OBJECTIVES: To investigate the problem of pricing and reimbursement of pharmaceuticals in Iran. A large amount of country's Health care expenditures, including insurance organizations' expenses, are spent for pharmaceutical products. However, the high amount of capital spent by the users for purchasing pharmaceuticals indicates a serious flaw in the system. As will be shown, this flaw is due to the structures, policies, and regulations of Iranian medical insurance system. **METHODS:** This is a descriptive study and, therefore, ethnographic site and fieldwork were used as the main source of information. Furthermore, information on the Internet and several Iranian online databases has been used for comparison purposes. **RESULTS:** Ministry of Health and Medical Education (MOHME) is the main responsible body for pharmaceuticals in Iran. However, different government organizations such as Ministry of Commerce, the Central Bank of Iran, and National Industries Organizations are involved in policy-making in this sector. MOHME decides how to allocate governmental supports and foreign currency quotas, to various related industries. This is done due to the fact that MOHME decides which pharmaceuticals should be covered and distributed in the country. However, prices are set by insurance organizations due to their bargaining power over MOHME. Insurance companies pay approximately 70-90% of the final price of a product. However, for purchasing expensive products, confirmation from insurance companies is needed. The reimbursed price is set at the level of the lowest priced equivalent on the market. **CONCLUSIONS:** These flaws and loopholes arise because of system's negligence on research and development methods and, therefore, lack of standard regulations on reimbursement decisions and priority settings. Inflexible profit margins for different products with different unit costs, incomplete support for vulnerable groups and patients with chronic diseases, and absence of rational pharmaceutical usage campaigns can be named as other major problems.

PHP132

PERSONALIZED HEALTH CARE IN FRANCE, GERMANY AND THE UNITED KINGDOM: ARE HEALTH TECHNOLOGY ASSESSMENT AGENCIES READY?

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OBJECTIVES: Personalized health care (PHC) is a treatment model that customizes health care based on biomarker-based prediction of likely response. It is increasingly being prioritized by politicians and payers—one recent example is the published strategy plan by the German Federal Ministry of Education and Research. A key policy question remains whether health care systems and health technology assessment (HTA) bodies are adequately prepared evaluating these new treatment options. **METHODS:** Existing HTA evaluation methods for therapies in France, Germany, and the UK were reviewed with respect to the applicability to PHC products based on information provided by decision-making bodies and the literature. **RESULTS:** Current HTA evaluation methods being applied to medical therapies, in general, need to be modified when applied to PHC. For example, traditional benefit evaluations that require randomized clinical trials are standard but cannot always be fulfilled in PHC. Furthermore, combined benefit assessments for typical PHC treatment—e.g., a pharmaceutical combined with a diagnostic test—lack experience about appropriate evaluation methods to use. Today, decison makers and manufacturers rarely make use of the opportunity to re-assess or for joint evidence generation. Finally, reimbursement for PHC is inflexible and does not fully reflect the value of targeting, including the reduction in uncertainty and greater appropriate use. Among these three, the UK seems the most open to PHC funding. HTA in France and Germany does not recognize the special economic and evidence features of PHC, though the French system is more open to innovative market access. **CONCLUSIONS:** If the largest EU health care systems are to secure the full benefits of PHC, they will need to provide for full and flexible reimbursement for innovative technologies and services based on value. Currently, the importance of PHC by health care politicians is not being reflected in the evaluation tools or reimbursement methods being applied.

PHP133

TRENDS IN REIMBURSEMENT DECISIONS IN IRELAND: AN ANALYSIS OF THE NCPE DATABASE FROM AN INDUSTRY PERSPECTIVE

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OBJECTIVES: To analyse trends in reimbursement in Ireland to help in the planning of HTAs from an industry perspective. **METHODS:** A database of all NCPE decisions and reimbursement for drugs from 2006 to April 2013 was developed from publically available NCPE reports and HSE websites. A descriptive analysis of the database was undertaken. **RESULTS:** From 2006 to April 2013 37% of drugs were reimbursed without a HTA and 63% were recommended for HTA (N=126). There were three HTAs undertaken in 2006 compared to 26 in 2012. High Tech (HT) drugs were more likely to attract a HTA compared to General Medical Services (GMS) drugs (83% vs. 51%). Of the HTAs completed, 57% resulted in a positive reimbursement recommendation within a median time from HTA submission to reimbursement of 7.9 months (min 3.9, max 16.3). The median time was 7.1 and 9.8 months for GMS and HT drugs respectively. Dominance almost perfectly predicted reimbursement; 83% reimbursed. Of the ICERs in the north-east quadrant, 54% resulted in a positive reimbursement recommendation (average ICER around €60,000/QALY). The cost per QALY for those not reimbursed in this quadrant was almost twice this at around €110,000. Finally, the average probability of cost effectiveness for reimbursed and non-reimbursed drugs were 60% and 30% respectively. **CONCLUSIONS:** Companies can expect more requests for HTAs especially for HT drugs. When HTAs are requested the probability of success is around 60% with an expected timeline of 8 months from submission to launch. Budget impact does have an important role to play as dominance is a strong predictor of reimbursement. The average cost per QALY for reimbursed drugs is above the €45,000/QALY threshold but does not take into account confidential discounts under patient access schemes. Finally, the threshold probability of cost effectiveness seems to lie between 30% and 60%.

PHP134

PARAMETER UNCERTAINTY IN VALUE BASED MULTI CRITERIA DECISION ANALYSIS: A SYSTEMATIC REVIEW OF METHODS

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OBJECTIVES: Multi criteria decision analysis (MCDA) aims to support decision-making where decisions are based on multiple criteria. In disciplines like engineering and environmental policy, MCDA is widely accepted and routinely used. The use of MCDA in HTA priority setting and reimbursement decisions is growing, but mostly limited to research projects. A factor that might influence acceptance is a perceived difficulty to value an MCDA's outcome when its inputs and outputs contain uncertainties. When this is the case, decision makers might not feel confident in accepting or rejecting its outcome. The objective of this study is to systematically review how parameter uncertainty is taken into account in value-based MCDA methods in general, and to discuss which of the approaches is appropriate for the setting of reimbursement decision making in health care. **METHODS:** A systematic literature review was conducted using the Scopus database. Found abstracts were categorized by MCDA method used. Then, themes and families of methods were identified by two independent reviewers. Selected full text articles were read to identify methodological details. **RESULTS:** The search strategy identified 635 abstracts, mostly from engineering and environmental journals and only 1.6% in health journals. Identified themes were fuzzy set theory (n=223), probabilistic framework (n=68), deterministic sensitivity analysis (n=140), Dempster-Shafer theory (n=14), Bayesian framework (n=7) and Grey theory (n=8). A large number of papers considered the Analytic Hierarchy Process in combination with fuzzy set theory (n=155). **CONCLUSIONS:** In the health literature there is little attention for parameter uncertainty. Methods to deal with parameter uncertainty in MCDA must strike a balance between comprehensibility and understandability. Several complex methods are developed for parameter uncertainty, but there seems to be a gap between the theory and the implementation of those methods. For simple applications, methods like deterministic sensitivity analysis are likely to be sufficient.

PHP135

AMNOG BENEFIT ASSESSMENT: TIME DELAY OF MARKET ACCESS FOR PHARMACEUTICALS IN GERMANY?

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OBJECTIVES: To investigate quantitatively, if and to which extent the German Arzneimittelmarkt-Neuordnungs-Gesetz (AMNOG) delays market access of pharmaceuticals. Secondary objective was to potentially identify predictors for access delay. **METHODS:** All AMNOG assessment procedures that were completed at the level of the joint federal committee (G-BA) by May 15 2013 were included (website www.g-ba.de). Time delay to dossier submission was calculated between the approval date of the European Medicines Agency (EMA) and the mandatory AMNOG dossier submission date. Submission date usually occurs when pharmaceuticals are made available and is decided upon by the manufacturer. We also included in the analysis the ordinal level classification and evidence certainty level for each product as assessed by Institute for Quality and Efficiency in Health Care (IQWiG) and G-BA as well as the ATC code. **RESULTS:** In n=17 (49%) of N=35 investigated pharmaceuticals a small time delay greater than 1.1 months (which is usually feasible) after EMA approval was observed, but only 20% had a delay >2 months. A negative correlation existed between the amount of time delay to dossier submission and the benefit level outcome as assessed by IQWIG (r=-0.258, n.s.) and the final result by G-BA (r=-0.484, p=0.003). Benefit assessment outcomes between IQWiG and G-BA were correlated moderately with r=0.442 (p<0.008). For both, IQWiG (r=0.841) and G-BA (r=0.773) certainty of evidence correlated highly with the benefit level outcome. **CONCLUSIONS:** This analysis highlights the impact of AMNOG on the market access of pharmaceuticals in Germany. Overall, only small time delays existed for most products. Time delay in market access correlated significantly with a negative assessment of additional benefit by G-BA. Evidence certainty clearly correlated with benefit outcomes.

PHP136

A COMPARISON OF COVERAGE AND REIMBURSEMENT DECISIONS IN GERMANY (AMNOG) AND SCOTLAND (SMC)

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OBJECTIVES: In Scotland, drug reimbursement is predominantly based on cost-effectiveness in contrast to the corresponding German AMNOG process. The study compares the reimbursement and pricing process in Germany (AMNOG), as reformed in 2011, and Scotland (SMC) based on reimbursement assessments. **METHODS:** All AMNOG and SMC appraisal decisions made in 2011-2012 were identified. Matching AMNOG-SMC cases were found and compared in terms of final appraisal decision and rationale. **RESULTS:** For 2011-2012, forty-one AMNOG cases over 60 subgroups and 193 SMC cases were identified; twenty five matching cases were compared as these were assessed by both organizations. Regarding these 25 cases, AMNOG deemed ten cases demonstrated no additional benefit, in two cases the additional benefit was unquantifiable, slight benefit was acknowledged in seven cases and in six there were significant benefits. Based on the benefit assessment the negotiated price rebates ranged from 4.7% to 70.7% based on manufacturer set price. No restrictions to subgroups were opposed to any reimbursement decision. The SMC reimbursed 18 products (72%), of which four were restricted to a certain population due to cost-effectiveness. SMC rejected 7 cases (28%) based on weak economic evi-

dence. Both organizations reached the same assessment regarding clinical benefit in only 13 cases (52%). **CONCLUSIONS:** AMNOG implements a more rigorous process with respect to clinical evidence assessment compared to SMC. All AMNOG decisions are positive; however final prices may resemble generic prices for products that demonstrate low additional benefit ("Festbetragsgruppen"). In comparison, a negative decision by SMC warrants re-submission and re-assessment of the set price for successful drug reimbursement. Orphan drugs are assessed as normal products in Scotland and may be rejected on the grounds of economic evidence, while in Germany the additional benefit is presumed and price negotiation starts automatically. Furthermore, the SMC assessment process starts later than the AMNOG process.

PHP137

ACCESSING THE PHARMACEUTICAL MARKETS OF BRAZIL, RUSSIA, INDIA AND CHINA

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While pharmaceutical sales in mature economies are declining, in emerging markets they have been expanding rapidly, with growth rates in double figures. Here we focus on market access in BRIC (Brazil, Russia, India and China) which together represent just over 40% of the world population.**OBJECTIVES:** To identify the processes and key stakeholders involved in gaining market access in BRIC; to assess the importance of health technology assessment (HTA) in gaining reimbursement in these countries; to identify opportunities and challenges to market access. **METHODS:** A review was conducted to identify the current processes and key stakeholders in market access in the BRIC countries and to identify favourable and unfavourable factors to market access. **RESULTS:** The licensing and reimbursement processes vary in the BRIC countries. Brazil follows processes similar to those in Western Europe, including HTA and public consultation as part of the reimbursement application. In China, the licensing process can take 4-6 years, though fast-tracking for innovative drugs has recently been introduced. Russia, China and India do not yet rely on HTA for reimbursement decisions. In India plans to use "pharmacoeconomic principles" in setting prices of new molecules have been announced. Opportunities in all these countries result from increasing affluence and life expectancy and the diseases associated with these. Some challenges to market access are: poor IP protection; protectionist measures; compulsory licensing; drive to use generics or biosimilars, often produced locally; price controls; variable health insurance/NHS coverage; and limited budgets for prescription drugs. **CONCLUSIONS:** HTA is now common practice in Brazil, but not yet in Russia, India or China. Although demand for new drugs is increasing in these markets, protectionism measures, competition from generics and budget constraints due to the increased burden and requirement for new high priced drugs present a challenge when accessing the pharmaceutical market in BRIC countries.

PHP138

PLACEBO-CONTROLLED TRIALS: ARE THEY ACCEPTABLE TO HEALTH TECHNOLOGY ASSESSMENT BODIES?

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OBJECTIVES: The gold-standard pivotal trial design has three arms with experimental medicine, placebo and active control however, often marketing authorisation is granted on placebo controlled (PLAc) trial(s). While PLAc trials are often still acceptable to the European Clinical Trials Directive and European Medicines Agency (EMA), they are less acceptable to Health Technology Assessment (HTA) bodies. The latter request an (in)direct comparison vs. the relevant active comparator(s) (AC) to demonstrate the added value of existing standard of care. We have investigated the hurdles encountered during HTA assessments for those drugs with marketing authorization based solely on PLAc studies. **METHODS:** We identified those drugs approved since 2010 by EMA based only on PLAc trials. We then reviewed the HTA assessments for these drugs in France (HAS), Germany (G-BA) and the UK (NICE and SMC) and compared these HTA assessments to others where the trial included an AC. **RESULTS:** Applications for 41 (45 indications) of the 220 drugs approved by EMA between 2010 and end of 2012 were based exclusively on PLAc trials. The number of indications already assessed and recommended (percentage) by HTA bodies are 19 and 11 (58%) for NICE, 33 and 18 (55%) for SMC, 24 and 20 (83%) for HAS, and 18 and 12 (67%) for G-BA. When compared to all HTAs irrespective of comparator being placebo or AC assessed since 2010, lack of an AC seemed to have no impact in HAS (83% vs 75% favorable opinion among all assessments) and G-BA (67% vs 58%) assessments but had a negative impact on SMC (55% vs 85%) and NICE (58% vs 64%) recommendations. **CONCLUSIONS:** The impact of no direct comparison with an AC varies across countries. The analysis seems to indicate that in absence of head-to-head data HTA agencies will accept indirect evidence against the right AC.

PHP139

THE IMPACT OF THE ECONOMIC RECESSION AND PHARMACEUTICAL-HEALTH SERVICE AGREEMENT ON THE PROBABILITY AND TIME OF REIMBURSEMENT OF NEW MEDICINES IN IRELAND

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OBJECTIVES: To assess the impact of the Irish economic recession (September, 2008) and the Irish Pharmaceutical Healthcare Association agreement (IPHA; November, 2012) on the probability of reimbursement decided by the National Centre for Pharmacoeconomic Evaluation (NCPE). We also aim to test whether the new IPHA agreement reduced the time-to-reimbursement for new medicines in the General Medical Services (GMS) and High Tech Drug Scheme (HTDS). **METHODS:** A database of all NCPE decisions since 2006 to present was compiled from publically available NCPE decision reports and a logistic model was used to test the occurrence of the recession and the IPHA agreement on the rate of positive reimbursement made by the NCPE. We also tested whether the new agreement had an impact on the time-to-reimbursement using a linear regression model. **RESULTS:** The results of the logit model suggest that neither the economic recession nor the agreement had any statistically significant impact on the probability of reimbursement. However, there was some evidence that the time-to-reimbursement was reduced after the agreement ($p<0.10$). **CONCLUSIONS:** Although the analysis suggests that these two events had no impact on the rate of reimbursement it is possible that the reimbursement price of new drugs may have decreased over this period which could have facilitated reimbursement. Unfortunately, details of the final price of medicines are not always known in the Irish system and it is therefore not possible to test this hypothesis using currently available data. Our analysis of time-to-reimbursement suggests that the new agreement may have satisfied one of its main objectives in getting new medicines onto the market sooner.

PHP140

MODELLING THE HEALTH TECHNOLOGY ASSESSMENT (HTA) PROCESS FOR INNOVATIVE DRUG TECHNOLOGIES (IDTS) IN THE TURKISH HEALTH CARE SYSTEM

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OBJECTIVES: Offering a standardized HTA process model through economic evaluation of IDTs in the Turkish health care system. **METHODS:** Current regulations on evaluation of innovative drug technologies through the reimbursement process are defined via a process flow scheme. A stepwise model is proposed to cover a standardized HTA system within the economic evaluation through an independent HTA body (Model HTA Authority). **RESULTS:** In the current system, economic evaluation content of a reimbursement application dossier is evaluated by Social Security Institution (SSI) through Technical and Main Commissions respectively. However this evaluation process is not standardized with respect to main variables such as scientific methodologies, timelines and responsibilities. This study offers a model, which initiates a re-defined application step for economic evaluation content of a IDT reimbursement dossier; parallel application to SSI and an independent HTA body (Model HTA Authority). Therefore, the Main Commission in SSI will be able to combine a general evaluation from the Technical Commission and an HTA report of the IDT by an independent HTA body. These reports will be available to owners of reimbursement applications until announcement of a final decision of SSI, and will become publicly available afterwards. **CONCLUSIONS:** IDTs are not involved in a standardized HTA process in the current Turkish health care system. However, pharmacoeconomic analysis reports are requested by SSI for reimbursement applications of IDTs. This study offers a model, which includes a standardized HTA process for IDT in the Turkish health care system. Applicability of this model may be tested through pilot projects and further steps may be defined for further excellence.

PHP141

CANADIAN PRIVATE PAYERS' PERCEPTIONS AND EXPECTATIONS OF SUBMISSION REQUESTS FOR DRUG REIMBURSEMENT SUBMITTED BY THE PHARMACEUTICAL INDUSTRY

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OBJECTIVES: To identify, from a private payer's perspective, the required elements to include in a pharmacoeconomic model and a budget impact analysis and compare them to that of the public payers' requirements. The secondary objective was to determine the preferred components to present in a submission regarding private payers. **METHODS:** A survey was sent to 21 submission reviewers from 14 private insurance companies offering drug reimbursement, using an online survey builder, *KwikSurveys*. The survey included 15 questions divided in 5 sections: General information, Clinical information, Pharmacoeconomic evaluation, Budget impact analysis and General appreciations. **RESULTS:** Nine reviewers from eight different companies, which represent 80% of the Canadian private payer market shares, responded to the survey. Results showed that 67% of participants follow the Canadian Agency for Drugs and Technologies in Health (CADTH) guidelines for economic evaluations. 88% of participants prefer a cost-effectiveness evaluation, while 75% prefer a cost-benefit evaluation. 100% of the participants would like direct drug costs and the indirect costs related to loss of productivity due to reduced working capacity to be included in the pharmacoeconomic model. 75% would like the costs to employer to hire and train replacement worker, the costs of premiums paid to, as well as benefits received from, private insurers to also be included in the model. 63% of the participants would like to see a population data-based model for their budget impact analysis. Similarly, 63% of the participants prefer a time horizon of 3 years for the budget impact analysis. **CONCLUSIONS:** The parameters to be considered in a submission sent to private payers are different from public payers' requirements. The perspective of the pharmacoeconomic model should be that of a private payer and the budget impact analysis should only consider a population covered by private payers.

PHP142

POINT OF CARE TESTS: THE LONG AND WINDING ROAD TO REIMBURSEMENT

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OBJECTIVES: Market access for innovative new technologies can be complex and time consuming. As cost-containment pressures in the European Union (EU) intensify, evidentiary hurdles to justify new point-of-care (POC) tests continue to grow. Decentralized health care decision making can also be a significant hurdle. This study aimed to characterize the process and identify challenges for Health Technology Assessment (HTA), pricing, reimbursement, and market access for a new POC test in the EU-5 countries. **METHODS:** We conducted desktop research of