reimbursement decisions. Our objective was to evaluate the lag between a drug's FDA approval and the publication of the first published CUA evaluating the product. **METHODS:** We used the FDA's website to identify newly-approved drugs from 2000-2010 (n=342). For each drug, we searched the Tufts Medical Center Cost-Effectiveness Analysis Registry and the NHS Economic Evaluation Database for CUAs evaluating the drug for the corresponding FDA-approved indication. We included drugs with a corresponding CUA in our dataset. When multiple CUAs for a drug were available, we included the CUA with the earliest publication date. We used multivariate regression to determine factors associated with time to CUA publication (years). Independent variables included drug approval year, study funder, i.e., whether the CUA was supported by industry, and whether the FDA assigned the drug priority review status. **RESULTS:** One hundred and fifty-six (45.6%) drugs in our sample had a corresponding CUA. Average time to CUA publication was 4 years (standard deviation 2.3 years). We divided drug approvals into three time intervals; 2000-2002 (mean time to CUA publication=5.3; SD=2.4), 2003-2006 (mean=3.9; SD=2.1) and 2007-2010 (mean=2.4; SD=0.97). We found that compared to CUAs for drugs approved from 2000-2002, time to CUA publication was 1.5 years shorter for drugs approved from 2003-2006 ($p<0.001$) and 3 years shorter for drugs approved from 2007-2010 ($p<0.0001$). Source of study support and FDA priority review status were not significantly associated with time to publication **CONCLUSIONS:** For FDA-approved drugs with a corresponding CUA, we found a substantial time lag between FDA approval and CUA publication, suggesting that decision-makers are making important drug coverage and reimbursement decisions without published cost-effectiveness evidence available. However, the time to CUA publication appears to have declined over time.

PHP12

THE TREND OF PRICE LEVEL FOR ANTI-INFECTIVE DRUGS IN CHINA: AN EMPIRICAL STUDY BASED ON MULTIPLE INDEX METHODS

Ma FF, Wu J, Zhao MY
Tianjin University, Tianjin, China

OBJECTIVES: To measure the trend of price level for anti-infective drugs in Tianjin, China from 2006 to 2010 using multiple index methods and to explore measurement bias induced by index methods and measurement units. **METHODS:** Data were extracted from inpatient claims in Tianjin Urban Employee Basic Medical Insurance database from 2006 to 2010. Laspeyres, Paasches, Fisher and chained Fisher index methods were employed to measure the price level. Price indices were calculated both at molecule level (defined by active ingredient) and product level (defined by molecule, strength, preparation and manufacturer). Units of quantity and price were defined as per DDD (Defined Daily Dose), per milligram of active ingredient, and per minimum unit separately to calculate the indices. **RESULTS:** At product level, 367 constantly used products (26% of total 1422 products) were included in unchained indices and 1041 products (73% of total products) were included in chained Fisher indices. The results of multiple indices consistently indicated that the price level decreased and the decreasing range indicated by different index methods were from 16% (Laspeyres-unit index at molecule level) to 27% (Laspeyres-DDD index at product level). The price indices at molecule level decreased slower than the counterparts at product level (22% vs. 25% in chained Fisher-DDD index). At molecule level, price indices based on per DDD decreased faster than per mg and per unit (22%, 21% and 18% in chained Fisher). Laspeyres indices decreased slower than Paasches at molecule level while the contrary was the case at product level. The results from chained Fisher and unchained counterparts were similar (25% vs. 26% at product level). **CONCLUSIONS:** The price level of anti-infective drugs decreased heavily in Tianjin, China. The chained indices were similar to the unchained counterparts which suggested that the price of newer and older products decreased at similar rate.

PHP13

PERFORMANCE EVALUATION OF THE ESSENTIAL MEDICINES SYSTEM IN CHINA BASED ON DATA ENVELOPMENT ANALYSIS: A CASE STUDY IN SICHUAN PROVINCE

Hu M[1], Liao W[1], Yang L[2], Lin T[1]
[1]*Sichuan University, Chengdu, China,* [2]*West China Hospital, Sichuan University, Chengdu, China*

OBJECTIVES: To establish performance evaluation model of the Essential Medicine System in China based on Data Envelopment Analysis(DEA), evaluate the relative efficiency of essential medicines system and analysis the main problem and impact factors on it. **METHODS:** 15 counties in Sichuan province were selected by stratified sampling as Decision Making Units(DMUs); for each county, 30% primary health care facilities, totally 284 facilities were involved as sample. Questionnaire survey was conducted to collect data of input and output indicators in 2010 and 2011 from sample facilities. 3 input indicators and 4 output indicators were set based on literature review, WHO's National Drug Policies Monitoring Indicators and experiential principle of DEA. Excel 2007 was used to encode data, DEAP 2.1 software was used to conduct CRS - CCR and VRS - BCC Data Envelopment Analysis, SPSS16.0 was used to conduct T-test and multiple linear regression analysis to exam the statistic difference between 2010 and 2011, and the influencing factors of efficiency. **RESULTS:** For input indicators, the average special funds of Essential Medicine System(x1) in 15 counties was raised from 0.52 million US$ in 2010 to 0.69 million US$ in 2011 the average number of essential medicines(x2) and drug delivery companies(x3) raised as well. For output indicators, average outpatient cost per visit(y1) and inpatient cost per admission(y2) decreased, while the outpatient visit times(y3) and discharge numbers(y4) kept no increasing as expected. The overall efficiency of Essential Medicines System in Sichuan province in two years were in relatively high level(0.908 in 2010 and 0.832 in 2011). Analysis on technical efficiency, scale efficiency, and return to scale showed the main existing problem was insufficient utilization of input health care resource. **CONCLUSIONS:** The effectiveness of implementation of Nation Essential Medicine System has been displayed, but health care resources should be adjusted and utilized rationally to improve the overall efficiency.

PHP14

DIVERGENT EVIDENCE REQUIREMENTS COMPARING THE AUTHORIZATION AND REIMBURSEMENT PROCESSES OF HIGH-RISK MEDICAL DEVICES – THE EUROPEAN SITUATION

Krueger LJ[1], Evers SM[2], Hiligsmann M[2], Wild C[3]
[1]*Heidelberg, Germany,* [2]*Maastricht University, Maastricht, Netherlands,* [3]*Ludwig-Boltzmann Institute for Health Technology Assessment, Vienna, Austria*

OBJECTIVES: In the last decade awareness has been raised due to unsafe and dangerous devices entering the European market, putting patient safety at stake. Consequently, evidence requirements may not be enough to ensure a high-quality and safe provision of medical devices in Europe.This research aims at exploring the authorization and reimbursement processes and the associated evidence requirements comparing four high-impact regions Europe, United States, Australia and Canada. **METHODS:** First, we performed a literature search about the authorization and reimbursement in the four high-impact regions. Second, seven high-risk medical devices were chosen as examples and current authorization and reimbursement status were assessed. Information was extracted from publicly available summaries, from PubMed, and from the clinical trial database (clincialtrial.gov), supplemented by the worldwideweb. **RESULTS:** The evidence required for the authorization and reimbursement processes clearly differs in the four high-impact regions. All seven devices have been authorized in Europe, three in Australia, one in the United States, and one in Canada. Currently none of the seven devices is recommended for reimbursement in the four high-impact regions. **CONCLUSIONS:** Looking at the difference in evidence requirements, more harmonization, transparency and specific regulations are needed worldwide for the authorization and reimbursement of high-risk medical devices to ensure a high-quality and safe provision.

PHP15

OVERVIEW OF EXTERNAL REFERENCE PRICING SYSTEMS IN EUROPE

Rémuzat C[1], Urbinati D[2], Roïz J[3], Kornfeld A[1], Toumi M[4]
[1]*Creativ-Ceutical, Paris, France,* [2]*Creativ-Ceutical, Luxembourg, Luxembourg,* [3]*Creativ-Ceutical, London, UK,* [4]*University Claude Bernard Lyon 1, Lyon, France*

OBJECTIVES: External reference pricing (ERP) is one of most common cost-containment tools used to reduce prices for in-patent pharmaceuticals in the European Union Member States (MS). The objective of this project was to provide an overview of ERP systems, both on processes and potential issues related to ERP systems in 31 European countries (28 EU MS, Iceland, Norway and Switzerland) (performed for the EU Commission). **METHODS:** A systematic structured literature review and consultation of representatives of competent authorities and international organizations were conducted to identify and characterize the use of ERP, to describe its impacts on the prices of pharmaceuticals and to discuss possible cross-country coordination issues in EU MS. **RESULTS:** All selected countries apply ERP except the UK and Sweden and 23 countries use ERP as main systematic criterion. ERP is based on legislated pricing rules with different levels of accuracy in the majority of European countries using ERP. ERP is applied either to all marketed drugs or to specific categories of medicines, mainly used for publicly reimbursed medicines. The number of reference countries included in the basket varies from 1 to 31. There is a great variation in calculation methods used to compute the price; 15 countries use average price, 7 countries use the lowest price, and 7 countries use other calculation methods. Among reported limitations of ERP application are reliable sources of price information, price heterogeneity, exchange rate volatility, and hidden discounts. Spill-over effects on other countries and downward price convergence have often been argued leading to pricing strategies from pharmaceutical companies. **CONCLUSIONS:** While ERP is widely used in Europe, processes and available price information vary from one country to another that may limit ERP application. Moreover, ERP spill-over effect is a major concern of pharmaceutical firms leading to implementation of the so-called "launch sequence strategies".

PHP16

THE ANALYSIS OF THE DRUG REIMBURSEMENT DECISIONS BEFORE AND AFTER THE POSITIVE LIST SYSTEM IN SOUTH KOREA

Hong JM[1], Jang S[1], Yang BM[1], Lee HJ[1], Kwon HY[2], Park MH[3], Bae EY[4]
[1]*Seoul National University, Seoul, South Korea,* [2]*Institute of Health and Environment, Seoul, South Korea,* [3]*Health Insurance Review and Assessment Service, Seoul, South Korea,* [4]*Gyeongsang National University, Jinju, South Korea*

OBJECTIVES: In Korea, the positive list system (PLS) was introduced in 2007 to ensure the good value for money in pharmaceutical expenditure. This study aims to investigate factors that are most influential in reimbursement decisions under the PLS. **METHODS:** To assess the 5 years operations and compare the results before and after the PLS, we analyzed the drug prices submitted from the companies, the reimbursement decisions made by Pharmaceutical Benefit Coverage Assessment Committee (PBCAC). We extracted data from published evaluation reports, PBCAC meeting minutes, and internal documents of Health Insurance Review and Assessment Service. **RESULTS:** Under the PLS, 71% of submitted drugs were recommended for reimbursement during January 2007- April 2012. For submissions demonstrated superiority or non-inferiority in clinical benefit, 79% of submissions were decided to be reimbursed. However, submissions with inferiority or uncertainties in clinical benefit were rejected regardless of the price. Comparing the negotiated price under the PLS to the relative price under the negative system, the negotiated price was 85% of the relative price. The probability of recommendation was high when ICER was under the GDP per capita, nevertheless submissions with high uncertainty in cost-effectiveness were rejected. Submissions which had low uncertainty and products for severe diseases or rare diseases were recommended for reimbursement despite ICER was high. **CONCLUSIONS:** This study confirmed clinical benefit was the main driver of the reimbursement decision making. Not only clinical benefit and cost-effectiveness but the disease severity, the uncertainty of evidence and reimbursement in other countries were also considered in the reimbursement decision making process. In addition, the drug prices were reduced a little after PLS introduced compared to those under the negative list system.