eunethta magazine

2019

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PRODUCTS
& SERVICES

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2018
YEAR IN REVIEW

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EUnetHTA Magazine

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EUnetHTA JOINTLY PRODUCED HTA REPORTS*

EUnetHTA Joint Assessments (JA) are Health Technology Assessments (HTA) jointly produced by at least four EUnetHTA partners in different European countries. JAs are centrally coordinated by the Joint Production Co-Leads and comprise a broad stakeholder involvement, including the use of a EUnetHTA submission file in addition to a scoping (e-)meeting with industry.

EUnetHTA Collaborative Assessments (CA) are primarily produced in non-pharmaceutical technologies. They only differ from EUnetHTA JAs with regard to coordination, i.e. the project management is performed in a decentralised manner by Joint Production Co-Lead and Joint Production Activity Centre Department Leads. In CAs, the use of submission file and scoping (e-)meeting with industry are optional.

PTJA07 **"Ustekinumab for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy, a biologic, or have medical contraindications to such therapies"**

PTJA06 **"Poltatuzumab vedotin in combination with bendamustine and rituximab for the treatment of relapsed/refractory diffuse large B-cell lymphoma (DBCL)"**

PTJA05 **"Enasidenib for the treatment of adult patients with relapsed or refactory acute myeloid leukaemia (AML) with an isocitrate dehyogenase 2 (IDH2) mutation"**

PTJA04 **"Sotagliflozin for Type 1 diabetes mellitus"**

PTJA03 "Alecensa as monotherapy is indicated for the first-line treatment of adult patients with ALK+ advanced NSCLC"

PTJA02 "Regorafenib (Stivarga©) indicated as monotherapy for the treatment of adult patients with Hepatocellular Carcinoma (HCC) who have been previously treated with sorafenib"

PTJA01 "Midostaurin (Rydapt©) with standard chemotherapy in FLT3 positive Acute Myeloid Leukaemia (AML)"

OTCA20 **"Prophylactic or therapeutic use of endoanchoring systems in Endovascular Aortic Aneurysm Repair (EVAR)"**

OTCA19 **"Screening for osteoporosis in general population"**

OTCA18 **"Regional hyperthermia for high-risk soft tissue sarcoma treatment"**

OTCA17 **"LBO laser for PVP in the treatment of Benign Prostatic Hyperplasia (BPH)"**

OTCA16 "Bioresorable stents in cardiovascular indications (coronary artery disease)"

OTCA15 **"Irreversible electroporation in liver and pancreatic cancer"**

OTCA14 **"Robotic surgery in cardiovascular and visceral indications"**

OTCA13 "Vagal nerve blockade for obesity" canceled: expiration of CE approval for the technology

OTCA12 "The use of C-reactive Protein Point-of-Care Testing (CRP POCT) to guide antimicrobial prescribing in primary care settings for Respiratory Tract Infections (RTIs)"

OTCA11 **"The use of 3D printing for implants and splints in connection with surgery"**

OTJA10 **"Stool DNA testing (e.g. ColoAlert, ColoGuard) for early detection of colorectal cancer"**

OTCA09 "High-Intensity Focused Ultrasound (HIFU) ablation for the treatment of prostate cancer"

OTJA08 "Continuous Glucose Monitoring (CGM real-time) and Flash Glucose Monitoring (FGM) as personal, standalone systems in patients with diabetes mellitus treated with insulin"

OTCA07 "Relative effectiveness assessment of Femtosecond Laser-Assisted Cataract Surgery (FLACS) compared to standard ultrasound phacoemulsification cataract surgery"

OTCA06 "Transcatheter Aortic Valve Implantation (TAVI) in patients at intermediate surgical risk"

OTCA05 "Repetitive transcranial magnetic stimulation for treatment-resistant major depression"

OTCA04 "Added value of using gene-expression signature for adjuvant chemotherapy decisions in early breast cancer"

OTCA03 "Screening of fetal aneuploidies whereby Non-Invasive Prenatal Test (NIPT)"

OTCA02 "Antibacterial-coated Sutures Versus Non-Antibacterial-Coated Sutures for the Prevention of Abdominal, Superficial and Deep Incisional, Surgical Site Infection (SSI)"

OTCA01 "Wearable Cardioverter-Defibrillator (WCD) therapy in primary and secondary prevention of sudden cardiac arrest in patients at risk"

= Patients have been involved in this assessment / **BOLD** = Ongoing assessment at time of publication / *Reports from 2016 - 2019

PARTNER PROFILE

JOINT PRODUCTION CO-LEAD PARTNER LBI-HTA

Austria held the Presidency of the Council of the European Union for the second half of 2018 and played a vital role in the progression of the HTA legislative proposal.

The EUnetHTA Network is privileged to have Gesundheit Österreich GmbH/ Geschäftsbereich (**GOG)**, Hauptverband der Österreichischen Sozialversicherungsträger (Association of Austrian Social Insurance Institutions) (**HVB)** and the University for Health Sciences, Medical Informatics and Technology (**UMIT)** as Austrian partners.

As an added bonus, *EUnetHTA Magazine* is highlighting the work of Joint Production (Work Package 4) co-leader Ludwig Boltzmann Institute - Health Technology Assessment (**LBI-HTA**).

LBI-HTA

Ludwig Boltzmann Institut
Health Technology Assessment

LBI-HTA:

The Ludwig Boltzmann Institute of Health Technology Assessment (LBI-HTA) is an independent nonprofit research institution (15 FTE researchers) supporting evidence-based decision-making in healthcare. LBI-HTA provides scientific input to facilitate efficient and appropriate use of health care resources in Austria. In line with the research policy set by the Ludwig Boltzmann Society, LBI-HTA focuses on translational research. Strong emphasis is put on research results that can be practically applied in the short or medium term. By having set up institutional partnerships between research-producing (LBI-HTA) and research-applying organizations (Ministry of Health, Main Association of Austrian Social Security Institutions, regional health funds), the quick transfer of research results is greatly enhanced.

LBI-HTA works in nine research areas, including “High Tech Medicine (in hospitals, non-pharmaceutical interventions)” and “Horizon Scanning in Oncology” (drugs, contributing to BeNeLuxA). LBI-HTA has been involved in international and European HTA collaboration activities from its conception. LBI-HTA is an active partner and Joint Production (co)-leader (Work Package 4) in EUnetHTA Joint Action3.

Participation in EUnetHTA

EUnetHTA Joint Action 3 (2016-20)

Work Package 1 – Network Coordination

Work Package 2 – Dissemination

Work Package 4 – Joint Production

Work Package 6 – Quality Management, Scientific Guidance and Tools

Work Package 7 – National Implementation and Impact

EUnetHTA Joint Action 2 (2012-15)

JA2 WP1 – Coordination

JA2 WP6 – Information Management Infrastructure and Services (IMIS)

EUnetHTA Joint Action (2010-12)

JA WP1 – Coordination

JA WP4 – Core HTA

JA WP6 – Information Management System

JA WP8 – Strategy and Business Model Development

Participation in International HTA Projects

LBI-HTA participates in many international HTA projects including:

- **HTAi** - Health Technology Assessment International
- **INAHTA** - International Network of Agencies for Health Technology Assessment
- **HTA.de -** German Society for Technology Assessment in Health Care
- **EbM Netzwerk** - German Network for Evidence-based Medicine
- **ISPOR** - International Societies for Pharmacoeconomics and Outcomes Research

From LBI-HTA: What is HTA?

https://hta.lbg.ac.at

NATIONAL IMPLEMENTATION AND IMPACT

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

USE OF EUnetHTA ASSESSMENTS BY LUDWIG BOLTZMANN INSTITUTE FOR HTA (LBI–HTA), AUSTRIA

The Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA) is an independent academic institute providing scientific decision-making support in the health sector. The Institute is funded by the Ludwig Boltzmann Society (40%), The Ministry of Health, Federation of Social Insurers and Regional Health funds (together 60%). The Institute works across a number of research areas covering a wide range of health technologies including high-tech medical devices, interventional procedures, oncology medicines, screening and prevention, rehabilitation and psychology. LBI-HTA was established in 2006 and publishes approximately 22 outputs each year including HTAs (timescale 6-8 months, 5-7 p.a.), decision support documents for the hospital benefit catalogue (timescale 3-4 months, 5-7 p.a.) and horizon scanning in oncology documents (timescale for production within 1 month, 8 p.a.). Outputs are published in a publicly accessible repository on the LBI-HTA website[1]. LBI-HTA has been a member of EUnetHTA since the first Joint Action starting in 2010.

Working practices

The process of identifying topics and timelines for producing HTA varies depending on the research area and output. For the evaluation of new high-tech interventions in hospitals, topics are proposed annually by stakeholders (such as hospitals or specialist clinicians) for inclusion in the benefit catalogue. Proposals are collected by the Ministry of Health and priorities are set and approved by the Federal Health Commission. Based on the final selection of topics LBI-HTA produces HTA for each of these topics. The HTA reports and recommendations produced by LBI-HTA are appraised and discussed by a committee of regional representatives of payers before a final decision on reimbursement and coverage is made by the Federal Health Commission. The procedure is carried out to strict timelines where HTA is completed from November to March each year. LBI-HTA produces its own reports and also adapts HTAs produced by other agencies or EUnetHTA. LBI-HTA has fewer procedural restrictions for other research areas, for example oncology medicines and is also able to take forward topics of own interest.

Use of EUnetHTA assessments

LBI-HTA is deeply involved in carrying out joint HTAs through EUnetHTA as the co-lead of Joint Production (Work Package 4 – WP4), and as authors and reviewers of joint and collaborative assessments. In addition, LBI-HTA has made changes to its processes to make it easier to use EUnetHTA assessments.

The changes include:

· searches of the POP database to identify overlaps with planned or ongoing projects from other agencies;

· adaptation of their report structures to reflect the HTA Core model and change of working language into English;

· the effect of making these changes reduces the resources required to make adaptations of EUnetHTA assessments.

For example, in some instances. LBI-HTA has been able to use the EUnetHTA assessment to replace the national assessment report without making any changes. Further, in situations where amendments to the assessments are required, the process changes mean that only minor changes are required by writing German summaries and adding recommendations for decision makers.

EUnetHTA assessment links to national report

Decision-support Other Technologies:

- Wearable cardioverter-defibrillator http://eprints.hta.lbg.ac.at/1109/
- German Exec Sum added reimbursement (fee-for-service) in hospitals Antibacterial-coated sutures EUnetHTA report was sent directly to decision makers without changes (was not added to LBI-HTA repository) central procurement in hospitals non-invasive prenatal tests http://eprints.hta.lbg.ac.at/1153/
- German Exec Sum added In-/exclusion in benefit catalogue of health insurances and mother-child care: Repetitive transcranial magnetic stimulation http://eprints.hta.lbg.ac.at/1130
- German Exec Sum added In-/exclusion in benefit catalogue of hospital interventions and of health insurances: High intensity focused ultrasound ablation http://eprints.hta.lbg.ac.at/1167/1/DSD_ 37_Update2018.pdf
- German Exec Sum added In-/exclusion in benefit catalogue of hospital interventions

Decision-support Pharmaceutical Technologies

- Regorafenib (Stivarga®) http://eprints.hta.lbg.ac.at/1138/ ESMO-scale added drug commissions in hospitals
- Midostaurin (Rydapt®) http://eprints.hta.lbg.ac.at/1140/ drug commissions in hospitals

This description was completed as part of the EUnetHTA implementation network https://www.eunethta.eu/national-implementation/

[1]http://eprints.hta.lbg.ac.at/

products & services

find out more at eunethta.eu

assessments

assessments

Pharma

Other Technologies

Assessments

Health Technology Assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner.

Pharma and OT Lines

EUnetHTA Health Technology Assessments are divided into two service lines: Pharmaceuticals (Pharma) and Other Technologies (OT). For information about the submission process
Pharma submission WP4_Pharmaceuticals@zinl.
OT submission EUnetHTA@hta.lbg.ac.at

JA

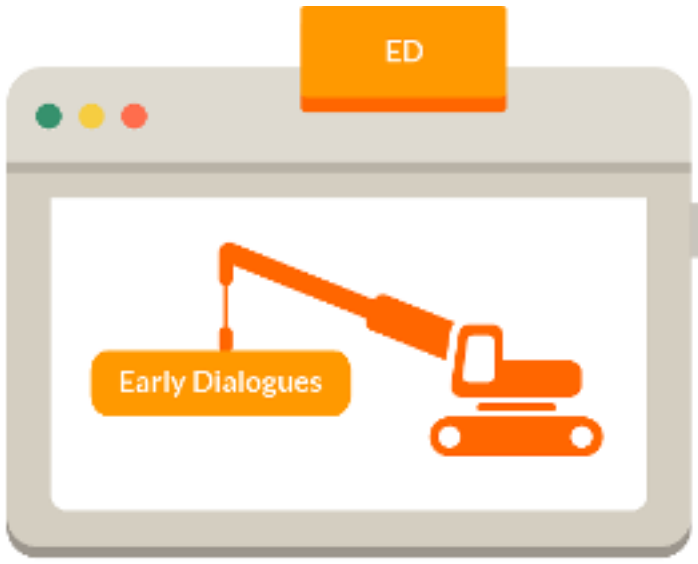
CA

Joint Assessments (JA)

Joint Assessments (JA) are produced by at least four EUnetHTA partners in different European countries. EUnetHTA processes, guidelines and the HTA Core Model® are used for the production of assessments, subject to extensive review procedures in order to ensure high quality. JAs are centrally coordinated and comprise broad stakeholder involvement, including the use of a EUnetHTA submission file in addition to a scoping (e-)meeting with industry.

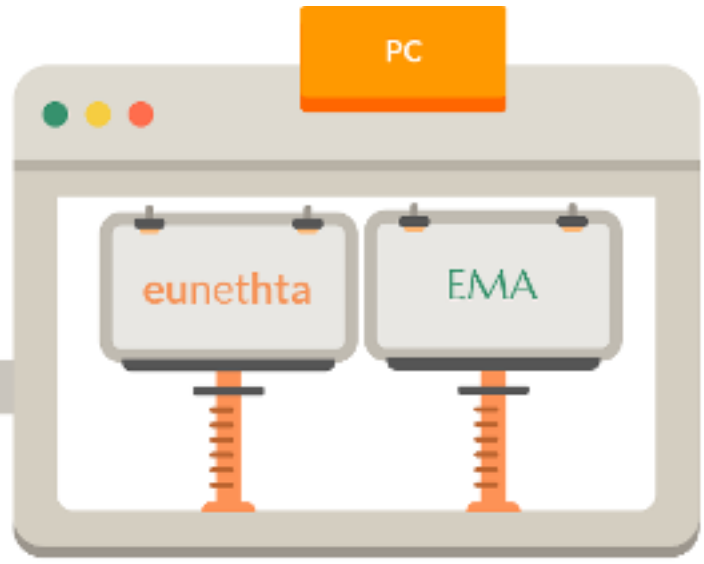
Collaborative Assessments (CA)

Collaborative Assessments (CA) are primarily produced in non-pharmaceutical technologies. They only differ from the EUnetHTA JAs with regard to coordination, i.e. the project management is performed in a decentralised manner by Joint Production Activity Centre Department Leads. In CAs, the use of submission file and scoping (e-)meeting with industry are optional.



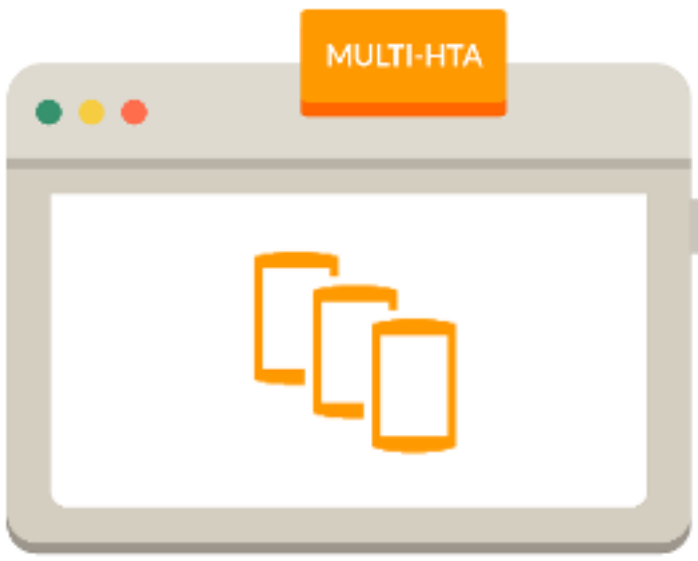
Early Dialogues (ED)

Support developers of medical technologies by providing a collaborative approach between a wide range of European HTA agencies. Supply prospective and timely advice, before start of clinical trials, to improve quality of data produced by developers that may lead to well-informed regulatory, HTA & reimbursement decisions. Find out more EUnetHTA-HAS@has-sante.fr



Parallel Consultations (PC)

Optimize the interaction with regulators for medicinal products through parallel European Medicines Agency (EMA) consultations in EMA-EUnetHTA multi-stakeholder Early Dialogues.



Multi-HTA

Multi-HTA Early Dialogues (ED) on evidence generation plans for new pharmaceuticals. These EDs aim to allow medicines developers to obtain simultaneous feedback on their development plans from multiple HTA bodies. The objective is to help generate optimal and strong evidence that satisfies the needs of HTA bodies.

Horizon Scanning (HS)

Horizon Scanning, Topic Identification, Selection and Prioritisation for European cooperation on HTA draft recommendations will be published on the EUnetHTA website during 2019.

National Implementation (NI)

The National Implementation service provides detailed usage of EUnetHTA assessments and practical case studies of how assessments are being used. Find out more niceeunethta@nice.org.uk

It all starts at eunethta.eu

Find how more
https://www.eunethta.eu
or contact us
eunethta@zinl.nl

PARTNER PROFILES

UNITED KINGDOM

It is not an understatement that without the contributions and efforts of the United Kingdom, EUnetHTA would not be where it is today. The United Kingdom has played a major part in the development and evolution of HTA cooperation in Europe. The UK has been a dedicated contributor to the EUnetHTA project and subsequent joint actions, as well as the EUnetHTA Executive Board.

As the UK continues to explore its future, our UK partners have steadily produced deliverables and enriched continued HTA cooperation in Europe. EUnetHTA extends sincere gratitude and appreciation for our partners Healthcare Improvement Scotland (HIS), the National Institute for Health Care and Excellence (NICE) and All Wales Therapeutics and Toxicology Centre (AWTTC). We know they will be valued partners for HTA cooperation in Europe and vital members of the EUnetHTA family in the future.

In the United Kingdom guidance about the use of health technologies is decentralised to each of the four countries. NICE guidance officially applies to England and Northern Ireland. In Scotland guidance is produced by HIS and in Wales for pharmaceuticals by AWTTC and for other technologies by Health Technology Wales (HTW). Certain NICE products and services are also used in Wales, Scotland and Northern Ireland. Decisions on how NICE guidance applies in these countries are made by their administrations. Each country also funds their own programme of Health and Care research that includes HTA and HTA-related activities, for example the National Institute for Health Research (NIHR) provides HTA for some NICE guidance.

The UK agencies in EUnetHTA work to support the benefits of collaboration and reduced duplication that Joint Action 3 aims to address.

HIS – SCOTLAND

Healthcare Improvement Scotland

Healthcare Improvement Scotland's (HIS) purpose is to have better quality health and social care for everyone in Scotland. Scottish Medicines Consortium (SMC) and Scottish Health Technologies Group (SHTG) are two key parts of HIS with specific roles in health technology assessment.

Scottish Medicines Consortium

SMC was formed in 2001. It provides advice to NHS boards and their Area Drug and Therapeutics Committees (ADTCs) across Scotland about the status of all newly licensed prescription only medicines (POMs) and all new formulations and new indications of established POMs. SMC aims to make this advice available as soon as practical after the launch of the medicine.

The horizon scanning function of SMC was introduced in 2005. Its aim is to improve financial planning at health board level through the provision of early intelligence on new medicines in development. A key output is the annual horizon scanning report, Forward Look.

SMC has been involved in EUnetHTA Joint Action 2 and joint action 3 and is currently involved in WP4 and 7.

Scottish Health Technologies Group

The Scottish Health Technologies Group (SHTG) is an advisory group set up to support planning and decision making in Scotland on the adoption and use of healthcare technologies, excluding medicines.

The group provides advice on the clinical and cost effectiveness evidence relating to existing and new technologies likely to have significant implications for the healthcare system and/or patient care in Scotland. The group also considers other aspects of healthcare technologies as required including organisational issues, patient and social issues and budget impact. It aims to promote greater awareness of the role of healthcare technologies, other than medicines, in delivering effective healthcare.

SHTG has been involved in EUnetHTA joint action 2 and joint action 3 and is currently involved in WP4 and 7.

EUnetHTA involvement

As Associated Partner

EUnetHTA Joint Action 3 (2016-20)

Work Package 7 – National implementation and impact

As Collaborating partner

EUnetHTA Joint Action 2 (2012-15)

JA2 WP5 – Applying the HTA Core Model for Rapid Assessment for national adaptation and reporting

JA2 WP7 – Methodology development and evidence generation: Guidelines and pilots production

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NICE – ENGLAND

NICE National Institute for Health and Care Excellence

National Institute for Health and Care Excellence (NICE) was set up in 1999 and works to improve the quality, sustainability and productivity of health and social care. NICE produces evidence-based guidance, standards and other resources to help health, public health and social care professionals deliver the best possible care with the resources available.

Its strategic objectives are:

· Deliver guidance, standards, indicators and evidence, using current and emerging digital technologies to help to achieve high-quality, sustainable services, supporting the health and care system to use its resources efficiently, and contributing to a thriving life sciences industry.

· Support the adoption of our guidance and advice and help maximise its impact by working with partners to produce practical tools and support.

EUnetHTA involvement

As Lead Partner

EUnetHTA Joint Action 3 (2016-20)

Work Package 7 – National Implementation and Impact

As Associated Partner

EUnetHTA Joint Action 3 (2016-20)

Work Package 1 – Network Coordination

Work Package 2 – Dissemination

Work Package 4 – Joint Production

Work Package 5 – Life cycle approach to improve Evidence Generation

Work Package 6 – Quality Management, Scientific Guidance and Tools

Work Package 7 – National implementation and impact

EUnetHTA Joint Action 2 (2012-15)

JA2 WP7 – Methodology development and evidence generation: Guidelines and pilots production

EUnetHTA Joint Action (2010-12)

JA WP4 – Core HTA

JA WP5 – Relative Effectiveness Assessment of Pharmaceuticals

JA WP7 – New Technologies

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AWTTC – WALES

AWTTC All Wales Therapeutics & Toxicology Centre

All Wales Treatment and Toxicology Centre (AWTTC) is a National Health Service (NHS) organisation working to make sure that all people in Wales can access clinically suitable and cost-effective new medicines as quickly as possible. It supports the best use of medicines to help patients in Wales to be healthier and better-informed. This is done by providing an understanding of prescribing and toxicology data to decision-makers, liaising with, informing and assisting healthcare professionals which involve patients and the general public, as well as engaging with the pharmaceutical industry.

AWTTC aims to be the authority on therapeutics and toxicology in Wales. Its work focuses on:

· Assessment of new medicines.

· Analysing trends in prescribing and improving the use of medicines in Wales.

· Producing guidance on best practices for prescribers.

· Improving medicines safety.

· Reporting serious suspected side effects of medicines (adverse drug reactions).

· Education and training for healthcare professionals and public/patient groups.

· Toxicology services and Specialist clinical services, the management of hypertension and suspected adverse reactions.

AWTTC is involved in EUnetHTA Joint Action 3 in National Implementation.

EUnetHTA Involvement

As Associated Partner

EUnetHTA Joint Action 3 (2016-20)

Work Package 7 – National Implementation and Impact

All Wales Therapeutics and Toxicology Centre

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EXPANDING DIALOGUE BETWEEN HTA BODIES AND STAKEHOLDERS

Written by Senior Scientific Officer Giovanni Tafuri, EUnetHTA

On 24 October 2018, I was invited to join a panel on 'Driving collaborative evidence generation and improving the scientific quality of evaluations' at the European Medicines Agency (EMA) within the workshop *Regulatory Science to 2025*.[1] The objective of the panel was to gather stakeholders' views on a variety of subjects regarding innovation, such as new clinical trial designs (e.g. basket and umbrella trials), precision medicine, the use of digital technology, artificial intelligence and Real World Data (RWD) in decision making. There is much to consider regarding innovation in HTA.

Having a view on these topics is not only challenged by a variety of HTA organisations and criteria across Europe, but mainly by the lack of concrete, positive examples in submissions made by manufacturers to the HTA bodies. As a consequence, the use of RWD in HTA, for example, is still mostly limited to the estimation of prevalence and incidence of diseases in relative effectiveness assessments, or the use of healthcare resources in cost-effectiveness assessments.

Secondly, there is a lack of agreed methodological frameworks at the HTA level. For instance, one of the potential challenges for the use of RWD is related to the way HTA bodies synthetize evidence. At this moment, for indirect comparisons and network meta-analysis, there is no single methodological accepted framework that can be used to pool evidence obtained from different study designs (randomised trials, observational studies and RWD). The same lack of an agreed framework applies to complex algorithms, artificial intelligence and health applications, although these technological advances are likely to emerge over the next ten years and pose several challenges to HTA.

In particular, algorithms that use artificial intelligence will aid decision making, providing clinicians and patients with predictions on expected prognosis and optimal treatment choices. This will require assessment of their ability to measure clinical utility in order to link these algorithms with the clinical outcomes in real life practice. However, existing economic evaluation methods appear to be insufficiently developed to evaluate them.

There are also ethical considerations. Although predictive and prognostic testing are extremely important for cost effectiveness purposes, tests for disease susceptibility biomarkers (e.g. BRCA1 gene mutation which indicates risk of breast and ovarian cancer) pose ethical issues which cannot be ignored by HTA bodies. For example, what are the consequences of testing positive for patients, their families and the health care system, especially where there is not enough evidence suggesting what to do (e.g. need to go through a mastectomy in case of BRCA1 mutation)? And how can current health-related quality of life instruments typically used in economic evaluations capture this? And finally, will we allow artificial intelligence to make decisions in situations such as end of life treatments?

As HTA bodies we should openly express our concerns to regulators about these challenges and engage in further dialogue and collaboration with them to make sure evidence requirements satisfy our needs. Multi-stakeholder synergies, not only with regulators, but also with academia and research institutions, will increasingly be needed to develop new methodological approaches that can be integrated into HTA guidelines.

[1]A six-month public consultation on the Regulatory Science strategy to 2025 has recently been launched by EMA. https://www.ema.europa.eu/en/news/regulatory-science-2025-launch-six-month-public-consultation

References

Love-Koh J et al. *The Future of Precision Medicine: Potential Impacts for Health Technology Assessment.* PharmacoEconomics 2018, Oct 26. doi: 10.1007/s40273-018-0739-x.

Barna A et al. *Evidence required by health technology assessment and reimbursement bodies evaluating diagnostic or prognostic algorithms that include omics data.* Int J Technol Assess Health Care. 2018 Jan;34(5):535

Hummel et al. *Methodological guidance, recommendations and illustrative case studies for (network) meta-analysis and modeling to predict real-world effectiveness using individual participant and/or aggregate data*. IMI Get Real. http://www.imi-getreal.eu/Publications/Deliverables-and-reports

PRIORITISATION LIST

EUnetHTA PRIORITISATION LIST (EPL)

https://www.eunethta.eu/assessments/prioritisation-list/

EPL

The EUnetHTA Prioritisation List (EPL) expresses the identified significant interest of national HTA bodies in relation to individual compounds as presented in the list. By pro-actively selecting those topics in direct collaboration with national bodies, EUnetHTA strives to increase implementation of Joint Assessments qualitatively and quantitatively at the national level.

There is a strong consensus within EUnetHTA that this approach will strengthen the methods and procedures of the pharmaceutical Joint Assessments to increase the benefits of EU cooperation on HTA and to shape the future model of collaboration. This facilitates national implementation and uptake of the Joint Assessments.

The EPL is based on the Innovation Observatory. The list was cross-checked with the open access Dutch Horizon Scan and the publicly available EMA list of medicines under evaluation to estimate regulatory timelines. In compiling the list, EUnetHTA partners were asked to indicate their interest, including using the assessment at the national level. The final prioritisation was based on this feedback and combined with the anticipated feasibility of the compatibility of timelines of the EUnetHTA assessment and estimated regulatory timelines. Therefore, prioritisation does not discriminate between pharmaceutical companies, compounds or indication. Of note, the EPL is an ad-hoc approach. As such, it will be evaluated and, in the future, may lead to a systematic approach.

The EPL stands complementary to the already well-established mechanism for voluntary submission of new compounds, which will continue in the future to run in parallel to the EPL.

Drug	Company	Indication	Type of submission	Expected year of positive CHMP opinion
Brolucizumab	Novartis	Neovascular age-related macular degeneration (nAMD)	NCE	2019
Cefiderocol	Shionogi	Severe gram-negative infections	NCE	2019
Darolutamide	Bayer	Non-metastatic, castration resistant prostate cancer	NCE	2019
Durvalumab	AstraZeneca	Advanced or metastatic non-small cell lung cancer (EGFR and ALK wild type) – first line	Type II variation	2020
Enasidenib	Celgene	Relapsed or refractory acute myeloid leukaemia (AML) with an isocitrate dehydrogenase 2 (IDH2) mutation	NCE	2019
ECCS-50 (Cytori Cell Therapy)	Cytori Therapeutics	Moderate to severe hand dysfunction due to scleroderma	NCE	2019
Lenti-D	BlueBird Bio	Cerebral adrenoleukodystrophy	NCE	2020
Rexmyelocel T	Rexgenero	Critical limb ischemia in patients with diabetes mellitus	NCE	2020
Ribociclib + alpelisib +fulverstrant	Novartis	HR-positive, HER2 negative postmenopausal breast cancer – second or third line	NCE (alpelisib)	2019
Ribociclib + fulvestrant	Novartis	Advanced HR positive, HER2-negative breast cancer in postmenopausal women, first or second line	Type II variation	2019
Satralizumab	Chugai Pharma	Neuromyelitis optica spectrum disorders	NCE	2019
Selonsertib	Gilead	Non-alcoholic steatohepatitis (NASH)	NCE	2019
Setmelanotide	Rhythm Pharmaceuticals	Pro-opiomelanocortin deficiency obesity	NCE	2019
Voxelotor	Global Blood Therapeutics	Sickle cell disease	NCE	2020

2018 in review

DEC

December 7: EUnetHTA-EMA bilateral, London. December 11: EUnetHTA- EFPIA Technical Meeting, Paris. Finalisation of Early Dialogues procedure for medical devices for launch in January 2019. EUnetHTA reaches social media milestone with 1200 followers on LinkedIn and 1600 followers on Twitter.

Final assessment: OTCA06 Transcatheter aortic valve implantation (TAVI). Project plan: OTCA19 Screening for osteoporosis in general population

NOV

EUnetHTA Prioritisation List (EPL) published. Implementation Report published. First pilot Early Dialogue for a medical device held. Relapsed or refractory Acute Myeloid Leukaemia (AML) patient group consultation begins. High-risk soft tissue sarcoma patient group consultation concludes.

Project plan: OTCA11 3D-printed implants versus non-3D printed standard implants.

OCT

Uses of EUnetHTA assessments reaches 100. October 1: HTA legislative proposal passes plenary vote in European Parliament. EUnetHTA publishes fall magazine: MEP Soledad Cabezón Ruiz; AIFA, Italy.

Final assessments: OTCA07 Femtosecond laser-assisted cataract surgery (FLACS). Project plans: PTJA03 Alecensa as monotherapy; OTCA15 Irreversible electroporation; OTCA17 Lithium triborate (LBO) laser.

AUG-SEPT

Diabetes Type 1 patient group consultation concludes. September 12-13: Amendments to HTA legislative directive adopted by ENVI, the Health and Food Safety Committee. EUnetHTA publishes summer magazine: EURORDIS, AOTMiT, Lithuania, Non-Duplication: What's in it for us?

Project plans: OTCA16 Bioresorbable Stents in cardiovascular indications (coronary artery disease).

JULY

July 1: Austria assumes Presidency of EU Council and seeks partial-general agreement for the first eight articles of HTA legislative directive. July 5: EUnetHTA-EMA bilateral, London. July 9: Over 300 policy makers, health care providers, patient representatives and other experts meet in Brussels and discuss views about the future cooperation on HTA.

Final assessments: OTJA08 Continuous glucose monitoring (CGM real-time). Project plans: OTJA10 Stool DNA testing; OTCA14 Robotic surgery in thoracic and visceral indications.

JUNE

Public consultation of Early Dialogues for medical device developers. National Implementatation report published (highest social media and webpage hit rate to date).

MAY

May 15: EUnetHTA Executive Board elects Chair Niklas Hedberg (TLV), Vice-Chairs Zoe Garrett (NICE) and Chantal Belorgéy (HAS), Dublin. May 25: Assembly and Forum: Cologne, Germany - including but not limited to DG Sante, EPF, HAI, UEMO, EFPIA, EMA, CADTH. Active live-streaming, social media and discussion about future of HTA cooperation in Europe. May 29: 1st EUnetHTA Workshop on HTA and Medical Device Regulation (MDR)/Invitro Diagnostics Regulation (IVDR), Vienna.

Final assessments: OTCA09 High-intensity focused ultrasound (HIFU). Project plans: OTCA12 C-reactive protein point-of-care testing (CRP POCT); OTJA08 Continuous glucose monitoring (CGM real-time); OTJA08 Continuous glucose monitoring (CGM real-time) and flash glucose monitoring (FGM).

MAR-APR

EUnetHTA.eu rebuilt and relaunched. April 20: Heads of Agency meeting, Brussels. First multi-HTA collaboration on post-launch evidence generation (PLEG) launched. EUnetHTA publishes spring magazine timed to Assembly and Forum: Scotland/HIS; BEUC; Denmark, Norway and Sweden; NCPE.

Final assessments: OTCA04 Gene-expression signature for adjuvant chemotherapy decisions; OTCA03 Screening of fetal aneuploidies whereby non-invasive prenatal test (NIPT). Project plans: OTCA09 High-intensity focused ultrasound (HIFU); OTJA08 Continuous glucose monitoring (CGM real-time); OTCA07 Femtosecond laser-assisted cataract surgery (FLACS).

JAN-FEB

January 31: A legislative proposal was adopted by the European Commission.

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