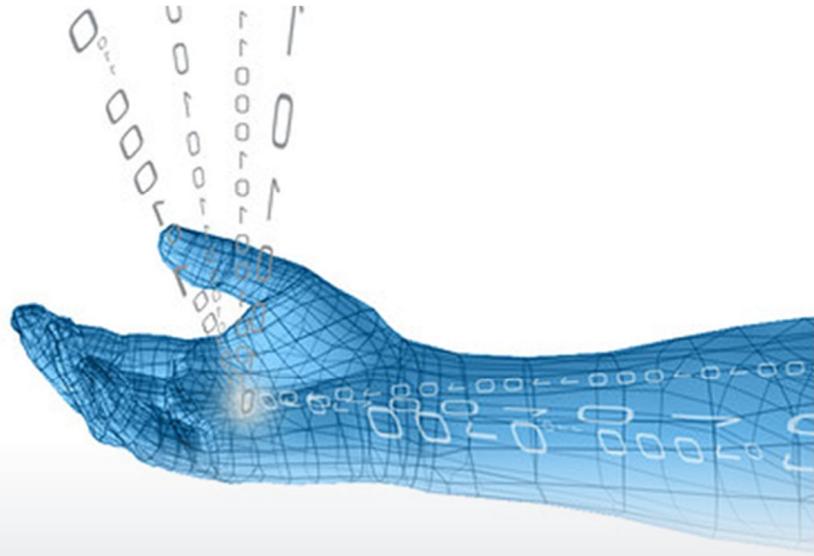


**Advanced Innovation**  
**Health Technology**  
**Assessment**



**EPPOSI'S RESPONSE TO  
EUNETHTA WP8 SURVEY ON EUNETHTA POLICY FOR THE HTA  
CORE MODEL AND CORE HTA INFORMATION  
(PUBLIC CONSULTATION)**

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21 rue Marie-Thérèse, B-1000 Brussels, Belgium  
Tel: +32 2 503 1307 – Fax: +32 2 274 1759  
E-mail: [info@epposi.org](mailto:info@epposi.org)  
[www.epposi.org](http://www.epposi.org)

**7. Can you agree with the 3 Dec 2012 version of the EUnetHTA Policy for HTA Core Model and core HTA information? \***

Cannot say

**8. If you answered "No" or "Cannot say", please explain here the reason. Please focus to explain only the reason(s) why you cannot agree with the policy (and indicate any other development needs in question 9).**

Epposi welcomes the EUnetHTA Policy for the HTA Core Model and core HTA information and congratulates all on such a comprehensive document.

*We also very much welcome the opportunity to provide stakeholder input into the document to demonstrate how the policy and ultimately the HTA Core Model and core HTA information can better meet the needs of patients & citizens, health professionals & academia as well as various sectors of the healthcare industry*

*Although we agree with the vast majority of the policy, we still have some outstanding points which prohibit us from 100% agreeing with the full policy document. These relate to:*

- **Transparency of Information:** We do not consider that there is currently sufficient transparency. This is due to lack of multi-language accessibility and also a lack of clarity as to what constitutes "low quality information".
- **Multi-stakeholder involvement in the editorial board and composition of project groups:** Whilst it is very much lauded that EUNetHTA has already thought to include health professionals and topic experts from science, in Epposi's experience, having a wider selection of stakeholders (*patients' organisations as well as industry*) participate in the process from the beginning can only enrich the outcome. We therefore strongly advocate for a broader selection of stakeholders in the composition of the editorial board for Core Model information and in relation to the composition of the project groups. Currently, the policy only makes mention of "Researchers" being included, but is not specific about other stakeholders. We would propose that the formulation of the editorial Board and the project groups in particular reflect "targeted end user" needs for EUNetHTA as well as "Other" collections. This could be achieved through replication of the stakeholder make-up of the HTA committees (science, expert patient representatives, HTA agencies) and with an extension of a relevant industry representative.
- If the final information will be widely available to all, then it really needs to meet the basic needs of its end user.

References: "There are two distinct but complimentary ways in which HTA can be strengthened: gathering robust evidence about the patients perspectives and ensuring effective engagement of patients in the HTA process from scoping through evidence gathering, assessment of value, development of recommendations and dissemination of findings".

*Facey K, Boivin A, Gracia J Hansen H, Scalzo A, Mossman J et al Patients' perspectives in health technology assessment: A route to robust evidence and far deliberation. Int J Technol Assess Health Care 26:3 (2010) 334-340.*

There is general agreement on the need for more patient focused HTAs methods and several HTA agencies and researchers are reviewing ways to incorporate the patients' or more generally the public's perspectives into their methods".

*Staniszewska S Brett J, Mockford C, Barber R. The GRIPP checklist: Strengthening the quality of patient and public involvement in research Int J Technol Assess Health Care 27:4 (2011) 391-399*

- **Flexibility of information slicing:** Currently, the policy only accounts for vertical slicing of information to produce collections reports. We believe that it will be more beneficial and in the interests of the longevity of the system (wider usage by end users) to allow cross-domain information slicing as well.
- **Withdrawal of low quality information: We would welcome some clarification on this.** There does not appear to be a definition of low quality and the information is very focussed on scientific evidence. How might this impact on patient-related information that might be collected outside of traditional clinical or observational trials?

### **9. How well does the 3 Dec 2012 version of the policy fit your principles, practices and expectations?**

Partly well

### **10. How can we improve the policy in the future?**

Epposi welcomes the spirit of collaboration exhibited by EUNetHTA in the opening of this document to public consultation. We do, however believe that the areas outlined below can lead to ensuring continued societal buy-in./ usefulness ...

**Envisage an extended Ontology which completes the current 9 EUNetHTA core domains to include generic questions covering a societal benefits approach to HTA**

**Please note that we are very happy to work with EUNetHTA on providing example questions related to these cross-cutting themes as part of WP4 or indeed how the policy could be enhanced in WP 9.**

Below we provide enriched definitions of the areas we think would be important to be able to integrate into the evidence gathering pool. They build on four of the EUNetHTA core model core domains (legal, social, ethical and organisational) on which Epposi stakeholders have been working for the past 2 years in order to provide interested parties (HTA agencies at national level) with a completion of some of the as yet unaddressed gaps of the EUNetHTA Core model from a societal benefits perspective.

#### **HTA Content:**

- **Patient-Defined Outcomes:** Epposi's definition: "patient-relevant" refers to how a patient feels functions or survives. Consideration is given here to both the intentional and unintentional effects of the intervention that in particular allow an assessment of the impact on the following patient-relevant outcomes to determine the changes related to disease and treatment.
- **Ethical Aspects:** Epposi's definition: Ethical Aspects reflect the correctness of human action, which is stamped by moral concepts and rules in specific cultures. These principles should strengthen the position of the patient, provide access to healthcare according to need and not ability to pay and aim to the providing the best affordable care to all its citizens
- **Psychological Aspects:** Epposi's definition: Psychological aspects assess how likely it is that patients' health will be improved by the proposed product, service, or technology. A primary assessment of patients' needs will help form a picture of the different stages a patient has to go through, the psychological and emotional problems that can occur in relation to that topic, and at what point decisions need to be made.
- **Continued Economic Activity:** Epposi's definition: People, who are able to work, can experience significant health, social, psychological and economic benefits from remaining in work. The impact of a healthcare intervention on the patient's ability to work and the economic effect should be considered in the HTA assessments
- **Significant Others:** Epposi's definition: Significant others are the family, partners, friends or others, who provide informal (unpaid) care, giving help or support to family members, friends, neighbours or others because of long-term physical or mental ill-health or disability or problems relating to old age

## HTA processes:

- **All Stakeholder Involvement:** Epposi's definition: Parties involved in healthcare (researchers, academia, manufacturers, patients, government bodies, physicians) should be closely involved in the HTA process; they should be consulted on both the content and administrative aspects. Every stakeholder should be involved where his/her expertise and knowledge are of the most value
- **Cross-Sectoral Policy Making:** Epposi's definition: Cross-Sectoral Policy Making means the collaboration between different parties not only in the healthcare sector but also outside healthcare sector. It aims at a more flexible use of resources by both the public and private sectors in order to avoid silo budgeting and overlapping expenditures to mitigate the economic and psychological burden of unemployment on the individual and society
- **Governance:** Epposi's definition: Governance is the process that ensures the equity in the healthcare, deals with the public comparison of quality and efficiency across local authorities and providers and the value for money invested in health care, aims in the improvement of the health outcomes and benefits from the patient perspective, focuses on the process orientation and coordinated services

All of the above definitions are shortly to be published in the Epposi White paper "Building a Framework for a Societal Benefits Approach to HTA". The outcomes are based on 2 years of think tank consensus building with experts from patients' organisations, HTA agencies, academia, the payer community, various sectors of the healthcare industry and policy makers at national level.

### **Inclusion of societal benefits approach elements into the Core HTA information collections and related project protocols (opportunity to cross cut domains in creating collections)**

Epposi's Societal Benefits Approach to HTA Framework (Epposi SBAHTA Framework) crosscuts four of the nine EUNetHTA Core Model domains (Ethical, social, legal and organisational). It would therefore be helpful to envisage a way in which to summarise this information as part of the collections report.

This will be a useful way to slice data which will be discussed during JA2 as part of the more general discussion on **Further EUNetHTA Collection types**

### **Inclusive usage and licensing**

Whereas

*The HTA Core Model can be used for producing non-commercial scientific information on health technologies (e.g. HTAs, literature reviews or other scientific studies).*

*The information produced can analyse one or more of the nine domains of HTA contained in the Model, or any other aspects of health technology.” (page 8),*

this would be an excellent opportunity to include the extended ontology to include societal benefits approach elements. This would then allow much more precise scientific research to be carried out on baseline information. HTA agencies and scientific bodies would be able to make an informed decision as to whether or not these elements enhance or detract from high quality and equitable HTA processes.

In particular, Epossi stakeholders support the possibility of non-commercial parties both using the Online Tool and Service to produce as well as publish Other Collections of core HTA information.

#### **Accessible language versions**

Of course it is logical and necessary to use a common language for the information in the database. However, this will also potentially exclude all non-English speakers from being able to access that data. While this should not be a problem with the scientific community it may well be a problem for patient representatives. It is impractical to translate the entire database into every EU language, however EUNetHTA may want to consider how other organisations such as the European Medicines Agency has handled this challenge successfully. The EMA translates summary documents and key reports into multiple languages. To encourage sharing of best practices across borders, EUNetHTA could also take this approach.

For more information please contact  
Jacqueline Bowman-Busato  
Epossi, Executive Director  
Tel: + 32 2 503 13 07  
Email: [Jacqueline.bowman@epossi.org](mailto:Jacqueline.bowman@epossi.org)