**PHP113**

**THE IMPORTANCE OF ECONOMIC EVALUATIONS IN THE ASSESSMENT OF REIMBURSEMENT APPLICATIONS**

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**OBJECTIVES:** To further the Swedish Health and Medical Care Assessment Authority Law, any decisions for reimbursability in health care should be based on three principles: the principle of human dignity, the principle of need and solidarity, and the principle of cost-effectiveness. The principle of human dignity is superior to the other two principles and the cost-effectiveness principle is subordinate to the other two. The Swedish Dental and Pharmaceutical Benefits Agency (TUV) must prioritize accordingly when assessing whether a pharmaceutical should belong to the reimbursement system. This study aims to investigate the importance of economic evaluations in decisions for admission of pharmaceuticals to the reimbursement scheme. **METHODS:** A review of the TUV decisions regarding admission of the reimbursability system dated January 2011 to March 2012 was conducted. The information extracted included e.g. decision outcome, type of economic evaluation employed and considered medical need. Subsequently, the reasons behind the decisions were analysed.

**RESULTS:** A total of 100 individual decisions for reimbursement were assessed. The vast majority of the 69 decisions leading to general reimbursement were made based on the result of an economic evaluation and a great medical need was the second most important reason. All of the eight negative decisions referred to the inability of the product to be considered a cost-effective alternative. The main reasons behind the 23 decisions for restricted reimbursement were a great medical need and that the product was cost-effective alternative for a specific subgroup. Hence, it appears that the principle for cost-effectiveness is considered more important than the principle of human dignity as medical need was the second most common consideration behind restricted reimbursement. **CONCLUSIONS:** The principle for cost-effectiveness appears to be the most important principle in decisions around a pharmaceutical’s admission to the reimbursement system, although the principal’s subordinate position to the principle of human dignity and the principle of need and solidarity.

**PHP114**

**REVIEW OF COST EFFECTIVENESS STUDIES OF HIGH BUDGET IMPACT DRUGS**

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**OBJECTIVES:** The recently made coverage decisions by UK’s NICE, Scotland’s SMC and the allocation of $1.1 billion for comparative effectiveness research by the United States, are strong indicators of trends in pricing and reimbursement that are likely to be observed in the future. To gain an additional insight into these trends, we analyzed the cost effectiveness studies for the top twenty highest selling drugs (~$90-100B worldwide sales) **METHODS:** The Top 20 drugs were selected based on their worldwide sales. For this analysis, we segmented these drugs into categories such as primary care, specialty, small molecules, biologics, therapy areas and availability of generic alternatives. We analyzed the cost effectiveness studies that were published in peer-reviewed journals. Search was conducted using generic names of the drugs and the phrase “cost effectiveness” in abstract of the published study. **RESULTS:** During 2007-2012, the number of published studies on “cost effectiveness” have increased by more than 52%. There is a large variability in ICERs for same drugs for different indications, in some cases also varying by biomarkers. Primary care drugs had lower and less variable ICERs than specialty drugs. Variations also exist in methodology used by different groups in modeling cost effectiveness, time horizon and comparator. Majority of primary care drugs were modeled for a time horizon of 35-40 years or lifetime to demonstrate cost effectiveness. **CONCLUSIONS:** This analysis shows the range, variability and methods used for calculation of ICER values for these high budget impact drugs and provides lessons for executives and policy makers.

**PHP115**

**THE SHARP DECREASE OF DRUG’S ACCESS TO REIMBURSEMENT IN FRANCE IN 2011**

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**OBJECTIVES:** In France, all drug’s indications are listed for reimbursement according to the advice of the Haute Autorité de Santé (HAS), which assesses the SMR level (Service Medical Rendu) – linked to the future drug reimbursement level, the ASMR (comparative added value) – linked to the future price and “official” target population. Until last year, 90-95% of SMR levels allowed reimbursement, hence a significant manufacturer focus on ASMR level (which is basically the basis of reimbursement price fixation). Following the “Mediator affair” in 2010, the HAS perceived high percentage of positive recommendations for reimbursement have been challenged by multiple administrative and political reports. We investigated the 2011 HAS reimbursement decisions for new drugs. **METHODS:** We considered all complete procedures for a first inscription or line extension with an HAS opinion published between Jan and Dec 2011. We also considered applications which have been withdrawn by companies (no HAS advice). We focused our analysis on specific level of recommendation by indication in 2010 HAS opinions. **RESULTS:** Sixty-two HAS opinions have been published in 2011: 30% less than in 2010 (65 opinions in 2010). Regarding the SMR and considering it is granted indication by indication: out of 81 SMRs granted for a first indication reimbursement, 30% (24) were considered “insufficient” (no reimbursement) – in 11 of these cases companies withdrew their applications. In 2010, the SMR “insufficient” represented only 11% of all the published advices (which was already higher than 2009: 6%). **CONCLUSIONS:** The number of positive recommendations for reimbursement has sharply decreased in 2011 versus 2010, going from 6-10% in previous years to overall 3%. A qualitative analysis shows that the HAS seems to have evolved the assessment criteria used for SMR.

**PHP116**

**ORPHAN DRUG PRICING AND ACCESS – CURRENT SITUATION AND FUTURE TRENDS IN EU**

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**OBJECTIVES:** In recent years, several European countries have made changes to their policies related to HTA, pricing and market access, funding and cost reduction. This has impacted orphan drug funding and this will continue in the future. The objective of this research is to assess the current and future orphan drug pricing and reimbursement environment analyzing the changing dynamics from all perspectives. **METHODS:** Interviews were conducted with a variety of stakeholders including regulators, politicians, academics, investors and patient groups across Europe, UK, Sweden, Romania, Poland and the Netherlands. Comparisons were also made with other mature markets such as Australia, and the US. **RESULTS:** Orphan definitions vary from 5 in 10,000 in EU to 1 in 10,000 in Australia. Pricing, payment and reimbursement mechanisms demonstrate variability across countries including financial incentives, protocol assistance, track procedures and market exclusivity. There is lack of clarity at the EU as well as country level. For instance according to AMNOG law in Germany, products with less than €50 million budget impact are not expected to be assessed. However IQWiG did assess orphan drugs in 2011-12. In the UK, with the introduction of value based pricing in 2014, orphan drug approvals are likely to improve. The number of orphan drug approvals and the share of pharmaceuticals spend will increase with as much as 2-3% absolute, current levels being at approximately 3%. However this may not translate into disproportionate drug expenditure. Regulatory as well as payers have accommodated in accepting sub-optimal clinical data, however in the future this is expected to change. **CONCLUSIONS:** Payers are expected to become sensitive to orphan drug data requirements. The drivers of pricing and reimbursement decision will remain the same at unmet need, disease severity and number of patients; however the expected magnitude of clinical effectiveness of the drug will be higher.

**PHP117**

**SMC DECISIONS: ARE THEY GETTING TOUGHER?**

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**OBJECTIVES:** To investigate whether trends exist in NHS drug funding decisions in Scotland over recent years. **METHODS:** In 2008, the Scottish Medicines Consortium (SMC) published an annual report illustrating drug submission statistics for that year. No further annual reports or related data has been published by the SMC since then. In the absence of such reports, a quantitative analysis was performed including all SMC appraisals published between January 2008 and December 2011 to investigate whether any trends exist in the decisions rendered by the SMC. The analysis was first performed on all submissions in total and then by submission type. **RESULTS:** On average 80 (range 73 – 88) submission assessments were performed by the SMC per year. The proportion of decisions granted by the SMC over the four years was relatively stable with an average of 37% ± 32% ± 31% accounting for full recommendations/ restricted recommendations and non-recommendations. In the restricted submission group, the proportion of recommended submissions has decreased gradually (20% ± 80% ± 0% in 2008 to 5% ± 15% ± 11% in 2011) with a parallel increase in restricted recommendations (4% ± 16% ± 5% in 2008 to 8% ± 50% in 2011). The number of non-submissions has also increased progressively over the four years, accounting for 19% ± 1% ± 4% of assessed submissions in 2011. High variations in the proportion recommendations (range 14 – 38%) and restricted recommendations (range 11 – 43%) granted for resubmissions were observed across the years. **CONCLUSIONS:** The analysis shows that over the four years investigated, the proportion of recommendations, restricted recommendations and non-recommendations granted for reimbursement submissions in Scotland remained fairly consistent. At a closer look, clear trends were evident for abbreviated submissions decisions. Eventually around 85% of SMC submissions will receive funding through either a full recommendation, restricted recommendation or resubmission recommendation.

**PHP118**

**ESTIMATING THE PROBABILITY OF A RECOMMENDATION FOR REIMBURSEMENT FOR A NEW DRUG IN THE UK USING AN MCDA APPROACH**

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**OBJECTIVES:** To develop a quantitative process to estimate the probability of a recommendation for reimbursement for a new drug with a cost per QALY of between 20,000 and 30,000 pounds in the UK. **METHODS:** To identify the most important attributes for the decision and their relative importance, a workshop was conducted: selection of 7 UK decision makers, pre-workshop questionnaires to validate the logistic model using participant ratings for a series of hypothetical products. **RESULTS:** The most important attributes identified for a recommendation for reimbursement and