exploratory analyses conducted and reported by an ERG is mentioned in 97% of ACBs and 84% of FADs, and had a clear influence on recommendations in 72% of ACBs and 47% of FADs. **CONCLUSIONS:** These results suggest that the additional analyses undertaken by independent Evidence Review Groups (ERGs) in the appraisal of company submissions to the NICE STA process are highly influential in the policy and decision-making process.

**PHP168**

**EALIZED MARKET ACCESS FOR PHARMACEUTICALS IN EU: WHAT IS THE IMPACT OF EMA’S ACCELERATED ACCUMULATION?**

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**OBJECTIVES:** In 2005, the accelerated assessment procedure (AAP) for medicines of major public health interest was introduced reducing timelines from 210 to 150 days and 100-120 days in Switzerland and the Netherlands. The objective is to determine market access (MA) status of products accepted for AAP in selected countries: France, Germany and United Kingdom (UK). **METHODS:** All products accepted for AAP in 2015 were extracted from the European Medicines Agency (EMA) website. Related HTAs were identified via websites of key HTA agencies in France and Germany. Positive recommendations were granted without any restriction in UK, while in Germany, G-BA recognised additional benefit in some specific subgroups. This analysis included 98 G-BA and 153 IQWiG evaluations for 88 different drugs across 41 disease conditions. 1,312 clinical outcomes were evaluated to determine the rates of outcome rejection. Rejection was defined as instances where the manufacturer submitted information and G-BA or IQWiG concluded that the data was not usable, instances of no data or incoherent data were excluded. **RESULTS:** 15% of outcomes were rejected. IQWiG outcomes were more likely to be rejected than Morbidity and Mortality outcomes (16% vs 12%; p<0.003). G-BA rejected more outcomes than Morbidity and Mortality outcomes (24% vs 18%; p<0.036). Intramurally, from EMA approval to reimbursement decision varied between HTA bodies, has providing the quickest and NICE the slowest route to MA (TC: 76-187, SMC: 113, G-BA: 182 and NICE: 314 days). In France, quick route to MA was slower than ACB at national assessment level. Such criteria includes some aspect of manufacturing that takes place locally, EMA listing of other therapeutics within the same class, date of approval, and the number of indications. Pharmacoeconomic analysis has not been considered consistently throughout the committee decisions, however, the key question is whether high value is determined by evidence variation across regional tenders, which sometimes rise to 20%, were not into consideration. **CONCLUSIONS:** To gain EDL-listing, an effort to ration the budget should include a request for delist older, less effective therapies, as well as provide a comprehensive overview of the difference between the therapist's nominal and real budget impact.

**PHP171**

**THE ROAD TO RUSSIAN PHARMACOECONOMICS: UNDERSTANDING THE DRIVERS FOR ACCESS TO HIGH-VALUE OR ORPHAN DISEASE DRUGS**

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**OBJECTIVES:** Access to medicines in Russia has traditionally been highly correlated with the national Essential Drug List (NBDL) inclusion. Although an explicit methodology of assessing the new drug dossier exists, significant variation in the current spectrum of decision drivers for pharmaceutical product assessment in Russia and the influence of pharmacoeconomics and regional price variability on this process. **METHODS:** The video-protocol of the decisions for drug inclusion in the Russian EDL in 2014 and 2015 were analysed (163 drugs) to identify the key drivers for Ministry of Health reimbursement and the role of pharmacoeconomics within it. Two categories of drugs were identified to test the research hypotheses: 1) drugs successfully securing a place on the EDL-2015 following an initial rejection for EDL-2014 (25 drugs), and 2) drugs unsuccessful in securing a place for both EDL-2014 and EDL-2015 (32 drugs). The Russian tender database system (taken EMA example) was used to analyze the regional price and reimbursement variations. **RESULTS:** Analysis of key decision-making drivers yielded the growing importance of secondary decision drivers in the face of currently stringent drug budget constraints at local levels. Such criteria includes some aspect of manufacturing that takes place locally, EMA listing of other therapeutics within the same class, date of approval, and the number of indications. Pharmacoeconomic analysis has not been considered consistently throughout the committee decisions, however, the key question is whether high value is determined by evidence variation across regional tenders, which sometimes rise to 20%, were not into consideration. **CONCLUSIONS:** To gain EDL-listing, an effort to ration the budget should include a request for delist older, less effective therapies, as well as provide a comprehensive overview of the difference between the therapist's nominal and real budget impact.
interventions under consideration were elicited for three case studies. A mathemati-
cal model was used to estimate weightings, global preference scores were calculated and the results were discussed with the committee members in a panel meeting. RESULTS: The number of relevant criteria varied between nine and 14 (out of 26) between respondents (n=5), with a median number of criteria of 12. The criteria were generally distributed over the three domains of effectiveness (81%), cost-effectiveness (16%) and strength of evidence (5%) were judged as most important. In the case of Pompe Disease, the disease burden (93 out of 100) and the effect size of alglucosidase alfa (91/100) were the highest, while the strength of evidence was perceived to be (55/100) and cost-effectiveness is low (28/100). There was large variation between members in importance and performance scores. The overall value (i.e. need to reimburse) of alglucosidase alfa for Pompe Disease is judged as 76 (out of 100), 39 for the smoking cessation program and 27 for the contraceptive pill. CONCLUSIONS: Theoretically and practically, differences in value judgements between and within committee members influence the consistency and validity of recommendations across innovations. At the same time, differences in judgments are viewed as a key strength of appraisal committees. The unique and complex context in which innovations are judged in appraisal committees complicates the use of the mathematical approach to MCDA. However, the explicit deliberation of the importance of criteria, supported by facts can bring structure to the decision process.

PHP174 VARIATIONS IN STAKEHOLDER PREFERENCES BETWEEN INNOVATIVE PRICING AGREEMENT TYPES ACROSS THE EU

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OBJECTIVES: Global medicines expenditure is forecast to hit $1.4 trillion annually by 2025 (primary sources, US and UK IMS Institute), an increase of approximately 30% from current levels. To manage global medicine spend, it is likely that payers and pharmaceutical companies will need to expand innovative contracting, with increased reliance on mechanisms that share risk and ensure predictable patient costs. Payer preferences and perceptions of implementation hurdles across types of innovative agreements are currently not well understood, leading to potential disconnect between pharmaceutical manufacturers and payers which may ultimately reduce timely patient access to medicines. METHODS: To understand stakeholder preferences in EU markets, a two-stage research approach was used. In a pilot focus group (n=5), payer stakeholders from each market were asked to estimate national patient preference ranks for innovative agreements, defined as performance-based (individual patient response), evidence development (e.g., patient registries), or financial-based risk-sharing (such as patient co-payment). This pilot study used an EUS online discrete-choice survey (target responses) to generate utility scores across product / agreement scenarios. RESULTS: Average preference rank (1 = not preferred, 5 = most preferred) for financial-based risk-sharing was 3.5, followed by performance-based (2.6) and evidence development (1.8). Evidence development was ranked highest in France but lowest in all other markets. Only the UK ranked performance-based schemes as the most-preferred option (4/5). Mandatory in-market negotiations (such as in Germany) were seen as a barrier to innovative contracting, through achieving a lowest acceptable price as a condition of reimbursement. CONCLUSIONS: In order to manage public medicine expenditure, innovative contracting may represent a better alternative to simple discounts or rebates, but uptake requires acceptance from stakeholders. Pilot results indicate that payer preferences vary across the EU, and that existing pricing access policies may act as a disincentive to innovation. Funded by Mundipharma International Limited

HEALTH CARE USE & POLICY STUDIES – Health Care Research & Education

PHP175 SIMULATING PATIENT-LEVEL PROFILES TO CAPTURE PATIENT HETEROGENEITY IN HEALTH-ECONOMIC APPLICATIONS

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METHODS: Clinical imperatives and clinical outcome assessments have become an integral part of a successful reimbursement submission. Health technology assessment (HTA) agencies include patient views in their appraisals to various extents. We simulated the inclusion of patient-level evidence in a traditional HTA submission to understand the extent to which HTA assessors would accept this evidence. This was achieved through development of a log-normal model, with predicted life expectancy at 2.23 years. Using patient characteristics and insights in stakeholder preferences in EU markets, a two-stage research approach was used. RESULTS: A total of 136 dosed variables were judged in the study. Payer preferences and perceptions of implementation hurdles across types of innovative agreements are currently not well understood, leading to potential disconnect between pharmaceutical manufacturers and payers which may ultimately reduce timely patient access to medicines. METHODS: To understand stakeholder preferences in EU markets, a two-stage research approach was used. In a pilot focus group (n=5), payer stakeholders from each market were asked to estimate national patient preference ranks for innovative agreements, defined as performance-based (individual patient response), evidence development (e.g., patient registries), or financial-based risk-sharing (such as patient co-payment). This pilot study used an EUS online discrete-choice survey (target responses) to generate utility scores across product / agreement scenarios. RESULTS: Average preference rank (1 = not preferred, 5 = most preferred) for financial-based risk-sharing was 3.5, followed by performance-based (2.6) and evidence development (1.8). Evidence development was ranked highest in France but lowest in all other markets. Only the UK ranked performance-based schemes as the most-preferred option (4/5). Mandatory in-market negotiations (such as in Germany) were seen as a barrier to innovative contracting, through achieving a lowest acceptable price as a condition of reimbursement. CONCLUSIONS: In order to manage public medicine expenditure, innovative contracting may represent a better alternative to simple discounts or rebates, but uptake requires acceptance from stakeholders. Pilot results indicate that payer preferences vary across the EU, and that existing pricing access policies may act as a disincentive to innovation. Funded by Mundipharma International Limited

HPV176 QUANTIFICATION OF PATIENT PREFERENCE ASSESSMENT: THE FEDERAL COMMITTEE LENS TO PHRASE EVIDENCE

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OBJECTIVES: The increased focus on value driven by patient centric strategies and innovative representations and clinical outcome assessments have become an integral part of a successful reimbursement submission. Health technology assessment (HTA) agencies include patient views in their appraisals to various extents. We simulated the inclusion of patient-level evidence in a traditional HTA submission to understand the extent to which HTA assessors would accept this evidence. This was achieved through development of a log-normal model, with predicted life expectancy at 2.23 years. Using patient characteristics and insights in stakeholder preferences in EU markets, a two-stage research approach was used. RESULTS: A total of 136 dosed variables were judged in the study. Payer preferences and perceptions of implementation hurdles across types of innovative agreements are currently not well understood, leading to potential disconnect between pharmaceutical manufacturers and payers which may ultimately reduce timely patient access to medicines. METHODS: To understand stakeholder preferences in EU markets, a two-stage research approach was used. In a pilot focus group (n=5), payer stakeholders from each market were asked to estimate national patient preference ranks for innovative agreements, defined as performance-based (individual patient response), evidence development (e.g., patient registries), or financial-based risk-sharing (such as patient co-payment). This pilot study used an EUS online discrete-choice survey (target responses) to generate utility scores across product / agreement scenarios. RESULTS: Average preference rank (1 = not preferred, 5 = most preferred) for financial-based risk-sharing was 3.5, followed by performance-based (2.6) and evidence development (1.8). Evidence development was ranked highest in France but lowest in all other markets. Only the UK ranked performance-based schemes as the most-preferred option (4/5). Mandatory in-market negotiations (such as in Germany) were seen as a barrier to innovative contracting, through achieving a lowest acceptable price as a condition of reimbursement. CONCLUSIONS: In order to manage public medicine expenditure, innovative contracting may represent a better alternative to simple discounts or rebates, but uptake requires acceptance from stakeholders. Pilot results indicate that payer preferences vary across the EU, and that existing pricing access policies may act as a disincentive to innovation. Funded by Mundipharma International Limited

HPV177 PSYCHOMETRIC TESTING OF THE FINNISH VERSION OF THE PROSTHESIS EVALUATION QUESTIONNAIRE

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OBJECTIVES: To translate and cross-culturally adapt the Prosthesis Evaluation Questionnaire into the Finnish language. RESULTS: The WEQ was translated and cross-culturally adapted into the Finnish version. The psychometric properties on adult lower-extremity prosthetic users. METHODS: The WEQ was adapted into Finnish adhering the ISPOR translation guidelines. Study participants completed the adapted Finnish WEQ, panic reported overview, psychometric analysis and insights were drawn from the trends. Also, a thorough literature search was conducted to understand the quantitative techniques proposed/used by HTA bodies to determine patient preference analysis. CONCLUSIONS: In the wake of availability of robust statistical techniques, there is a limited evidence regarding use of patient preference analysis in AMNOG submissions. Hence, there is an urgent need of discerning patient preferences and incorporating them in payer utility scores. The test of new patients were rehabilitated to prosthesis use and had completed all questionnaires. Psychometric testing of the Finnish version of the Prosthesis Evaluation Questionnaire. Validity assessment included criterion validity testing and linear regression analysis in the predictors of the 15 AD and gender standardised regression coefficients β. RESULTS: Minor linguistic changes were made for Finnish cultural adaptation. The mean (SD) FEQ score was 65 (2.37). Cronbach’s alpha was ranged from 0.67 to 0.76 for the scales. The total score showed no floor or ceiling values. Reproducibility of the 10 separate scales ranged from 0.78 to 0.87. Seven of the 10 scales had statistically significant correlations with general pain and six scales with general health. Convergent and discriminant validity assessments. CONCLUSIONS: The Finnish version of the WEQ was successfully adapted for Finnish prosthetic users. Psychometric testing of the Finnish version of the WEQ showed internal consistency and test-retest reliability. The WEQ is valid in assessing the HROQ. In Finnish adult major lower-extremity amputees who have rehabilitated to become lower-extremity prosthetic users.

PHP178 EPIDEMIOLOGICAL CHARACTERISTICS OF HOSPITALIZATIONS DUE TO ADVERSE DRUG REACTIONS (ADRs) RELATED TO ORAL ANTICOAGULANTS IN SPAIN: 2010-2013

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OBJECTIVES: Adverse drug reactions (ADRs) are a major public health problem and are associated with substantial costs as well as a potential impact on patient quality of life. The objective of this study was to describe the epidemiological characteristics of hospitalizations due to ADRs to oral anticoagulants and to provide an overview of the main anticoagulants and their most common adverse effects. The study was based on a retrospective observational study on hospital discharges in patients diagnosed with ADRs to oral anticoagulants. METHODS: We performed a retrospective observational study on hospital discharges in patients diagnosed with ADRs to oral anticoagulants.