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 healthcare 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 non-linkage group. With the advent of VBP, the price of a drug should in principle reflect its 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 the 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 price. **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 systematized 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 changes were controlled by the Pricing and reimbursement committee within MoH. Medicines are separated in two groups according to their price control – with registration of maximal retail prices for OTC and out of the reimbursement list (30 days procedure), and regulation of prices for publicly financed medicines (30 days procedure) by inclusion in the PDL. In the process 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 (NHI) and 68 for inpatient care to the Ministry of Health. 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 margin. Only 5 medicines decrease their prices after the transformation, but a year after 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 within the benefit assessment process without being able to provide better sources and transparent, publically available data. Best available sources were used to gather comparative information. **CONCLUSIONS:** The pricing and reimbursement processes. Areas of divergence appear to be principally related to contextual aspects. Areas of divergence appear to be principally related to contextual aspects.

**PHP140**
**CHALLENGES IN THE DATA COLLECTION REGARDING PATIENT POPULATION AND TREATMENT COSTS FOR ANTIVIRAL INTERVENTIONS USING THE EXAMPLE OF MORBUS DUPUYTRENI**

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**OBJECTIVES:** To analyze the influence of regulatory changes for medicines pricing and reimbursement on medicines price. **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 systematized 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 changes were controlled by the Pricing and reimbursement committee within MoH. Medicines are separated in two groups according to their price control – with registration of maximal retail prices for OTC and out of the reimbursement list (30 days procedure), and regulation of prices for publicly financed medicines (30 days procedure) by inclusion in the PDL. In the process 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 (NHI) and 68 for inpatient care to the Ministry of Health. 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 margin. Only 5 medicines decrease their prices after the transformation, but a year after 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 within the benefit assessment process without being able to provide better sources and transparent, publically available data. Best available sources were used to gather comparative information. **CONCLUSIONS:** The pricing and reimbursement processes. Areas of divergence appear to be principally related to contextual aspects.
Kockaya G1, Daylan Kockaya P1, Erguzhan G2

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OBJECTIVES: Health policy changes may effect the conducted studies in all fields. Pharmacoeconomics dossiers for the reimbursement applications for new medicines need to be given before year 2008. New molecules need to show cost-effectiveness and possible budget effect with their applications for reimbursement to the National Health Security System from 2008. This policy changing may effect pharmacoeconomics and health outcome studies in Turkey. The aim of the study is to evaluate the change of pharmaceutical dossiers for reimbursement and economic studies. The criteria are specific for Turkey in years. METHODS: Database of ISPOR Outcome Research Database were searched online from the beginning of database (1998) to 2011 with the key words “Turkey” and “Turkish”. The inclusion criteria were taken as study must be sponsored by Turkish funded companies and abstracts 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 was 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 Multiple 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 and health outcome studies positively. In other words, pharmaceutical industry and the government started to invest in pharmacoeconomics and health outcome studies after 2008.

PHP142 DRUG SHORTAGES AROUND THE WORLD AND THE UNDERLYING REASONS Holford A3, Rinde H2, Maniadakis N2

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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, and 83 in 2010. Different scenarios from 2010 to 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, on all levels, as the least preferred intervention. 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 Lambooj M3, Hummel M2

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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 of efficiency, health gains, satisfaction with 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. Rating of the decision criteria, and their importance to stakeholders for the selection of IT innovations, shows that stakeholders ranked the decision criteria. Furthermore, stakeholders prioritized the selected IT innovations according to their importance of the decision criteria and prioritized the selected IT innovations according to their importance of the decision criteria and prioritized the selected IT innovations among the stakeholders. CONCLUSIONS: Differences in preferences concerning IT innovations were caused by different expectations about the respective costs and benefits of the innovations. For example, patients prioritize the IT innovations that improve system efficiency, doctors, nurses and patients strongly doubt the health gains of the innovations, resulting in diverging preferences for the health care innovations. For physicians, managers, health care insurers and policy makers showed significant differences in their expectations about their respective costs and benefits of the innovations and prioritized the selected IT innovations according to these decision criteria. The majority of the stakeholders 22(63%) noted insufficiency of hours dedicated to PE.

PHP144 ECONOMIC EFFECT OF CLINICAL TRIALS FOR TURKEY Kockaya G1, Deniz M2, Uresin AY2

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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 an attractive market potential due to the geographical 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 Faculty were examined from 2006 to 2010. Studies sponsored by pharmaceutical companies were included. Pharmacoeconomic criteria for reimbursement applications 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 pharmaceuticals estimated total budget was € 459 million and Istanbul Medical Faculty could take € 59 million of all estimated budget 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 nephrology 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 Goad C1, Sainz G2, Ceava E2, Philips Z2

1Abacus International, Manchester, UK, 2Amgen Ltd., Uxbridge, UK

OBJECTIVES: To use a database of previous National Institute for Health and Clinical Excellence (NICE) health technology assessment (HTA) decisions (HTA inSite) to understand the impact of four clinical evidence scenarios on the outcome of NICE technology appraisals (TAs). METHODS: We identified published NICE TAs related to the following evidence 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 critic 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 surrogate 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, if there was important to apply the evidence and re-submitted was not 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 uncertainty risk.

PHP146 PHARMACEUTICAL ECONOMICS FOR PHARMACY STUDENTS IN THE RUSSIAN FEDERATION Makhinova T1, Makhinova EN2, Rascati KL3

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OBJECTIVES: One priority for improving Russian health care is the optimization of health care resource use. Pharmaceutical (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 course, and 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) in 10 (mean = 10, range 4-18) hours; in 12 (mean = 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 = 70). After the survey, 32 (84%) respondents stated that the included PE courses were required courses. The majority of the instructors 22(63%) noted insufficiency of hours dedicated to PE. CONCLUSIONS: The majority of Pharmacy schools