restraints and objections about the viability of the fund are still a matter of debate, focused particular on the development of a flexible mechanism for primary health care that will ensure equitable access and benefits for members and improve the quality of services.

PHP136

GENERIC PRICE LINKAGE AS A POLICY CHOICE: REVIEW OF RECENT DEVELOPMENTS

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OBJECTIVES: Price capping of generics against the originator (also known as price linkage) has been in use for some time despite studies questioning its efficacy as a cost-containment mechanism. In particular, a 2007 study from Norway – where internal reference and generic price linkage to the originator co-existed for some time - found that both originator and generic prices fell significantly, but the price decline impact was sharper for originator drugs in the reference pricing group than in the price caps group. This study seeks to evaluate if price capping remains a policy of choice in the current austerity climate. **METHODS:** Research focused on a review of current pricing and reimbursement (P&R) regulations for generics in European Union countries and major markets outside the EU to identify which countries have adopted or are in the process of adopting new price caps or have amended existing price caps for generics versus the originator from the start of 2010 to date. The review includes both original laws related to price capping and interpretation of the place of price linkage in each country's pharmaceutical P&R system from secondary sources and from IHS Global Insight's proprietary Same Day Analysis archive. **RESULTS:** France, Portugal, Hungary, the Czech Republic, Romania, Slovakia, Greece, Japan and Canada are among the countries which have recently amended their use of price linkage in an attempt to contain pharmaceutical spending. **CONCLUSIONS:** While price caps remain popular, it is rare for countries to use them in isolation. Internal reference pricing is typically also in use. Among countries which have recently made changes to their price linkage system, Romania, Hungary and Poland have also undertaken changes to their internal reference pricing system, as governments attempt to tackle the cost-containment paradigm from all sides.

PHP137

CHANGES IN THE MEDICINES PRICING AND REIMBURSEMENT APPROACH IN BULGARIA

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OBJECTIVES: To analyze the influence of regulatory changes for medicines pricing and reimbursement on medicines prices. **METHODS:** Regulatory analysis was performed towards the Drug Law, Regulation on positive drug list (PDL), and on medicines reimbursement rules. All medicines affected by the changes were systemized by the way of dispensing and financing. Comparative analysis of the changes in medicines prices before and after 30 of March 2011 was developed as well a year later for absolute and relative change of the prices. **RESULTS:** The pricing and reimbursement processes are controlled by the Pricing and reimbursement committee within MoH. Medicines are separated in two groups according to their price control – with registration of maximal retails prices for OTC and out of the reimbursement list (30 days procedure); and regulation of prices for publicly financed medicines (60 days procedure) by inclusion into the PDL. In the beginning of 2011 the Ministry council initiated regulatory changes. 150 INN of medicines that were financed via the centralized procurement procedures organized by the MoH were separated in 2 groups. 82 INN for outpatient care were transferred to national health insurance fund (NHIF) and 68 for inpatient care to hospitals. For the 82 INN were changed not only the procurement and financing institution but also the way of prices establishment through regulated as reference prices with regressive margins. Only 5 medicines decrease their prices after the transformation, but a year later all medicines decreased their prices. For the medicines transferred to hospitals the biggest hospitals managed to contract lower prices than before but small ones were unable to do so. In general total cost of the supplied medicines weighed by quantity procured was lower than before the changes. **CONCLUSIONS:** Regulatory changes led to positive economic impact but still the long term consequences remain unclear for all medicines.

PHP138

IMPACT OF VALUE BASED PRICING ON FUTURE OF PATIENT ACCESS SCHEMES IN THE UK

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OBJECTIVES: Patient access schemes (PAS) are commonly used in the UK as a way to reduce a drug's Incremental Cost Effectiveness (ICER) per Quality Adjusted Life Year (QALY) ratio and gain NICE acceptance without reducing the list price. With the advent of value based pricing (VBP) in 2014, the role of PAS is expected to change. This study examines if PAS will continue to be used in the UK after VBP is introduced and what their role is likely to be. **METHODS:** Stakeholders involved in the current NICE health technology assessment process were interviewed to understand how PAS use may evolve following the introduction of VBP. Secondary research was conducted of government proposals for VBP implementation, the NICE response to VBP consultation and the current usage of PAS in the UK based on NICE assessments and data from the IHS Global Insight Risk Sharing database. **RESULTS:** With the advent of VBP, the price of a drug should in principle reflect its value taking into account the level of uncertainty related to its efficacy. All drugs that pass the VBP test should, in theory, be reimbursable, thus, eliminating the need for a PAS that adjusts the cost of treatment allowing it to meet the UK's ICER per QALY threshold. Contrary to these expectations, primary research indicates that PAS would continue to be used as payers attempt to secure a price lower than the NICE-set VBP. **CONCLUSIONS:** PAS would remain a fact of life in the UK even after VBP is implemented. This would apply not only for older drugs launched before VBP, but also for new drugs and new indications marketed post-2013 because payers are expected to see the NICE-established VBP as a recommended maximum price and attempt to negotiate that down through a PAS.

HEALTH CARE USE & POLICY STUDIES - Health Care Research & Education

PHP139

WHICH CRITERIA ARE CONSIDERED IN HEALTH CARE DECISIONS? INSIGHTS FROM AN INTERNATIONAL SURVEY OF POLICY AND CLINICAL DECISION MAKERS

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OBJECTIVES: Defining and applying decision criteria are key to accountability and reasonableness in decisionmaking and to ensure the most beneficial allocation of health care resources. Objectives were to gather data on criteria considered by policy and clinical decisionmakers in health care decisions globally. **METHODS:** An online questionnaire was developed with 43 criteria organized into 10 clusters. Using snowball sampling, decision makers were invited by an international task force to report which criteria they consider and how these criteria weighed when making decisions on health care interventions in their context. For each criterion, respondents reported "currently considered", "should be considered" and weight assigned. Differences in proportions of participants reporting consideration of each criterion were explored with inferential statistics across levels of decision (micro, meso, macro), decision-maker perspective, and world region. **RESULTS:** A total of 140 decision makers (1/3 clinical, 2/3 policy) from 23 countries in five continents completed the survey. Most relevant criteria (top ranked for "Currently considered", "Should be considered" and weights) were Clinical efficacy/effectiveness, Safety, Quality of evidence, Disease severity and Impact on health care costs. Organizational and skill requirements ranked high for consideration but low for weights. For a majority of criteria, the number of decision makers reporting that they 'should be considered' was higher than that reporting they are currently considered ($P<0.05$). For more than 75% of criteria, there were no statistical differences in proportions across levels of decision, perspective and world region. Differences in proportions across several comparisons were statistically significant for criteria: Population priorities, Stakeholder pressure/interests, Capacity to stimulate research, Impact on partnership and collaboration, and Environmental impact ($P<0.05$). **CONCLUSIONS:** Results suggest a significant international agreement among decision makers on the relevance of a core set of normative and feasibility criteria and on the need to consider a wider range of criteria in decision-making processes. Areas of divergence appear to be principally related to contextual aspects.

PHP140

CHALLENGES IN THE DATA COLLECTION REGARDING PATIENT POPULATION AND TREATMENT COSTS FOR NON-DRUG INTERVENTIONS USING THE EXAMPLE OF MORBUS DUPUYTREN

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OBJECTIVES: Since 2011, pharmaceutical companies have to submit a benefit assessment dossier for new drugs in Germany. The dossier must contain information about the additional benefit to an appropriate comparative therapy (ACT), costs and the potentially targeted patient population. This work's aim is to display the challenges in collecting the information for Xiapex®, approved for treatment of Dupuytren's contracture in patients with a palpable cord, which was compared to limited fasciectomy. **METHODS:** A systematic literature review, national and international, was used to determine epidemiological figures and cost data. Where no information was available, necessary data was assessed from claim data. To determine the percentage of patients with palpable cord a Delphi study was conducted with office based hand surgeons and orthopaedists. **RESULTS:** No valid data basis was found for national epidemiological figures. Estimations based on European prevalence data (1,7%-2,4%) lead to 1,34-1,9 Mio. Germans affected by Mb. Dupuytren. Thereof, approx. 35.800 surgeries are conducted in Germany per year. The Delphi-study revealed an estimation of 53,5% patients with palpable cord, resulting in 19.153 patients eligible to Xiapex® treatment. No literature was found for treatment costs of Mb. Dupuytren. Actual costs (inpatient and outpatient care plus additional costs) were therefore selected from available claim data resulting in a weighted average of 2087,58€ per patient and year. **CONCLUSIONS:** With a surgical procedure as ACT, dossier developers have to face challenges due to the lack of transparent, publically available data. Best available sources were used to gather the information needed. The fact that the German IQWiG challenged our data within the benefit assessment process without being able to provide better sources of information underlines the necessity of an improvement regarding the availability and open access to suitable data. This will increase validity of data in the required dossier for an informed consequent decision making.

PHP141

EFFECTS OF CHANGING HEALTH POLICY ON PHARMACOECONOMICS AND HEALTH OUTCOME STUDIES IN TURKEY

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OBJECTIVES: Health policy chances may effect the conducted studies in all fields. Pharmacoeconomics dossiers for the reimbursement applications for new medicines were not mandatory before year 2008. New molecules need to show cost-effectiveness and possible budget effect with their applications for reimbursement to Social Security Institution from 2008. This policy changing may effect pharmacoeconomics and health outcome studies in Turkey. The aim of the study is to evaluate the improvement of pharmacoeconomics and health outcome studies which are specific for Turkey in years. **METHODS:** Database of ISPOR Outcome Research Digest were searched online from the begining of database (1998) to 2011 with the key words "Turkey" and "Turkish". The inclusion criteria were taken as study must be specific for Turkey. Included abstract evaluated for increasing abstract numbers in years, distribution in study topics and diseases areas. **RESULTS:** A total of 108 abstracts were searched from the database; 80 of them were matched with inclusion criteria. First abstracts were published in 2000. There were only one or two abstracts per year until 2008. After year 2008, published abstracts numbers were increased year by year and reached up to 18 per year in 2011. 55% of all abstracts were Cost Studies(CS). It was followed by Health Care Use & Policy Studies(HP) (13.7%) and Conceptual Papers (CP) (8,7%). 15% of all abstracts were Multipl Disease studies. It was followed by Mental Health (15%) and Allergy(12.5%). **CONCLUSIONS:** It was shown that the policy changing in 2008 as to require pharmacoeconomics dossiers in the reimbursement application effected Turkey specific pharmacoeconomic and health outcome studies positively. In other words, pharmaceutical ýndustry and the government started to invest in pharmacoeconomics and health outcome studies after 2008.

PHP142

DRUG SHORTAGES AROUND THE WORLD AND THE UNDERLYING REASONS

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OBJECTIVES: To analyze real occurrences of drug shortages throughout 2010 and 2012 and the underlying reasons. **METHODS:** We conducted a systematic search in the scientific literature, media and public domain on occurrences of drug shortages and the perceived underlying reasons. The type of drug shortages were categorized and considered in context to their impact on access to medicines and health care system efficiency. **RESULTS:** While there were 20 publications of any type around this subject in Pubmed in 1995, the number increased with 34 in the year 2000, 70 in 2005, 99 in 2010, and 128 in 2011. The publications have discussed the health consequences, workarounds, and the health consequences of the workarounds. In February 2012, 110 drugs were listed on the FDA Web site, including at least 14 commonly used cancer chemotherapy drugs. Likewise, drug shortages are reported in many countries around the world including European countries such as Spain, France, UK, Russia, Portugal, Greece, or Rumania. Over the years, the reasons for drug shortages have changed from being predominantly caused by shortages in the active ingredients or insufficient distribution systems to currently often being the consequences of strong cost-containment measures or economic crisis. **CONCLUSIONS:** Drug shortages are increasingly observed over the last decade. Drug shortages can have multiple reasons and are currently often induced by economic or cost-containment reasons, and to misaligned incentives in the supply chain.

PHP143

EXPLORATORY TEST OF STAKEHOLDER THEORY IN THE IMPLEMENTATION PROCESS OF IT-INNOVATIONS IN HOSPITAL CARE

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OBJECTIVES: The main hypothesis in this study is that stakeholders have different preferences concerning IT innovations in hospitals, and these preferences are caused by perceived cost/benefit ratios. This will translate in disagreement between stakeholders on which innovations to implement first, possibly explaining the slow diffusion of innovations in health care. **METHODS:** Analytic Hierarchy Process (AHP) was used to quantify stakeholders positions in their priority of nine IT innovations. These innovations were selected after a systematic literature review and expert interviews. In the AHP, decision criteria related to costs and benefits of the innovations were defined: improvement in efficiency, health gains, satisfaction with care process, and required investments. Stakeholders judged the importance of the decision criteria and prioritized the selected IT innovations according to their expectations of how well the innovations would perform on these decision criteria. **RESULTS:** Sixty-two respondents, including patients, nurses, physicians, managers, health care insurers and policy makers showed significant differences in their expectations about their respective costs and benefits of the innovations, resulting in diverging preferences for the health care innovations. For instance, self tests are one of the most preferred innovations by health care insurers and managers, due to its expected positive impacts on efficiency and health gains. However, physicians, nurses and patients strongly doubt the health gains of self tests, and accordingly rank self tests as the least preferred innovation. **CONCLUSIONS:** We found clear differences in expectations of different stakeholder groups on IT innovations. The differences can be understood from the perspective of costs and benefits per stakeholder for each innovation. This study gives a first quantitative insight in stakeholder differences and presents a novel way to study stakeholder differences. The results may be used by decision makers to include alignment of stakeholder positions in implementation processes.

PHP144

ECONOMIC EFFECT OF CLINICAL TRIALS FOR TURKEY

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OBJECTIVES: Clinical studies are the main drivers of innovation in drug research. Pharmaceutical companies invest 15-20% of their revenue to clinical research for developing new treatments. Due the high investment opportunities, countries take actions to obtain the maximum share from global clinical studies market. Turkey has a good potential due the geological location. The aim of the study is to show possible economic effect of clinical studies to Turkey. **METHODS:** Application documents/files for the Ethic Committee of Istanbul Medical Facultyy were examined from 2006 to 2010. Studies sponsored by pharmaceutical companies were included. Pharmaceutical companies estimated budgets were accounted. Distribution of different disease areas of the studies and budgets were evaluated. **RESULTS:** Total number of applications for clinical studies have risen from 177 to 252 from 2006 to 2010. All industry sponsored clinical trials were reported as 184 for the given timeline. Approved sponsored pharmaceutical trials estimated total budget was € 859 million and Istanbul Medical Faculty could take € 59 million of all estimated budget in given timeline. Average cost for per clinical trial and per patient were calculated as € 467k and € 5k for Turkey. The highest estimated budget was hold by cardiological trials with € 61 million, followed by oncology and norology with € 59 million for the given timeline. **CONCLUSIONS:** It was shown that clinical trials may have a great impact to Turkey's economy. If Turkey may increase new launched trials, this is an opportunity for Turkey to take extra investment. Because these number are below the potential of pharmaceutical trials investment amounts when compared total pharmaceutical market. In addition, it is needed to account possible effects to reimbursement agencies. Due the potential impact of clinical studies for Turkey, decision and policy makers need to take action to improve clinical studies in Turkey.

PHP145

USING AN EVIDENCE DATABASE OF PREVIOUS NICE HTA DECISIONS TO MAXIMISE RE-REVIEW STRATEGY

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OBJECTIVES: To use a database of previous National Institute for Health and Clinical Excellence (NICE) health technology assessment (HTA) decisions (HTA inSite)1to understand the impact of four clinical evidence scenarios on the outcome of NICE technology appraisals (TAs). **METHODS:** We identified published NICE TAs containing evidence applicable to the following scenarios: 1) Efficacy data with a non-significant but positive trend; 2) Surrogate endpoints used in place of real endpoints; 3) Composite endpoints where statistical significance was driven by some, but not all, of the individual components; and 4) Efficacy data from observational studies. For each scenario, multiple submissions and re-submissions were identified using HTA inSite. The analysis focused on the evidence submitted, the final decision and critique by NICE, and any changes in approach by the manufacturer at re-submission. **RESULTS:** Clear patterns emerged for each scenario. For example NICE accepted data from surrogate endpoints (scenario 2) in all of the 4 submissions analysed. This was due to support by clinical experts and a clear rationale for the surrogates as established markers of efficacy. Observational data (scenario 4) were accepted in the absence of randomised controlled trials (RCTs), or in addition to RCTs where long-term or country-specific evidence was required. However, it was important to acknowledge and report any potential bias associated with the design of observational studies. **CONCLUSIONS:** An evaluated database can be used to understand the impact of any clinical evidence scenario on NICE decisions. The results can be used to inform submission strategy and assess decision outcome risk.

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PHARMACOECONOMIC EDUCATION FOR PHARMACY STUDENTS IN THE RUSSIAN FEDERATION

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OBJECTIVES: One priority for improving Russian health care is the optimization of health care resource use. Pharmacoeconomic (PE) methods allow economic evaluation of pharmaceutical products and services. The objective of this study was to investigate the extent of PE education in 2012 across pharmacy schools/departments in Russia. **METHODS:** A survey was e-mailed to 47 pharmacy schools listed on the federal educational portal www.edu.ru. Follow-up phone calls were made to non-respondents. Questions were used to determine: whether PE topics were taught and under what discipline, whether it was a required (base) or elective (variable) course, the number of academic hours dedicated to PE, the number of students in the course, topics covered, resources used, an opinion of the instructor on the sufficiency of the number of hours devoted to PE, and suggestions on PE education improvement in pharmacy schools. **RESULTS:** Forty-three schools replied to the survey (91.5% response rate). PE education was offered at 35 (81%) schools of pharmacy: in 25 (58%) schools PE topics were covered under required (base) course with median number of hours 3 (range 0.5-10, mean=4) and in 10 (23%) schools PE topics were covered under elective (variable) course with median number of hours 31 (range 16-54, mean=32). Eight (19%) pharmacy schools did not teach PE. The median numbers of students taking PE were 36 (range 12-220, mean=42) and 53 (range 24-350, mean=86) for required (base) and elective (variable) courses respectively. The majority of the instructors 22(63%) noted insufficiency of hours dedicated to PE. **CONCLUSIONS:** The majority of Pharmacy schools