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IMPACT OF GENERICS POLICY ON THE GENERIC PENETRATION

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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 pharmavite database. **RESULTS:** There is a wide variability between countries concerning generic entry policy. 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.

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

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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.

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

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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 monniera* on 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.

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

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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 Fluoroquinolones, 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.

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IRRATIONAL USE OF ANTIBIOTICS IN CHILDREN BY MEDICAL PRESCRIBERS

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OBJECTIVES: To assess 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 Fluoroquinolones. 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.

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

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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 GAIÁ, 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.

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

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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,