and most important step that causes properly usage of such products as well as preventing the side effects from abuse of such products and for highly consumed products such as sunscreen cares and depliants.

**PHPS3**

IMPLEMENTATION AND ASSESSMENT OF PERIODIC SAFETY UPDATE REPORTING SYSTEM AT TERTIARY CARE TEACHING HOSPITAL, KARNATKA, INDIA: A DRUG CONTROLLER GENERAL OF INDIA INITIATIVE

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OBJECTIVES: To implement the PSUR system in all wards of hospital. Reporting of PSUs for all the running newly launched drugs since 2011 in hospital periodically to DCG (I), New Delhi and assessment of the PSUR system functioning in the hospital. METHODS: Prospective observational study. Drug safety reporting either manual or through internet. Preparation and implementation of the electronic system of data collection of drugs and Cosmetics Act, India. RESULTS: To implement the DCG (I) initiative, PSUR program, one PSUR committee, one drug safety review panel and one Delphi panel for PSUR system assessment has been constituted. Drug safety reporting and assessment tools are prepared and validated. A manual reporting system of drug safety has been set up and one link on hospital intranet website will be very soon available for online drug safety reporting through each ward and departments of hospital. Necessary training on drug safety reporting is provided to all health care professionals. Online hospital information services are in use to track the prescription of these drugs to the in-patients and then, these patients are extensively followed for any drug related problem during their hospital stay. All the associated drug safety reporting, analysis and actions towards PSUR are done to ensure patient’s safety and are validated and used delivering technical so. Further, since its inception two PSURs has been successfully submitted to DCG (I) at six months regular interval and third one is ready for submission. CONCLUSIONS: All the necessary preparations and work towards PSUR system based PSUR setup will create an environment for healthy safety reporting and helps the regulatory authorities for safety related decisions.

**PHPS4**

PHARMACOECONOMIC RESEARCH AND APPLICATION IN 10 ASIAN COUNTRIES BETWEEN 2003 AND 2013: SYMACMIC REVIEW

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OBJECTIVES: To describe and analyze specific aspects of pharmacoeconomic research and application in 10 Asian countries in recent years from 2003 to 2013. METHODS: Our study concentrated on 10 Asian countries, including China, Indonesia, Japan, Malaysia, Singapore, South Korea, Taiwan, Thailand and Vietnam. Literature was collected and reviewed systematically from United States National Library of Medicine- PubMed. Grey literature was also taken into account. Pharmacoeconomic studies and/or 48 pharmacoeconomic application studies were included. This review followed the Cochrane systematic review guidelines and PRISMA flow diagram. Publication was analyzed by regions, economic evaluation techniques used, drug groups analyzed. The state of these pharmacoeconomic studies was identified with options being for scientific interest, undertaken to support reimbursement issues directly or performed in the framework of clinical guidelines or formulations. RESULTS: There is an increasing in the number of pharmacoeconomic studies in Asia in the later period (2008-2013) compared with the first five years considered (2003-2007). Most pharmacoeconomic studies were carried out in Japan (26%), China (22%), Thailand (15%), Taiwan (12%) and South Korea (10%). Cost-effectiveness analysis and cost-benefit analysis were the most popular economic evaluation techniques used in 84% of total studies published. Antiinfectives for systemic use, antineo- plastic and immunomodulating agents, nervous system and cardiovascular system drugs were most commonly used. Drugs were mostly researched and accounted for 41.79%, 19.78%, 10.45% and 8.21%, respectively. Status of pharmacoeconomics applications varied among countries. CONCLUSIONS: The number of pharmacoeconomic studies in Asia increased from year to year. This study carried out in 10 specific countries (85% total) and concentrated on 4 specific drug groups. Types of pharmacoeconomics applications and research focci differ considerably amongst Asian countries.

**PHPS5**

AN ANALYSIS OF PRICING PREMIUMS GRANTED THROUGH SUBMITTING LOCAL RCT AND PHARMACOECONOMICS DATA IN TAIWAN

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OBJECTIVES: The purpose of this study was to understand the drivers of the pricing premiums for submitting local RCT and/or local pharmacoeconomics data (PES) for reimbursement recommendations in Taiwan. METHODS: We identified 21 new drugs granted reimbursement recommendations from 2003 to 2013. We excluded products that submitted local RCT and/or local FE data in their reimbursement submission to the NHIA between January 2012 and March 2014 in analysing this study. RESULTS: Of the 6 products that submitted local RCT data, 3 received the maximum 10% pricing premium for submitting these data. Abatacept was not granted any premium for not being a new molecule and benidipine hydrochloride was not granted any premium since its price comparator was an existing product that was already priced based on local data. Serafinb has yet to receive a decision for the premium granted. Of the 7 products that submitted local FE data, 5 received a premium. 2 received a 1% and 2 premium respectively for submitting data with high cost-effectiveness, 1 received a maximum premium for using local PE data in the analysis, and 2 received a 5% premium for submitting data that were accepted by the NHIA. 2 products did not receive any premium, as their data were considered to be incomplete or inappropriate. Of the submissions highlighted the product’s cost-effectiveness against the comparator. CONCLUSIONS: A 10% pricing premium through local RCT data is likely achievable as long as the product with local RCT data is a new molecule whose comparator has not been priced based on local data. On the other hand, achieving the maximum 10% pricing premium for submitting local FE data seems difficult to achieve, as of now, a 5% premium seems to be the maximum achievable. A premium as low as 1-2% is likely if there is any uncertainty in the data.

**PHPS6**

REVIEW OF TAIWAN NHIA’S TWO-STAGE NEW DRUGS LISTING AND REIMBURSEMENT ASSESSMENTS (2013-2014)

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OBJECTIVES: In Taiwan, the Second-Generation National Health Insurance (2G-NHI) Act was implemented since Jan. 1st, 2013. Thereafter, listing and reimbursement of new products are 2-stage assessments performed by the Expert Advisory Committee (EAC) and Pharmaceutical Benefits Reimbursement Scheme (PFRS) of National Health Insurance Administration (NHA). EAC primarily evaluates clinical comparativeness and effectiveness evaluation of new products, and assessments are rated as Category 1 (substantial improvement), 2A (moderate improvement) or 2B (similar) compared to current standard therapy which are also used for pricing comparators. PFRS further appraises the EAC’s suggestions and make final reimbursement recommendation. The objective of this study was to analyze the trends of the PFRS appraisals from 2013 to February 2014. RESULTS: A total of 33 new drugs underwent EAC assessments and PFRS appraisals were reviewed for their Categories. Further analysis was conducted to understand the trends based on the therapeutic indications and comparators. RESULTS: There were 21 new drug products recommended by the EAC from January to February 2013 to 2014. Approximately 57% of them were rated as Category 2B, 38% as Category 2A, and only 5% as Category 1. A new trend revealed that Category 2B new drugs were easier to be listed and reimbursed. The only Category 1 new drug is an orphan drug in western countries used to mobilize haematopoietic stem cells for autologous trans-
plantation purpose. Almost all Category 2A new drugs fulfilled the unmet medical need for the innovation purpose. Almost no Category 2A drugs were approved for reimbursement. CONCLUSIONS: Almost all Category 2A new drugs fulfilled the unmet medical need for the innovation purpose. Almost no Category 2A drugs were approved for reimbursement.

Fisher Elteto, Koves, Szulc (EKS) method. The EKS method is widely used by the regulatory authorities to derive the target price. The use of EPR for both patented and generic drugs. With regards to the type of price level used, ex-manufacturer price was the dominant option. The formula to derive the target price was developed. 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 governed by programmes and range from national tax funded schemes to private insurance schemes. 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 differ in different jurisdictions in the Asia-Pacific region. 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 2009 to October 2013 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 benefit" and Category 2 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. Although few Category 2A drugs were considered to provide lower efficacy, safety, or convenience over the comparator (53%). Of the 2 Category 1 products, plexinaxor was rewarded for its curative potential in hemolytic 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%), 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.