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Republika Hrvatska

The future of HTA cooperation in Europe

What an HTA Agency can expect

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EC Legislative Proposal on HTA: **Recognition of importance and support - Why?**

- **Long-term sustainability** of EU HTA cooperation
- **↓ duplication**
- **Ensure the use of joint outputs** in MS
- **Appropriate stakeholders involvement**
- **Improve the availability of innovative health technologies** for EU patients
- **Ensure efficient use of resources**
- **Strengthen the quality of HTA** across the EU

Key elements :

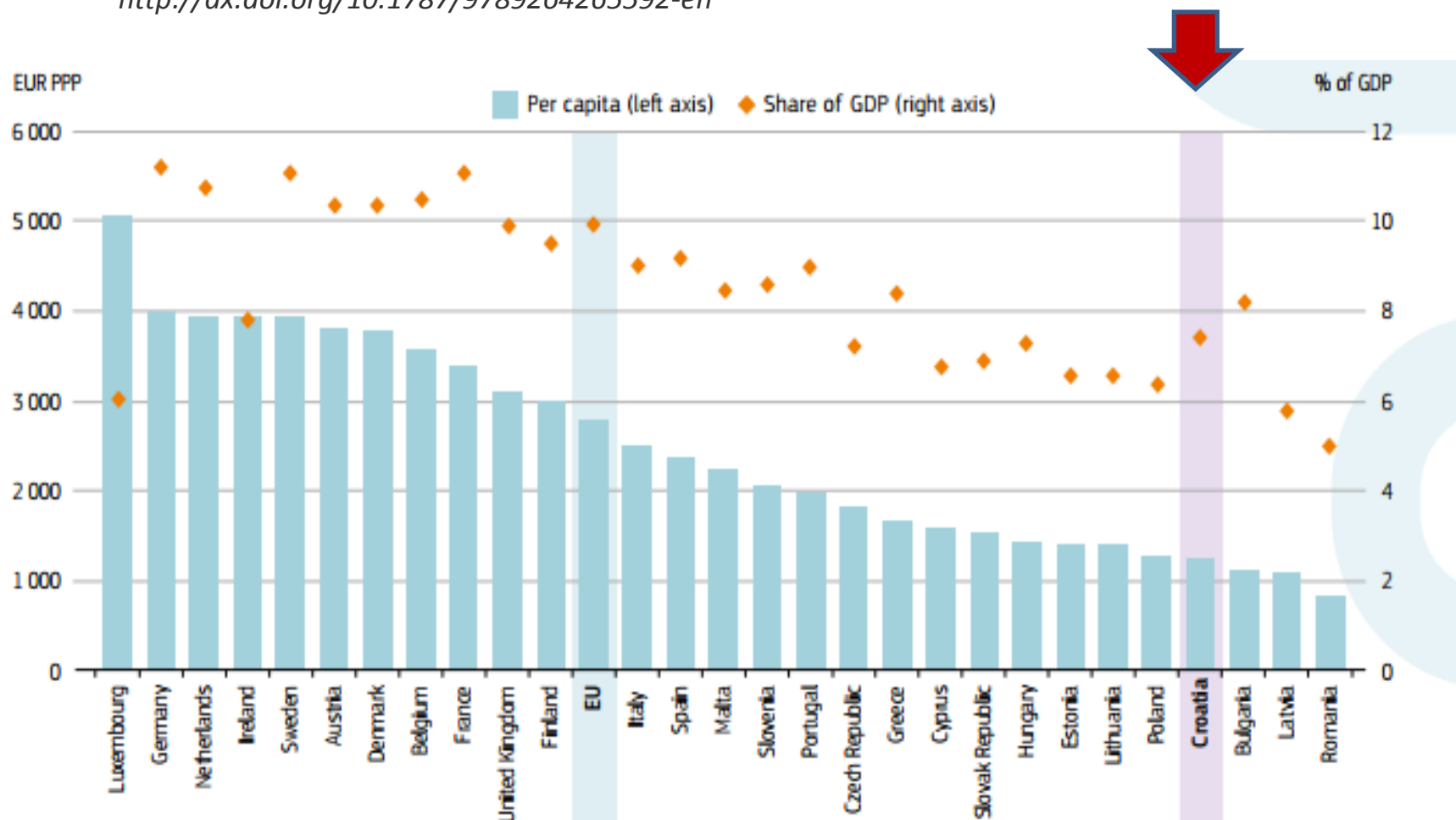
- **Member States driven scientific work**
- **Focus on clinical assessment**
- **High quality and timely output**
- **Use of joint work – no duplication**
- **Fit for purpose**
- **Transparency and stakeholders' involvement**
- **Four areas of joint work**
- **Pragmatic approach**

Evidence is global, decision is local

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

Health care spending in the EU

OECD/EU (2016), *Health at a Glance: Europe 2016 – State of Health in the EU Cycle*, OECD Publishing, Paris.
<http://dx.doi.org/10.1787/9789264265592-en>




Sources: OECD Health Statistics, Eurostat Database, WHO Global Health Expenditure Database (data refer to 2015).

Agency for Quality and Accreditation in Health Care and Social Welfare, Department for Development, Research and HTA (October 2009)

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

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

- **Procedure for 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*

Plan for establishment of HTA process:

- **Croatian HTA Guideline**, <http://aaz.hr/hr/procjena-zdravstvenih-tehnologija>
- **Production of HTA Reports (national, international)**, <http://aaz.hr/hr/procjena-zdravstvenih-tehnologija/baza>
- **International collaboration**, <http://aaz.hr/hr/projekti>, <http://www.aaz.hr>
- **National collaboration, education and HTA promotion** (congress, meetings, WSs, publications in Croatian language), <http://aaz.hr/hr/procjena-zdravstvenih-tehnologija/edukativni-materijali>
- **Scientific Publications**, <http://aaz.hr/hr/procjena-zdravstvenih-tehnologija/publikacije>
- **Web page**, <http://www.aaz.hr/>, <http://aaz.hr/hr/procjena-zdravstvenih-tehnologija>; <http://aaz.hr/hr/projekti>

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

- **EU Projects** (**EUnetHTA JAs**; 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 Programme (2015)**, <http://www.ispor.org/Education/HTATraining/Index>

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



Ludwig Boltzmann Institut
Health Technology Assessment



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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

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

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

HTA reports , 2011- December 2017



Rapid HTA - national level	HTA - national level	HTA - international level (author or co- author)	HTA - international level (adopted)
5	21	15	9





eunethta

European network for HTA

Project (2006-2008)

Collaboration (2009)

JA1 (2010-2012)

JA2 (2012-2015)

JA3 (2016-2020)



EUnetHTA JA1 2010-2012

- Facilitation of national strategies for continuous development and sustainability of HTA
- HTA training and capacity building
- Anti-VEGF in diabetic macular oedema: A systematic review
- **The pre-market clinical evaluation of innovative high-risk medical devices**
- **Prognostic tests for breast cancer recurrence**
- **Abdominal Aortic Aneurysm (AAA) screening**

EUnetHTA JA2 2012-2015

- **Fecal Immunochemical Test (FIT) versus guaiac-based fecal occult blood test (FOBT) for colorectal cancer screening**
- Intravenous Immunoglobulins in MCI and Alzheimer disease
- **Structured Telephone Support (STS) in adults with chronic heart failure**
- **Duodenal-jejunal bypass sleeve (EndoBarrier®) for the treatment of obesity with or without type 2 diabetes**
- **Transcatheter mitral valve repair in adults with chronic mitral valve regurgitation**
- Canagliflozin for the treatment of Diabetes Mellitus Type 2
- **Ramucirumab (Cyramza®) in combination with Paclitaxel as second-line treatment for adult patients with advanced gastric or gastro-oesophageal junction adenocarcinoma**
- New pharmaceuticals in Chronic Hepatitis C

EUnetHTA JA3 2016-2020

- **Wearable cardioverter-defibrillator (WCD) therapy in primary and secondary prevention of sudden cardiac arrest in patients at risk**
- **Antibacterial-coated sutures versus non-antibacterial-coated sutures for the prevention of abdominal, superficial and deep incisional, surgical site infection (SSI)**
- **Regorafenib (Stivarga©) indicated as monotherapy for the treatment of adult patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib treatment**
- **Alectinib as monotherapy for the first-line treatment of adult patients with *ALK*-positive advanced non-small cell lung cancer**
- **Continuous glucose monitoring (CGM real-time) and flash glucose monitoring (FGM) as personal, standalone systems in patients with diabetes mellitus treated with insulin**
- **The use of 3D printing for implants and splints in connection with surgery**

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)



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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



EUnethTA 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 (AAZ), Croatia



Main Association of Austrian Social Security Institutions (HVB)



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**

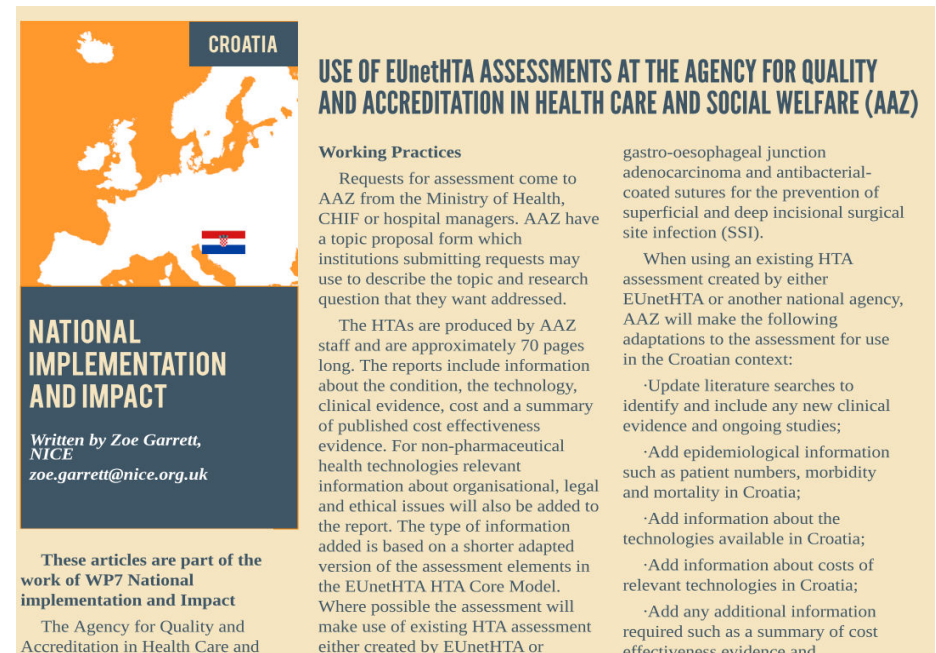


An analysis of HTA and reimbursement procedures in EUnetHTA partner countries: final report

- Case Study 4: Use of EUnetHTA assessments at the Agency for Quality and Accreditation in Health Care and Social Welfare (AAZ), Croatia

Added value of joint work and use

- Sharing the expertise: ↓ time for the production of national HTA reports, ↑ the number and quality of national reports, ↑ local competence and capacity in HTA
- ↑ international and scientific visibility through joint work and publishing of scientific papers; national awareness and political recognition of the concrete benefits of joint HTA



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



- **Wearable cardioverter defibrillators for the prevention of sudden cardiac arrest: a health technology assessment and patient focus group study.** *Med Devices (Auckl)*. 2017 Nov 14;10:257-271.
- **Duodenal-Jejunal Bypass Liner for the Treatment of Type 2 Diabetes Mellitus and/or Obesity: a Systematic Review.** *Obes Surg*. 2014;24(2):310-23.
- **Vascular endothelial growth factor inhibitors (anti-VEGF) in the management of diabetic macular oedema: a systematic review.** *Br J Ophthalmol*. 2011.
- **HTA in Central, Eastern, and South European countries: Croatia.** *IJTAHC*. 2017;14:1-8.
- **HTA Implementation Roadmap in Central and Eastern European Countries.** *Health Econ*. 2016;25:179-92.
- **Comparison of current and preferred status of HTA implementation in Central and Eastern European countries.** *Value Health*. 2015;18(7):A538.
- **European collaboration on relative effectiveness assessments: What is needed to be successful?** *Health Policy*. 2015.
- **EUnetHTA: further steps towards European cooperation on health technology assessment.** *IJTAHC*. 2014;30(5):475-7.
- **Collaboration in Health Technology Assessment (EUnetHTA Joint Action, 2010-2012): Four case studies.** *IJTAHC*. 2013;12:1-8.
- **Commentary: Europe needs a central, transparent, and evidence based regulation process for devices.** *BMJ*. 2013;7;346:f2771.
- **Pre-market Clinical Evaluations of Innovative High-Risk Medical Devices in Europe.** *IJTAHC*. 2012;28:278-84.

Conclusion

Systematic and sustainable use of HTA at national/regional 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**

2018, **Proposal for a Regulation of the European Parliament and of the Council 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.”

