

EFPIA WORKING GROUP ON HEALTH TECHNOLOGY ASSESSMENT

Date: 16/02/2016

Location: EFPIA office, Brussels

Participants

EFPIA: A. Rappagliosi, E. Frénoy (Brussels' office), EFPIA WG Members

SANTE: D. Schnichels, J. Boehm, F. Giorgio, K. Hanslik

Purpose of the meeting

DG SANTE was invited to the EFPIA Working Group on HTA. The purpose of the meeting was to present the EU activities on HTA and to discuss the possible ways of HTA collaboration in the area of relative efficacy (REA) in view of the upcoming new Joint Action 3 on HTA.

Presentations

D. Schnichels thanked for the invitation and explained his new role as the Head of Unit in charge also of HTA file, and then all participants introduced themselves (tour de table).

A. Rappagliosi (EFPIA) presented the industry views on:

Joint REA:

EFPIA supports Joint REA at EU level as different assessment approaches lead to inconsistent access decisions, inconsistent evidence requirements, duplication of procedures and patient access delays. Alignment of data requirements and assessment approaches can reduce controversies and end duplication both for authorities and companies. A common approach to reuse is also essential. Reference to the Article 15 on HTA is made (Member states are invited to exchange information and avoid duplication). EFPIA considers that the focus should be put on clinical aspects of HTA at EU level.

Joint REA at EU level is composed of four elements: description of health problem, the technology and its place in treatment pathway, relative efficacy and relative safety. The focus of the cooperation shall be on these aspects.

- **EFPIA's views on Joint Action EUnetHTA 3:**

The first JA was critical on methodological toolbox, the second was important for the launch of the pilots, and the JA 3 should implement the REA on a bigger scale. A core group of Member States shall lead the work on the pilots, all Member States shall integrate the REA in their national HTA activities. There is an urgent need for a definition on "re-use" and the role of safety analysis needs to be carefully considered and tested (*EFPIA 15 recommendations*). EFPIA is committed to propose products for the Joint REA.

J. Boehm made the presentation on:

- the HTA activities at EU level:

First political discussions on HTA started in 2008 at the occasion of the Pharma Forum. The current role of the Commission is to bring Member States competent authorities (EU affairs and operational departments) together in the area of HTA (HTA Network) and to build the scientific and technical expertise (Joint Action on HTA). All Member States agree today on the HTA cooperation on clinical level, as part of the overall process which leads to market access.

The operational arm of such cooperation, the Joint Action 3 on HTA is currently under negotiations. This new Joint Action shall reflect the HTA Strategy (adopted by HTA Network Members in 2014), focusing namely on: production (significant number, moving from pilots), mainstream (what is produced at EU level should be re-used at national level, and Member States shall define the “re-use criteria”), defragmentation (post market requirements to be taken into account), sustainability post 2019. The active involvement of companies in particular in proposing pilots for joint work is key to the success of the JA.

Jerome thanked EFPIA for the input to the preparation of the Joint Action 3.

Discussion

The biggest concern for EFPIA members is that the Joint REAs are so far not reused at national level, thereby it is important and urgent to have clear re-use criteria and aim at replacing parts of the national reports. EFPIA also called for an early scientific dialogue between regulators, HTA bodies and industry to determine evidence requirements and data needs. On Timing/Process it was considered essential that the joint REA report is issued around or shortly after marketing authorisation in order to avoid delays in market access, for this support of companies to enable timely access to data by HTA bodies is essential. The experience gained in regulatory scientific advice shall be used possibly to align processes and timelines, interaction with companies is important during the process. On methodologies: it was considered important to adopt EUnetHTA methodologies as the "golden" standard and create convergence on national requirements and methodologies.

EFPIA companies are generally committed to support Joint Action 3 , the concerns is more on how this can be done, therefore clarity and transparency on the process and the outcome of the cooperation is essential to attract more interest.

Follow up

European Commission asked EFPIA to share some ideas on: the re-use criteria, possibly as position paper from the Working Group or EFPIA; on HTA long term vision; share executive summary of the EFPIA studies on the topics.