of sixteen countries from the region according to different criteria: characteristics, quality, using Drummond’s checklist), use of local data, addressed inputs limita-

...er's demand for economic evaluations originating from CEE and former Soviet countries. The HTA model was based on a “score-card” system with 6 criteria. HAS (France) opinion, NIC/SMC/AVMG (UK) opinion, the number of EU countries with reimbursement, relative efficacy, relative safety and relative patient-reported-outcomes (PRO), but no role of impact. From October 2013, the HTA projects funded by the HTA Unit with an acceptance rate of about 80%. Most of the drugs accepted for reimbursement were oncological (23%), other main therapeutic areas were diabetes (16) and osteoporosis (11). The HTA process was moved into the responsibility of the National Agency for Drugs. CONCLUSIONS: The implementation of the quick-HTA in Romania took a good start, using a mixture of information, from benefits and cost-effectiveness in other countries, to relative effectiveness and safety. However, the lack of consideration for the local context and the political disagreements led to a temporary suspension of this quick-HTA process in Romania.

Anastasaki E., Lohrbarg D., Augustin M., Blome C., Lassale C.

University Medical Center Hamburg-Eppendorf, Hamburg, Germany

OBJECTIVES: Since January 2011, pharmaceutical manufacturers are obliged to submit benefit-risk assessment reports for every drug reimbursement application in Germany. The dossier is usually evaluated by the Institute for Quality and Efficiency in Health Care (IQWiG). Using the recently established German Certification Committee (G-BA) decides on additional therapeutic benefit related to mortality, morbidity, quality of life (QoL) and side effects. As QoL is among the most contested of these criteria and remains comparably unspecified, this qualitative study’s aim was to analyze definitions and the role of QoL in early assessments of benefit (EAB) in Germany.

METHODS: As most of the documents are freely available on the G-BA’s website, this study included all relevant documents of the first completed 66 assessments (11.2011-12.2013). We conducted a qualitative content analysis screening the dossiers, IQWiG evaluations, G-BA decisions and the protocols of the oral hearing for relevant links to QoL and synonyms. In a process of independent analysis and joint consensus building by two researchers, relevant text passages were extracted and reduced to key content on the term’s usage. During analysis, a system of codes was developed accounting for a wide variety of recurring QoL-related definitions and references to its importance. RESULTS: Even though key players did not necessarily share the same QoL definition, the concept’s relative importance was highlighted in numerous references. G-BA decisions criticized the lack of or the inadequate presen-

...tions, making it difficult to assess the impact of QoL on HTA decisions. CONCLUSIONS: QoL in a particular sense is of pivotal importance in Germany’s early assessment of benefit.

The demand for reliable QoL data is growing.

Anastasaki E., Walker A.*, Bradshaw S.*

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