Employee Basic Medical Insurance (UEBMI) claims of Tianjin city from April 2008 to March 2010 were used to compare the patients’ outpatient visit, total spending, drug spending, and OOP spending before and after the implementation of the EMP. The intervention group consisted of patients who visit the primary care institution which implemented EMP at least once before and after EMP and did not visit the control primary care institution which did not implement EMP, vice versa for the control group. A difference-in-difference approach was used to estimate the effects adjusting for patients’ socio-demographic characteristics and disease severity. Notably, a non-normal distribution was used to test the statistical significance of the results. OBJECTIVES: To estimate the cost. METHODS: Benchmark plans for the top five states provide coverage of 4215 drugs belonging to 158 classes defined as USP. While four states (FL, IL, NY, TX) and TX had a similar number of covered drugs (median of 892 drugs), CA had a significantly lower number of covered drugs, amounting to 28% less than the other four states. On average, 10% of the drugs were in the class called “No USP Class,” highlighting the limitation of CMS designated USP classification system for the new plans. In CA, FL, IL, NY and TX there were 18, 7, 8, 11 and 8 classes, respectively, for which only 1 was covered. In CA, 32 classes were classified as conventional and 3175 classes were divided into the other states, and these other indicated conditions such as Anti-Diabetes and Pain medications. CONCLUSIONS: Review of new benchmark plans shows some states can have a significantly lower patient choice of therapies. There is a need for new policy measures to ensure that all patients have equal access to new treatments.

PHI15
AN ASSESSMENT OF THE THERAPEUTIC BIOLGIC PRODUCTS LICENSED BY THE FDA AND THE EMA
Graziano A1, Olasupo O2, Seoane-Vazquez E1
1Facility of Pharmaceutical Sciences, Bronx, NY, USA, 2Pharmacy & Health Sciences, Boston, MA, USA
OBJECTIVES: To assess the role of CE studies in pricing drugs in Jordan. A premium price (i.e., a price compared with the price of comparable substitute(s) was 1.7 (1.5). The price was always negotiated downwards close to the price of the available substitutes. A premium price (i.e. +10% to 20%) was advocated to reward for added generic benefit. CONCLUSIONS: The JFDA was comprehensive in responding to most of drug pricing applications. Decisions are straightforward with most comparisons made between drugs having similar clinical profiles. However, where CE evidence required there is no formal decision rules laid down, thus an official set of decision tools was warranted. This would include details of the perspective to be adopted, the comparisons to be made, form of economic evaluation and sources of data.

PHI19
THE DIFFERENCE BETWEEN THE MAXIMUM RETAIL PRICE AND TENDER PRICE: A COMPARATIVE STUDY ON BRANDNAME AND GENERIC DRUGS
Li S
Department of Health Economics, School of Public Health, Fudan University, Shanghai, China
OBJECTIVES: To compare the percentage between maximum retail price and tender price of brandname and generic drugs. METHODS: A large database analysis was used. The data was formed by merging two sub-databases, one was the tender prices of 94 antimicrobial drugs and circulatory system drugs collected from the centralized tendering of drug purchases across all the provinces (autonomous regions, municipality directly under the central government) of mainland China over the period of 2005-2013, the other was the corresponding maximum retail prices issued by the National Development and Reform Commission of China. The percentage differences between the maximum retail price and tender price (provincial average) was then calculated by year for antimicrobial drugs and circulatory system drugs, respectively. The generic-brandname ratio of the concerned percentage differences was also calculated. RESULTS: The percentage difference between maximum retail price and tender price for generic drugs was large, while the corresponding difference in brandname drugs was much smaller. The generic-brandname ratio of the concerned percentage differences increased from 1.7 in 2005 to 5.7 in 2013, except a mild decrease in 2009 and a moderate decrease in 2012. CONCLUSIONS: It may be the time to lift price control on drugs in China since the maximum retail price issued by the national government was too high as compared with tender price to exert effect on generic drugs, while for brandname drugs the maximum retail price was too close to tender price, which also consequently diluted the significance of maximum retail price. KEYWORDS: Maximum retail price, Tender price, Price reform, large database analysis.

PHIP1
THE IMPACT OF NEW DRUG PRICING POLICY ON MARKET COMPETITION AMONG OFF-PATENT DRUGS IN SOUTH KOREA
Kwon H1, Kim H2, R Reich M1
1Harvard TH Chan School of Public Health, Boston, MA, USA, 2National Health Insurance Service, Seoul, Korea
OBJECTIVES: This study aims to evaluate the impact of the new pricing policy implemented as of April, 2012 in South Korea on market competition among off-patent drugs since the reform has taken an objective to introduce market competition mechanisms among off-patent drugs. According to the new pricing scheme, prices of brand-name and generic drugs are to be set by the same level after the patent expiration. METHODS: The data used for this study were extracted from the National Health Insurance Claims database. We established a monthly panel dataset pertaining to pharmaceutical consumption between January 2011 and June 2013 (30 months). Proxies of market competition were considered as dependence variables such as the average of patient visits, market share of originators and relative ratio of utilization (originator/generic). Independent variables including policy effect, number of generic drugs, vintages of the first generic drugs, month after the patent expiration and market value. RESULTS: The new pricing policy has resulted in no competition mechanism. Rather the policy shows more favorable to originators than generic drugs. Price dispersion has significantly decreased to 0.92 after the new pricing regulations. Market share of the originators has not significantly changed. The Vintages-originator-to-generic utilization ratio has significantly increased to 6.12 (p<0.001) after the new policy. This study offers different results to the government’s intention. CONCLUSIONS: Price competition cannot be successfully achieved even through measures of demand-side. The bigger market share should be delivered through demand-side measures such as the reference pricing or compulsory substitution to lowest drugs applied in some European countries.
OBJECTIVE OF this study was to assess the characteristics of the reviews performed by the PMPRB in the period of 1998 to 2014. METHODS: Data for all the applications performed by the PMPRB in the period 1998 to 2014 were derived from the PMPRB webpage. Descriptive analysis, and trend analysis were conducted. RESULTS: PMPRB reviewed a total of 1,457 formulations/strengths corresponding to 689 active ingredients and combinations of the substances in the study period. Seventy percent of PMPRB prices were within the guidelines and accepted. Two percent of the prices exceeded the guidelines but did not trigger the criteria for commencing an investigation, however, the patentee is expected to be notified. Three percent of agreements were determined by the variable ‘status of application’. Chi-square was used to determine the number of patentees submitted a Voluntary Compliance Undertaking (VCU). Finally one percent of patentees did not submit a VCU and PMPRB decided that a patentee is not responsible for their infringement. The PMPRB issued a Notice of Hearing. Drug prices that were within guidelines ranged from 92.6% (2001 to 2004) to 95.2% (2005 to 2009) respectively. However, it decreased to 69.8% in 2010-2014. CONCLUSIONS: The majority of the reviews performed by the PMPRB concluded that the prices were not excessive.

PHP21

CHANGES OF THE HUNGARIAN HEALTH INSURANCE PHARMACEUTICAL BUDGET BETWEEN 2007-2013
Boncz I1, Ágoston I1, Cskávári T2, Vajda R2, Molics B1, Oláh A3, Danku N4, Mópely B5, Endrödy K6
1University of Pécs, Pécs, Hungary, 2University of Pécs, Zalaegerszeg, Hungary

OBJECTIVES: At the end of 2006, there was an important reform in the Hungarian pharmaceutical market, including serious changes in the health insurance reimbursement system. The main objective of our study is to assess the changes in the health insurance pharmaceutical budget between 2007-2013. METHODS: Data were derived from the nationwide administrative dataset of the National Health Insurance Fund. The database contains all the only health care financing agency in Hungary. We analyzed the changes of the health insurance pharmaceutical budget between 2007-2013. Results: are given in Hungarian Forint (HUF) and US dollars (USD). The annual average currency exchange rates were applied according to the data of the Central Bank of Hungary. The Hungarian pharmaceutical budget was 323.6 (2007), 325.7 (2008), 354.2 (2009), 357.2 (2010), 351.1 (2011) and 280.0 (2013) billion HUF. The average annual exchange rate between Hungarian Forint and US dollar was 183.88 (2007), 171.80 (2008), 202.36 (2009), 208.15 (2010), 200.94 (2011), 225.37 (2012) and 223.70 (2013), which means that Hungarian Forint significantly weakened compared to USD. After the changes in currency exchange rate, the Hungarian pharmaceutical budget measured by US dollars was 1.76 (2007), 1.90 (2008), 1.70 (2009), 1.72 (2010), 1.88 (2011), 2.00 (2012) and 2.55 (2013) billion USD. CONCLUSIONS: Due to the agreement and implementation of the new legislation of 2009, the pharmaceutical market, including serious changes in the health insurance reimbursement system. At the end of 2006, there was an important reform in the Hungarian pharmaceutical market, including serious changes in the health insurance reimbursement system. The elements of the new era are: liberalization of inter-brand competition; introduction of international tendering; decentralization of the decision-making processes; and transformation of health insurance pharmaceutical budget between 2007-2013. This change was more remarkable in USD as the Hungarian currency weakened between 2007-2013. Department of Pharmacy, University of Pécs, Zalaegerszeg, Hungary

PHP22

EFFECT OF THE U.S.-PERU FREE TRADE AGREEMENT ON PERUVIAN NEW DRUG POLICIES AND THE REGISTRATION OF PHARMACEUTICAL PRODUCTS
Araco LE, Montagne M
MCPHS University, Boston, MA, USA

OBJECTIVES: One controversial issue surrounding the Free Trade Agreement (FTA) is patient protection and access to medicines. The FTA necessitated changes in Peru’s pharmaceutical reimbursement system. The new era of the FTA in Peru will affect the approval process for the registration of pharmaceuticals. The effectiveness and efficiency of the FTA are coordinated by the pharmacists. Only 9 (45%) of the committees distribute the information. The Pharmacy and Therapeutics Committee (P&TC) is a policy formulation, implementation, and review committee whose members are charged by physicians and 100% of them are coordinated by the pharmacists. Only 9 (45%) of the committees distribute the information to their members or more two years before the meeting date. The average number of meetings is 12 (SD = 6) meeting per year, drug availability, formulary changes, drug safety related issues were frequently discussed in each meeting of 11(55%) hospital P&TC committees. Formulary non adherence is less frequent than the average. Of 30 drugs deleted or added to the formulary are 6.3 (SD = 5.9), 19.2 (SD = 18.9) drug per year, respectively. CONCLUSIONS: Adopting F&T Committee in Saudi government hospitals is a common practice, however, it considered in early stage in private hospitals and more likely to be contributed to the accreditation requirements, therefore, more study to be done to study the quality of the committees in private hospital to ensure the effectiveness of formulary system.

PHP24

PRINCIPLES OF POLICY FRAMEWORK IN THE PHARMACEUTICAL WHOLESALE AND RETAIL SYSTEM IN 21 COUNTRY IN THE SHARED ECONOMIC EUROPEAN COUNTRIES
Isztal A1, Csanadi M1, Hanko B2, Kalo Z3
1Syenon Research Institute, Budapest, Hungary, 2Semmelweis University Faculty of Pharmacy, Budapest, Hungary, 3Prospecta Ltd, Budapest, Hungary

OBJECTIVES: To determine the influencing factors and main principles of regulatory and policy framework in the pharmaceutical wholesale and retail system to identify good practices for adaptation in Central European (CEE) countries. METHODS: A comprehensive review of scientific literature and expert interviews were conducted to identify influencing factors in three major categories: general political, business economic and health policy principles. RESULTS: Regulatory and policy framework related to the pharmaceutical wholesale and retail system is influenced by multiple stakeholders with different interest. Health policy demands timely access to high quality medicines to maximise health gain for the population with respect to equity. Budget constraints necessitate public need for a sustainable and efficient pharmaceutical distribution channel. To overcome these constraints, pharmaceutical wholesalers and pharmacies have to improve operational efficiency by taking into account economies of scale/ scope; or positive synergies of horizontal and vertical integration. According to general political objectives policy makers may choose from 1) budgeted vs. liberalised system, 2) monopolistic vs. competing wholesalers and community pharmacies 3) national vs interna- tional, 4) public vs. private ownership. Pharmacists may consider the provision of high quality and cost effective pharmaceutical products and the traditional profession and professionalism influence on the health policies. CONCLUSIONS: Evidence base of policy and regulatory framework related to pharmaceutical trade can be improved based on the comprehensive review of scientific evidence on major principles to harmonise different objectives of stakeholders. However, publications with relevance to CEE and in general lower income countries are very limited.

PHP25

ORPHAN AND ULTRA-ORPHAN TECHNOLOGIES IN THE NEW ERA OF PAYMENT REFORM: UNITED STATES PAYER PERCEPTIONS
Tariq S1, Brogan AP2, Coit D3
1RTI Health Solutions, Research Triangle Park, NC, USA, 2RTI Health Solutions, Research Triangle Park, NC, USA, 3RTI Health Solutions, Manchester, UK

OBJECTIVES: To understand United States (US) payer perceptions and challenges in the evaluation of emerging health technologies with orphan and ultra-orphan designations. METHODS: In-depth, qualitative, one-on-one interviews were conducted with US payer decision makers from the RTI Health Solutions US Commercial Payer Advisory Panel. RESULTS: In the US, patient access to orphan and ultra-orphan technologies is seldom denied due to the rarity of the diseases, unmet needs, and lack of alternative treatments. Payers identify the biggest challenges as lack of clinical and comparative efficacy data and pressures from advocacy groups, patients, and prescribers to fund the ever-increasing numbers of orphan and ultra-orphan technologies, which are often very expensive and have limited clinical evidence. Payers estimated that spending for orphan and ultra-orphan technologies will increase significantly in the next 5 years, leading to concerns over future funding and budgets. Payers were interested in data that could have an impact on costs, cost offsets, resource utilization, readmissions, and real-world outcomes in their settings. Payers identified ‘ orphan’ and ‘ ultra-orphan technologies’ are often not available inpatient populations and unmet needs accompanied by well-defined treatment courses (e.g., when to stop treatment). Benefits of new technologies may not be captured in traditional health economic which overemphasizes the adoption of effective formal models to the value of the new technology and who is judging that value. Rising costs of orphan and ultra-orphan technologies will have more impact on market access in the future, over time there will be increasing resistance to high prices.