primary endpoints. The latter implies only in 67 percent of the assessments a primary endpoint to be relevant for the benefit-harm-balancing. Moreover, explorative mortality endpoints reached the highest agreement and explorative endpoints capturing health-related quality of life no agreement, referring to the mutual relevance of endpoints for the risk-benefit-ratio and the benefit-harm-balancing.

CONCLUSIONS:

The missing information transparency of the assessment reports compared to the information offered within the early benefit assessment makes an assignment of endpoints with respect to the mutually relevant clinical trial sometimes troublesome. To warrant, in the long run, a broader confirmatory basis for decisions in health care supported by HTA, a closer inter-institutional cooperation of approval authorities and German HTA jurisdictions seems favorable.

OP136 Clinical Benefit Of Oncological Therapies At The Time Of Approval

AUTHORS:

Nicole Grössmann (Nicole.Groessmann@hta.lbg.ac.at), Claudia Wild

INTRODUCTION:

In the last decade an increasing number of high-priced, new cancer treatments received marketing authorization in Europe. What is actually known about the clinical benefit of those therapies at the time of approval needs to be elucidated in order to inform decisions about the use and reimbursement of these novel treatment options. Thus, the aim of the current analysis was to systematically investigate oncological therapies approved between January 2009 and April 2016. We extracted, as well as quantified the level of knowledge of the clinical benefit at the time of marketing authorization.

METHODS:

To assess the benefit of new interventions as well as expanded indications, we extracted the median gain of the two study endpoints: progression-free survival (PFS) and overall survival (OS). Information is based on approval documents provided by the European Medicines Agency (EMA) and assessments from the Austrian Horizon Scanning programme (HSO). We included all cancer therapies approved in Europe between 1 January 2009 and 15 April 2016.

RESULTS:

Cancer drugs for 134 new indications approved since 2009 were identified. In the case of thirty-seven indications (27 percent), no data was available for PFS or for OS. A positive difference in median overall survival was reached by seventy-six licensed indications (55.5 percent); twenty-two (16 percent) of them showed a difference of more than three months. Regarding the study endpoint progression-free survival, an improvement was shown in ninety indications (65.2 percent).

CONCLUSIONS:

Scarce knowledge regarding the clinical benefit of anti-cancer therapies is available at the time of approval. In addition, the survival benefit of the approved indications is less than three months in the majority of approved therapies.

OP138 Access To Orphan Drugs In The United Kingdom And Other European Countries

AUTHORS:

Bernarda Zamora (bzamora@ohe.org), Martina Garau, François Maignen, Phill O'Neill, Jorge Mestre-Ferrandiz

INTRODUCTION:

Under the Orphan Regulation, the European Medicines Agency (EMA) intended to incentivize the research and development of new treatments for rare and

https://doi.org/10.1017/S0266462317001957 Published online by Cambridge University Press