the level of supportive clinical data (Phase 1: a mean of 158 days, Phase 2: 170 days, Phase 3: 196 days), whether the drug was a first approval or line extension (175 vs. 192 days), or whether it was approved under an accelerated FDA pathway or not (172 vs. 184 days) **CONCLUSIONS:** The FDA breakthrough therapy designation is proving a popular means by which promising drugs can gain patient access on preliminary data packages from as little as Phase I supportive data. However, although this pathway has enabled earlier access, it does not speed the required review times with the average of 6 month review being in line with FDA priority review targets.

PHP32

PROFILE OF DEMANDED MEDICINES AND INFLUENCE OF INTELLECTUAL PROPERTY RIGHTS PROTECTION IN MINAS GERAIS, BRAZIL

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OBJECTIVES: This study analyzes the influence of intellectual property rights protection on the profile of drug request by litigation in the Health Department of Minas Gerais state (SES-MG), Brasil, the public spending and its interfaces with the rational use of drugs and the incorporation of new technologies in the Unified Health System (SUS). **METHODS:** This is a descriptive observational study of litigation by drugs attended by SES-MG. There were analyzed 4,140 records of lawsuits in 2010 attended by SES-MG and 1,065 rulings published in the website of the Court of Minas Gerais State, in the period from 2007 to 2009. **RESULTS:** In 2010, SES-MG attended 28,104 prescriptions requirement of legalization, the average being 2.2 medications per patient. The prevalence of polypharmacy was 10.6%. In addition to individual lawsuits, the SES-MG attended 19 civil suits which included 135 medicines. The ten most demanded drugs were protected by patents. Of these, only three were included on the list of essential medicines. For all products there were prescriptions by brand name, an average of 50% of the requests had required supply trademark. The survey indicated a prevalence of jurisprudential injunction and the use of prescription drugs cited as evidence, without medical expertise. Ensuring the constitutional right to health was the speech used in more shares. It was observed that the lawsuits are at odds with the rational use of medicines recommended by World Health Organization (WHO). **CONCLUSIONS:** The annual expense to ensure access to medicines for litigation is growing and represents a major challenge for the public manager. The high prevalence of new medicines prescribed by trademark and growth of biological drug prescriptions show the need to review and strengthen the policy of generic drugs in Brazil.

PHP33

COMPETITION AND STRATEGIC REGULATION IN THE ARGENTINE PHARMACEUTICAL MARKET. A COMPARATIVE STUDY OF SIX THERAPEUTIC CLASSES

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OBJECTIVES: To analyze how main determinants of competition in six therapeutic target groups -analgesics, tranquilizers, peptic ulcer treatment, cholesterol treatment, benign prostatic hypertrophy and ACE inhibitors- were affected by regulations and drug policies implemented at national level during the last decade in the pharmaceutical market in Argentina. **METHODS:** The database corresponds to the annual information on retail sales in the Argentine pharmaceutical sector generated by IMS for the period 2005-2012. The estimation strategy takes the form of econometric models of ordinary least squares with year fixed effects and robust standard errors. The dependent variables explain the market shares of each product/brand per therapeutic class, explained by prices, participant active principles, and a set of variables capturing product differentiation mechanisms implemented by pharmaceutical firms. Each therapeutic class' regression was exposed to a vector of variables capturing the structure of the regulatory framework. **RESULTS:** In general, prices do not show to be significant determinants of market shares, unlike factors associated with mechanisms of product differentiation do, proving they facilitate the development of brand loyalty and adherence, even with relatively higher prices. On the other hand, the inclusion of new active principles in the Compulsory Health Program (CHP) will act as a boost for priority prescriptions, while the production of generic medicines increases competition, reducing market shares. In addition, the impact of these policies rests heavily on the structure of competition in each therapeutic class. **CONCLUSIONS:** The main health policy recommendations suggest: the need to develop new areas of collaboration with the pharmaceutical sector, enhancing competition in markets with higher levels of concentration, facilitating the evaluation of policies on generic medicines, and successfully regularizing the structure of drugs and products available through the CHP.

PHP34

AN ANALYSIS OF WARNING LETTERS ISSUED TO PHARMACEUTICAL COMPANIES REGARDING MISLEADING HEALTH OUTCOMES CLAIMS 2009-2013

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OBJECTIVES: While analyses of FDA warning letters issues to pharmaceutical companies for misleading promotional outcomes claims have been published for 1997-2008 (Stewart 2002; Salas 2008; Covington, 2009; Yang 2010; Chatterjee, 2012; Neumann 2012), there are no published analyses to date that specifically identify the focus of promotional claim violations from 2009-2013. **METHODS:** Warning letters for promotional materials issued by the FDA to pharmaceutical manufacturers from 2009-2013 were downloaded and assessed by two investigators for misleading claims broadly classified clinical, quality of life (QoL), and economic. Clinical claim violations were then stratified according to the following categories: unsubstantiated efficacy, safety and tolerability, superiority, broadening of indication and/or omission of risk information. QoL claims categories included unsubstantiated and/or health-related (HRQoL). Economic claim categories included cost superiority/savings of one drug compared to another. **RESULTS:** In the 5-year study period, 178 letters containing 655 violations for 204 drugs across multiple therapeutic areas were issued by the FDA all of which were clinical. Most often multiple violations for >1 drug were contained in a single letter. On average, ~36 warning letters were issued per year. Omission of risk information was the most frequently violation claim (29.0%) followed by unsubstantiated/overstatement of efficacy claims (24.76%), and broadening of indication (11.6%). There were no misleading QoL, or economic claims issued. Warning letters were primarily directed to manufacturers of oncology (17.5%), psychiatry (9.6%), cardiovascular (9.6%), and pain (8.8%) products. Approximately half (49.5%) of claims contained promotional materials directed to physicians. **CONCLUSIONS:** We found that misleading clinical outcome claims, specifically omission of risk information and inaccurate efficacy, formed the majority of the promotional violations. Compared to the preceding 6 years (2003-2008), substantially more FDA warning letters were issued (65 vs 178) possibly indicating greater surveillance by the FDA of pharmaceutical promotional materials 2009-2013.

PHP35

CHARACTERISTICS OF PRODUCTS WITH PRICE CHANGES AFTER A POLICY CHANGE IN EGYPT

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OBJECTIVES: In Egypt, the Ministry of Health and Population (MOHP) sets pharmaceutical prices from ex-factory to retail. In July 2012, the pricing policy changed from a cost plus to an external reference pricing method which was effective in October 2012. Our goal was to identify the characteristics of products with price changes after the policy implementation. Methods: We used MOHP lists and IMS data to pre-identify products with price changes. **METHODS:** We used MOHP lists and IMS data to pre-identify products with price changes. In addition, purchase and sales data were obtained from a chain pharmacy in Alexandria for all transactions pre- and post- the policy change (April - Jun 2012 and 2013) to validate price changes, assess sales activity, and identify any additional products with price changes. Bivariate analysis and a logistic regression model were done to identify the determinants of price increase or decrease per Daily Defined Dose (DDD). **RESULTS:** A total of 206 products were subject to price changes; 66% of the products had price increase, 70% were generics, 36% were essential drugs, 40% of the products had prices less than 1EGP[1]/DDD, 30% were between1 and 5EGP/DDD and 30% were higher than 5EGP/DDD. Half of the products were produced by domestic private companies, 27% by multinational firms, 21% by state-owned companies and 2% were imported. The products of state-owned firms had 23 times the odds of the products of multinational firms to have a price increase. Similarly, the cheapest products had 9 times the odds of a price increase compared to high priced products. Compared to brand name drugs, generics had 6.8 times the likelihood of a price increase. **CONCLUSIONS:** Being the product of State-owned firms, a product whose price was ≤ 1EGP/DDD or a generic were the main determinants of price increase. [1] 1 EGP=$0.14 USD

PHP37

A FRAMEWORK FOR STRENGTHENING PHARMACEUTICAL MANUFACTURING IN SUB-SAHARAN AFRICA

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OBJECTIVES: The healthcare profile in sub-Saharan Africa is changing due to economic growth, an increasing middle class, urbanization, and rising incidence of non-communicable diseases. These factors increase demand for medications. Pharmaceutical spending in the region is projected to reach $45 billion by 2016. Despite this rapid growth and gap between availability and demand, companies have yet to initiate local pharmaceutical manufacturing due to the challenges of doing business in the region. We report on a framework to assess these challenges and feasibility of overcoming them. **METHODS:** We undertook a series of key stakeholder interviews in Namibia, including distribution, private sector, regulatory, and governmental representatives. Namibia had virtually no drug manufacturing at time of assessment despite political will to undertake manufacturing. **RESULTS:** In-country pharmaceutical manufacturing is viewed as important for health and economic development and stability. Key areas identified for concern included product selection, education, training, quality control, perceptions of quality, supply chain, role of public and private sectors, and market demand. Creation of a facility at the local university was recommended to build public trust, enhance training, and facilitate distribution. Product areas for initial consideration may include sterile water/saline, alcohol hand rub, oral preparations, topical preparations, total parenteral nutrition, or cancer chemotherapy. **CONCLUSIONS:** In order to create a sustainable health care system in sub-Saharan Africa, local pharmaceutical manufacturing will be necessary to provide a consistent supply of medicine. Product selection is of key importance to match local demand and be reasonably competitive economically. Viable choices could be niche products or large volume generics. Regulatory and quality concerns will have to be thoroughly addressed to establish a successful system. Technical expertise will have to be increased and maintained. Overall, if concerns are addressed early and thoroughly, local manufacturing could provide increase political and economic stability in sub-Saharan Africa while improving health.

PHP38

DEVELOPING ALGORITHMS FOR IDENTIFYING BENEFICIARIES WITH HIGHER THAN EXPECTED UTILIZATION OF OPIOIDS ANALGESICS

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OBJECTIVES: Considerable attention is given to managing opioid use in order to avoid addiction and possible diversion problems. A Pharmacy Quality Alliance workgroup has been working on a pharmacy quality measure where morphine equivalent