

plantation purpose. Almost all Category 2A new drugs fulfilled the unmet medical needs for infection control, cytotoxic therapy in preterm labor, or new mechanism for cardiovascular disease. **CONCLUSIONS:** Category 2B new drugs with less financial impact to NHI system seem easier to reach listing and reimbursement goal in the 2-stage assessments. Reasonable budget impact and cost-effectiveness analysis are as important as robust comparative effectiveness data for PBRs appraisals. There is a need for long-term observation and further analysis.

PHP57

AN ANALYSIS OF THE KEY VALUE DRIVERS FOR HTA ASSESSMENTS IN TAIWAN

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OBJECTIVES: The purpose of this study was to identify the main value drivers behind the innovation category designations (1, 2A, 2B) assigned during the Taiwanese reimbursement process. **METHODS:** All products assessed for reimbursement from January 2012 to March 2014 by the National Health Insurance Administration (NHIA) were considered in this analysis. The details of the assessments have been extracted from the NHIA meeting minutes and Center for Drug Evaluation (CDE) reports. **RESULTS:** Category 1 designations are given to drugs that show “substantial clinical improvement”, Category 2A designations to drugs that exhibit “moderate improvement”, and Category 2B designations to drugs that provide similar clinical value to comparators. Since 2012, 94 of 113 products received positive decisions from the NHIA. 19 received Category 2A (26%), 51 received Category 2B (71%), while 2 received Category 1 (3%). Most Category 2B drugs were considered as alternative therapeutic options with similar efficacy (94%) to an existing product; others were considered to provide better clinical value but a larger budget impact or higher price (6%). Most Category 2A drugs were considered to provide additional efficacy, safety, or convenience over the comparator (53%). Of the 2 Category 1 products, plexixafor was rewarded for its curative potential in hematologic malignancies, as well as its potential reduction of hospitalisation costs; azacitidine was rewarded for being a first-in-class therapy for Myelodysplastic Syndrome. 22 of 94 products did not receive any category, as they were indication expansions. 17 of 113 assessed products received negative decisions due to their significant budget impact (59%) or lack of clinical benefit (41%). 2 out of 113 decisions are pending. **CONCLUSIONS:** Both clinical and economic considerations heavily drive the assessment outcomes in Taiwan. In order to achieve a positive assessment outcome in Taiwan, a product needs to provide a combination of favourable clinical and economic data.

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FROM REGULATORY APPROVAL TO SUBSIDISED PATIENT ACCESS IN THE ASIA-PACIFIC REGION: A COMPARISON OF SYSTEMS ACROSS AUSTRALIA, CHINA, JAPAN, KOREA, NEW ZEALAND, TAIWAN AND THAILAND

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OBJECTIVES: Pharmaceuticals can be marketed when regulatory approval has been obtained. However other barriers may need to be cleared before patients can gain access to subsidised medicines. In the Asia-Pacific region these subsidised systems are often government programmes and range from national tax funded schemes (Australian Pharmaceutical Benefits Schedule) through to coverage of a specific population (Thailand Social Security Scheme for office workers). Navigating these systems can be as simple as submitting a pricing application or as complex as a full scale societal health technology assessments. The aim of this study is to compare the processes and timings between regulatory approval and subsidised access to medicines across the Asia-Pacific region. **METHODS:** Reimbursement guidelines from seven different jurisdictions in the Asia-Pacific region were reviewed. Differences in processes and time from regulatory approval to subsidised access were captured between Australia, China, Japan, Korea, New Zealand, Taiwan and Thailand. **RESULTS:** Only Australia and Thailand allows evaluation of reimbursement in parallel with regulatory evaluation. Parallel processing has been discussed in Korea and Taiwan but has not been implemented. The time between regulatory approval and subsidised access differs across jurisdictions. In general additional processes such as health economic evaluation, pricing negotiation, budget approval and administration prolong time to subsidised access well beyond 6 months post regulatory approval. Japan is unique as a reimbursement price should be published within 60 days after regulatory approval. **CONCLUSIONS:** While most jurisdictions in the Asia-Pacific region differ in terms of regulatory and access approval processes all but one of the jurisdictions included in this study require a regulatory approval letter before reimbursement can be sought. Parallel processing can shorten time for patients to access new medicines however other factors such as health economic evaluation, pricing negotiation, budget approval and administration are also important.

PHP59

A COMPARISON OF ASIAN AND GLOBAL PHARMACEUTICAL PRICES USING AN EKS METHOD

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OBJECTIVES: The study aimed to determine the differences between Asian and Global Pharmaceutical prices. **METHODS:** The indices were developed using the Fisher Elteto, Koves, Szulc (EKS) method. The EKS method is widely used by the Organisation for Economic Co-operation and Development (OECD) but has not yet been applied to pharmaceutical prices. IMS MIDAS data was used to estimate prices and sales volumes. In order to construct the indices, the products needed to be defined as like. The definition of like in this study was based on molecules which are deemed to deliver equivalent health outcomes. The price indices were developed for countries in World Health Organisation (WHO) regions. The analysis compares prices across 56 countries over the period from 2005 to 2011 and included

42 molecules which were sold in each country for the period. The countries were organised into the WHO regions. In total, around 1,000,000 unique national, product brands were accessed for the analysis. **RESULTS:** Pharmaceutical price indices vary substantially between regions. The Asian regions recorded the lowest prices. The indices were as follows: South-East Asian Region D 0.21; South-East Asian Region B 0.31; European Region B 0.37 Western Pacific Region A; 0.44 European Region A 0.45; African Region E 0.46; European Region C 0.49; Western Pacific Region B 0.51; Eastern Mediterranean Region D; 0.54; Region of the Americas D 0.87; Region of the Americas B 0.90; Eastern Mediterranean Region B 1.11. **CONCLUSIONS:** This is the largest exercise ever undertaken in comparing international pharmaceutical prices. It also employs a more robust method than previous studies. The analysis shows Asian region pharmaceutical prices are the lowest in the world.

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PRINCIPLES OF EXTERNAL PRICE REFERENCING SYSTEM – A REVIEW

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OBJECTIVES: Review existing literature to understand the prevalent external price referencing (EPR) systems and to audit for directionality of the current mechanisms against the components defined in WHO/HAI (World Health Organization/Health Action International) project on EPR. **METHODS:** English publications between October 2000 and March 2013 investigating EPR systems were identified through EBMs Reviews – Cochrane Database of Systematic Reviews, NHS Economic Evaluation Database; Embase; and MEDLINE searches. Publications on EPR systems were analyzed in three relevant groups. Qualitative analysis was done to audit the directionality. **RESULTS:** 101 out of 598 articles were found to be relevant and were placed and allocated into three relevant focus groups - 43 general, 44 individual country, and 14 disease specific reference pricing articles. Regional distribution of publications was as follows: 49 RE (Region Europe), 12 Americas, and 15 Asia-Africa-Oceania. Number of publications over years was ranging from 3 to 10 with a significant peak in 2011 at 21.52 articles were found to have directionality against the components defined in WHO/HAI project, and the use of several approaches for setting the price was commonly discussed. Use of EPR was discussed for both patented and generic drugs. Publications showed directionality towards use of several approaches for EPR and were directing the use of EPR for both patented and generic drugs. With regards to type of price level used, ex-manufacturer price was the dominant option. The formula to derive the target price was directing towards average price. **CONCLUSIONS:** There is a growing trend towards increase in number of publications on EPR with lead from RE. A number of discussions around the components raised on WHO/HAI Project indicate that it is a useful tool to lay out options for ERP. Growing number of publications will provide more robust evidence for commonly used options of each component.

PHP61

ECONOMIC IMPACT OF NEW RURAL COOPERATIVE MEDICAL SCHEME IN CHINA

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OBJECTIVES: In 2003, China introduced a heavily subsidized voluntary health insurance program, the New Rural Cooperative Medical Scheme (NRCMS). This paper evaluates the effectiveness of the NRCMS by assessing its impact on health care utilization and out-of-pocket health expenditure. **METHODS:** We employ propensity score matching (PSM) with single difference and double difference based on data from China Health and Nutrition Survey (CHNS) from 1991 to 2009. To check the robustness of our results, we also use a bounding approach to test how strongly an invariant unobserved variable influences the selection process. For the out-of-pocket payments (OOP), a two-part model is used to correct for the large number of zero values and the skewness of the data. **RESULTS:** We find no evidence of an increase in the utilization of formal medical care and preventive services. There is a large, positive effect on the utilization of village clinics, and large, negative effects in town hospitals, county hospitals and city hospitals. For the two-part model of out-of-pocket (OOP) payments, we find a small, positive impact on the probability of positive OOP payments and a small, negative impact on the actual level of OOP payments. All the effects on the incidence of catastrophic medical payments based on different thresholds are insignificant. **CONCLUSIONS:** The results indicate that the NRCMS did not increase the overall utilization but directs people from high-level to low-level medical facilities. The substitution effect among different levels of facilities may be due to more generous reimbursement in low-level facilities. In addition, there is no reduction on the out-of-pocket medical payments or the incidence of catastrophic health payments. Therefore, the impact of NRCMS on increasing utilization and reducing financial risk is found to be limited. The lack of effectiveness may be attributed to a relatively low premium and shallow benefit coverage.

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REGULATORY APPROVAL TO PATIENT ACCESS, AN EVALUATION OF EU5 AND US NATIONAL TIMING DIFFERENCES

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OBJECTIVES: To examine the time between regulatory approval and launch/pricing and reimbursement (P&R) approval in the EU5 and US. **METHODS:** New molecular entities, formulations and combinations approved by the EMA between January 2009 and December 2013 were included in the analysis. FDA approval dates were retrieved and launch dates were gathered as follows: USA: Date wholesale acquisition cost was effective; UK/Germany: Product availability/introduction; France: P&R decision (Agrément collectivities/date published in Journal Officiel); Italy: First P&R Decree publication on Official Gazette; Spain: Date of commercialization; and Time comparison for general medicines vs. orphan and oncology indications was made including shifts over time. **RESULTS:** Time from approval to launch in the US aver-