the reliability of the anchor and the estimated MID. METHODS: We performed a simulation study in which the reliability of the anchor used for MID estimation was varied systematically. Features of real-life data (e.g., skewed distribution, discreteness of PRO score) and anchors were used to generate simulated PRO scores and anchors. MID was then estimated on the basis of the simulated data. RESULTS: Compared to the MID value obtained with an anchor with perfect reliability (\( \rho = 1 \)), a marked attenuation of the MID was observed when reducing the reliability of the anchor. Thus, an anchor with reliability 0.7 gave rise to a 24% to 35% decrease of the MID estimate and an anchor with reliability 0.5 led to a 45% to 55% reduction. Based on the findings and on theoretical considerations, we suggest a method for bias correction. CONCLUSIONS: When determining the MID of a PRO scale by an anchor-based method, the reliability of the anchor plays a crucial role. Anchors with poor to moderate reliability may lead to considerable underestimation of the MID. Bias correction is possible provided the reliability of the anchor is known.

**PODIUM SESSION III: PRICING AND MARKET ACCESS**

**PR1**

**THE APPLICATION OF PHARMACOECONOMIC MODELING TO ESTIMATE A VALUE-BASED PRICE FOR NEW CANCER DRUGS IN A PUBLICLY FUNDED HEALTH-CARE SYSTEM**

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**OBJECTIVES:** Value-based pricing has recently been discussed by international organizations as a means to estimate a drug price that is linked to the benefits it offers patients and society. However, one of the challenges would be to identify an appropriate threshold that would provide the reliability of the anchor is known.

**RESULTS:** The use of the WHO criteria for estimating a value-based price is feasible. However, the costs for chemotherapy were obtained from Canadian cancer centers. Utility estimates measured as quality-adjusted life-years (QALYs) were determined by interview with 24 oncology nurses and pharmacists using the Time Trade-Off technique. The monthly price of the new drug was then modeled using a threshold of $117,000 per QALY gained, which is three times the Canadian per capita GDP as recommended by the WHO. RESULTS: The analysis suggested that a monthly price of $2180 would be cost-effective from the Canadian public health perspective. If the drug were able to improve patient quality of life or survival from 3 to 6 months, the monthly price could increase to $4100 and $3430 and offer the same value. CONCLUSIONS: The use of the WHO criteria for estimating a value-based price is feasible. However, one of the challenges would be to identify an appropriate threshold that would provide the reliability of the anchor is known.

**PR2**

**DECIDING ON VALUE FOR MONEY: A COMPARISON OF THE DUTCH, BELGIAN, SWEDISH, AND FRENCH DRUG REIMBURSEMENT SYSTEMS**

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**OBJECTIVES:** Many countries are adapting their pharmaceutical reimbursement system, increasingly emphasizing the role of pharmacoeconomics in decision-making. The aim of our study is to analyze European pharmaceutical systems to obtain insight into best practice systems that deliver value for money. METHODS: The analytical Hutton Framework was used for comparing and assessing “fourth hurdle” drug reimbursement systems in the The Netherlands, Belgium, Sweden, and France. We investigated policy documents, explored literature, and conducted interviews with policymakers and representatives of the pharmaceutical industry. RESULTS: All systems have a centralized decision body, even though the financial responsibility may be regional (Sweden). Only in Sweden, the minister has no role at the individual reimbursement level. In the Netherlands and Sweden, enlisted drugs are fully reimbursed. All countries attempt to increase transparency. However, in Sweden manufacturers may withdraw their application before the final reimbursement decision, guaranteeing confidentiality at the expense of less transparency. Policies to deal with uncertainty vary per country: financial risk-sharing agreements by price/volume contracts—France—versus outcomes-based agreements for expensive inpatient drugs—the The Netherlands. The actual value of a drug and disease severity is reflected in the level of reimbursement in France and Belgium, whereas in the Netherlands and Sweden, enlisted drugs are fully reimbursed. All countries attempt to increase the importance of pharmacoeconomics in decision-making. However, no country expresses the relative importance of cost-effectiveness compared to other criteria nor applies a strictly defined threshold. CONCLUSIONS: This study reveals that while there is a convergence in scientific evaluation processes, important differences remain between the Dutch, Belgian, Swedish, and French regulatory frameworks. All countries recognize that pharmacoeconomics plays a major role in decision-making on value for money, but for the time being, pharmacoeconomics seems to play a rather undefined role.

**PR3**

**THE IMPACT OF FINNISH PHARMACEUTICAL PRICING SCHEME IN COST-EFFECTIVENESS ANALYSES**

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**OBJECTIVES:** Finnish retail prices for drugs are determined with a pricing scheme (PS). The PS is of the form “multiplier × wholesale price × fixed sum.” The multiplier ranges from 1.125 to 1.5 (being smaller for higher wholesale prices). The fixed sum ranges from 0.5 to 47.68 euros (being larger for higher wholesale prices). Although PS is regressive, it nevertheless provides higher absolute pharmacy margins for drugs with higher wholesale prices. At the lower end of wholesale prices, PS results in retail prices that do not cover dispensing costs. Despite this, the retail prices (excluding VAT 8%) are used to represent all drug and drug delivery costs in economic evaluations. This study assesses the impact of this Finnish system-derived “distortion” in cost-effectiveness analyses. METHODS: The cost utilities of new hypothetical treatments were assessed in a setting where the new and old treatments produce different amounts of quality-adjusted life-years (QALYs) and the only cost difference comes from the pharmaceutical prices. The treatments are assumed not to differ regarding the real costs of drug delivery and patient survival. The PS-induced computational cost difference was deducted from the all price differences of new and old treatments to estimate the impact of PS on the incremental cost-effectiveness ratio (ICER). RESULTS: The computational cost differences due to PS ranged from 7.3 to 1951 euros and the QALYS gained ranged from 0.004 to 0.070 in estimated scenarios. The respective ICERs increased by 104 to 487,840 euros/QALY due to the PS. CONCLUSIONS: The PS significantly worsens the ICERs obtained for more expensive and often innovative pharmaceuticals. The Finnish PS is problematic when the aim is to provide optimal, cost-effective treatments to Finnish patients. In the current form, the PS discourages innovation and may prevent reimbursement of otherwise cost-effective treatments.

**PR4**

**GLOBAL MARKET ACCESS STRATEGY: AN INTEGRATED APPROACH**

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**OBJECTIVES:** To develop a framework for integrating pricing and reimbursement with health economics and outcomes research and health policy to achieve commercially desirable prices and levels of access in 2010 and beyond. METHODS: A review of recent pricing policy and regulatory changes of countries, especially those in the financially troubled Eurozone, was conducted. This was supplemented by a review of P&R decisions for a selection of drug launches between 2005 and 2009 and categorized according to the level of therapeutic innovation and disease type (conventional, rare diseases, oncology); a search was performed on the OHE and NHS EED databases and HTA reports to establish the level of published value evidence in support of these launches, and finally, the components of most importance to a market access strategy were identified and validated through interviews across different stakeholders. RESULTS: The review identified since January 2010, there have been 11 pricing policy and regulatory changes. From the review of recent P&R decisions and stakeholder interviews, the main components identified were: competitive and environmental analysis (market assessment, reimbursement, revenue forecasts, policy trends); analysis of payer’s decision drivers (payer, physician, and other stakeholder qualitative analysis (market assessment, reimbursement, revenue forecasts, policy trends); analysis of payer’s decision drivers (payer, physician, and other stakeholder qualitative analysis (market assessment, reimbursement, revenue forecasts, policy trends); analysis of payer’s decision drivers (payer, physician, and other stakeholder qualitative analysis (market assessment, reimbursement, revenue forecasts, policy trends); analysis of payer’s decision drivers (payer, physician, and other stakeholder qualitative analysis (market assessment, reimbursement, revenue forecasts, policy trends); analysis of payer’s decision drivers (payer, physician, and other stakeholder qualitative analysis (market assessment, reimbursement, revenue forecasts, policy trends); analysis of payer’s decision drivers (payer, physician, and other stakeholder qualitative analysis (market assessment, reimbursement, revenue forecasts, policy trends). The review of the P&R decisions also demonstrated an increasing trend toward deployment of risk-sharing schemes since 2008. CONCLUSIONS: Development of a successful market access strategy requires an understanding of pricing, health economics and outcomes research, health technology assessment (HTA), and health policy, and continually keeping vigilant and adapting to rapid changes in the policy environment. This research gives direction to health economics, P&R, and government affairs professionals for the development of an integrated framework for the design and implementation of a global market access strategy.