions are required to disclose information on charitable donations:

quarterly

in a public place at the healthcare institution

on the official website of the healthcare institution and / or website of the authorities controlling the relevant institutions

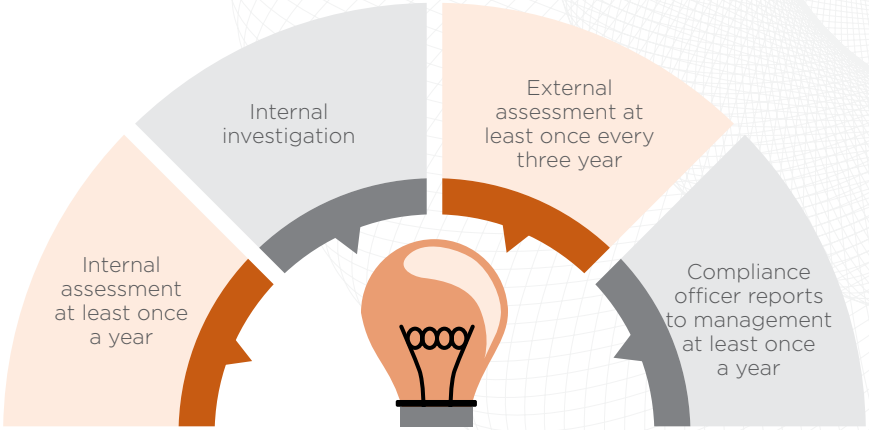
in a form specified by the MoH*

* The approved MoH form is available here (in Ukrainian only).

Certain categories of legal entities are required to put into effect an anti-corruption programme:

Any public / municipal company or business and companies with a state / municipal share of over 50 percent	✓ average number of recorded employees in the referred financial year exceeds 50 ✓ gross revenues derived from sales for such a period exceed UAH 70 million (approximately EUR 2.4 million)
All legal entities (irrespective of the form of their ownership)	✓ engaged in public procurement ✓ cost of procurement exceeds UAH 20 million (approximately EUR 700,000)

The above-mentioned categories of legal entities shall adopt anti-corruption programmes based on the Model Anti-Corruption Programme approved by National Agency on Corruption Prevention.



Detection of corruption risks

Internal and external corruption risks are distinguished in the Model Anti-Corruption Programme.

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