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between 2005 and the 30th of June 2010. We observed their administrative path. Among those available in the first teaching hospital group in France (42 hospitals), we evaluated the potential variables associated with the unit price growth rate before and after MA. **RESULTS:** During the study period, 77 ATUs obtained a MA, mostly after a European approval. Cancer represented the major therapeutic area with 21 drugs. After MA, 9 previous ATUs (12%) were not considered by the High commission for health (HAS) to have neither major nor important medical benefit and 19 (25%) were not supposed to bring some benefits compared to existing therapies. For the price growth rate's analysis, 57 drugs were retrieved (9 previous free ATUs were excluded): 68.4% had a decreasing price after MA whereas 17.5% increased and 14% were stable. Overall mean price growth rate was -12.1% ± 22.6%. The improvement in medical benefit assessed by HAS was not a predictor of the growth rate (p=0.392). **CONCLUSIONS:** From these results, pharmaceutical companies seem marketing these compassionate drugs, for which the benefit/risk ratio is only presumed, at a price that guarantees a margin for future negotiations.

PHP10

TWO PHASES STUDY ON THE PERSPECTIVE OF HEALTH CARE PROFESSIONALS ON CURRENT MECHANISMS FOR AUTHORIZING THE PRESCRIPTION OF SPECIFICALLY CONTROLLED MEDICINES IN SPAIN

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OBJECTIVES: An inspection system that controls the prescription of specific groups of pharmaceutical products exits in Spain. It requires certain prescriptions to be authorized by a medical inspector. Traditionally, it has been carried out manually. Currently, the implementation of an electronic system has modified the whole process of prescription and dispensation of medicines countrywide. This study aims to explore health care professionals' views on the impact of the implementation of an electronic system on the prescription and dispensation of specifically controlled medicines in the country. **METHODS:** Observational, exploratory, two phases study. This abstract reports on phase 1 that included a literature review, a review of current legislation, and telephone, audio-tape recorded semi-structured interviews with primary care physicians, endocrinologists, pharmacists, medical inspectors and regional health authorities from urban and rural areas across country until data saturation. A content analysis of interview transcriptions was conducted. Data triangulation was performed. **RESULTS:** A total of 58 interviews were conducted (21 primary care physicians, 11 endocrinologists, 6 pharmacists, 9 medical inspectors, 11 health authority representatives). Three mechanisms for authorizing the prescription of specifically controlled medicines exist across regions: manual, electronic, and linked to electronic dispensation. The electronic system speeds up the process and favors that the prescription of treatments more strictly adjust to the clinical condition they have been authorized for. From health authorities' and medical inspectors' perspective, the inspection of prescription contributes to avoiding medicines misuse. From the physicians' view, the inspection system mostly serves to control the spending on medicines. Alternative strategies based on professional training and education would more effectively contribute to preventing treatments mishandling. **CONCLUSIONS:** Electronic mechanisms for authorizing the prescription and dispensation of specifically controlled medicines vary across regions. Differences on the perceived ultimate value of the inspection system exist amongst physicians, medical inspectors and health authorities.

PHP11

FACT OR FALLACY: DOES MEDICAL TECHNOLOGY DRIVE HEALTH CARE SPENDING?

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OBJECTIVES: Health care spending has risen steadily in most countries, becoming a concern for decision-makers worldwide. Commentators often point to the diffusion of new medical technology as a key driver for burgeoning expenditures. This paper critically appraises this conjecture, based on an analysis of existing literature, with the aim of offering a more detailed and considered analysis of the impact of technological innovation on spending. **METHODS:** Key databases (e.g., PubMed, EMBASE) were searched to identify relevant literature. Several categories of studies (e.g., multivariate analyses, policy analyses) were included to cover different perspectives and issues regarding the relationship between medical technology and costs. Applicable abstracts were identified and selected articles reviewed. A standardised template was developed to extract relevant information from the select literature, which was then analysed for key themes across: impact of technology on costs, factors influencing this relationship, and noted methodological challenges in measuring such linkages. **RESULTS:** A total of 150 studies were reviewed. The analysis suggests that the relationship between medical technology and spending is complex and often conflicting. Study conclusions were often contingent on varying contextual factors, such as the sector examined, availability of other interventions, population trends, and the methodological approach employed. Moreover, the impact of medical technologies on costs differed across technologies; some (e.g., cancer drugs, invasive devices) had significant financial implications, while others were cost-neutral or cost-saving. Several studies examined technology in general, making it difficult to tease out the contribution of different types of interventions. **CONCLUSIONS:** Ascertaining the impact of technological advances on spending is difficult to quantify (and qualify). Issues of causality and incomplete knowledge of the interactions between technology and other factors affecting expenditures often constrain the reliability of analyses. We argue that it would be more productive to ask if investments in medical technology result in better value in health care.

PHP12

THEN AND NOW: THE EVOLUTION OF INTERNATIONAL REFERENCE PRICING GLOBALLY

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OBJECTIVES: This study assesses the evolution of international reference pricing (IRP) across 34 countries, from 2006 to 2011. Its current influence on innovative drug pricing in the leading five European Union (EU) markets was also considered. **METHODS:** An international reference pricing matrix was created and reviewed to see if the basket of countries referred by nations to price their pharmaceuticals had changed. Pharmaceutical prices were also used to review 2011 prices of five randomly selected innovative blockbuster molecules across EU-5 countries; the molecules in question were bevacizumab, adalimumab, etanercept, rosuvastatin and infliximab. **RESULTS:** The EU-5 markets lead the reference basket used by countries in their price setting process both in 2006 and 2011. Countries that reference these markets are varied and not limited to economically similar markets both within and outside the EU. While there have been additions and deletions, many countries have largely maintained their reference basket of countries. Since 2006, more emerging markets have become IRP prescribers. Unlike Brazil, and Turkey, which followed IRP prior to 2006 and exclusively use developed country prices to price their own products, the newer emerging market followers have also chosen to include neighbouring countries and/or economically similar country prices in their mechanism. A comparison of 2011 prices across the EU-5 markets showed less price variation between countries that followed IRP compared to those that followed free pricing, but prices were not necessarily lower. **CONCLUSIONS:** Countries using IRP still rely on EU-5 drug prices to price their medicines. However, new adopters of the mechanism are including similar and neighbouring countries to arrive at affordable rates and prevent parallel export. With more emerging markets rolling out IRP, it is notable that in the absence of a set formula that identifies the lowest prices, this technique is one of cost harmonization rather than cost containment.

PHP13

A SURVEY OF PRICING TRENDS AROUND THE WORLD

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OBJECTIVES: We surveyed pharmaceutical prices in 18 countries (mix of developed and emerging countries). The goal of the survey was to analyze and compare drug prices in an attempt to determine the countries where drug pricing procedures are more favorable or more stringent, as well as the countries where price cuts are common and where price increases can still be expected. **METHODS:** The methodology was based on estimated ex-manufacturer pricing data from PharmOnLine International, looking at current and historical drug prices in 18 countries. For each country, all prescription drugs by average manufacturer prices were looked at, as well as by therapeutic area. Several case studies were also analyzed. **RESULTS:** With countries having their own legislation and standards when it comes to drug pricing, significant price differentials are seen between countries. By far, conditions are still most favorable in the US. Legislation is more restrictive in other markets, notably in the European Union. Our data finds that the ongoing pricing reform in Germany has already had a significant impact on drug prices, which are dropping. Conditions are more attractive for innovative drugs in certain emerging countries - including Brazil or Russia - where pharmaceutical companies are increasingly investing as demonstrated with the large number of innovative drugs marketed in those countries. Additionally, a significant number of case studies demonstrate that innovative drugs are highly priced and that price increases can still be expected in those countries. **CONCLUSIONS:** With stringent pricing legislations in developed countries, opportunities are now seen in emerging countries where pharmaceutical companies increasingly invest. In these markets, the challenge is seen at the reimbursement and volume levels. Nevertheless, with governments enhancing their healthcare systems, the data points to the conclusion that the basket of drugs funded will increase in the near future.

PHP14

MULTIPLE INDICATION PRICING, REIMBURSEMENT AND FUNDING DYNAMICS: THE CASE OF ORPHAN INDICATIONS

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OBJECTIVES: Indication expansion is a commonly utilized strategy to maximize return on investment for novel pharmaceuticals. As orphan drug designation can confer pricing, reimbursement and funding benefits, such indications can provide attractive targets for launch or follow-on indications. We aim to understand how expansions into or out of orphan indications affect a product's total pricing and reimbursement opportunity. **METHODS:** Centering our research on orphan indications, we explored three potential scenarios that could be reached when expanding a products indication (from highest to lowest frequency of occurrence): 1) Orphan (current) to Orphan (indication expansion); 2) Non-Orphan (current) to Orphan (indication expansion); and 30 Orphan (current) to Non-Orphan (indication expansion). We conducted analogue analysis across a variety of key global markets to understand the implications on pricing and reimbursement for a product moving between these groupings. **RESULTS:** The analogue analysis indication expansion between orphan indications is relatively common, particularly in oncology. Expansion in this way did not significantly impact product funding or access restrictions, although pricing can be affected by the increased patient population size. Further-

more, regulatory requirements stipulate that a new orphan status application must be submitted for each indication. Under EMA regulations, orphan and non-orphan indications cannot be granted under the same marketing authorization. Although expansions between orphan and non-orphan indications are more common in the US, no examples of expansion from a non-orphan to orphan indication were identified by the authors. **CONCLUSIONS:** While indication expansion between orphan indications is relatively common, examples of expansion into or out of orphan indications are less frequent due to the regulatory restrictions. Pricing and reimbursement dynamics in all cases are reflective of the trade-offs between price potential and population size across indications.

PHP15

PRICE NEGOTIATIONS IN KOREAN PHARMACEUTICAL BENEFIT SYSTEM: HOW COMPATIBLE WITH CEA?

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OBJECTIVES: Korea introduced a new positive list system in 2007 together with a price negotiation procedure. Importantly, these two systems are run by two different, independent organizations, namely the Health Insurance Review & Assessment Service (HIRA) and the National Health Insurance Corporation (NHIC). HIRA reviews the cost-effectiveness data in submissions and makes listing decisions, then NHIC takes over and sets the reimbursement price via negotiations with manufacturers. The aim of this study is to compare the difference in price after cost-effectiveness appraisal by HIRA and price negotiation by NHIC, and to analyze the factors that NHIC has considered to determine the reimbursement price. **METHODS:** All 35 submissions made to the NHIC between August 2007 and June 2008 were reviewed. 19 submissions concluded with agreement, 15 failed and one case was suspended. In this review only 15 cases of successful negotiations were included. The level of the reimbursement price compared to the submitted price for both essential drugs and non-essential ones and factors affecting the final price were analyzed. **RESULTS:** The discrepancy between reimbursement price and cost-effective price was about 12.33±11.44% on average. For 3 essential drugs, the price level was almost equal to the submitted price whereas the average level was 84.94 ±11.21% of the cost-effective price for non-essential drugs. The major factors affecting negotiations to determine the final price were narrowed down to total cost of substitutes, the foreign price, and the pharmaceutical budget impact. **CONCLUSIONS:** Our findings have demonstrated that drug pricing within the new environment has been done independently of cost-effectiveness appraisal. The payer has exhibited limited bargaining power for essential drugs. Overall, 87.67% of the cost-effective price was accepted during price negotiations, and the total cost of substitutes, foreign prices and pharmaceutical budget impact were considered equally when fixing the reimbursement price. A limitation of this study is that the result may not be generalized because of insufficient cases.

PHP16

EXTRAPOLATING STRATEGIC INSIGHTS THROUGH MARKET SEGMENTATION: A CONCEPTUAL FRAMEWORK

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OBJECTIVES: Primary research is often only conducted in a limited number of key markets despite a product being launched across a wider range of countries. In order to understand the implications of research findings across geographies, markets can be grouped by common underlying factors. **METHODS:** Market segmentation frameworks were developed based on key decision drivers which can be applied at different points in a product lifecycle. Within each framework, markets can be segmented in up to two domains to distinguish segments. In-depth secondary research was conducted in EU27 markets to understand key pricing, reimbursement, access and uptake processes. Qualitative analysis of these findings permitted us to place markets in the segmentation framework, allowing extrapolation of findings across similar markets. **RESULTS:** Markets can be segmented in several domains, depending on areas of interest for the research in question. For example, in the case of peri-launch segmentation, most new pharmaceuticals aim to secure optimal pricing and reimbursement – therefore an understanding of similarities and differences in these areas are of greatest interest. Markets can be assessed in terms of HTA data requirement, degree of centralization of decision making, pricing regulations (fixed vs. 'free' pricing) or pricing decision drivers. This approach was applied to understanding market similarities for a novel, hospital administered product in a rare disease area. All 27 EU markets were segmented by level of price regulation into three groups: price set by manufacturer, price set through negotiation or strict price regulation. Understanding pricing drivers in each group allowed results from primary research undertaken in only 6 of these markets to be used by the manufacturer in all EU27 markets. **CONCLUSIONS:** Applying these conceptual frameworks to drive market segmentation, key similarities and differences between markets can be used to extrapolate findings from primary market research, or determine what strategic options are applicable to a given market.

PHP17

CHARACTERISTICS OF HIGH COST AMBULATORY DRUGS IN FRENCH HEALTH CARE SYSTEM

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OBJECTIVES: In 1994, in French health care system, a supplement status for ambulatory reimbursement drugs, called "exception drugs", was established. This status enables to reimburse only specified indications of particularly costly drugs. In this study we analyze what characteristics a drug should possess in order to be considered as an "exception drug". **METHODS:** Included in the study, were drugs that had status of "exception drugs" as of April 2011. The clinical (actual benefit, improvement of actual benefit) and economic (amount reimbursed by National Health Insurance) characteristics were collected from official and publicly available websources, as well as supplement restrictions for prescription (any prescription or only the first one must be accomplished by a hospital practitioner; prescription must be accomplished by a specialist; or prescription requires specific following during the treatment). **RESULTS:** As of April 2011, there were 56 "exception drugs" in trade name and 30 in generic name. The drugs from 9 ATC classes level I were presented; the most numerous were A16 (Other alimentary tract and metabolism), H01 (Pituitary and hypothalamic hormones and analogues), B03 (Antianemic preparations). Supplement restrictions for prescription was applied to 33 drugs. Some "exception drugs" (10) had also the status of drugs financed out of DRG payment system. Most of the drugs, 91.07% (51/56) had high level of actual benefit. Around half of the "exception drugs", 42.86% (24/56) had level of improvement in actual benefit from I to III. In 2009, part of reimbursed amount of "exception drugs" was 7.73% from all reimbursed drugs, whereas in 2004 it was 2.85%. Interestingly, in 2009 four "exception drugs" constituted about 1% of the reimbursed amount each, and 40 – less than 0.1%. **CONCLUSIONS:** The analyzed types of characteristics, both economic and clinical, can be used as criteria for establishing the status of "exception drug".

PHP19

DOES PHARMACEUTICAL PRICE REGULATION AFFECT THE ADOPTION OF GENERIC COMPETITION IN THE OECD?

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OBJECTIVES: Generic competition is an effective cost-containment mechanism that improves static efficiency and stimulates pharmaceutical innovation. No prior study has empirically analysed the relative delays in adoption of generic competition within the OECD. This study aims to investigate how price regulations in the OECD affect timing of generic adoption following the first global generic launch. **METHODS:** Drawing upon data from 1999 to 2008, we estimate the impact of ex-ante price and market size expectations on the probability of generic launch using discrete-time duration modeling with cloglog and logit regressions. The econometric strategy employs both parametric and non-parametric duration dependence and includes controls for local generic competition, firm characteristics and molecule heterogeneity. **RESULTS:** Ex-ante profit expectations result in faster adoption; both expected price and market size increase the probability of launch. Our findings suggest that neither molecule nor firm characteristics have a significant effect on generic adoption across different specifications. **CONCLUSIONS:** Evidence indicates that regulation has a significant impact on timing of adoption; however, generic competitors tend to follow a locally oriented strategy in contrast to research-intensive pharmaceutical firms.

PHP20

MARKET ACCESS BARRIERS FOR BIOSIMILARS IN SPAIN AND GERMANY: EPOETIN ALFA EXAMPLE

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OBJECTIVES: Biosimilars are predicted to reduce prices of biologicals. Among biosimilars, epoetin alfa has the largest market penetration in Germany and Spain. The aim of this study was to describe the political, technological, economical and social factors that impact on epoetin alfa sales and price in both European countries, which greatly differ in their generic market size. **METHODS:** Revisions of regulatory legislation and policies regarding biosimilars at country and European levels have been conducted. Estimations of market shares in units for epoetin alfa originator and biosimilars plus darbopoetin alfa, a second generation biological, were calculated. Epoetin alfa pricing trend was followed. All data was extracted from IMS MIDAS database, using standard units and ex-manufacturer price. **RESULTS:** Both countries are under the same regulatory framework and have policies that promote generic penetration, although automatic biosimilar substitution is banned. Price of first launched biosimilar was approximately 30% below originator price in both countries. In Germany, originator price decreased about 16% after launch of second biosimilar, whereas in Spain, originator price trend have no changes to date. Regarding originator market shares, they did not change after launch of biosimilars in Spain, while in Germany marked reductions were observed along with biosimilars market share increases. In Spain, market shares of darbopoetin alfa were reduced when epoetin alfa biosimilar sales started, but no changes of the kind were documented in Germany. **CONCLUSIONS:** Although both countries face similar political and technological factors; in Spain, social and economical ones could negatively impact stakeholder perception. In this country, the introduction of biosimilars do not modify market share of the originator despite it has a price about 30% higher. In Germany, stakeholders pose minimum resistance to biosimilars, as market share and price of originator are immediately reduced after the entry of biosimilars.

PHP21

ADOPTION OF NEW MEDICINES IN THE OECD: REGULATION, INNOVATION AND SCALE

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OBJECTIVES: Most OECD countries employ pricing controls to contain rising health care expenditures. The recent financial crisis has resulted in further pressure to