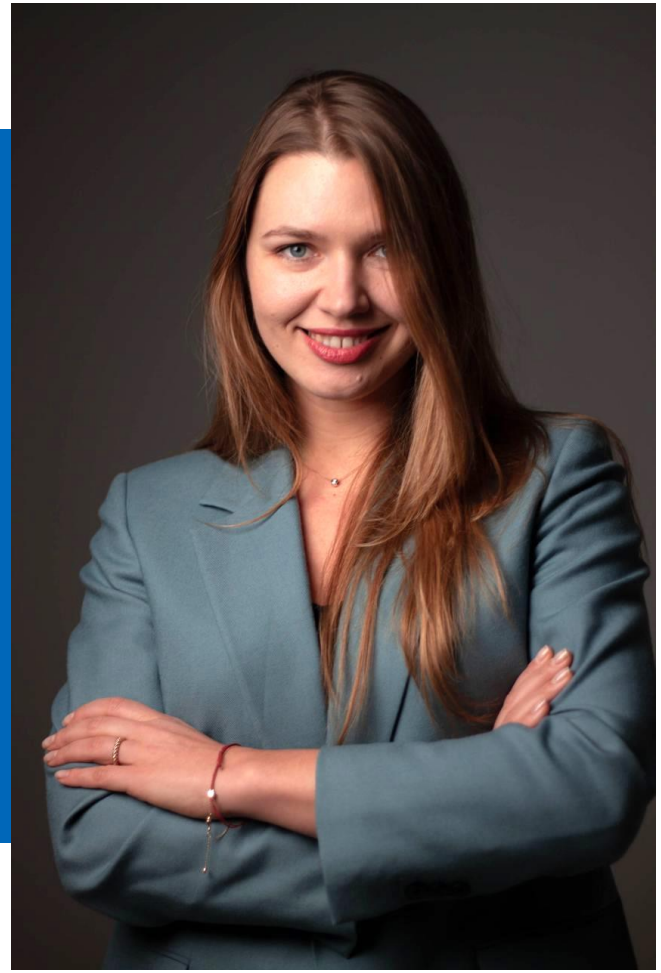
State Expert Center MoH Ukraine

How Do We Facilitate the Implementation of Needed Novel HTA Methodologies in National and EU HTA Practice?

18 November 2024, Barcelona, ISPOR Europe 2024



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ISPOR Ukraine Chapter President

Agenda

- Current HTA landscape in Ukraine
- GAP analysis of methods
- Perspectives for improvement of HTA methods in the nearest future

Overview of HTA tool in Ukraine: legislation, processes and methods

National legal framework for HTA in Ukraine: current state and perspectives

Strategic & legal national framework

2019

Establishment of HTA Department at State Expert Centre of the MOH of Ukraine

2020

- Approval of the Decree by the Cabinet of Ministers of Ukraine №1300 “On the approval of the procedure for the state HTA” dated 23 December 2020, with amendments in 2024 (Decree by the CMU № 494 dated 3 May 2024)
- Temporarily authorized body for HTA is State Expert Centre of the MOH of Ukraine

2021

- Approval of the guideline “State health technology assessment of medicines”, approved by the Order of the Ministry of Health № 593 dated 29 March 2021
- Launch of HTA expertise of submissions for medicines

2023

- Development of project of HTA guideline for medical devices
- Approval of amendments to HTA guideline for medicines (Order of the MOH № 1741 date 6 October 2023

2024

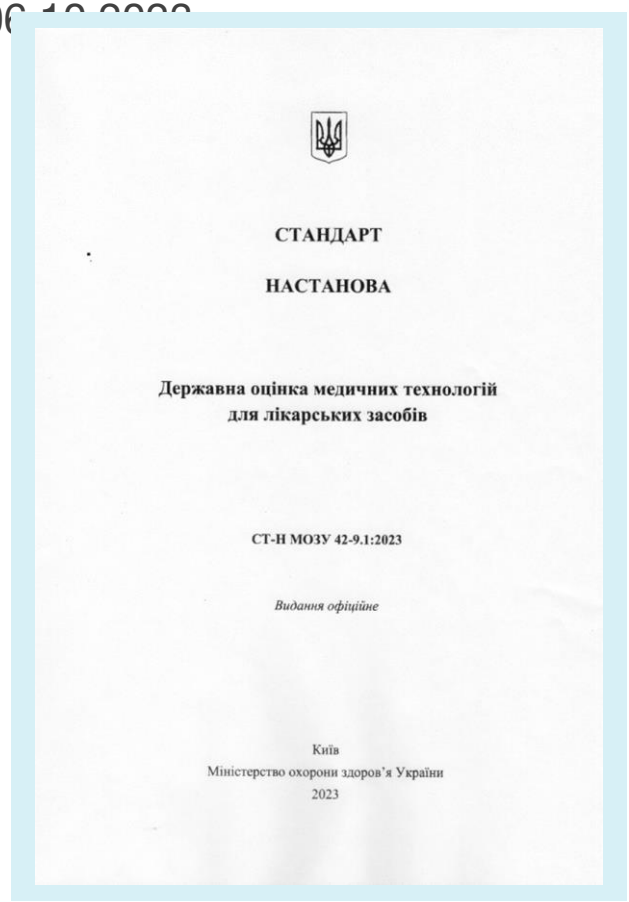
- Introduction of scientific advice before HTA submission
- Establishment of HTA committee for appraisal

Till 1.01.2026

- Establishment of new independent HTA agency (according to the requirements of the CMU Decree №1300)

Updated HTA method guideline for medicines, 2023

For the first time in Ukraine, in pursuance of the Decree Cabinet of Ministers of Ukraine №1300, the guideline “State health technology assessment of medicines” was approved by the Order of the Ministry of Health dated 29.03.2021 № 593, with amendments approved by the Order of MOH № 1741 dated 06.12.2022


СТАНДАРТ

НАСТАНОВА

Державна оцінка медичних технологій
для лікарських засобів

СТ-Н МОЗУ 42-9.1:2023

Видання офіційне

Київ
Міністерство охорони здоров'я України
2023

https://moz.gov.ua/article/ministry-mandates/nakaz-moz-ukraini-vid-29032021--593-pro-zatverdzhennja-nastanovi-z-derzhavnoi-ocinki-medichnih-tehnologij-dlja-likarskih-zasobiv?fbclid=IwAR1whyAuMx-DGHN43ByK4h0XraWKwc3Qh2mmXA6gw0M706KT4Ro9Q3vax8o

Capacity building and improvement of expertise of HTA team

Since 2016 experts of the HTA Department raised and continue to raise the level of their professional skills, knowledge and practical skills by participating in educational programs:

- capacity building for expert committee with Syreon research institute (2016);
- capacity development program with the National Institute for Health Care and Excellence (NICE International) (2023-2024);
- completed project of the USAID "Safe and Affordable Medicines for Ukrainians" (SAFEMed) concerning the application of the horizon scanning tool and core principles of HTA with Radboud University, Netherlands (2023);
- with the Norwegian Institute of Public Health (NIPH) on medical technology demand forecasting for budget impact analysis (2024)
- with Krzysztof Landa, ex-adviser to the Minister of Health of Ukraine, ex-deputy Minister of Health of Poland, expert in the field of health care, evidence-based medicine, HTA for evaluating medical products (2023-2024);
- ISPOR short courses "Introduction to Modeling" and "Pharmacoeconomic Modeling – Applications" (2019);
- ongoing project of the USAID "Safe and Affordable Medicines for Ukrainians" (SAFEMed) regarding HTA for medical devices

syreon Research Institute

ISPOR Improving healthcare decisions

NICE National Institute for Health and Care Excellence

Radboud Universiteit

USAID United States Agency International Development

NIPH Norwegian Institute of Public Health

Results of GAP analysis

Results of GAP analysis: methodological issues to set up a recommendation for cost effectiveness threshold ICER for all medicines/disease specific

Ukraine

Level of cost effectiveness	Indicator of cost effectiveness
Dominant	Less costly, higher benefit
Very cost effective	<1 GDP per capita
Cost effective	1-3 GDP per capita
Not very cost effective	3-5 GDP per capita
Not cost effective	Over 5 GDP per capita

GDP per capita/ Ukraine (2021) = 131 944,00 UAH (3 665 $)

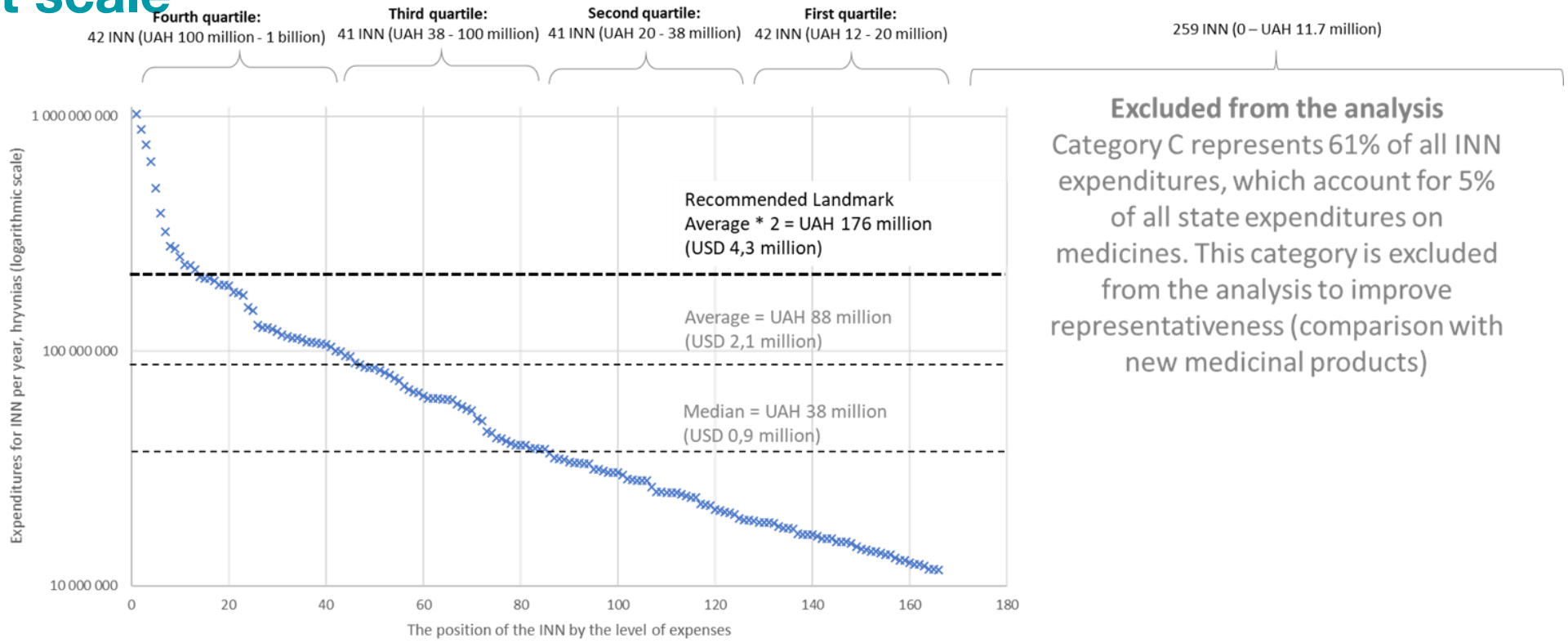
UK, NICE (20 - 30 thousands GBP)

Level of cost effectiveness	Indicator of cost effectiveness
Very cost effective	< 0,6 GDP per capita
Cost effective	0,6-0,9 GDP per capita
Not cost effective	Over 0,9 GDP per capita

GDP per capita UK = 31 422,01 GBP (40 284,64 $)

World Bank national accounts data, and OECD National Accounts data files
current US$ - https://data.worldbank.org/indicator/NY.GDP.PCAP.CD?locations=UA-GB
current LCU - https://data.worldbank.org/indicator/NY.GDP.PCAP.CN?locations=UA-GB

Results of GAP analysis: methodological issues to set up a budget impact scale



insignificant | **moderate** | **average** | **large**

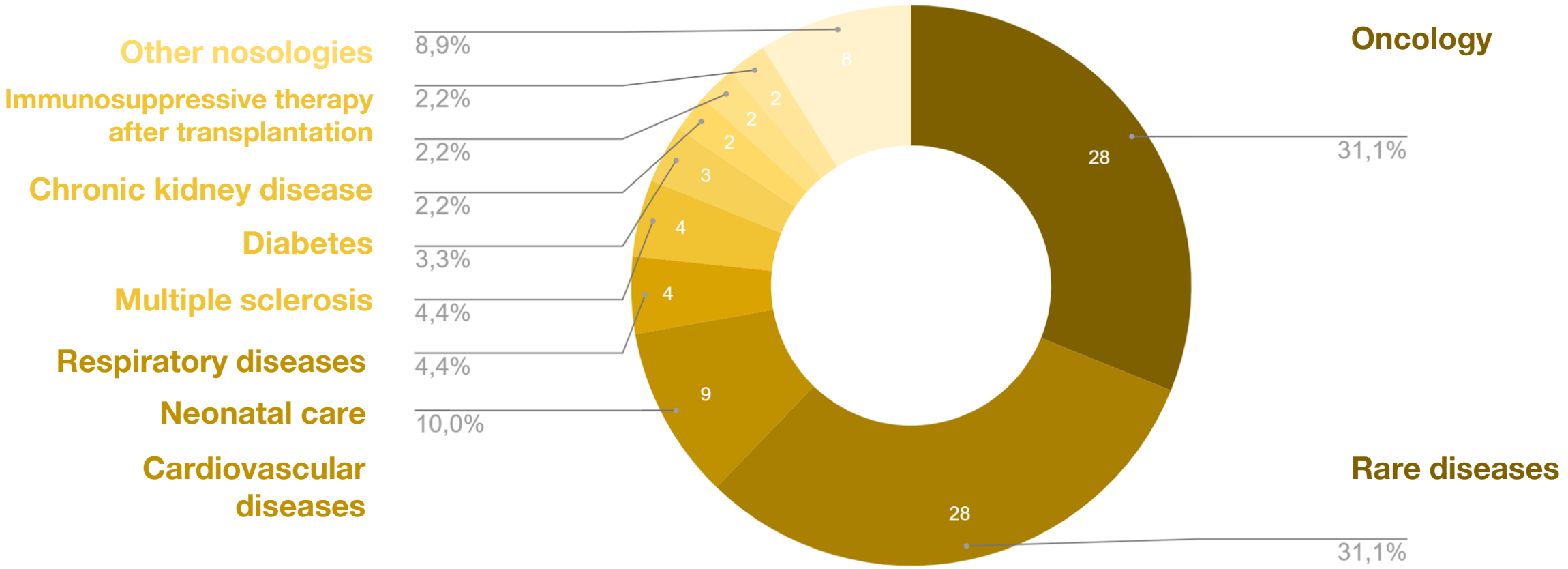
Budget impact scale

UAH 20 million (USD 0,5 million)

UAH 38 million (USD 0,9 million)

UAH 100 million (USD 2,4 million)

Patient centricity results and impact: analysis of HTA recommendations in Ukraine



Managed entry agreements (MEA) introduction in Ukraine

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- 38% recommendations to conduct MEA
- 12 MEA were implemented in 2022-2024

Fabry disease:

-agalsidase beta

Spinal muscular atrophy:

- risdiplam

Pompe disease:

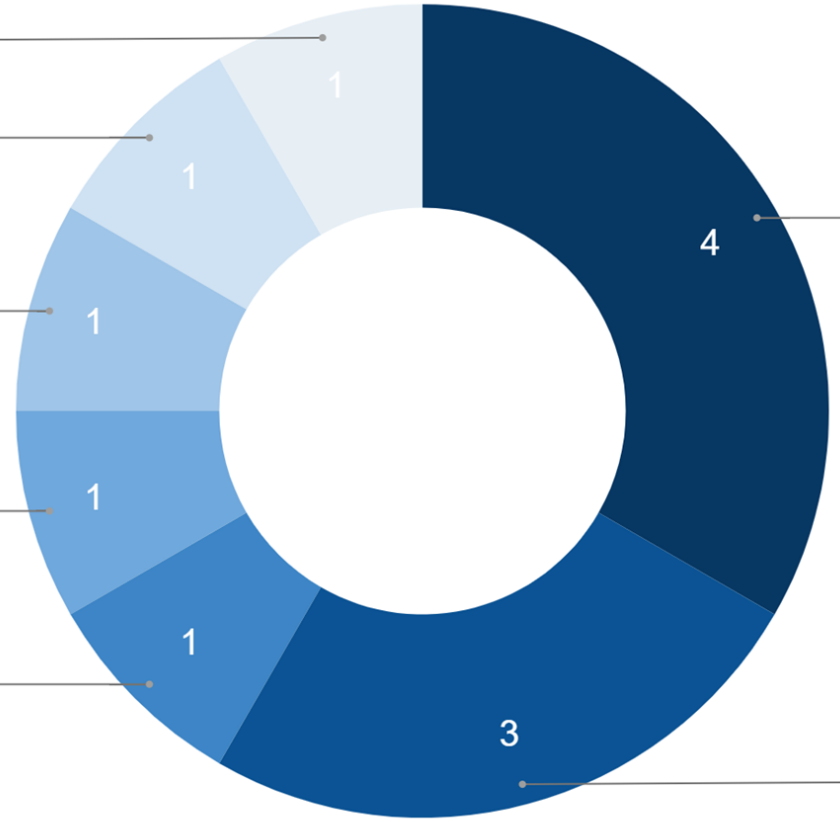
- alglucosidase alfa

Hereditary angioedema:

- plasma-derived C1-esterase inhibitor

Hemophilia:

- factor VIII inhibitor bypassing activity



Mucopolysaccharidosis:

- elosulfase alfa
- galsulfase
- idursulfase
- laronidase

Gaucher disease:

- imiglucerase
- velaglucerase alfa
-taliglucerase

https://www.dec.gov.ua/materials/derzhavna-oczinka-medychnyh-tehnologij-zayavy-ta-dosye/?role=ua
https://www.kmu.gov.ua/news/vpershe-v-ukraini-patsiientam-budut-bezoplatno-dostupni-liky-proty-spinalnoi-miazovoi-atrofii

Perspectives for improvement of HTA methods in the nearest future

Perspectives for new HTA methods?

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- Optimization approaches in HTA
- Setting up of ICER thresholds
- Setting up of BIA scale
- Alternative to naive treatment comparison assessment for single arm trials
- Benchmark to use AI tools (for example search strategies, data extraction)
- Approaches to analyze consistency between RCT and RWD, critical assessment of RWE
- New procedure for all member states of EU for implementation of Regulation (EU) 2021/2282 and conduct JCA for HTA
- Joint economic assessment and modelling, optional?

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