# eunethta magazine

FALL 2018

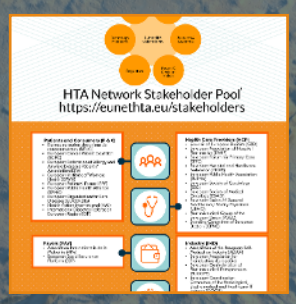
## HTA PROPOSAL UPDATE

## HTA REPORTS

## IMPACT
ITALY

## INTERVIEW
CABEZÓN RUIZ
MEP

## PARTNER PROFILES
AIFA




## WORKING TOGETHER
STAKEHOLDERS

# IN THIS ISSUE





EUnetHTA Magazine

*https://www.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:** EUnetHTA@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

# 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

# HTA Legislative Proposal Directive 2011/24/EU

## status and update

eunethta JAs
2018
2017
2016
2015
2014
2013
2012
2011
2010

**OCT 1**

### European Parliament vote

The European Parliament voted in favour of the ENVI Committee's report, giving the rapporteur a mandate to negotiate with the Council on the basis of the report.

**SEPT 12-13**

### 62 amendments adopted by Committee on Environment, Public Health and Food Safety (ENVI)

- Relative Effective domains (CURRENT, TECHNICAL, SAFETY, EFFECTIVENESS) form basis of future cooperation
- Domains (ECONOMIC, ETHICAL, ORGANISATIONAL, SOCIAL, LEGAL) remain with Member States for national appraisal

**JUL 9**

### The Way Forward for HTA Cooperation - the view of stakeholders

On 9th July 2018, over 300 policy makers, healthcare providers, patient representatives and other experts discussed their views about the future cooperation on Health Technology Assessment (HTA). The discussions indicated that, after 20 years of joint work, HTA should be given a fair chance to become more structured, sustainable and efficient, better allowing for an optimal use of resources and sharing of expertise across the EU.

**JUL 1**

### Austria assumes Presidency of EU Council

Austrian presidency aims to reach compromise agreement amongst Member States for the first eight articles of the directive.

**JAN 31**

### EC adoption

A proposal for a Regulation was adopted by the European Commission on 31 January 2018. It is the result of an extensive reflection process following the results of the impact assessment outlined below. It is sent to the European Parliament and the Council with the aim of adoption by 2019.

European Commission

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's proposal objectives include:

1. Improve the availability of innovative health technologies for EU patients;

2. Ensure efficient use of resources and strengthen the quality of HTA across the EU;

3. Improve business predictability.

**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.


IMPACT

**Written by Rossella Di Bidino, UCSC GEMELLI**

***Agostino Gemelli Teaching Hospital https://www.ucsc.it***

# USE OF EUnetHTA ASSESSMENTS AT THE HOSPITAL LEVEL: THE EXPERIENCE OF THE GEMELLI TEACHING HOSPITAL, ITALY

EUnetHTA produces Joint Assessments involving national HTA organizations. Adaptation is an essential step in order to translate a European assessment into an informative tool even for hospital decision makers. Integrating the EUnetHTA experience with the perspective of Hosptial-Based Health Technology Assessment (HB-HTA) is a crucial step. Looking to realities as the Fondazione Policlinico Universitario 'Agostino Gemelli' allows us to identify opportunities and criticalities of that adaptation plus an integration process.

The Gemelli Teaching Hospital is a health care institution of high complexity located in Rome, Italy, with a capacity of 1,547 beds. It is affiliated with the Università Cattolica del Sacro Cuore (the largest private university in Italy), and serves the Italian national health system, Servizio Sanitario Nazionale (SSN). Since 2001, the HTA Unit and Innovation Units support informed decision-making in the selection of technologies at the hospital level. The HTA Unit has been a partner of EUnetHTA since 2010 and has participated as a co-author on assessments. As part of its activity, the HTA Unit carries out rapid, comparative and multi-domain assessments for all technologies discussed by the Drug and Devices Board (Commissione per la Farmacoterapia e Dispositivi Medici (COFT-DM)), which is responsible for decisions relating to the hospital formulary. In 2017, 54 drugs and 48 medical devices were evaluated: 86% and 70% of assessed technologies, respectfully, were approved for introduction, with or without restrictions by COFT-DM.

One recent example of partial adaptation of EUnetHTA assessments is the JA PTJA03 on Alecensa (alectenib) as monotherapy indicated for the first-line treatment of adult patients with ALK+ advanced NSCLC. Indeed, we are currently assessing it both in first line and in advanced NSCLC patient previously treated with Crizotinib. Clinical and safety evidence was taken both from the JA and EMA documents. The HTA Unit compared the JAs' comparators with national/European guidelines and available alternatives in the Hospital Formulary. Gemelli is integrating the JAs with a rapid assessment of the expected budget impact (i.e. cost of therapy, expected number of patients under treatment per year) and organizational implications (if any).

For its hospital assessment, the HTA Unit merges already available external assessments, mainly focused on efficacy and safety aspects as happens in the JAs, with regional decisions and internal economical and organizational implications. The process of adaptation and integration of the JAs requires the interpretation of evidence with a different perspective. It's relevant to compare a technology to all other available hospital alternatives and to assess its added value taking into account the overall clinical pathway.

Indeed, a hospital is responsible to not only allow access to health technology, but also to assist patients along their care pathway. Therefore, comparators could differ from those selected in the JAs given the scenario considered and the ethical implications relevant at the hospital level. Furthermore, HB-HTAs should take into account internal strategies and hospital mission. In this way, decision-makers can integrate external decisions regarding technologies with internal context elements and managerial constraints on budget, while guaranteeing access to care.

Following that approach, JAs can impact decision-making regarding acquisition, and implementation or discontinuation of technologies at the hospital level. Timing of JAs is a crucial element in order to respond promptly to hospital decision-maker needs. Taking into account drugs and medical devices, in an ideal scenario where JAs are available soon after the EMA and regulatory agency decisions, the Hospital-HTA could dedicate more resources to adaptation and less to evidence retrieval. In that scenario, only economical and organizational aspects must be assessed de novo.

The recent proposal of regulation on HTA is aligned with hospital needs both in terms of expected timing and the content of JAs. Furthermore, the proposed annual Horizon Scanning could support hospital HTA to play a more strategic role in assisting decision makers to anticipate the arrival and the expected impact of emerging technologies. Even if not explicitly mentioned in the proposal, hospitals could participate in JAs with their experts as well as relevant stakeholders and collectors of real world data. The Gemelli Teaching Hospital experience with HTA proves how European and national policies could better align with local needs.

# INTERVIEW: SOLEDAD CABEZÓN RUIZ MEP

## EXPANDING DIALOGUE BETWEEN HTA BODIES AND STAKEHOLDERS

Each quarter, EUnetHTA Magazine asks three questions to key stakeholders and participants in the HTA world. For our Fall edition, we talked with Soledad Cabezón Ruiz, Member of the European Parliament and EP Rapporteur for Directive 2011/24/EU, the HTA legislative proposal.

### About Ms. Ruiz

Soledad Cabezón is one of the most active and enthusiastic MEP in health files. Since the beginning of her mandate in the European Parliament (EP) she has been very committed with patients affected by the Hepatitis C virus and their treatment, pushing for an EP own-initiative (INI) report on improving Access to Medicines, for which she was the rapporteur. This work was determinant on compelling European Commission on the review of health Research and Development (R&D) incentives and on a Health Technology Assessment proposal. Regarding this, she is currently finishing her work as rapporteur of the Regulation on Health Technology Assessment, where she has fought for an independent, objective and scientific methodology as the core topic of the proposal.

As a politician and as a cardiologist, she is also very committed to Thalidomide victims. More than 50 years after the biggest health disaster in Europe, her efforts to encourage the EU to recognize more Thalidomide victims are well known. She is also a fierce defender of European health systems as one of the values most appreciated by European citizens and as the most important basis of the EU social pillar. Working on R&D is also her priority, asking for reinforcing health research not only to fight against current threats but also to allow all citizens to access R&D results.

Currently she co-chairs the Health Intergroup and has also been involved in the opinion on anti-microbial resistance (AMR,) putting all her commitment and efforts into a global strategy to combat AMR.

Read more about AMR at https://ecdc.europa.eu/en/antimicrobial-resistance

### Three questions

a) Why is the HTA legislative proposal important?

b) How does the Proposal impact the average European citizen?

c) Could you describe some of the challenges you are facing in the European Parliament on this dossier?

### From Ms. Ruiz

The European Parliament launched the debate about the access to medicines at the beginning of the current legislature. A veiled discussion was already happening, but the economic crisis and the high prices of medicines such as the drugs for hepatitis C treatment were the decisive factors to acknowledge a problem that goes beyond high prices. It is the mismatch between research and clinical needs, as well as inadequate research quality due to an excess of incremental research at the expense of genuine innovations (up to 85% according to different studies). On the other hand, a number of studies bring to light the lack of evidence of certain medicines such as the new oncological treatments, whose prices have suffered an exponential increase without a significant increase of the survival rate.

In recent years, the European Commission has presented initiatives, like research incentives in health fields. However, access to health technologies and guiding research priorities toward clinical needs requires a general approach and, if possible, a legislative proposal with that objective.

The proposal of a regulation for a Health Technology Assessment at the European level can be a decisive step in this regard, depending on the final terms of the report and provided that the position of the ENVI Committee is respected. We must not forget that the access to health technologies was at the origin of the European Parliament's request in its report on options for improving access to medicines.

***Soledad Cabezón Ruiz, Member of the European Parliament (S & D)***

S&D

From Ms. Cabezón's Twitter feed: Miembro de la Comisión de Medio Ambiente, Salud Pública y Seguridad Alimentaria.

***@SoledadCabezon***

# INTERVIEW: SOLEDAD CABEZÓN RUIZ MEP (CONT.)

*Read more about Ms. Ruiz and other Members of the European Parliament* ***http://www.europarl.europa.eu/meps/en/125041/SOLEDAD_CABEZON+RUIZ_home.html***

*Read about the organisation and structure of the European Parliament* ***http://www.europarl.europa.eu/portal/en***

Until now, there has been concern within the European Commission about the competitiveness of the health technology industry in Europe, but industry cannot be at odds with access to medicinal products nor can it renounce to the quality of the innovation as competitiveness criterion.

Conversely, the reality in Europe is that not all Member States have the same expertise and capacity to carry out the evaluation. The collaborative network EUnetHTA has also helped but the truth is the work done has not been fully seized.

1. We have an assessment of the contribution of new medicines and medical devices to what already exists in each Member State. However, this means not only duplicating work and losing efficiency, but also missing the opportunity to improve the quality of the health technology (medicines and medical devices) because research is aimed for national deficiencies. On the other hand, access to health technologies by patients can be improved in terms of quality and time, as we will be able to identify the real contribution and the time in accessing will be shortened.

2. At present, there exists a collaborative network of national agencies at the European level, but its voluntary nature prevents us from seizing the opportunities provided by a European assessment, despite the quality of the assessment processes and EUnetHTA's reports. A European assessment allows improving the quality of the available evidence and the assessment itself, so it must be used. As an example, a number of studies have demonstrated that many anticancer medicines have often shown marginal survival gains despite the high prices of many of them.

Another equally important element is confidence in the health system that a scientific, independent and transparent process might bring.

3. Although the elimination of duplications can also benefit industry, the European Parliament has focused the process on patients, on whose benefit proposals need to justify the opportunity aspect.

Being able to differentiate the contribution of new medicinal products will benefit the sustainability of health systems. In addition, opening other areas to collaboration, such as disinvestment in obsolete technologies or new sectors like precision medicine, will also contribute in this respect.

4. This regulation can contribute to improve access to medicines in terms of quality and research priorities in the Union, and indirectly to the sustainability of health systems. However, the problem of high prices of some medicines and medical devices is a priority that needs a proactive attitude or, at least, receptive on the part of the Council. In the absence of a global legislative initiative, possible measures to improve access to medicinal products by European citizens includes but is not limited to a new Transparency Directive (Directive relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems), developing the flexibility of TRIPS at the Union level, and a public-private relationship in health and/or in the patent system.

***Grateful acknowledgement*** *to Mario López and Sonia Mario Sanchez Gomez*

*All images courtesy of* https://multimedia.europarl.europa.eu/

# PARTNER PROFILE

## ITALY

As a major economy in the European trading bloc and one of the largest population centers in Europe, the importance of Italy cannot be understated. Italy also plays a major role in Health Technology Assessment. Regional in nature with a national focus, Italy's HTA agencies are key partners in the EUnetHTA consortium:

**Agenas** - National Agency for Regional Health Services

**CRUF/AOUIVR** - Centro Regionale Unico sul Farmaca del Veneta

**DGFDM IT** - Sede del Ministro – Ministero della salute

**RER** - Regione Emilia-Romagna

**UCSC GEMELLI** - University Hospital A. Gemelli

**UVTA/AOP** - Unita di Valutazione Technology Assessment

**Veneto/CRUF** - Regione Del Veneto – Area Sanita E' Sociale

In this issue, we focus on Agenzia Italiana del Farmaco, or **AIFA**, the Italian Medicines Agency, with an accompanying piece from Giovanni Tafuri (next page), the recently appointed Senior Science Officer for EUnetHTA.

## AIFA

The Italian Medicines Agency (AIFA) is the national authority responsible for drug regulation in Italy.

AIFA is a public body operating autonomously, transparently and according to cost-effectiveness criteria, under the direction of the Ministry of Health and under the vigilance of the Ministry of Health and the Ministry of Economy.

AIFA cooperates with the Regional Authorities, the National Institute of Health, Research Institutes, Patients' Associations, Health Professionals, Scientific Associations the Pharmaceutical Industry and the Distributors. The mission:

- Promote good health through medicines

- Set fair pharmaceutical policies and assure their consistent application nationwide

- Manage the value and cost of medicines

- Promote pharmaceutical research and development

- Demonstrate independence and leadership both at home and internationally.

More specifically, the Agency:

- guarantees access to medicines and their safe and appropriate use as means to protect public health;
- ensures unity of the national pharmaceutical system in agreement with the regional authorities;
- ensures innovation, efficiency and simplification of the marketing authorisation procedures, in order to grant rapid access to innovative drugs and to drugs used for rare diseases;
- provides drug expenditure governance in the framework of economic and financial viability and competitiveness of the pharmaceutical industry;
- encourages investments in research & development in Italy;
- enforces the relationship with the Agencies of other Member States, the European Medicines Agency (EMA) and other international bodies;
- interacts with the community of patients' associations, the scientific medical world, pharmaceutical companies and distributors;
- promotes pharmaceutical culture and knowledge.

**Participation in EUnetHTA**

- EUnetHTA Joint Action (2010-12)
  - JA WP5 – Relative Effectiveness Assessment of Pharmaceuticals
  - JA WP7 – New Technologies
- EUnetHTA Joint Action 2 (2012-15)
  - JA2 WP5 – Applying the HTA Core Model for Rapid Assessment for national adaptation and reporting
  - JA2 WP7 – Methodology development and evidence generation: Guidelines and pilots production
- EUnetHTA Joint Action 3 (2016-20)
  - Work Package 7 – National implementation and impact
  - Work Package 5 – Life cycle approach to improve Evidence Generation

**http://www.agenziafarmaco.gov.it/**

# AIFA: EXTENDED

## ITALIAN MEDICINES AGENCY

**Primary mission**

The Italian Medicines Agency (AIFA), established in 2004, is responsible for all matters regarding the chain of pharmaceuticals for human use, including marketing authorisation, pharmacovigilance, and the pricing and reimbursement of pharmaceuticals in Italy. AIFA operates autonomously under the direction and vigilance of the Ministry of Health and the Ministry of Economics, cooperating with the Regions. AIFA works to:

- guarantee the right to health to all citizens;
- guarantee the uniformity of the pharmaceutical system on national territory;
- ensure that patients have access to innovative medicines and to orphan drugs;
- ensure economic balance with respect to pharmaceutical spending ceilings.

**HTA at AIFA**

AIFA applies HTA methods along the life cycle of medicinal products: starting from early dialogues and horizon scanning activities up to the assessment of the evidence available at market entry for pricing and reimbursement decisions. This life cycle includes the collection of post-launch evidence generation to support re-assessment when new evidence becomes available.

It performs horizon scanning analyses for the identification of emerging therapies in order to efficiently manage innovation and to assess their possible impact on the National Health Service.

AIFA has gained extensive experience in HTA early dialogues, at both the national and European level, which allows the development of a targeted clinical development program that can address the Agency's evidence requirements.

The HTA & Pharmaceutical Economy Division evaluates the manufacturer's dossier, performs health technology assessments, appraises and performs health economic evaluations in order to provide AIFA Committees with relevant evidence for pricing and reimbursement decisions. Moreover, HTA supports AIFA evaluation of medicines' innovativeness, by the application of defined criteria: medical need, added therapeutic value and the quality of the evidence, using the GRADE instrument. Since January 2018, a full report explaining the rationale for the Agency Committee's decision on innovativeness is made publicly available on AIFA's website.

AIFA manages the collection and analysis of Real World Data through the Monitoring Registries system, which has been implemented in Italy since 2005 in order to address uncertainties identified at the time of approval, to allow the implementation of Managed Entry Agreements (MEAs) and to re-assess pharmaceuticals following market entry.

**Pricing and reimbursement process**

In Italy the pricing and reimbursement decision-making process takes place after the submission of the application by the manufacturer, supported by the pricing and reimbursement dossier. AIFA exclusively regulates the prices of pharmaceuticals reimbursed by the National Health Service. Indeed, the Agency establishes the pricing and reimbursement conditions of medicinal products at a national level, with the support of its Committees: the Technical Scientific Committee (CTS) and the Price & Reimbursement Committee (CPR). The CTS delivers binding opinions on the therapeutic value of medicines by defining the place in therapy (the role of the medicine in its specific therapeutic context) for the purpose of reimbursement classification; it also expresses binding opinions on innovativeness and identifies the technical parameters for possible application of managed entry agreements (MEAs). On the basis of the CTS evaluation, the CPR carries out the negotiation with pharmaceutical companies to set the prices according to predefined criteria (CIPE Deliberation nr.3/2001), including cost-effectiveness. The outcome of the negotiation is a two-year renewable contract with the manufacturer.

**Involvement with EUnetHTA**

Since 2009 AIFA has been involved, as a partner, in EUnetHTA Joint Actions (JA). During JA1, AIFA collaborated on the development of Rapid HTA Core Model® for Rapid Relative Effectiveness Assessment and of methodological guidelines, and worked as author of the first pilot on relative effectiveness assessment of pharmaceuticals.

During JA2, AIFA was involved in several assessments, both as a primary author and a dedicated reviewer. It was also part of the team, led by NICE, which elaborated the Manufacturer Submission File to support joint assessments.

During JA3, AIFA has dedicated resources to Evidence Generation, with the involvement in Strand A (Early Dialogues (ED)) as member of the Early Dialogue Working Party (EDWP) and in Strand B (Post-Launch Evidence Generation (PLEG) and registries with real world evidence Generation) as activity center for the conduction of PLEG pilots.

AIFA is a partner in Joint Production and contributes to the working group on Topic Selection (TISP) with the goal to develop recommendations for topic identification, selection and prioritisation for European cooperation on HTA.

Moreover, AIFA has allocated resources to National Implementation, dedicated to implementation of joint work and impact activities.

Finally, AIFA has been an elected member of the EUnetHTA Executive Board since 2018 and is part of the newly established working party for the HTA Core Model, with the aim to take into account the requirements of the Companion Guide and the experiences of JA3 Joint Production.

***Grateful acknowledgement*** *to Agnese Cangini*

# INTERVIEW: GIOVANNI TAFURI

## EUNETHTA APPOINTS NEW SENIOR SCIENTIFIC OFFICER (SSO)

The Senior Scientific Officer (SSO) plays a key role at EUnetHTA, but what is that role? *EUnetHTA Magazine* took some time to speak with the recently appointed SSO, Giovanni Tafuri.

***https://www.eunethta.eu/stakeholders/***

***"What I feel is a priority now is the production of the Joint Assessment Reports. A coordinated effort is needed to make sure we increase the volume, still making sure our work is of the highest quality as possible, consistent and structured in a transparent way."***

***- Giovanni Tafuri***

**Background and experience**

Giovanni Tafuri has a background in Pharmacy, holds a Masters degree in "International Health Care Management, Economics and Policy" from Bocconi University, and a PhD in "Pharmaceutical Policy and Regulation" from the Division of Pharmacoepidemiology and Clinical Pharmacology of Utrecht University. He held research positions in different national and international institutions, such as the Laboratory of Regulatory Policies of the Mario Negri Institute for Pharmacological Research in Milan, the Department of Therapeutic Research and Medicines Evaluation of the Italian National Health Institute in Rome, and the Department of Essential Medicines and Health Products of the World Health Organization in Geneva, Switzerland.

Prior to this appointment, he has worked with different roles at the Italian Medicines Agency for almost 12 years mostly in the HTA and Policy Department. During the years at AIFA, he represented the Agency at different international arenas, such as the Medev and the HTA Network, and was involved in the work done during EUnetHTA Joint Action 2, especially contributing to Joint Assessment reports and Early Dialogue procedures. Furthermore, Giovanni joined EMA as a seconded national expert at the Office of Scientific Advice for two years (2015-2017), where he conducted research on the process of parallel consultation with regulators and HTA bodies.

**1. How do you see your role as Senior Scientific Officer?**

The Senior Scientific Officer has an overarching role of scientific coordination across the different work packages. One of the key tasks is to make sure the work is consistent and to facilitate scientific cooperation among the different EUnetHTA partner institutions. Obviously given the number of activities, the focus needs to shift from time to time towards priorities. What I feel is a priority now is the production of the Joint Assessment Reports. A coordinated effort is needed to make sure we increase the volume, still making sure our work is of the highest quality as possible, consistent and structured in a transparent way.

**2. What are the challenges you are facing as you assume your role?**

EUnetHTA has over 80 partner institutions across Europe contributing to the current Joint Action within different working groups. The number of players involved and the heterogeneity of the different HTA systems make this work challenging but also very stimulating. It is a great learning process and a unique opportunity to understand the variety of HTA systems in place in Europe, as well as finding common ground for our work.

**3. What opportunities do you see for continued European HTA cooperation?**

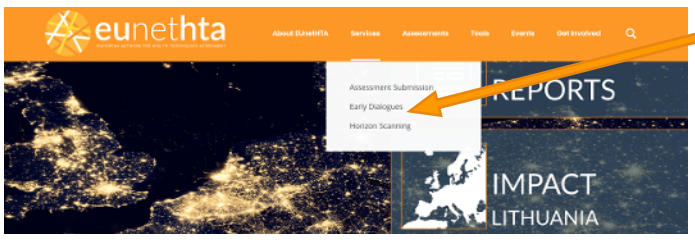
The HTA legislative proposal is under discussion. Furthermore, this scenario is constantly evolving, posing new opportunities and challenges to HTA bodies, such as the nascent field of ATMPs, the successful development of medicines for rare diseases, a stronger involvement in the HTA processes advocated by the patients community, and above all, the issue of sustainable access. All these issues may require re-thinking and re-shaping our national HTA processes and criteria. This can hardly be tackled through an isolated approach, and for that I believe in the need for an integrated approach among Member States.

COMING NOVEMBER 2
EARLY DIALOGUES FOR MED./TECH. DEVICES

## FOCUS: EARLY DIALOGUES

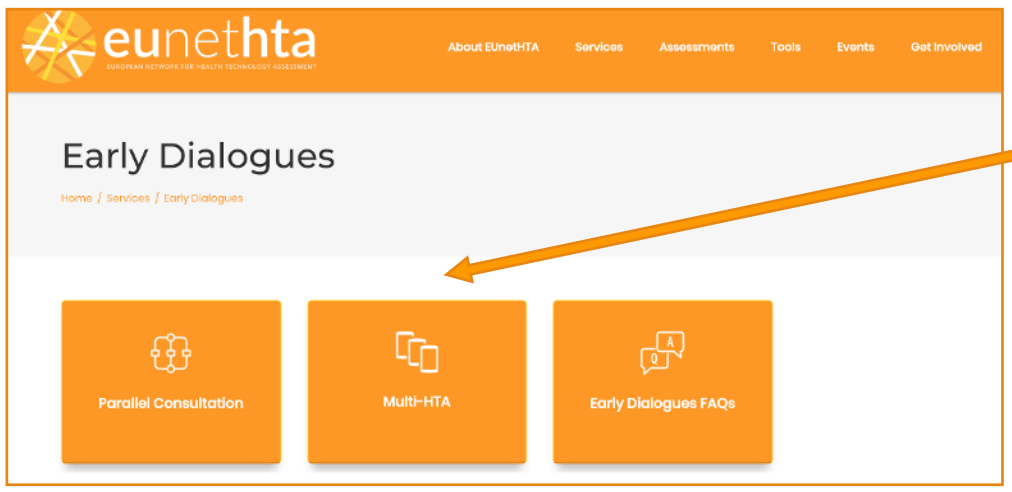
**Focusing on EUnetHTA products, services and processes**

- *Early Dialogues*




### Early Dialogues
### https://www.eunethta.eu/services/early-dialogues/

Find out about Parallel Consultations (PC) and Multi-HTA Early Dialogues (ED)




**What is Parallel Consultation?**

The procedure is a single gateway for Parallel Consultations with EMA and HTA bodies on their evidence-generation plans.

The main benefits of the parallel consultation procedure include:

- streamlined procedure for applicants;
- increased mutual understanding and problem-solving ability between EMA and HTA bodies through a more structured interaction;
- improved coordination with, and greater participation of HTA bodies in parallel consultations through EUnetHTA's Early Dialogue Working Party (EDWP) and the EUnetHTA Early Dialogue (ED) Secretariat.

EMA's scope and the fees charged for this procedure are the same as for standard scientific advice.

Some HTA bodies may charge fees for their participation in Parallel Consultations. The EUnetHTA ED Secretariat can provide information on HTA-associated fees.

EMA and EUnetHTA have published the following documents (all available on the same web page):

- joint guidance for the Parallel Consultation procedure which explains how to apply and highlights the actions for each party and preferable timelines;
- 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:
  - Letter of Intent for Parallel Consultation
  - Parallel Consultation briefing document template

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

For information regarding the regulatory aspects, please contact

**EUnetHTA ED Secretariat: EUnetHTA-HAS@has-sante.fr**

**EMA Scientific Advice Secretariat: scientificadvice@ema.europa.eu**

**What is Multi-HTA?**

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

For medicine developers who prefer to engage in a Parallel Consultation providing dialogue with both regulators (the EMA) and HTA bodies, please refer to EUnetHTA/EMA Parallel Consultations.

The Multi-HTA ED procedure involves EUnetHTA's Early Dialogue Working Party (EDWP). This robust and stable group of HTA bodies is constituted by HTA partners with a substantial experience in ED, high level of commitment and participation in JA3 EDs.

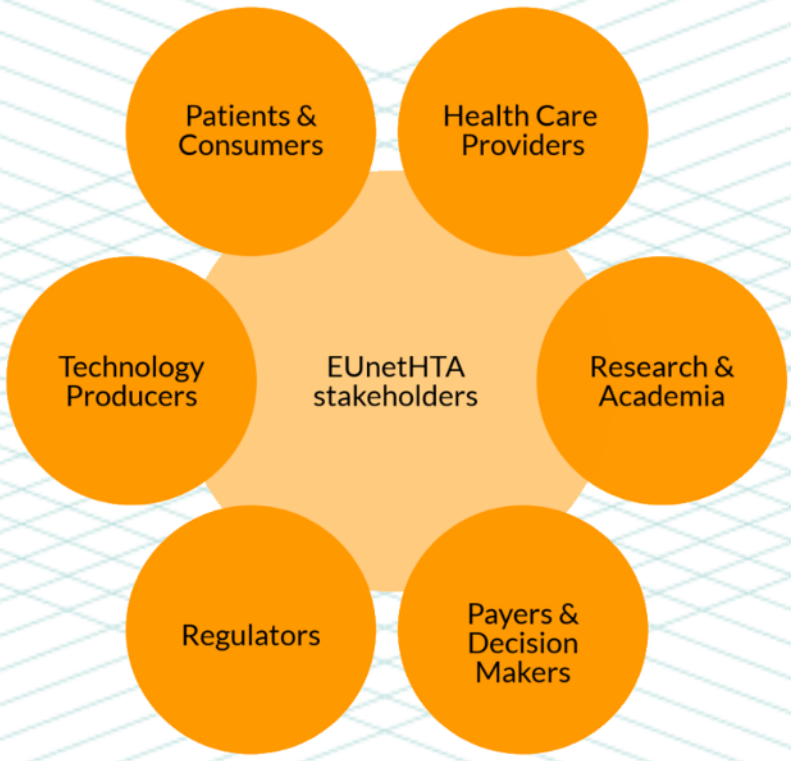
Currently, the EDWP is made up of the following HTA bodies: HAS (France), G-BA (Germany), AEMPS (Spain), AIFA/RER (Italy) [shared seat], NICE (UK), NIPN (HU), NOMA (NO)/TLV (SE) [shared seat], RIZIV-INAMI (BE)/ZIN (NL) [shared seat].

Due to limited resources, it is expected that not all the requests for multi-HTA EDs will be accepted by the EDWP.

Some HTA bodies may charge fees for their participation in Multi-HTA ED procedures. The EUnetHTA ED Secretariat can provide information on HTA-associated fees.

Companies willing to apply for a Multi-HTA Early Dialogue should complete a Letter of Intent to EUnetHTA ED Secretariat at EUnetHTA-HAS@has-sante.fr. Questions about EUnetHTA EDs should be directed to the same address.

# working together




# HTA Network Stakeholder Pool[1]

**Patients and Consumers (P & C)**

- Bureau européen des unions de consommateurs (BEUC)
- European Cancer Patient Coalition (ECPC)
- European Federation of Allergy and Airways Diseases Patients' Association (EFA)
- European Institute of Womens Health (EIWH)
- European Patients' Forum (EPF)
- European Public Health Alliance (EPHA)
- European Organisation for Rare Diseases (EURORDIS)
- Health Action International (HAI)
- International Diabetes Federation European Region (IDF)

**Health Care Providers (HCP)**

- Council of European Dentists (CED)
- European Association of Hospital Pharmacists (EAHP)
- European Forum for Primary Care (EFPC)
- European Hospital and Healthcare Federation (HOPE)
- European Public Health Association (EUPHA)
- European Society of Cardiology (ESC)
- European Society of Medical Oncology (ESMO)
- European Union of General Practitioners/ Family Physicians (UEMO)
- Pharmaceutical Group of the European Union (PGEU)
- Standing Committee of European Doctors (CPME)

**Payers (PAY)**

- Association Internationale de la Mutualité (AIM)
- European Social Insurance Platform (ESIP)

**Industry (IND)**

- Association of the European Self-Medication Industry (AESGP)
- European Association for Bioindustries (EuropaBio)
- European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
- European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR)
- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- Medicines for Europe
- MedPharmPlast Europe (MPPE)
- Medtech Europe (MTE)
- Plasma Protein Therapeutics Association Europe (PPTA Europe)

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EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

1. DG Sante https://ec.europa.eu/health/technology_assessment/policy/network_en