PHP113 THE IMPORTANCE OF ECONOMIC EVALUATIONS IN THE ASSESSMENT OF REIMBURSEMENT APPLICATIONS

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OBJECTIVES: According to the Swedish Healthcare Act, any decisions for reimbursement 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 prioritise 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 to the reimbursement system. The decisions dated January to March 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 for 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 had no solidarity.

PHP114 REVIEW OF COST EFFECTIVENESS STUDIES OF HIGH BUDGET IMPACT DRUGS (2007-2012)

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OBJECTIVES: The recently made coverage decisions by UK’s NICE, Scotland’s SMC and the allocation of $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 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 CERs for same drugs for different indications, in some cases also varying by biomarkers. Primary care drugs had lower and less variable CERs than specialty drugs. Variations also exist in methodology used by different groups in modeling cost-effectiveness. The 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 drop in the number of eligible drugs for reimbursement. 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 had no solidarity.

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 pricing 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, policymakers, academics, pharmaceutical companies from the 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 1.2 in 10,000 in Australia. Pricing, payment and regulations mechanisms demonstrate variability across countries including financial incentives, protocol assistance, fast-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 pharmaceutical spend will increase with as much as 1-2% absolute, current levels being at approximately ~3%. However this may not translate into disproportionate drug expenditure. Regulatory as well as payers have been accommodative 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 safety profile; however the expected magnitude of clinical effectiveness of the drug will be higher.

PHP117 SME 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 and dates. 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% for full recommendations/ restricted recommendations and non-recommendations. In the abbreviated submission process, the proportion of recommended submissions has decreased gradually (20% [80%] abbreviated submissions in 2008 to 8% [50%] in 2011) with a parallel increase in restricted recommendations (4% [16%] in 2008 to 8% [50%] in 2011). The number of non-submissions has also increased progressively over the last three years, accounting for 19% of assessments performed by the SMC 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 submission 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: A multi-criteria process was used to assess recommendations for reimbursement for 7 UK decision makers, post-workshop questionnaire to validate the logistic model using participant ratings for a series of hypothetical products. RESULTS: The most important attributes identified for a reimbursement and