was developed and administered with the support of the main Italian OAT patients’ association. Returnee 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 47/22 valid questionnaires were returned from all over Italy. The OAT management model in this sample relies on hospital-based anticogulation 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.

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

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OBJECTIVES: The Hellesc Society for Pharmacoeconomics and Outcomes Research (HESPOR) assessed the effectiveness of recent policy reforms on controlling pharmacist 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 approach as pharmaceutical expenditure rose to 2.66% of GDP in 2007, 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 an 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.

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 the evaluations submitted in pharmaceutical reimbursement procedures 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 held to finalize the draft 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 improve the quality of their economic evaluations and predict outcomes of the health technology assessment process. The transparent method of simple technology assessment may improve the consistency of pharmaceutical reimbursement decisions and the utilization of economic evaluations in other fields of health care decision-making.

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 public 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 analysed 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 result 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 pharmacological treatments (hypolipidemic drugs). In contrast, cardiovascular mortality, 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-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.

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 these shortages. 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 shortages, and thus 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.

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 drug pricing. The purpose of this 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 (OEFP) of Hungary covering the year 2007. 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,