PHP25
DIFFERENTIAL EFFECTS OF TWO PHARMACEUTICAL COST CONTAINMENT POLICIES ON OUTPATIENT PRESCRIPTION DRUG EXPENDITURES IN KOREA
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OBJECTIVES: To evaluate the impacts of two pharmaceutical cost containment policies-financial incentive for physicians to reduce their prescription drug expenditures and lump-sum drug price cut implemented in Oct. 2010 and Apr. 2012 respectively-on prescription drug expenditures from 2009 to 2012 in the national health insurance system of Korea. METHODS: Claims data for outpatient services in a random sample of 1,625 clinics were drawn from the national health insurance database, with follow-up of 2012 to 2013. Segments of two proposals were used to evaluate changes in prescription drug expenditures and non-drug expenditures per claim for selected common diseases—gastric ulcer & gastro-esophageal reflux disease (adults), acute upper respiratory infection (URI) (adults/children), and acute lower respiratory infection (LRI) (adults/children). RESULTS: Prescription drug expenditures increased immediately after the implementation of financial incentive program in gastric ulcer & gastro-esophageal reflux disease and URI in adults. Monthly trends of prescription drug expenditures significantly decreased after the policy in all diseases analyzed. Lump-sum drug price cut suddenly dropped prescription drug expenditures. However, monthly trends of drug expenditures significantly increased after that. Neither of the two policies has changed the overall level of non-drug expenditures. CONCLUSIONS: Lump-sum drug price cut incentive to physicians for reducing prescription drug costs was associated with increased non-drug expenditures without increasing non-drug expenditures. However, it increased the monthly trends of prescription drug expenditures after the sudden reduction. The differential effects of two policies provide implications for pharmaceutical cost containment strategies in health insurance system.

PHP26
INSIGHTS IN EUROPEAN DRUG SHORTAges: A SURVEY OF HOSPITAL PHARMACISTS
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OBJECTIVES: Drug shortages are a complex and global phenomenon. When a drug cannot be delivered at the moment of patient demand, every stakeholder in the healthcare system is affected. METHODS: This study aims to investigate the characteristics, clinical impact, financial impact and management of drug shortages in European hospitals. An online survey was designed and distributed to hospital pharmacists and interviews with Belgian pharmacists. The online survey was sent to subscribers of Hospital Pharmacy Europe between June and September 2013. Descriptive statistics of the respondent’s answers were calculated. RESULTS: One hundred sixty-one respondents were considered in this study. Results show variations between drug shortage characteristics in European regions and countries. Besides manufacturing problems, a role for European and national policy measures related to the market access and trade of pharmaceuticals, such as tendering and parallel trade, are also discussed as a root cause for drug shortages. Further, respondents indicate drug shortages in Europe are associated with clinical risks for patients such as medication error and substitution on hospitals and increased workload for the hospital pharmacy. The median number of hours spent to the management of drug shortages by hospital pharmacists was estimated to be 12.85 hours/week. While pharmaceutical companies were usually informed of the shortage, 59% of respondents already had or were already planning to have an action plan in the management of shortages, a role is still reserved for the government. CONCLUSIONS: This study showed drug shortages have a significant effect on hospitals, their personnel and patients. Mandatory notification in advance and centralized information is preferable to reduce workload for hospital pharmacists. Further, this will allow early anticipation of drug shortages and facilitates mitigation of the clinical impact on patients. Monitoring of the policy effect on the availability of drugs is required to reveal and tackle the root causes behind drug shortages.

PHP27
AN UPDATE ON HOW NICE MANAGE OFF-LABEL COMPARERS
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OBJECTIVES: NICE in the UK has a remit to compare new interventions to established care, which could include off-label indication. The objective was to update the assessment of how frequently NICE request off-label comparators and the subsequent implications. METHODS: All NICE single technology appraisal (STA) scopes from 01/01/08 to 18/12/13 were reviewed. Off-label comparators were identified as those that were being used outside their licence according to the Electronic Medicines Compendium. In cases where off-label comparators were requested in the scope, the manufacturer’s submission, the Evidence Review Group report and the Appraisal Committee report of the STA were reviewed. Ninety-nine STAs and NICE guidance were reviewed and three were not requested.
RESULTS: Of 111 completed STAs reviewed, the scope of 31 (27.9%) requested comparison to at least one off-label comparator; the proportion has been relatively constant since 2009. Since the previous analysis at the end of 2012, there has been a slight shift to more manufacturers not compared to the requested off-label comparator (51.6% at end 2013 versus 45.8% at end 2012; driven by 80% of 2012 cases). NICE accepted the decision to not compare to the off-label agent in a much smaller proportion of public countries at 3% compared to the 2012 figure of 3.3%. Two appraisals where NICE had originally rejected the new technology in favour of an off-label comparator had been re-appraised and NICE reversed their decision and now recommend the new interventions (TA274 and TA301). Overall however, NICE have rejected 8 new interventions (25% with scope of off-label comparators requested) between 2008 and 2013 for not being cost-effective, thereby indirectly recommending the off-label alternative. CONCLUSIONS: NICE have rejected new interventions in favour of off-label comparators. However, there may be a recent shift towards more manufacturers choosing not to compare to the requested off-label comparator and for NICE to accept this decision.

PHP28
POINT OF CARE TESTS: THE LONG AND WINDING ROAD TO REIMBURSEMENT IN THE UNITED STATES AND CANADA
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OBJECTIVES: To present an overview of the landscape for innovative new technologies that can be complex and time consuming. As cost-containment pressures intensify, evidentiary hurdles to justify new point-of-care (POC) tests continue to grow. Centralized health care decision making and governmental changes in regulation can influence these budget decisions. Test reimbursement processes may differ for outpatient versus inpatient use. Currently, the evidence hurdle for a POC test is not as high as for prescription medicines. However, when a test is variable, adequate data to meet decision makers’ needs is not well understood. No roadmap exists for navigation of the critical path for POC tests, and evidence requirements in the US and Canada are not well established. Access for a POC test will be complex; regardless of pathway, decisions regarding reimbursement and adoption of new technologies are diverse and dispersed across and within countries with varying levels of required evidence.

PHP29
REAL LIFE IMPACT OF EXTERNAL REFERENCE PRICING IN EUROPE USING A SIMULATION MODEL
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OBJECTIVES: External reference pricing (ERP) is one of the most common cost-containment tools used to reduce prices for in-patient pharmaceuticals in European Union Member States. The objective of this paper was to assess the real life impact of ERP in Europe using a simulation model. METHODS: A simulation model (developed for the EU Commission) was built to simulate the evolution of drug price over time through the ERP process. Real-life cases of medicinal products were randomly selected from medicines approved via the European Medicines Agency centralised procedure between 2000 and 2012 and including off-patent/non patented drug, cheap/ medium-priced/expensive drugs, and orphan/non orphan drugs. IMS price database was selected as source of information, covering 26 European countries and including over 5,000 drugs. The model was run from launch date until 2013 and the impact over the period were compared to actual recorded prices and interpretation of outcomes was enlightened with the French and Scottish Health Technology Assessment (HTA) reviews. RESULTS: Fifty three medicines were included as source of real life impact of ERP. The analysis followed three scenarios: 1) When a product was initially recognized as an innovative product by HTA, actual price of this product appeared to consistently achieve a higher price than the ERP model price; 2) Actual price of the product tended to become lower than ERP model price over time when a product had been already on the market for a long period and generated high revenue; 3) Low GDP countries tended to be the last to achieve drug entry, suggesting the use of launch sequence strategy from the marketing authorization holder. CONCLUSION: The ERP model predicted to well predict actual prices. ERP seems to be modulated by drug innovation as acknowledged by HTA. More research is needed to understand the role of launch sequence for price optimization.

PHP30
COMPARISON OF PREDICTABILITY OF MEDICAL DEVICE DEVICE REVIEW PERIOD IN THE UNITED STATES AND JAPAN
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OBJECTIVES: “Device Lag” is one of the most imminent issues for medical device industry to focus for the coming years. In order to effectively approach this structured problem, the recognition of related facts and figures are the key factors. The purpose of this research is to provide the analysis of predictability difference among medical device categories in US and Japan and its background. METHODS: Based on medical device review data of US and Japan, we attempted to analyze the predictability of medical device review period. RESULTS: Analysis of predictability of medical device review period in the United States and Japan based on medical device review data was performed. Since the establishment of PMA (Pre-market Approval) system in Japan and PMAH (Pre-market Approval) system in the United States, the review period of medical device in the United States was significantly longer than that in Japan, however, the medical device approval period was getting faster in Japan. CONCLUSION: The difference of predictability is a significant issue among the medical device categories in the United States, for the identification of which the advisory committee classification was used, the standard deviation of FDA review time was the smallest in the fields of Endoscopy (0.5 days) followed by Microbiology (211.0 days) and Pathology (246.6 days) and the largest in the fields of General & Plastic