OBJECTIVES: To investigate the problem of pricing and reimbursement of pharmaceuticals in high-income countries. The amount of country-specific expenses, 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 of the system of insurance organizations. 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 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 Organization are involved in policy-making in this sector. MOHME has the powers to allocate governmental supports and foreign currency quotas, to various related industries. This is done due to the fact that MOHME decides which pharmaceuticals will be covered by the insurance and the ones that are distributed in the market. The role of 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. Inflatable 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 PHARMACEUTICAL TECHNOLOGY ASSESSMENT AGENCIES READY? 

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OBJECTIVES: Personalized health care (PHC) is a treatment model that customizes health care according to each individual’s lifestyle, the underlying disease, environment and risk factors. In recent years, PHC is increasingly being prioritized by politicians and patients—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 personalized health care. Furthermore, the HTA methodologies are compared with 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. Today, decision makers in the health care system rarely make use of the opportunity to re-assess or 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 medical therapies. If the largest EU health care systems recognize 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 of reimbursement methods 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 publicly 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 and 43% resulted in recommending further clinical trials (average ICER and 0% 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: Comparing the reimbursement and pricing process in Ireland (AMNOG), as reformulated in 2011, and Scotland (SMC) and Germany (AMNOG) and 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 39% of these cases were identified around five key subgroups as assessed by both organizations. Regarding these 25 cases, AMNOG deemed ten cases demonstrated no additional benefit, in two cases the additional benefit was questionable, and in seven cases the benefit was rejected for the most products. Time delay in market access correlated significantly with a negative assessment of additional benefit by G-BA. Evidence certainty abstracted clearly with benefit outcomes.

PHP134 PARAMETER UNCERTAINTY IN VALUE BASED MULTI CRITERIA DECISION MAKING: A SYSTEMATIC REVIEW OF METHODS 

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OBJECTIVES: To perform a multi criteria decision analysis (MCDA) 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 by the fact 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 the result of the use of this tool. How can we assess 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 = 8) 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. Simple applications, methods like deterministic sensitivity analysis are likely to be sufficient.
ence. Both organizations reached the same assessment regarding clinical benefit in only 34% of cases. OBJECTIVES: Assess just over 40% of the world population. Of all NCPE decisions since 2006 to present was compiled from publically available agreement on PLAc trials. The number of indications already assessed and recommended for new high priced drugs presents a challenge when accessing the pharmaceutical market in BRIC countries.

In the current system, economic evaluation is now common practice in Brazil, but not yet in Russia, India or China. Although demand for new drugs has increased in these markets, market access can be complicated by 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.

The licensing and reimbursement processes vary significantly between countries. The health technology assessment (HTA) process is considered an important component of the reimbursement process in Brazil, but not yet in Russia, India or China. Although demand for new drugs has increased in these markets, market access can be complicated by 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.

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OBJECTIVES: To identify the processes and key stakeholders involved in obtaining market access in Brazil, 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 for new drugs in Brazil 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 pharmacoeconomic evaluation as part of the reimbursement application. In India, the licensing process can take 4-6 years, though fast-tracking for innovative drugs has recently been introduced. India, China and India do not yet rely on HTA for reimbursement decisions. In India, however, a re-defined process is to be implemented 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, protection of local medicine manufacturers and European and National Medical Community (EMA), they are less acceptable to Health Technology Assessment (HTA) bodies. The latter request an (in)direct comparison vs. the relevant active control. In the current system, economic evaluation is now common practice in Brazil, but not yet in Russia, India or China. Although demand for new drugs is increasing in these markets, market access can be complicated by 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.

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