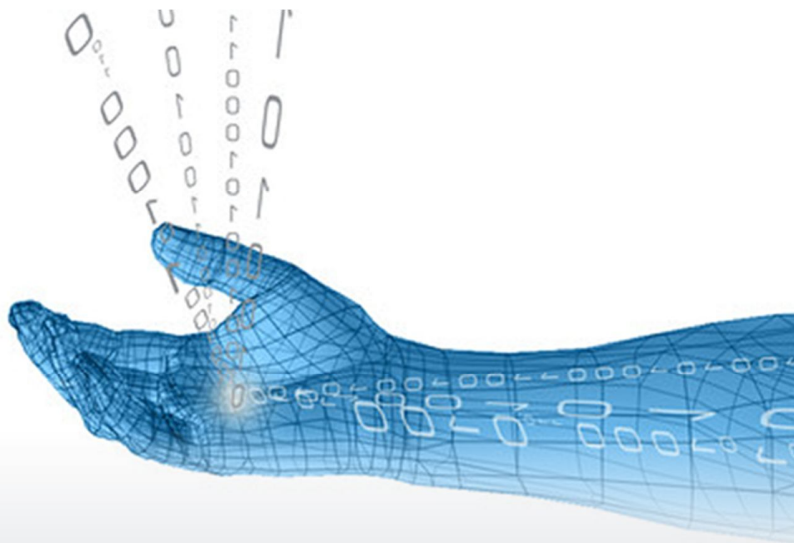




**Advanced Innovation  
Health Technology  
Assessment**



## EPPOSI AIP-HTA WHITE PAPER

*How can societal benefits be integrated into National Health Technology Assessment in a way which positively contributes to the realisation of better health outcomes for EU citizens as well as a smart sustainable economy?*

---



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)



*How can societal benefits be integrated into National Health Technology Assessment in a way which positively contributes to the realisation of better health outcomes for EU citizens as well as a smart sustainable economy?*

## Acknowledgments

---

Eposi would like to thank all those who have participated in its Advanced Innovation Programme in Health Technology Assessment (AIP-HTA). We are particularly grateful to Professor Han Severens, Professor of Evaluation in Health Care at iBMG (*Institute of Health Policy and Management*) Erasmus University for his valuable help and advice in setting the AIP-HTA research framework and for the support and contributions of the following organisations:

### Patients' Organisations

EATG (*European AIDS Treatment Group*); ECPC (*European Cancer Patient Coalition*); EFCCA (*European Federation of Crohn's and Colitis Associations*); EFNA (*European Federation of Neurological Associations*); EGAN (*European Genetic Alliances' Network*); EURORDIS (*Rare Diseases Europe*); European Women's Health Institute; GAMIAN-Europe (*Global Alliance of Mental Illness Advocacy Networks - Europe*); IBTA (*International Brain Tumour Alliance*); IPOPI (*International Patient Organisation for Primary Immunodeficiencies*); Retina Europe; WFIP (*World Federation of Incontinence Patients*)

### Science, Academia & Public Administrations

iBMG (*Institute of Health Policy and Management*) Erasmus University; Council for HC and Consumption; Delft University of Technology; ESHG (*European Society for Human Genetics*); HTAi; NICE (*National Institute for Clinical Excellence*); Office of Health Economics; RAPS (*Regulatory Affairs Professionals Society*); University of Manchester; University of Southern Denmark

### Industry and Payer Community

Abbott; AIM - Association Internationale de la Mutualité; Amgen; Baxter; Bristol Myers-Squibb; CSL Behring; EDMA (*European Diagnostic Manufacturers Association*); Eli Lilly; F. Hoffman La Roche; Genzyme; Gilead; GSK; Johnson & Johnson; Medtronic Europe; MSD; Novartis; Pfizer; Shire; St Judas Medical.

### Observer members

European Commission – DG Health and Consumers (*Sanco*); European Parliament

Eposi would also like to thank you the authors of this White Paper, Ms Anastasia Naoum, Dr Andrea Pavlickova, Kevin Veninga and Ms. Jacqueline Bowman-Busato.

### Contact

Ms Jacqueline Bowman-Busato  
Eposi Executive Director  
Jacqueline.bowman@eposi.org  
+32 2 503 1307



**Advanced Innovation  
Health Technology  
Assessment**

*How can societal benefits be integrated into National Health Technology Assessment in a way which positively contributes to the realisation of better health outcomes for EU citizens as well as a smart sustainable economy?*

## Key Words

---

Societal Benefits

Value

Patient-defined outcomes

Ethical aspects

Psychological aspects

Productivity and workability

Informal caregivers

Stakeholder involvement

Governance

Cross-sectoral policy making

Integrated budgeting

Published by Epposi (*European Platform for Patients' Organisations, Science & Industry*)

International Non-Profit Association No: 7198/2003

Registered Office: 21 rue Marie-Thérèse, B-1000  
Brussels,

Belgium

Copyright © Epposi 2013

All rights reserved. Except for the quotation of short passages for the purpose of criticism and review, no part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, without the prior written permission of the publisher.





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

*How can societal benefits be integrated into National Health Technology Assessment in a way which positively contributes to the realisation of better health outcomes for EU citizens as well as a smart sustainable economy?*

## Contents

---

Acknowledgments .....	2
Key Words .....	3
Contents .....	4
Key Messages .....	5
Introduction .....	9
The relationship between Epposi's initiative and EUnethTA's HTA Core Model™ .....	9
Epposi's Solution: Epposi HTA Societal Benefits Framework .....	9
The Epposi Framework for a Societal Benefits Approach to HTA .....	11
1. Societal Value .....	11
2. Patient-defined Outcomes .....	13
3. Significant Others (informal caregivers).....	14
4. Continued Economic Activity .....	17
5. Psychological Aspects.....	18
6. Ethical Aspects .....	20
7. Governance .....	21
8. Cross-sectoral Policy Making.....	22
9. All Stakeholder Involvement .....	24
Conclusions & Summary of recommendations .....	25
Annex A: Summary of Epposi's case studies .....	28
1. AGNSS case study – UK .....	28
2. Continuous Economic Activity case study – Sweden .....	29
3. Medical Devices case study – Germany .....	30
4. Conditional Reimbursement case study – the Netherlands .....	31
Annex B – Detailed Methodology .....	32
About the research.....	32



*How can societal benefits be integrated into National Health Technology Assessment in a way which positively contributes to the realisation of better health outcomes for EU citizens as well as a smart sustainable economy?*

## Key Messages

---

The Challenge – regulators and stakeholders agree the principle, but cannot agree on the substance for inclusion of a societal benefits approach to HTA as applied to pharmaceutical, medical devices and diagnostics HTA content and processes at national level.

Increasing numbers of HTA agencies in Europe consider criteria beyond purely economic assessment and clinical evidence in their health technology assessments. However, despite general agreement on the need for social or societal elements there is still lack of integrated principles for a Societal Benefits Approach to HTA.

There is evidence to suggest that health systems that already adopt elements of a broader societal perspective towards Health Technology Assessment content and processes are more successful in optimizing efficiency and societal benefit. This is both for niche as well as more general patient populations. Moreover, this approach is more likely to identify potentially distorted clinical decisions and health policies, which may result from adoption of narrower perspectives used by various healthcare system stakeholders. Narrow perspectives are able to distort the results of Health Technology Assessments, healthcare decisions and health policies for society.<sup>1</sup>

At European level, these concepts are encapsulated in the social elements of EUnetHTA's HTA Core Model®. However, Epossi desk and primary research revealed that there are many gaps in these elements to which Epossi can add value in clarification and completion.

Epossi has contributed to the policy and scientific discussion by proposing some clarification and completion to the social elements of EUnetHTA's HTA Core Model® in terms of definition, scope and interlinkages.

Epossi firstly clarified the definition & scope of a societal benefits approach to HTA as "Societal benefits mean a process that involves principles of solidarity, transparency, equality and effectiveness, where the involvement of all stakeholders plays a crucial role and can be achieved by better targeted use of monetary and non-monetary resources across relevant policy sectors. The scope of societal benefits in HTA includes a clear ethical aspect that extends to the inclusion of workability and the quality of life of patients, families and care-givers in the framework."<sup>2</sup>

This enhanced definition was consolidated with the development of a glossary of terms and a basic taxonomy - all validated by experts in the field through the Epossi multi-stakeholder enhanced Policy Delphi method.

We have demonstrated through 4 case studies that such an approach can be applicable to the medtech and diagnostics industries as well as the pharmaceutical industry, to niche as well as larger patient populations.

Epossi was able to demonstrate that elements of a societal benefits approach are being adopted across issues as diverse as multi-decision criteria analysis (AGNSS case in the UK), conditional reimbursement in the Netherlands, Continued economic activity in Sweden, and the case of Medical devices in Germany

---

<sup>1</sup> Drummond et al, "Key principles for the improved conduct of health technology assessments for resource allocation decisions", International Journal of Technology Assessment in Health Care, 24:3 (2008):252

---

<sup>2</sup> Epossi Expert Meeting, November, 2011 [http://www.epossi.org/images/stories/HTA\\_Expert\\_Meeting\\_10Nov11\\_Report\\_-\\_Executive\\_Summary.pdf](http://www.epossi.org/images/stories/HTA_Expert_Meeting_10Nov11_Report_-_Executive_Summary.pdf)



*How can societal benefits be integrated into National Health Technology Assessment in a way which positively contributes to the realisation of better health outcomes for EU citizens as well as a smart sustainable economy?*

Epposi conclusions and policy recommendations on the key elements to be included in the societal elements of the EUnetHTA's HTA Core Model® reflect the need for pragmatism and all stakeholder engagement in managing healthcare systems.

Epposi's Societal Benefits HTA Framework (SBHTAF) focuses on a multi-stakeholder approach to ensure that all relevant social elements (psychological aspects, ethical aspects, continued economic activity, patient involvement) are included in the framework and, moreover, to identify how these elements could be integrated in national HTA content and processes.

A societal benefits approach can be included into existing HTA content and process frameworks at national level by overlaying the nine-domains identified by Epposi stakeholders so long as societal value is placed as an overarching consideration.

Core beliefs underpinning Epposi's framework and related recommendations are summarised below:

Epposi's recommends that there should be a societal benefits approach to HTA which

- is applicable to all types of technologies and healthcare systems;
- builds on the acknowledged **HTA Core Model® social domains** of ethical, legal, social and organizational;
- consists of domains which cover all aspects of health technology content and processes; and
- starts from a collaboration of all interested parties to assessing the psychological and economic burden of the patient and the need for affordability of healthcare services.

<b>Societal Value</b>	<p><b>Principle</b></p> <ul style="list-style-type: none"> <li>▪ The aim of a societal value in a health care system is better value for all, delivering affordable, efficient and sustainable services, contributing to the wider economy and the nation.<sup>3</sup></li> </ul> <p><b>Recommendation</b></p> <ul style="list-style-type: none"> <li>✓ Priority for health and medical care should be given to the person whose need of care is greatest and not according to their ability to pay<sup>4</sup>;</li> <li>✓ Every citizen should be entitled to receiving the best affordable care, which shall be provided with respect for equal dignity of all human beings and for the dignity of the individual<sup>5</sup>.</li> </ul>
<b>Patient defined outcomes</b>	<p><b>Principle</b></p> <ul style="list-style-type: none"> <li>▪ Patients are at the core of their care needs and therefore represent a good source of information.<sup>6</sup></li> </ul>

<sup>3</sup>Ministry of Health and Social Affairs. "Health and medical care in Sweden". *Ministry of Health and Social Affairs*. Factsheet.15.June 2005: 1

<sup>4</sup>Department of Health. "The DH guide: a guide to what we do and how we do it". *Department of Health(DH)*.December 2007:

<sup>5</sup>Department of Health. "The DH guide: a guide to what we do and how we do it". *Department of Health(DH)*.December 2007:

<sup>6</sup>Delwel, G.O.et al. "Guidance for Outcomes Research for the assessment of the cost-effectiveness of in-patient medicines".*The Health Insurance board (CVZ)*.270.1<sup>st</sup> December 2008:41-42



	<p><b>Recommendation</b></p> <ul style="list-style-type: none"> <li>✓ Patient-defined outcomes should not only incorporate the clinical outcomes of a specific treatment and/or disease but also extend to how a patient copes with that situation<sup>7</sup>;</li> <li>✓ A combination of information sources, including: Interviews with GPs, patient registries, structured interviews with patients and family members, Randomized Control Trials (RTCs) should be used;</li> <li>✓ Patient-defined Outcomes measures should be HTA case-specific.</li> </ul>
<p><b>Significant others</b></p>	<p><b>Principle</b></p> <ul style="list-style-type: none"> <li>▪ Significant others are all the relevant persons, who provide informal (unpaid) care, giving help or support to family members, friends, neighbours or others and are directly impacted because of long-term physical or mental ill-health or disability or problems relating to old age.<sup>8</sup></li> </ul> <p><b>Recommendation</b></p> <ul style="list-style-type: none"> <li>✓ Significant others who have an impact on overall disease management, especially in the chronic care domain, are essential and should be involved in HTA processes and content.</li> </ul>
<p><b>Continued Economic Activity</b></p>	<p><b>Principle</b></p> <ul style="list-style-type: none"> <li>▪ People, who are able to work, can experience significant health, social, psychological and wider economic effects from remaining in work.</li> </ul> <p><b>Recommendation</b></p> <ul style="list-style-type: none"> <li>✓ HTA should not focus too narrowly on employed (<i>paid</i>) work, which has a direct benefit to society through tax revenues, but also on unpaid work which has a direct societal benefit but an indirect economic benefit.</li> </ul>
<p><b>Psychological Aspects</b></p>	<p><b>Principle</b></p> <ul style="list-style-type: none"> <li>▪ Psychological aspects assess how likely it is that patients' health will be improved by the proposed product, service, or technology. This includes health benefits to families, carers and society.</li> </ul> <p><b>Recommendation</b></p> <ul style="list-style-type: none"> <li>✓ Workability and rehabilitation should be directly linked to a patient's well-being and psychological health status and this interlinkage should be taken into account in HTA processes.</li> </ul>

<sup>7</sup> Eposi stakeholder survey, June 2013

<sup>8</sup> Eposi Stakeholder survey, June 2013



<p><b>Ethical Aspects</b></p>	<p><b>Principle</b></p> <ul style="list-style-type: none"> <li>▪ Ethical aspects are understood as Equality and Equity in Healthcare, Quality of life for patients and carers, Justice in Healthcare, Dignity and Patient's Comfort, Access according to need, Accessibility in Healthcare, Faster access to care;</li> </ul> <p><b>Recommendation</b></p> <ul style="list-style-type: none"> <li>✓ Ethical Aspects should reflect the correctness of human action, which is stamped by moral concepts and rules in specific cultures;</li> <li>✓ Access to health care is a right, not a luxury and priority should be given to the worst-off since health resources are limited<sup>9</sup>.</li> </ul>
<p><b>Governance</b></p>	<p><b>Principle</b></p> <ul style="list-style-type: none"> <li>▪ Governance provides the ground rules on how HTA should be framed<sup>10</sup>;</li> <li>▪ Governance is the process by which meaningful information and knowledge to be able to make decisions on the direction of a change process as well as the momentum to realise the changes is gathered.</li> </ul> <p><b>Recommendation</b></p> <ul style="list-style-type: none"> <li>✓ Transparency and public access to official records should be considered as important aspects in governance</li> </ul>
<p><b>Cross-sectoral Policy Making</b></p>	<p><b>Principle</b></p> <ul style="list-style-type: none"> <li>▪ Cross-sectoral policy making is the process that should enforce the collaboration between different parties not only in the healthcare sector but also outside healthcare sector;</li> <li>▪ 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<sup>11</sup>.</li> </ul> <p><b>Recommendation</b></p> <ul style="list-style-type: none"> <li>✓ A holistic approach should be adopted in the healthcare decision-making;</li> <li>✓ A cross-sectoral collaboration could result in a better allocation of human and economic resources.</li> </ul>
<p><b>All Stakeholder Involvement</b></p>	<p><b>Recommendation</b></p> <ul style="list-style-type: none"> <li>✓ Parties involved in healthcare should be closely involved in the HTA process; they should be consulted on both the content and administrative aspects;</li> <li>✓ Every stakeholder should be involved where his/her expertise and knowledge are of the most value;</li> <li>✓ Transparency in collaboration and clearly defined roles between the different interested parties is highly recommended.</li> </ul>

<sup>9</sup> Epossi stakeholder survey on domains, January 2013

<sup>10</sup> Epossi Expert Meeting (June 2012)

<sup>11</sup> Epossi Expert Meeting, June 2012





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

*How can societal benefits be integrated into National Health Technology Assessment in a way which positively contributes to the realisation of better health outcomes for EU citizens as well as a smart sustainable economy?*