under the Community Drugs Scheme. Of these, 2 treatments were reimbursed after a price reduction, 2 were borderline, and 1 treatment was cost-effective under the General Medical Services scheme but not the Drugs Payment Scheme. Of the 11 products reimbursed by NCPE, 3 were recommended by NICE (45%), 6 by SMC (55%) and 1 by AWMSG (9%). None of the 11 treatments were reviewed by NICE, SMC and/or AWMSG. Furthermore, 2 of the 11 treatments have been withdrawn in Scotland, England and Wales. Limited clinical/economic data was the reason for the one non-recommendation by the SMC. A more detailed analysis will be presented. CONCLUSIONS: Although requirements for HTA submission in the countries, demonstrating cost-effectiveness is a key factor for reimbursement in all markets investigated.

**PHP1**

**EFFECTS OF THE POTENTIAL GENERIC SUBSTITUTION IN PORTUGAL. DOES REGULATION MATTER?**

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OBJECTIVES: Considering the pharmaceutical expenditure trend and the current economic and social context in Portugal, this study aims to 1) analyse the national and international policy environments in Europe and US, concerning INN prescription and generic substitution, and 2) calculate the effect of generic substitution in Portugal, in terms of savings for the NHS and patients. METHODS: We conducted an international regulatory analysis review and generics market data. We estimated annual savings under the assumption of gradual increase in generics market share, and considering the difference between branded and generic medicines prices for each group of the Reference Price System (RPS). The database includes sales from Portuguese community pharmacies. RESULTS: The INN prescription is allowed in 20 countries of all 27 European countries and in all 50 US states. The generic substitution by pharmacists is allowed in 21 European countries (mandatory in 8) and in all US states (mandatory in 14). Despite the high increase from 2002, generics market share in Portugal is still below the European average, further enhanced with a slowdown in its growth reviewed since 2005. The doctors prescribed 39.1% of drugs by brand name with no permission for substitution in 2009. The simulations generated savings of €120.4 million (50.8% for the NHS and €69.6 million for patients), less 11.1% of the medicines expenditure covered by the RPS. CONCLUSIONS: The market shares observed seem to reflect the different legislative frameworks. In Portugal, despite the growing share of generics, there is still a large potential market with significant opportunities of additional savings for the health system and patients, and may contribute to a higher pharmaceuticals accessibility as well to maximize therapeutic adherence.

**PHP2**

**ASSESSMENT OF PHARMACEUTICAL EXPENDITURE TRENDS IN PORTUGAL—PRICING AND REIMBURSEMENT POLICY**

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OBJECTIVES: The Stability and Growth Pact approved by the Portuguese Government in 2010 limits the annual growth of public expenditure in 1% for drugs reimbursed in outpatient sector. Considering the 10.4% increase in pharmaceutical expenditure from the National Health Service (NHS) in the first 4 months of 2010, this study aims to identify the main factors of expenditure growth and implications of legislative modifications in Portugal. METHODS: We have considered the policy changes concerning pricing and reimbursement and analyzed the database that includes sales from Portuguese community pharmacies and drugs prescription data. The statistical analysis of monthly data by product was performed with Statistical Analysis System (SAS), version 8.2. RESULTS: The new legislation approved in June 2009, that establishes the generics reimbursement at 100% for pensioners whose income is below the national minimum wage was responsible for more €20.4 million of NHS spending in 2010. The average reimbursement rate of the top 10 branded drugs recently reimbursed increased significantly for this trend: for example, the reimbursement rate raise for some antidiabetics (from 37% to 69%) was responsible for €1.5 million (10.3%) of NHS expenditure increase. Nevertheless €10.7 million (21.5% of NHS expenditure growth) are explained by the top 10 branded drugs recently reimbursed (5 oral antidiabetics and 1 insulin). The reform in reimbursement system approved for July 2010 also predicts major changes in the expenditures trends. CONCLUSIONS: The legal framework has a high impact in pharmaceuticals expenditures trends, and consequently in public financial burden and patients co-payments. The different policy measures adopted should be assessed on a periodic basis in order to monitor the market dynamics and to identify the strategies that support the sustainable expenditure growth.

**PHP79**

**REFINING INPATIENT PSYCHIATRIC FACILITY REIMBURSEMENT: LESSONS FROM OTHER MEDICARE PROSPECTIVE PAYMENT SYSTEMS**

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OBJECTIVES: The Inpatient Psychiatric Facility Prospective Payment System (IPF PPS) is the youngest of the Medicare PPSs. Inpatient Psychiatric Facilities (IPFs) were excluded from the acute care inpatient diagnosis-related groups (DRG) system as it was thought to be a poor predictor of resource use for psychiatric patients. Although the IPF PPS was to include a patient classification system to reflect the differences in resource use and costs among IPFs, it was implemented without an associated assessment tool. This project reviews Medicare PPSs in which diagnosis is not an adequate predictor of resource use; compares data collected via the related assessment instrument, and discusses applicability to the IPF PPS. METHODS: The Medicare prospective payment systems were evaluated and the relevant systems identified. The systems defined criteria were defined and the related assessment instruments explored for identifying measures. RESULTS: Under the current IPF PPS, Medicare pays for the per diem costs associated with furnishing covered inpatient psychiatric services via a nationally established base rate adjusted by geographic, facility and patient factors. Patient characteristics are limited to seventeen Medicare severity-diagnosis related groups (MS-DRGs), age, length of stay and certain co-morbidities but, unlike home health, skilled nursing and rehabilitation facility systems, do not account for functional status or other contributors to resource consumption. CONCLUSIONS: Patients in IPFs may vary in care needs despite common MS-DRG classification, thus requiring different resources. With limited ability to adjust beyond primary diagnosis, the current IPF PPS may misalign facility payment and expenses, ultimately impacting access to care. By analyzing other Medicare PPSs policy makers may positively contribute to the refinement of this newest system.

**PHP80**

**EFFECTS OF REFERENCE PRICING AND TENDER CONTRACTS IN GERMANY**

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OBJECTIVES: The therapeutic reference price (RP) system in Germany is regarded as a successful mechanism to reduce pharmaceutical spending. However, later introduced price directed measures such as the so-called payer contracts (pharmaceutical tender contracts (TC)) interact with the reference price mechanism. The aim of this paper is to compare and analyze the effects of both instruments on pharmaceutical price, volume and expenditure for substances at the period around loss of exclusivity. METHODS: A group of frequently prescribed drugs with patent expiry between the years of 2001 and 2008 are investigated and the sales and unit data in the statutory health insurance system are analyzed for one year before and for the year after patent expiry. RESULTS: The data show for the group with reference price and no tender contract (RP+TC−) and with no reference price but tender contracts (RP+TC+) similar level for the sales but significantly higher volume data for the first group. In the first year post patent expiry there seems to be a significant drop of sales and volume 9–12 month post patent expiry—a period, when usually the reference price is set. The figures for the groups with tender contracts (TC+) show a more steadily decline post patent expiry. The group RP+TC− is in terms of cost containment (sales decline) the most prominent one. If no regulation takes place, sales and volume increases even post patent expiry. CONCLUSIONS: Reference pricing and tender contracts are two cost containment measures, which are equally effective if applied alone, and which have additional impact, when applied together.

**PHP81**

**EFFECTS OF COST-CONTAINMENT METHODS TO DRUG PRICE LEVEL IN EUROPE**

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OBJECTIVES: Due to the dynamic increase of pharmaceutical expenditure in the last decade different cost-containment method has been introduced by the European public insurance companies. The cost-effective drug reimbursement system might influence the price level either in a direct or an indirect way, so the pricing strategy should be based on demand drivers and on factors of the regulatory environment as well. The goal of this analysis was to identify the effect the certain reimbursement solutions and local market characteristic on average price level of the predefined submarket. METHODS: Before the statistical analysis we have built a comprehensive, standard-based and continuously updated international drug database based on official sources which supported the analysis trough getting wider access to data's. Because of the expected domestic introduce of international reference price system, we handled it with an extra attention among the explanatory variables. RESULTS: The variance of international pharmaceutical price level by the examined submarket found to be remarkable which can be explained by the difference product supply and the different apply of cost-containment methods of price regulation. CONCLUSIONS: The most effective way to curb the increased expenditure by the patient and the public insurance companies seems to be international reference price system; however the effect of this method differs across the countries.

**PHP83**

**A PROPOSAL FOR CLASSIFICATION OF PUBLIC FUNDING RESTRICTIONS**

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OBJECTIVES: Increasingly difficult situation of health care systems forces decision makers to limit access to publicly funded drugs compared to registration conditions. To keep the transparency, the decisions to deny health intervention to some group of patients have to be publicly justified—simple intuition is not enough. The objective is to present initial classification and details of methods to generate public funding restrictions. METHODS: A pool of public funding decisions has been identified through search of internet websites of the institutions that recommend or actually make public funding decisions. The specific conditions restricting the access were identified, grouped and further analyzed together with their justification if available. RESULTS: All restrictions generally aim to optimize the performance of the decision