eunethta magazine

SPRING 2018

HTA REPORTS

IMPACT SCOTLAND

European Commission

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2018 FORUM

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HOW TO GET INVOLVED

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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 WP4 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 WP4 Co-Lead and WP4 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.

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"

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)"

= Patients have been involved in this assessment

BOLD = Ongoing assessment at time of magazine publication

*Reports from 2016 - 2018

NATIONAL IMPLEMENTATION AND IMPACT

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

USE OF EUnetHTA ASSESSMENTS BY THE SCOTTISH HEALTH TECHNOLOGIES GROUP (SHTG), SCOTLAND

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

The Scottish Health Technologies Group (SHTG) is part of Healthcare Improvement Scotland (HIS). It produces mainly rapid reviews, which are used to develop national advice for Scotland about any non-pharmaceutical health technologies.

SHTG produces approximately 25 HTA-related outputs per year including horizon scanning outputs, evidence notes (rapid reviews), and Innovative Medical Technology Overviews (IMTOs). Both evidence notes and IMTOs include a summary of the clinical and cost effectiveness evidence and include brief consideration of organisational and patient issues.

1.1 Working practices

The majority of topics that SHTG assess come from national or regional health planning committees. Decisions to carry out further work on a topic are made during an evidence review committee (ERC) meeting following an initial work-up by the HIS research (cont.) team, exploring the topic area, research question and available evidence.

Chosen topics are subject to a scoping stage which clarifies the research question and the most appropriate assessment product. After this, the evidence product is produced by the HIS researchers. The ERC then prepare a draft advice statement based on the evidence product. Companies and other stakeholders peer review both the evidence product and advice statement.

The draft advice statement is finalised by the full SHTG, a national scientific committee including representatives from all NHS Scotland territorial health boards, special health boards, academia, industry, the public and HIS research staff. To support this process, the SHTG committee members receive the evidence note, the peer review comments and the draft advice statement. The process from topic referral to production of advice typically takes approximately six months.

1.2 Use of EUnetHTA assessments

SHTG adapted two EUnetHTA assessments: transcatheter implantable devices for mitral valve repair and endovascular therapy using mechanical thrombectomy devices. The EUnetHTA assessments were adapted to be evidence notes. The adaptation process included:

· Condensing the EUnetHTA assessment to fit SHTG evidence note format;

· Removing interventions that were not appropriate to the Scottish context;

· Adding national context information (population size and clinical information);

· Adding health economic evidence (searches for health economic evidence were developed, and the literature reviewed);

· Updating clinical searches.

Drivers that supported the use of EUnetHTA assessments included:

· Having flexibility in and responsibility for the topic selection process;

· Having a high level legal framework that is not directive of procedures;

· Having standard operating procedures that refer to the use of secondary sources of evidence to support the development of evidence review products;

· Being able to follow routine quality assurance processes which meant that any deviations from standard operating procedures would be flagged.

This article is part of the work of WP7 national implementation and impact. Registered Intranet users can read more about the SHTG experience of using EUnetHTA assessments at: goo.gl/3o2nNz

Grateful acknowledgement *to the Scottish Health Technologies Group (SHTG), part of Healthcare Improvement Scotland (HIS); Karen Macpherson and Lorna Thompson.*

Want to know more about the Scottish Health Technologies Group?

Healthcare Improvement Scotland | SHTG

Healthcare Improvement Scotland

INTERVIEW: MONIQUE GOYENS OF BEUC

EXPANDING DIALOGUE BETWEEN HTA BODIES AND STAKEHOLDERS

Each quarter, EUnetHTA Magazine asks three questions to key stakeholders. For our Spring edition, we talked with Monique Goyens, Director General of BEUC, Bureau Européen des Unions de Consommateurs/the European Consumer Organisation.

About the European Consumer Organisation (BEUC)

Ms. Goyens: The European Consumer Organisation (BEUC) defends the interests of all Europe's consumers and represents 43 independent national consumer organisations from 31 European countries. We bring consumers' viewpoints from across Europe to the EU policy-making arena.

BEUC was created on 6 March 1962 by the consumer organisations of Belgium, Luxembourg, France, the Netherlands, Italy and Germany. After working together for a number of years, these organisations decided to create a European association, based in Brussels. BEUC is acknowledged as a trustworthy representative by both decision makers and opponents alike, thanks in particular to the collective skills, knowledge and expertise of our member organisations.

1. BEUC makes sure vulnerable groups such as children, the elderly and low-income consumers are taken into consideration. How can HTA, including the work of EUnetHTA, ensure that the perspectives of these groups are included?

Ms. Goyens: HTA assists governments in their decisions to allocate their resources in medicines, surgeries or medical devices that have an added value compared to existing ones. This is crucial in a time where healthcare systems are struggling because of austerity measures and demand for care is increasing, particularly from the more vulnerable categories you mentioned. Indirectly, HTA can help save important budgets that can be used to address their needs. HTA also helps prioritising health interventions that represent the greatest value for society. In fact, the 'personalised medicine' model will increasingly address the needs of very small populations: HTA can ensure that governments consider the societal perspective when deciding which treatments they should reimburse and to which extent.

2. Your website tells how the name "BEUC" is often pronounced very differently, but your website (very wittingly) also says as for pronunciation, let's just say it's a question of consumer choice! Does the current European HTA system provide better choices for consumers and end-users of Pharma and Other Technology devices?

Ms. Goyens: Although HTA's aim is to ensure consumers are offered technologies that truly make a difference and do not waste public money, the current system spurs inequalities around Europe. Consumers who live in Member States with robust HTA systems are sure to access effective medicines. It advantages them compared to those who live in countries where such system is not in place, or where authorities assess only some health technologies. As a result, health systems reimburse obsolete and ineffective medicines or surgeries, which ultimately has no added value for consumers.

3. Part of BEUC's policy is to ensure that consumer policy at the EU level is sustainable, with reduction of negative social and economic impacts, while improving well-being for all. How can EUnetHTA's current and planned activities purposely better assist in that policy?

Ms. Goyens: EUnetHTA was rightly set up to increase the collaboration among countries. By pooling resources, countries can avoid double work which wastes precious public resources and time, at the expense of consumers, whose access to quality healthcare depends on the country of residence.

Additionally, we see more and more drugs being approved with low or even uncertain value. This can induce governments to pay for health technology of little value, whilst resources could be used to cover relevant health needs. EUnetHTA can play a big part developing a common robust methodology that ensures high quality assessments, and ultimately provides governments with tools to better decide what and how much to reimburse. The first step would be to demand that the pharma industry discloses *all* the available data, including the negative results that remain secret all too often.

Monique Goyens,

Director General of BEUC

BEUC The European Consumer Organisation

From BEUC's Twitter feed: BEUC represents 43 independent national consumer organisations in Brussels and defends the interests of European consumers.

http://www.beuc.eu/

@beuc

Proposal for a Regulation of the European Parliament and of the Council on Health Technology Assessment and Amending Directive 2011/24/EU Explanatory Memorandum

Proposal

HTA

On 31st of January 2018 the European Commission has adopted a legislative proposal for sustainable cooperation on Health Technology Assessment (HTA) at the EU-level. The proposal consists of five chapters comprising a total of 36 articles.

CHAPTER I – General provisions

This chapter outlines the subject matter of the proposal and defines the key terms used in the proposed Regulation. To ensure consistency with other Union legislation, the definitions of 'medicinal product', 'medical device', and 'health technology' in the proposal are aligned with those applied in Directive 2001/83/EC, Regulation (EU) No 2017/745, and Directive 2011/24/EU respectively. The Member State Coordination Group on Health Technology Assessment (the Coordination Group) is formally established in Article 3 along with its composition, roles and responsibilities to oversee the joint work referred to in Chapter II.

The Coordination Group will be Member State-led and manage the overall governance of the joint work. The Group will meet regularly to provide guidance and steer the cooperation. Under the authority of the Coordination Group, a number of sub-groups consisting of experts nominated by Member States will carry out the joint work foreseen in this proposal. For example, for the joint clinical assessments, Member States' HTA bodies acting as assessor and co-assessor will carry out the clinical assessment, prepare a draft report and consult relevant stakeholders. The Coordination Group will thereafter approve the joint reports which will then be published by the Commission and included in a list of health technologies having undergone joint clinical assessments.

This joint work is based on the annual work programme of the Coordination Group which is outlined in Article 4 of the proposal. The annual work programme provides clarity on the planned work of the Group and allows health technology developers to foresee any expected involvement they may have in the joint work for the year ahead.

How was EUnetHTA involved?

EUnetHTA was consulted during the drafting process and the work of EUnetHTA consortium will be used as the basis of cooperation beyond 2020.

In 2016, the European Commission started work on strengthening 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 this would extend to improving the functioning of the single market for health technologies.

CHAPTER II - Joint work on health technology assessment at Union-level

This chapter establishes the four pillars of the future cooperation between Member States at Union-level (the joint work) namely, joint clinical assessments, joint scientific consultations, the identification of emerging health technologies, and voluntary cooperation. The work will be Member State-led through the Coordination Group.

Section 1 - Joint clinical assessments

The joint clinical assessments will be one of the main proponents of the future joint work and, following the end of the transitional period, participation in the assessments and use of the joint clinical assessment reports at Member State-level will be mandatory. As described below, there will be a progressive phase-in approach to the annual number of joint clinical assessments carried out during the transitional period.

Scope

Joint clinical assessments are limited to:

- medicinal products undergoing the central marketing authorisation procedure, new active substances and existing products for which the marketing authorisation is extended to a new therapeutic indication;
- certain classes of medical devices and in vitro diagnostic medical devices for which the relevant expert panels established in accordance with Regulations (EU) 2017/745 and 2017/746 have given their opinions or views and which have been selected by the Coordination Group set up under this Regulation based on the following criteria:
  - unmet medical need;
  - potential impact on patients, public health, or healthcare systems (e.g. burden of disease, budget impact, transformative technology);
  - significant cross-border dimension;
  - Union-wide added value (e.g. relevance to a large number of Member States);
  - the resources available to it.

This relatively limited scope and the selection criteria reflect the need to take a proportionate approach concerning the type and amount of health technologies assessed at Union level. By focusing on the most innovative technologies and selecting those with the most Union-wide and public health impact, the EU added value of the assessments will be maximised.

European Commission

The timing of the procedure for joint clinical assessments for medicinal products will be coordinated with that of the central marketing authorisation procedure (i.e. the joint clinical assessment report will be available at the time of or shortly after the final Commission Decision granting marketing authorisation), ensuring its timeliness for supporting Member States decision-making at the time of market launch.

Taking into account the more decentralised market access pathway for medical devices, the timing of the joint clinical assessment will not necessarily be aligned with the timing of the conformity assessment i.e. it will not always be at the time of market launch. Instead, the Coordination Group will consider the most appropriate time point for a joint clinical assessment in line with the abovementioned selection criteria.

The identified scope and phase-in approach take into account the current level of duplication among Member States' HTA bodies, the EU added value of a joint approach, and stakeholder views and concerns.

Progressive implementation

The proposal provides for progressive implementation of the amount of joint clinical assessments during the transitional period. This means that the number of joint clinical assessments will increase gradually during the first three years after the date of application, taking into account specific selection criteria (same as those used permanently for medical devices, described above). The Coordination Group will select the health technologies based on these criteria and include them in the annual work programme. Following the end of the transitional period, all medicinal products falling within the scope and granted marketing authorisation in a given year will be assessed, while a selection of medical devices falling within the scope will undergo assessment.

Preparation of joint clinical assessment reports

The joint clinical assessments will cover the four assessment domains described in the definition of 'clinical assessment' in Chapter I. A step-by-step procedure on how the joint clinical assessment reports will be prepared is outlined in this section. Member States, through their HTA authorities and bodies, will be in the lead, selecting the assessor authority or body which will draft the report providing support and comments throughout the drafting process, and approving the final reports. The selection of the assessors and co-assessors will be a particularly important step in ensuring the quality of the report and the independence of the drafting process and this selection will thus be made based on specific procedural rules to be developed in tertiary legislation. The health technology developer whose health technology is the subject of the report, as well as patients, clinical experts and other stakeholders will also be given opportunities to provide input in order to ensure a thorough, independent and transparent assessment process. Once verified by the Commission, the final reports will be published and then used by the Member States.

The detailed procedural rules for each step in the process will be further developed in tertiary legislation while the common rules and documentation developed in tertiary legislation for clinical assessments at Member State-level will also be used for joint clinical assessments, ensuring a consistent approach across national and Union-level clinical assessments. The development of the tertiary legislation will take as a basis the work on common procedures, methodologies and documents already being developed in the EUnetHTA Joint Action 3.

Use of joint clinical assessment reports by Member States

The proposal does not oblige Member States to carry out a HTA on health technologies which are the subject of joint clinical assessments. However, where Member States do carry out HTAs on such health technologies, there is a requirement for mandatory use of the joint clinical assessment report and no repetition of the clinical assessment in Member States' overall HTA processes. This means that Member States will continue to carry out non-clinical assessments i.e. on the non-clinical HTA domains (e.g. economic, organisational, ethical) and will draw conclusions on the overall added value of the assessed health technology based on the joint clinical assessment report and their own non-clinical assessment.

Section 2 - Joint scientific consultations

The proposal provides for the possibility for health technology developers to make a request to the Coordination Group for a joint scientific consultation. The joint scientific consultations, commonly referred to as 'early dialogues', allow a developer in the development phase of a health technology to seek the advice of HTA authorities and bodies on the data and evidence likely to be required as part of a potential future joint clinical assessment. The Coordination Group will carry out an annual number of joint scientific consultations based on its annual work programme, taking into account the resources available to it.

The preparation of joint scientific consultation reports will mirror the approach taken for joint clinical assessments as described above. The main difference will be that the joint scientific consultation reports approved by the Coordination Group will be addressed to the health technology developer, will not be published, nor will they bind the developer or the Member States at the time of (joint) clinical assessment. To ensure transparency, information on the consultations will be included in the Coordination Group's annual reports.

(continued next page)

Section 3 - Emerging health technologies

The joint work would also encompass an annual study to be carried out under the responsibility of the Coordination Group on the identification of emerging health technologies. This exercise, commonly referred to as 'horizon scanning', will act as a key input for the annual work programmes, helping to ensure that the health technologies expected to have a major impact on patients, public health or healthcare systems are identified at an early stage in their development and are included in the joint work of the Coordination Group. The proposal requires the Coordination Group to fully consult with all relevant interest groups during this exercise.

Section 4 - Voluntary cooperation

Under this section, the proposal provides for the possibility for Member States to continue to cooperate on a voluntary basis at Union-level. This voluntary cooperation would allow for HTA on health technologies other than medicinal products or medical devices, non-clinical assessments, collaborative assessments on medical devices i.e. on medical devices not selected for joint clinical assessment, and cooperation on the provision of additional evidence which can facilitate HTA.

Voluntary cooperation should take advantage of the outputs from research on HTA, such as methods for the use of real world evidence to reduce the uncertainty on effectiveness, the evaluation of innovative technologies (e.g. 'eHealth', personalised medicine) and the assessment of non-clinical domains (e.g. the impact of medical devices on the organisation of care).

This cooperation will benefit from the support framework set up under this proposal while participation in it and use of the results would be fully voluntary.

CHAPTER III - Rules for clinical assessments

This Chapter lays down common rules for carrying out clinical assessments at Member State-level which will then be developed in detail in tertiary legislation. These rules will ensure a harmonised approach to clinical assessment across EU Member States. In the development of the rules, use will be made of the tools already developed under the EUnetHTA Joint Actions as a base and the common rules will also be used for the joint clinical assessments at EU-level. An important part of these rules will be to ensure that clinical assessments, whether carried out at EU or Member State level, are done in an independent and transparent manner, free from conflicts of interest.

CHAPTER IV - Support framework

This chapter sets out the support framework which will support the joint work at EU-level. It provides for its funding and support from the Commission acting as its secretariat and providing its IT infrastructure. A stakeholder network is also established under this chapter along with reporting and monitoring obligations placed on the Commission.

The Commission will support the work of the Coordination Group and the sub-groups, in particular by providing scientific, administrative and IT support (as described in detail in the section on budgetary implications).

CHAPTER V - Final provisions

This chapter outlines the timeline for the implementation of the Regulation. Following the entry into force, a three-year period before the date of application is proposed which will allow for the development and adoption of all tertiary legislation (the implementing and delegated acts) provided for in the proposal as well as the preparatory steps necessary for the joint work. Following the date of application, a further three-year transitional period is envisaged to allow for a phase-in approach in terms of the work undertaken and to allow Member States to fully adapt to the new system. During this transitional period, Member States would have the option to delay their participation in the joint work on joint clinical assessments and joint scientific consultations. Under such circumstances they would not be obliged to use the output of this joint work at Member State-level but would be obliged to use the common rules for their own clinical assessments. Member States will not be able to delay their participation partially i.e. for only one category of health technology or for only one part of the joint work.

The proposal also includes a safeguard clause allowing clinical assessments to be carried out at national level using means other than the common rules, on grounds related to the need to protect public health specific to the Member State wishing to invoke the clause. Such measures would need to be justified and notified to the Commission for an assessment of the justifications presented.

Future European cooperation on HTA: a step forward in improving healthcare for all

EPF

NDA Group welcomes proposal for new HTA regulation in Europe

IPPOSI statement on European Commission's HTA proposal

European HTA is On Its Way—At Last

Phamaceutical Executive

Cancer patients welcome proposal on future cooperation on Health Technology

ECPC

What payers think about the latest HTA proposal AIM

EU will Bewertung von Arzneimitteln an sich ziehen

GKV - Spitzenverband

New EU plan to assess medicines' added value will benefit consumers

BEUC

EFPIA views Commission's proposals on Health Technology Assessment (HTA) as positive step

European Commission issues legislative proposal on health technology assessment (HTA)

Myeloma Patients Europe

It's time to strengthen EU-HTA cooperation

EU HTA Cooperation: Market Access Challenge or Opportunity?

Decision Resources Group

EURORDIS calls to adopt the European Commission's proposal for a future European cooperation on Health Technology Assessment

Harmonizing Europe's Health Technology Assessment – Opportunity or Can of Worms?

APC0

Proposal of EU-commission for Europe-wide assessment – will HTA become centralized?

SKC

HTA: Advancing Towards EU Collaboration

EPF

Health Action International (HAI) Statement on Commission Proposal on HTAs

The new HTA proposal: blessing or curse?

Incisive Health International

Commission reassures 'worried' member states on Health Technology Assessment

EURACTIV

Feedback from Global Medic Force Foundation

HTA Position Paper of CPME, the European organisations of patients, consumers, healthcare providers and payers

First general AIM Response to the European Commission Proposal on HTA

Expert Analysis: EU Commission's Proposed Regulation On HTA

Medtech Insight

EU Boosts Health Technology Assessment

MSL Group

European Commission Proposes Stronger Cooperation for Health Technology Assessment

Knobbe Martens

EC Legislative Proposal

Roundtable

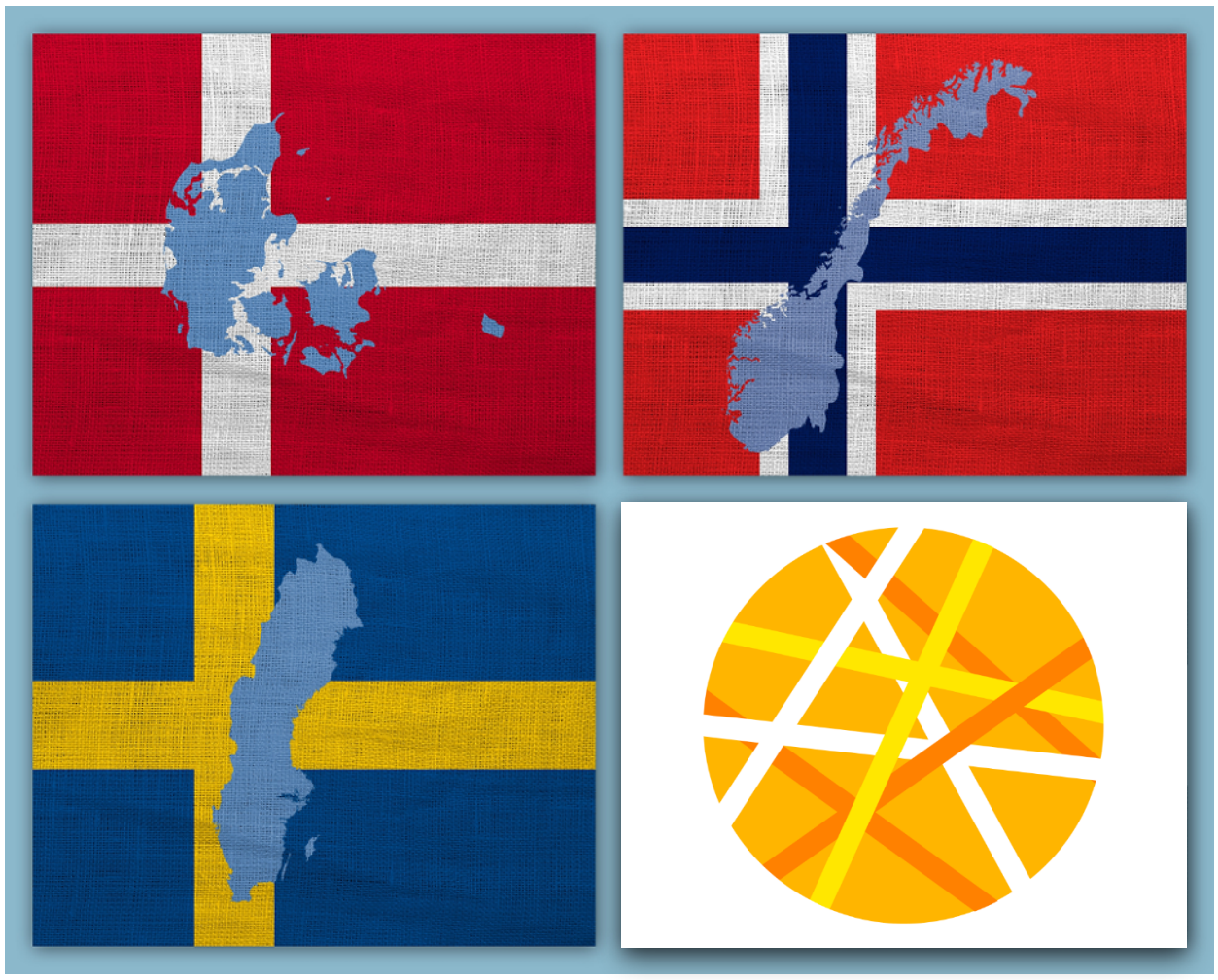
round-table • **UK** /ˌraʊnd'teɪ.bəl/ **US** /ˌraʊnd'teɪ.bəl/ *adjective*

A round-table discussion/meeting is one where people meet and talk in conditions of equality.

Comments and idea headings have been randomly placed for size and editing. No endorsement or priority is implied or given.

PARTNER PROFILES

DENMARK, NORWAY AND SWEDEN



Anyone who has lived in Scandinavia knows there is a good-natured rivalry among Denmark, Norway and Sweden. Hundreds of years of history and similar languages have evolved into fierce competition: very funny **Twitter wars** between Denmark and Sweden, cross-country **ski medals**, the number of **Eurovision** wins (grandmaster Sweden at six, Norway and Denmark running neck and neck at three each) and the most serious of all, cloudberry-picking disputes along the Norwegian (*molte*) and Swedish (*hjorton*) border. These rivalries, good-hearted in nature, complement cooperation: compromise, working together to find solutions that no one country can solve, and active participation in the European project. It is no less for EUnetHTA. All three countries play very active and progressive roles in the EUnetHTA consortium.

DEFACTUM – DENMARK

Primary mission: In DEFACTUM we seek to increase social equality in health. Amongst other things, we support decision-makers on interventions and technology within healthcare, based on interdisciplinary research and development activities.

History: Under different names, DEFACTUM has a long history as a research and evaluation institution, always operating on both regional, national and international level. From the onset, DEFACTUM featured a division for health technology assessments. DEFACTUM only does assessments on other technologies and not on pharmaceuticals.

Involvement with the EUnetHTA project: DEFACTUM has participated in the EUnetHTA collaboration since Joint Action 1 (JA1), first as voluntary participants engaged in the development of the EUnetHTA Core Model. In Joint Action 2 (JA2) and Joint Action 3 (JA3), DEFACTUM has been appointed as the official representative of Denmark in the EUnetHTA collaboration.

In JA2 DEFACTUM was deeply involved in further developing the EUnetHTA Core Model, with a special focus on the patients and social aspects. DEFACTUM also participated in testing the Core Model in international HTA collaborations. The testing of different collaboration models, when conducting HTAs in international collaborations between agencies, was a main task in this work.

In JA3 DEFACTUM is involved in Joint Production and National Implementation and Impact. Hence, DEFACTUM continues to work with the Core Model, now with a focus on producing international HTAs in collaboration with other agencies and to distribute and make use of these HTAs in a national context.

Grateful acknowledgement *to Lotte Groth Jensen.*

Denmark	
Norway	
Sweden	

NIPHNO – NORWAY

Vision of the Norwegian Institute of Public Health

The Norwegian Institute of Public Health (NIPHNO) acts as a national competency institution placed directly under the Ministry of Health and Care Services.

NIPHNO is responsible for knowledge production and systematic reviews for the health sector and provides knowledge about the health status in the population, influencing factors, and how these may improve. The institute focuses on:

- infectious disease control;
- physical and mental health;
- environmental factors, substance abuse, tobacco, nutrition, physical activity and other factors that affects health status and inequality;
- health-promotion and preventive measures in the population;
- global health.

NIPHNO Strategy

NIPHNO provides knowledge for public health and the health and care services. This knowledge supports the institute's activities with regard to emergency preparedness, advice, health analysis, research and services.

Primary mission for HTA at NIPHNO

HTA reports of different formats are commissioned by the Specialist Health Service in particular at the national level for their decision-making processes. HTA at NIPHNO is organised in the Division for Health Services and HTA is a major activity and has high priority. The Division also includes a range of related activities such as Cochrane and EPOC activities, Campbell Secretariat, Commonwealth Fund and cooperation with other international organizations, performing systematic reviews, and in addition produces quality indicators based on measurements of activities in the specialist health service. Activities related to global health is an expanding field.

Brief History of Health Technology Assessment at NIPHNO

The Ministry for Health and Care started as a working group in 1996 to prepare the establishment of a centre for HTA based on international experience. Centre for health technology assessments (in Norwegian: Senter for medisinsk metodevurdering (SMM)) was established in 1997 at the research institution SINTEF in Oslo.

In 2003, the Ministry for Health and Care initiated work to establish a new centre, The Norwegian Knowledge Centre for the Health Service (NOKC) at the Directorate for Health. Three institutions including SMM formed the centre for methods and knowledge assessment in a broad sense in the fields of health and care established in 2004. From January 2016, it became part of the Norwegian Institute for Public Health (NIPH) organized in the Division for Health Services (Område for helsetjenester).

Involvement in EUnetHTA

The Norwegian Knowledge Centre for the Health Services (NOKC) at the Norwegian Directorate for Health was involved in EUnetHTA from the planning stage in 2005 for the first EUnetHTA Project of 2006–2009. From 2005, NOKC led Work Package 3 Internal Evaluation (WP3) as well as being represented in Work Package 1 Steering Committee (WP1). NOKC also took part in the other work packages.

NOKC participated in Joint Action 1 (JA1) (2010–2012) as a partner organisation in several work packages. This resulted in several jointly produced methodological guidelines and HTA reports which were published internationally and implemented nationally. In Joint Action 2 (JA2) (2012–2015) NOKC led Work Package 2 HTA Dissemination and Capacity Building (WP2) and participated as a partner in several other work packages.

Currently, in EUnetHTA Joint Action 3 (JA3) (2016–2020), NIPHNO leads Work Package 4 Joint Production (WP4). This work package is responsible for producing joint health technology assessments. These assessments should be fit for purpose, of high quality, of timely availability, and cover the whole range of health technologies. The production processes of the assessments are continuously improved and updated to best fit the purpose. WP4 is also working to develop and refine a system of horizon scanning, topic selection and prioritisation in close collaboration with other relevant work packages. It is essential that the reports are actually used in national settings, and an additional aim of WP4 is therefore to develop a process that facilitates implementation of assessments. Last, but not least, WP4 will develop recommendations for the production process as part of a sustainable model of European collaboration on jointly produced assessments after 2020.

Questions about NIPHNO or WP4?
WP4.LP_EUnetHTA.JA3@fhi.no

Grateful acknowledgement *to Anna Lien Espeland and Ingvil Von Mehren Sæterdal.*

NOMA – NORWAY

Primary mission: The Norwegian Medicines Agency /NoMA (Statens legemiddelverk) is an agency of the Ministry of Health and Care Services (Helse & omsorgsdepartementet/HOD). NoMA is in charge of marketing authorisation, classification, vigilance, pricing, reimbursement and providing information on medicines to prescribers and the public. NoMA works to:

- Ensure that medicines in Norway are safe and effective;
- Ensure that the patients have access to medicines regardless of their ability to pay;
- Support correct medical and cost-effective use of medicines;
- Ensure that medical devices placed on the market and put into service in Norway meet the regulatory requirements.

International cooperation: NoMA represents Norway in EU scientific committees and working parties, and other international bodies such as the United Nations and EDQM. NoMA participates in the European co-operation between Competent Authorities for medical devices, EU committees and working groups, and in the process of assessments of medicines on behalf of The European Medicines Agency.

Involvement with the EUnetHTA project: NoMA joined EUnetHTA in November 2016 in JA2.

NoMA allocated resources to Joint Production and further development of European joint HTAs, and has participated as a co-author in the Joint assessment (Midostaurin/ Rydapt) in collaboration with FIMEA. NoMA has established a team of assessors and an allocated statistician.

NoMA also contributes in the working group Topic Selection (TISP) with the goal to develop a process for identification and criteria for prioritization of methods/topics suitable for European HTA. NOMA is in continuous dialog with WP4 Lead, NIPHNO, and Co-Lead, ZIN concerning new activities and further development of the process of Joint Assessments, especially for pharmaceuticals.

NoMA is a partner in Evidence Generation in Strand B: PLEG and registries with real world evidence generation, and in Strand A: Early Dialogues (ED), where we participate in EDWP (sharing a place with TLV). NoMA has a very active role in developing Early Dialogues (ED) as a process, collaboration with EMA and direct contribution in different types of EDs. NoMA has a permanent team for ED and members share responsibilities for participation in ED (e-meetings and F2F meetings).

NoMA is a also partner in WP7-Implementation and Impact activities. NoMA acts as Implementation Lead with the main responsibility to develop a strategy for increased use and the development of EUnetHTA products to develop national processes in Greece. NOMA has chosen to extend Nordic cooperate n supporting activities and plans to work together with HTA agencies from Denmark (DEFACTUM) and Finland (FIMEA).

Grateful acknowledgement *to Krystyna Hviding.*

TLV – SWEDEN

Primary mission: TLV is an HTA body responsible for pricing and reimbursement decisions in Sweden. We make health economic assessments of pharmaceuticals and medical devices. We apply a life cycle perspective in our work and follow the market and individual products over time. Our vision is: The most possible health care for the tax payers' money.

TLV is an governmental agency under the Ministry of Health founded in 2002.

We have worked since then within the new reimbursement legislation stating a value-based approach. In the ever-changing environment with new challenges and opportunities, TLV has the assignment to develop the pricing and reimbursement system. Since the rapid increase in the launch of high cost medicines, the benefits of developing the system have become more evident. Especially, cooperation with payers and providers (county councils) has increased. Evaluation of new medicines are often made in teams consisting of a health economist, a pharmacist and a legal advisor.

Involvement with the EUnetHTA project

TLV participates in the EUnetHTA as a partner since JA3 (June 2016). TLV was an associated member in JA2. In JA3 TLV is the lead partner in WP3, Evaluation.

TLV is also a member of WP1, WP4, WP5A and B (in WP5B as an activity center lead).

Out of three joint assessments (REAs) in 2017 within WP4, TLV has participated in two:

- **PTJA01**: Rydapt (AML) - TLV reviewer;
- **PTJA03**: Alecensa (lung cancer) - TLV main author together with the co-authors HVB (Austria) and AAZ (Croatia).

Within WP5A, TLV has participated in three scientific advices together with the MPA and in eight scientific advices together with other HTA:s and the EMA.

Within 5B, TLV is leading one of two post-license evidence generation pilots (PLEG).

Grateful acknowledgement *to Anna Strömgren.*

SBU – SWEDEN

The Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) is an independent Swedish national authority. Since the 80's, SBU assessments have provided reliable guidance and supported key decisions in health care, to practitioners as well as politicians and decision makers. In 2015, SBU was assigned an additional task – assessing interventions in social welfare. The agency is also involved in two EUnetHTA work packages, contributing to an effective HTA network across Europe.

SBU is tasked by the government with assessing healthcare and social service interventions from a broad perspective. This means to always include medical, economic, ethical and social aspects.

Society provides support for people in different ways – in the form of medical care, care for elderly and disabled, and special care when, for instance, substance abuse is involved. Society provides special healthcare and social services to children who are vulnerable or who are having difficulties in school. But what type of treatment, care or support is the safest and most effective? Which methods and interventions are worth the effort, and which are the most cost-effective?

SBU promotes better health care and social services by providing decision makers with systematically developed assessments of the available scientific evidence. Raising awareness about systematic assessment methods and how to identify potential sources of bias when interpreting scientific reports, is another important aspect of the work we do at SBU. We therefore also provide education to the scientific community and clinical professionals on current systematic evaluation methods.

Our history in brief

Founded in 1987, SBU was one of the very first HTA organizations in the world. The Swedish government expanded SBU's assignment to include social welfare in 2015. We have since published several well-received reports that evaluate the evidence and identify scientific uncertainties relevant to social services. There are approximately 80 employees at SBU, the majority with PhD.

To maximize the impact of SBU's reports, we specifically identify which professionals, patient groups, politicians, administrators and media outlets should be targeted for each report. SBU reports include:

SBU Assessment reports are the result of a careful systematic evaluation of all the available scientific evidence, by a team that includes several experts in relevant scientific areas. More about our scientific method in our methods handbook.

SBU Commentary
Summarizes and examines selected systematic reviews published elsewhere. Experts help the staff place the results in Swedish context. Prior to publication, the report is subject to internal and external reviews.

SBU Evidence Map
Systematically evaluates the quality of systematic reviews in a field to identify reliable evidence and gaps in scientific knowledge. SBU Evidence Maps are generated with the help of experts in the field. Prior to publication, the maps are examined by an independent expert, as well as our quality and priority group.

SBU Policy Support
Identifies and presents available scientific evidence to support policy and decision making, including the development of national guidelines, at other government agencies. In consultation with professional experts, SBU staff generates supporting documentation to address the various questions that have been posed.

SBU Enquiry Response
Consists of systematic literature searches to highlight studies that can address questions received by the SBU Enquiry Service from Swedish healthcare or social service providers. Relevant references are compiled by an SBU staff member, in consultation with an external expert when needed. The quality of the studies identified is not systematically reviewed.

Evidence Gap
Identifies methods or practices for which no conclusive systematic review of benefits and harms has been published. Gaps in scientific evidence appear on the SBU website to help researchers and granting agencies identify areas that need research or systematic review. An additional objective is to offer healthcare and social service providers a basis for setting priorities.

SBU's involvement in the EUnetHTA project

SBU is a long-standing Partner in the European initiative, with our involvement dating to before JA1. During JA1 we were a Lead Partner during and during JA2, we were a Co-lead Partner. Now in JA3, SBU participates in two Work Packages:

WP6 focuses on improved efficiency and quality of joint work. Within WP6, SBU is participating in the development of guidance for reviewing economic evaluations, focusing particularly on the transferability of economic results from one setting to another, the assessment of context-specific costs, and how conflicts of interest and publication bias should be evaluated.

SBU will also act as dedicated reviewer of the standards of procedure (SOP): *Identification of and interaction with external stakeholders (external experts, patients and manufacturers),* and possibly other SOPs regarding patient involvement or ethics.

EUnetHTA WP7 focuses on National Implementation and uptake of international HTA-reports and tools in member states. SBU concentrated its involvement in the initial phases of the WP7; the first report was published in 2017.

Grateful acknowledgement *to Debora Egenvall.*

NCPE

EUnetHTA PARTNER NCPE CELEBRATES 20th ANNIVERSARY

Skillfully managing challenges has contributed to NCPE's success

This year is the 20th anniversary of the foundation of the National Centre for Pharmacoeconomics (NCPE) in Ireland – a high-performing national agency with sole responsibility for conducting Health Technology Assessments (HTAs) of all new medicines for the Irish healthcare payer. From modest beginnings in 1998, the centre was funded by the Department of Health to cover five staff members, the aim of which was to promote expertise in Ireland for the advancement of the discipline of pharmacoeconomics through practice, research and education.

In those early formative years, the practice component of NCPE activities constituted less than five pharmaceutical assessments per year. However, during the period 1996 to 2006, Ireland's population increased at an annual average rate of 1.6% - the largest population growth in the EU at the time. With that came a myriad of challenges for the healthcare sector – the issue of accessibility to and affordability of prescription medicines in Ireland was becoming more and more prominent.

In 2006 an agreement between the pharmaceutical industry and the healthcare payer allowed the payer, for the first time, to request and use evidence of cost effectiveness of medicines in the reimbursement decision. Subsequently the requirement to consider cost-effectiveness in reimbursement decisions was enshrined in law through the 2013 Health Act. During this time, the work of the NCPE has evolved and expanded. Today NCPE is an autonomous, independent body whose primary activity is to conduct HTAs of all new medicines for the healthcare payer.

Research and education activities, in association with hospitals and universities, are key to supporting the quality and efficiency of this primary activity. In 2017, the centre received 21 submissions for HTA and now employs a staff of 14. Operational links with key stakeholders and service providers, forged since inception, remain stronger than ever. The alliance of practice/research/education ensures the integrity and quality of the HTA process, and reinforces the position of the NCPE at the forefront of the science in Ireland. The NCPE is now recognised as a key support to evidence-based decision making on pharmaceutical reimbursement by the healthcare payer and the Department of Health. NCPE's work is having an impact across the country, and will continue to evolve to support Ireland's as well as Europe's health care decision-makers.

Want to know more about NCPE?

National Centre for Pharmacoeconomics

NCPE Ireland

Grateful acknowledgement *to Cara Usher.*

EUnetHTA.EU REBUILD

IMPROVED SERVICES AND STAKEHOLDER INVOLVEMENT

EUnetHTA.eu successfully rebuilt

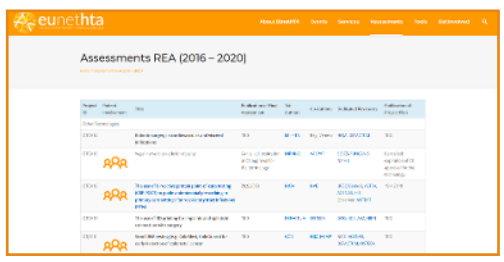
The Secretariat, under the direction of EUnetHTA's Executive Board and in cooperation with the Project Management Group (PMG), has rebuilt and secured EUnetHTA.eu. The rebuild allows the continued and sustainable evolution of EUnetHTA while maintaining the progress of previous Joint Actions and projects.

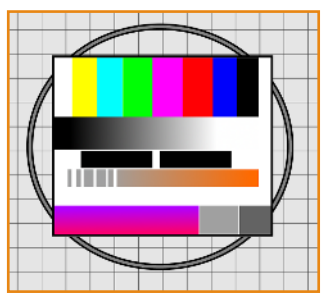
Broken Links

With the transfer of over 800 documents and thousands of links, it is inevitable that there are broken links. To date, there have been 60+ redirections. The Secretariat does its utmost to correct broken links in a timely manner: **support@zinl.nl**.

What is new?

- **Improved cross-platform branding and social media capability**
- **Clear access and guidance to EUnetHTA products and services**
- **Dedicated one-stop Rapid Effectiveness Assessments (REAs) page**
- **New opportunities for targeted collaboration and production**
- **Ability to live stream and enable greater stakeholder participation**





GOVERNANCE

EUnetHTA means collaboration
EUnetHTA means taking decisons together
EUnetHTA means sharing responsbility

Review of Executive Board Governance Structure

Since the start of Joint Action 3 (JA3), the Zorginstituut (ZIN) has established a Directorate for the Joint Action consortium, divided into two separate entities – the Director's office and the EUnetHTA Secretariat. The Director's office supported the day-to-day work of the Director of EUnetHTA. The EUnetHTA Secretariat functions as a management unit for EUnetHTA activities implemented via Work Packages 1 to 7, for cross Work Package activities and for the relevant governance and other bodies of the consortium.

The role of the Director of EUnetHTA, which was primarily representative and acted as Chair of the Executive Board, was originally appointed to Dr. Wim Goettsch. Dr Goettsch is an internationally recognized expert on scientific research for HTA and implementation through collaboration within the EU and globally. Recently, Dr. Goettsch accepted a new position as special HTA-advisor at ZIN. In this new role, he is responsible for the alignment of European Health Technology Assessment methods with the processes of Zorginstituut Nederland. Due to the new role, Dr. Goettsch discontinued his position as Director of EUnetHTA on March 15, 2018.

The Secretariat, together with EUnetHTA's Executive Board, are considering the necessary changes to the governance of EUnetHTA in order to ensure continued progress during the current phase of EU collaboration on HTA. The representative position of EUnetHTA Director and corresponding duties will be transformed into the newly duly-elected Chair of the EUnetHTA Executive Board. This is a 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.

What does this mean for partners and stakeholders in the EUnetHTA consortium?
- high transparency in leadership
- sustainable governance
- continuity in operational management

EUnetHTA carries forward its high level of excellence and service

Directorate = eunethta@zinl.nl

Secretariat = eunethta@zinl.nl

2018 EUnetHTA FORUM

Be part of the discussion on HTA in Europe!

Cologne, Germany

LIVE STREAMING

May 25, 2018

Delivering Products and Services

Register here

eunethta

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