**METHODS:** SMC submissions between 2008-01-01 until 2011-02-01 were reviewed. From these, 23 a priori defined predictor variables were extracted. Among these were “BI” i.e. high and low net budget impact defined as above €500,000, “certainty-of-ICER” defined as an ICER (base-case or sensitivity analysis) above €30,000, “comparator” defined as active or placebo/uncontrolled trial and “Childhood disease” i.e. the application is for a childhood disease or not, with childhood defined as below or above 15 years of age. The impact of these variables was estimated by means of odds ratios in univariate and multivariate logistic regression analyses. RESULTS: Two hundred forty-nine drug applications were reviewed; 151 (61%) received a positive recommendation and 98 (39%) were rejected by SMC. Based on the univariate analyses the following variables were included in the final multivariate model: “BI”, “certainty-of-ICER”, “comparator” and “Childhood disease”. The other 19 variables such as chronic use, negative risk profile, type of endpoint and societal impact were excluded during the backward selection process for the multivariate model. A positive reimbursement was 47.31 more likely for “Childhood disease” versus “non-Childhood disease”, 25.1 for certain versus uncertain ICER, 3.381 for active versus placebo/uncontrolled trial and 2.381 for low versus high BI. The corresponding output OR [95%CI] from the regression was [47.31(1.961-9.9)] for “Childhood disease”, [0.04 [0.01-0.1]] for “certainty-of-ICER”, [0.30 [0.11-0.75]] for “comparator”, [25.11 [16-31]] for “BI”. The model explained 6% variation in the outcome and predicted reimbursement rates of 60.9% for “BI”=1, 33.8% for “certainty-of-ICER”=1, 25.1% for “comparator”=1, 3.38 for “Childhood disease”=1 and 9% for “active/placebo/uncontrolled trial”=1. CONCLUSIONS: Most critical predictors for reimbursement were uncertain ICER and Childhood disease. Future research should add granularity by also including reimbursement restrictions as outcome. External validity should be tested by out of sample predictions for new drugs.

**PHI016**

**CLINICAL TRIAL ACTIVITY IN GREECE: OPPORTUNITIES MISSED, SOON TO BE FORGOTTEN?**

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**OBJECTIVES:** Clinical trials (CTs) represent important investments in the clinico-economic setting, as well as in the “human capital” of developed economies. The purpose of the study was to depict CT activity in Greece for 2010. METHODS: A questionnaire-based survey was conducted among the members of the Hellenic Association of Pharmaceutical Companies (SFFE). Each company was requested to return via email one questionnaire per interventional CT approved by the Hellenic National Ethics Committee in the year 2010. Items in the questionnaire focused on the following points: phase of the trial, duration, number of patients, CT sites, therapeutic area of the agent under survey and planned budget for the study. The survey lasted for 4 months (December 2010-March 2011). RESULTS: Fifty of the 65 SFFE members returned questionnaires (response rate 77%). The majority of CTs was phase-III trials (67%), mainly on oncology (26.5%), endocrine disorders (16.4%) and cardiovascular diseases (13.9%). Most CT sites were affiliated with a university (46%) or an NHS hospital (46%), enrolling 4.5-7.5 patients, on average, depending on CT phase. The average budget per CT was 296,600€ (s.d.: 389,948€). In total, 120 interventional CTs were approved in 2010 in Greece, with the total investment estimated at 6.6 million Euro (SFFE). Each company was requested to submit an annual report. CONCLUSIONS: Compared to its European peers, the number of CTs conducted in Greece is extremely low. Within a global market context, this constitutes a problem of lost research opportunities and underuse of the country’s acknowledged scientific capacity. Major hurdles could be identified in the “bureaucracy” and complexity of the approval process, mainly within NHS, lack of acknowledgement of CT as key priority for research investment and lack of a strong framework for health technology assessment. Quick changes are necessary, in order to cover the distance lost.

**PHI017**

**PUBLIC HEALTH AND PREVENTION IN EUROPE: IS IT COST-EFFECTIVE?**

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**OBJECTIVES:** In the public debate surrounding public health and prevention, it is sometimes assumed that preventive interventions are by definition cost-effective. This study aims to explore whether preventive pharmaceutical interventions are more cost-effective than a curative approach to diseases. METHODS: A descriptive study identified European economic evaluations in the Tufts Medical Center Cost-
Effectiveness Analysis Registry between 2000 and 2007. Data were extracted on publication year, target population, intervention, patient sample, disease, prevention status, and incremental cost–utility ratio of each economic evaluation. Preventive interventions were defined as measures preventing disease onset. Curative interventions related to measures identifying patients with risk factors or preclinical disease or interventions limiting disability after harm has occurred. Results were also presented by disease category. However, preventive interventions had a significantly lower median incremental cost–utility ratio of 0.6255 € per quality–adjusted life year and were thus more cost-effective than curative interventions (12.917 € per quality–adjusted life year) (p = 0.002).

CONCLUSIONS: Although the cost-effectiveness of preventive interventions varies substantially, preventive interventions tended to be more cost-effective than curative interventions.

**PHP109 TENDERING OF BIOSIMILARS IN THE UK – DOES LAUNCH PRICE ACTUALLY MATTER?**

Veep Veep 1

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OBJECTIVES: In the light of the austerity drives and cost containment practices, payers increasingly resort to procurement procedures in order to award contracts for the supply of both conventional drugs and biosimilars. The tough reality of health economics in conjunction with the commitment of large generic manufacturers, who continue to invest despite the challenges, may mean that tendering of biosimilars may actually be a tool to increase biosimilars’ market share by demonstrating price competitiveness. This study aims to evaluate how initial list price, together with other tendering and pricing factors, influence safety and quality inclusion in the hospital formulary incorporation of new biosimilar drugs in the UK.

METHODS: A data framework was developed from secondary research of existing biosimilar prices, product profiles, clinical data submitted and current landscape. The framework was validated through telephone interviews conducted across various regions in the UK (n = 7). The focus of the interviews was on the initial tendering as a part of the procurement process for biosimilars in the UK.

RESULTS: Majority of respondents indicated price to be the primary criteria for formulary inclusion, although some pharmacists highlighted efficacy and safety parameters as influencing factors. CONCLUSIONS: The development of clinical commissioning consortia and the expansion of the biosimilar market as major biologicals come off patent mean that more decisions about biosimilar purchasing could be made jointly with primary care. Tendering as a mode of procurement for biosimilars, removes the prescriber’s influence which is the acceptance-limiting step for biosimilars currently due to the concerns on efficacy and safety. From a hospital procurement pharmacists’ point of view, it is unclear whether a price discount strategy will significantly increase the market share of biosimilars, considering the potential price competition from subsequent entrants.

**PHP110 UTILIZATION OF PHYSIOTHERAPY SERVICES IN HUNGARY**

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OBJECTIVES: Physiotherapy services are reimbursed on a fee for service method in Hungary. Altogether 151 specialties, and smaller community hospitals were relatively more efficient than their larger and medium-sized counterparts. Interestingly, the results revealed that small-sized urban hospitals were relatively more efficient than any other community hospital type. From a management and policy perspective, the study indicates that both rural and large community hospitals may use urban or small

**PHP111 ISPOR: AWARENESS, DRIVERS AND BARRIERS TO INVOLVEMENT OF UK CANCER NETWORK STAKEHOLDERS**

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OBJECTIVES: ISPOR’s mission is to increase the efficiency, effectiveness, and fairness with which the available health care resources are used to improve health together with a strong vision be recognized globally as the authority for outcomes research and its use in health care decisions towards improved health. Despite modest increases in ownership and conference attendance of health care decision makers still remains low, related to those involved in academia, industry and consultancy. Assessing if some of those responsible for utilising HEOR data in cancer provision and care practice are aware of ISPOR and its full resources and the drivers and barriers for involvement could provide an opportunity for increased membership and active involvement.

METHODS: To elucidate the level of awareness of ISPOR, its publications and other resources, interviews were undertaken with stakeholders within 12 NHS Cancer Networks in the UK. A data framework was developed to support a series of structured telephone interviews according to the British Healthcare Business Intelligence (BHBI) Legal and Ethical Guidelines for Healthcare Market Research.

RESULTS: Spontaneous awareness of ISPOR is relatively limited within the NHS Cancer Network stakeholders, with even less awareness to Value in Health. Notable areas of interest were Oncology, Patient Adherence and Persistence and Patient Reported Outcomes. The main barriers to membership of ISPOR was its initial awareness and more effective involvement would be limited due to existing NHS commitments, financial resources and levels of individual interest/relevance to existing NHS role. Organizational involvement for ISPOR. NHS stakeholder networks would support increased levels of engagement.

CONCLUSIONS: To enhance the awareness of ISPOR, its resources, conferences and educational support, ISPOR should consider a more targeted awareness campaign with key NHS clinical networks such as NHS Cancer Networks, British Oncology Pharmacy Association and evolving Clinical Commissioning Groups.

**PHP112 INTER-INDIVIDUAL COUNTRY VARIABILITY IN MONOCLONAL ANTIBODIES (mAbs) REIMBURSEMENT AND COVERAGE FOLLOWING EMA APPROVAL**

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OBJECTIVES: Therapeutic monoclonal antibodies (mAbs) are capturing an increasingly larger proportion of the pharmaceutical market. Their specificity for biological targets allows them to effectively treat a variety of indications. Yet, despite their successes, the various stakeholders’ viewpoints in European Union (EU) countries are often at odds. We explore mAbs as a drug class, specifically, how they are approved for use by the European Medicines Agency (EMA) and other regulatory bodies and how stakeholders’ opinions diverge from regulatory decisions.

METHODS: The following were summarized for mAbs approved for use in EU countries between 2000-2011: regulatory decisions; comparing and contrasting payer coverage decisions in selected EU countries; and position statements from patients, advocacy groups, and medical organizations. Discrepancies between initial or post-approval regulatory decisions and the statements of the other stakeholders were highlighted.

RESULTS: Nineteen mAbs have been approved by the EMA during the past 10 years. The summary data show how stakeholders use clinical data to reinforce their agenda. For instance, bevacizumab has been undergoing battles in both the US and the EU: regulators want to remove specific labeled indications based on safety and effectiveness data and NICE has advised against coverage for treating metastatic colorectal cancer, citing inadequate benefits for the costs, while patients fight for continued access to the therapy to extend their life at all costs. CONCLUSIONS: After product approval, physicians have traditionally been the key treatment decision makers; however, the influence of other stakeholders on availability and pharmaceutical coverage is increasing and competing. This study aimed to define the extent of influence of these decisions made by regulators and payers has forced drug manufacturers to not only show that it is safe and efficacious to regulators, but to demonstrate a product’s value to patients and payers. Incorporating the viewpoints of payers as well as patients in the drug development process will narrow the gap between stakeholders.

**PHP113 MEASURING THE ORGANIZATIONAL PERFORMANCE IN TENNESSEE: A CASE OF COMMUNITY HOSPITALS**

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OBJECTIVES: Recent increase in competition among hospitals, and managed care, and the impact of Medicare Prospective Payment System; properly measured hospital performance has become important to evaluate the impact of policies on the hospital industry. This study assessed the influence of hospital governance on hospital performance and efficiency, and it also attempted to systematically address the issue of ‘whether participation by insider and outsider business community stakeholders on the hospital governing board is related to hospital’s economic performance’. METHODS: The study was focused on 144 community hospitals in Tennessee; those provided general and acute care services from 2000 to 2006. An input-oriented and output-oriented Data Envelopment Analysis (DEA) using multiple input and output variables, which is non-parametric, flexible, and a mathematical programming approach for the performance assessment, was used to measure the efficiency by estimating the optimum level of outputs, given the mix of inputs. The dataset was developed to support a series of structured telephone interviews according to the British Healthcare Business Intelligence (BHBI) Legal and Ethical Guidelines for Healthcare Market Research.

RESULTS: The study was focused on 144 community hospitals in Tennessee; those provided general and acute care services from 2000 to 2006. An input-oriented and output-oriented Data Envelopment Analysis (DEA) using multiple input and output variables, which is non-parametric, flexible, and a mathematical programming approach for the performance assessment, was used to measure the efficiency by estimating the optimum level of outputs, given the mix of inputs. The dataset was developed to support a series of structured telephone interviews according to the British Healthcare Business Intelligence (BHBI) Legal and Ethical Guidelines for Healthcare Market Research.

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