PHP45

IMPACT OF GENERICS POLICY ON THE GENERIC PENETRATION

Ammar H[1], Rémuzat C[2], Toumi M[3]
[1]Creativ-Ceutical, Paris, France, [2]Creativ-Ceutical France, Paris, France, [3]University Claude Bernard Lyon 1, Lyon, France

OBJECTIVES: There is an important heterogeneity in generic penetration among EU countries. A North-South gradient in generics market share is often quoted with no reference to policy. Our aim was to compare policies, conditions of penetration and impact of the generics entries in selected countries to represent large and small, Northern and Southern, Eastern and Western EU countries. **METHODS:** We identified policies and generics market share in volume and value in France, UK, Germany, Poland, Greece, Hungary and Portugal. We browsed websites of EU and national (when applicable) drug agencies, ministry of health, HTA bodies, payers, manufacturer unions etc. We completed our research with literature search and grey reports, as well as Datamonitor reports, IMS data and proprietary pharmavitae database. **RESULTS:** There is a wide variability between countries concerning generics entry policy. Generics are available from date of their market approval up to 180 days after. Generics prices range from par price to 60% lower than branded product. In some countries, the generics entries impact the price of the whole class by regulatory rules, while it may be company free decision in others. In Hungary, brands are excluded from the market at generic entry. Besides, discount on brands vary from 0 to 50%. Generic substitution is driven by either local mandatory requirements or financial pharmacist incentives. As a consequence, the generic market share varies between 25 to 80% in volume and 20 to 70% in value. The lowest savings are found in Southern EU while UK and Germany have the largest savings. Even though Hungary eliminates brands after generic entry, the mix keeps favouring remaining brands in the same class. **CONCLUSIONS:** Generics policy varies dramatically from one country to another. This explains the major differences observed across countries on the drug budget associated with generic entry.

PHP46

TRENDS IN PREVALENCE OF DRUG USE AMONG DUTCH CHILDREN FROM 2005 UNTIL 2010

Joosten SGL[1], Houweling LMA[2], Penning FJA[2]
[1]Utrecht University, Utrecht, The Netherlands, [2]PHARMO Institute for Drug Outcomes Research, Utrecht, The Netherlands

OBJECTIVES: There has been growing attention for over-medicalization of children. We examined trends in outpatient drug use among children in the Netherlands from 2005 until 2010. **METHODS:** The PHARMO Record Linkage System, containing amongst others outpatient pharmacy dispensing data of ~3.2 million inhabitants in the Netherlands, was used for this study. For every year in the study period 2005-2010, the number of children aged 0-18 with a dispensing for any drug and per anatomical group was counted and extrapolated to the Netherlands, standardized for age and gender. Prevalence of use was reported per 10,000 children and was stratified by calendar year and age group. **RESULTS:** In all age groups, drug use increased between 2005-2008, but has been descending since. The highest increase was found among adolescents (12-18 years): drug use increased from 4,910/10,000 in 2005 to 5,496/10,000 in 2008, but declined to 5,378/10,000 in 2010. Among infants and toddlers (<2 years), use of dermatologicals, anti-infectives, respiratory drugs and drugs acting on the alimentary tract increased between 2005-2008. Since 2008, the largest decrease was found for anti-infectives and respiratory drugs (−236 and −136/10,000, respectively). Among children (2-11 years), use of dermatologicals, neurologicals and drugs acting on the alimentary tract increased between 2005-2008, while use of anti-infectives decreased (−192/10,000). Between 2008-2010, use of anti-infectives kept decreasing (−224/10,000). Among adolescents, drug use increased for all anatomical groups between 2005-2008, with the highest increase for drugs acting on the alimentary tract, respiratory drugs, dermatologicals and neurologicals. Between 2008-2010, use of neurologicals and drugs acting on the alimentary tract kept increasing, while use of anti-infectives decreased (−138/10,000). **CONCLUSIONS:** Drug use increased between 2005 and 2008, especially among adolescents, but has been descending since. A substantial increase in use was observed for drugs acting on the alimentary tract, dermatologicals and neurologicals, while the use of anti-infectives decreased over time.

PHP47

DOSE DEPENDENT EVALUATION OF INTESTINAL P-GP ACTIVITY AFTER ONE WEEK ORAL ADMINISTRATION OF BACOPA MONNIERA

Singh R[1], Panduri J[2], Chhonker YS[1], Chandasana H[1], Shrivastava P[1], Kumar D[1], Bhatta RS[1]
[1]Central Drug Research Institute, Lucknow, Uttar Pradesh, India, [2]National Institute of Pharmaceutical Education and Research, Raebareli, India

OBJECTIVES: *Bacopa monniera* has been used as Ayurvedic medicine from time immemorial to improve memory and intellect. P-glycoprotein expressed in intestinal epithelia is an important efflux transporter that plays an important role in bioavailability of orally administered drugs. However any modulation in their activity results in altered pharmacokinetics of co-administered P-gp substrate drugs. The aim of this study was to evaluate the dose dependent effect of *Bacopa monnieraon* intestinal P-gp activity after one week oral administration in male Sprague Dawley rats. **METHODS:** Modulation in P-gp activity was evaluated by everted gut sac methodology using digoxin (10 μM) as P-gp substrate. Digoxin transported from mucosal to serosal side of intestine was estimated using HPLC-UV method. Transport of Lucifer yellow (5 μM) a cellular integrity marker across intestinal sac was estimated by fluorescent detector. Viability of tissue was assessed by monitoring the increase in ratio of glucose transport. **RESULTS:** *Bacopa monniera* significantly inhibited the intestinal P-gp activity by 2.17 ($p<0.001$), 3.67 ($p<0.001$) and 5.25 ($p<0.001$) fold at 15.5, 31 and 62 mg/kg/day dose respectively when compared to control. Tissue integrity was not disturbed and was found to be viable up to 90 minutes. **CONCLUSIONS:** *Bacopa monniera* inhibited the P-gp activity after one week oral administration. Alteration in P-gp mediated pharmacokinetic parameters might be possible.

PHP48

IRRATIONAL USE OF ANTIBIOTICS IN BALOCHISTAN. A WARNING FOR HEALTH CARE SYSTEM

Jan SU
University of Balochistan, Quetta, Balochistan, Pakistan

OBJECTIVES: To investigate the irrational prescription habit of antibiotics by medical practitioners in patients of with minor diseases and diarrhea in the area. **METHODS:** Eighteen pharmacies were randomly selected in various areas of Balochistan Province and 402 prescriptions of those patients with complaints of minor injuries, fever and diarrhea were evaluated for use of antibiotics. **RESULTS:** 303 out of 402 prescriptions (about 75 %) were containing antibiotics and the patients with minor injuries, fever and diarrhea were using these mostly in an irrational manner. These prescriptions were prescribed by medical practitioners of all specialties including general physicians. A small number of non medical doctors (about 2%) were also responsible for these prescriptions. These antibiotics were mainly Flouroquinolones, Aminoglycosides and Beta-Lactams **CONCLUSIONS:** This study indicates that this type of irrational practice is the reflection of state and regulatory affairs in the country and this is a warning for all developing countries which need strict regulations for antibiotics prescriptions especially when there is no need.

PHP49

IRRATIONAL USE OF ANTIBIOTICS IN CHILDREN BY MEDICAL PRESCRIBERS

Jan SU
University of Balochistan, Quetta, Balochistan, Pakistan

OBJECTIVES: To asses and obtain data on the present irrational use and prescribing habit of medical practitioners for prescribing antibiotics for children in general symptoms and diarrhea. **METHODS:** Prescriptions of child patients were analyzed from May 2010 to March 2012 from 2 public/general Hospitals and 10 private clinics in different community areas. The data were directly interpreted and analyzed over the dispensing counters of Pharmacies by Hospital and community Pharmacists. **RESULTS:** In public/general hospital 420 out of 560 (75%) patients were prescribed antibiotics for diarrhea, fever, otitis media and minor injuries, where as in private clinics 191 out of 210 (91%) of the patients were prescribed at least one antibiotic for these diseases. The antibiotics were mainly Amoxicillin, Co-amoxiclav, Ciprofloxacin, Norfloxacin and Flouroquinolones. It was also observed that in some cases the antibiotics of choice was not recommended. This irrational prescribing habit of the medical practitioners was observed everywhere in the area both in public Hospitals and in private clinics. **CONCLUSIONS:** This study showed that the irrational antibiotic use in children is a common practice which is an alarming situation and needs strict regulatory strategies for control.

PHP50

AMBULATORY PHARMACEUTICAL SPENDING ANALYSIS BASED ON RISK STRATIFICATION IN PATIENTS WITH CHRONIC CONDITIONS

Uso Talamantes R[1], Trillo Mata JL[1], Guadalajara Olmeda N[2], Sancho Mestre C[2], Vivas Consuelo D[2]
[1]Conselleria de Sanidad, Valencia, Spain, Spain, [2]Universidad Politecnica de Valencia UPV, Valencia, Spain, Spain

OBJECTIVES: Risk adjustment models allow stratifying the population, considering chronic disease as a predictor of drug costs. In this paper, we analyze outpatient drug spending using Clinical Risk Groups (CRG) to obtain patient risk stratification. **METHODS:** The study included 5,248,276 patients living in Valencian Community. The classification of patients was carried out using CRG. The necessary information was obtained from existing records in the database of Primary Health Care (PHC) pharmaceutical information system GAIA, and the computer application ABUCASIS. We analyzed the predictive power of the model using regression analysis, taking as the dependent variable the neperian logarithm of the annual PHC drug costs per patient, and as independent variables the health status of patients, demographic characteristics, use of health system. **RESULTS:** The CRG3 groups 5 and 6 represent a 74, 4% of total pharmaceutical spending while patients in this group are only 25% of the total. The system of grouping patients CRG3 is a good predictor of drug expenditures, except for the CRG3 groups 8 and 9 The model obtained could be a useful tool for managing pharmaceutical budget policies and patient management. **CONCLUSIONS:** To use the CRG3 grouping system is generally a good estimator of pharmaceutical expenditure in primary care. However, the CRG3 groups should be adjusted according to their pharmaceutical expenditure in hospital pharmacy.

PHP51

PERCEPTION OF PARALLEL TRADE OF PHARMACEUTICALS IN POLAND – RESULTS OF NATIONAL MARKET RESEARCH

Baran-Lewandowska I, Hermanowski T
Department of Pharmacoeconomics, Medical University of Warsaw, Warsaw, Poland

OBJECTIVES: Conduct qualitative and quantitative surveys and evaluate the perception of parallel trade (PT) of pharmaceuticals among pharmacists and consumers in Poland; learn about experiences concerning PT phenomenon; develop and verify hypotheses concerning potential PT risks and opportunities. **METHODS:** Individual in-depth interview (IDI) and focus group interview (FGI) with PT experts,

direct interviews and auditorium/e-mail/internet/postal surveys among pharmacists (28/27 questions for public pharmacies (PP)/hospital pharmacies (HP) respectively) and consumers (13 questions). **RESULTS:** The survey was conducted between May and October 2011 among PP (N=958) and HP (N=91). 38.1 % PP and 59.3% HP confirmed that the level of their knowledge of PT is definitely unsatisfactory and requires substantial broadening. The majority of pharmacists believe medicines from PT to be as safe as other medicines (83.4 %/74.2% PP/HP respectively). Almost 40% of pharmacists agree that the introduction of PT medicines has increased competitive pressure and contributed to a decrease in the prices of medicines registered using other regulatory procedures. Pharmacists indicated that the most desired solutions which would support the PT development in Poland are a nationwide information campaign concerning PT and training for pharmacists on the legal and economic aspects. The survey among consumers revealed that 90% of respondents had not ever heard about PT. 51% of consumers indicated that lower price is the most important factor in convincing them to purchase PT medicines. **CONCLUSIONS:** Pharmacists have limited knowledge about PT. There is a strong need for training directed at pharmacists. The hospital market is still under-explored in Poland and therefore represents a very attractive opportunity for the PT development. Only 10% of consumers are familiar with the PT concept which reveals the urgent need for a nationwide campaign to highlight the issue of PT. Product price is the most important incentive for consumers that in convincing them to purchase PT products.

PHP52

THE CARDIOVASCULAR DRUG UTILISATION IN CROATIA IN THE PERIOD 2007-2010, TRENDS AND PERSPECTIVES

Draganic P[1], Macolic-Sarinic V[2], Zezelic S[1]
[1]*HALMED, Zagreb, Croatia,* [2]*Halmed, Zagreb, Croatia*

OBJECTIVES: An extensive insight into drug utilization as an economic and a public health issue can only be obtained when related to the integrated health state of the respective population.Our target is to investigate the utilization trends of cardiovascular drugs in Croatia during the period 2007- 2010, thus focusing on the most common pharmacological/therapeutic subgroups. This allows us to make direct comparisons with the number of patient's hospital admissions connected to cardiovascular events. **METHODS:** The data of drug utilization in Croatia is collected and analyzed by the Croatian Agency for Medicinal Products and Medical Devices HALMED. By applying the Anatomical-Therapeutic-Chemical methodology (ATC), the given data is used to calculate the number of defined daily doses (DDD) and DDD per 1000 inhabitants per day (DDD/1000/day) between 2007-2010, whereas the data of hospital statistics is analyzed by The Public Health Institute. **RESULTS:** The utilization of all cardiovascular drugs indicate an increase of 47.55% (from 248.88 DDD/1000/day in 2007 to 367.23 DDD/1000/day in 2010), while the total cost increased for 13.09% (from 863,601,721 KN in 2007 to 976,657,904 KN in 2010). The utilization of the lipid modifying agents (C10) increased the most (78.93%), followed by agents acting on the renin-angiotensin system (57.51%) and succeeded by calcium channel blockers (28.46%). The total number of hospital admissions related to cardiovascular diseases decreased from 84,413 in 2007 to 81,575 in 2010. **CONCLUSIONS:** During the period 2007-2010 the utilization of cardiovascular drugs increased significantly. In the same period the number of hospital admissions of the patients with main cardiovascular events (3.4%) indicated a decrease. It is necessary to undertake further analysis of these co-founders.

PHP53

IDENTIFICATION OF FACTORS AFFECTING THE MEDICINE EXPENDITURES IN PUBLIC HOSPITAL IN MALAYSIA

Chan BL[1], Ibrahim MIM[2], Shafie AA[3], Bahri S[4]
[1]*Universiti Sains Malaysia, Penang, Malaysia,* [2]*University Sains Malaysia, Penang, Malaysia,* [3]*Universiti Sains Malaysia, Penang, Malaysia,* [4]*Bahagian Perkhidmatan Farmasi, KKM, Selangor, Malaysia*

OBJECTIVES: In Malaysia public sector, medicines spending in Ministry of Health health facilities has increased by 428% from 1998 to 2008. The ultimate aim of this research is to examine the trend of medicine expenditure and to identify the factors associated with the changes in medicine expenditure. **METHODS:** This was a cross-sectional study. It studied prescriptions from 2007 to 2009 at the Pharmacy Department of SFMS Hospital in Johor State. Simple linear regression and multiple linear regression analysis were conducted. **RESULTS:** Total medicines expenditures for outpatient and inpatient rose every year. In outpatient, volume of medicine utilization increased over the years. Medicine expenditure declined in 2009 despite the continuous rise of medicines utilization. Median cost per medicine declined throughout these three years. Inpatient had a continuous rise in medicine expenditure. Median cost per medicine was fluctuating between 2007 and 2009 and was about 35% lower than outpatient. In outpatient, median cost per medicine was significantly different between years 2007, 2008 and 2009 for all variables except for hospital discipline Paediatric and X-ray. Meanwhile in inpatient, the exception was for Dermatology, X-ray, Ophthalmology and Dental. The study found that volume of medicine utilization, which includes the number of medicines, number of medicines per prescription and duration of supply, contributed significantly to the increase of medicine expenditure. Demographics, price and new medicine approved in the formulary were found to have no impact. **CONCLUSIONS:** The increase of medicine utilization rate could be due to the increase of population; the increase of the elderly population and new treatment guidelines and treatment which was previously not available. Other factors include off-label prescribing, irrational prescribing and poly-pharmacy. These three factors can lead to medication wastage and higher cost of treatment. Duration of medicine supply must be carefully monitored as longer duration might result in medication wastage.

PHP55

COMPULSORY LICENSES FOR NON-COMMUNICABLE DISEASES: IMPLICATIONS FOR PHARMACEUTICAL PRICING IN LOW-INCOME COUNTRIES

Wasserman M[1], Priest VL[2]
[1]*Double Helix Consulting, London, UK,* [2]*Double Helix Consulting, Asia-Pacific, Singapore, Singapore*

OBJECTIVES: The signing of the TRIPS agreement in 1995 and Doha Declaration in 2001 have allowed low and middle-income countries to issue compulsory licenses (CLs) for medicines in times of national emergency. While normally for infectious diseases, given the epidemiologic transition occurring in these countries along with the development of insurance systems, it is likely that the trend in the next decade will be towards a higher demand for more expensive medicines to treat non-communicable diseases (NCDs). We sought to determine the impact of CLs for medicines that treat NCDs and make recommendations as to how pharmaceutical companies and governments can work together in the future. **METHODS:** We analysed a series of cases where a CL was issued, or the manufacturer successfully negotiated to retain patent rights for drugs treating NCDs to determine the relative impact of the CL or negotiations, prices were benchmarked and compared before and after CL issuance in 2012 US dollars using the medical commodities consumer price index and relevant exchange rates. **RESULTS:** Of nine CL cases identified, six resulted in an issued license, two were withdrawn, and one was negotiated and resulted in a discount and cost sharing agreement. For licenses issued, the average price reduction was 86.2% and supply was issued to a generics manufacturer. Roche recently decreased the prices of three of its products by an average of 91.0% in India - indicating there may be a trend to reducing price in order to protect patent rights and avoid CL issuance. **CONCLUSIONS:** Low-income countries are increasingly using CLs to obtain lower prices for medicines to treat NCDs. Price negotiation tended to result in a greater price decrease than issued CLs, highlighting the importance placed on retaining patent rights. Pharma companies could consider proactively seeking cost-sharing arrangements to provide access to low-income patients and maintain market exclusivity.

HEALTH CARE USE & POLICY STUDIES - Equity And Access

PHP56

HORIZONTAL EQUITY IN PRIMARY HEALTH CARE SERVICES IN TIMES OF ECONOMIC CRISIS IN GREECE: EX ANTE AND EX POST FINDINGS

Zavras D, Kyriopoulos II, Pavi E, Kyriopoulos J
National School of Public Health, Athens, Greece

OBJECTIVES: To investigate the horizontal equity concerning the use of primary health care services in Greece in 2006 and in 2011. Given that the economic crisis affects the health care system in Greece, the comparison between the findings depicts the post-crisis effects on the use of primary health care services. **METHODS:** The research is based on two cross-sectional surveys, which took place in 2006 and in 2011, and the sample size was 4003 and 6569 respectively. Moreover, a random, stratified sampling was applied in both cases, which took into account the age, the gender, the urbanization rate and the geographical region. **RESULTS:** The Concentration Index for the measurement of horizontal equity (CHE) can be estimated as C_U-C_N. The C_U index depicts the use of primary health care services, based on the number of medical visits. Additionally, the C_N index intends to specify the use of primary health care services in terms of need for care. It is also noteworthy that C_N was estimated after applying the Poisson Regression method (dependent variable: use of primary health care services, independent variables: self assessed health status and chronic health problems). According to the results, C_{HE} was -0.06 in 2006, as C_U and C_N were estimated at -0.14 and -0.08 respectively. Furthermore, C_U was -0.06, while C_N was estimated at -0.04 in 2011. Therefore C_{HE} decreased to -0.02. **CONCLUSIONS:** The low-income individuals tend to use primary health care services more than the high-income individuals, regardless the economic crisis. This finding can be explained, as the low income is usually accompanied with a lower health status. Generally, as C_{HE} is close to zero, there are not strong indications of inequality. However, C_{HE} increased in 2011 (closer to zero), which implies that the inequality shifted from higher income individuals.

PHP57

EMERGING DRUG REIMBURSEMENT MODELS: LESSONS AND IMPLICATIONS FROM CANCER DRUG ACCESS SCHEMES

Aggarwal S
Novel Health Strategies, Bethesda, MD, USA

OBJECTIVES: Cancer drugs are the world's highest selling category of therapeutic products. Due to their premium price and budget impact, several new drug reimbursement models have been implemented worldwide by public and private payers. These models have potential implications for coverage and reimbursement of all branded products. This study reviewed recent cancer drug reimbursement models and developed lessons and implications for future products. **METHODS:** Reviewed cancer drug reimbursement schemes in developed and emerging markets. Interviewed payers and KOLs to develop lessons and implications for future products. **RESULTS:** Public and private payers worldwide have implemented several new models for cancer drug reimbursement to manage budgets and control costs. In the US, private payers are piloting single source compendia and third party protocols (eg. P4 Oncology) to limit off-label use of cancer drugs. In the UK, NICE has successfully negotiated lower price and discounts for first few cycles of therapy. In Italy, AIFA has implemented registry based patient access for cancer drugs. In India, several manufacturers have implemented novel pricing strategy for first few cycles of therapy. In Germany, IQWIG has proposed to use correlations between surrogate endpoints and patient relevant outcomes to determine value of cancer drugs. Due to increased cost pressure on payers, such models are likely to inspire