


Health Technology Assessment

European Patients' Forum Seminar Report





“It is important to have one unified, strong patients’ voice across the EU to really understand and value the patients’ experience and views in assessing a technology or service”

**EPF President
Anders Olauson**



Dear Readers,

We are pleased to present to you our report on the Health Technology Assessment (HTA) spring seminar which took place in Brussels on May 18 2010. The seminar was organised in conjunction with our Annual General meeting and gathered more than 80 patient leaders from around Europe. HTA is defined as a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in healthcare.

HTA has come to the forefront of European health policy relatively recently, primarily as part of a strategy to ensure the sustainability of healthcare systems, and to enhance EU cooperation and good practice in this area of HTA.

Involving patients in HTA processes is important as they are individual experts who know precisely how a disease impacts on their daily life and how specific treatments can influence its quality. The European Commission has recognized the importance of patients in this respect; however, this is happening only in an ad hoc, piecemeal fashion across the Member States with some reservations in a number of countries on the added value of involving patients. This seminar's aim was to respond to this gap.

During the seminar, we heard from a number of speakers who each touched upon the importance of involving patients in different aspects of HTA. Stepping in for Health Commissioner Dalli was Dr. Andrzej Rys, a high level representative from DG Sanco who delivered a personal message to EPF members and observers. Through his message he reiterated his strong commitment to putting patients at the heart of EU health policy. He stated that HTA is an important area to explore further as it can hold the key to unlocking the potential for identifying the most efficient new therapies at EU level.

The seminar also provided participants the opportunity to explore political developments at EU level, both in relation to HTA and the HTA/Stakeholder dimension of the Cross Border Healthcare Directive.

The workshop conclusions, led by Panos Kavanos from the London School of Economics outlined the key issues of involving patients in HTA and discussed recommendations on how to move forward in providing the patient's voice.

Although there is still some way to go to achieve patient involvement in HTA in Europe, it is possible through breaking down existing barriers and continuing to build capacity. We hope that this report will provide you with an overview of the points discussed and that the conclusions will inspire future action.

*Yours Sincerely,
Anders Olason, EPF President*

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● Purpose of the Seminar

Health Technology Assessment (HTA) has become a priority area at EU level, primarily as part of a strategy to ensure the sustainability of healthcare systems, and to enhance EU cooperation and good practice in this area.

In an attempt to address the issue of involvement of patients and patient organisations in HTA processes, EPF organised a seminar which targeted EPF membership and patient group allies. The purpose of the event was to enable patient leaders across different parts of Europe to learn more about the science, methodologies, processes and policies behind HTA, and share ideas on how they can get involved in a constructive, meaningful way as patient representatives. The seminar was also an opportunity to explore political developments at EU level in relation to HTA.

● Structure of Report

This report is divided into two sections. The first section is a summary of all presentations that took place at the HTA seminar. It looks at the importance of involving patients and patient organisations in HTA processes and the challenges and barriers associated with it. The second part of the seminar, participants broke out into four different parallel workshops. The conclusions of the three parallel workshop sessions are summarised in the second part of this report.

● Seminar Speakers

Dr. Andrzej Rys, Director of Public Health and Risk Assessment in Directorate General for Health and Consumers of the European Commission. Dr. Rys's presentation focused on the Commission's role and future plans to include patients and patient organisations in the HTA process. He further discussed Commissioner Dalli's health priorities and how they relate to the context of HTA.

Anders Olauson, EPF President opened the seminar and set the stage for the plenary presentations. Mr. Olauson spoke about the initiatives that have been made to involve patients and patient organisations in HTA processes but that more work to involve patients was important.

Jean Mossman from the European Federation of Neurological Associations provided a helicopter view of HTA in different settings. Ms. Mossman pointed out the importance of HTA to patients, what they hope to gain from HTA and the patient input to HTA processes.

Dr. Michael Wilks from the Standing Committee of European Doctors looked at the HTA process from the perspective of health professionals and the level of cooperation needed between health professionals and patients.

Andreas Rappagliosi from the European Federation of Pharmaceutical Industries and Associations provided an industry perspective on HTA. Mr. Rappagliosi provided four important programmes in HTA in previous years and challenged the audience with four difficult questions that need to be addressed regarding HTA.

Jerome Boehm, the Head of EU level activities on HTA from the European Commission provided key messages on HTA from the Commission and what work is currently being done on HTA at the EU level.

Dr. Iris Pasternack, a Research Officer in the Finnish Office for HTA (FINOHTA) discussed advantages to HTA cooperation at the EU level and presented the HTA core model as a structure for HTA generation and reporting the advices on methodologies.

Dr. Albert Jovell presented HTA from a doctor versus patient perspective and began his presentation with his definition of HTA from a "modern viewpoint". Mr. Jovell further explained HTA in terms of efficacy and effectiveness of the process.

Individual presentations of each speaker are available on EPF's website at: <http://www.eu-patient.eu/Initiatives-Policy/Events/Annual-General-Meeting-2010/AGM-Presentations-and-Reports/>

SECTION I



● Setting the scene: Brief Introduction to Health Technology Assessment (HTA) in the EU

Health Technology Assessment (HTA) is at the forefront of European health policy in order to contribute to the sustainability of healthcare systems and there is currently strong emphasis on enhancing EU cooperation and good practice in this area. HTA is a multidisciplinary process, which includes medical, social, and ethical issues. It is also about the process of “testing” the effectiveness of healthcare technologies in regards to a particular medical condition.

When referring to healthcare technologies, one must remember that this entails a wide spectrum of fields, from prevention, rehabilitation, the use of vaccines, pharmaceuticals, medical devices to the effectiveness of surgical procedures. Comparing costs and how it may relate to other technologies that are available on the market assesses the effectiveness of technologies. However, a challenge to introducing and assessing new technologies and markets around Europe is that the European Union does not have a ‘common health market’ as there are 27 distinct healthcare systems, with different ways of providing and financing healthcare. HTA can improve decision making on the investment in new healthcare technologies.

How one values patient involvement in health technologies should also be addressed. For instance, there are many different types of treatments and devices, and if and where the patient becomes involved may vary depending on the type of technology used or the approach of HTA agencies. The perception of the effectiveness of a treatment may differ depending on whether one is a payer, patient, informal carer or health professional involved in the healthcare of a patient. Different perspectives on the definition of patient involvement in HTA need to be addressed when designing HTAs.

HTA methodologies on pharmaceutical products and medical devices are becoming well established; however, for health interventions, there is currently only very ad-hoc expertise and methods available.

Finally, HTA is increasingly being used as a planning tool as the quality of healthcare, effectiveness of different treatments and the need to contain health costs becomes more important. Over the last couple of years the European Union has witnessed important developments in HTA.

There are four significant programmes that were launched in 2009:

- The EUnetHTA Joint Action 2010/2012. This a joint HTA initiative between the European Commission and the Member States, involving also relevant stakeholders, which builds on the achievements of a number of previous European initiatives including the EUnetHTA Project (2006-2008) and the relative effectiveness component of the Pharmaceutical Forum.

- The European Medicines Agency (EMA) Initiative: The European Commission (EC) invited stakeholders in 2009 to look at EMA's engagement and governance issues. A road map was published by the agency, which showed the willingness of the EMA to go beyond the simple assessment of drugs in terms of quality and safety and look also at how the EC and EMA can further collaborate. One of the EMA initiatives aims at getting medicines faster to patients and anticipating payers input in the regulatory process and scientific capacity.
- The Swedish Presidency Initiative: launched at the end of July 2009 for assessing long-term drug effectiveness. Discussions are now taking place regarding pilot studies in orphan medicines, cancer and biologics.
- EURORDIS/CAVOD initiative by patient organisations taking a role in HTA in relation to orphan drugs: Its aim is to facilitate informed decisions, foster Member States' commitment to common assessment reports and use review of scientific data.

What common denominators do these HTA initiatives share?

All these initiatives aim to ensure a good level of exchange of information. The more information is shared, the more we can hope that decisions on new technologies are made on the basis of good quality information on the product and that there is a better understanding between all actors. They also claim at different levels that there is a need for more integrated assessment methodologies that go beyond mere clinical and economic considerations. These initiatives are in place to complement each other and avoid duplications based on increased Member States' collaboration. Another common denominator is the involvement of health stakeholders. All this is a step forward compared to the past where the feasibility of this type of cooperation was looked at with some scepticism.



● Patients and Health Technology Assessment

Health Technology Assessment (HTA) is becoming an increasingly important subject for patients throughout the European Union. In a Europe built of democracy and human rights, it is important that HTA engages with all patients on an equal basis with all stakeholders. Most European countries follow the Aristotelian path, which means treat equals equally and treat those that are unequal, unequally. In many instances patients often communicate to health professionals and society in general about how they would like to be treated. We need to be sensitive to these messages.

The European Patients' Forum's (EPF) baseline position is that patients as individual experts, and patient organisations should be involved meaningfully in HTA processes. Though this is happening only in an ad hoc, piecemeal fashion across the Member States, with some reservations in a number of countries on the added value of involving patients. There is limited knowledge and knowhow across the broad EU patient community on the science and the policy rationale behind HTA and mechanisms to get involved effectively. It is important to involve patients meaningfully in HTA processes in order to match needs and expectations of patients and effectiveness and sustainability of healthcare systems.

European Commission representatives at the seminar noted that actions are taking place to improve the involvement of patients in HTA processes. Dr. Andrzej Rys from the European Commission said that Commissioner for Health Mr. John Dalli has highlighted that there are three core priorities in the field of health that are highly relevant in the context of HTA. First, patients should come first and therefore HTA should understand which health interventions provide the best patient outcomes. Second, it is important to know which innovative technologies contribute most to improving the health of a patient. Finally, HTA can be used to compare costs of different technologies, which allows us to better help balance public budgets which will consequently affect patients. There are many different options to sustainable healthcare systems but more evidence is needed in order to make a comparison between them.

The HTA core model - a tool developed by the EUnetHTA project takes into consideration a number of patient perspectives in the HTA process and increases the relevance of the assessment. The premise of this HTA Core Model is that there are a number of common issues in each HTA and across Member States, which can be therefore more efficiently addressed at EU level.

The tool was developed in an attempt to define and standardise elements of an HTA. This tool provides a structure for HTA generation and reporting and advice on methodologies. An example where this tool was used was in an HTA report that looked at surgery for severely obese patients. The report provides a comprehensive chapter on the perspective of patients. The researchers found ample research on patient's perceptions and attitudes about obesity during, after and before the operation and other issues such as returning to work.

In order to share data as effectively as possible and to be transparent, the information within an HTA report is split into assessment elements. It is a collection of answers/questions and a brief summary. The aim is to encourage users of HTA to take into consideration all the domains of an HTA core model including social aspects. The core model will be reviewed during the EUnetHTA Joint Action and is still undergoing changes.

The social aspects' area has been divided into three areas:

- **Major life areas**
 - Issues: What kind of changes does the use of the technology generate in the patients' role in the major life areas?
 - What kind of changes does the implementation and use of the technology mean for patients' physical and psychological functioning in his or her major life areas?
- **Individual**
 - Issues: How do patients and significant others (such family members) react and act upon the technology?
- **Communication**
 - What is patients' and significant others' knowledge and understanding of the technology?
 - What are the consequences in decision-making?

Users are required to read through all these questions and if it is deemed important then the “user” will have to translate the issue into a research question. For more information about the HTA Core Model, visit: <http://www.eunetha.net/upload/WP4/Final%20Deliverables/Core%20HTA%20on%20Drug%20Eluting%20Stents.pdf>

Advantages and opportunities of involving patients in HTA

It was stressed in each presentation that when it comes to assessing ways to address and treat a disease, patients should be regarded as experts. Only patients and their formal or informal care givers know exactly how a disease impacts on their daily life and how specific treatments or disease management strategies can influence patient's health status and quality of life. The individual experiential knowledge held by It was stressed in each presentation that when it comes to assessing ways to address and treat a disease, patients should be regarded as experts. Only patients and their formal or informal care givers know exactly how a disease impacts on their daily life and how specific treatments or disease management strategies can influence patient's health status and quality of life.

The individual experiential knowledge held by the patient has for too long been an untapped resource. Understanding the patients' expertise would allow a better understanding of issues that need to be taken into



consideration in HTA processes. This in turn would allow more informed decisions based on HTA results, and hence better health outcomes. More specifically, HTA can provide information to support a range of decisions such as whether to create primary and secondary prevention programmes, which technologies should be paid for, whether to exclude or implement new technologies and can help patients decide which treatment options best suit their needs. Jean Mossman emphasised in her presentation that currently only economic and clinical indicators are prevalent in HTA and for this reason, the evaluation of patient views should be better integrated in each HTA. This can be done by collecting patient evidence through both a qualitative and quantitative way. It can be collected through surveys, focus groups, self help and support groups, in hospital and clinical settings.

Advantages to HTA cooperation at EU level

- One important advantage of HTA collaboration is the potential to avoid duplication of work. There were more than 10 HTA reports written on the HP vaccinations within a couple of years. There were more than five agencies assessing the impact of one drug on more than 20 projects working on cancer issues. More can be done with unbiased high quality, relevant and reliable answers if duplication of work can be avoided.
- Through the use of a European pool of experts the quality of HTA can increase.

Patient's involvement in HTA

Patients are concerned that HTA looks only at the impact on health services. Patients want HTA to look also at the impact new health services, products and technologies have on their personal and professional lives. This can include their desire to continue working, amid the side effects of treatment, staying independent, active and mobile. Patients also want HTA to understand the impact of treatment and illnesses not only on their own life but also on the life of their close relatives. Patients are looking to ensure that HTA offers a true reflection of a technology's value is thoroughly assessed. Involvement, transparency and accountability are therefore conditions sine qua non for patients to trust HTA.

The sustainability of our healthcare systems is at stake. In a society where the population is ageing and patients' life expectancy has increased the challenge is to meet increasing healthcare needs within a given amount of resources. Patients need to seek involvement in HTA as they are payers of our healthcare systems. Another reason why patients should be involved is that they are experts when it comes to their own condition. At the same time however, there should be no disease-specific discrimination but severity criteria of the condition should be taken into account in HTA methodologies.

● Promoting Patient Involvement in HTA

Perceptions of patient involvement in HTA by various stakeholders

A Viewpoint from the European Commission

From DG Sanco's perspective, it is believed that patient satisfaction, reward for innovation and cost containment should be the primary objectives of HTA.

A few key messages were noted during the presentations on HTA from the European Commission:

- HTA decisions should first serve the needs of patients over and above rewards for innovation
- The HTA objective is broader than cost containments
- HTA should not only focus on pharma products but also on medical devices and other interventions
- From an EU perspective, it is very important to emphasise implementations on HTA decisions as it is more relevant at national level, because of the wide range of value issues and economic capacities
- There is strong belief that EU cooperation can bring significant added value but mainly to address clinical issues, where substantial scientific questions are at stake
- From a clinical perspective core methods and data can be jointly developed for possible reuse at national level

Pooling of expertise in order to face new challenges such as personalised medicines will bring added-value and minimise duplication of efforts. It should be clear that the final objective is not harmonisation of the decisions, as HTA processes ultimately need to fit with the specific needs and characteristics of national and regional healthcare systems, but rather some standardisation of the methodologies for gathering of clinical data. The latter requires, however, strong Member States' commitment and willingness to take effective decisions and reach a concrete agreement at EU level.

Stakeholders' involvement is a key success factor of cooperation at the EU level. There needs to be a wide range of stakeholder representation so that all relevant constituencies can be well represented. A sustainable cooperation platform is needed for this and long-term solutions are currently being evaluated.

A Viewpoint from the Healthcare Professionals

Patients as well as their informal carers should be actively and meaningfully engaged as equal partners in the HTA decision-making process. Patient involvement in HTA means a two-way process. It is not just about the HTA agencies providing the patient with all necessary information about the objective of the assessment,



the role of the patient, gathering and analysing data from the perception of the patient but more importantly about involving patients from the beginning. HTA should take into consideration such aspects as patient dignity, fatigue, staying independent, staying active and mobile when assessing a technology on a patient. Patients can tell how a technology is likely to fit into their daily lives. Treatment is about bringing benefits to the patient and not to the health economist.

There is a popular understanding that decisions are based on evidence, but this is not completely true. As a clinician when you make decisions, there are many factors that are going to influence you (incentives, physiological presumptions play a role). If you want to have a good assessment, you have to be able to grasp a number of these factors. The theoretical HTA is wonderfully explained but in practice it is difficult to see.

Patients have an asymmetrical relationship with their doctors, primarily because it is believed that doctors have the knowledge and the patients do not. Patients do not have just one disease. A person with a chronic disease should be regarded as suffering from three distinct diseases: the organic, the emotional and the social disease. The disease affects not only the individual's physical well-being ("organic disease"), but also the way he/she perceives and experiences the condition ("emotional disease") as well as the way he/she relates him/herself to other people, whether family members, friends, colleagues or anyone else ("social disease"). It is also important to remember that a doctor helps prevent and treat diseases but does not experience the patients' disease.

A doctor's duty is to give a patient the correct diagnosis of a disease but also to provide a treatment. It is important to understand the life of that patient (i.e. does s/he live alone, has the doctor provided too much information all at once, does s/he have any other medical conditions that may affect the compliance of a treatment?). This is where HTA should take into consideration these factors because this is what is happening in reality. But it was noted that emphasis and responsibilities should not be placed only on good HTA practices because sometimes it may be that you just have a bad doctor.

HTA is based on outcome assessments whereas patients live the process. Doctors amongst themselves disagree on certain issues. For instance, should doctors have to screen a 50-year-old male for prostate cancer every year? This means a lot of the decision process will be left to the patient. This also means that a patient is its own individual and treatments will work differently for each patient.

In terms of assessment and introduction of the technology, we need to get engaged. This includes healthcare professionals and patients as they have a joint interest in looking at the relevance of the technology, the ease of use, the interoperability between different systems and how it can be integrated into the healthcare system without too much disruption and, last but not least, how the value of that technology can be effectively

communicated. Those people who need to be involved in the whole process is not only patients but also the industry and health managers. Information sharing is a good way to ensure the continuity of care.

A Viewpoint from Industry

Pooling of expertise will avoid duplication of efforts and resources not only for HTA bodies and payers but also for the industry. In this respect new decision-making processes between regulators, HTA bodies and stakeholders are needed. It is necessary to understand how far HTA bodies and payers are ready to cooperate with industry in terms of clinical trials. The key point is that sustainable cooperation is needed.

Challenges and obstacles to patient involvement in HTA

Identifying suitable and effective mechanisms for integrating patients' perspectives and consideration into HTA process is a challenge not only for patient groups but for all health stakeholders and policy makers. At times HTA agencies tend to involve patients in very late stages and in doing so they fall short of integrating patient self-reported outcomes in the assessment process.

A key challenge is to find ways for patients and their advocacy groups to access HTA. Although the patient movement has become much stronger and "skilled" over the last decade its involvement in HTA is still rather limited. There is a general belief that a number of structural barriers to their involvement should urgently be addressed.

Another barrier and challenge that was presented during the seminar is that HTA can sometimes be government-based and can be "closed" and not open to other stakeholders.

It is equally important to understand what factors are involved in the HTA process and what kind of contribution they make to the process and through which channels. Therefore, identifying precisely what patients can bring to HTA processes, how and to what extent can they do, therefore, another key challenge that needs to be addressed by policy-makers.

Four questions were asked during the presentations that need to be addressed. The first question is working towards common standards at European level in the Relative Effectiveness assessment to better meet the needs of Europe's payers. The second question is whether the separation between EU Relative Effectiveness and national appraisals will improve patient access performance. Third, to address the extent to which



pan-EU relative effectiveness assessment can be undertaken and accepted by Member States. Finally, full stakeholder involvement in the assessment and appraisals of technologies needs to be implemented in order to reduce controversies, in order to ensure transparency and improve accountability.

Ways to overcome the challenges and view patients and patient organisations as equal partners in HTA

It was widely acknowledged during the seminar that in order to integrate the patients' perspective and to play a constructive role in HTA processes, patient organisations and their advocacy groups have to work together and speak with one single voice instead of acting alone. Patients need to develop expertise and pool their knowledge to share with decision-makers in a clear and non-conflictual way. To be able to do that patient groups need to develop internal capacity, gather solid patient evidence on both treatments and the ways HTA is performed in order for them to be recognised as equal partners in HTA processes.

Investing in capacity building and making the voice heard, however, entail costs. In a time of severe budget constraints ensuring that patient organisations be effectively resourced represents a major challenge, as this seems to work against the sustainability of the overall healthcare system and the need to cut down on expenditure. Addressing this trade-off should be a priority for policy makers.

The Commission plans to increase the HTA knowledge among patient organisations and health professionals. The Commission believes that a sustainable cooperation structure should be established and hopes that this will be set up in the coming years.

● Putting Ideas Into Practice

A new phase of HTA development was launched earlier this year through the Joint-Action (JA) EUnetHTA between the European Commission and Member States authorities involving also relevant stakeholders, aimed at helping develop reliable, timely, transparent and transferable information to contribute to HTAs in EU countries.

During the EU Commission high-level Pharmaceutical Forum, the 27 Ministers of Health agreed on two basic principles.

Core Principles on Relative effectiveness: under this framework, it was established that there needs to be a process for transparency to all parties, the ability for stakeholders to participate and to discuss the source of evidence, outcomes should be communicated in a clear and timely manner and the assessment should be eligible for updating.

Guiding principles for good practice in pricing and reimbursement policy is the second component to the agreed framework. This includes ensuring that there is timely access to valuable innovations, affordable medicines are available and that the availability of these medicines is distributed equally. Other guiding principles include limiting price control, setting up an environment that fosters the right environment for price competition and recognising innovation by giving consistent rewards. The current interest in innovation would need to involve a broader spectrum, including patients and professionals.

SECTION II



● Summary of Parallel Workshop Sessions

The conclusions of the three parallel workshop sessions are summarised below. During all three workshops a few reoccurring themes emerged.

The science and methodologies behind HTA, diversity and commonality across the EU

Moderator: Ms. Jean Mossman, *European Federation of Neurological Associations*

Rapporteur: Christoph Thalheim

Issues & barriers in HTA

- Patients contribution hindered by difficulties in access and communication
- There still exists an imbalanced doctor-patient relationship (notion of doctor supremacy, fear, preferential care)
- Patient may be unclear about the role and ability to contribute, does not want to appear foolish and lack of familiarity with technical terms may hinder the involvement of patients in research
- For both patients and the HTA bodies, there is a lack of resources which include time, money and expertise
- There is not a very strong and consistent collection of the data that is comparable between different countries
- Not enough is understood about the impact of the health technology on the daily life of the patient
- There is not clear definition and assessment of quality of life in the patients' specific environment
- Lack of clinical assessments taking place on EU or national level

Recommendations

- Need to find a mechanism to exchange HTA specific experiences among patients and patient groups
- Develop training courses for HTA agencies on the importance of involving patients as the experts and how to go about doing so
- Training and support together with patient experience and expertise are needed to act meaningfully

Politics of HTA at EU level and national level: How can patients' groups best get involved?

Moderator: Panos Kavanos

Rapporteur: Walter Atzori

The premise of this parallel session was that while patient involvement has increasingly been recognised as an important element of HTA there are still concerns over the quality of patient's contribution, the ability of patients to offer added value to HTA processes, and perhaps even more importantly, there seems to be a

widespread misunderstanding about the role of patients and patient organisations in HTA. Although patients are the main beneficiary of health products and services, they continue to represent the weakest stakeholder group in HTA. Consequently, their ability to influence HTA processes is very limited.

Issues and barriers to HTA

- **Relative lack of patient involvement in HTA decisions and patients' ability to influence the process resulting in lack of transparency and low level of trust and acceptability**

We cannot expect patients to trust HTA and decisions taken on the basis of the latter if they are not engaged in these processes. Patients have to be able to bring their perspective to the attention of HTA experts to allow for more informed decisions on new health products, services and technologies. In this respect, there is a need not only to develop patients' expertise, but also take action with a view to enabling the patients to put the case forward in a satisfactory and meaningful way throughout the HTA process from designing to final reporting. To be able to effectively participate in HTA patients needs being regarded as equal partners and provided with effective channels to influence not only HTA processes but also decisions taken on that basis of HTA reports. HTA experts and policy decision-makers need to understand that the added value patients can offer is huge as it comes directly from their unique experience of living with the condition and the impact a given product or technology can have on the way the patient manages that condition.

- **There is a lack of mutual understanding between patients and key HTA experts which creates a barrier to promoting patient-centred HTA processes**

Investing in trust between different actors is crucial. This requires concrete action to ensure that HTA experts and patients are able to communicate and understand each other. This element is, however, too often neglected in HTA practice.

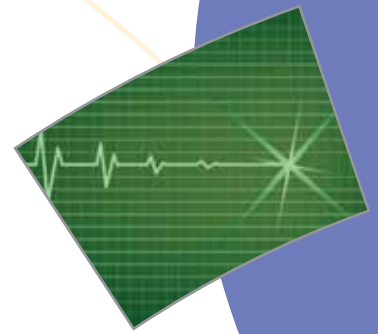
- **Currently too much emphasis is placed on cost-effectiveness in HTA but not enough on the effectiveness of the overall healthcare systems**

As HTA continues to be seen as a mechanism for ensuring more cost-effective health products, services and technologies, indicators not directly linked to clinical and economic aspects are often overlooked in current HTA practice. When it comes to the wider healthcare systems Member States seem not to have the same level of concern about effectiveness as for the sustainability of the system.

- **Patients do not have the possibility to appeal against rejected Health Technology Assessments**

Recommendations

- Developing transparent HTA procedures including clear frameworks for integrating patients' input
- Ensuring patient involvement from the very beginning (patients are sometimes involved in late stages when



their ability to influence decisions is limited)

- Patients' need to have access to information about HTA in a concise and timely way
- Patients groups need being adequately trained and resourced to be able to effectively participate in HTA. New funding sources, other than traditional ones available, have to be identified
- Investing in Health Literacy and training is a prerequisite for meaningful patient involvement in HTA
- EU-wide platforms to support patients organisations in participating in HTA should be set up
- Patient organisation themselves should be able to improve the way they interact with each other and with decision-makers.
- Strengthening trust and improving mutual understanding between all actors involved in HTA should be a key priority.
- Concrete steps to bridge the knowledge and language gap between experts involved in HTA processes and patients is needed. Specific resources should be identified and made available for this purpose.
- We need to shift away from mere cost-effective considerations in HTA to include real patients' needs and patient's self-reported perceptions of a new drug or technology.
- Policy makers need to find the right balance between ensuring that new solutions are more cost-effective than existing ones and the need to take into consideration patient-related indicators in performing HTA.
- Appeal should not be a privilege of certain bodies and actors, i.e. manufactures, but patients and patient organisations should also be entitled to appeal against a rejection decision in particular when the technology has been considered safe and can bring about important benefits for the patients. This would ensure enhanced transparency and reliability of HTA decisions, more added value and more patient-centred HTA processes.

Applying the Value+ Model on patient involvement in HTA processes

Moderator: *Maria Navarro*

Rapporteur: *Gunta Anca*

The EPF-led project Value+ focused on patient involvement in European health projects produced a model for the involvement of patients and patient groups. Under many aspects the model could be applied to an HTA context.

Issues and barriers in HTA

- There is a lack of information and knowledge provided to patients in understanding HTA processes. This includes information about different agencies, funding opportunities and whether indeed there is patient involvement in HTA
- There is not enough training available for both HTA professionals and patients on how to communicate and

work together. Too often patients are asked to learn the language of health professionals, but are professionals ready and able to understand the language of patients?

- The role of clinical indicators is very much emphasised in HTA; however, there is not a similar weight for the social and individual aspects
- HTA researchers base their work on scientific information; patients' evidence may not be considered as such if it does not respond to scientific criteria
- There are barriers on the side of the patient community too. Patient groups need to be more assertive, to work as a united movement and to uphold to professional working standards

Recommendations

- Develop specific methodologies to better involve the individual patients and patient organisations
- Provide training for both patient organisations and HTA professionals in order to create a common culture of thinking and working together
- Provide tools for dissemination of information on HTA at different levels (individual, organisational and professional)
- Indicators need to be improved and/or developed and integrated into HTA methodologies in order to capture effectively the social, ethical, and quality of life aspects relevant to patients
- Patients have a role to play both in the process of HTA as well as in committees appraising the results of assessments and making the decisions
- HTA agencies need to develop tools to better value qualitative research which is most often at the basis of patients' evidence versus quantitative research
- There needs to be one collective voice among all patient organisations



● Conclusions and EPF'S Future Engagement in HTA

EPF President Anders Olauson closed the session emphasizing the importance of the seminar for widening the understanding of HTA and its significance to patients. He noted that EPF will continue its work at EU level to promote meaningful involvement in the Health Technology Assessment processes. He reiterated the need for understanding and valuing the patients' experience and views in assessing a product, technology or service. He also expressed again the reoccurring theme throughout the seminar - the importance of having one unified strong patients' voice in our work for patient involvement in HTA processes.

Mr. Olauson concluded "The process should be opened to all. You need to involve all stakeholders. Decisions should be informed and grounded on data. You have to have the right to appeal. Uncertainties should be made explicit and finally, latent conflicts of interest and disagreements should be elicited and negotiated. So there needs to be more transparency. These are the basic principles of deliberative democracy".

We need to ensure a high level of health literacy among patients and citizens in order that they can take care of themselves and to take care of others. HTA is part of the process but we also needs mechanisms to facilitate "navigation" through this process, including appropriate support and resources that complement existing material. This will be the next step for EPF in close consultation with our members'.

● About the European Patients' Forum

The European Patients' Forum was set up in 2003 to become the collective patients' voice at the European level, manifesting the solidarity, power and unity of the European Union patients' movement. EPF is a not-for-profit, independent organisation and umbrella representative body for patient organisations throughout Europe. We currently represent 44 member organisations that consist of chronic disease specific patient organisations working at the European level and national coalitions of patient organisations. In total, we reflect the interests of an estimated 150 million patients affected by various diseases in the EU.

EPF's vision is to establish patient-centred equitable healthcare through the European Union. Our core values emphasise a patient-centred approach to healthcare, inclusiveness, non-discrimination, patient empowerment, consultation and independence and transparency. We adopt a holistic interpretation of healthcare to include prevention, and the social, economic, environmental, cultural and psychological aspects of health.

EPF acts as a catalyst and consultative partner for positive change in EU healthcare systems and as a “watchdog”, closely monitoring EU policy and legislative initiatives. We offer our members EU healthcare intelligence, and baseline patient rights policy responses to enable them to focus on disease specific responses. We support dialogue and negotiation among a broad range of EU level health stakeholders and facilitate the exchange of good practice and challenges of bad practice on patients' rights, equitable access to treatment and care, and health-related quality of life between patient organisations at the European and Member State level.

Acknowledgements

The seminar was made possible thanks to unrestricted grants from GSK, Novartis and Pfizer and a supporting unrestricted grant from AMGEN.

We would also like to thank the presenters, moderators, rapporteurs and last but not least, the participants for helping to make this seminar a success.

“The HTA Seminar has exceeded my expectations in every way. It has helped me and other patient groups better understand how to become more involved in HTA, and also to understand the role we can play together with the European Patients’ Forum in representing the voice of patients”.

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