Framework for a joint EUnetHTA-EFPIA Advisory Working Group to facilitate the involvement of pharmaceutical companies in the pilot work in Joint Action 2.

In the second Joint Action on HTA, EUnetHTA aims to conduct rapid relative effectiveness assessments (REA) of 10 pharmaceuticals (WP5), full HTA on three technologies that may be pharmaceuticals (WP4), provide early scientific advice (ESA) on pharmaceuticals and develop a template for submissions (ST) (WP7). These activities require the involvement of pharmaceutical manufacturers to share their experience of existing HTA systems and provide information on compounds selected for piloting, and make proposals of compounds for REA, HTA, and ESA. Therefore it is suggested that EUnetHTA and EFPIA collaborate in order to facilitate a successful involvement of pharmaceutical companies in the pilot work of EUnetHTA JA2. The collaboration is focused on the above listed tasks of JA2 and is a specific activity with pharmaceutical companies in parallel to the activities in the EUnetHTA JA2 Work Packages (WPs), Stakeholder Advisory Groups (SAGs), and the Stakeholder Forum (SF).

Scope of collaboration

EUnetHTA and EFPIA will engage with a view to facilitating continuous process improvements, so that the pilots can best address the viability and usefulness and the successful conduct of the EUnetHTA work plan, and if appropriate, assist in developing a sustainable process for the longer term, post JA2.

EUnetHTA and EFPIA agree to set up a Joint Advisory Working Group in order to assist WP4, WP5 and WP7 in the development of guiding principles, processes and closely monitor progress in parallel to the pilots of REA and ESA and integrate experiences in an iterative and timely manner, whilst also fostering scientific discussion on areas of relevance to European collaboration on HTA. This should aim to support building the basis for the permanent network of HTA agencies to be set up by October 2013 (Directive 2011/24/EU). Other relevant stakeholders, such as national decision-makers, might also be involved in the discussions, where relevant.

EUnetHTA commits to clarify the purpose of various pilots, and EFPIA commits to facilitating interaction with individual companies for piloting purposes.

The joint advisory group will advise primarily on the following activities:

- Process of REA/procedure manual (WP5);
- Process of full HTA when the topic selected is a pharmaceutical treatment (WP4);
- Process of scientific advice (WP7 and additional tender, where relevant), including HTA-only scientific advice and parallel advice with regulatory agencies, whilst learning from previous pilot projects conducted by HTA agencies in individual Member States (such as the UK or Sweden), by HTA agencies and the EMA, or multi-stakeholder pilots coordinated by the Tapestry networks;
- Process of developing a submission template (ST) (a modular template for evidence submissions that includes the evidence requirements from European HTA organisations and reflects the HTA Core Model) (WP7);
- Scientific workshops on methodologies and evidence generation in relation to the pilots, involving representatives of other stakeholder group;

The scope of collaboration might evolve as activities unfold. Any expansion will need an agreed revised version of this structure.

The specific proprietary product related content of the REA, HTA, ESA, and ST will necessarily have to be out of scope of this collaboration, since these address competitive information.

This collaboration will complement, but not replace other existing EUnetHTA structures and forms of stakeholder engagement, in particular, the SF and SAGs, and EFPIA's involvement in them.

Membership and meetings

The Joint Advisory Working Group will be composed of representatives of EUnetHTA members and EFPIA members; the European Commission and the European Medicines' Agency may also be invited to join on a case by case basis as appropriate. Additionally, it may be suggested to include one representative per stakeholder group from the SF as observer in this Joint Advisory Working Group. The overall coordination of the Joint Advisory Working Group will be shared by the EUnetHTA and EFPIA Secretariats. It is important to ensure that the membership builds on expertise in the various activities considered (in particular on the technology producers that are involved in the pilots).

EUnetHTA and EFPIA agree to meet on a regular basis, for instance every year in order to integrate the experiences, plus additionally as needed in order to secure an effective implementation of the pilots and to advance the discussions, in particular in the early phases of JA2 (for instance after 2-5 REA / Core HTA pilots). Depending on the subject of discussions, meetings can be scientific workshops or expert meetings in person, or by electronic means. EFPIA and EUnetHTA Secretariats commit to facilitating the organisation of such meetings.

Transparency

The membership is determined by the focus of work on pharmaceuticals. However, it is important to ensure that other stakeholders are fully aware of the outcomes of the collaboration in this Working Group. To this end, EUnetHTA and EFPIA agree to publish this agreement on the structure for collaboration on their respective websites as well as the outcomes of all their discussions. The EUnetHTA Stakeholder Forum will also be informed of progress of work during their meetings.