

market share across Europe. G-CSFs have achieved the highest market penetration levels by value and GH the lowest across Europe. We identify four main drivers of market penetration differences. Price has the highest impact along with the response rate to the therapy. The efficacy of biosimilars in clinical trials as well as the economic mind-set of prescribers (office-based vs. hospital-based) also drive biosimilar market uptake. **CONCLUSIONS:** The study concludes with policy implications to regulate the uptake of biosimilars given different market conditions.

## PHP40

## AMNOG: PRICING REFORMS IN ACTION

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**OBJECTIVES:** The recent AMNOG health care reforms in Germany provide a unique view of a changing pricing system in Europe. With other European markets such as the UK planning similar reforms, we aimed to review the impact of AMNOG on drug pricing in Germany and distil lessons for other markets facing similar reforms. **METHODS:** Secondary research was conducted to review IQWiG's benefit assessment activity since the AMNOG reforms. The outcomes of these benefit assessments were assessed alongside rationale for decisions and pricing outcomes. **RESULTS:** At the time of writing, 24 products have been subject to benefit assessments by IQWiG. Of these, 12 were considered to show some level of added benefit relative to the comparator, with the remainder showing no benefit. Selection of inappropriate comparators was commonly cited by IQWiG as a reason that no additional benefit was demonstrated. Under AMNOG, products displaying no added benefit will be subject to automatic reference pricing, subjecting these products to generic pricing levels. As a result, there have been a number of high profile instances of manufacturers withdrawing products from the German market as a result of negative benefit assessment – most notably GSK with Trobalt and Pfizer with Xiapex. In instances where additional benefit is shown, Brilique is currently the only product has progressed through price negotiations with the GKV, resulting in a modest price premium. **CONCLUSIONS:** The AMNOG reforms provide an excellent live example of a national level shift towards a "value based" pricing system. The benefit assessments and consequent price levels may provide an indicator of pricing that may be achieved following the implementation of value based pricing in the UK. However, policy makers in the UK should be conscious of the potential negative implications of these reforms in the way of product withdrawals.

## PHP41

## USE OF SPECIAL PAYMENTS TO ENCOURAGE THE ADOPTION OF INNOVATIVE MEDICAL TECHNOLOGIES IN THE ENGLISH NHS

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**OBJECTIVES:** A number of jurisdictions have adopted special funding arrangements to provide extra payments to hospitals using certain technological innovations to encourage use where existing financing may be absent or insufficient. The objective of this research was to explore the use of these arrangements for medical technologies in the English NHS. **METHODS:** A structured on-line survey instrument was developed to gain insights into the use of special payments. An invitation to participate with a link to the on-line survey was disseminated to NHS hospital Finance Managers. A total of 25 surveys were returned and analysed. **RESULTS:** The majority (75%) of responding hospitals have sought support from Commissioners to approve special payments. In 35% of cases, the payment was for medical devices, followed by drugs (31%), diagnostics (19%), and other technologies (15%). Respondents highlighted specific technologies where special payments have been negotiated, including Transcatheter Heart Valves, Neuromodulation Implants, and Gastric Bands, among others. In most cases, such arrangements were requested because the technology was either excluded from the PBR system or the existing HRG tariff was not sufficient to cover costs. In half of the examples, the technology was fully or partially paid for. However, it was not uncommon for Commissioners to request additional evidence before making a decision or reject special payment applications altogether. A range of evidence (therapeutic benefit, reduced hospital admissions/length of stay, costs/cost-effectiveness) is considered to determine payment amounts. Once negotiated, payment arrangements are typically put in place for 1-3 years. Overall, NHS managers had mixed perceptions of the effectiveness of special payments and identified several challenges, such as a disinterest and insufficient expertise amongst Commissioners to consider submitted evidence and the length of time to agree payments. **CONCLUSIONS:** While special payments provide some flexibility for encouraging the adoption of technological innovation, a number of improvements are needed to effectively meet this aim.

## PHP42

## HEALTH ECONOMICS IN THE CZECH REPUBLIC AND INSURANCE COVERAGE DECISION MAKING IN 2008-2009: A RETROSPECTIVE ANALYSIS

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**OBJECTIVES:** Since 2008 the Czech legislation requires health economic analysis (HEA) to be a part of all new drug reimbursement applications submitted to State Institute for Drug Control (SUKL): without any specific guidelines, however. In order to see the real-world impact of the legislation change, we investigated past (2008/2009) innovative molecules' dossiers in terms of quality of their HEAs according to newly (2012) developed methodology of SUKL and also their impact on the respective decisions on coverage. **METHODS:** We selected all (22) applications for inno-

vative drugs limited to specialized centers. We then briefly described the HEAs in terms of their perspective and type of analysis. The HEAs were further confronted with a 'HEA checklist' based on the new SUKL methodology to identify common drawbacks and faulty issues in past HEAs. Consequently the respective coverage decisions were investigated. **RESULTS:** Of the innovative molecules' 22 dossiers investigated, only in 13 (59%) HEA was present. Two (15%) were cost-minimization studies, the rest were cost-effectiveness analyses, of which three (23%) were cost-utility. There was no apparent standardization in the analyses along with an obvious lack of transparency. Indeed, 'proper description of input data and their sources' was the point in the HEA checklist to be most often marked as 'unsatisfactory'. Review of the consequent SUKL's coverage decisions revealed that, irrespective of the HEA quality and even presence, all 22 (100%) applications were given a positive coverage decision. **CONCLUSIONS:** The present pilot study showed that in the first two years since introducing the obligation of health economic analyses be part of coverage applications, the system was largely ineffective. This finding stresses the necessity of introduction of a standardized methodology into the assessment and appraisal processes. Moreover, our study identified the key problematic areas to be specifically addressed by both the authors and assessors of future analyses.

## PHP43

## HOW WILL HEALTH CARE REFORM IN RUSSIA AFFECT DRUG PRICING AND REIMBURSEMENT?

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**OBJECTIVES:** In an effort to remedy a highly fragmented system of health care financing, Russia has introduced a series of reforms targeted streamlining public and private funding. We aimed to understand how the recent reforms have impacted pricing and reimbursement and how this is expected to change in the future. **METHODS:** We conducted in-depth secondary research through an analysis of Russian health care policies including the new DLO reimbursement programme and the Essential and Most Important Medicines List (EML). Research was also conducted on the roles of private insurance companies and private out-of-pocket expenses. Expectation of how these reforms will shape pricing and reimbursement in the future was assessed through a qualitative survey of key payers. **RESULTS:** Increases in the percentage of GDP spent on health care and the procurement of additional funding have led to a boom in the size of the Russian pharmaceutical market. However, although medicines on the EML are fully reimbursed, coverage does not include drugs for most outpatients, resulting in significant out-of-pocket spending. Private insurers have also failed to produce competition due to lack of incentives and legislation has caused rises in drug pricing. Payers expect that economic growth and increased government spending on health care will continue to increase the commercial attractiveness of the Russian pharmaceutical market. However, several competing factors may cause legislative barriers to entry and create a more challenging pricing and reimbursement environment. These concerns arise from a newly imposed price cap on EML medicines, the exclusion of certain drugs from the EML, legislation encouraging domestic growth, and a lack of transparency regarding reimbursement decisions. **CONCLUSIONS:** New drug pricing regulations and funding will likely create advantages for domestic pharmaceutical companies while potentially decreasing foreign presence by creating a tougher pricing and reimbursement environment.

## PHP44

## PUBLIC FINANCING OF MEDICINES IN PORTUGAL (2007-2011): ACCESSIBILITY TO MEDICINAL PRODUCTS WITH NEW MOLECULES OR NEW THERAPEUTIC INDICATIONS

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**OBJECTIVES:** Accessibility (time to financing decision) to new medicines is a major concern in Europe. Recently the European Commission has proposed to streamline and reduce the duration of national decisions on pricing and reimbursement of new medicines. The objective of this study was to evaluate the accessibility to medicinal products with new molecules or new therapeutic indications (NMNTI) in Portugal, since 2007 and characterize the determinants of the assessment process by the Portuguese Ministry of Health. **METHODS:** Data on 119 NMNTI reimbursement applications to the PMH between January 2007 and June 2011 was kindly provided by submitting pharmaceutical companies. Time to financing decision was assessed using the Turnbull non-parametric estimator and variability in time to financing decision was explored using accelerated failure time regression models with Gaussian mixture distributions, both allowing for interval, left and right censoring. The likelihood of public financing and its determinants was evaluated through the estimation of logistic regression models. **RESULTS:** Median time from submission to decision 331 days (95%CI: 292-398) was excessive relative to those in the Law for the decision: 70 days (hospital) and 110 days (ambulatory). In hospital medicines no decision was taken in less than 70 days. Only 10% of the decisions from ambulatory drugs were taken within the timelines in the law. Of particular concern was median decision times for orphan medicines (718 days), oncology drugs (743 days) and new therapeutic indications of medicines already reimbursed (890 days). From a vast number of variables studied, only in cardiovascular medicines the likelihood of non-public financing was significant lower (p=0.026). **CONCLUSIONS:** Accessibility to new medicines or medicines with new therapeutic indications in Portugal is compromised by an excessively long assessment process by the Portuguese Ministry of Health. Of particular concern is accessibility to orphan and oncology drugs.