eunethta magazine

FALL 2017

eunethta
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

INTERVIEW
COMMISSIONER ANDRIUKAITIS

ASSEMBLY & FORUM

PARTNER PROFILES
LITHUANIA

WPs
COMMUNIQUÉ

IMPACT
HUNGARY/FINLAND

EMA
PARALLEL CONSULTATIONS

IN THIS ISSUE

4 **INTERVIEW**
Vytenis Andriukaitis, EU Commission

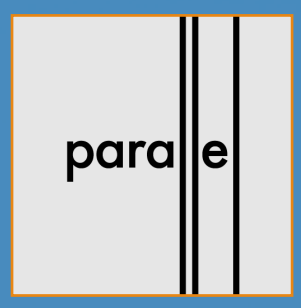
5 **PARTNER PROFILES: LITHUANIA**
HI and VASPVT

6 **COMMUNIQUÉ**
WPs 1-7 Updates and Developments

8 **NATIONAL IMPLEMENTATION AND IMPACT**
Focus: Hungary and Finland

10 **PARALLEL CONSULTATIONS**
EUnetHTA and EMA

12 **MEET THE DIRECTORATE**



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EUnetHTA Magazine

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@EUnetHTA
eunethta@zinl.nl

ON THE HORIZON

Welcome to the inaugural issue of *EUnetHTA Magazine*.

As HTA continues to grow and evolve, and EUnetHTA is a major part of that storytelling, we can shine a bigger light on our work in a more visual, informative and creative way.

To celebrate our first issue, we have an interview with European Health and Food Safety Commissioner Vytenis Andriukaitis in our regular column **Three Questions.**

This inaugural issue of *EUnetHTA Magazine* also gives us a chance to highlight the 81 organisations and institutions of the EUnetHTA network. As people are at the heart of EUnetHTA's mission, we have produced a "snapshot" video of our partners and a glimpse into their home cities. The right links will take you to Youtube or you can play it directly from the screen.

As we welcome you to Amsterdam, or if you are reading this in another city of our extended European family, we hope you enjoy this premiere issue of *EUnetHTA Magazine*.

The opinions, beliefs and viewpoints expressed by the various authors and forum participants in this publication do not necessarily reflect the opinions, beliefs and viewpoints of EUnetHTA or official policies of the EUnetHTA. While every effort has been made to ensure that information is correct at the time of going to print, EUnetHTA cannot be held responsible for the outcome of any action or decision based on the information contained in this publication and/or website. The publishers or authors do not give any warranty for the completeness or accuracy for this publication's content, explanation or opinion. Nothing in this publication should be taken as a recommendation to invest, determine or evaluate any asset. © EUnetHTA. All rights reserved.

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HELDHAFTIG VASTBERADEN BARMHARTIG - VALIANT STEADFAST COMPASSIONATE

THE 2017 EUnetHTA ASSEMBLY AND FORUM

The EUnetHTA JA 3 Directorate would like to extend a very warm welcome to participants of the 2017 EUnetHTA JA3 Assembly and Forum.

If this is your first time in Amsterdam, you will undoubtedly see the symbol of Amsterdam, three white crosses on a black and red background. While some believe the Xs have their roots in the three disasters of old Amsterdam: fire, floods and the Black Death (untrue), we hope your visit to our city and participation in the Assembly and Forum will be much more productive.

Amsterdam is a city that has been built on hard work and dedication over many centuries. In the spirit and motto of our city, *heldhaftig, vastberaden, barmhartig*, our combined efforts to advance Health Technology Assessment continue to produce measured, high-quality and sustainable results that benefit all of Europe and remain *valiant, steadfast and compassionate.*

BUILDING. PROGRESS. ADVANCEMENT.

INTERVIEW: COMMISSIONER ANDRIUKAITIS

THE BENEFIT AND IMPACT OF HTA ON AND FROM SMALLER STATES

Each quarter, EUnetHTA Magazine endeavours to ask three questions to a key stakeholder focusing on issues in the HTA world. In this inaugural issue, we have the extraordinary honour of three questions with European Health and Food Safety Commissioner Vytenis Adriukaitis. A heart surgeon from Lithuania and one of the original signatories to reborn Lithuania, Commissioner Adriukaitis' work tells of exemplary service to not only his native country but all the European community.

Health Technology Assessment (HTA) brings order to intense medical, social, economic and ethical issues related to the use of a health technology. What benefits do you see for participation in HTA for smaller states?

EU cooperation on Health Technology Assessment (HTA) will enable us to increase the use, quality and efficiency of HTA. It will help us share and reuse the results of health technology assessments jointly produced, as well as to avoid duplication of efforts between Member States. All countries will benefit from it, and in particular smaller Member States who may not have as many resources as the larger ones, or who may simply have different public health priorities or healthcare financing models. Successful cooperation on HTA could improve the sustainability of health systems in all EU countries, as it will help Member States allocate national resources to effective health interventions. For the patient, it could consequently contribute to better health outcomes and more equitable access to health technologies.

You have led a distinguished (and interesting!) career that has seen dramatic changes for smaller states like Lithuania, including equal responsibilities in much larger entities like the European Union. What can larger state HTA members learn from smaller ones?

All health systems in the EU are unique and there is no one-size-fits-all solution. However, despite their differences, countries should have the common goal to guarantee equal access to health services and therapies to everyone. EU legislation has provided many tools to facilitate this. However, lengthy national reimbursement and authorisation procedures, lack of information, and other obstacles, have hampered this universal access. European and national regulatory authorities, patients' organisations and industry should work together to overcome such barriers and inequalities. I believe that smaller countries can play an important balancing role in keeping HTA reliable and a feasible system for all EU countries.

Finally, your Twitter feed says you are a medical doctor, historian, humanist and, admirably, not a bureaucrat. From this viewpoint, what value does HTA bring to European patients?

Aside from faster and more equitable access to health technologies, which I have already mentioned, I believe that HTA will bring greater patient involvement and empowerment. With an ageing population and the need to meet ever-increasing healthcare needs with the same resources, patient involvement in HTA is both necessary and beneficial. Patients need to seek involvement in HTA, not only because they foot the bill for our healthcare systems, but also to foster trust. To this end, we should focus on increasing transparency and on giving patients the tools and expertise to put forward their perspective in a satisfactory and meaningful way throughout the HTA process - from the design phase to final reporting.

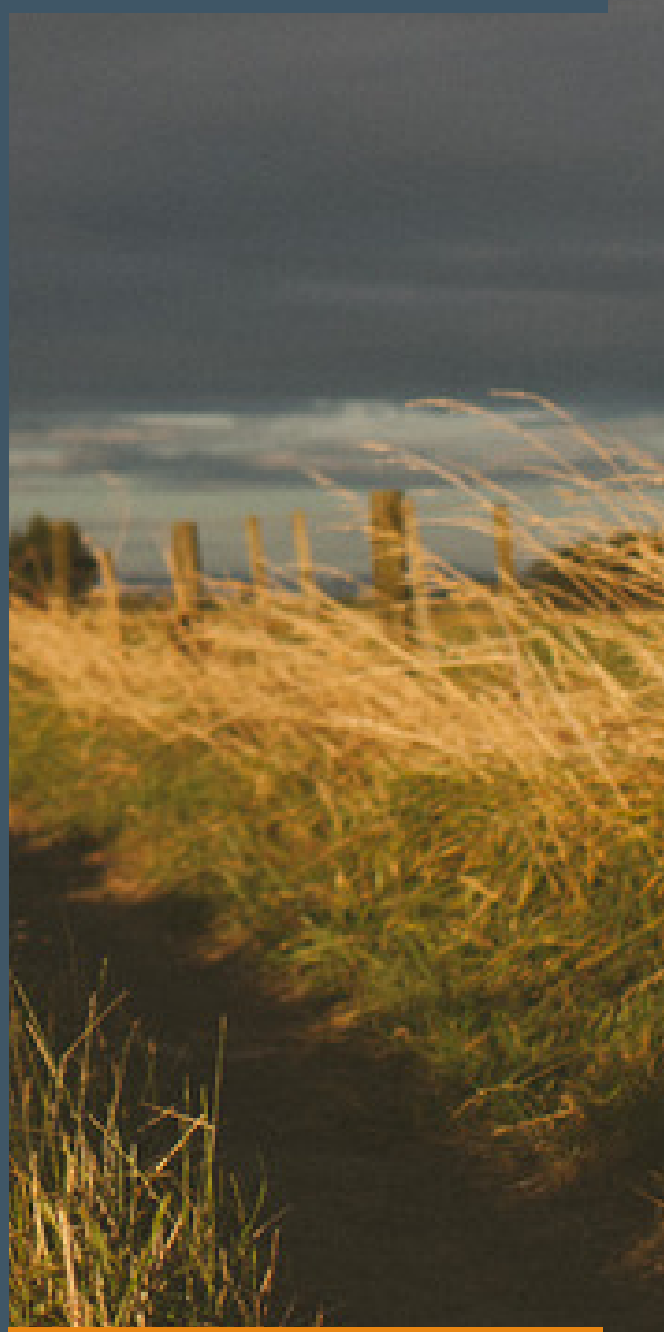
Vytenis Andriukaitis

Twiiter feed: Member of @**EU_Commission** in charge of Health and Food Safety. Medical doctor, historian & humanist. Not a bureaucrat.

http://on.fb.me/1xeMBqg

cab-andriukaitis-webpage @ec.europa.eu

@V_Andriukaitis



THREE QUESTIONS

PARTNER PROFILES: LITHUANIA

HIGIENOS INSTITUTAS (HI)

The Institute of Hygiene was established on 17 May 1808 in Vilnius. Today the Institute is a budgetary institution of the Ministry of Health, which carries out state functions in the areas of monitoring Lithuanian residents' health state and healthcare institution activities, assessing public health inconsistencies and public healthcare technologies, investigating the effects of the working environment on health and assessing occupational healthcare technologies. The Institute of Hygiene consists of three specialised centres:

Health Information Centre develops the assessment of monitoring Lithuanian residents' health and the factors that influence it, as well as manages and creates public health registers and information systems.

Public Health Technology Centre carries out research on public health inconsistencies and develops the assessment of public healthcare technologies, while also preparing and testing innovative interventions in the public healthcare practice.

Occupational Health Centre develops research on the effects of the working environment on health as well as the assessment of occupational healthcare technologies, while also preparing and testing innovative interventions in the occupational healthcare practice.

source: http://www.hi.lt/en/

AKREDITAVIMO TARNYBA (VASPVT)

VASPVT has been an active member of the EUnetHTA network since 2006 and is a founding member of the EUnetHTA consortium.

MAIN ACTIVITIES

- Health care organisations
  - Licencing
  - Supervision
  - Accreditation
- Health care specialists
- Medical devices (due to EU regulations)
- Regulation and management of medical devices (national level)
- Health technology assessment
- Supervision of health care quality
- Supervision of patients' rights

source: http://www.vaspvt.gov.lt/en

2,85 mil. people on the Baltic

Lithuanian lands were united under Mindaugas in 1236; over the next century, through alliances and conquest, Lithuania extended its territory to include most of present-day Belarus and Ukraine. By the end of the 14th century Lithuania was the largest state in Europe. An alliance with Poland in 1386 led the two countries into a union through the person of a common ruler. In 1569, Lithuania and Poland formally united into a single dual state, the Polish-Lithuanian Commonwealth. This entity survived until 1795 when its remnants were partitioned by surrounding countries. Lithuania regained its independence following World War I but was annexed by the USSR in 1940 - an action never recognised by the US and many other countries. On 11 March 1990, Lithuania became the first of the Soviet republics to declare its independence, but Moscow did not recognise this proclamation until September of 1991 (following the abortive coup in Moscow). The last Russian troops withdrew in 1993. Lithuania subsequently restructured its economy for integration into Western European institutions; it joined both NATO and the EU in the spring of 2004. In January 2014, Lithuania assumed a nonpermanent seat on the UN Security Council for the 2014-15 term; in January 2015, Lithuania joined the Eurozone.

In the best of humanist traditions, did you know:

- Lithuanian is one of the oldest languages in the world.
- Basketball is probably the most popular sport in Lithuania.
- Granny Velykų Bobute delivers Easter eggs, not the Easter bunny.
- There is an oak in Lithuania, the *Stelmuze*, that is possibly the oldest tree in Europe (1500-2000 years old).
- Lithuania has its own aroma, *Lietuvos Kvapas*, made of wild flowers, spices and forest fruit.
- The Lithuanian word for thank you, *ačiū*, sounds much like the English word "Achoo!"

historical text and map courtesy of World Factbook

WP1

IT

- An independent needs assessment has been conducted and under the direction of the Executive Board, an Internet rebuild is imminent.

- Users should now be experiencing x2 to x3 faster Intranet load times.

- The Intranet now has 300+ users.

- With our goal of a response time of 24-48 hours, the Secretariat has successfully resolved over 400 direct or indirect requests for assistance.

MEETING WITH HEADS OF AGENCIES/HIGH-LEVEL REPRESENTATIVES AND HEADS OF EUROPEAN PHARMACEUTICAL COMPANIES

On 13 June, in a meeting facilitated by the EUnetHTA Directorate and supported by DG SANTE, European stakeholders of Health Technology Assessments (focus pharmaceuticals) came together to discuss important new developments for further cooperation.

The EUnetHTA Directorate and DG SANTE specifically welcomed the participation and strong commitment of high-level representatives of HTA agencies[1] representing the EUnetHTA extended Executive Board[2] as well as Heads of Europe of several EFPIA member companies that actively support EUnetHTA JA3 by considering products to submit for European rapid assessments. Representatives of relevant stakeholders were also invited to join the meeting.

Primary focus was given to “Early Dialogues” and “Joint REA”. The discussion focused on what both sides, HTA Agencies and industry, can contribute to avoid duplication as well as which challenges would need to be addressed to facilitate increased submission of dossiers for joint work within EUnetHTA JA3.

On “Early Dialogues”, the EUnetHTA Early Dialogue Working Party was announced. It will, together with the EMA, establish a single European joint scientific advice process involving regulators and HTA bodies.

On “Joint REA”, participants underlined the importance of uptake at the national level, in particular in author countries, and agreed to feedback experiences from ongoing assessments regularly to ensure timely update of EUnetHTA processes.

Moving forward, participants welcome to continue regular interactions at both European and national level and aim at continuing to:

- Discuss adaptations to processes within national HTA agencies and within companies that are needed to ensure uptake of European reports;
- Ensure the lessons from ongoing EUnetHTA assessments feed into improved European processes moving forward, in particular in light of a post-2020 scenario and a possible Commission initiative;
- Broaden the discussion to all relevant stakeholders to ensure success of European cooperation post-2020.

The EUnetHTA Directorate, with the support of DG SANTE, invites the participants to a follow up meeting in 2018. A first interaction at the technical level to prepare for the high-level follow-up meeting is scheduled before the end of 2017.

[1] Or agencies for HTA responsibilities

[2] The meeting was open to agencies of countries represented in EUnetHTA Executive Board

EXECUTIVE BOARD (ExB)

Addendum comprising changes to the grant agreement under submission to the assembly for approval.

PROJECT MANAGEMENT GROUP (PMG)

The Directorate has received updated work plans from work packages and has compiled the first full draft of the central work plan, year 2.

WPs

ASSESSMENTS

WP4 OTCA01 on "Wearable cardioverter-defibrillator (WCD) therapy in primary and secondary prevention of sudden cardiac arrest in patients at risk"

WP4 OTCA02 on "Antibacterial-coated Sutures Versus Non-Antibacterial-Coated Sutures for the Prevention of Abdominal, Superficial and Deep Incisional, Surgical Site Infection (SSI)"

WP4 OTCA05 on “Repetitive transcranial magnetic stimulation for treatment-resistant major depression”

"Regorafenib (Stivarga©) indicated as monotherapy for the treatment of adult patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib" final project plan is now available.

"Midostaurin with standard chemotherapy in FLT3 positive Acute Myeloid Leukaemia" iroject plan is now available.

WP2

Stakeholder analysis ongoing with an estimated completion date: November 2017.

Leaflet, training strategy and communication strategy - dissemination plan are complete.

Dissemination registry is currently testing – available in the commons section of WP2.

WP invites all members to participate in a survey on all activities EUnetHTA partners are undertaking which disseminate EUnetHTA research and activities.

Survey available in the Commons section of the Intranet.

WP3

Bi-annual Report II finalized.

In process of completing yearly Interim Report.

Establishment of partner survey to be conducted in autumn.

Preparation of direct partner interviews for autumn.

WP4

AC-A Pharma update: 3 JA ongoing

PTJA01: (Midostaurin) First draft assessment/internal review.

PTJA02: (Regorafenib) Second draft assessment.

PTJA03: (Alecensa) Scoping/draft project plan.

AC-B Other technologies update: 3 CAs published and 4 CAs ongoing

OTCA03: (NIPT) First draft assessment.

OTCA04: (MammaPrint) Second draft assessment/internal review.

OTCA06: (TAVI) First draft assessment phase.

OTCA07: (FLACS) Team building finalised, start in September.

To access the published assessments and project plans, please follow this link:

http://tinyurl.com/yc3umcp7

WP4 is also currently working on establishing a working group on topic identification, topic filtration/selection and prioritisation.

WP5

5A - Launch of parallel procedure for EDs with EMA on July 4, 2017: EUnetHTA becomes one-stop-shop for HTA involvement in parallel EDs

5A - Aim to conduct 13-15 EDs by the end of Y2. Currently 8 EDs in progress (2 Multi-HTA and 6 parallel consultations).

5B1 - First PLEG (disease specific) pilot ongoing and due in October 2017.

5B1 - Selection of candidates for the second pilot has a new deadline of December 2017.

5B2 - Draft Registry Standards tool to be circulated for comment to WP partners in September 2017.

WP6

WP6A: Elaboration of JA3 Rapid REA process flows and development of corresponding standard operating procedures based on the JA2 procedure manuals is done in close collaboration with WP4 and still work in progress. The proof of concept version of WP6A’s central deliverable, the EUnetHTA Companion Guide, is about to be presented at this year’s EUnetHTA Assembly. The EUnetHTA Companion Guide will be EUnetHTA’s new and comprehensive repository to support WP4 assessment teams containing all output of WP6A and WP6B.

WP6B: Work on inventory of JA1/JA2 methodological documents & tools and work on roadmap for JA3 was completed. Activities related to the HTA Core Model are delayed. A new activity lead will be appointed soon. The JA2 guideline on information retrieval was updated and a new guideline on critical assessment of economic evaluations is currently under development.

WP7

Case studies available on the Intranet news feed and WP7 workroom; identifying Year 2 case studies.

Ongoing work to set up an implementation network to support implementation of EUnetHTA products, reinforce dissemination and collect feedback on their use.

Consultations with partners and stakeholders on final report on mechanisms to support and encourage the reuse of jointly produced HTA reports and reuse of national and regional HTA information from Member States’ reports ended 1.9; final report in preparation.

USE OF EUnetHTA ASSESSMENTS AT THE NATIONAL INSTITUTE OF PHARMACY AND NUTRITION (NIPN)

HUNGARY

NATIONAL IMPLEMENTATION AND IMPACT

Written by Zoe Garrett, NICE

zoe.garrett@nice.org.uk

The HTA Department in the National Institute of Pharmacy and Nutrition (NIPN) produces reports that are used by the National Health Insurance Fund (NHIF) and Ministry of Human Capacities to make decisions about national reimbursement and pricing of pharmaceuticals and other health technologies. The HTA Department produces approximately 200 outputs per year including 90-100 pharmaceutical reports, 90-100 reports about medical aids used by patients and four to five healthcare technology reports about medical devices used by physicians in hospitals. The pharmaceutical and healthcare technology reports include a review of the company's submitted evidence of clinical effectiveness, cost effectiveness and budget impact. The reports for medical aids include a clinical overview and assessment of budget impact comparing the prices and attributes of the devices.

1.1 Working Practices

For all technologies, companies submit for reimbursement to the National Health Insurance Fund (NHIF) who forwards the submission to NIPN for review. Companies can submit for reimbursement in Hungary following receipt of marketing authorisation once a product is reimbursed in three other European countries. NIPN do not know in advance if and when an assessment will be requested.

NIPN reviews the evidence submitted and provides a report to NHIF. In their review, NIPN will check the appropriateness and robustness of the company's submission including the appropriateness of the proposed place in therapy, appropriateness of the included clinical evidence and a critical evaluation of the health economic evaluation (not for medical aids) and budget impact analysis. The consistency of the clinical data with the cost-effectiveness modelling will also be checked. The reports for medical devices contain a recommendation on the reimbursement of the technology. These reports are then sent back to NHIF who formulate an initial decision. The final decision is made by a Committee that includes representatives of NHIF, the Ministry of Human Capacities and NIPN.

NIPN has 43 days to prepare the review of the evidence submission of a pharmaceutical, 30 days for a healthcare technology and 15 days for a medical aid.

1.2 Use of EUnetHTA Assessments

In their national procedures, NIPN used the EUnetHTA reports for canagliflozin for the treatment of type 2 diabetes mellitus and ramucirumab in combination with paclitaxel as second-line treatment for adult patients with advanced gastric or gastro-oesophageal junction adenocarcinoma to support their national assessments. NIPN review company submissions rather than produce HTAs. Therefore, NIPN used EUnetHTA assessments and specifically the relative effectiveness data as a source of information in the clinical effectiveness section of their report to support their review of the company submission (for example, in the case of canagliflozin, NIPN's report questioned the non-inferiority of the product based on the analysis in the EUnetHTA assessment) and check the comparability of the data submitted. The use of EUnetHTA assessments to support the review process is an additional step in the NIPN procedure and so there are currently no time or resource savings from using a EUnetHTA assessment in the national process. Instead, having the EUnetHTA assessment can improve the quality of the NIPN review. Drivers that support the use of EUnetHTA assessments include:

- completing a large number of assessments each year meaning that there is overlap with national and EUnetHTA assessments for pharmaceuticals;

- having no restrictions to what evidence can be used to support their review process. Therefore, data from EUnetHTA assessments can be used to support the review and in sensitivity analysis ·updating the methods guide for pharmaceuticals so that it supports use of data from EUnetHTA assessments in their reports;

· having a consistent scope and evidence base in the EUnetHTA assessment with that submitted for the national assessment by the company.

NATIONAL IMPLEMENTATION AND IMPACT (CONT.)

Written by Zoe Garrett, NICE

zoe.garrett@nice.org.uk

USE OF EUnetHTA ASSESSMENTS AT THE FINNISH MEDICINES AGENCY (FIMEA)

FINLAND

The HTA unit of the Finnish Medicines Agency (FIMEA) produces mainly rapid reviews for single indications of new hospital medicines. These reports support decision-making about uptake and use of a medicine by hospitals. By special request, they also carry out assessments of outpatient pharmaceuticals including single and multiple technology assessments. FIMEA produce approximately 10 reports per year. The reports include an assessment of relative effectiveness and also cost and budget impact analysis.

1.1 Working Practices

The responsibility of choosing topics for assessment rests with FIMEA. The topic selection process starts with the list of CHMP positive opinions. From this list, inpatient medicines will be selected and new active substances and major variations to licensed indications prioritised. Hospital districts can be asked about topic prioritisation if needed. FIMEA completes the HTA themselves. Internal or external clinical experts are consulted during the assessment. The assessment includes conclusions about the pharmaceutical based on the clinical and economic profile; these conclusions are developed by the FIMEA staff. Companies are asked to provide evidence about the available clinical information (completed and ongoing clinical trials, subgroup analysis etc.), budget impact and any budget impact models available. If the company submits commercially confidential material and it is used in the report, the company gets the opportunity to comment before the report is published on the website and before the public consultation. The assessment normally starts soon after the CHMP opinion and with the aim to produce a report within two–three months, e.g. at the time of marketing authorisation.

1.2 Use of EUnetHTA Assessments

FIMEA adapted two EUnetHTA assessments: ramucirumab in combination with paclitaxel as second-line treatment for adult patients with advanced gastric or gastro-oesophageal junction adenocarcinoma and new pharmaceuticals for the treatment of chronic hepatitis C. Data from the EUnetHTA assessment was used to support the process of national assessment. The final product was published in the standard FIMEA format (which is based on EUnetHTA core model). The adaptation process included:

- condensing the EUnetHTA assessment into the FIMEA format;
- adding subgroup information considering treatment duration, previous treatments and next line treatments;
- adding national context information;
- adding economic evidence (costs and budget impact);
- clinical searches including PubMed, Medline and clinicaltrials.gov to check for any additional evidence;
- writing the report in Finnish with summaries in Swedish and English.

The key drivers that support the use of EUnetHTA assessments is a flexible assessment process within the agency and the fact that the same staff are involved both in national assessments and international collaboration. The biggest challenge when using EUnetHTA assessments is the timing of the availability of EUnetHTA reports relative to marketing authorisation. The adaptation of ramucirumab was only possible because FIMEA were reviewers of the EUnetHTA report and thus had early access to the report. Furthermore, the current frequency and availability of joint reports is low and unpredictable, and for most of the new medicines joint assessments are not available. This limits the ability of FIMEA to use EUnetHTA reports in national procedures.

These articles are part of the work of WP7 national implementation and impact.

Grateful acknowledgement to NIPN: Laszlo Nagyjanosi, *Head of the HTA Department*; Veronika Doczy, *Medical Expert*; Viktoria Szerencses, *Health Economics Analyst*.

FIMEA: Vesa Kiviniemi, *Head of Assessment*; Piia Rannanheimo, *Pharmacoeconomist*; Tuomas, Oravilahti; *Pharmacoeconomist*, Ulla Härkönen, *Research Physician*.

EMA AND EUnetHTA STEP UP INTERACTION TO ALIGN DATA REQUIREMENTS

A new joint platform for parallel consultation will provide advice to medicine developers and facilitate access to medicines for patients

The European Medicines Agency (EMA) and the European Network for Health Technology Assessment (EUnetHTA) are stepping up their efforts to provide developers of medicines with simultaneous, coordinated advice on their development plans and facilitate alignment of data requirements.

This initiative provides a single gateway for requests for parallel consultations with EMA and HTA bodies in the Member States on evidence-generation plans to support decision-making on marketing authorisation and health technology assessment. Not only will these consultations be possible for initial evidence generation but also for post-authorisation data collection. The objective is to help generate optimal and robust evidence in an efficient development plan that satisfies the needs of both regulators and HTA bodies.

“Enabling patients’ access to medicines is no longer a job for regulators alone. Today, we need to work with all decision-makers in healthcare to make sure that medicines that can make a real difference to people’s lives can actually reach them,” said EMA Executive Director Guido Rasi. “Our work with EUnetHTA aims to align our respective requirements as much as possible so that developers can generate one set of data that allows the assessment of both the benefits and risks of a medicine and its added value.”

This new initiative replaces the existing tool for parallel scientific advice by EMA and HTA bodies which required medicine developers to contact Member States’ HTA bodies individually. It also builds on previous initiatives and pilots on HTA-regulatory collaboration led by EMA, EUnetHTA and the European Commission (see notes).

Medicines developers will need to notify simultaneously EMA and EUnetHTA of their intention to request parallel advice. EUnetHTA’s Early Dialogue Secretariat, recently created to facilitate such consultations, will then coordinate the involvement of the HTA bodies that will take part in the parallel advice, taking into account the preferences of the requester.

EUnetHTA created the Early Dialogues Working Party (EDWP), composed of HTA bodies with demonstrated experience in Early Dialogues/Scientific Advice, to ensure high-quality advice and consistency over time.

The main benefits of this new platform will be:

- increased mutual understanding and problem solving ability through a more structured interaction between EMA and HTA bodies;

- improved coordination with, and greater participation of HTA bodies, as a result of the creation of an Early Dialogue Working party and an Early Dialogue Secretariat at EUnetHTA;

- streamlined logistics for the requesters.

These advantages are expected to lead to more robust outcomes resulting from the parallel consultation on evidence-generation plans for pharmaceuticals.

“Balancing access to new and innovative medicines with the sustainability of healthcare resources requires an assessment of the added value of new treatments. HTA bodies strive to evaluate, based on the available data, the added benefit that a new medicine brings to patients over existing treatments. As clinical studies form the evidence basis for both regulators and HTA bodies, our strengthened involvement in early dialogues and our collaboration with EMA will support the generation of evidence that better meets the needs of HTA bodies and will support informed decisions at national level,” said EUnetHTA Joint Action 3 Director Wim Goettsch.

As patients are at the heart of both EMA and EUnetHTA’s missions, patient representatives will be involved in parallel consultations on a routine basis so that their views and experiences can be incorporated into the discussions.

How stronger interaction between regulators and HTA bodies will benefit patients

Patients have access to medicines through a two-step process. First, a medicine requires a marketing authorisation from a medicine regulatory agency, which is based on the assessment of the balance of the benefits versus the risks of the medicine. Following regulatory approval, HTA bodies assess the value of the medicine versus other treatments available and, based on this assessment, provide recommendations to payers and other decision-makers. While there is some overlap between evidence requirements of regulators and HTA bodies, each may have specific requirements that need to be accounted for in the development plan.

Closer interaction between regulators and HTA bodies during the development of medicines is therefore expected to close these gaps and allow the development plan to address the needs of all parties. This early dialogue can also facilitate discussion on evidence generation required after the launch of a medicine to allow the continuous assessment of the benefit-risk balance and long-term effectiveness of the medicine.

EMA with its scientific committees, EUnetHTA, HTA bodies and the European Commission have been working closely in the past few years on various levels to reinforce HTA-regulatory collaboration and achieve timely patient access and sustainability of health care while providing incentives for innovation.

Notes

EUnetHTA was established to create an effective and sustainable network for HTA across Europe – working together to develop reliable, timely, transparent and transferable information to contribute to HTA in European countries, creating a sustainable system of HTA knowledge sharing, and promoting good practice in HTA methods and processes.

The secretariat for Early Dialogues at EUnetHTA is operated by Haute Autorité de Santé (HAS), France. Scientific coordination is performed by HAS and Gemeinsamer Bundesausschuss (G-BA), Germany.

Regulatory only scientific advice and multi-HTA advice are still available.

More information on the work of the European Medicines Agency: www.ema.europa.eu

EMA-EUnetHTA Parallel Consultation Guidelines and Templates

EMA and EUnetHTA have published joint guidance for the parallel consultation procedure which explains how to apply and highlights the actions for each party and preferable timelines.

EMA and EUnetHTA have also published common templates, which medicine developers should use for notifying EMA and EUnetHTA of their intent to participate and provide information and questions as part of the procedure:

Some HTA bodies may charge fees for participating in the parallel consultation procedure. The EUnetHTA ED secretariat can provide information on HTA associated fees.

EMA's scope and the fees it charges for this procedure are the same as for standard scientific advice. For more information, see Fees payable to EMA.

For information on participation of HTA bodies, please contact the EUnetHTA ED secretariat.

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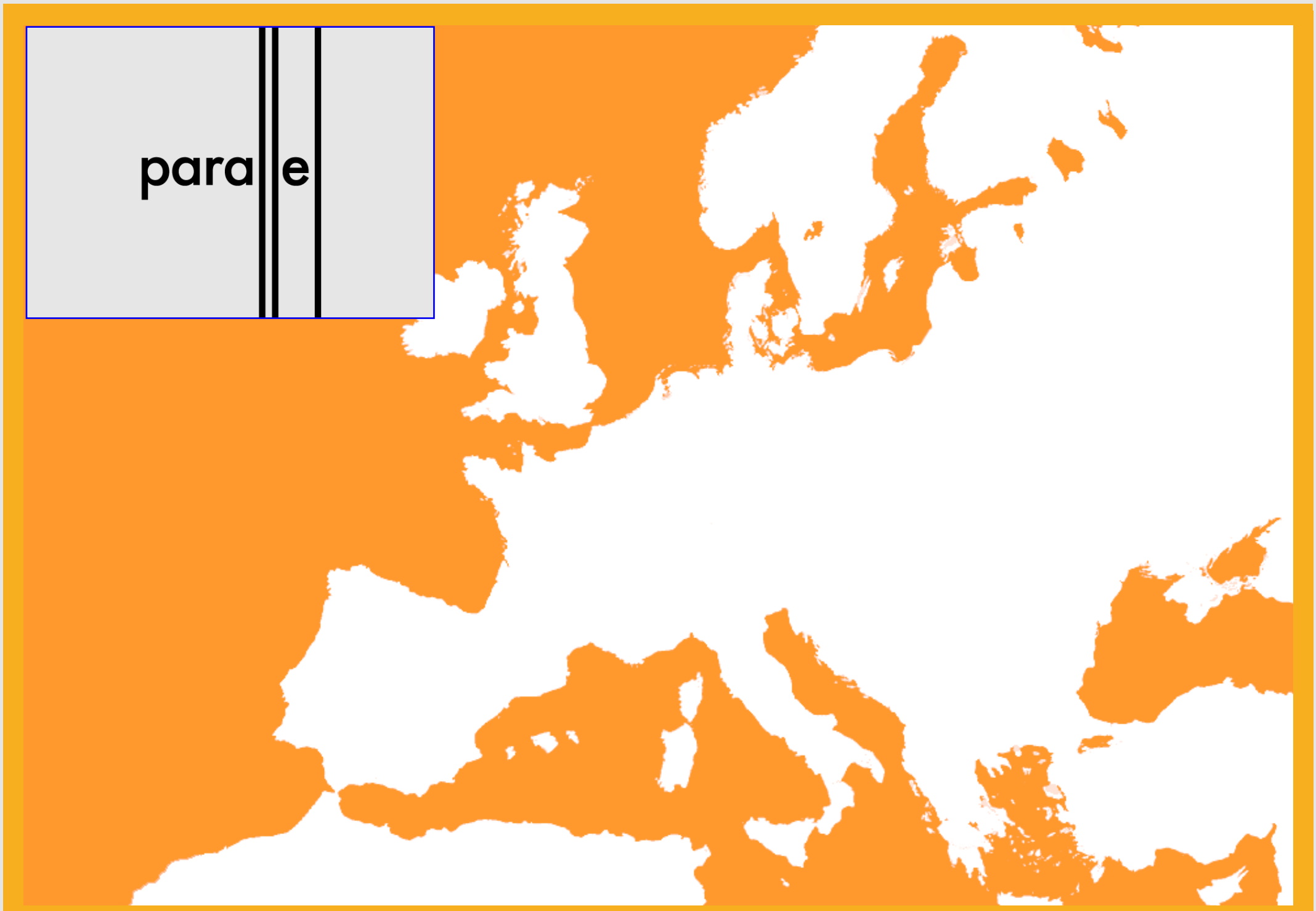
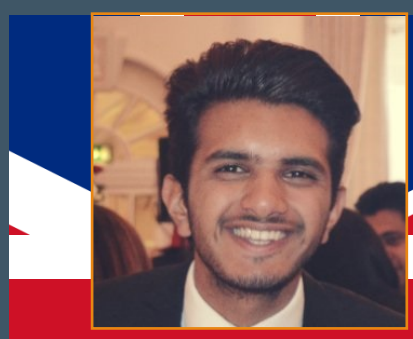
For information on regulatory aspects, please contact the EMA scientific advice secretariat.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH





Ali Hussain

Assistant Project Manager WP1

Anne Willemsen

Assistant Project Manager WP4

Charles Kinney

Communications Officer

Christiana Grosaru

Project Manger WP1

Ewold van Elderen

IT Assistant

Johanna Kloker

Administrative Assistant

Linda Krom-Hoogenboom

Financial Officer

Marcus Guardian

Chief Operating Officer

Michelle Mujoomdar

Senior Scientific Officer

Wim Goettsch

Director

MEET THE DIRECTORATE

Coming together is a beginning; keeping together is progress; working together is success. Henry Ford

Most of you are familiar with EUnetHTA Director Wim Goettsch and Chief Operating Officer Marcus Guardian, but who readjusts the columns, fixes the Intranet, checks your finance reports, coordinates the SABA, creates the spreadsheets and tries to answer your questions in a (reasonably) human amount of time?

Meet the EUnetHTA JA3 Directorate.

eunethta