

Health Technology Assessment (HTA) in Croatia: the present and the future

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Outline

1. HTA in Croatia (definition and framework)
2. Current status
3. The Croatian Guideline for HTA Process and Reporting
4. Future perspective at national and EU level



HTA

Multidisciplinary proces

- **summaries** information about **medical, social, economic** and **ethical issues** related to the use of a health technology
- in a **systematic, transparent, unbiased, robust** manner
- to **inform the formulation of safe, effective, health policies** that are **patient focused** and seek to achieve **best value**

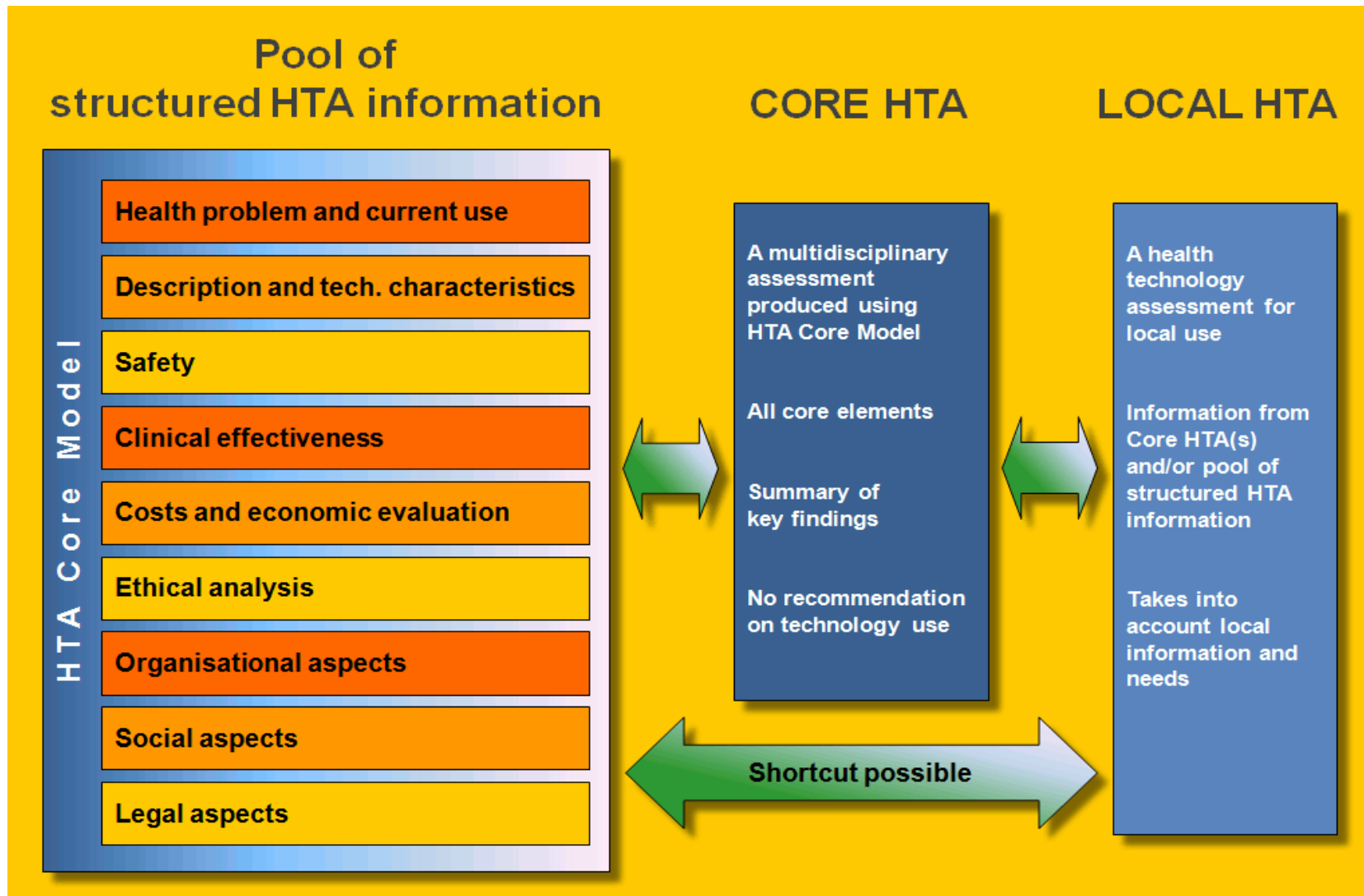


Aims

- As **transparent, independent, scientific, multidisciplinary, evidence-based HTA process and reports** should serve as ***recommendation*** for **evidence-based health care policy and decision making**, in *strategic planning* and *investment*, as well as in *disinvestment* opportunities, in decision on *funding (reimbursement)* and *management* and the *implementation of technologies* in health care
- HTA should serve as **bridge between research, decision-making and high quality health care** by ***optimizing the use of healthcare resources*** to ***maximize patient outcomes***



Core HTA Structure



Croatian Framework for HTA

- 2006, **Strategy** of the development of the Croatian Health Care System 2006-2011
- 2007, **Act on Quality of Health Care**
- December 2009, **Ordinance** regarding reimbursement on drugs (*Official gazette No. 155/09*) and Ordinance regarding reimbursement on medical devices (*Official gazette No. 138/09*) – HTA not mentioned
- October 2010, **Plan and program** of measures for quality assurance, improvement, promotion, and monitoring of health care quality



February 2006, *Strategy for the development
Croatian Health care system 2006 - 2011*

- The **importance of HTA** and **evidence-based decision-making** in Croatian medicine
- **Investments** in new technologies or decisions to include certain procedures **under the coverage** of the HZZO need to be **based on the best available evidence** (principles of evidence-based medicine) and **cost-effectiveness**
- The assessment of new technologies should be in charge of an **independent institution** (National Institute for Health and Clinical Excellence, NICE, UK, as an example)



Institutionalization of the Agency for Quality and Accreditation in Health

- 2007, ***Act on Quality of Health Care***: The Agency for Quality and Accreditation in Health (as **legal, public, independent, non-profit institution**), responsible for **HTA process and report** and **database on HTA**

Health technologies: pharmaceuticals, medical devices, diagnostic and screening techniques, surgical procedures, other therapeutic technologies and procedures, and health promotion activities

- Three departments: 1) Department for Quality and Education, 2) Department for Accreditation in Health, and 3) **Department for Development, Research and HTA**
- **Formal HTA activities** actually began in **October 2009**



October 2010, **Plan and program** of measures for quality assurance, improvement, promotion, and monitoring of health care quality

- Establishing a system for assessing health technologies (drugs, medical devices, medical procedures)
- Setting of indicators for the assessment and introduction of new health technologies
- Request for Agency opinion in the process of public procurement of health technology for health care carriers, when such opinion is needed according to the decision of the Minister of Health
- Request for Agency opinion in the process of public procurement of new health technology for health care carriers, when such opinion is needed according to the decision of the Minister of Health
- Request for Agency opinion in the process of public advertising of health technologies (which must be an integral part of the advertisement on health technology)
- Request for Agency opinion on health technology for all original medicines, medical devices and medical procedures, if committees and professional services of Croatian Institute for Health Insurance (HZZO) needed them



Annual HTA budget and permanent staff in HTA Agencies or Units in some European countries:

Country	Since	Annual HTA budget (US \$ million)	Population served (million)	Permanent staff in HTA Department	Consultants
Finland	1995	2.0	5.1	18	65
Latvia	1995	0.05	2.3	8	variable
Denmark	1997	3.8	5.4	15	variable
Norway	2003	4.0	4.5	30	100
Croatia	2007 (formal activities from 2009)	~0.4 (for <u>whole</u> Agency in 2009, 2010) ~0.9 (in 2011)	4.4	1 (out of three planned in 2009) 1 (from April 2011, for one year period) 1 was contracted (from September 2010 - March 2011)	



First experience in Croatia (from October 2009,

<http://www.aaz.hr/main.php?ID=4>)

International collaboration was established;

- Membership in international society, **HTAi** (November 2009)
- Agency's appointment (by Croatian Ministry of Health) and participation in **EUnetHTA Joint Action** Project (2010-2012) as a **EUnetHTA Partner** (March 2010), and active participation in preparation of **EUnetHTA JA 2** Project (2012-2014)
- Two **meetings** were organized; 1) a one day meeting with international experts for main HTA users (January 2010), and 2) HTA symposium during the 1st Croatian congress on pharmacoeconomics and outcome research with international participation (April 2010)
- **TAIEX Project**, http://ec.europa.eu/enlargement/taieux/dyn/taieux-events/detail_en.jsp?EventID=43260; December 2010, organized by the Technical Assistance Information Exchange Instrument of the European Commission (TAIEX) in co-operation with our HTA Department: **2 days Workshop - "Health Technology Assessment; main principles, HTA process and report"**
- **Application for MATRA** Project in April 2011



International Projects in the framework of the Second Programme of Community Action in the Field of Health (2008-13)

EUnetHTA Joint Action Project (2010-2012)

- EUnetHTA JA: co-funded by the European Commission and participating organizations during a period of 3 years, 2010-2012
- **Aim:** including **work on relative effectiveness of pharmaceuticals, to put into practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level**
- The EUnetHTA JA grant agreement was signed by the EU Executive Agency for Health and Consumers (EAHC) and the Coordinator (National Board of Health of Denmark) on behalf of 33 partners in 23 EU Member States and Norway
- Croatia participated as **EUnetHTA Partner**, as newly admitted **organization in March 2010**, financed **outside of the EUnetHTA JA budget**, with active scientific input in two Works packages, and voting rights on Plenary Assembly

EUnetHTA Joint Action 2 Project (2012-2014)

- EUnetHTA JA2 will be co-funded by the European Commission and participating organizations during a period of 3 years, 2012-2014 (currently in preparation process)
- **Aim:** to facilitate **collaborative production of Core HTA and different types of HTA Reports on relative efficacy or short and long term effectiveness** when applicable, to **avoid duplication of assessments** through **timely, scientific, transparent, unbiased, objective, independent process**, with **appropriate stakeholders consultations**
- HTA JA2 - test all possible models of collaboration, because JA output will **prepare ground for future establishment of a regular European HTA Network** according **Cross Border Health Care Directive**
- Croatia will participate as **Associated Partner (inside EU funds)**; Works Packages are not yet finally established
- Indicative amount: 6.600.000€ (EU co-funding 70%)





eunethta

European network for HTA Joint Action between European Commission and EU Member States

A total of **35 government appointed organisations** from **24 EU Member States, Norway and Croatia** and a **large number of relevant regional agencies** and **non-for-profit organisations** that produce or contribute to HTA

EUnetHTA Joint Action 2010–2012 | www.eunethta.eu



Experience in HTA JA 2010-1012

- Agency's appointment (by Croatian Ministry of Health) and participation in **EUnetHTA Joint Action** as a **EUnetHTA Partner** (March 2010)

WP8: Strategy and Business Model Development (from March 2010)

- ***Facilitation of national strategies for continuous development and sustainability of HTA***
 - *Section coordinated by AHTAPol (Poland)*
- ***HTA training and capacity building***
 - *Section coordinated by ISCIII (Spain)*

WP4, strand B: development of two Core HTA Report (from April 2011)

- ***SCREENING: Abdominal aorta aneurysm screening***
- ***DIAGNOSTIC: Genetic test for cancer***



WP8: Strategy and Business Model Development; Facilitation of national strategies for continuous development and sustainability of HTA , HTA training and capacity building

- March 2010, e-meeting: „Introduction to WP8 National Strategies, Presentation of draft concept of the survey and preparation to f-t-f Warsaw meeting 19-20 April”
- May 2010, WP8 WS, “HTA capacity and facilitation of national strategies for HTA sustainability”, Warsaw, Poland
- July 2010, EUnetHTA WP8 Survey, on Strategy and business model development
- February 2011, WS work on the 1st draft of the “Facilitation of the national HTA strategies development document”, *Warsaw, Poland on the basis of „**Survey on national strategies for continuous development and sustainability of HTA, Results of Barrier analysis**”*
- December 2011, WP8 partners and other EUnetHTA Partners HTA training course (in EUnetHTA tools and other available HTA process support solutions), Prague, Czeck Republic



WP4, STRAND B, development of two Core HTA Report

e-meetings and e-mails

- Production of two Core HTAs and Validation of the Core HTAs:

2 HTA Topics:

SCREENING - Abdominal aorta aneurysm screening

DIAGNOSTIC - Genetic test for cancer

- WS April 2011, Rome and September 2011, Wien; 19 researchers of a Core HTA (10 per core hta) divided among participating APs + 2 from Strand B leader + 1 from LP
- several e-meetings will be arranged to support practical work within both strands, *every 2 months*



WP7 New Technologies (LP – **HAS, France**, Co-LP – **LBI-HTA, Austria**)

2 Strands – WP7A (Facilitating Evidence Generation), WP7B (collaboration on (pre-coverage) assessments)

- Quarterly **e-mail requests for Planned and Ongoing Projects (POP) Database**
- December 2010, EUnetHTA WP 7B, invitation for **“Collaboration on new high tech interventions in hospitals“**

Topic 1: ***Intravitreal vascular endothelial growth factor (VEGF) inhibitors for the treatment of diabetic macular edema***



Zechmeister I, Huic M. Anti-VEGF in diabetic macular oedema: A systematic review.
Decision Support Dokument No. 43. 2011.

This evidence-analysis has been commissioned by the Austrian Ministry of Health.

VASCULAR-ENDOTHELIAL-GROWTH-FACTOR-INHIBITORS (ANTI-VEGF) FOR DIABETIC MACULAR OEDEMA

SYSTEMATIC REVIEW

VIENNA AND ZAGREB, MARCH 2011



Ludwig Boltzmann Institut
Health Technology Assessment



Agencija za
kvalitetu i
akreditaciju
u zdravstvu



EUnetHTA JA2

- EC Health and Consumers DG, November 12 2010, Letter to Health Attaches - Preparation for 2nd Joint Action on HTA
- Invitation for participation in WS on JA, January 2011, Luxembourg



EUnetHTA JA2

February 28 2011 e-meeting on HTA JA 2

March 8 2011 1st preparatory meeting for the 2nd JA on HTA, Brussels

March 18 2011 Invitation for active participation in **“Task Force”**

Task Force members: Gottfried Endel, HVB, Austria; Claudia Wild, LBI, *Austria*; Raf Mertens, KCE, Belgium; Patrice Chalon, KCE, *Belgium*; Mirjana Huic, Agency for Quality and Accreditation in Health, *Croatia*; Finn Børllum Kristensen, NBoH/EUnetHTA Secretariat, Denmark; Julia Chamova, NBoH/EUnetHTA Secretariat, *Denmark*; Kristian Lampe, THL, *Finland*; Francois Meyer, HAS, *France*; Mairin Ryan, HIQA, *Ireland*; Marina Cerbo, AGENAS, *Italy*; Wim Goettsch, CVZ, *Netherlands*; Gro Jamtvedt, NOKC, *Norway*; Iga Lipska, AHTAPol, *Poland*; Anders Lamark-Tysse, DG SANCO, *EU Commission*

HTA JA2 Associated Partners (APs) guidelines for decision in which JA2 work packages organisation will participate in

- a JA2 AP should commit to contribute resources to **one of the 2 production WPs (WP4 and 5)**
 - not to participate in more than 3 WPs (to allow sufficient availability of resources to be dedicated to the production WP) – maximum 3 WPs
 - indicate in which chosen work package they will be willing and able (financially, competence-wise) to participate as an **“active contributor”** (eg, willing to accept a task of “primary investigator”/“investigator”) and as **“less-active contributor”** (eg, task of “reviewer”)
- **April 2011 2nd preparatory meeting for the 2nd JA on HTA, Brussels**



DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare

Article 15 - Cooperation on health technology assessment

1. *The Union shall **support and facilitate cooperation** and **the exchange of scientific information** among Member States **within a voluntary network connecting national authorities or bodies responsible for health technology assessment** designated by the Member States. *The members of the network **shall participate in, and contribute to**, the network's activities **in accordance with the legislation of the Member State where they are established.****
2. The objectives of the Union support referred to in paragraph 1 shall be to:
 - a) support Member States in their cooperation through the national authorities or bodies referred to in paragraph 1; and
 - b) support Member States in the **provision of objective, reliable, timely, transparent and transferable scientific information on the short- and long-term effectiveness of health technologies**, and to enable **an effective exchange of this information** between the national authorities or bodies.



3. In order to fulfill the objectives set out in paragraph 2, **the network** on health technology assessment **may receive Union aid**. Aid may be granted in order to:

- (a) contribute to the financing of administrative and technical support;
- (b) support collaboration between Member States in developing and sharing methodologies for health technology assessment including relative effectiveness assessment;
- (c) contribute to the financing of the provision of transferable scientific information for use in national reporting and case studies commissioned by the network;
- (d) facilitate cooperation between the network and other relevant institutions and bodies of the Union;
- (e) facilitate the consultation of stakeholders on the work of the network.



4. Arrangements for granting the aid, the conditions to which it may be subject and the amount of the aid, shall be adopted in accordance with the regulatory procedure referred to in Article 15(2). **Only those authorities and bodies in the network designated as beneficiaries by the participating Member States shall be eligible for Union aid.**
5. The appropriations required for measures provided for in this Article shall be decided each year as part of the budgetary procedure.
6. Measures adopted pursuant to this Article **shall not interfere with Member States' competences in deciding on the implementation of health technology assessment conclusions** and shall not harmonize any laws or regulations of the Member States and shall fully respect the responsibilities of the Member States for the organization and delivery of health services and medical care.



Croatian Guideline for Health Technology Assessment Process and Reporting (with international peer-review process)

- *HTA Department and multidisciplinary HTA Working Group* (appointed by Agency for this purpose)

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II HTA process

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3 Assessment process

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Appendix I: BIBLIOGRAPHY OF RECOMMENDED HTA GUIDELINES AND METHODOLOGY REFERENCES

Appendix II: **A Code of Practice for Declaring and Dealing with Conflicts of Interest in HTA process**

Appendix III: **Authorship**

Appendix IV: **Selected Data Sources on Croatian Population Health, Healthcare Resource Use and Costs**



- **1st version:** based on and accepted from HTA Guidelines: National Institute for Health and Clinical Excellence (*NICE*), The Canadian Agency for Drugs and Technologies in Health (*CADTH*), Belgian Health Care Knowledge Centre (*KCE*), Danish Centre for Health Technology Assessment (*DACEHTA*), and *EUnetHTA Core model* with adaptation to Croatian setting
- The part of this Guideline, Guide for Croatian primary health economic analysis, is solely accepted and adapted from NICE HTA Guidelines
- Future update: according the changes in Croatian legal framework on HTA, the process of first pilot HTA, and possible future scientific HTA methodological changes



- Whole HTA process: organize as “**network**”
- Each HTA Report (STA, MTA): designated as ‘**internal**’, or ‘**internal plus external**’, depending upon the resources and expertise available
- If **part of HTA** designed as “**external**”, *national* as well as *international* academic and scientific institutions, Cochrane centers, and HTA Agencies or units or organization from EUnetHTA will be contacted for a contract of part of specific HTA project
- *Agency, as legal person, takes whole responsibility for the whole process and final form and content of all Agency HTA reports*



I Introduction and legal framework

- Croatian HTA reports **as recommendation**, with aims to support policy-makers at **national level**, particularly Croatian **MoH**, and **HZZO**, in making evidence-informed decisions on the strategic planning, investment, management and the implementation of technologies in health care, on funding (reimbursement) and coverage of health technologies, as well on **hospital level** on request from hospitals directors and policy teams
- **Health technologies**: pharmaceuticals, medical devices, diagnostic and screening techniques, surgical procedures, other therapeutic technologies and procedures, and health promotion activities
- **HTA process** should have **main parts**: Topics suggestion and selection process, Definition of Scope for HTA, Assessment process, Appraisal process, and Report preparing and publishing
- In the beginning, part of HTA process, Appraisal process, will be defined later in new version of Guideline after future changes in legal framework
- A Single Technology Assessment (**STA**): a single technology for a single indication
- A Multiple Technology Assessment (**MTA**): more than one technology, or one technology for more than one indication



1 Topics suggestion and selection process

- **Topics** suggested and requirements: Croatian Ministry of Health, Croatian Institute for Health Insurance, private health insurance company, industry, health professionals' societies, clinical and public health professionals, patients' societies, hospitals directors and policy teams, as well as Agency staff through HTA Topic Proposal Form
- Agency HTA staff review: to ensure they are appropriate, to check whether they are already included in its work, then filtered according to **selection criteria and check list**:
 - a) burden of disease (population affected, morbidity, mortality)
 - b) resource impact (i.e. the cost impact on Croatian Institute for Health Insurance or the public sector)
 - c) policy importance (i.e. whether the topic falls within a government priority area)
 - d) whether there is inappropriate variation in practice across the country
- Topics **approved and prioritized quarterly** by the HTA Advisory Committees



2 Scope prepared

- The Agency develops a final scope that describes the boundaries of the assessment and the issues that will be investigated
- **Objectives and research questions** are defined for each approved topic, with the assistance of HTA Advisory Committee members and clinical experts, as necessary, according the so-called **PICO structure** (**Population/patients** with the disease of interest; **Intervention(s)**, i.e. the technology under assessment; **Comparison(s)**, which should serve as reference or gold standard; **Outcomes** which encompass the endpoints for assessing effectiveness, safety, and economics)



3 Assessment process

A “**pre-assessment**” of the existing evidence on each selected topic is prepared by HTA Department staff (including existing Core HTA and/or HTAs from other countries), final decision about HTA process, **Assessment phase**, will be done according Algorithm;

Algorithm for HTA process (Assessment phase):

1. Already published Core HTA and/or HTAs from other countries (Yes or No)

If Yes, HTA will be critically appraise for quality by INAHTA checklist for the appraisal of HTA Reports; further adaptation will be done according EUnetHTA Adaptation Toolkit with **new health economic analysis** according the part of this guideline -Guide for Croatian primary health economic analysis

If No, 2. Already published Systematic Reviews (SR) on clinical effectiveness and safety (Cochrane database of SR, DARE database) and SR of economic analyses (Yes or No)

If Yes, SR will be critically appraised and new clinical trials will be added if necessary, with **new health economic analysis** according the part of this guideline - Guide for Croatian primary health economic analysis

If No, 3. New SR on clinical effectiveness and safety (with protocol) and SR of economic analyses (with protocol) (will be based on Cochrane Handbook for Systematic Reviews or the CRD guidance for systematic reviews), with **new health economic analysis** according the part of this guideline - Guide for Croatian primary health economic analysis



- Each project designated as ‘**internal**’, or ‘**internal plus external**’, depending upon the resources and expertise available
- If ***part of HTA*** will be designed “**external**”, *national and international* academic and scientific institutions, and HTA Agencies or units or organization from EUnetHTA will be contacted for a contract of specific HTA project; for each external project, an internal liaison researcher is appointed (A project multidisciplinary team)
- All authors must satisfy established **Agency’s Code of Practice for Declaring and Dealing with Conflicts of Interest in HTA process**, and **Authorship criteria**
- If the project is assessing a drug or medical device, industry will be contacted for information; Agency provides guidance on the process for this contact, and format for document submission

4 Appraisal process defined in the future after necessary changes in HTA legal framework

- Members of the HTA Pharmaceutical, and Devices and Systems Advisory Committees, appointed by the Agency, in the beginning will serve as part of the research team up to and including the protocol phase, but not beyond this phase (In the future they will serve in Appraisal process)



5 HTA Reports

- **Several types** of HTA report:

Full HTA report (STA, MTA) in English language and Summary of full English report for the larger international community, Summary of full English report translated to Croatian language, Short Advice to the Minister of Health and Short Advice to the HZZO in Croatian language, Short Advice to Hospitals, Short Advice to health professionals, and Short Advice to patients, written in lay language

- **Quality assessment:** internal review, international peer-review (including clinicians, methodologist, and economist)
- **The Final reports:** published on Agency's web site and subsequently in print
- **Update** of each HTA Report: every 2 years, or before (when there is significant new evidence that is likely to change the recommendations)



Element of HTA	Reference case for economic analysis
Defining the decision problem	The scope developed by the Agency
Comparator	Therapies routinely used in the Croatian health system, including technologies regarded as current best practice
Perspective on costs	Croatian Institute for Health Insurance (HZZO, as public payer) (societal perspective, including all cost and benefits outside the health care system, may be presented in addition, if considered relevant for some topics)
Perspective on outcomes	All direct health effects on individuals
Type of economic evaluation Time horizon	Cost-effectiveness analysis (CEA) or Cost-utility analysis, (CUA), depending on the particularities of the technology being assessed sufficiently long to reflect all important differences in costs or outcomes between the technologies being compared
Synthesis of evidence on outcomes	Based on a Systematic Review with/or without Meta Analysis (Head-to-Head RCTs preferred, indirect comparisons and observational studies may be accepted)
Measure of health effects	Natural units (CEA) or QALYs (CUA)
Source of data for measurement of HRQL	Reported directly by patients and/or carers (EQ-5D)
Source of preference data for valuation of changes in HRQL	Representative sample of the public (using a choice-based method)
Discount rate	An annual rate of 5 % on both costs and health effects (in sensitivity analyses between 3% and 10%)
Equity weighting	An additional QALY has the same weight regardless of the other characteristics of the individuals receiving the health benefit
Sensitivity analysis, Modelling, Subgroup analysis	Yes

Future Croatian HTA perspective

At national level

- First pilot STA, further permanent STAs and MTAs process and reports; Further educational activities for HTA users, HTA doers, and promotion of HTA

At international level

- Active participation in current EUnetHTA JA and JA 2; Further collaboration and education on HTA; Further application for different EU Projects

According *Cross-Border Health Care Directive*, with Article 15 on Cooperation on health technology assessment - **prepared for participation and contribution to the cooperation and exchange of objective, reliable, timely, transparent and transferable information among Member States within a voluntary network** (in accordance with the legislation of the Member State where they are established) **connecting national authorities or bodies responsible for health technology assessment designated by the Member States**

- Importance of *support and commitment of government institutions, adequate legal framework and funding, educated permanent staff, national and international cooperation and collaboration (network)*



Thank you for your attention!

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- Conflict of interest: None

