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

I. Introduction.

The interaction between the umbrella organisations representing patient and consumer organisations, healthcare providers (professionals and hospitals), and social payers within the Stakeholder Forum of the European Network for Health Technology Assessment (EUnetHTA) that was established in 2008, has revealed a number of shared views on Health Technology Assessment and its role in the effective organisation of health care delivery across Europe. The purpose of this position paper is to inform the community about the common vision of the non-industry stakeholders on Health Technology Assessment and to stress the importance of the stakeholder involvement in the HTA policy.

II. Definitions

Health technology is referred to as any intervention that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. This includes pharmaceuticals, medical devices, procedures and organisational systems used in health care.[1]

Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic, legal and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value[2].

HTA is intended to provide a bridge between the world of research and the world of decision-making[3], supporting decisions on the implementation of evidence-based medicine within the relevant local context taking into account, for example, economic, ethical, organisational, social and legal aspects.[4]

III. Application of HTA in Europe

In Europe, HTA has become increasingly important in reimbursement decision-making regarding pharmaceuticals, following the examples of Australia and Canada where such assessments were structurally introduced in the early 1990s. [5]

Recent comparative analysis of the applied assessment methods and reimbursement procedures has demonstrated a rather high degree of variability across the Member States.

On the methodological level, differences have been identified in the assessment criteria applied (cost-effectiveness, budget impact, degree of innovation etc.), the choice of the appropriate comparator for the technology under assessment, the accepted outcome measures and the approaches to extrapolate the available short-term data and to grade the level of evidence.[6]

On the procedural level, divergence was found in the degree of stakeholders' involvement in the reimbursement decisions, the status of the recommendations of the authorised HTA bodies (binding vs non-binding), the content of the national guidelines and the public availability of the assessment reports.[7]

Initiatives to align the HTA methodologies within and outside of Europe are driven by a number of organisations, such as the International Network of Agencies for Health Technology Assessment (INAHTA), the European Network for Health Technology Assessment (EUnetHTA), the European Medicines Agency (EMA), the Cochrane Collaboration, the Agency for Health Care Research and Quality (AHQR), the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) etc. However the involvement of non-industry stakeholders in the process stays limited.

IV. Our vision regarding HTA

The founding principles of the European Union establish solidarity amongst its citizens, a value crucial for the concept of Social Europe. Differences in health technology assessment and appraisal methods across Europe as described above pose some challenges to the implementation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.

While final reimbursement decisions including the level of reimbursement will reflect the national context and logically differ across Member States, sharing information and using transparent approaches in the assessment and decision-making are likely to shorten the time-to-market of effective health technologies and to make the reimbursement decision more understandable for the citizens of Europe.

Healthcare systems in Europe vary in terms of their sustainability and efficiency.[8] What most of them have in common is a regulated service supply and the challenge of a responsible budget allocation across an increasing number of new health technologies. Recent surveys have highlighted a number of relevant concerns. European consumers feel insecure that they are not in control of health care costs[9]. Healthcare providers acknowledge that in modern care, obsolete or ineffective technologies are sometimes used[10]. While research on decision makers' perceptions with regard to their mission is limited, several obstacles to making optimal use of HTA information have been identified: the knowledge gap due to limited access to scientific literature; quality and generalisability issues of HTA reports; inflexibility of the budgets.[11] In this context, our healthcare systems could benefit from a revision of certain organisational and financial principles.

Considering the above, the undersigned organisations are concerned about the sustainability of the principles of solidarity and equal access in healthcare. The non-industry stakeholders underscore the

importance of HTA in helping national authorities to make better decisions and generate more health from their investments in health care. Validated methods to integrate individual and societal values in health technology assessment and appraisal procedures are needed. A number of tools such as Discrete Choice Experiment[12], Stochastic Multicriteria Acceptability Analysis[13], Multi-Criteria Decision Analysis[14] are under research. With the active involvement of stakeholders this research has the potential to make HTA a practical and comprehensive tool that supports evidence-based decision-making and at the same time bridges the gap between the generated knowledge and the day-to-day practice.

V. Recommendations

1. Processes

Patients, consumers, providers and payers in Europe are (directly or indirectly) involved in reimbursement decision-making and/or in the implementation of those decisions. To maximise the added value of HTA, these stakeholders need to be actively engaged in several HTA related processes such as:

- Adoption of common working definitions and best practice principles for HTA;
- Priority setting for the development of new assessment methodologies to support decision makers;
- Prioritisation of the technologies to be assessed;
- Development of multinational epidemiological research, implying efficient cross-border exchange of clinical data, and appropriate initiatives to establish interoperable registries;
- Identification of unmet medical needs and prioritisation of R&D through early dialogue with the national authorities and industry, with active (non-binding) participation of the HTA agencies;
- Identification of the need for HTA expertise development and participation in the training development;
- Dissemination of information on HTA to the general public.

2. Reimbursement

Differences in reimbursement status should not be a barrier to cross-border healthcare, patient mobility and freedom of choice. Greater transparency as regards reimbursement decisions and the decision making process could be enhanced through the involvement of non-industry stakeholders to:

- identify the criteria that play a role in the reimbursement process
  (e.g. criteria that pertain to the broader societal perspective, including clinical need, prevalence of disease, ethical and equity issues, incentives to adopt new technology etc.)
- systemise the consideration of these criteria;
- develop quantitative and/or qualitative approaches to assess technologies based on these criteria, taking into consideration the specific local context[15]
- ensure that there is appropriate separation of responsibilities between payers, policymakers, evaluators and decision-makers;
- ensure wide stakeholder input into the HTA appraisal and decision-making;

- ensure public disclosure of decisions, including the reasons for recommendations to reimburse or not reimburse a technology;
- ensure appropriate accountability measures, including appeal procedures, quality assurance programmes/audits of evaluation processes, and the publication of system performance indicators[16].

3. <u>European HTA collaboration</u>

The development of a collaborative model for European HTA research requires considerable organisational effort and a new culture of dialogue between all stakeholders. We support the activities of EUnetHTA to date and recommend to clearly define the roles of the non-industry stakeholders within the EUnetHTA Stakeholder Forum. Involvement of the non-industry stakeholders is crucial on the level of HTA governance, where the strategic research priorities are being determined, and on the level of practical implementation such as contribution to the electronic registers.

The undersigned organizations are dedicated to working together towards the above mentioned objectives and call for EU policies in support of this cooperation. We plead for a value chain wherein the European HTA collaboration contributes to a more transparent decision making and better healthcare for European citizens.

[1] INAHTA (International Network of Agencies for Health Technology Assessment). (June 8, 2009). HTA glossary

[2] http://www.eunethta.eu/Public/About_EUnetHTA/HTA/

[3] Battista, RN: The scientific basis of health services. BMJ Publishing Group, 1996

[4] EUnetHTA HTA CORE Model for medical and surgical interventions. WP4. 2008 Available at URL: https://fio.stakes.fi/htacore/HTACoreModel_Handbook_2012-09-17.pdf

[5] Annemans L, Cleemput I, Hulstaert F, Simoens S "Valorising and creating access to innovative medicines in the European Union."Frontiers in pharmacology. 11 October 2011

[6] EUnetHTA JA WP5: 11 Relative Effectiveness Assessment (REA) of Pharmaceuticals. Background Review. Available at URL http://www.eunethta.eu/upload/WP5/Link1.pdf. Access October 2012

[7] EUnetHTA JA WP5: 11 Relative Effectiveness Assessment (REA) of Pharmaceuticals. Background Review. Available at URL http://www.eunethta.eu/upload/WP5/Link1.pdf. Access October 2012

[8] CPME Statement on Health Technology Assessment in Relation to Cross-Border Healthcare (CPME 2011/131 FINAL EN)

[9] "2011 Survey of Health Care Concumers. Global Report" produced by Deloitte Center for Health Solutions http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/US_CHS_2011ConsumerSurveyGlobal_062111.pdf

[10] CPME Statement on Health Technology Assessment in Relation to Cross-Border Healthcare (CPME 2011/131 FINAL EN)

[11] McGhan WF, Al M, Doshi JA, Kamae I, Marx SE, Rindress D. The ISPOR Good practices for Quality Improvement of CER Task Force Report, Value Health. 2009 Nov-Dec;12(8):1086-99

[12] Editors: Mandy Ryan Ph.D, Karen Gerard M.Sc, Mabel Amaya-Amaya Ph.D. Using Discrete Choice Experiments to Value Health and Health Care. The Economics of Non-Market Goods and Resources. Volume 11. 2008

[13] Tervonen, T., Valkenhoef, G. v., Buskens, E., Hillege, H. L. and Postmus, D. A stochastic multicriteria model for evidence-based decision making in drug benefit-risk analysis. Statistics in Medicine, 30 (12): 1419-1428, 2011

[14] https://www.evidem.org/

[15] https://www.evidem.org/

[16] A comparative analysis of the role and impact of Health Technology Assessment. Charles River Associates. May 2011

About Us

AIM, The Association Internationale de la Mutualité (AIM) is a grouping of autonomous health insurance and social protection bodies operating according to the principles of solidarity and non-profit-making orientation. Currently, AIM's membership consists of 48 national federations representing 27 countries. In Europe, they provide social coverage against sickness and other risks to more than 160 million people. AIM strives via its network to make an active contribution to the preservation and improvement of access to health care for everyone.
More info: www.aim-mutual.org
Contact: corinna.hartrampf@aim-mutual.org and irina.odnoletkova@mloz.be

AIM endeavors to voice concerns and ideas raised within the sphere of non-profit health insurance institutions in the EU. AIM positions, requiring validation through its own statutory decision-making process, do not commit its individual member organizations. Therefore, AIM involvement does not detract from its member organizations taking dissentient views.

HOPE, the European Hospital and Healthcare Federation, is an international non-profit organisation, created in 1966. HOPE represents national public and private hospital associations and hospital owners, either federations of local and regional authorities or national health services. Today, HOPE is made up of 34 organisations coming from the 27 Member States of the European Union, Switzerland and the Republic of Serbia.
HOPE mission is to promote improvements in the health of citizens throughout Europe, high standard of hospital care and to foster efficiency with humanity in the organisation and operation of hospital and healthcare services.
Contact: sg@hope.be

BEUC, The European Consumer Organisation has a membership of 40 well respected, independent national consumer organisations from 30 European countries (EU, EEA and applicant countries). BEUC acts as the umbrella group in Brussels for these organisations and our main task is to represent our members and defend the interests of all Europe's consumers.
Contact: ipa@beuc.eu

The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues. We believe the best possible quality of health and access to healthcare should be a reality for everyone.
More info: *www.cpme.eu* Contact: *constance.colin@cpme.eu*

EURORDIS, The European Organisation for Rare Diseases represents more than 500 rare disease organisations in 48 countries, covering more than 1,000 rare diseases. It is the voice of the estimated 30 million patients affected by rare diseases throughout Europe.
EURORDIS is a non-governmental patient-driven alliance of patient organisations and individuals active in the field of rare diseases, dedicated to improving the quality of life of all people living with rare diseases in Europe. It is supported by its members and by the French Muscular Dystrophy Association (AFM), the European Commission, and corporate foundations and the health industry.
EURORDIS was founded in 1997. More information on: www.eurordis.org

ESIP represents a strategic alliance of over 40 statutory social security organisations in 15 EU Member States, Croatia and Switzerland. ESIP's mission is to preserve high profile social security for Europe, to reinforce solidarity based social insurance systems, and to maintain European social protection quality.
More info: www.esip.org Contact: esip@esip.org
Note: ESIP members support this position in so far as the subject matter lies within their field of competence. competence.