



Making Medicines Affordable



### “Appropriate Stakeholder Consultation”

*in the EU Health Technology Assessment (HTA) Network established in accordance with Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare.*

19 June 2013, Brussels

To:

European Commission representatives: Andrzej Rys, Tapani Piha, Jérôme Boehm, Flora Giorgio

EUnetHTA representatives: Finn Børllum Kristensen, Julia Chamova

Health Attachés of the Member States’ Permanent Representations to the EU in Brussels

Subject: Call for a Multi-Stakeholder Forum in the implementation for “Appropriate Stakeholder Consultation” in the EU HTA Network.

Dear Sir/Madam,

As stipulated in the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare under article 15 “Cooperation on health technology assessment “

- The Union shall support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States
- The network shall be based on **the principle of good governance including transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations.**

On the topic of **appropriate stakeholder consultation for the HTA Network**, members of the Stakeholder Forum (signatories enclosed) of EUnetHTA Joint Actions, defined jointly the following considerations and requests and we are reaching out to other stakeholders to join.

Based on our experience in the EUnetHTA Joint Actions, we are confident of our respective abilities to bring value as Stakeholders and we are committed to facilitate the implementation of appropriate stakeholder involvement at all levels of the planned EU HTA network. Within the future HTA network we see a key role for a “Multi-Stakeholder Forum”.

Firstly, we want to stress **the importance of stakeholders’ involvement** in public projects/programmes and that a “Multi-Stakeholder Forum” should be established to contribute to both the strategic and technical/scientific levels of the HTA network based on a transparent stakeholder involvement policy. At the strategic level, stakeholders will contribute with their experiences regarding the future and value of HTA. At the technical/scientific level, involvement will ensure the contribution of relevant expertise as well as different perspectives and experiences. Involvement of a “Multi-Stakeholder Forum” composed of European associations representing patients, consumers, providers, payers and industry should allow for a good representation of European geographies and peculiarities.

As HTA should be intended to support healthcare decision-making and policy-making it is clear that as a part of good governance the HTA assessment must remain independent from stakeholders’ interests. However we also strongly believe that any HTA needs to take into account all relevant information including medical, social, economic, societal and ethical information, and information directly provided by stakeholders. Specific information needs should be addressed and involvement from the start is essential. As such it will facilitate further endorsement of the HTA outcomes by all stakeholders.

Secondly, we consider that a “**Multi-Stakeholder Forum**” will **ensure the most effective and efficient model for stakeholder consultation**, rather than ad-hoc interactions with single stakeholders.

A “**Multi-Stakeholder Forum**” will facilitate the appreciation of different stakeholders’ needs and interests and will facilitate the building of a consensus view or one indicating the different perspectives of stakeholders. In this way it will ensure that points of common value are addressed and ensure appropriate stakeholder input to the HTA network. Existing successful multi stakeholder models need to be investigated further, but a first suggestion would foresee a model with comprehensive representation and equitable participation and that provides a platform for open dialogue between stakeholders.

We consider it to be critical that appropriate stakeholder consultation becomes an **integral part of the implementation of the HTA network’s good governance** avoiding any issues at a later stage. The views and expectations which stakeholders expressed with view to setting up the Stakeholder Forum for EUnetHTA Joint Action 2 regarding stakeholder involvement should also be taken into consideration in future discussions (our letter of 26 April 2012).

Besides the expression of our strong interest for a “Multi-Stakeholder Forum”, we call for the European Commission to facilitate the dialogue between the Commission, Member States’ representatives of the HTA network and EUnetHTA to define together the **modalities of a “Multi-Stakeholder Forum”** (set-up, coordination, chairing modalities, secretarial support, financing, legal basis etc.) to ensure **appropriate stakeholder consultation** (consultation throughout the full process, at both the strategic and technical/scientific levels).

We would also appreciate the opportunity to discuss Article 15 point 3 (e), which states “aid can be granted by the Union in order to facilitate the consultation of stakeholders on the work of the HTA network”, to ensure equity in representation and participation in stakeholder involvement.

We look forward to hearing from you and remain

Yours Sincerely,

- **AESGP**, The Association of the European Self-Medication Industry
- **BEUC**, The European Consumers' Organisation
- **COCIR**, European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
- **CPME**, Standing Committee of European Doctors
- **EDMA**, European Diagnostic Manufacturers Association
- **EFPIA**, European Federation of Pharmaceutical Industries and Associations
- **EGA**, European Generic Medicines Association
- **EPF**, European Patients' Forum
- **ESIP**, European Social Insurance Platform
- **ESMO**, European Society Medical Oncology
- **EUCOMED**, European Association Medical Technology
- **EuropaBio**, European Association of Bioindustries
- **HIO**, Cyprus Health Insurance Organisation
- **Weight Watchers International**

Under consideration with their members:

- **AIM**, Association Internationale de la Mutualité (International Association of Mutual benefit societies)
- **EURORDIS**, European Organisation for Rare Disorders
- **ESC**, The European Society of Cardiology

