eunethta magazine

SUMMER 2018

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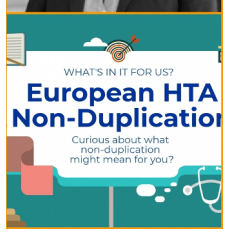

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EUnetHTA Magazine

eunethta.eu

@EUnetHTA

eunethta@zinl.nl

HOW TO GET INVOLVED

General information and stakeholder involvement: EUnetHTA@zinl.nl

Questions about general assessment production: WP4.LP_EUnetHTA.JA3@fhi.no

EUnetHTA assessments on Pharmaceuticals: WP4_Pharmaceuticals@zinl.nl

EUnetHTA assessments on Other Technologies: sabine.ettinger@hta.lbg.ac.at, judit.erdos@hta.lbg.ac.at, julia.mayer@hta.lbg.ac.at

Early Dialogues: EUnetHTA-HAS@has-sante.fr

EMA/EUnetHTA Parallel Consultations: EUnetHTA-HAS@has-sante.fr

National Implementation: NICEEUnetHTA@nice.org.uk

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EUnetHTA JOINTLY PRODUCED HTA REPORTS*

What are Joint and Collaborative Assessments?

EUnetHTA Joint Assessments (JA) are Health Technology Assessments (HTA) jointly 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 that are subject to extensive review procedures in order to ensure high quality. 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. CAs facilitate timelines that are aligned with national work programmes and contribute to the sustainability of assessment production after 2020 due to decentralised coordination.

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 - 2018

IS IT LIGHTS OUT FOR THE HTA LEGISLATIVE PROPOSAL?

HTA LEGISLATIVE PROPOSAL

In 2016, the European Commission launched the formal process to strengthen EU cooperation on Health Technology Assessment in response to calls from EU countries, the European Parliament, and interested parties to ensure its sustainability beyond 2020. In its 2017 Work Programme, the European Commission announced that a key objective would be to reduce the duplication of work for national HTA bodies.

How was EUnetHTA involved?
EUnetHTA was consulted during the drafting process and the work of the EUnetHTA Consortium will be used as the basis of cooperation beyond 2020.

An unprecedented heat wave gripped much of Europe this summer, putting demands on the European electrical grid system. The system, however, managed to handle the unexpected demand and is intact. Like that large international and cooperative electrical system, the HTA Legislative Proposal has weathered difficulties but is also still intact. While some Member States have legitimate and justifiable concerns, the HTA Proposal has also been broadly supported by a coalition of Member States, industry, health professionals and patients who see real benefits in European HTA non-duplication.

Commissioner Andriukaitis, passionately speaking at the July 9th event "The Way Forward for HTA Cooperation – the Views of Stakeholders" in Brussels, where over 300 policy makers, healthcare providers and patient representatives discussed future cooperation on Health Technology Assessment, said, ”We understand the need to fully respect the competences and the diversity of Member States. We believe that adequate and balanced solutions could be explored and we are open to engage in and facilitate this discussion with the co-legislators.”[1]

Participants at "The Way Forward for HYA Cooperation" gave important recommendations on the way forward:

Engaging with patients and clinicians on HTA. *Transparent and systematic engagement with stakeholders is needed, both on product-specific reports and on a broader strategic level. The involvement of patients and health professionals in the joint clinical assessment guarantees that the reports consider patient-relevant endpoints. Appropriate resources such as training are needed to enable their contributions.*

Generating evidence that meets the needs of patients and health system decision makers. *A higher involvement of stakeholders will generate the relevant evidence that meets the needs of the health system decision-makers (including regulators, HTA and payer bodies) and that is also relevant for patients. The issue of transparency is key for the success and acceptance of the exercise.*

Managing uncertainty in the post-launch phase. *Post-launch evidence is a key component of the re-assessment of health technologies. Registries and real world data form an important part of the body of evidence on the effectiveness and efficacy of medical devices. The EU’s Digital Single Market offers numerous opportunities for interoperable ICT solutions, common standards, data security and digital competences.*[2]

EUnetHTA, as always, remains neutral, but our work through three Joint Actions and the contributions of our 81 partner organisations and institutions is the basis of future cooperation. While the future of the HTA Proposal is uncertain, there is a very stark reality that will most likely happen if consensus cannot be formulated: there will be no Commission funding for European HTA cooperation post 2020.

It remains to be seen what will become of the work of our partners, or the substantial efforts of the EUnetHTA Secretariat to build a lasting framework for cooperation. However, no agreement seems a waste of genuine, well-intentioned and dedicated European cooperation. HTA cooperation produces and will produce very tangible benefits not only for patients, but also improve the quality and sustainability of health systems at when Europe needs them most.

What are these tangible benefits?
Regardless of the outlying altruistic nature of the HTA Proposal, non-duplication saves hard cash while serving the interests of stakeholders, especially patients, who are or should be at the heart of everything we do. Indeed, all stakeholders benefit from non-duplication. Member of European Parliament Soledad Cabezon might have said it best by remarking, “The right to health is a fundamental right and a key factor for social cohesion and productivity. European HTA is about giving patients the best possible healthcare alternatives.”[3]

When looked at in an overarching visual way (back page), passage of the HTA Proposal might come down to the bottom line: the Proposal will save time, money and effort, if given the chance.

While the future is uncertain for the HTA Proposal, EUnetHTA will continue to serve the needs of all its stakeholders and do its utmost to continue to provide its deliverables under our mandate until 2020. European HTA cooperation is a long end-game that, left unresolved, will have repercussions on European health long past 2020. Commissioner Andriukaitis also said on July 9th, “Europe cares for patients.” The HTA Proposal is “...an opportunity to establish a mechanism that ensures that HTA is used to its maximum potential.”[4]

When extra power is needed, Europe has built a system to send power where it is needed most. It is also not lights out for the HTA Proposal. Europe reaches consensus and builds systems through frank dialogue and the viewpoints of participants. The HTA Legislative Proposal is no exception.

[1] https://twitter.com/EU_Health
[2] https://goo.gl/TttGh5
[3] https://twitter.com/EU_Health
[4] https://goo.gl/TttGh5

NATIONAL IMPLEMENTATION AND IMPACT

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

USE OF EUnetHTA ASSESSMENTS BY THE STATE HEALTH CARE ACCREDITATION AGENCY, LITHUANIA

This article is part of the work of EUnetHTA's National Implementation and Impact

VASPVT (The State Health Care Accreditation Agency, Lithuania) has an HTA department that produces HTAs of non-pharmaceutical health technologies. The agency is under the Ministry of Health (MoH) and the department supports decision making processes within the MoH about the use of non-pharmaceutical health technologies in Lithuania. The HTA department was established in 2011 and its work is guided by a national HTA strategy that was developed in 2015. The department produces two to three de novo HTAs each year and also carries out adaptations of HTA produced by other countries. VASPVT have been involved in EUnetHTA since the first Joint Action. In JA3 they have been co-authors for the assessment of HIFU (OTCA09), dedicated reviewers for the assessments of antibacterial sutures (OTCA02) and irreversible electroporation in liver and pancreatic cancer (OTCA15) and observers for Femtosecond laser-assisted cataract surgery (OTCA07).

Working practices

Topics for assessment are usually proposed by technology distributors or the MoH but can also be proposed by stakeholders. VASPVT works with an Evaluation Committee under the MoH to support topic selection and prioritisation. The Minister of Health approves a list of prioritised topics for which VASPVT will do HTA. Once the HTA is complete, VASPVT prepares conclusions and recommendations about the technology. The evaluation committee is authorised by the MoH to make a decision about whether to propose the technology for implementation, and if the decision is positive,whether the technology should be sent to the National Health Insurance Fund for implementation. The completed HTA is published on the VASPVT website.

Use of EUnetHTA assessments

VASPVT has adapted three EUnetHTA JA3 assessments: OTCA01 wearable cardioverter-defibrillator, OTCA02 antibacterial sutures and OTCA09 high-intensity focused ultrasound. VASPVT acted as reviewers for OTCA02 and co-authors for OTCA09 and committed to carrying out an adaptation of these assessments. OTCA01 was chosen as being particularly relevant to the Lithuanian context because of a high prevalence of cardiovascular disease. VASPVT used the availability of these assessments as an opportunity to raise awareness at the MoH of the findings in the reports.

VASPVT prepared a summary in Lithuanian of the EUnetHTA assessment. All sections of the EUnetHTA report were used to prepare the summary including information from the four domains of the Rapid Effectiveness Assessment (REA) (health condition, technology description, effectiveness and safety) and also the legal, social and organisational aspects. The summaries prepared had slightly different structures and lengths reflecting the different reasons for carrying out the adaptations, differences in the EUnetHTA reports (for example the length of text in the anti-bacterial sutures report) and evidence available.

No changes to the contents of the EUnetHTA report were made. However, local information was added to the summary including the use of the technology in Lithuania, and assessment of the functional value of the technology against given criteria, recommendations and conclusions. The assessment of the functional value of the technology is included in all assessments completed by VASPVT at the request of the MoH.

As Lithuania has very limited human resources for HTA, EUnetHTA assessments are helpful in allowing them to save time by adapting an assessment rather than starting an assessment from the beginning. Using EUnetHTA assessments also supports a high quality of information. EUnetHTA assessments include a range of experts, professionals and information that VASPVT can draw on this when preparing its adaptations. By freeing up staff time, EUnetHTA assessments help VASVPT to assess more health technologies per year that can be presented to the MoH.

This interview was carried out as part of the EUnetHTA implementation network.

***Grateful acknowledgement* to** Vitalija Mazgelė and Kristina Grigaitė

INTERVIEW: EURORDIS

EXPANDING DIALOGUE BETWEEN HTA BODIES AND STAKEHOLDERS

From EURORDIS' Twitter feed: An alliance of rare disease patient organisations working together to improve the lives of 30m people living with a rare disease in Europe.

https://www.eurordis.org - @eurordis

Each quarter, EUnetHTA Magazine asks three questions to key stakeholders. For our Summer edition, we talked with Matteo Scarabelli, HTA Patient Engagement Manager, and François Houÿez, Director of Information and Access to Therapies and Health Policy Advisor, of **EURORDIS**, a non-governmental patient-driven alliance of patient organisations representing 808 rare disease patient organisations in 70 countries.

WHAT IS EURORDIS?

Officially instituted in 1997 to support the adoption of the EU Regulation on Orphan Medicinal Products, EURORDIS is a non-governmental patient-driven alliance of more than 660 rare disease patient organisations across the 28 EU Member States and 800+ patient organisations worldwide.

Rare diseases are defined in the EU as disorders that affect less than 1 person in 2,000. An estimated 6,000 distinct rare diseases exist, of which 1,200 have more than five published cases. All together, they are estimated to affect 30 million people in the EU.

EURORDIS seeks to improve the life of people living with rare diseases. Its mission is to support research policies, facilitate networking, and raise awareness among their members and the wider EU patient community about the therapeutic, regulatory, and legal issues concerning their condition and quality of life.

Through dedicated training programmes, information campaigns, and the constitution of patients' Task Force on Treatment and HTA, EURORDIS organises and supports the active participation of patients in research and development, regulatory activities, health policies development, partnership with researchers, scientists and, more recently, with HTA agencies.

EURORDIS achieves its mission to be the public voice of the rare diseases community through patient empowerment assets such as programmes like the Open Academy, and the Community Advisory Boards, together with regular activities such as mentoring patients programme for involvement at EMA and in HTA. In addition to a series of surveys carried out over the years, the Rare Barometer Survey aims at ensuring that EURORDIS advocacy work is systematically based on a patient perspective. Moreover, EURORDIS attends and organise scientific and policy conferences, such as the European Conference on Rare Diseases, on a two years basis.

Liaising with others patients and consumers organisations, EURORDIS cooperates with EMA in patient engagement, documents review, consultations and definition of priorities, and has been involved in EUnetHTA since the first Joint Action.

EURORDIS IN EUnetHTA

EURORDIS participated in the early stages of the EU cooperation through its role in the EUnetHTA Stakeholder Forum during JA1 and JA2, contributing to the preparation of guidelines and the definition of methods. In addition, EURORDIS was invited to help the identification of patients to take part in HTA Early Dialogues during the SEED Project and is now cooperating with JA3 Partners to set and improve Patient Engagement procedures.

EURORDIS has many expectations for JA3 concerning the selection of relevant topics for joint HTA, the improvement of patient engagement, the clarity of the reports for professionals and the public, and the preparation of future permanent cooperation.

As one of the premiere representatives of Patients and Consumers, EURORDIS has contributed to the HTA Network's reflections and to the definition of its programmes and strategies, including Strategy for EU cooperation on HTA (2014), Reuse of Joint Work in national HTA activities (2015), Synergies between Regulatory and HTA issues on pharmaceuticals (2016), and HTA Network Multi-Annual Work Programme (2016-2020). Particularly, especially in the last two years, EURORDIS has provided its input to the shaping of the EC legislative proposal for future European permanent cooperation on HTA.

PATIENT ENGAGEMENT: INVOLVING PATIENT EXPERTS

Another way EURORDIS is achieving its objectives is through the engagement of patient experts in scientific discussions and the decision-making process. Patients have their own experience of the disease. Such a personal knowledge and real-life perspective are a source of objective information and evidence for assessors of a health technology or programme. This is the main value that patients can bring if they are correctly involved, as they have something to say about all aspects of HTA, and in particular about the description of benefits and secondary effects, or organisational and social aspects. That is why it is vitally important that patients understand what HTA is, how it is performed and for which purposes, and, finally, what role they can play.

EURORDIS has always been engaged in mentoring patients for Regulatory as well as for HTAs procedures, by not only identifying the right profiles, but also by introducing and accompanying them through the understanding of the procedure and contents, towards a

direct and personal interaction of patients with the assessors.

Moreover, ensuring that patients are able to understand the outcome of HTA is also a guarantee of visibility and transparency for the public, as the interest of patients and that of the general public to be informed are fully aligned. That is also the basic reason of our work, namely to support the patients' right to be involved in decisions affecting their lives and let such an involvement be effective and recognized.

THE FUTURE OF HTA

After more than 20 years of cooperation in HTA, EURORDIS realises the potential and the limits of voluntary cooperation. Acknowledging these factors is a necessary step to develop long-term and effective cooperation. If the future cooperation as foreseen by the European Commission is the logical extension of the current work, the best legacy EUnetHTA could leave is a set of clear methods and procedures, agreed to by all actors from assessors to patients and consumers, together with greater confidence among partners.

1. These are dynamic times for medicine and health, providing unique challenges but also unseen opportunities. Is European cooperation on HTA reaching its potential with respect to informing European and national policies in the field of rare diseases?

EURORDIS: Since the 1990s, European projects such as EUR-ASSESS have proven that cooperation on HTA at the European level is feasible, although the main goals have yet to be reached. In fact, after the discussions about the guidelines, the source of data and on some important organisational issues, we are looking forward to seeing cooperation in HTA delivering a truly European outcome, shaped jointly and fully recognised by all actors. Indeed, as the uptake of the joint work at national level and the application of agreed guidelines remain voluntary, the cooperation's effectiveness is strongly limited. What has been achieved so far shows that the cooperation can work, but also that cooperation on a voluntary basis only is not enough to ensure that decision-making on coverage and reimbursement is systematically evidence-based.

Bringing the most valuable information to all national actors is the first way to inform policies on rare diseases, as well as decision makers and experts in the definition of treatment and care management guidelines.

2. Where and how does EURORDIS see greater patient involvement in topic selection for EUnetHTA products and services?

EURORDIS: First, the patient involvement mechanism as a whole is a learning-by-doing process. That is why it has to be improved starting from some simple issues, such as communication and timing. We need improvement on both sides (EUnetHTA and patients/consumers organisations) by working continuously together so as to build mutual trust.

For instance, during Joint Action 3 and for the first time, patients submitted a topic proposal for the assessment of a medical device with a significant cross-border dimension for a rare disease. In spite of the result, the main difficulty was to understand the EUnetHTA internal decision-making process and the questions on which the decision were based. Indeed, it seems to us more relevant to know if we need a technology to be assessed jointly than if any health authority has ever expressed an interest in that technology. So, the point remains the improvement of coordination between patients and consumers organisations and EUnetHTA, which could be reached by fostering a dialogue on a scientific/medical level with HTA experts, clinicians and patients, to decide which technologies should be assessed jointly. For this, more needs to be done together to raise mutual trust about what patients can bring and how, from the early and fundamental steps, such as drafting of the rules of procedures and identification of emerging technologies.

3. In light of EURORDIS' mission to improve the quality of life for people living with rare diseases in Europe, how can EUnetHTA's current and planned activities purposely better assist in that mission?

EURORDIS: EUnetHTA has to build mutual trust between all HTA actors and refine and assimilate agreed methods, so as to prove that it is possible to work together and provide accurate evidence-based HTA reports, bringing solid information on health technologies to decision-makers everywhere in the EU.

In particular, the main contribution for people living with rare disease, from an HTA perspective, would be to fully assume the importance of considering quality-of-life (QoL) as essential as the main clinical domains, such as clinical efficacy and safety. Patients want, of course, to live longer, but not necessarily to the detriment of their quality of life. A major advantage in terms of quality of life might be seen as more valuable than a minor increase of survival. On that point, EURORDIS sees a main contribution HTAs can bring its cooperation with Regulators.

In general, if we consider a treatment that is proven to ensure a higher rate of survival than another one and if this gain overwhelms the risks, even affecting QoL, Regulators are more likely to grant a positive opinion to it. Inversely, HTAs can consider reimbursing a treatment that ensures a significant improvement in QoL even with no increase of a slight reduction of survival compared to the first.

Indeed, patients might want more life in their days than more days in their lives. Therefore, if patients agree that it is better to prolong survival for four months with a preserved QoL (Treatment A), rather than prolong life for six months with a deteriorated QoL (Treatment B), HTAs can accept this logic and report that to decision-makers.

This is why an HTAs-Regulators dialogue prior to the marketing authorisation is not just welcome but needed, and we support any initiative in this direction, such as the strategy to establish synergies between EMA and EU HTA cooperation. In that sense, the creation of a permanent scientific secretariat for HTA at EU level with adequate resources is the best way to achieve this purpose.

Grateful acknowledgment to Matteo Scarabelli and François Houyez

PARTNER PROFILE

POLAND

Poland has experienced a nearly miraculous turnaround in its economic fortunes since the change of government in 1989-1991. The country has had nearly constant growth, and even managed to avoid the 2009 financial crisis, to become the largest economy in the Eastern grouping of EU Member States. Perhaps more than anything, this growth may be due to the hard-working and dedicated efforts of the Polish people.

Poland also plays an important role in Health Technology Assessment. The Agencja Oceny Technologii Medycznych i Taryfikacji (Agency for Health Technology Assessment and Tariff System), know by its acronym AOTMiT, is a vital member of the EUnetHTA network, participating in all three EUnetHTA Joint Actions and the EUnetHTA Executive Board.

AOTMiT

AOTMiT's mission includes:

- Preparing reports on the assessment of healthcare services;
- Preparing the Agency's verification analyses regarding the assessment of a medicine, a foodstuff for particular nutritional purposes, or a medical device;
- Issuing opinions on health programs of ministers and local government units;
- Issuing the President's recommendation regarding:
  - Qualifying a given health care service as a guaranteed benefit along with specifying the level or method of its financing;
  - Removal of a given healthcare provision from the guaranteed services list;
  - Changes in the level or method of financing the guaranteed benefit;
  - Reimbursement of a given drug, a foodstuff for particular nutritional purposes, a medical device;

Participation in EUnetHTA

- EUnetHTA Joint Action (2010-12)
  - Coordination
  - Core HTA
  - Relative Effectiveness Assessment of Pharmaceuticals
  - New Technologies
  - Strategy and Business Model Development
- EUnetHTA Joint Action 2 (2012-15)
  - Applying the HTA Core Model for Rapid Assessment for National Adaptation and Reporting
  - Methodology Development and Evidence Generation: Guidelines and Pilots Production
- EUnetHTA Joint Action 3 (2016-20)
  - National Implementation and Impact
  - Life Cycle Approach to Improve Evidence Generation
  - Quality Management, Scientific Guidance and Tools

Participation in International HTA Projects

AOTMiT participates in many international HTA projects including:

- **HTAi** - Health Technology Assessment International
- **INAHTA** - International Network of Agencies for Health Technology Assessment
- **MEDEV** - Medicine Evaluation Committee
- **ISPOR** - International Societies for Pharmacoeconomics and Outcomes Research

aotmit.gov.pl

STAKEHOLDERS

EXTENDING ENGAGEMENT

EUnetHTA Increases Direct Engagement for Evidence Generation, National Implementation and Patients Group

With the successful rebuild of EUnetHTA.eu, EUnetHTA has been able to extend its reach to stakeholders.

Evidence Generation

Following on the successful launch of the Joint Action 3 procedures for EUnetHTA Early Dialogues (ED) for Pharmaceutical products, EUnetHTA Evidence Generation Lead Partner HAS successfully conducted (now closed) a public consultation on Early Dialogues for Medical Devices.

The procedure is a single gateway for Early Dialogues with European HTA bodies on their evidence-generation plans for medical devices.

National Implementation and Impact

Have you used a EUnetHTA Assessment and are not a member of the EUnetHTA network? We would like to get your feedback about how and when you used the assessment. National Implementation and Impact now has the capability of conducting password-protected usage surveys to users of EUnetHTA HTAs outside the EUnetHTA network. The survey is available **HERE** and by contacting National Implementation and Impact Lead Partner NICE at NICEEUnetHTA@nice.org.uk

Patients Group

EUnetHTA is excited about greater patient involvement. We recognise that patients and those who support them have unique knowledge about what it is like to live with a specific disease or medical condition. We believe patient groups can help us understand patients' unique perspectives by collecting and presenting patients' and carers/care-givers' views and experiences by engaging with a wide range of patients. EUnetHTA recently started a new Joint Assessment on a medicinal product for the treatment of Type 1 Diabetes. For this specific assessment on a medicinal product for Type 1 Diabetes, an 'open call for patient group submission' is being used.

EUnetHTA extended the Type 1 Diabetes patient survey, found HERE until August 22, 2018. EUnetHTA strives to be transparent in the information used. We commit ourselves to making all patient submissions publically available on our webpage, at the timing of publication of the project plan for this assessment. In due course, this can be found **HERE**. Of course, we will anonymise the data from individual patients prior to publication.

EUnetHTA IN SOCIAL MEDIA

REAL-WORLD METHODOLOGY APPLICATION

EUnetHTA usually checks social media at least once a day. We promote the work of our partners as well as stakeholder engagement and events. Imagine our surprise when Marta Rodriquez Millan, a student at Maastricht University, gave a round of thanks on LinkedIn:

Today (I) had the pleasure of presenting my Master Thesis Dissertation to the B1 Health Systems Performance Assessment at the European Commission, DG SANTE. The topic was "A systematic literature review report of Costs and Economic Evaluation: The addition of ultrasonography as part of the universal screening of breast cancer in combination with mammography in women aged 40-74". For this thesis I used EUnetHTA - European Network for Health Technology Assessment methodology to structure my results. Thank you again to the wonderful comments and feedback on the topic from the colleagues , it was great to have such interesting and insightful conversations.

Beside a human interest piece, Marta reminded us that HTAs are of little use unless someone is using them. That is why we are here. It also never hurts to remember that HTAs aren't "things on a shelf"; there are real people behind everything we do.

We reached out to Marta to ask her about her work. Marta responded, "I have just written my Master Thesis at Maastricht University, regarding the methodology of Health Technology Assessment (HTA). I was able to conduct an economic-based study surrounding the factors that subsidize to the cost-effectiveness of the addition of ultrasonography as part of the universal screening of breast cancer in combination with mammography in

women aged 40-74 using the EUnetHTA Core Model. The methodology of EUnetHTA has been of interest to me because of the great potential that it has and the ability to structure all relevant information so that it can be used for policy makers to make decisions. I hope to one day be working for an organization that uses the knowledge of EUnetHTA methodology to analyze new technologies in Europe."

Congratulations, Marta!

GOVERNANCE

EUnetHTA ELECTS A NEW EXECUTIVE BOARD

At a May 2018 session held in Dublin, the recently elected and reformed EUnetHTA Executive Board (ExB) was installed. The representative position of EUnetHTA **Director** and corresponding duties have been transformed into the newly duly-elected **Chai**r of the EUnetHTA Executive Board. This is the first but important step in a new phase of collaboration that potentially supersedes a project character and continues the opportunity to build a sustainable future for collaboration post 2020. Niklas Hedberg, of the Dental and Phamaceuticals Benefit Agency, Sweden (TLV) was elected Chair. Zoe Garrett, of the National Institute for Health and Care Excellence, UK (NICE) and Chantal Bélorgey, of the French National Authority for Health, France (HAS) were elected Vice-Chairs.

EUnetHTA Magazine asked the new Chair and Vice-Chairs about the change to governance and future contributions to EUnetHTA:

1. The change to governance for the ExB is bold and will create new opportunities for EUnetHTA. How can the ExB better serve the needs of EUnetHTA?

2. In your unique role with your institution, what contribution do you believe you can make to EUnetHTA during your term?

CHAIR NIKLAS HEDBERG

Biography

Niklas Hedberg is the Chief Pharmacist at the Swedish governmental authority, the Dental and Pharmaceuticals Benefits Agency (TLV), in Sweden.

Since May 2018, Niklas is the Chair of the EUnetHTA Executive Board. He has been a member of the EUnetHTA Executive Board and EUnetHTA lead partner for Evaluation (TLV) since June 2016.

Niklas has been involved in the national pricing and reimbursement decision making for pharmaceutical products since 2001, and for medical devices since 2009. He has broad experience in different aspects of value-based evaluation. Since 2009, Niklas has had a special interest in joint scientific advice.

Between August 2009 and March 2014, Niklas was the Head of the Department for Pharmaceutical Submissions at TLV. Before that he held positions as investigator, medical assessor and project leader in the agency.

From Chair Hedberg

By introducing an enforced governance structure, the ExB has shown that we are willing to take a bigger responsibility for the success of EUnetHTA than before. The new governance includes clarifying our roles, adapting the meeting cycle, opening up for more strategic discussion in the Board, identifying and closely following the biggest risks in the project and electing one chair and two vice-chairs for the ExB. The ExB can be more present and visible for EUnetHTA partners and can clearly point out the direction the project needs to go. One important early step is to make meeting notes from the ExB meetings available for EUnetHTA partners.

Personally, I am proud to be a member of the ExB and its elected Chair. As part of the Lead Partner on Evaluation, I bring an evaluation perspective with me which I think can be of benefit in this situation when the ExB needs to look back, reflect and to some extent re-think to make sure the second half of the project comes with increased output in terms of production, implementation, added value and a basis for a sustainable network, however that may look after the political process going on right now.

VICE-CHAIR ZOE GARRETT

Biography

My academic background is in speech and language therapy and health services research. I joined NICE in 2005 as a Health Technology analyst in the Technology Appraisals team supporting the NICE Appraisal Committee to make recommendations about the use of pharmaceuticals and medical devices in the National Health Service. I was involved in the first NICE single technology appraisals and also helped set up the NICE scientific advice programme. I moved to EUnetHTA in Joint Action 2, leading the development of the Evidence Submission Tool, before managing National Implementation and Impact in Joint Action 3 (JA3).

From Vice-Chair Garrett

Collaborative HTA has the potential to improve resource issues faced by many agencies and to support evidence-based decision making about health technologies for a range of HTA users. The Executive Board has a fundamental role in ensuring that a permanent mechanism of HTA cooperation is able to respond to the needs of all EUnetHTA partners. Through my role managing National Implementation, I would like the Executive Board to understand the user needs of all partners.

The success of EUnetHTA relies on the contributions of all its partners to meet its objectives: to support implementation of its outputs and to create a sustainable model of HTA cooperation for the future. To meet the needs of partners, it is important for the Executive Board to listen to partners, be willing to suspend their own beliefs and for the voices of all partners to be seen as valid and equally important. Partners must be able to scrutinize the procedures and the decisions made by the Executive Board, because the decisions made during JA3 have the potential to affect everyone in the future.

VICE-CHAIR CHANTAL BÉLORGEY

Biography

Chantal Bélorgey, MD, PhD, is the Head of the Health Technology Assessment and Public Health Division at the French Health Authority (Haute Autorité de Santé - HAS). The division is in charge of providing scientific expertise (clinical and medico-economics) for health technologies reimbursement and price decisions. It covers pharmaceuticals, medical devices and other technologies including public health recommendations. Within EUnetHTA, HAS leads Evidence Generation in charge of Early Dialogues.

From Vice-Chair Bélorgey

Before becoming Head of the HTA division at HAS in June 2016, I led the Department of Recommendations, Medicines and Quality of Expertise at the French National Cancer Institute (INCa). Previously, I was advisor to the Minister of Health (2012-2014) in charge of Health Technologies. I served for 19 years at the French National Agency for Health Products Safety (ANSM) where I was heading the Division of Medicines in Onco-Hematology and the Department of Clinical Trials Assessment and Expanded Access Medicines. I have never witnessed, in my career, the arrival of so many innovative and disruptive technologies (pharma but also MD/IV diagnostics) on the market. More and more, HTAb must assess these new technologies which are launched despite a low set of evidence and a high degree of uncertainty. To face this new challenge, HTAb would definitely benefit from EU cooperation via further early dialogues with industry to give consolidated recommendations on the optimal development plan, more joint assessments in order to share common analyses of evidence quality and evidence gaps and finally common requests for post-launch data generation when needed.

I am convinced of the importance of JA3 to ensure a sustainable and efficient collaboration for all HTA partners all along products life-cycle. Entering in the last stage of JA3, the role of the ExB is to lead EunetHTA to succeed in its objectives; as such it is critical in identifying hurdles that could jeopardize success, in proposing solution and in making final decisions. The new and enlarged ExB is now composed of one Chair and two Vice-Chairs who should help to closely monitor overall EUnetHTA activities to ensure important topics are addressed. As Vice-Chair, I would like to bring my experience of EUnetHTA acquired through Evidence Generation activities (i.e. implementation of new organization & procedure, development of adapted tools, conflict of interest and funding hurdles...) as well as my perspective as a head of HAS' HTA division regarding the impact of EUnetHTA activities on the national level both in terms of resources and use.

WHAT'S IN IT FOR US?

European HTA Non-Duplication

Curious about what non-duplication might mean for you?

ADVANTAGES OF COOPERATION

MEMBER STATES

- Benchmark of excellence for quality standards
- Improved access to high-quality products
- Managing budgetary resources and impact
- Greater access to more high-quality HTAs

STANDARDS | PRODUCTS | MANAGED RESOURCES | HIGH-QUALITY HTAs ACCESS

HTA BODIES

- Managed resource allocation
- Resources freed for specialised national tasks
- Improved evidence base for decisions

MANAGED RESOURCES | FREED RESOURCES | IMPROVED EVIDENCE BASE

PATIENTS & CONSUMERS

- Improved availability of innovative products
- Greater transparency and increased participation in the decision-making process
- Potential access to medicines in most countries

PRODUCTS | DECISION-MAKING | ACCESS

HEALTH CARE PROVIDERS

- More opportunities for innovative products
- Improved evidence base for decisions
- More opportunities to participate in the decision-making process

PRODUCTS | IMPROVED EVIDENCE BASE | DECISION-MAKING

PAYERS

- Better awareness of upcoming products and budgetary impact

AWARENESS | BUDGET

REGULATORS

- Opportunities for synergies within the HTA process
- Transmission of innovative products into markets

OPPORTUNITIES | MARKETS

INDUSTRY

- Steamlined processes for clinical assessment in 27 countries
- Predictability of processes

PROCESSES | PREDICTABILITY

COMMITMENT non-duplication