Innovation of HTA Methods. How Can the IHTAM Framework, Developed By HTx Project, Support the Introduction, Development, and Implementation of New HTA Methods in HTA Practice?

Ukraine perspective

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ISPOR Ukraine Chapter President
8 November 2022

UKRAINE COUNTRY PERSPECTIVE

Population	44 134 693 people
GDP per capita	3 724,9 US dollars
Healthcare exp.	7,1% of GDP (248,13 US dollars per capita)
Medicines exp.	56,5% of total household spending on health
Out-of-pocket	51,1% of current health expenditure

https://data.worldbank.org/indicator/SP.POP.TOTL?locations=UA
https://data.worldbank.org/indicator/NY.GDP.PCAP.CD?locations=UA
https://data.worldbank.org/indicator/SH.XPD.CHEX.GD.ZS?locations=UA
https://data.worldbank.org/indicator/SH.XPD.CHEX.PC.CD?locations=UA
https://data.worldbank.org/indicator/SH.XPD.OOPC.CH.ZS?locations=UA
https://www.euro.who.int/__data/assets/pdf_file/0008/381590/ukraine-fp-eng.pdf

Development of HTA Function in Ukraine

START

January – June 2019

- HTA Department established at the State Expert Center of MOH
- HTA Department Director and 29 experts employed at the HTA Dept
- **1st National HTA Forum conducted**
- **HTA Roadmap developed**

July – December 2019

- **HTA Communication strategy developed**
- HTA approach used to select medicines for 4 benefits packages (stroke, MI, childbirth and neonatal care (tariffs calculated))
- HTA approach used for 2020 nomenclature

January – June 2020

- Evidence summaries for Covid19 developed
- HTA Webinar Series - HTA Around the Globe launched

July – December 2020

- Second National HTA Forum conducted
- HTAi Regional Meeting in Ukraine
- Positive List concept developed
- **COMU Decree on state HTA procedure approved**

January – June 2021

- HTA Roadmap V2.0 developed
- Capacity-building activities (HTA Roundtable and HTA Webinar Series 2.0)
- Options analysis for Pricing Strategy in Ukraine
- First expansion of NEML after 2017
- **HTA guidelines published**

July – December 2021

- **2 HTA Roundtables and 7 webinars conducted**
- HTA Orders are drafted
- Conducted a qualitative review of HTA progress
- Model positive list created
- HB HTA webinar conducted
- HTA Agency creation postponed

January – June 2022

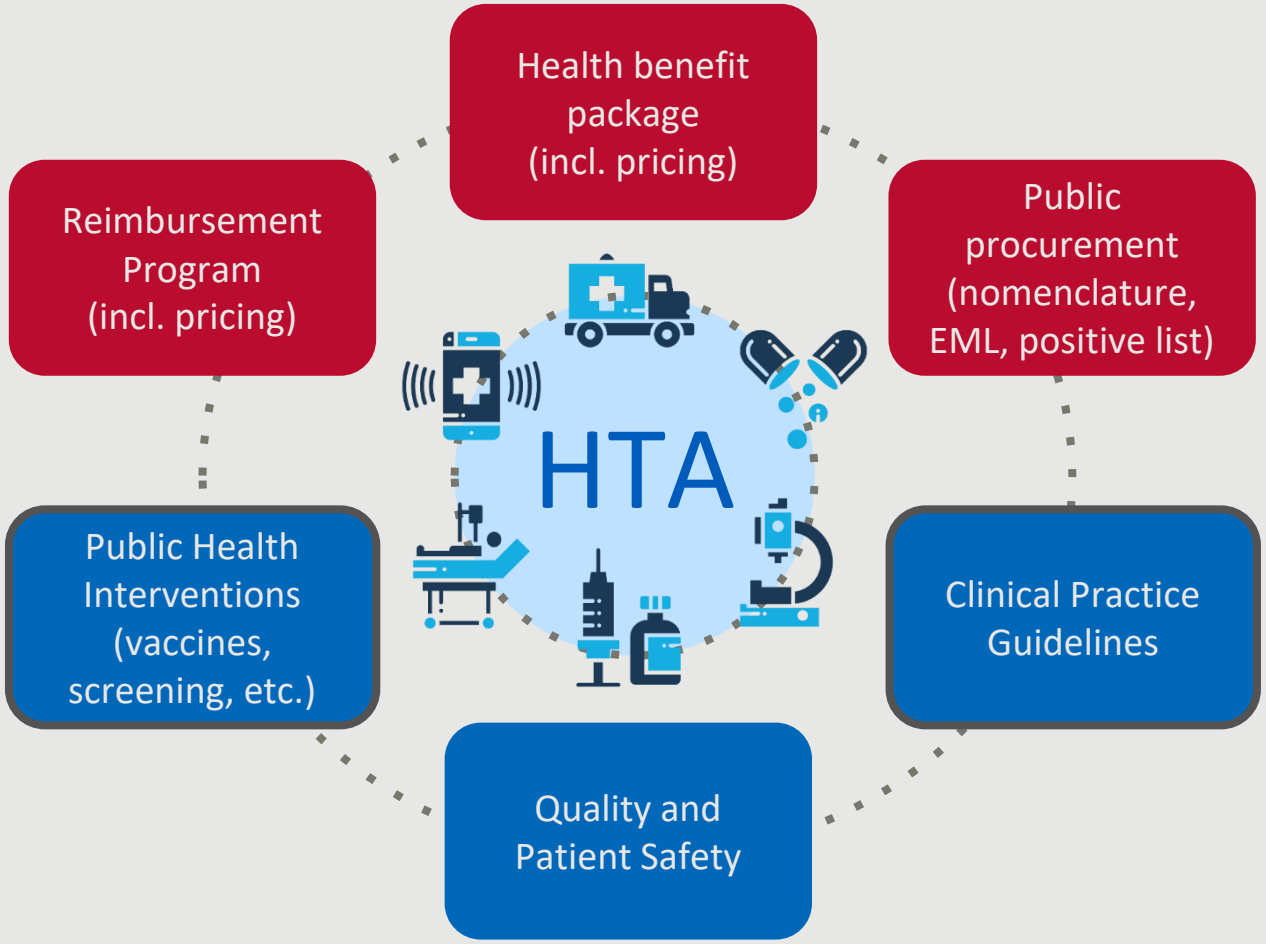
- Conducted situation analysis on the war's impact on the pharmaceutical sector
- HTA orders registered by MoJustice
- NEML updated
- Stakeholder meetings held

July 2022 – present

- HTA orders on MOH Working Group and HTA Expert Committee approved
- First meetings of WG and EC conducted
- Patient Call Center support, biweekly reports started
- HTA comprehensive capacity building program started
- NEML updated
- Legislations for pricing policy on whole NEML drafted

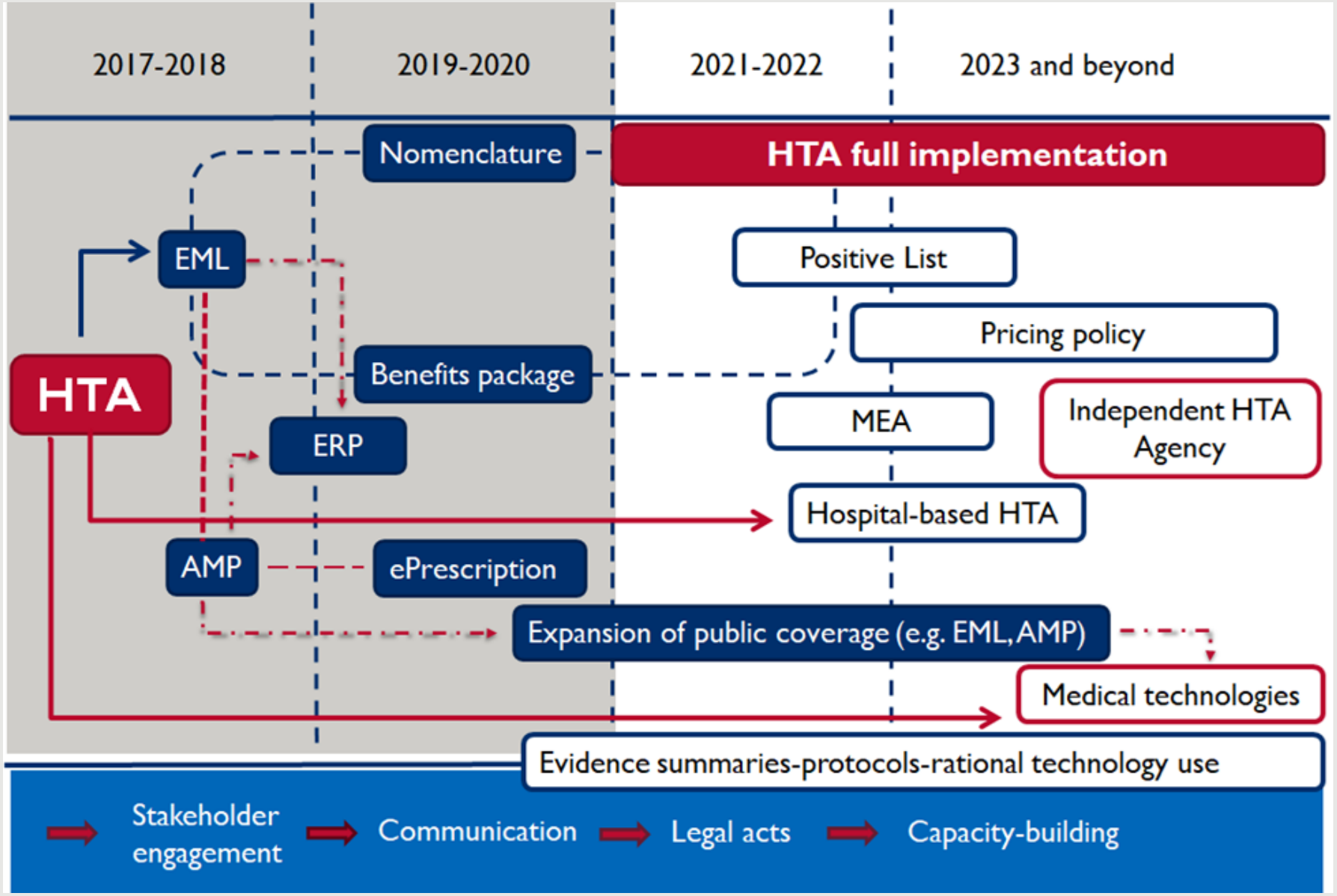
HTA fully legalized and integrated in decision making process by mid-22

Health Technology Assessment in Ukraine



A health technology assessment (HTA) is an evidence-based instrument to identify which medicines, medical devices, and treatment regimens are optimal for the government to support. **It is designed to serve as a key priority-setting tool for Ukraine's health care system.**

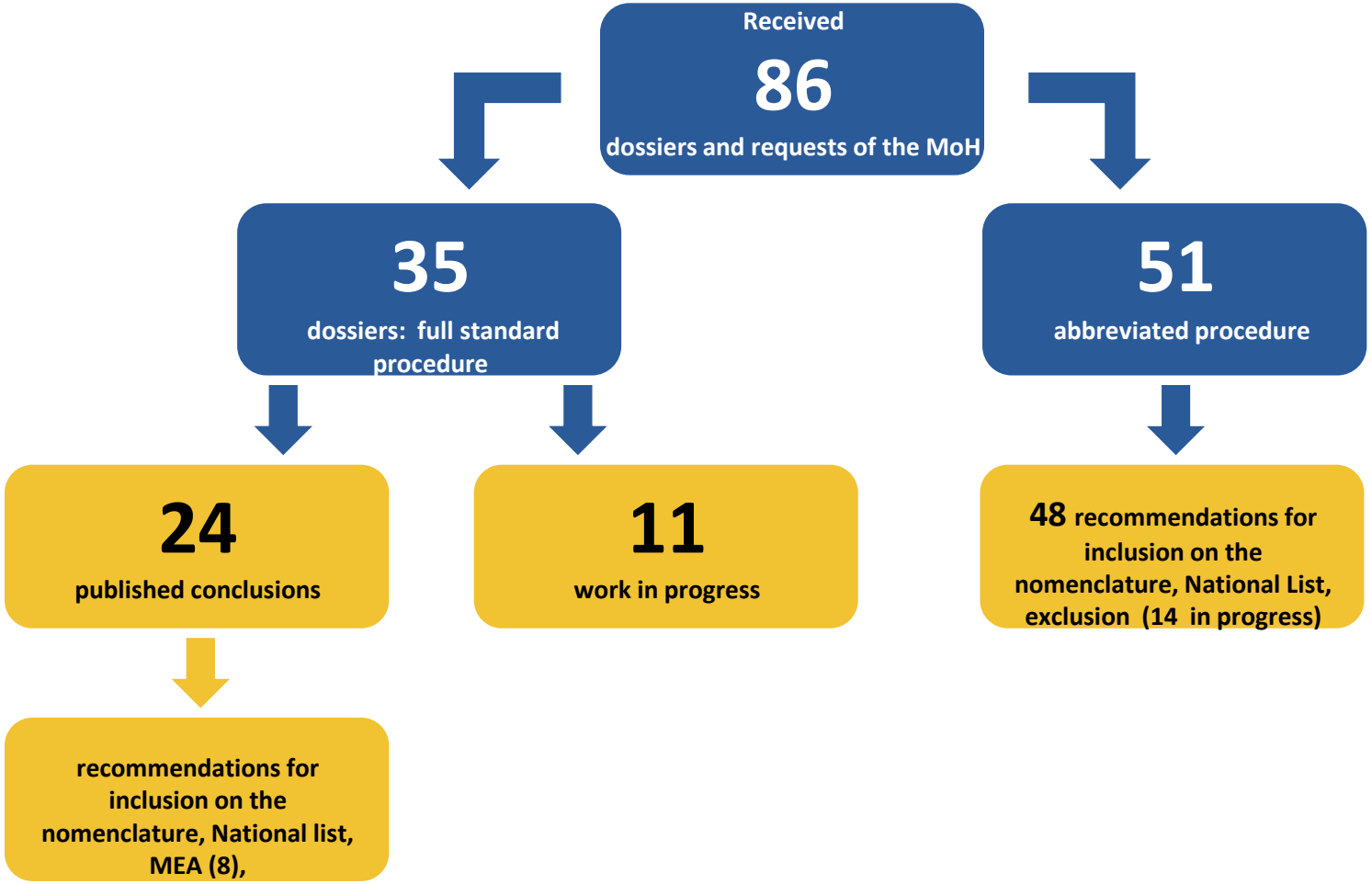
Establishment of HTA in Ukraine: 2017-2023 and beyond



HTA DEPARTMENT IN UKRAINE: RESULTS 2021-2022

72

HTA conclusions with recommendations for the Ministry of Health of Ukraine



https://www.dec.gov.ua/materials/derzhavna-oczinka-medychnyh-tehnologij-zayavy-ta-dosye/

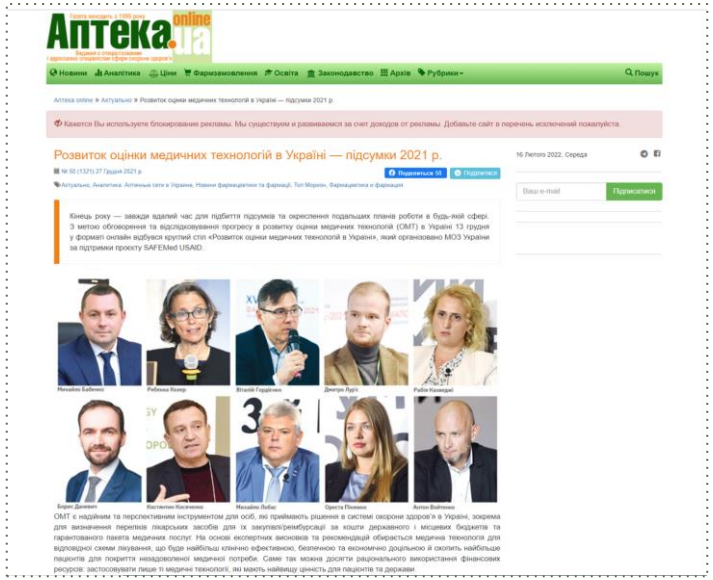
HEALTH TECHNOLOGY ASSESSMENT IN UKRAINE: RESULTS 2021-2022

In November-December 2021, the SAFEMed project conducted a qualitative study on the progress of HTA development in Ukraine in the form of interviews with key stakeholders

According to the survey, **the overall level of satisfaction** with the implementation of HTA in Ukraine

100%

but with some suggestions for improvement



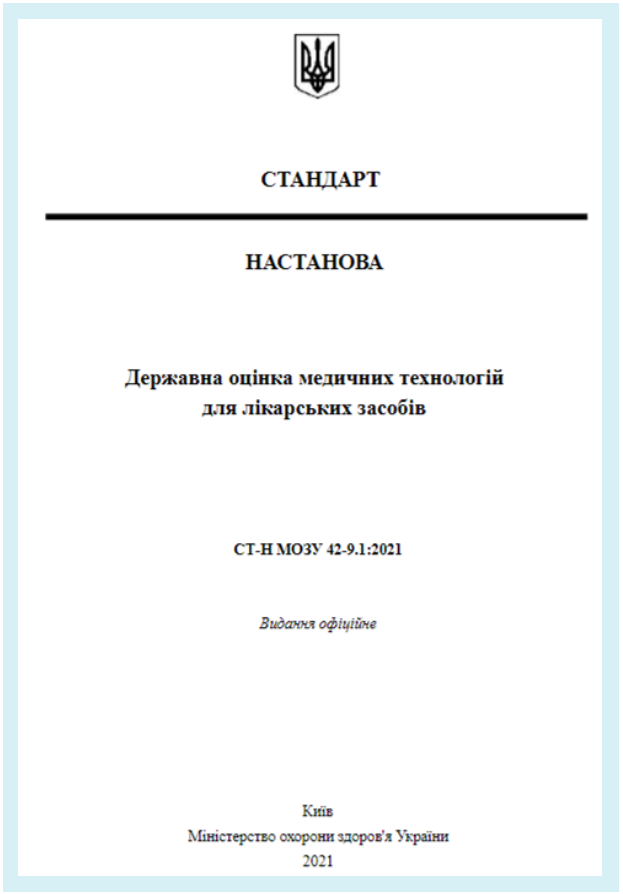
https://www.apteka.ua/article/622737

Respondents:

- applicants (pharmaceutical companies);
- Expert Committee on the Selection and Use of Essential Medicines;
- HTA Department of SEC of Ministry of Health of Ukraine;
- National Health Service of Ukraine (NHSU);
- State Enterprise "Medical Procurement of Ukraine";
- consulting companies.

Case of HTA Guideline development

For the first time in Ukraine, in pursuance of the Resolution of the 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 March 29, 2021 № 593



СТАНДАРТ

НАСТАНОВА

Державна оцінка медичних технологій для лікарських засобів

СТ-Н МОЗУ 42-9.1:2021

Видання офіційне

Київ
Міністерство охорони здоров'я України
2021

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

Launch of HTA trainings by HTA Department in 2021

In order to methodologically support the HTA procedure, the experts of the HTA Department developed and conducted 20 training seminars on the new HTA guidelines including for applicants

International cooperation and joint assessments EUnetHTA

PTJA09

Brolucizumab for the treatment of adults with neovascular (wet) age-related macular degeneration (AMD)

ROLE - OBSERVER

PTJA14

Pretomanid as part of a combination regimen with bedaquiline and linezolid, in adults for the treatment of pulmonary extensively drug resistant (XDR), or treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB)

ROLE - DEDICATED REVIEWER

PTJA15

Remdesivir for the treatment of COVID-19

ROLE - DEDICATED REVIEWER

PTJA16

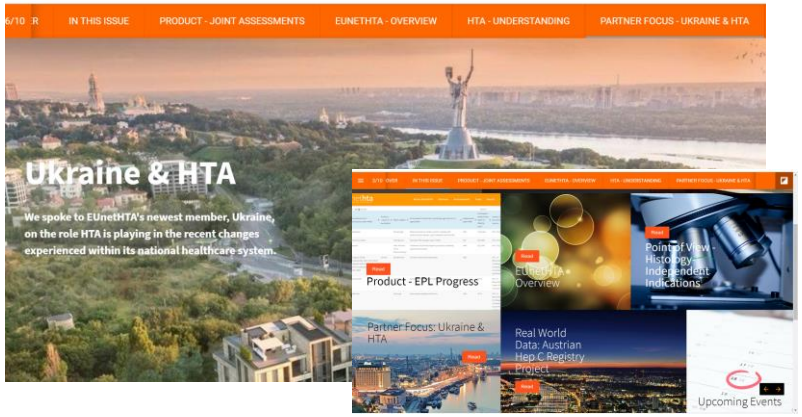
Venetoclax with a hypomethylating agent for the treatment of adult patients with newly-diagnosed acute myeloid leukaemia (AML) who are ineligible for intensive chemotherapy

ROLE - DEDICATED REVIEWER

PTRCR18

Dexamethasone for the treatment of COVID-19.
Rapid Collaborative Review

ROLE - DEDICATED REVIEWER



Case of RWE use in the HTA

RWE IN HTA RECOMMENDATIONS FOR DECISION MAKING: ANALYSIS FROM UKRAINIAN PERSPECTIVE

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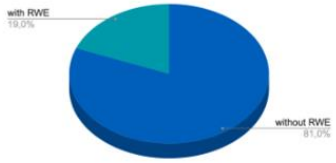
OBJECTIVES

To examine how real world evidence (RWE) is used in HTA recommendations for decision making in the established HTA procedure in Ukraine as the common trend for European HTA organizations is moving towards the wider use of RWE in HTA processes.

METHODS

HTA conclusions with recommendations developed by HTA Department of State Expert Center (SEC) of MOH of Ukraine were analyzed regarding the criteria of RWE use as add on to efficacy data in the recommendations, which are published in open access on the website (https://www.dec.gov.ua/materials/derzhavna-oczinka-medychnyh-tehnologij-zayavy-ta-dosye/).

Figure 1: RWE in HTA recommendations based on manufacturers submissions in Ukraine as of June 2022



Total number of published HTA recommendations based on manufacturers submissions as of June 2022	21
Number of published HTA recommendations based on manufacturers submissions that included RWE as of June 2022	4

RESULTS

Submission of RWE in HTA dossiers is recommended as additional information to the efficacy data as a part of clinical chapter of submission according to HTA Guideline "The state health technology assessment for medicines" by the Order of the MoH of Ukraine №593 dated 29 March, 2021. The HTA Department led to the following main results in 2021-2022 according to the main procedure: 57 dossiers and MoH requests were submitted, of which for 37 HTA conclusions and recommendations were developed. 19% of HTA recommendations based on manufacturers submissions included RWE (Figure 1). RWE was consistent with the results of randomized clinical trials (RCT) of medicines in oncology and the medicines used to prevent cytomegalovirus (CMV) reactivation and disease in CMV-seropositive recipients of allogeneic hematopoietic stem cell transplantation. There were also recommendations to collect real world data in the local settings among the published HTA conclusions. For example, RWE for antibiotics plays a crucial role in filling gaps in evidence that is not addressed by traditional approaches such as RCT, especially for reserve groups of antibiotics that are indicated for the treatment of pan-resistant microorganisms.

CONCLUSIONS

Use of RWE in HTA recommendations in Ukraine showed a prospective trend as a part of the additional support of medicines' assessment, which requires further analysis of transferability opportunities and evidence generation in local settings.

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Thank you!

Stand with Ukraine!

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