observed that the orphan designation system in Japan has achieved certain results for increasing the accessibility of necessary drugs to patients suffering with rare diseases. However, several drugs are still not available in Japan, partly because of the difference in definitions of orphan disease among the 3 regions. To increase the accessibility to orphan drugs, further policy interventions should be considered.

PHP18

SCIENTIFIC EVIDENCE FOR THE RELATIONSHIP BETWEEN PHARMACEUTICAL BUDGET OF HEALTH INSURANCE FUND AND THE POLITICAL ELECTION CIRCLES IN HUNGARY

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OBJECTIVES: There is a continuous problem in Hungary—and assumable in many other countries—with planning the health insurance pharmaceutical budget. In Hungary there is a substantial gap between the planned and the actual budget resulting in an overspending of the planned pharmaceutical budget. The aim of our study is to analyze the gap between the planned and the actual health insurance pharmaceutical budget. **METHODS:** Data were derived from the nationwide administrative data set of the National Health Insurance Fund Administration (OEP), the only health care financing agency in Hungary. We analyzed the difference between the planned and the actual pharmaceutical budget of OEP between 1994 and 2006. Outcome (overspending rate) is measured with the following formula: the difference between the planned and the actual budget is divided with the planned budget. **RESULTS:** During the period of 1994–2006 we found significant overspending of pharmaceutical budget of OEP which varied between 3.4–36.6% of actual pharmaceutical expenditures. The peak of overspending showed a 4 years circle with the highest figures in 1994 (21,5%), 1998 (32.1%), 2002 (36.6%) and 2006 (30.4%). These 4 calendar years correspond with the time of national political (parliamentary) elections. **CONCLUSIONS:** We found the highest overspending of the Hungarian pharmaceutical budget in the years of national political elections. It is a scientific evidence for the political influence of the health insurance pharmaceutical budget. The overspending does not relate to any specific political parties or governments because it was a general phenomenon in Hungary between 1994–2006.

PHP19

ANALYSIS OF THE GREEK PHARMACEUTICAL MARKET: THE FRAMEWORK, THE FACTS AND THE TRENDS (1998–2008)

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BACKGROUND: The Greek economy is being called upon to manage one of the highest proportions of public debt versus GDP in the European Union and the Euro zone. In turn, the health care sector is subject to the distortions of the Greek public sector, as there is no official method of measuring and evaluating the services being provided. **OBJECTIVES:** The objective of this analysis was both to interpret the development of pharmaceutical expenditure, based on the most significant changes in the pricing and reimbursement system, as well as to evaluate the institutional changes based on their effectiveness. **METHODS:** The analysis reflects the evolution of pharmaceutical expenditure and interprets the changes in the regulatory framework that took place in Greece from 1998–2008. It should be noted that there is significant confusion around the actual level of pharmaceutical expenditure, as the data provided for 2003–2007 (provisional data) from the National Statistical Service of Greece are not in agreement with OECD's data. Following a more careful analysis of the data, numerous questions arise with respect to their reliability, as there is no explanation for the apparent rate of change with regard to the factors that could influence expenditure (e.g. changes in the pricing or reimbursement system). Therefore the actual level of pharmaceutical expenditure is also in question. **RESULTS:** After analyzing the price changes in the top 100 selling pharmaceutical products in Greece, throughout the indicated period, it became obvious that the cause of increasing pharmaceutical expenditure cannot be attributed to increasing prices, but to other factors mainly associated with over-consumption. **CONCLUSIONS:** Finally, taking into account the intense pressures on public financing of the health care system, it is important for any future measures to constrain costs to be based on reliable and accurate data and to target the entirety of the system.

PHP20

QUALITY ASSURANCE OF FOURTH HURDLE CONCERNING TO MEDICAL DEVICES

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OBJECTIVES: The Slovak guidelines for economic evaluation, although appearing to be generic, have been written focusing on pharmaceuticals. The objective of this study was to analyze the quality of submitted economic studies and related critical appraisals process and to develop a policy-relevant, publicly available Slovak critical appraisal checklist for improving the quality of economic evaluation for reimbursement submission of dossiers concerning to medical devices. **METHODS:** We created a working group to review previously submitted economic evaluations and related critical appraisals in order to identify potential technical and methodological problems. The working group consisted of two independent academic experts who scrutinized previous submissions and critical appraisals concerning to medical devices between 2007–2010. **RESULTS:** Evidence suggests that the methods of economic evaluation can be equally applied to drugs and devices in general. However, there are several specific methodological issues that require more attention if reliable and informative evaluations of devices are to be conducted. These issues are underestimated within the Slovak Republic. It is well known that expenditures for medical devices do not result in the most cost-effective outcomes. Economic evaluations of medical devices are mandatory but the quality of evaluations and critical appraisals are poor. Our analysis shows that the simplified questionnaire, which is currently used for the critical appraisal process within Slovakia should be replaced by a new Slovak critical appraisal checklist, which will be detailed enough to address the specific problems in the local economic evaluations process. **CONCLUSIONS:** The transparent method of technology assessment can improve the consistency of reimbursement decisions making related to medical devices in Slovakia. Therefore in addition to the available Slovak health economic evaluation guidelines a detailed checklist for appraisal processes specific for medical devices have to be prepared. The economic evaluation of devices raises additional challenges and the current Slovak guidelines overlook several issues.

PHP21

EARLY ACCESS: ANALYSIS OF THE FRENCH ATU SYSTEM

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OBJECTIVES: The French cohort ATU provides early access to medicines for serious or rare diseases prior to marketing authorization (MA) for groups of patients. This study determines the length of time of patient access before MA for different types and classes of products subject to a cohort ATU. **METHODS:** All medicines subject to a cohort ATU between 1994 and 2009 were obtained from the website of Afssaps. Products which were never authorized were excluded. Time from initiation of a cohort ATU to marketing authorization was determined. Subgroup analyses were performed for orphan products, products developed by small and medium enterprises (SMEs), and products in major indication classes. **RESULTS:** 87 products matched the inclusion criteria. Products were available on average 23 (range 0–121) months prior to MA. Orphan drugs (N = 13;15%) and non-orphan drugs were available 19 months (2–74) and 24 (0–121) months before MA respectively. Drugs developed by SMEs (N = 5;6%) were available on average 34 (9–59) months before MA, while drugs developed by larger companies were available 22 (0–121) months before MA. Blood products (ATC = B;N = 10;11%) were available on average 53 (2–121) months before MA, and anti-infectives (ATC = J;N = 31;36%) 15 (0–70) months, followed by 13 (1–74) months for oncology products (ATC = L;N = 19;21%). The average length of time before MA decreased from 21.4 between 1994 and 2003 to 3.7 between 2004 and 2008. **CONCLUSIONS:** This study demonstrates that the cohort ATU provides access to medicines several months before MA and has been used primarily by larger pharmaceutical companies. The length of time of access before MA differs by indication and type of product and has been shorter in recent years. Price level and indication should reflect future authorized indications and price. The lower than expected number of orphan drugs subject to a cohort ATU may be the result of more frequent use via the nominative ATU or in clinical trials.

PHP23

ECONOMIC EVALUATION OF TELEHEALTH/TELEMEDICINE AND COST-EFFECTIVENESS ARGUMENT AMONG KEY DECISION-MAKERS

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OBJECTIVES: To gather insights into global (5EU, US, emerging markets) national policy & key decision-makers' beliefs & perceptions on current and future landscape as well as impact and value of telehealth/telemedicine initiatives within health care programmes from health economic perspectives. **METHODS:** Both primary and secondary research was used for this study. Literature reviews with compilation of all relevant and up-to-date information including data in local languages. Primary research focused on market specifics where clarification and market insights were required (such as MOH, budget-holder's organizations, Public Health Institutions, senior health care professionals). **RESULTS:** Benefits for improving both accessibility and quality of health care through telehealth/telemedicine have vast potential. These initiatives require substantial investment, whereas human and financial resources are limited. It is important to demonstrate economic viability, in addition to technical and clinical evaluations, in order to understand the optimal conditions under which new telehealth/telemedicine programmes should be unfolded. Traditionally, cost-effectiveness analysis is used to evaluate telehealth/telemedicine programmes. Such an approach is represented only by monetary differentials (fixed, variable, marginal, and direct and indirect costs) and has numerous limitations due to the lack of available data as well as constant changes in technological progress. As discovered, it is imperative to add a range of different analytical techniques to traditional cost analyses. Other factors—such as perception and investment choices, quality of health care provision, consumer choice and political environment—should be taken into consideration. **CONCLUSIONS:** To understand the criteria national leaders use, and the supporting evidence they require, to allocate monetary resources for innovative telehealth/telemedicine programmes—traditional monetary analysis is not enough and we recommend two supplementary approaches: societal and perceptual analysis. This will allow further insights on views and value that telehealth/telemedicine initiatives deliver—and the priority within health care programmes—in order to reveal the willingness to pay among key decision-makers.