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OBJECTIVES: During 2009-2011 major healthcare reforms were proposed and implemented in a number of nations, for example, Affordable Care Act in the US, AMNOG in Germany, HSPT in France, KVG in Switzerland and NHS proposed reform in the UK. These reforms have major implications on pricing, market access and HEOR strategy for drug and device products. **METHODS:** To understand the implications of these trends, we analyzed 2009-2011 reform bills and proposed changes worldwide. Additionally, we interviewed public and private payers, key opinion leaders and payer-influencers to understand implications of these reforms on drug and device manufacturers. Stakeholders ranked various data collection methods on a scale of 1-10 (1-least important and 10-most important). **RESULTS:** The global healthcare landscape is expected to undergo significant change during 2012-2016. In the US, government will play increased role as a single payer, especially with–Medicare, Medicaid and CHIP programs– which will cover 114 million Americans, at a cost of $784 billion. In Germany, AMNOG bill marked the end of free drug pricing and would lead to increased insurance premiums (now 15.5% of wages). In the UK, NHS has proposed to replace PCTs with 500-1000 GP-led consortia and use value-based pricing for expensive drugs and devices. Randomized controlled trial, budget impact model and systematic reviews —ranked highest (7.5-9.1) among payers. Overall, payers view that in the future, health economic assessments would play critical role in pricing, coverage and reimbursement of branded products. **CONCLUSIONS:** This analysis shows that global healthcare landscape is expected to undergo significant change during 2012-2016. Discussions with payers, KOLs and payer-influencers highlights increased importance of HEOR data in the future.

PHP104

IDENTIFYING FACTORS INFLUENCING DRUG REIMBURSEMENT IN SCOTLAND

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OBJECTIVES: Estimate the effect size, by means of odds ratios, of explanatory variables on the reimbursement decision by the Scottish Medicines Consortium (SMC). **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 18 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 47.3:1 more likely for "Childhood disease" versus "no Childhood disease", 25:1 for certain versus uncertain ICER, 3.33:1 for active versus placebo/uncontrolled trial and 2.38:1 for low versus high BI. The corresponding output (OR [95%CI]) from the regression was (47.3[7.1-961.9]) for "Childhood disease", (0.04 [0.01-0.11]) for "certainty-of-ICER ", (0.30 [0.11-0.75]) for "comparator" and (0.42 [0.16-1.10]) for "BI". The R2 statistic for the multivariate model was 0.41 and in-sample prediction was 82%. **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.

PHP105

COST-EFFECTIVENESS IN DRUG REIMBURSEMENT DECISION MAKING: A TOOTHLESS TIGER?

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OBJECTIVES: Since 2005, reimbursement requests for outpatient drugs claiming added therapeutic value require pharmacoeconomic evidence to obtain reimbursement in the The Netherlands. This study aims to obtain insight into the role of pharmacoeconomics in actual decision making. **METHODS:** We studied public reimbursement reports from 2005 onwards and investigated in detail the role of pharmacoeconomics next to therapeutic value and budget impact in decision making. **RESULTS:** From 2005 - April 2011, the Dutch reimbursement agency evaluated 304 dossiers, 186 concerned outpatient drugs of which 113 were submitted with a claim of added therapeutic value. In total, 26 out of 113 were denied reimbursement, 60 were classified having added therapeutic value (Annex 1B), 27 were clustered with equivalent drugs (Annex 1A). Only 30% of the submissions (18 out of 60 positive 1B decisions) contained pharmacoeconomic evidence; 37%, 12% and 22% were exempted due to orphan status, being a HIV drug, or other unknown reasons, respectively. Three out of the 18 submissions with pharmacoeconomic evidence only supplied a cost-minimisation analysis, 4 only a cost-effectiveness analysis (1 alongside a cost-minimisation analysis); 11 supplied a cost-utility analysis. Uncertainty was often related to (assumed) treatment utilities and the applied pharmacoeconomic model, only 9 submissions included a cost-effectiveness plane and an acceptability curve. Interestingly, 4 (2) submissions were judged as "insufficiently (moderately) founded" pharmacoeconomic evidence but still received a positive decision, presumably due to their added therapeutic value, treatment modality, expected budget impact, or orphan status. **CONCLUSIONS:** Although cost-effectiveness is a formal reimbursement criterion in the The Netherlands, only 18 out of 60 positively evaluated submissions contained pharmacoeconomic evidence. Only robustness of evidence is evaluated. Even "insufficiently founded" evaluations can yield positive reimbursement decisions. Hence, cost-effectiveness does not seem prominent in actual decision making, resulting in uncertainty about value for money of currently reimbursed drugs.

PHP106

WHEN IS LOWER LEVEL EVIDENCE OF EFFECTIVENESS ACCEPTABLE IN REIMBURSEMENT DECISIONS?: A DECISION ALGORITHM TO GUIDE POLICY MAKERS

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OBJECTIVES: Reimbursement decisions require evidence of effectiveness and a randomised controlled trial (RCT) is seen as the best study design to demonstrate effectiveness. However, there may be situations where a (double-blind) RCT will not be considered necessary, appropriate, methodologically feasible, or ethical. The aim of this study was to develop a decision algorithm to determine the appropriate level of evidence when assessing the effectiveness of a medical intervention. **METHODS:** The initial algorithm was based on the literature and interviews with personnel at the Health Care Insurance Board (CVZ), the central reimbursement authority in the The Netherlands. In addition to the results of a previous study of 72 reimbursement dossiers concerning medical specialist care, we also retrospectively studied 20 reimbursement dossiers made by CVZ to identify any arguments why lower level evidence could be accepted. We then interviewed several Dutch and foreign experts. Our algorithm was continuously refined during the study and prospectively validated using new reimbursement dossiers. **RESULTS:** RCT evidence was lacking in most positive reimbursement decisions (8/9), but also in most negative reimbursement decisions. Methodological issues can play a role in accepting lower levels of evidence, e.g. when blinding is impossible. Moreover, an RCT may be unsuitable (e.g. due to time constraints) or viewed as unnecessary (e.g. in testing parachutes). Finally, ethical reasons can play a role in accepting lower level evidence. Our decision algorithm contains a stepwise approach to determine the appropriate evidence level, which includes (double-blind) RCTs, observational comparative effectiveness research or non-comparative effectiveness research. **CONCLUSIONS:** Policy regarding acceptance of lower level evidence in reimbursement decisions needs to be transparent. Our decision algorithm can guide decision makers in reaching a structured and well-founded decision as to whether lower level evidence of effectiveness is appropriate.

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

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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 (SFEE). 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 SFEE 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 35.6 million Euros. **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.

PHP108

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-