ON May 2010 Greece reached an agreement with a joint team of the International Monetary Fund, the European Commission and the European Central Bank, to correct severe fiscal problems. According to the Agreement, public pharmaceutical expenditure should be reduced from 1.9% to 1% of GDP, while the reduction on health services and social security expenditure should be accounted for 1.5 billion euros and 1.2 respectively. The aim of the study was to evaluate the impact of the measures taken in order to improve the past health expenditure and provision of services. METHODS: For the purpose of the study, we used data from the Stand-By Arrangement and its reviews, Hellenic Statistical Authority and Greek System of National Accounts, as well as published data in the literature to calculate costs of wages in public and private sector. RESULTS: The increase of unemployment (from 9% to 15%) resulted in increased demand for public hospital care by 24% as a consequence of reduced demand (>30%) in hospital units of private sector, while a decrease in demand for primary health care in both public and private sector by 10% and 35% respectively was observed. In addition, the cost of time in public hospitals is steadily increased, due to surgical interventions and the use of high technology services, as well as because of reductions on hospital budgets for medical equipment procurements. CONCLUSIONS: Although the impact of the implemented reforms and policies in private health expenditures is already visible for the significant reduction of health services inputs causes a decrease in quantity and quality of services. The need for balanced development relating both to supply and demand side requires structural reforms in healthcare sector as well as transition from a costly technological model to a health system based on primary care and public health.

IN SEARCH OF REFORM FOR THE GREEK HEALTH CARE SYSTEM: DEPICTING THE KEY OPINION LEADERS’ VIEWS

Tsiantou V, Athanasakis K, Favi E, Kyriopoulos J
National School of Public Health, Athens, Greece

OBJECTIVES: Financial crisis in Greece raised the need for more efficient use of resources in the health care sector. A number of policies have been proposed for this purpose. The aim of this study was to investigate the views of healthcare Key Opinion Leaders (KOLs) on the proposed interventions. METHODS: Seventy-two KOLs were invited to participate in an expert panel survey. For the purpose of the study, a closed questionnaire was developed comprising of six sections based on the proposed policies i.e. audit, economic evaluation, financial management, pricing, health care funding and procurement system. During the meeting KOLs were asked to select the answers that best represented their views on the appropriateness/feasibility of each policy under study and express their opinion in an open discussion that followed. RESULTS: Forty experts (55.5%) accepted the invitation. The majority of participants argued that audit is necessary in the health sector but half of them believed that at present it is not feasible. They thought that a certified public institution should be responsible for the audit process. The indicators and standards to be set have to be the same, generally recognized locally. Very interesting was the finding that the audit report should be a criterion for each institution’s (hospital) funding and if results are negative then a penalty should be imposed. Implementation of economic evaluation in decision-making was considered extremely important in the hospital’s financing was reported as necessary and the most suitable reimbursement technique is a combination of global budget and DRG system. Physicians should be reimbursed based on qualitative criteria. Finally, procurement system should and can be reformed immediately according to the expert panel. CONCLUSIONS: All proposed interventions were evaluated positively but experts considered that is a greater need for surgical mechanism and reform of the procurement system to be implemented first.

Landmark CER Study Methods Reviews

Cummins G, Britton K, Doyle J
National School of Public Health, Athens, Greece

OBJECTIVES: To identify and characterize publicly available cases and related treatment options to multiple stakeholders. Payors have experience utilizing self-generated CER information to inform policy decisions including: formulary tier place, prior authorization requirements, other utilization control techniques, and cost control mechanisms. However, wide acceptance and regular use of CER has yet to be fully realized. The Quintiles New Health Report 2011 survey assessed how and to what extent national payors were receptive to the implementation of CER. METHODS: The New Health Report 2011, designed by Quintiles, surveyed multiple stakeholders to better understand each stakeholder’s perceptions toward health care, focusing on perceived value. More than 200 biopharmaceutical executives, 133 managed care executives, 500 physicians, and 30 MCOs were sampled in the survey. The focus was payor perspective in relation to value and CER. RESULTS: Thw vast majority of payors valued CER and vocalized their desire for more CER data, fewer than half of payors actively promoted CER on their websites or in published literature. Some payors do advocate and sometimes require CER from manufacturers, 85% of surveyed payors utilized self-generated CER data rather than data provided by manufacturers. Biopharmaceutical executives were overwhelming in agreement to invest more in long-term outcomes data, but only 44% had even access readily available outcomes data to demonstrate value, while 48% admitted that they did not have any access at all to CER information. CONCLUSIONS: A large percentage of payors recognize the short/long term value and utility of CER data, but are not accessing the available data and/or are not sure how to access the data. To encourage greater utilization of CER, stakeholders must be more assertive in capturing and evaluating CER information, while partnering together to create more transparent and standardized CER guidelines.

THE BURDEN OF EVIDENCE IN THE PHARMACEUTICAL APPRAISAL PROCESS

Carlson Medical Consulting, Cambridge, UK

OBJECTIVES: The emergence of evidence-based medicine (EBM) in the past decade has raised the level of the scientific data required during the drug appraisal process. It is no longer sufficient to prove that a new treatment is better than placebo in one clinical trial; healthcare decision makers additionally require information on how it performs in multiple trials, including against other treatments in the same disease area. Systematic reviews, meta-analyses, comparative effectiveness studies and head-to-head trials are becoming essential in the appraisal process as decision makers demand higher levels of evidence from manufacturers. This analysis reviews the number of PubMed articles indexed by PubMed over the period was 6.0%, which represents the background increase in the body of scientific evidence. In contrast, the mean annual change for systematic reviews was 27.4% (from 388 in 2001, to 3406 in 2010), 23.2% for meta-analyses (462 to 2,996), 80.5% for comparative effectiveness studies (5 to 247) and 23.1% for head-to-head trials (11 to 53). These increases are all substantially higher than the background increase in PubMed articles. The increase in comparative effectiveness studies in particular illustrates the strength of interest in this area of research. CONCLUSIONS: EBM is now accepted globally as the preferred method of appraising new treatments, as the pharmaceutical industry adapts to this landscape, the number of studies examining the evidence base has increased considerably in the past decade. The next movement in the industry has already arrived, that of direct comparative effectiveness, and whilst the number of head to head studies has already increased we can expect to see further increases over the next decade.

CURRENT STATUS AND TRENDS IN PERFORMANCE-BASED SCHEMES BETWEEN HEALTH CARE PAYERS AND MANUFACTURERS

Carlson G1, Gries K2, Sullivan SD3, Garrison L3
University of Washington, Seattle, WA, USA, 1University of Washington Department of Pharmacy, Seattle, WA, USA

OBJECTIVES: To identify and characterize publicly available cases and related trends for performance-based schemes. METHODS: We performed a systematic review of performance-based schemes over the past 15 years (1996 – 2011) using publicly available databases and reports from colleagues and healthcare leaders. These were categorized according to a previously published taxonomy of scheme types and assessed in terms of the underlying product and market attributes for each scheme. Macro-level trends were identified and replicated across the scheme adoption, countries involved, types of schemes, and product and market factors. RESULTS: Our search yielded in excess of 110 schemes. From this set, we identified:
58 schemes that included a coverage with evidence development component, 25 that included a conditional treatment continuation component, 35 that included a performance-based component, and 37 that included a patient level financial utilization component. Each type of scheme addresses fundamental uncertainties that exist when products enter the market. There has been a continued upward trend in terms of total schemes adopted per year and the number of countries that have implemented performance-based schemes. Despite the continuing optimism, challenges persist including those related to 1) the cost and burden of implementation; 2) the need for consistent processes for scheme development, data collection, reporting, and evaluation; and 3) negotiating follow-on agreements after scheme initiation. Thenceforward, the challenges faced differ by country, health system, and project.  

CONCLUSIONS: There is continued enthusiasm among countries for using performance-based schemes for new medical products. Given the interest to date and the potential to meet the goals of interested stakeholders, these schemes may become a common element in health care coverage and reimbursement strategies. Further investigations into the challenges and their impact on the results and experiences with the schemes implemented thus far are needed.

PHP147 OPINIONS ON MARKET ACCESS NEEDS DIFFER BETWEEN CULTURES AND STAKEHOLDER SECTORS – RESULTS OF A SURVEY OF ISPOR DELEGATES  

Koral A, Johnson KI  
Complete Medical Group, Macclesfield, Cheshire, UK  

OBJECTIVES: To determine whether stakeholders’ opinions on market access issues, in particular the need for QALYs, and risk-sharing, differ by sector and geography.  

METHODS: A self-completion questionnaire was prepared and distributed to a cross section of delegates at the 13th European ISPOR Conference 2010. The questionnaire comprised 7 items, with both ordinal-polynomial Likert scales and open ended responses. Analyses were performed to discriminate between the stakeholder groups by using cross-tabulation tests, Chi-square tests for independence, and other descriptive statistics for nominal categorical data. The level of agreement between responder groups was obtained from Cohen’s Kappa coefficients and radar plots.  

RESULTS: Respondents included representatives of over 60 companies and organisations from over 30 countries. Highly significantly different responses were observed between members from European and non-European countries, with the greatest overall level of agreement being between the industry and academic sectors (87.5%, K = 0.75). Fewer respondents from European countries favoured the use of the QALY than those from non-European countries (31.8% vs. 69.2% respectively). More academic/risk-sharing respondents from non-European countries favoured the QALY than exclusive industry/risk-sharing or agency respondents (62.1% vs. 36.6% vs. 21.4% respectively). More academics felt that manufacturers should offer patient access schemes (PAS) routinely (41.4% vs. 19.4% vs. 14.3%). Of non-European respondents, 50.0% felt risk sharing should form part of all health technology assessments compared with only 25.0% of respondents from European countries. The majority of non-European respondents (53.8%) expressed the need for manufacturers to provide PAS routinely, only 16.3% of European respondents agreed. Only 13.3% of respondents from European countries thought indirect comparisons are a substitute for head-to-head trials, compared with 36.6% of respondents from non-European countries. No other significant differences in opinions on the need for cost-utility analysis or cost-per-QALY thresholds were found.  

CONCLUSIONS: Opinions on market access related issues differ significantly between European and non-European ISPOR members, and between stakeholder groups.

PHP148 GLOBAL PHARMACEUTICAL RISK-SHARING AGREEMENT TRENDS IN 2010 AND 2011  

Ando G1, Reinaud F2, Bharath A2  

OBJECTIVES: With payers increasingly looking at ways of cutting pharmaceutical reimbursement costs, pharmaceutical companies need to consider creative solutions to market access for new compounds. The objective of this research was to examine the most recent global trends for 2010 and 2011 in pharmaceutical risk-sharing agreements, which are now a critical part of market access strategies in many countries. METHODS: Secondary research was conducted examining reimbursement decisions around the world, with a special focus on Australia, Belgium, Canada, China, France, Germany, Hungary, Italy, The Netherlands, New Zealand, Poland, Spain, UK and United States. This was supplemented by primary research with payers, government agencies and HTA organisations through interviews in native languages to understand the role which risk-sharing agreements have – or have not – played in their respective markets. RESULTS: Forty-five new risk-sharing agreements were found under the period of review (January 2010-May 2011), nearly double the total for 2005. Of the new agreements, the majority were performance-based agreements, though there were six new examples of performance-based agreements. 40% of the new agreements were concluded with the UK’s NICE, whilst Australia and Italy remain other important markets in this area. However, a significant number of newer countries are beginning to see these agreements, including Belgium, Bulgaria, Canada and New Zealand. The majority of new agreements were concluded between pharmaceutical companies and key market makers. Analysis of market trends over time. Around half of the agreements were in the oncology area, but there are signs that risk-sharing is becoming increasingly prominent in other therapeutic areas, including blood disease, mental health, pain treatment, immunology, ophthalmology and cardiovascular care. CONCLUSIONS: Risk-sharing agreements are a reality for pharmaceutical companies in many key markets, and need at least to be considered as an alternative market access strategy in certain therapeutic areas.

PHP149 NEGOTIATION OF PHARMACEUTICAL COMPANIES ON THE DRUG PRICE-VOLUME NEGOTIATION IN SOUTH KOREA  

Kim E1, Lee B2, Lee EK2  
1GlaxoSmithKline Korea, Seoul, South Korea; 2Sookmyung Women’s University, Seoul, South Korea  

OBJECTIVES: In Korea, although drug price has continuously decreased due to many price reduction mechanisms, the volume has been increasing. Because this risen volume is considered a main contributor of increasing pharmaceutical expenditure, government adopted price-volume negotiation in 2008. This study attempted to analyze the status of price-volume (PV) negotiation and identify problems and the solutions to improve the price-volume negotiation. METHODS: The comprehensive questionnaire was designed based on Korea price negotiation guideline which was validated by three pilot interviews. On the basis of status, awareness, satisfaction, problems/solutions. Pharmaceutical company’s people involved in market access were interviewed face-to-face. The response rate was 80% (n=34). Multinational and local company accounted for 59% and 41%, respectively. RESULTS: Most important factors for PV negotiation were budget impact and price from the Korean PV formula. 69% of 16 PV cases were derived from the price calculated by PV formula and only 42% reached the consensus on budget impact because of different data sources. Most respondents agreed with the objective of the risk-sharing system but the overall satisfaction was significantly low, 1.9 out of 5-point scale. Main reasons are unpredictability of selecting PV product, discreditable NHIC data and non-transparency of the negotiation process. Also, 76.5% of respondents was against PV negotiation because of the government’s unnecessary interventions and concern on weakening the pharmaceutical industry. Especially, respondents worried about profit deterioration due to duplicated price reduction. In response, they suggested the advanced PV model with a more specific PV inclusion criteria and the choice between price reduction and pay-back. Additionally, generic promotion and pay-back system activation to contain the drug cost is required. Furthermore, price-volume negotiation in Korea must be improved to motivate the pharmaceutical industry through adopting their opinions on advanced PV model which includes pay-back.

PHP150 PHARMACEUTICAL PRICING UNDER UNCERTAINTY: RISK-SHARING CONTRACTS  

Rodriguez-Ibeas B1, Arizti I2, Antonanzas F3  
1University of La Rioja, Logroño, La Rioja, Spain; 2Fundación Rioja Salud – CIBER, Logroño, La Rioja, Spain  

OBJECTIVES: Pharmaceutical pricing decisions are adopted in a context of uncertainty with regard to the efficacy and safety of the drug as well as to their budgetary implications. Traditionally, pharmaceutical firms have received a fixed price per unit sold regardless of health outcomes and sales volume. This pricing policy tends to increase health budgets and may restrict the access to pharmaceutical innovations for patients. Recently, health authorities have begun to use risk-sharing contracts based on health outcomes to cope with the aforementioned problem. In this paper, we carry out a theoretical modelling of the risk-sharing contracts, emphasizing the variables and parameters that are relevant in the relationship between health authorities and pharmaceutical firms. METHODS: We have elaborated a theoretical model that describes the interaction between a pharmaceutical firm and a health authority. In the first stage of the game, the health authority chooses the pricing policy, either paying to the firm for treated patient or for cured patient, and in the second stage, the firm, given the pricing policy and the prescribing behaviour of the physicians, selects the price that maximizes its expected profit. We solve the risk-sharing contracts using the fitted equilibrium as the solution concept. RESULTS: Risk-sharing contracts are not always optimal in terms of social welfare. Their optimality depends on the parameters of the problem, being conditioned by the prescribing behaviour of the physician, the efficacy of the drug and the monitoring costs. We characterize the parameters for which each pricing policy is socially optimal. CONCLUSIONS: Before using risk-sharing contracts, their convenience must be addressed for each particular case. As a necessary condition, the existence of objective quantitative health indicators is required. Otherwise, it is difficult to implement the pricing policy only based on cured patients.

PHP151 EVIDENCE ON THE IMPACT OF MANAGED ENTRIES ON PATIENTS, PATIENTS, MANUFACTURERS, AND HEALTH CARE WORKERS  

Ferrario A, Nicod E, Kanavos P  
London School of Economics and Political Science, London, England, UK  

OBJECTIVES: Managed entries (MEs) are innovative pricing and reimbursement agreements aiming to share the risk related to the introduction of new, high-cost drugs between the payer and the manufacturer. This study aims to review evidence on the impact of MEs on payer, patients, manufacturer, and health care workers and to analyse emerging trends in managed entries at international level. METHODS: A systematic literature review (grey and peer-reviewed) was performed complemented by search of health technology assessment agency’s websites and selective review of the key decision makers in key European countries. RESULTS: Evidence exists of improved cost-effectiveness and lower drug price following the implementation of coverage with evidence development in Sweden. Data from France shows that price-volume agreements led to rebates totalling around 3% of the total drug bill. Evidence from Italy shows that authorization with a risk-sharing agreement was associated with more rapid patient access in comparison to authorization without such an agreement. It is unclear whether managed entries