DELEGATED ACT ON POST-AUTHORISATION EFFICACY STUDIES
(ARTICLE 10B OF REGULATION (EC) NO 726/2004 AND ARTICLE 22B OF DIRECTIVE 2001/83/EC)
Deadline for Public Consultation: 18 February 2013

Comments from European network for Health Technology Assessment, EUnetHTA.

The following joint response to the public consultation on PAES of HAS, France, CVZ, Netherlands, and IQWIG, Germany was facilitated by the European network for HTA (EUnetHTA).

Since its start in 2006 EUnetHTA has developed tools and collaborated to facilitate provision and exchange of information on additional data collection when there is not sufficient evidence to determine the long-term effectiveness of technologies including pharmaceutical.

EUnetHTA aims at reducing unnecessary duplication of work and developing collaboration to share information. Taking into consideration the different remits of pharmaceutical regulatory work and HTA EUnetHTA has since 2010 had an on-going activity with EMA to facilitate the use of information coming out of regulatory work for the purposes of the work done by HTA.

As partners in EUnetHTA with specific distinguished responsibility for HTA processes on national level and as lead participants in relevant EUnetHTA initiatives and concrete cross-border HTA coordination activities, the above mentioned institutions endorse the comments on the draft delegated act given by their Partner organisation Haute Autorité de Santé (HAS), France (attached) with additional comments provided by IQWIG (attached).

IQWIG general remarks to the HAS response:
Overall, we highlight the different remits and requirements of regulatory bodies like the EMA and health technology assessments (HTA) bodies. Robust data from PAES which provide regulatory authorities with valuable key information, may not fulfil the requirements of national HTA bodies, and, therefore, not be stringently required for HTA purposes. In particular cases however a consultation process regarding PAES seems reasonable (this with respect to point 5.). Here the development of the conditions and process of collaboration between EMA and HTA bodies of the EUnetHTA network seems a good approach.

2. THE CONTEXT OF A POST-AUTHORISATION EFFICACY STUDY

Consultation item No 1: Do you think that a delegated act on the situations in which a post-authorisation efficacy study may be required will be of added value and that the Commission should consider bringing forward a draft delegated act? Please provide reasons for your opinion.

See comments provided by HAS

Consultation item No 2: Do you have any comments on the above? Do you agree that generally speaking post-authorisation efficacy studies should focus on generating efficacy data?

See comments provided by HAS

IQWIG amendment to the HAS response:
We agree with HAS about the recommendation to shorten this chapter
Internationally there is still considerable diversity in guidelines for national health care decision-making affecting the study types included. Therefore, this chapter should just provide a common understanding for further discussion using “efficacy” and “effectiveness”.

Consultation item No 3: Please comment on the seven different situations described above. Do you agree that in these situations, a competent authority may ask for a postauthorisation efficacy study? Are there any other situations not covered by points 5.1 to 5.7 in which it would also be justified to oblige a marketing authorisation holder to conduct an efficacy study? If this is the case, could you please elaborate on these situations and, if possible, give specific examples to underpin the need?

See comments provided by HAS

IQWIG amendment to the HAS response:
5.4. Studies in the context of the European standard of care
=> There is no commonly agreed European standard of care. This might lead to national concerns about autonomy and generalizability which antagonizes the intention of this act.

Consultation item No 4: Do you have any comments on the above?

See comments provided by HAS

Consultation item No 5: Please feel free to raise any other issues or make any comments which have not been addressed in the consultation items above.

See comments provided by HAS

EUnetHTA Secretariat, Copenhagen, February 18th, 2013