S8 schemes that included a coverage with evidence development component, 25 that included a conditional treatment continuation component, 35 that included a performance-based scheme 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 adopting the performance-based schemes. Despite the continued enthusiasm, 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. Furthermore, the challenges faced differ by country, health system, and product. CONCLUSIONS: There is continued enthusiasm for 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. However, further international cooperation is needed regarding the attitudes and perceptions of various stakeholders as well as evaluating the results and experiences with the schemes implemented thus far.

PHP147 OPINIONS ON MARKET ACCESS NEEDS DIFFER BETWEEN CULTURES AND STAKEHOLDER SECTORS – RESULTS OF A SURVEY OF ISPOR DELEGATES
Koyal A, Johnson KI
Complete Medical Group, Maclesfield, 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 presented 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 sectors: industry, public health system, 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%). More significantly, a higher proportion of respondents from non-European countries adhered to the QALY than expected (K = 0.75). More academically oriented respondents expressed the need for manufacturers to provide PAS routinely; only 16.3% of European countries (expected to be 28.5%) 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 34.7% 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 A3
OBJECTIVES: With payors 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 payors, 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 2009. Of the new agreements, the majority were performance-based agreements, with 6% of the agreements being performance-based. 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 IDENTIFICATION OF PHARMACEUTICAL COMPANIES ON THE DRUG PRICE-VOLUME NEGOTIATION IN SOUTH KOREA
Kim E1, Lee B2, Lee E3
1GlaxoSmithKline Korea, Seoul, South Korea, 2Seokmyung 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 major contributor of increasing pharmaceutical expenditure, the 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 guidelines and validated by three pilot interviews. To verify the 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 unwillingness in negotiations and PV formula 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 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 drugs price increase are pre-eminent mechanisms for future considerations. The 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-ibias R1, Azizi P2, Antonanzas F2
1University of La Rioja, Logroño, La Rioja, Spain, 2Fundación Rioja Salud - CIBIR-, 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 two-stage game 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 game backward using the perfect equilibrium as the solution concept. RESULTS: Risk-sharing contracts are not always optimal in terms of social welfare, and their optimality depends on the parameters of the problem, being conditioned by the prescribing behaviour of the physicians, the efficacy of the drug and the monitoring costs. We characterize the parametric regions 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
Ferraro 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 supplemented by search of health technology assessment agency’s websites and subsequent reviews with 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 drugs 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
constitute a reward for manufacturers, however, various benefits have been reported such as reimbursement for drugs which received an initial negative recommendation (e.g. botremizum and trabectidine, UK) and competitive advantage in the form of better formulacy position (sitagliptin & metformin, USA); not to mention the possibility of granting discounts while leaving list prices untouched. Considerable administrative burden is placed on health care staff due to the diversity of existing schemes, the complex nature of PAS reimbursement, and lack of management capacity at current staffing levels.

CONCLUSIONS: Although evidence on the impact of PAS is patchy, the systematic literature review showed that there are already lessons to be learnt. Preliminary findings seem to suggest that PAS have indeed the potential of meeting payer, patient, and manufacturer expectations, yet important threats such as implementation difficulties, administrative burden and lack of management capacity need to be addressed.

PHP152
THE ADMINISTRATIVE BURDEN OF PATIENT ACCESS SCHEMES IN THE CHANGING UK HEALTH-CARE SYSTEM: A FOLLOW-UP STUDY
Haynes S1, Timb B2, Hamerslag L3, Costello S2
1Costello Medical Consulting Ltd, Cambridge, UK, 2Costello Medical Consulting, Cambridge, UK

OBJECTIVES: In the UK, Patient Access Schemes (PAS) have become common in health technology submissions, and have been instrumental in enhancing the availability of otherwise non cost-effective treatments. Despite notable efforts towards recognising and reducing the administrative impact of PAS on frontline staff, evidence suggests that they still result in a significant burden. The study presented here aimed to assess the burden of PAS administration, and how this could change if and when the planned changes to the UK healthcare system are enacted. METHODS: A literature search was conducted and freedom-of-information requests were sent to the Patient Access Scheme Liaison Unit (PASLU) for data on PAS administration. A questionnaire developed from our previous pilot study on the administrative burden of PAS was distributed to hospital pharmacists across the UK, and a call for participants was hosted on the Royal Pharmaceutical Society website. RESULTS: Value Based Pricing (VBP) is expected to be introduced in the UK within the next 12 months. The Pharmaceutical Price Regulation Scheme comes to an end and PAS approved before this point will continue to be used, although additional PAS may not be introduced under VBP. It is unclear from the available literature how this will affect the role of PASLU and the administration of the remaining PAS. The return-rate for our questionnaire was low; however, responders voiced similar concerns to those related in our pilot study namely the poor recognition of the burden of PAS and the resources required to manage them. Responders were also unclear about how administration of PAS would change with the move to VBP. CONCLUSIONS: The role of PAS in the changing NHS, and the burden such schemes could have is uncertain. Clear guidelines on the impact of healthcare reform are necessary, alongside additional support to facilitate effective PAS implementation even after VBP is introduced.

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PHP153
SOME SHORTAGES AND ALTERNATIVES TO THE PATENT SYSTEM FOR PHARMACEUTICALS
Antonanza P1, Juarez-Castello CA, Rodriguez-Ibarra R
1Pharmaceuticals, La Roja, Spain

OBJECTIVES: Pharmaceutical patents have been a useful instrument to promote innovations in some fields. The signature of the TRIP agreement by the World Trade Organization (WTO) in 1994 has implied the generalization of a strong patent system. The objectives of this study is to review some existing alternatives to patents that may both reduce their negative impact in the accessibility to new drugs of patients from less developed countries and promote research in neglected diseases. METHODS: We have reviewed the literature on this field and identified different alternatives proposed by international institutions as well as by non governmental organisations. We describe the options and their potential impact on public health. RESULTS: There are several proposals: i) the intensive use of exceptions and flexibility conditions of Doha’s Declaration, especially, compulsory licensing, ii) the volunteer licensing through the “patent pool”, iii) GSPOA initiative that targets the identification and assessment of priorities dealing with R&D referred to diseases prevalent among the developing countries, iv) the approach based on prizes, aiming to incentive innovation through competition by separating the cost of R&D and the price of the drug, v) the Advance Market Commitments to ex-ante obtain the commitment to fund the donations the new agent once it has been developed, and vi) the Priority Review Vouchers that provides incentives to invest in drugs for neglected tropical diseases by offering a transferable voucher to the pharmaceutical firm that allows a priority review process for the authorisation of another agent. CONCLUSIONS: Most of the solutions are partial and do not pursue a radical change in the current patent system. In spite of these proposals, there are still many diseases with no treatment as the market does not guarantee a return.

PHP154
IRANIAN HEALTH SYSTEM DECENTRALIZATION REFORM: A QUALITATIVE STUDY ON THE VARIOUS LEVELS OF AUTONOMY GRANTED TO PUBLIC HOSPITALS AFFILIATED WITH MINISTRY OF HEALTH IN IRAN
Jafarinezhad M1,2, Ibrahimipour H1, Dehnavi-Tjangi R1
1Tehran University of Medical Sciences, Tehran, Tehran, Iran, 2Mashhad University of Medical Sciences, Mashhad, Khorasan, Iran, 3Kerman University of Medical Sciences, Kerman, Kerman, Iran

OBJECTIVES: We aimed to explore the key organizational elements and the degrees of autonomy that is granted to Iranian corporitized hospitals (trustees hospitals) affiliated with the Ministry of Health after the Iranian health system decentralization reform. METHODS: All 18 Iranian corporitized hospitals (that meet our criteria) involved to the study. In all, 27 Hospital Top Managers were interviewed (82% response rate). The semi-structured interview questions were developed using the “pre- and post-reform knowledge models”, the “framework” method was used for the analysis. RESULTS: Nine themes explain the key organizational elements include: decision right in “strategic”, “human resources”, “financial” and “physical resources” management, “product” and “process” related, “market” expansion, “residual claimant” and “social functions”. Decision right in “strategic”, “human resources” and “physical resources” management was very limited. The hospitals were permitted to generate revenue (fee-for-services) but weren’t the residual claimant, completely. The hospital was exposed to product market but limited in the type of product that can be purchased. Decision right in “physical and financial resources” was the main accountability mechanism. Several insurance programs and governmental budget were used to protect poor people. CONCLUSIONS: We can see a kind of unbalanced and inconsistent autonomy. More decision right in “strategic” and “human resources” management, and procurement market should be granted, and also the hospital needs to be the residual claimant. Government needs a regulatory and accountability mechanism to guarantee hospitals performance and balance the revenue generating and social values objectives.

PHP155
REVIEW OF COST EFFECTIVENESS MODELS OF HIGH BUDGET IMPACT DRUGS
Agarwal S
Novel Health Strategies, Bethesda, MD, USA

OBJECTIVES: The recently made coverage decisions by UK’s NICE, Scotland’s SMC and Canada’s ICER have provided a comparative ‘holy grail’ to US policy makers. In the United States, strong indicators of trends in pricing and reimbursement that are likely to be observed in the future. To gain an additional insight into these trends, we analyzed the cost effectiveness studies for the top twenty highest selling drugs (>$90-100B worldwide sales). METHODS: The Top 20 drugs were selected based on their worldwide sales. For this analysis, we segmented these drugs into categories as primary care, specialty, small molecules, biologics, therapy areas and availability of generic alternatives. We analyzed the cost effectiveness studies that were published in peer-reviewed journals. Search was conducted using generic names of the drugs and the phrase ‘cost effectiveness’ in abstract of the published study. RESULTS: During 2005-2010, the number of published studies on ‘cost effectiveness’ has increased by more than 30%. There is a large variability in CERs for same drug for different indications, in some cases also varying by biomarkers. Primary care drugs had lower and less variable CERs than specialty drugs. Variations also exist in methodology used by different groups in modeling cost effectiveness, especially for time horizon and comparator. Majority of primary care drugs were modeled for a time horizon of 35-40 years or lifetime to demonstrate cost effectiveness. CONCLUSIONS: This analysis shows the range, variability and methods used for calculation of ICER values for these high budget impact drugs and provides lessons for executives and policy makers.

PHP156
NOVEL DRUG REIMBURSEMENT MODELS: LESSONS AND IMPLICATIONS FROM CANCER DRUG ACCESS SCHEMES
Agarwal S
Novel Health Strategies, Bethesda, MD, USA

OBJECTIVES: Cancer drugs are the world’s highest selling category of therapeutic products. As these products are high budget impact drugs, reimburrsement models have been implemented worldwide by public and private payers. These models have potential implications for coverage and reimbursement of all branded products. This study reviewed recent cancer drug reimbursement models and developed lessons and implications for future products. METHODS: We reviewed cancer drug reimbursement schemes in developed and emerging markets. Interviewed payers and KOLS to develop lessons and implications for future products. RESULTS: Public and private payers worldwide have implemented several new models for cancer drug reimbursement to manage budgets and control costs. In the US, private payers are piloting single source compendia and third party protocols (e.g. P4 Oncology) to limit offset-label use of cancer drugs. In the UK, NICE has successfully negotiated lower price and discounts for first few cycles of therapy. In Italy, AIFA has implemented registry based pricing for some oncology drugs. In India, several manufacturers have implemented novel pricing strategy for first few cycles of therapy. In Germany, IQWIG has proposed to use correlations between surrogate endpoints and patient relevant outcomes to determine value of cancer drugs. Due to increased cost pressure on payers, such models are likely to inspire novel reimbursement schemes for other branded products. CONCLUSIONS: Cancer drug reimbursement models are setting new benchmark for payers to manage access and control costs. These models have significant implications for other expensive branded products.

PHP157
USING THE CEAC FOR VALUE BASED PRICING: DON’T CHANGE THE GOALPOSTS
Roberts G
Double Helix Consulting, London, UK

ISSUE: One approach under consideration for the proposed value based pricing of pharmaceutical is the UK is to have different willingness to pay thresholds. However these are problematic to define, lack transparency and not readily understood by the wider public. OVERVIEW: Different willingness to pay thresholds have been