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

IQWiG gratefully acknowledges the public consultation regarding the DELEGATED ACT ON POST-AUTHORISATION EFFICACY STUDIES, in the following abbreviated by PAES.

In general, we agree with the statements of EUnetHTA and HAS.

From the perspective of IQWiG, we would like to add the following amendments, provided here along the respective subchapters.

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..

[Amendment 1]
4. EFFICACY VERSUS EFFECTIVENESS

=> 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”.

[Amendment 2]
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.