was developed and administered with the support of the main Italian OAT patients' association. Returned questionnaires were checked for consistence and valid data were summarised. Travelling costs and earning losses were evaluated according to published prices. **RESULTS:** A total of 4722 valid questionnaires were returned from all over Italy. The prevalent OAT management model in this sample relies on hospital-based anticoagulation clinics. Patients incur significant transportation, earning loss, and other out-of pocket costs at an estimated mean overall monthly cost of about €30. The distribution of costs in the population is wide, and depends mainly on monitoring frequency, home-clinic distance, and employment status. **CONCLUSIONS:** This study contributes to clarify the organisational models of the Italian OAT population and delivers data on patients' costs that may be used when evaluating alternative management options.

HEALTH CARE USE & POLICY STUDIES – Drug/Device/Diagnostic Use & Policy

PHP9

HELSPOR'S ASSESSMENT OF THE PHARMACEUTICAL POLICY REFORMS IN GREECE: COST-CONTAINMENT AND ECONOMIC EVALUATION CRITERIA

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OBJECTIVES: The Hellenic Society for Pharmacoecnomics and Outcomes Research (HELSPOR) assessed the effectiveness of recent policy reforms on controlling pharmaceutical expenditure in Greece. **METHODS:** The latest available data on pharmaceutical expenditure in Greece derived from the National Statistical Service (NSS) were analyzed for the period of 2000–2007. **RESULTS:** Pricing and reimbursement systems implemented in Greece have been based on cost-containment rather than economic evaluation criteria. Cost containment policies introduced in the past (positive reimbursement list, pricing at the lowest EU price) had limited or no effect. In 2006, the reimbursement list was abolished and currently all marketed prescription medicines are reimbursed by Social Insurance. This, however, does not appear to be a sustainable system, as Insurance Funds exhibit significant deficits and hospitals incur enormous debts (in December 2008, hospital debt towards pharmaceutical companies was €2.66 billion, exhibiting a remarkable increase within a year (38.3%)). Although two laws have been voted to introduce a reimbursement system that would replace the positive list, none has yet been implemented. The outcome of the past and current pharmaceutical policies in Greece has been the increase of pharmaceutical expenditure. Pharmaceutical expenditure rose to € 4.5 billion in 2007, accounting for 21.6% of total health care expenditure and 2% of GDP. Pharmaceutical expenditure increased over the period 2000–2007 at a mean annual growth rate (MAGR) of 13.4%, a rate higher than total health care expenditure (10.3%). **CONCLUSIONS:** Pharmaceutical policy reforms have increased expenses for Insurance Funds and hospitals. Implementation of economic evaluation criteria could be a start for rational decision making and cost containment in the pharmaceutical sector.

PHP10

QUALITY ASSURANCE OF FOURTH HURDLE IN HUNGARY—A METHODOLOGICAL APPROACH

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OBJECTIVES: Despite the availability of Hungarian methodological guidelines the quality of economic evaluations submitted in pharmaceutical reimbursement dossiers are rather heterogeneous. The 10–12 point international critical appraisal checklists are not detailed enough to filter the problems occurring in Hungarian studies, therefore they are not widely used. As a consequence only small proportion of economic evaluations are published in medical journals, which limits the development of health economic skills and the broad utilisation of economic rationale in medical decision-making. The aim of our study was to develop a relevant Hungarian checklist for the critical appraisal of economic evaluations. **METHODS:** Fifty economic evaluations submitted for reimbursement of pharmaceuticals in 2007–8 were scrutinized by two independent reviewers to identify the most common methodological problems. Reviewers had no intention to revise previous reimbursement decisions. Based upon the assessment of 10 studies, a draft checklist was developed. After assessing 25 reports, an extended workshop was settled to reconcile the opinion of reviewers and to improve the checklist. The reviewers scrutinized the second 25 economic evaluations according to the checklist. The checklist was finalized at a second workshop. **RESULTS:** The final checklist consists of 3–8 dichotomised questions in several major topics concerning comparator selection, effectiveness, costs, sensitivity analysis, methodological approach and interpretation of results. When the checklist is used for critical appraisal, reviewers may exclude non-relevant question items. **CONCLUSIONS:** Our checklist is based on current Hungarian practice. As the published checklist will be officially used for the appraisal of economic evaluations in reimbursement dossiers, submitters can assure the quality of their economic evaluations and predict outcomes of the health technology assessment process. The transparent method of single technology assessment may improve the consistency of pharmaceutical reimbursement decisions and the utilization of economic evaluations in other fields of health care decision-making.

PHP11

DOES PHARMACEUTICAL CONSUMPTION IMPROVE HEALTH CARE STATUS?

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OBJECTIVES: To determine whether there is a relationship between pharmaceutical consumption and health care results. This issue is of highest importance in the French political debate, France being one of the countries in Europe with the highest pharmaceutical consumption and related expenses. **METHODS:** The levels of health care status of seven European countries (France, Denmark, Germany, Italy, Spain, Sweden and the UK) are compared through a range of indicators coming from sources (OECD, Eurostat, WHO) or scientific publications and systematically analyzed in comparison with health care and pharmaceutical expenses in each country. The analysis first relies on global health care indicators such as life expectancy, life expectancy without disability and mortality rates by causes. A focus is then made on the two major causes of death in Europe: cancer and cardiovascular diseases. Analysis is conducted on 2004 data. **RESULTS:** The highest life expectancy at 65, both for men and women, is positively correlated with the level of pharmaceutical consumption and expenses. Several studies (OMS) have suggested the high level of performance of the French health care system. The rather low level of life expectancy at birth for men is mostly the results of high mortality rates for external causes (suicides, injuries), independent from the health care system. Low mortality rates for cardiovascular diseases are associated with good management of risk factors through pharmaceutical treatments (hypolipidemic drugs). Regarding cancer, good results in terms of survival rates at five years are associated with a level of drug consumption high in value but more moderate in volume, this suggesting the use of innovating products. **CONCLUSIONS:** While it is not possible to demonstrate a firm cause-to-effect relationship between the relatively high investment in health care and the relatively better health care status in France compared with its European neighbours, a range of facts and figures do converge in support of this hypothesis.

PHP12

SHORTAGES IN THE AMERICAN MEDICAL DRUG MARKET

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OBJECTIVES: The purpose of this study was to characterize the drugs in short supply in the American market on or before June 1, 2009 and to determine if certain characteristics affect the duration of drug shortages. **METHODS:** We examined if the US Food and Drug Administration's policy of identifying which drugs in short supply are "medically necessary" is effective in reducing the length of those shortages and if the market concentration (the number of manufacturers) of a drug is associated with the length of its shortage. Medical drug shortages create disruptions for buyers such as hospitals and pharmacies. They can affect public health, especially when the drug has few or no alternatives and can be considered medically necessary. We compiled publicly-available data from the American Society of Health-Systems Pharmacists (ASHP) and the Food and Drug Administration (FDA) to determine the lengths of shortages, whether each drug had been deemed "medically necessary" by the FDA, and the number of active or defunct manufacturers for each drug. Using that data, we performed statistical analyses to test two null hypotheses: 1) that there is no association between a drug in short supply being labeled "medically necessary" by the FDA and the length of its shortage; and 2) that there is no association between the number of manufacturers for a drug in short supply and the length of its shortage. **RESULTS:** We failed to reject our null hypotheses for both active shortages and resolved shortage drugs as listed by the ASHP on June 1, 2009. **CONCLUSIONS:** These results suggest that the FDA's policy of determining which in-shortage drugs are "medically necessary" did not reduce the duration of those shortages. The findings also indicate the number of manufacturers for a particular drug or device in short supply is not associated with the length of its shortage.

PHP13

CALCULATION OF DELAY OF DECISION-MAKING ON PHARMACEUTICAL REIMBURSEMENT IN SIMPLIFIED PROCEDURE IN HUNGARY

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OBJECTIVES: On the 1st of May 2004 Hungary—together with many European countries—joined to the European Union which resulted in several changes in the Hungarian legislation. In the coverage policy of pharmaceuticals, the Directive 89/105/EEC of the Council of the European Communities on Transparency was implemented Hungary in order to provide regulation on decision on drug prices. The aim of our study is to calculate the average delay of decision-making on pharmaceutical reimbursement. **METHODS:** The data derive from the drug reimbursement database of the National Health Insurance Fund Administration (OEP) of Hungary covering the 4 year period of 2005–2008. We calculated the delay as the time between the submission of application by the manufacturer and the first day of reimbursement of drug. Our analysis covered drugs submitted within the frame of simplified procedure, drugs submitted in the normal procedure were omitted. **RESULTS:** Between 2005–2008 the total number of applications was 519, 440, 399, 377; while the average delay was 94,

95, 62, 55 days respectively. Most of the application represented new generic drugs (252, 213, 264, 225 pieces). Between 2005–2008 the average delay for new generic drugs was 75, 64, 58, 56 days. **CONCLUSIONS:** The introduction of EU transparency directive provided a strong regulatory framework for decision-making process on drug reimbursement. In the simplified procedure we did not found significant differences in time delay of decision according to submission categories. However, in 2007 the average delay significantly decreased compared to previous years.

PHP14

A POLICY ANALYSIS OF THE PORTUGUESE GENERIC MEDICINES MARKET

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OBJECTIVES: This study aims to conduct a descriptive analysis of the policy environment surrounding the generic medicines retail market in Portugal. The policy analysis focuses on supply-side measures (i.e. market access, pricing, reference-pricing and reimbursement of generic medicines) and demand-side measures (i.e. incentives for physicians to prescribe, for pharmacists to dispense and for patients to use generic medicines). **METHODS:** The policy analysis was based on an international literature review. Also, a simulation exercise was carried out to compute potential savings from substituting generic for originator medicines in Portugal using IMS Health data. **RESULTS:** Portugal has developed a successful generic medicines market by increasing reimbursement of generic medicines (until October 2005), by introducing a reference-pricing system, by encouraging physicians to prescribe by international non-proprietary name (INN), and by allowing generic substitution by pharmacists. However, the development of the generic medicines market has been hindered by the existence of copies, pricing regulation, certain features of the reference-pricing system, weak incentives for physicians to prescribe generic medicines and a financial disincentive for pharmacists to dispense generic medicines. Increased generic substitution would be expected to reduce public expenditure on originator medicines by 45%. **CONCLUSIONS:** The development of the Portuguese generic medicines market has mainly been fuelled by supply-side measures. To support the further expansion of the market, policy makers need to strengthen demand-side measures inciting physicians to prescribe, pharmacists to dispense and patients to use generic medicines.

PHP15

BIOSIMILARS: HGH TO TNFS, HOW WILL PAYERS RESPOND?

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OBJECTIVES: Biologic agents have helped revolutionize the treatment of a number of chronic and acute diseases. These highly valued products have also placed a significant cost burden on health care systems. For example, the average annual price of TNFs in the EU5 is €12,400 per patient (MSP). Payers, understandably, are eagerly awaiting the arrival of biosimilars. However, because of their biologic nature, biosimilars are not exact copies of the drugs they seek to emulate. This important difference between biosimilars and traditional generics has resulted in greater requirements for regulatory approval and has led some markets to take positions on their (non) interchangeability. Given these dynamics, this research explores likely price discounts of anticipated biosimilars, provides an analysis of what lessons can be taken from traditional generics and forecasts how biosimilars might change the standard of care for their respective therapy areas. **METHODS:** Review the EMEA data requirements and current prices of biosimilars on the European market. Review current biosimilar environment, including a review of current biosimilar pricing and uptake. Limited primary research. **RESULTS:** The most commonly anticipated price discount of biosimilars is 20–30% to the parent drug. This expectation is largely driven by past experience with biosimilar human growth hormones, erythropoietins and G-CSFs. **CONCLUSIONS:** Biosimilars will introduce a new competitive dynamic to the biologic market. However, because of the considerably higher cost of bringing biosimilars to market and the potential to differentiate biosimilars, the initial price discount of biosimilars will be more similar to a me-too like pricing strategy as opposed to what has been seen with competitive generic markets (e.g. fluoxetine). Importantly, even at a 20–30% discount, there will be sufficient cost-savings to encourage the use of biosimilars over their parent drug.

PHP16

PARALLEL TRADE OF PHARMACEUTICALS IN POLAND

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OBJECTIVES: To prepare detailed analysis of parallel trade of pharmaceuticals in Poland and to build a model calculating direct and indirect savings resulting from this phenomenon. **METHODS:** Diligent analysis of parallel trade based on data provided by IMS Health and gathered from The Polish Office for Registration of Medical Products, Medical Devices and Biocidal Products preceded by systematic literature review. **RESULTS:** Parallel import (PI) of pharmaceuticals in Poland has been possible since Poland became an EU member in May 2004. Since that date the PI licences have been granted for 352 medicines in Poland (73% prescription medicines, 20% OTC, 5% hospital and 2% veterinary). Currently, there are 18 parallel traders operating on the Polish market although only 5 have a significant share. Pharmaceuticals offered by parallel importers in Poland are exported mainly from Greece (33%), the Czech Republic (17%), France (12%), and the UK (12%). The share of parallel trade in total pharmaceutical market reached 0.5% in January 2009 compared to 0.3% in December 2007. The sales value from parallel import was PLN 82 million in 2008. Available analyses prove that medicines from parallel trade are cheaper than original products in Poland by about 20 to 60%. Up to now, there were no scientific studies of savings, resulting from parallel import in Poland. Detailed study on this topic is planned in cooperation with recognized European experts on parallel trade—University of Southern Denmark researchers. **CONCLUSIONS:** Parallel import is expected to grow in the next few years in Poland. Therefore, it is necessary to implement a reliable model of support for parallel importers by means of appropriate directives introduced by the Polish Government. In order to convince decision-makers that parallel import could be a source of substantial savings a detailed study is going to be conducted according to methodology mentioned above.

PHP17

CAN ELECTRONIC NOTIFICATIONS ABOUT SUBSTITUTES CHANGE PHYSICIANS' DRUG PRESCRIPTION HABITS? DEFINITELY YES!

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OBJECTIVES: Diffusion of electronic patient record (EPR) systems is almost universal in ambulatory medical services in Israel. The drug prescription module of the most widely-used EPR system has an intervention capacity of electronically notifying physicians about generic or therapeutic drug substitutions. This notification is triggered when the physician's first choice of a prescribed drug does not meet preferences of the health maintenance organization (HMO). The objective of this paper was to study whether and how such an intervention can influence physicians' drug prescription habits and help contain costs. **METHODS:** We monitored system use for 40 consecutive weeks in the second largest HMO in Israel, covering more than 1.2 million prescriptions, and recorded physicians' willingness to comply and prescribe a substitute drug in response to the system's notification. **RESULTS:** Findings show that *electronic notifications about substitutes can change physicians' drug prescription habits toward compliance with HMO preferences*. Higher physician compliance was found for generic substitutes than for therapeutic substitutes. Moreover, compliance was based on a cognitive decision process triggered upon notification. Examining the notification and deciding whether to comply or not lasted 2 to 5 seconds, hence not time consuming. An increase in compliance over time, until stabilization, was also observed. The direct financial savings on drug expenditures were estimated at 4.7%, mostly for chronic drugs, implying long-term saving. **CONCLUSIONS:** The results show that embedding notifications about substitute drugs in an EPR's drug prescription module can be effective and impact drug prescription behavior toward compliance, yet this compliance is context-dependent rather than automatic. In addition, long-term cost containment can be achieved without decreasing the quality of care.

PHP18

COMPARATIVE ANALYSIS OF THE IMPACT OF POSITIVE DRUG LIST SYSTEM BETWEEN NEW DRUGS VS INCREMENTALLY MODIFIED DRUGS IN SOUTH KOREA

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OBJECTIVES: In Korea, Positive List System(PLS) was introduced as a drug listing system in Jan 2007. This study aimed to comparatively analyze the impact of the PLS introduction on the listing of incrementally modified drugs(IMD) and new drugs(ND). **METHODS:** Database for new drug coverage assessment was established based on selective drug listing assessment data from HIRA website and MOHW reference publications. They analyzed the two-year drug listing data submitted to the Drug Review and Evaluation Committee (2007.1.–2008.12) since the introduction of PLS. SAS version 9.1 was used for descriptive analysis and logistic regression in statistical analysis. **RESULTS:** After the introduction of PLS, success rate of coverage decision was 74.6% and 50.6% for IMD and ND, respectively; for drug price agreement rate, 73.6% and 85.0%; for final drug listing rate, 54.9% and 43.0%, placing IMD higher than ND. Time to coverage decision for IMD and ND was 109.0days and 155.7days, respectively; time to drug listing was 192.9days and 260.0days, respectively, indicating much shorter time to decision and listing for IMD than general ND. The final listing rate was 52.1% for multinational pharmaceutical companies while being 48.6% for domestic drug makers. The factors having the largest influence on insurance listing were cost-effectiveness for IMD and financial impact for ND. **CONCLUSIONS:** The introduction of PLS resulted in higher coverage rate and shorter time to final listing for IMD compared to ND. The factors affecting the insurance listing differed between IMD and MD, with cost-effectiveness being the major factor for IMD.

PHP19

APPLYING "VALUE BASED" PRICING TO REGENERATIVE MEDICINE BASED PHARMACEUTICALS

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OBJECTIVES: Recent advances in embryonic stem cell based therapies are moving regenerative medicine based products into clinical trials and closer to entering the pharmaceutical arena. As these therapies edge closer to entering the market, it is important that appropriate health technology assessments are in place to deal with these new market entrants. Both autologous and allogenic products are under development, however, this analysis will focus on allogenic products and the challenges they will face. Allogenic products are derived from cells or tissues and likely to be marketed "off the shelf," similar to conventional biopharmaceutical products. While regulatory