PHP17

ECONOMIC EVALUATION: A CHALLENGE IN INCORPORATING NEW HEALTH TECHNOLOGIES TO THE BRAZILIAN PUBLIC HEALTH SYSTEM (SUS)

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OBJECTIVES: To reveal the main causes of non-compliance for technology incorporation requests into the Brazilian Public Health System (SUS) for the period of 2012 and 2013. **METHODS:** This was a descriptive cross-sectional study. The analysis was performed using the database of National Committee for Technology Incorporation (CONITEC) submitted applications for incorporation in the years 2012 and 2013. The CONITEC, which belongs to the Ministry of Health of Brazil, is responsible for the incorporation, exclusion or alteration of new medicines, procedures and products on the public health system. The presentation of economic evaluation by applicants (economic study and a budget impact analysis) is necessary to enable the analysis of the proposed requirements. **RESULTS:** Out of the 142 external (outside the Ministry of Health) requests submitted for analysis, 56 (39%) were non-compliant, 50 (89%) of them were due to problems in the economic evaluation. Out of the economically non-compliant, 16 (32%) presented problems in the economic study only and 32 (64%) of them presented problems in both items. The main problems observed were not submitting an economic study, not submitting the economic model used in the study, and presenting an economic study using a different perspective than the one of SUS. **CONCLUSIONS:** The high percentage of non-compliance due to the economic evaluation points out the difficulty faced in completing these studies. It is important to invest in initiatives, human resources, training and spreading of economic evaluation knowledge which enables clarifying the required criteria for applying for an incorporation request.

PHP19

PROGRESS IN PERSONALIZED MEDICINE IS SLOWER THAN SOME HAD EXPECTED, PARTLY BECAUSE OF THE SCIENCE AND PARTLY BECAUSE OF INSUFFICIENT ECONOMIC INCENTIVES, PARTICULARLY FOR INVESTING IN MOLECULAR DIAGNOSTICS (MDX)

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OBJECTIVES: Ten years after completion of the Human Genome Project, progress towards making personalized medicine a reality has been slower than expected. This paper seeks to identify how evidence has been generated by critically evaluating successful MDx case studies, and, to the extent possible, identify any lessons from them. **METHODS:** A literature review identified nine examples of success where diagnostic tests are bringing personalized medicine into clinical practice with positive health and economic impact for patients, health care systems, and manufacturers. **RESULTS:** Each case demonstrates that a companion MDx can provide information to patients and health care providers; allow for a targeting of treatments or other interventions to a subset of the population despite differences in whether they are prognostic, predictive, or used for monitoring; offer the potential for the health system to deliver more health gain. **CONCLUSIONS:** There is a diversity of approaches in developing MDx and the range of challenges posed both by the science and in acceptance and use. Moreover, because of the great potential value of personalized medicine for patients and health systems alike, there is a compelling rationale that both payers and the public sector should help fund research on the clinical effectiveness of MDx.

PHP20

ASSESSMENT OF PHARMACEUTICAL PRODUCTS APPROVED BY THE UNITED STATES FDA AND REGISTERED IN PERU

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OBJECTIVES: In spite of the globalization of the pharmaceutical industry, differences exist in the number and characteristics of the pharmaceutical products available in each country. This study compared the pharmaceutical products approved in the US and registered in Peru as of December, 2013, and assessed differences in approvals of chemical entities, therapeutic biologics and orphan drugs, and generic entry. **METHODS:** Information about pharmaceutical products approved in the US and Peru was obtained from the US Food and Drug Administration (FDA), and the General Directory of Medicines, Supplies, and Drugs of Peru (DIGEMID), respectively. Descriptive statistics and chi-square tests were performed in the analysis. Significant level was set at 0.05. **RESULTS:** A total of 2,409 approved pharmaceutical products were listed by the FDA as of December, 2013 of which 763 (31.7%) were also registered by DIGEMID, including 39.1% of generic multisource products and 25.1% of brand single source products. A total of 112 biologic products were listed by the FDA and 64 (57.1%) were also registered in Peru. There were 368 products with orphan indications approved by the FDA and 112 (30.4%) were also registered in Peru. Generic competition was available for 46.8% of the products approved by the FDA and 57.8% of the products approved by DIGEMID ($p<0.001$). **CONCLUSIONS:** Peru has substantially less pharmaceutical products approved than the US, especially for brand products without generic competition and orphan drugs. The highest percentage of products approved in both countries corresponded to therapeutic biologics. Part of the differences in drug approvals can be explained by variations in the epidemiological profile of both countries. The relatively small size of the Peruvian pharmaceutical market and limited purchasing power may result in reduced incentives for pharmaceutical companies to register new molecular entities and products for orphan diseases in Peru.

PHP22

EVALUATING CRITICISM OF THE FDA ACCELERATED APPROVAL PATHWAY - EMA EVALUATION OF DRUGS THAT HAVE BEEN WITHDRAWN FOLLOWING ACCELERATED APPROVAL BY THE FDA

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OBJECTIVES: Since 1992, the Food and Drugs Administration (FDA) accelerated approval pathway has enabled market entry of drugs for serious conditions based on a surrogate endpoint that is likely to predict clinical benefit with confirmatory trials to be completed post-approval. However, five drugs have since been withdrawn or severely restricted following accelerated approval due to lack of efficacy (bevacizumab, [indication: breast cancer; withdrawn 2011; approved 2009], amifostine [indication: renal toxicity; withdrawn: 2006; approved: 1996], gefitinib [withdrawn: 2005; approved: 2003), safety concerns (gemtuzumab, withdrawn 2010; approved 2000), or lack of confirmatory trial data (celecoxib, indication: Familial Adenop Polymatosis [FAP], withdrawn: 2011, approved 1999), leading to criticisms that this pathway allows drugs to enter the market prior to their efficacy and safety being adequately demonstrated. This research aims to evaluate these criticisms by comparing how the drugs were assessed by the European Medicines Agency (EMA). **METHODS:** EMA and FDA evaluations of these drugs were sourced; the approval decision, date, and rationale were compared, alongside any post-approval restrictions/withdrawals. **RESULTS:** EMA appraisal information was publically available for bevacizumab, gefitinib, gemtuzumab, and celecoxib. Gemtuzumab (EMA refused, 2008) and gefitinib (EMA submission withdrawn 2005 after failing Phase III trial) were not granted EMA licences in the FDA-approved indications. In contrast, bevacizumab (2007) and celecoxib (2003) were EMA-approved with the same data package used to gain approval by the FDA. In 2011, celecoxib was withdrawn for FAP in both Europe and US due to lack of confirmatory trial data. However, bevacizumab was EMA approved a year earlier than the FDA and has not been withdrawn by the EMA in this indication. **CONCLUSIONS:** FDA accelerated approval pathway criticism due to post-approval drug withdrawals may be overstated, as the EMA approved two of the five drugs subsequently withdrawn by the FDA, one of which the EMA has not withdrawn.

PHP23

ESTIMATION OF CHANGE IN PRESCRIPTION DRUG EXPENDITURES ON THE REFERENCE PRICING SYSTEM IN SOUTH KOREA

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OBJECTIVES: A reference pricing system is a policy strategy that sets a reimbursement level or reference price for a group of therapeutically interchangeable drugs, i.e. the reference group. A patient is responsible for any difference between the reference price and the price of a more costly drug. The purpose of this study was to estimate future prescription drug expenditures after implementation of the reference pricing system in South Korea. **METHODS:** Korean national health insurance data collected for January, April, July, and October in 2011 were obtained from the Health Insurance Review and Assessment Service. All medications were included to estimate drug expenditures, except patented drugs and orphan drugs. A reference group was defined as the category including drugs with same ingredient or same therapeutic class. Possible scenarios after the introduction of the reference pricing system, such as a copay deduction program for only drugs below the reference price by the government, price lowering by companies and changes in prescribing patterns, were included in the model. **RESULTS:** A base-line copay rate of 20.4% was calculated. When a reference price was set at the average price of drugs in the reference group, patient co-payment rates were estimated to increase to 23.9%. However, when we assumed that companies reduce the price by 5% and prescribers changed 10% of prescriptions to avoid patients paying additional co-payments, co-payment rates were estimated to be 22.9%. In addition, the copay deduction could help decrease co-payment rates to 19.6%. **CONCLUSIONS:** Reference pricing system can contribute to a reduction in prescription medication expenditures for third-party payers. The co-payment for patients could be increased by moving additional financial burden from the insurer to patients. However, an increase in co-payment rates could be limited and total drug expenditures could be reduced by copay discounts, medication price reductions or prescribing changes.

PHP24

PHARMACEUTICAL COMPANIES PRICING STRATEGIES AFTER GENERIC ENTRY INTO THE NEW ZEALAND MARKET

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OBJECTIVES: This study evaluates pharmaceutical companies pricing strategies after generic entry into the New Zealand market in the period 2007-2012, and its effects on drug utilization and expenditures. **METHODS:** Market data derived from IMSHealth. Data include active ingredient, route, dosage form, strength, brand/generic status, prescription drug (Rx)/over-the-counter status, date of market entry, ex-manufacturer standard unit sales, and ex-manufacturer NZ dollars sales. NZ$ were adjusted to 2012 using the NZ consumer price index. Study sample includes the 37 products of the top 125 products by sales in the period 2007-2012 that experienced generic entry during the study period. **RESULTS:** Sales of products in the top 125 by sales amounted NZ$3.1 billion; 46.6% of the overall NZ market. Brands accounted for 95.8% of the expenditures. The average ex-manufacturer price per standard unit was NZ$55.9 (95%CI: NZ$43.8-67.9) for Rx, and NZ$ 685.8 for therapeutic biologics (95%CI: NZ$482.3-889.2). The median price at generic entry date was 27.4% of the median brand price. The median price at generic entry date of study sample was NS$1.18 per unit for brands and NS$0.32 for generics. In 2012, the median price per unit was down to NZ$0.83 and NZ$0.22 for brands and generics, respectively. Standard unit sales increased on average 14% (95% CI 7%-21%) after first year of generic entry. Several brand products (clopidogrel, letrozole, omeprazole, pantoprazole) were discontinued after generic entry. **CONCLUSIONS:** Generic entry resulted in an average 30% reduction in the average drug price. Brand companies either reduced the brand price to match generic prices, or maintained the brand price at levels immediately before generic market entry. The first strategy resulted in the brand keeping large