

HTA in Croatia: Past, present and the future

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Agency for Quality and Accreditation in Health Care and Social Welfare, October 2009

- 31/12/2018 → Ministry of Health, from 01/01/2019 →

September 2012, **Croatian National Health Care Strategy 2012-2020**

November 2011, **Act on Quality of Health Care and Social Welfare**

HTA and database on HTA at national level;

Proposes Ordinance on HTA to the Minister of Health;

Provides continuous education in the field of HTA;

National and international collaboration in the field of HTA

- **Ordinance on HTA** - *public consultation process finished in October 2016, still not in place (reasons not known)*

December 2018, new **Act on Quality of Health Care** (Official Gazette, 118/2018), **HTA - MoH responsibility**

Plan for establishment of HTA process

Croatian HTA Guideline

Production of HTA Reports (national, international)

International collaboration

National collaboration, education and HTA promotion

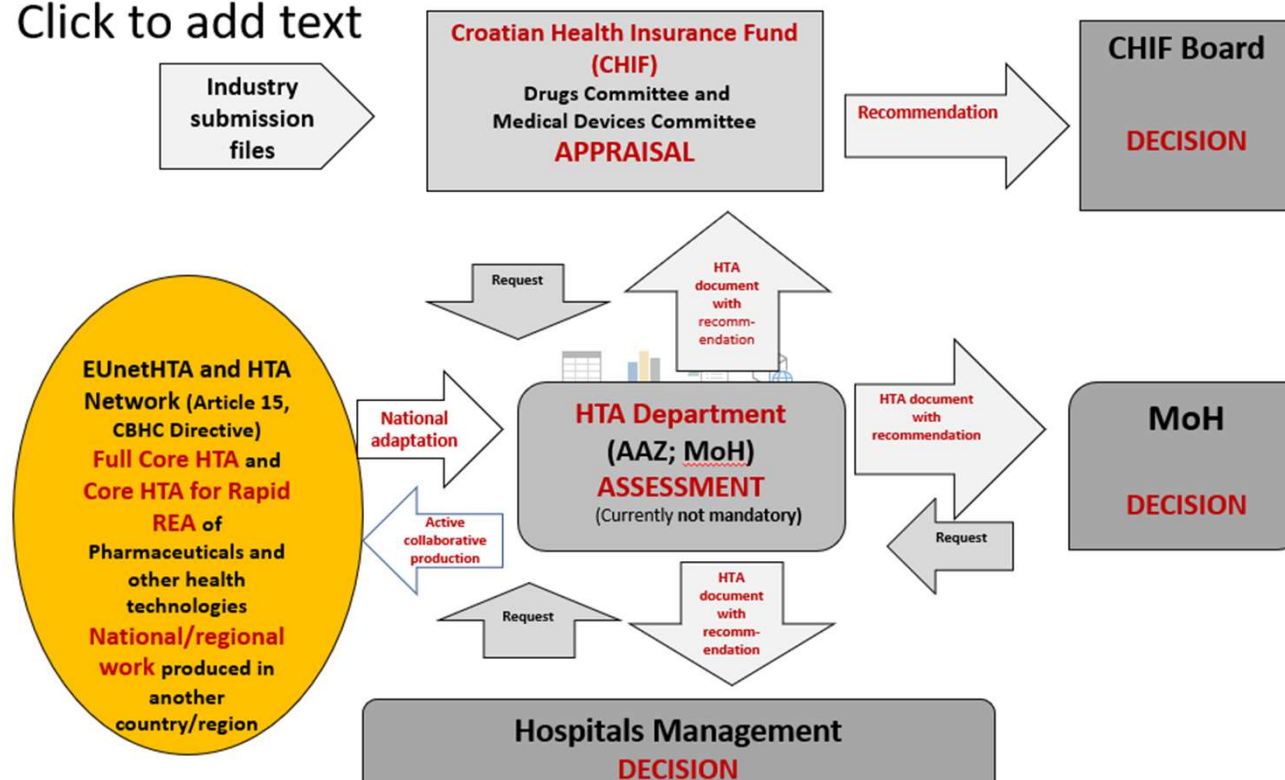
Scientific Publications

Web page



Croatian process of decision-making and HTA process (AAZ, October 2009 - 31/12/2018; MoH, 01/01/2019 →)

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“The **Croatian Guideline for Health Technology Assessment Process and Reporting”, 1st edition, February 2011 (with **international peer-review process**),**

<http://aaz.hr/hr/procjena-zdravstvenih-tehnologija>

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Production of HTA Reports (national, international) <http://aaz.hr/hr/procjena-zdravstvenih-tehnologija/baza>

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

SYSTEMATIC REVIEW

VIENNA AND ZAGREB, MARCH 2011



**Agencija za kvalitetu i akreditaciju u zdravstvu i socijalnoj
skrbi**

Odjel za razvoj, istraživanje i zdravstvene tehnologije

**Transkateterska implantacija aortne valvule (engl.
Transcatheter Aortic Valve Implantation-TAVI): Procjena
zdravstvene tehnologije (engl. HTA), Broj 01/2012.**

Veljača 2012. godine

Agency HTA Database, <http://aaz.hr/hr/procjena-zdravstvenih-tehnologija/baza>

HTA reports, 2011 - October 2019



Rapid HTA - national level	HTA - national level	HTA - EU level (author or co-author)	HTA - EU level (adopted)
5	30	18	16

Agencija za kvalitetu i akreditaciju u zdravstvu Republike Hrvatske

Baza procjena zdravstvenih tehnologija

- Strategija za procjenu
- Metodologija procjene
- Baza procjena zdravstvenih tehnologija
- Edukativni materijali
- Reputativni stručni savjetnici i stručnjaci
- Organizacijski i financijski aspekti
- Ostali poslovanjski aspekti

- **Ataluren (Translarna) za liječenje Duchenneove mišićne distrofije** koje je posljedica delecije/mutacije u discrofiji gena, u pokrenutih bolesnika. Procjena zdravstvene tehnologije (eng). HTA, Broj 28/2018
- **Isaxazamib (Ninlaro) u kombinaciji s lenalidomidom i deksametazonom, za liječenje odraslih bolesnika s multiplelm mijelomom koji su primili barem jednu prethodnu terapiju.** Procjena zdravstvene tehnologije (eng). HTA, Broj 27/2018
- **Karfilazemib (Kyprolis) u kombinaciji s lenalidomidom i deksametazonom ili samo s deksametazonom, za liječenje odraslih bolesnika s multiplelm mijelomom koji su primili barem jednu liniju liječenja.** Procjena zdravstvene tehnologije (eng). HTA, Broj 26/2018
- **Daratumumab (Darzalex) u kombinaciji s lenalidomidom i deksametazonom ili bortezomibom i deksametazonom, za liječenje odraslih bolesnika s multiplelm mijelomom koji su primili barem jednu prethodnu terapiju.** Procjena zdravstvene tehnologije (eng). HTA, Broj 25/2018
- **Atezolizumab u monoterapiji za liječenje odraslih bolesnika s lokalno uznapredovalim ili metastatskim rakom pluća re-malnih stanica, koji su prethodno primili kemoterapiju (eng): Atezolizumab (Tecentriq®) as monotherapy for the second line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC).** Procjena zdravstvene tehnologije (eng). HTA): Procjena zdravstvene tehnologije (eng). HTA, Broj 24/2018
- **Sustavi za kontinuirano mjerenje glukoze u realnom vremenu (rCGM) i "flash" sustavi mjerenja glukoze (FGM) kao osobni samostalni sustavi kod bolesnika sa teškom bolešću liječenih insulinom (eng): Continuous glucose monitoring (CGM) real-time and flash glucose monitoring (FGM) as personal, standalone systems in patients with diabetes mellitus treated with insulin). Procjena zdravstvene tehnologije (eng). HTA, Broj 23/2018**
- **Alectinib kao monoterapija za prvu liniju liječenja odraslih bolesnika s uznapredovalim, ALK-pozitivnim karcinomom pluća ne-malih stanica (eng): Alectinib (Alecensa®) as monotherapy for the first line treatment of adult patients with ALK-positive advanced non-small cell lung cancer (NSCLC).** Procjena zdravstvene tehnologije (eng). HTA): Procjena zdravstvene tehnologije (eng). HTA, Broj 22/2018

Example:

Particle Beam Radiation Therapies for Cancer: HTA, 05/2013

Building of PBT centre in Croatia not recommended

Small number of patients with clear indications for treatment

Extremely high costs of building and equipment (in UK about 150 mil pounds)

Patients with clear indications should be sent to international PBT centres

<http://aaz.hr/hr/zdravstvene-tehnologije/baza/radioterapija-tumora-cesticama-snopom-protona-ugljikovih-iona-iona-helija-ili-drugim-cesticama>

International collaboration, <http://aaz.hr/hr/projekti>, <http://www.aaz.hr>

Evidence is global, decision is local

EU Projects (**EUnetHTA JAs** 2010-2021; European study on Quantifying Utility of Investment in Protection from Tobacco – **EQUIPT**; Sustainable intEgrated care modeLs for multi-morbidity: delivery, Financing and performance - **SELFIE**)

HTA Network, http://ec.europa.eu/health/technology_assessment/policy/network/index_en.htm

HTAi, ISPOR, ISPOR HTA Roundtable Europe, ISPOR HTA Council

WHO National Contact Point on HTA

TAIEX Project (2010), 2 days Workshop - “Health Technology Assessment; main principles, HTA process and report”

ISPOR HTA Training Programe (2015),
<http://www.ispor.org/Education/HTATraining/Index>

For small and medium size and CEE countries, European cooperation on HTA is essential, due to limited human and financial resources

Alectinib (Alecensa®) as monotherapy for the first line treatment of adult patients with ALK-positive advanced non-small cell lung cancer (NSCLC), January 2018 (02/03/2018 – request from CHIF; 26/03/2018 final national HTA report)



Agencija za kvalitetu i
akreditaciju u zdravstvu
i socijalnoj skrbi

Služba za razvoj, istraživanje i zdravstvene tehnologije

EUnetHTA Joint Action 3 WP4

Rapid assessment of pharmaceutical technologies using the HTA Core Model®
for Rapid Relative Effectiveness Assessment

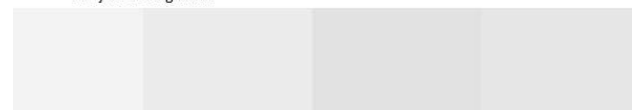
**ALECTINIB AS MONOTHERAPY FOR THE FIRST-LINE TREATMENT OF
ADULT PATIENTS WITH ALK-POSITIVE ADVANCED NON-SMALL CELL
LUNG CANCER**

Project ID: PTJA03

**Alectinib kao monoterapija za prvu liniju liječenja odraslih bolesnika s
uznapredovalim, ALK-pozitivnim karcinomom pluća ne-malih stanica /engl.
Alectinib (Alecensa®) as monotherapy for the first line treatment of adult
patients with ALK-positive advanced non-small cell lung cancer (NSCLC)/:
Procjena zdravstvene tehnologije (engl. HTA), Broj 22/2018.**

Prilagodba EUnetHTA JA3 zajedničke procjene zdravstvene tehnologije "Alectinib (Alecensa®) as
monotherapy for the first line treatment of adult patients with ALK-positive advanced non-small cell
lung cancer (NSCLC)", Project ID: PTJA03, na nacionalnu razinu

Ožujak 2018. godine



Appropriate Patient involvement



EUnetha Joint Action 3 2016-2020

Continuous glucose monitoring (CGM real-time) and flash glucose monitoring (FGM) as personal, standalone systems in patients with diabetes mellitus treated with insulin

Project ID: **OTJA08**

Project description and planning



Agency for Quality and Accreditation in Health Care and Social Welfare

Agency for Quality and Accreditation in Health Care and Social Welfare (AAZ), Croatia



Hauptverband der österreichischen Sozialversicherungsträger

Main Association of Austrian Social Security Institutions (HVB)



Norwegian Institute of Public Health

The Norwegian Institute of Public Health (NIPHNO)

Patient involvement methods: two different methods, one involving individual patients and second involving patient organisations

Focus group (with individual patients) in **Croatia** – one for **adults** and one for **children/parents**

Two patient organisations: one at European level - **International Diabetes Federation European Region** and one at national level - **Diabetes Scotland**

HTA Network (Expert Group) meetings

PROVIDING GUIDANCE FOR THE PREPARATION OF THE **IMPLEMENTING ACT** AND FOR THE SUBSEQUENT DETAILED **RULES OF PROCEDURES**

HTA Network WG meetings on “**Long term provisions for EU cooperation on HTA**” (2013-2014)

Active work on **HTA Network Strategy Paper for EU cooperation on HTA**

HTA Network WG meetings on “**Reuse of joint work in national activities**” (2014-2015)

Active work on **HTA Network Reflection paper on Reuse of Joint Work in national HTA activities**

Croatia acted as **Rapporteur**

HTA Network WG meetings on “**Multi-Annual Work programme 2016-2020**” (2016)

Active work on **HTA Network MWP 2016-2020**

Croatia acted as **Chair and Rapporteur**

Questionnaires on

Inception Impact Assessment

Mapping HTA methodologies

Mapping of HTA national organizations

Involvement in Study on impact analysis of policy options for strengthened EU cooperation on HTA

Scientific publications, <http://aaz.hr/hr/procjena-zdravstvenih-tehnologija/publikacije>

Examples: - HTA in Central, Eastern, and South European countries: Croatia. *Int J Technol Assess Health Care*. 2017 Aug 14:1-8.;

EUnetHTA: further steps towards European cooperation on health technology assessment. *Int J Technol Assess Health Care*. 2014;30(5):475-7.

EUnetHTA WP7 research and analysis activity 1: Final report



eunetha
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

An analysis of HTA and reimbursement procedures in EUnetHTA partner countries: final report

USE OF EUnetHTA ASSESSMENTS AT THE AGENCY FOR QUALITY AND ACCREDITATION IN HEALTH CARE AND SOCIAL WELFARE (AAZ)

Working Practices

Requests for assessment come to AAZ from the Ministry of Health, CHIF or hospital managers. AAZ have a topic proposal form which institutions submitting requests may use to describe the topic and research question that they want addressed.

The HTAs are produced by AAZ staff and are approximately 70 pages long. The reports include information about the condition, the technology, clinical evidence, cost and a summary of published cost effectiveness evidence. For non-pharmaceutical health technologies relevant information about organisational, legal and ethical issues will also be added to the report. The type of information added is based on a shorter adapted version of the assessment elements in the EUnetHTA HTA Core Model. Where possible the assessment will make use of existing HTA assessment either created by EUnetHTA or

gastro-oesophageal junction adenocarcinoma and antibacterial-coated sutures for the prevention of superficial and deep incisional surgical site infection (SSI).

When using an existing HTA assessment created by either EUnetHTA or another national agency, AAZ will make the following adaptations to the assessment for use in the Croatian context:

- Update literature searches to identify and include any new clinical evidence and ongoing studies;
- Add epidemiological information such as patient numbers, morbidity and mortality in Croatia;
- Add information about the technologies available in Croatia;
- Add information about costs of relevant technologies in Croatia;
- Add any additional information required such as a summary of cost effectiveness evidence and

NATIONAL IMPLEMENTATION AND IMPACT

Written by Zoe Garrett, NICE, zoe.garrett@nice.org.uk

These articles are part of the work of WP7 National implementation and Impact

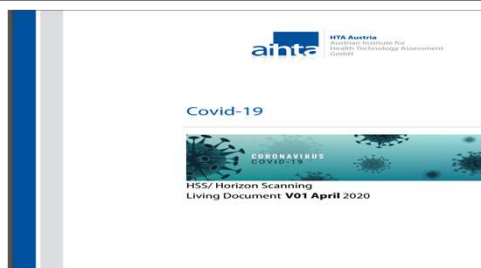
The Agency for Quality and Accreditation in Health Care and

Web page, <http://aaz.hr/hr/projekti>, <http://www.aaz.hr/>, <http://aaz.hr/hr/procjena-zdravstvenih-tehnologija>;

Involvement related to COVID-19 at EU level

Horizon scanning for COVID-19

Austrian Institute for Health Technology Assessment (AIHTA), from April 2000 – ongoing, <http://eprints.aihta.at/1234/>



EUnetHTA collaboration for COVID-19

EUnetHTA COVID-19 **Rolling** Collaborative Reviews and EUnetHTA **Rapid** Collaborative Reviews

COVID-19 therapeutics sub-group of the European expert group on SARS-CoV-2 variants

Report of the COVID-19 therapeutics sub-group COVID-19 therapeutics portfolio – list of ten most promising candidates, October 2021;

Report of the COVID-19 therapeutics sub-group COVID-19 Therapeutic Innovation Booster, April 2022

Conclusions

Systematic and sustainable HTA proces at national level and sustainable HTA collaboration at EU level

in line with:

2011, Article 15 of Directive 2011/24/EU

2014, Strategy paper for EU cooperation on HTA

2015, Reflection paper on Reuse of Joint Work in national HTA activities

2021, Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU

2014, 67th World Health Assembly Resolution: Health intervention and technology assessment in support of universal health coverage

“If you want to go fast, go alone. If you want to go far, go together.”

