their relative importance weights (%) were: robustness of clinical evidence (31%); robustness of cost estimates (25%); availability of alternative treatments (8%); incremental efficacy (8%); relative safety (7%); ease of adoption (7%); incremental impact on QOL (5%); budget impact (4%); unmet need (3%); size of population (1%). The attribute levels and relative value for a positive reimbursement recommendation (0–1) for the most important attribute, robustness of clinical evidence, were: ‘endpoint’ (0.5); ‘clinical endpoints’ not relevant to the proposed indication; ‘clinical endpoints, indirect comparisons needed’ (0.25); ‘all clinical endpoints and comparators relevant for NHS’ (1). The estimates of the probability of a favorable reimbursement recommendation for the hypothetical products included in the post-workshop questionnaire analyzing the logistic regression model for the most important attribute, attribute levels, and value scales of different product attributes that influence a positive reimbursement decision in the UK.

**PHP19**

**VALUE AND THE MULTIPLE CRITERIA USED IN OECD COUNTRIES’ MEDICINE REIMBURSEMENT DECISION-MAKING PROCESSES USING HEALTH ECONOMIC EVIDENCE**

Bending MW, Smith TA

**OBJECTIVES:** The meaning of ‘value’ and the criteria for judging it are increasingly being debated in countries with established reimbursement processes using Health Technology Assessment (HTA). The objective of this study is to determine the criteria used in decision-making to determine value in OECD countries’ decision-making processes using health economic analysis (HEA).

**METHODS:** A review of reimbursement agencies’ websites, relevant literature and contact with individual agencies identified the criteria used to determine value for medicines in processes using HEA. Countries are categorised by how HEA is used in decision-making processes, nature of the cost-effectiveness threshold range (explicit, implicit, no threshold), threshold range where identified and the use of such evidence alongside other decision-making criteria (burden of disease, severity, innovation and others). Details of the judgments reported with respect to the criteria in documents justifying the decision are examined.

**RESULTS:** Twenty-four OECD countries use formal HTA of which 17 require HEA in submissions for certain medicines. Cost-effectiveness thresholds are identified in nine countries, explicitly stated in three. Implicit threshold ranges are identified in four (based on past decisions), whilst in two implicit willingness-to-pay thresholds are used for decision-making. Use of HRQoL as a criterion is compared by other criteria (severity, need, burden of disease, end of life, innovation, amongst others). Some countries use cost-effectiveness thresholds central to their decision-making, some report them equally amongst other criteria, whilst in others it is unclear how such criteria is judged. Details relating to the judgement of criteria used in appraisals are sparse.

**CONCLUSIONS:** Multiple criteria are common in countries using HEA, although some are country specific. Reporting of these criteria and their respective use and interpretation alongside the cost-effectiveness threshold range suggests variation in the meaning of value. Multi-criteria decision analysis could provide clarity in the justification of the reimbursement decision and the meaning of value.

**PHP120**

**NEW PRICING DYNAMICS IN BIG FIVE EU: CASE STUDY OF BIOSIMILAR GM-CSF PRODUCTS**

Aggarwal S

**OBJECTIVES:** During 2011-2012 significant price cuts were implemented in various markets in the European Union. These price cuts have introduced new pricing dynamics affecting reference pricing and intra-EU parallel export of expensive drugs.

**METHODS:** To understand new pricing dynamics in the big five EU (UK, France, Germany, Italy and Spain) we analyzed the trend in pricing for branded and biosimilar GM-CSF products. Prices were analyzed for percentage discount compared to branded GM-CSF product and relative price levels in five selected markets.

**RESULTS:** Recent reimbursement policy changes, and price cuts were also analyzed.

**CONCLUSIONS:** The different pricing dynamics affecting reference pricing and intra-EU parallel export of expensive drugs.

**PHP122**

**THE USE OF QUANTITATIVE AND QUALITATIVE CRITERIA FOR MAKING DRUG FUNDING DECISIONS**

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**OBJECTIVES:** Every day health care decision makers on the national, regional and local level face the challenge of making complex funding decisions. The complexity in drug funding decisions comes from balancing quantitative criteria such as clinical efficacy together with personal experience of decision makers.

**METHODS:** Relevance of decision-making criteria was investigated using the logistic regression model for the most important attribute, attribute levels, and value scales of different product attributes that influence a positive reimbursement decision in the UK.

**RESULTS:** Twenty-six have gone through re-assessment process, corresponding to 24 SMRs/indication, out of which only 21 were analyzable: 10 SMRs have been modified (only 2 increased and the rest lowered) and 11 unchanged. In 8 of these cases, the manufacturer was asked for the re-assessment. 6 full therapeutic classes have been reviewed in 2011, including Alzheimer’s and antipsychotics, resulting in a harmonization and a decrease of the SMR levels.

**CONCLUSIONS:** Manufacturers should now ensure that reassessment and relisting doses in France incorporate as much of relevant clinical, safety and real-life information as possible in order to maintain the reimbursement level.

**PHP123**

**IMPORTANCE OF HEALTH-RELATED QUALITY OF LIFE AS AN ENDPOINT IN BENEFIT ASSESSMENT ACCORDING TO THE GERMAN AMNOG**

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**OBJECTIVES:** Health-related quality of life (HRQoL) might be one important objective reported endpoint (PRO) in determining the additional benefit of pharmaceuticals recently evaluated according to the newly established German law for reforming the market for pharmaceuticals (AMNOG). A comparative analysis is performed to gain insight how HRQoL was implemented in the benefit dossier by the pharmaceutical manufacturer on the one hand and how it was assessed in the benefit assessment by the Institute for Quality and Efficiency in Health Care (IQWiG) on the other hand.

**METHODS:** We reviewed 23 published benefit dossiers and the corresponding benefit assessments, which the IQWiG performed since the implementation of the AMNOG in 2011. Corresponding statements concerning HRQoL in benefit dossiers and benefit assessment were faced narrative.

**RESULTS:** Eighteen benefit dossiers (78%) ‒ including 19 IQWiG (including 311 cases were analyzable: 14 SMRs while 17 SMRs remained unchanged. Almost 50% (6/13) of SMR initially rated as “important” were changed to “insufficient” (7%), 35% to “moderate” (35%) and 5% to “fair” (5%). HAS and manufacturer have the right to ask for re-assessment anytime after the initial reimbursement listing; in all cases, a relisting process is compulsory every 5 years. We analyzed HAS advice and relisting actions for the hypothesis that the “Mediator safety” “affair” would have impacted the process.

**CONCLUSIONS:** We considered all complete procedures for relisting, re-assessments and class reviews and focused on drugs for which a HAS advice was published between Jan and Dec 2011. We compared previous and recent recommendations and their impact. Twenty-six drugs have gone the relisting process, corresponding to 33 different indications, out of which 31 were analyzable. HAS modified 14 SMRs while 17 SMRs remained unchanged. Almost 50% (6/13) of SMR initially rated as “important” were changed to “insufficient” (7%), 35% to “moderate” (35%) and 5% to “fair” (5%). 19 drugs have gone through re-assessment process, corresponding to 24 SMRs/indication, out of which only 21 were analyzable: 10 SMRs have been modified (only 2 increased and the rest lowered) and 11 unchanged. In 8 of these cases, the manufacturer was asked for the re-assessment. 6 full therapeutic classes have been reviewed in 2011, including Alzheimer’s and antipsychotics, resulting in a harmonization and a decrease of the SMR levels.

**CONCLUSIONS:** Manufacturers should now ensure that reassessment and relisting doses in France incorporate as much of relevant clinical, safety and real-life information as possible in order to maintain the reimbursement level.