IMPROVING INITIAL EVIDENCE GENERATION FOR HEALTH TECHNOLOGIES

Improving initial evidence generation for health technologies, combining two approaches:

- **Product-specific:** Early Dialogues between HTA agencies and companies on the development of new drugs or devices
- **Disease-specific:** Development of one pilot Disease-Specific Guideline for technology developers

Work Package 7 / Subgroup 1

Background

Recommendation by the High Level Pharmaceutical Forum (2008): National authorities and companies to engage in early dialogues with the aim of improving the generation of appropriate data for products in development (Recommendation 6).

First Early Dialogue Initiatives: Single HTA advice (since 2009) and parallel regulatory - HTA advice organized by the EMA with a limited number of HTA bodies (since 2010).

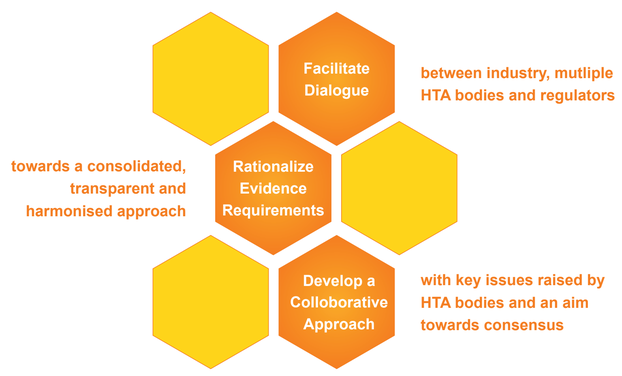
EUnetHTA JA2 WP7 (2012-2015): EUnetHTA establishes the first pilots of multi-HTA EDs for drugs, extending their scope to include medical devices and developing, in parallel, a pilot disease-specific guideline.

Product-Specific Approach ➲ Multi-HTA Early Dialogues

Objectives

The Early Dialogue (ED) overarching aim is to provide prospective, transparent and timely advice by HTA bodies to product sponsors so that they may integrate specific HTA needs in the product development.

Advice during early phases of development of a health technology



EUnetHTAPartners: 8 countries - HAS (France), HVB (Austria), KCE and INAMI (Belgium), RER-ASSR and AIFA (Italy), G-BA and IQWiG (Germany), GYEMSZI (Hungary), ZIN (Netherlands), TLV (Sweden).

Scope

Pilot EDs may be requested for a new technology, with supposed added benefit for patients, during the initial phase of its clinical development (e.g. end of phase II) to address questions pertaining to relative effectiveness and cost effectiveness.

Pilot EDs are: ■ prospective in nature ■ focused on development strategies and not on pre-evaluation of available data ■ limited to one indication and/or one line of treatment ■ non-binding ■ confidential ■ free of charge.

Methods Towards Defining an ED Procedure

- 2 preparatory multi-HTA EDs were undertaken by voluntary HTA bodies and companies prior to EUnetHTA JA2.
- A draft procedure was developed based on this preliminary work; the procedure was further amended in EUnetHTA JA2 with the undertaking of 8 drug EDs.
- A survey was conducted on the experience of the 8 EDs with the aim of improving the procedure.
- An ED on an MD remains to be conducted (scheduled in 2015).
- In this first series of EDs, a medical expert and an EMA representative were present; other EUnetHTA stakeholders were kept informed of organizational and procedural developments.
- The ED process was presented and discussed at the Medical Device Industry Representative meeting (May 2014)[1].

ED Draft Procedure (figure 1)

- Exchanges between HTA bodies, prior to the face to face (FTF) meeting with the company, allow for identifying questions in advance with the aim of reaching, as often as possible, a common position.
- During the FTF with the company, company questions are addressed one by one with a summary opinion expressed by the meeting Chair. The opinion of each HTA organization representative is given when appropriate.
- The specific advice on the product in development is non-binding and confidential.
- Detailed meeting minutes are provided by the company and validated by HTA partners.

Figure 1

D-75 / Pre-submission: draft application file submitted to the coordinator (HAS).
D-60 / Start of Procedure: revised draft application sent to participating HTA bodies.
D-45 / Teleconference: between HTA bodies to identify any missing information; list of points requiring clarification sent to company.
D-30 / Additional information: provided by company.
D-7 / Draft written answers: submitted by all participating HTA bodies to coordinator; compiled and resubmitted to HTA participants.
D-0 / Face to Face Meeting: closed HTA body meeting (morning); meeting with the company (afternoon).
D+7 / Detailed draft meeting minutes: provided by company.
D+20 / Final meeting minutes: reviewed and corrected by all HTA participants.

1. The EUnetHTA- Medical Device Industry Expert meeting: "Current experience and developments in HTA of medical technologies in Europe" was jointly organised by EUnetHTA, EUCOMED/EDMA and COCIR (published on the EUnetHTA website June 26, 2014).

Results

- To respond to high demand from involved parties, the number of planned ED drug pilots was increased from 3 to 10 (including 2 preparatory pilots).
- Therapeutic domains covered: Rheumatoid Arthritis, Haematology, Neurolog, Gynaecology and Dermatology.
- Participation from small to large-size firms, including 1 SME.
- Survey input received from 11 HTA bodies, 8 manufacturers and 1 EMA observer.

Sample results from ED survey

Key to ED success - company perspective: ■ provide templates for submission ■ focus on problematic areas for discussion during FTF ■ HTA answers to be supported ■ responses summarized by Chair ■ presence of external expertise in the field.

Key to ED success - HTA body perspective: ■ company position supported per question ■ HTA bodies to discuss completeness of data and key issues ■ HTA bodies' written responses exchanged prior to FTF; importance of internal discussion between HTA bodies.

Survey results to be published on EUnetHTA website.

Early Dialogue Follow-Up with the SEED Project

- **Project sponsored by the European Commission (Call for tenders).**
- **Consortium of 14 HTA bodies from 10 countries , led by HAS.**

SEED Partners: HAS (France), HVB (Austria), KCE (Belgium), HIQA (Ireland), RER-ASSR and AIFA (Italy), G-BA and IQWiG (Germany), GYEMSZI (Hungary), ZIN (Netherlands), AVALIA-T, ISCIII and AETSA (Spain), NICE (UK)

Main deliverables

- *10 EDs to be conducted between May 2014 and March 2015, 3 on MDs and 7 on drugs.*
- *Final report to include a proposal for a permanent model of EDs in Europe.*

SEED and EUnetHTA

- *All agencies members of SEED consortium are also partners of EUnetHTA.*
- *EUnetHTA procedure (amended after the survey) used as a basis for SEED EDs.*
- *Proposal for permanent model of ED to be submitted to EUnetHTA Plenary Assembly for discussion before drafting of final report for SEED.*

www.earlydialogues.eu

Disease-Specific Approach ➲ Disease Specific Guideline

Objective

The Disease Specific Guideline (DSG) aim is to provide recommendations on the type of data to be produced during the development of technologies (initial evidence generation) to support relative effectiveness and cost-effectiveness assessment in a given condition. DSGs should:

- Provide non-binding guidance to manufacturers in developing a technology with regards to its evidence requirements.
- Assist health technology assessors with the interpretation and processing of data.

Methods

- Topic selection based on criteria and proposals made by WP7 partners and after consultation of stakeholders: osteoarthritis.
- Development of a concept paper on DSG for osteoarthritis by an authoring agency.
- Ongoing development of DSG outlining the data requirements for the initial assessment of health technologies for osteoarthritis of the hip and knee (stakeholder consultation in 2015).

Poster developed by The French National Authority for Health (HAS).
Content on SG1 Early Dialogues and Disease Specific Guidelines (Lead by HAS) as part of EUnetHTA Work Package 7 (HAS as Lead and IQWIG as Co-Lead).

The contents of this poster arise from the EUnetHTA JA 2 which has received funding from the EU, in the framework of the Health Programme. Sole responsibility for its contents lies with the author(s) and neither the EUnetHTA Coordinator nor the Executive Agency for Health and Consumers is responsible for any use that maybe made of the information contained therein.