

health care use resulting from ADRs and STEs. The prevalence-based cost-of-illness analysis included direct costs for drugs, from the Swedish Prescribed Drug Register, and health care use, based on national statistics, during a 30 day study-period. **RESULTS:** Of the 7099 respondents, 1,377 reported at least one ADE and 943 reported an ADR or STE. During the study-period, respondents with/without self-reported ADEs respectively reported 124/164 general practitioner visits, 182/310 nurse visits, 191/310 specialist physician or emergency department visits, 39/48 home-health care visits, 159/283 other somatic visits, 4/4 psychiatrist visits, 120/72 other psychiatric visits, 20/17 hospitalizations, 267/228 health care contacts by phone or mail, and the use of 3,908/8,663 prescription medicines. The average direct cost per respondent was higher among respondents reporting ADEs compared to those not reporting an ADE (mean \pm SD): EUR 202.0 \pm 901.2 vs. EUR 61.2 \pm 356.9 ($p < 0.001$). The average direct costs of respondents reporting at least one ADR or STE were EUR 239.6 \pm 950.7, and costs resulting from ADRs or STEs were EUR 16.8 \pm 150.5 and EUR 33.4 \pm 266.9, respectively. **CONCLUSIONS:** According to our results, the resource use and costs associated with ADEs are extensive, and occurs both in hospitals and primary care. There is a need to further examine the relationships between self-reported ADEs and the high overall COI, and study the indirect costs of self-reported ADEs.

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IS ORPHAN DESIGNATION A DRIVER OF ORPHAN DRUG PRICING?

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OBJECTIVES: Policy makers pay more and more attention to the orphan drug market. Pharmaceutical companies are suspected to take advantage of the legislation. Moreover, granted an orphan designation (OD) could be associated with higher prices. The aim of this work is to assess the impact of the current European orphan drug legislation on prices within the rare disease market of the largest University Medical Center in France (AP-HP). **METHODS:** We included all drugs with exclusively rare disease indications, with or without (control group) European OD prior to European marketing authorization. We collected 2011 AP-HP prices and additional characteristics: prevalence of rare diseases; alternative drug existence and improvement in medical benefit (ASMR) assessed by the French National Authority for Health (HAS). **RESULTS:** From drugs indicated for rare diseases available in AP-HP, we retrieved those for which all additional characteristics were documented: 41 drugs with OD, 17 without OD. The contribution to the growth of the overall drug expenditures in AP-HP reached 1.16 points out of 3.40 points for OD drugs (99% of growth was explained by 3 drugs) and 0.39 for non OD drugs. No statistically significant difference in the price distribution was found between OD drugs (median: €180.4; interquartile range: €679.9) and non OD drugs (median: €443.9; interquartile range: €1433.1) ($p = 0.19$). The price distributions were scattered (standard deviation: 1040.2 and 3512.1 respectively). Other characteristics between the two groups were not statistically different. **CONCLUSIONS:** Concerns on the growing budgetary pressure of orphan drugs may affect social solidarity, and yet this study underlines the heterogeneity of the rare disease market. From these study results, OD approval should not be considered as the only price inflation cause. If the legislation should be adapted to limit windfall effects for pharmaceutical companies, the support of innovation in a fairness and egalitarian way is needed.

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USE OF ESTIMATES IN THE ECONOMIC MODEL OF THE IMPACT OF NEW HEALTH COVERAGE IN PRIVATE BRAZILIAN MARKET

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In Brazil, the mandatory coverage of medical assistance by HMOs are reviewed every two years by the regulatory agency of the government. The incorporation of new technologies brings as a consequence the concern about rising costs. Most HMOs in Brazil does not have sufficient structure for conducting studies to evaluate adequately the impact on its budget. **OBJECTIVES:** Evaluate the economic impact of expansion of coverage through an economic health model that allows to simulate the results of any HMOs. **METHODS:** We developed a decision support tool that automatizes the analysis of economic impact of new coverage according to the profile of the HMOs. The default rates used were based on the annual incidence of diseases and their prevalence according to sex, age, and history of use of procedures in the population. The costs of events considered the tariffs applied by HMOs and benchmarked prices commonly used. Adjustment coefficients were developed based on indicators of the real world in order to better reflect the market. As a basic principle, we followed the guidelines of the International Society of Pharmacoeconomics and Outcomes Research - ISPOR regarding the best practices. **RESULTS:** The total addition in the medical and hospital expenses resulting from the incorporation of technology was of \$ 2.02 per capita per month (plus 1.97%). The relative impact of major procedures was of \$ 1.02 for immunobiological therapy (0.99%), \$ 0.70 for eye treatment with antiangiogenic chemotherapy (0.68%) and \$ 0.30 for the other corporate events (0.29%). **CONCLUSIONS:** The use of tools based on economic models enables to simulate variations in utilization rates, access to the use of procedures and costs, reducing the uncertainty of some health indicators. This makes it possible to predict scenarios that better represent the incorporation of technologies in the Brazilian private HMOs' market.

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HEALTH EXPENDITURE AND DRUG EXPENDITURE - COMPARISON OF TWO WESTERN BALKANS COUNTRIES

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OBJECTIVES: To compare health expenditure as total % of GDP, per capita PPP and in US dollars as well as total drug expenditure with top ten ATC groups with highest expenditure in 2009 and 2010 in Bosnia & Herzegovina (B&H) and Croatia (CRO). **METHODS:** Research was based on data published in latest official annual reports from two national Drug Agencies and official reports from The World Bank. Top ten ATC groups were identified and compared for the period of two years – 2009 and 2010. **RESULTS:** The Health expenditure in 2009 as total (% of GDP) in B&H was 10.94 and in CRO it was 7.83. Total drug expenditure in B&H was 238.8 mil EUR compared to 269 in 2010 (increase of 11,23%), while in CRO it was 625.6 mil EUR compared to 664.5 in 2010 (increase of 5,85%). Top 10 ATC 1st level drug groups with highest expenditure in both countries in 2009 and 2010 were rather similar but on ATC 2nd level we observed significant differences in the share of relevant ATC groups with leading C09, J01 and L01 for 2009 and C09, J01 and A10 for 2010 in B&H. Leading groups in CRO for 2009 were L01, J01 and C09, and for 2010 J01, C09 and L01. No drugs from C10 group were present in top ten ATC 2nd level in B&H. **CONCLUSIONS:** CRO has universal health care system with twice smaller increase in total drug expenditure compared to B&H. B&H needs unique essential drug list as it is a country with decentralized health care system including drug politics and positive reimbursement drug lists.

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SYSTEM-WIDE IMPACT OF PAYMENT SCHEMES FOR INTEGRATED CARE OF CHRONIC DISEASES IN EUROPE: EVIDENCE FROM AN EMPIRICAL ANALYSIS

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OBJECTIVES: Different payment schemes have been implemented in Europe to stimulate integrated chronic care and to reduce health care expenditure. We aimed to investigate the impact of different payment schemes on national total health care expenditures. **METHODS:** We first identified European countries with payment reforms directed at integrated chronic care. Further, we conducted 14 interviews with chronic care experts in England, the Netherlands, Germany, Denmark, Austria, and France to get detailed information about the reforms and the facilitators and barriers for implementation. Last, we used a difference-in-differences (DID) model to estimate differences in health care expenditure trends before and after the introduction of a payment scheme between intervention countries and control countries. Intervention countries included countries with a pay-for-coordination (P4C), pay-for-performance (P4P), and/or bundled payment for integrated chronic care. We used OECD and WHO data from 1996 to 2010. **RESULTS:** The interviews showed that P4C in Austria, Denmark and France failed to control growing health care expenditure. This was attributed mainly to misaligned incentives between public insurers and local authorities. In contrast, P4P in France and England appeared to have a positive impact on reducing costs. The large financial incentives for care providers and explicit activity-based guidelines were the most important success factors. Bundled payments in the Netherlands and Germany increased transparency and promoted quality of care but at higher costs. These findings are in line with the quantitative results where the health care expenditure per capita decreased by 70 euro ($p = 0.002$) after the implementation of P4P and increased by 75 euro ($p = 0.040$) after the implementation of bundled payments. The P4C had an insignificant effect. **CONCLUSIONS:** Payment schemes are potentially powerful tools to stimulate the delivery of integrated care and influence health care expenditure. P4P appears to be the most appealing in reducing health care expenditure.

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STAKEHOLDERS'S VIEWS REGARDING THE IMPACT OF FINANCIAL CRISIS ON THE PHARMACEUTICAL MARKET IN GREECE

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OBJECTIVES: Pharmaceutical market was put in the centre of the Stand-By Arrangement (SDR) agreement. The main target was to control pharmaceutical expenditure and to implement new policies in the pharmaceutical sector. Given these reforms the aim of the study was to evaluate stakeholder's views regarding these measures and the future of the pharmaceutical market in Greece. **METHODS:** A qualitative study, using the method of semi-structured interviews was conducted using an open-ended questions guide. In total 17 interviews (out of 24 targeted stakeholders) were conducted, tape recorded, transcribed and content analyzed. The participants represented public and private sector organizations and academic organizations as well that are involved in the pharmaceutical market and policy. **RESULTS:** Rising pharmaceutical expenditure, chronic distortions of the pharmaceutical market such as increasing number of health professionals and lack of strict regulations were mentioned as the main characteristics of the pharmaceutical market in Greece. These problems along with the financial crisis in Greece created a pessimistic environment for the pharmaceutical market and magnified the existing problems because of the hasty and non-organized decisions that were taken under the pressure of economic crisis. Stakeholders estimated that the next 4-5 years will be hard for the industry and the recession in this sector cannot be avoided. However, they predict that after this period everything will come back to normal. **CONCLUSIONS:** Stakeholders representing the public sector had more positive views compared to those coming from the private sector or academic institutions that expressed negative opinions or were in generally more skeptical. The greatest concern however on all groups was that the continuous reforms could lead to the destabilization of the pharmaceutical market and thus having a negative impact on the quality of the provided services and products.