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THE PHARMACISTS' AND PATIENTS' SIDE OF POLICY MEASURES IN PHARMACEUTICAL MARKETS: THE EFFECTS OF CHANGING PHARMACY MARGINS

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OBJECTIVES: Under current economic and financial framework, some important revisions were made to the National Pharmaceutical Policy in Portugal, aimed at decreasing prices and contributing to lower public expenditure in the Health Sector. The Decree-Law 112/2011 introduced a new margin system both for pharmacies and wholesalers. A linear margin scheme, expressed as a percentage mark-up on the consumer price before VAT was thus replaced by a regressive system combining: i) a fixed fee that increases with the ex-factory price of drugs; ii) a regressive margin expressed as a percentage of the ex-factory price. This paper aims to assess: costs associated to the pharmacy dispensing and other pharmacy services provided; the proportion of purchased medicines on total prescribed; the perception of pharmacists and patients regarding changes in access to medicines, namely possible shortages of medicines in Portuguese pharmacies, and other issues. **METHODS:** In order to access the effects of this policy measure, surveys were carried out to consumers and pharmacies across the country. Four surveys were administered in week 25 to 29 June: survey to Pharmacy Owner; survey following each prescription sale (one day census); survey about pharmacy services not associated to the dispensing of medicines (5-day census). Pharmacists were also requested to administer a survey to patients presenting a prescription. **RESULTS:** To be completed after analysis of the surveys (after 29 June) **CONCLUSIONS:** We will elaborate on a more efficient distribution of medicines in view of both the economic sustainability of pharmacies and the impact on patients.

HEALTH CARE USE & POLICY STUDIES - Risk Sharing/Performance-Based Agreements

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TRENDS IN THE USE OF HEALTH ECONOMIC DATA TO INFORM GLOBAL MARKET ACCESS DECISIONS: PRELIMINARY RESULTS FROM AN ONLINE SURVEY

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OBJECTIVES: To explore opinions among professionals in health economics and related fields on global trends in the use of health economic (HE) data in various market access decision-making processes. **METHODS:** An on-line survey was administered to professionals who work with HE data. The survey captured professional background characteristics and respondents' opinions on trends in the role of HE data in various decision-making areas and specifically in applying HE analysis to individualized medicine and orphan medications. **RESULTS:** Seventy three professionals completed the survey; 53% from Europe, 30% United States, and 16% from other countries. 25% were from the pharmaceutical/medical technology industry, while 75% were from academia/government and other institution types. The area where most respondents expected an increasing role for HE data was in reimbursement decisions (89%), followed by manufacturers' internal pricing (78%), clinical guideline development (70%), and clinical practice (59%). Opinions on whether cost-effectiveness analysis of individualized medicine will become a dominant approach in the next three years varied widely with 49% of respondents in agreement and 19% disagreeing. Equally, 37% of the respondents agree and 37% disagree that orphan drugs should be subjected to the same value-based assessments as other products, with 26% being neutral. **CONCLUSIONS:** While there is strong agreement that the role of HE data will increase in the areas of pricing, reimbursement, clinical guideline development and clinical practice, there remains some disagreement about how specific HE approaches and policies will be applied in the near future. Further research is warranted to better understand the use of HE data in market access decision making globally.

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PHARMACOVIGILANCE AND THE CASE STUDY OF VIOXX

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OBJECTIVES: Pharmacovigilance as a part of drug safety surveillance consists in collecting and analysing adverse effects reports and is intended to evaluate the safety of medicinal products and to eliminate drugs whose risks outweigh therapeutic benefits. The research aims were: to recognize the rules of current pharmacovigilance practices, to examine their capacity to effectively manage public health and to propose an improved pharmacovigilance model. **METHODS:** The rules of drug safety monitoring in the United States, Canada, the UK and Poland have been presented, analysed and compared. In order to assess the effectiveness of the respective national practices, an additional analysis covered reports prepared by health care professionals, consumers and MAHs, submitted to the responsible health care agencies (FDA, Health Canada, MHRA and URPL, WMIpB). Based on the results, an improved pharmacovigilance model was proposed. A case study of VIOXX® was used to review different pharmacovigilance practices by analysing reports on this recalled drug, including the incidence and type of adverse effects reported, principles of pharmacovigilance signal detection and measures, taken by the agencies. The model was then subject to final evaluation. **RESULTS:** The anal-

ysed pharmacovigilance practices allowed to collect sufficient data on adverse effects, but none of the agencies raised any alarm addressing safety issues before the product was recalled by the manufacturer. **CONCLUSIONS:** The procedures underlying pharmacovigilance practices need to be amended by adopting the ideas proposed in the model, especially in the area of data analysis and signal detection, for instance: rigorous five-year safety monitoring of new products, especially post-marketing surveillance; publicly available adverse effects reports collected by the agencies; publicly available standards of signal detection based on MAHs declarations in SPCs; and including clinical trials' analysis in standard drug safety monitoring.

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FUNDING THE UNFUNDABLE: THE AUSTRALIAN APPROACH FOR SPECIALTY PHARMACEUTICALS

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OBJECTIVES: Specialty drugs are high-cost drugs for treating complex chronic conditions, such as cancer and autoimmune disorders. Most are biologics, and they provide highly targeted treatment for which there are few other viable treatment options, but at prices that are substantially higher than traditional medications. This study examines how Australia funds specialty pharmaceuticals under its publicly funded, national drug coverage system. **METHODS:** Review of the literature and analysis of prescription volume and expenditures (2010-2011). **RESULTS:** Inherent in all decisions on coverage of new health technologies is uncertainty, arising from the absence of complete information about comparative (long-term) effectiveness, incremental cost-effectiveness, adoption and diffusion, and economic impact. Uncertainty is more pronounced for specialty drugs due, in part, to their high cost. In response, Australia created a Complex Authority Required Highly Specialized Drugs Program under the Pharmaceutical Benefits Scheme to fund and deliver specialty drugs. This program currently includes 34 drugs (e.g. adalimumab, etanercept, imatinib). Subsidized access to these drugs is restricted to subsets of patients who must show evidence of the clinical need (e.g. pathology report to confirm the diagnosis) and whose condition is inadequately controlled by existing, less expensive therapies. For continued access to many of these agents, patients must also demonstrate adequate clinical improvement; clinical outcomes are evaluated according to predetermined quantifiable criteria. Because of the availability of multiple effective agents for a single clinical indication (e.g. rheumatoid arthritis), Australia was the first country to establish an 'interchangeability rule' under a publicly funded system that allowed eligible patients to trial an alternate medicine without the need to re-qualify against the initial criteria. Analysis is underway to assess the current status of this program, including uptake and economic impacts. **CONCLUSIONS:** Australia has created an innovative funding approach to balance the benefits, risks, and costs of specialty pharmaceuticals.

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TRENDS IN THE USE OF INNOVATIVE CONTRACTING MODELS BETWEEN THE PHARMACEUTICAL INDUSTRY AND PAYERS IN EUROPE

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OBJECTIVES: To provide an overview of past and current models and practices in innovative contracting in Germany, the UK, Sweden, Italy and France. Another aim was to uncover the experiences of different stakeholders with innovative contracting in Germany and the UK. **METHODS:** A comprehensive literature search on innovative contracting from 2008 onwards was performed. Information on the country involved, drug type, characteristic of the therapeutic area, timeframe, terms of the agreement and stakeholders involved was extracted. Interviews with 22 stakeholders from Germany (n=14) and the UK (n=8) were conducted. Stakeholders included pharmaceutical company staff, payers, medical practitioners, governmental bodies and academics. **RESULTS:** The countries showing the highest activity in the use of innovative contracting were the UK (23 from 60 contracts), followed by Sweden (15/60) and Italy (10/60). Most schemes were applied to oncology drugs (29/60). The most frequently mentioned innovative contract model in the literature was the Coverage with Evidence Development (CED) scheme (23/60). From the interviews, it was observed that most stakeholders applied these schemes mainly to arrange broad market access, and were successful in their implementation (32%). Where stakeholders avoided innovative contracting schemes, this was due to their complexity, high administrative burden, and uncertainty of its benefits, particularly for payers. The high administrative burden was regarded as the greatest pitfall of innovative contracting schemes, being mentioned by 45% of the stakeholders. For the future, they prefer the use of simple rebate schemes. **CONCLUSIONS:** Innovative contracting provides a valuable tool for new innovative pharmaceuticals to gain market access whilst keeping the impact on payers' budgets under control. These schemes have not yet gained widespread acceptance, and stakeholders in the UK and in Germany are suspicious as to their benefit and their future relevance. Systematic research is needed to allow for the evaluation of these schemes.

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GLOBAL PHARMACEUTICAL RISK-SHARING AGREEMENT TRENDS IN 2011 AND 2012: SLOWING DOWN?

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OBJECTIVES: It would appear that ongoing economic austerity would lend itself to cost containment in health care through a natural increase in use of pharmacoeconomic strategies in general, and risk-sharing agreements in particular. How-