



The European Association for Bioindustries

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Dear Ms Bistrup,

I would like to thank you for the opportunity to comment on the Proposal for EUnetHTA Collaboration 2009+.

EuropaBio is the European Association for Bioindustries, solely and uniquely bringing together bioscience companies from all fields of research and development, testing, manufacturing and distribution of biotechnology products. It has 84 corporate members operating worldwide, 8 associate members, 6 BioRegions and 25 national biotechnology associations representing some 1800 small and medium sized enterprises involved in research. Its mission is to promote an innovative and dynamic biotechnology-based industry in Europe.

Our successful positioning as a single entry point for reaching Europe's biotech industry has seen us invited by the European Commission to be a Member of the High Level Pharmaceutical Forum, and to participate in its Working Group on Relative Effectiveness. We were also involved and highly supportive of initiatives on HTA undertaken within the frame of HTAi Society.

As a general comment, EuropaBio welcomes this EUnetHTA initiative, as we believe that it represents an important step forward in the European process of disseminating and understanding of HTA principles and methods. EuropaBio strongly supports the goal of developing a sustainable collaboration to advocate and facilitate robust, transparent and predictable HTA analysis that will serve as a useful and independent tool in the hands of decision makers.

We call on EUnetHTA to promote throughout Europe the four pillars of HTA, namely: assessment of medical, social, economic and ethical issues, as well as the continued development of methodological guidelines for HTA consistent with these pillars and, in general, with the definition of HTA adopted by EUnetHTA.

However, we also propose that both in relation to methodological issues and in the case of the assessment of health technologies (core HTA information), EUnetHTA take in consideration the following principles that could form the basis of a common European standard for HTA:

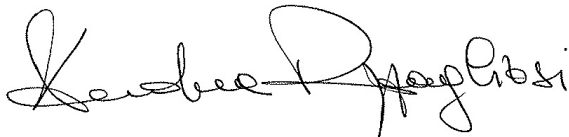
- 1. A broader perspective.** HTA should seek to determine the value of a technology whilst considering a wide range of perspectives that include economic, medical, technological, social, ethical, psychological and anthropological aspects. This evaluation should also take place in the context of the whole budget for healthcare, and be equally made for processes, procedures, service costs and products. HTA should take account of issues such as the policy context, community need, alternative treatment, uniqueness, disease rarity, utilization patterns, cost-effectiveness, budget-impact, organization and staffing impact, future evidence that will become available, ethics, access and healthcare funding mechanisms within this framework, HTA may reach different conclusions on the same technology in different countries or regions.
- 2. An improved early-stage dialogue.** HTA should be based on an in-depth interaction to discuss specific data required in order to decide on the reimbursement of a product, and looking at it's specific field and patient need. This would create predictability by clarifying payer expectations and the ability of industry to meet these expectations. At present, dialogue generally starts once a medicine has been approved and the data generated. What constitutes therapeutic progress, and whether and at what level to fund this progress should be much clearer, and the rarity of the disease should be taken into account.
- 3. Flexibility.** HTA is a flexible process that should be used collaboratively. The use of HTA to make reimbursement decisions should have as its key objective the rapid uptake of innovative health interventions and technologies and improve health outcomes for patients, without losing out of sight our social values. A proper use of clinical and/or cost-effectiveness assessment of a medicines should be aimed at increasing the understanding of its different benefits, relevance to patients and public health and impact on the healthcare system.
- 4. The “right” timing.** A ‘one size fits all’ approach to the timing and procedure of appraisals fails to take account of the complexity of conducting assessments and ignores differences in treatments and therapeutic areas and patient populations. Often the sort of data needed to confirm cost-effectiveness and clinical effectiveness is data on real-life clinical use of a medicine. This can only be collected once a medicine has been on the market for a period of time, which again may differ depending on prevalence. Manufacturers should therefore be able to submit health outcomes information to the relevant government bodies throughout a product’s lifecycle. This evidence should receive appropriate attention and reward from payers.
- 5. Managing uncertainty.** Uncertainty in economic evaluation of innovative therapies is often managed by a call for more evidence. However, the willingness to invest in research to obtain additional evidence may be limited by the number of patients available, the heterogeneity and natural history of the disease, the mechanism of action of the therapy, and the ethical burdens surrounding the choice of specific patient population. If the region of uncertainty is wide but includes the possibility of significant benefits, interim funding may be considered, provided that data are collected during use of the therapy in order to improve the informed decision.

6. Patient and public involvement. Both patients and the public have to be regularly informed about what the use and procedures of HTA are and how it fits in making the healthcare system more efficient for them. They should have the same right as other stakeholders and actors of the process in the evaluation of new therapies, which should not just be based on economics but also. Patient and public involvement needs to be clear, transparent and become a key structural element of any evaluation of innovative therapies.

In addition, EuropaBio considers it extremely important that all stakeholders in the health sector are involved in the decision making process of the future EUnetHTA collaboration. In this perspective, EuropaBio supports the eventual inclusion of representatives of patient organizations, scientific and learned societies and manufacturers in the Steering Committee

Thank you very much again for the opportunity to comment, and we look forward to being involved in the next stages of this process, and to ensuring that innovation is properly rewarded in Europe in the future.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Andrea Rappagliosi'. The signature is fluid and cursive, with a large initial 'A' and 'R'.

Andrea Rappagliosi
Chair
Healthcare Council