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 approved 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, and although the process is not without controversy, through 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.

PHP2
PROFILE OF DEMANDED MEDICINES AND INFLUENCE OF INTELLECTUAL PROPERTY RIGHTS PROTECTION IN MINAS GERAIS, BRAZIL
Nascimento LC1, Guerra Junior AA2, Silva RL1
1College of Pharmacy, Federal University of Minas Gerais, Belo Horizonte, Brazil, 2Law School, Federal University of Minas Gerais, Belo Horizonte, Brazil

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), Brazil, the public spending and its interfaces with the rational use of drugs and the incorporation of new technologies in the Unified Health System (SUS). The study analyzed the trade conflict 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 thorough the brand’s representation. The study indicated a prevalent infringement of intellectual property rights with 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 majority of patents were registered with the national and regional agencies 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 growing number of biological drug prescriptions show the need to review and strengthen the policy of generic drugs in Brazil.

PHP3
COMPETITION AND STRATEGIC REGULATION IN THE ARGENTINE PHARMACEUTICAL MARKET: A COMPARATIVE STUDY OF SIX THERAPEUTIC CLASSES
Macara D, Palacios A
Center for the Study of State and Society (CEDES), Buenos Aires, Argentina

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 pharmacetical market in Argentina. METHODS: The database corresponds to the information on retail sales of the six selected classes 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 growth of biologics drug prescriptions show the need to review and strengthen the policy of generic drugs in Brazil.

RESULTS:

1 drug was contained in a single letter. On average, ~36 warning letters for identifying beneficials with higher than expected utilization of opioids analogies Verona D1, Banahan III B2, Hardwick SP3, Clark JP4, 1University of Mississippi, Oxford, MS, USA, 2School of Pharmacy, Madison, WI, USA

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 letters containing 655 violations for 204 drugs across multiple therapeutic areas were issued by the FDA of all 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 (24.9%, 11.6%). There were no violations for safety, tolerability, or economic claims issued. Warning letters were primarily directed to manufacturer of oncology (17.5%), psychiatry (6.6%), cardiovascular (9.6%), and pain (8.5%) 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 (2006-2011), substantially more warning letters were possibly indicating greater surveillance by the FDA of pharmaceutical promotional materials 2009-2013.

PHP5
CHARACTERISTICS OF PRODUCTS WITH PRICE CHANGES AFTER A POLICY CHANGE IN EGYPT
Mohamed O1, Kreiling D2
1Merck & Co. Inc., Lebanon, NJ, USA, 2School of Pharmacy, Madison, WI, USA

OBJECTIVES: In Egypt, the Ministry of Health and Population (MOHP) sets pharmaceutical prices from ex-factor 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 identify producing and 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 of the drug (January - April - June 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 characteristics of descriptive dose daily dose (DDD) of the product. 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/DDD, 30% were between 1 and 5EGP/DDD, 25% were higher than 5EGP/DDD. Half of the products were produced by domestic private companies, 23% by multinationals, 21% by state-owned companies and 2% were imported. The products of state-owned firms had 23 times the odds of price increases, while those of multinationals had 7.4 times the odds of price increases. The products of state-owned firms had 23 times the odds of price increases, while those of multinationals had 7.4 times the odds of price increases. CONCLUSIONS: Being the product of State-owned, and a product whose price was ≤ 1EGP=0.14 USD

PHP7
A FRAMEWORK FOR STRENGTHENING PHARMACEUTICAL MANUFACTURING IN SUB-SAHARAN AFRICA
Marr M1, Adamson B1, Rennie T1, Stergachis A1
1Division of Global Health, University of Washington, Seattle, WA, USA, 2University of Namibia, Windhoek, Namibia

OBJECTIVES: The pharmaceutical sector in Sub-Saharan Africa is changing due to economic growth, an increasing middle class, urbanization, and rising incidence of non-communicable diseases. Pharmaceutical supply chain and manufacturing could provide increase political and economic stability in sub-Saharan Africa while improving health.

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 framework for strengthening pharmaceutical manufacturing in sub-Saharan Africa will be 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 infrastructure, in-country sub-saharan 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 in Sub-Saharan Africa will be a boost for priority prescriptions, while the production of generic medicines increases competition, reducing market share.

In general, 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 share.

In general, 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 share.

In general, 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 share.

In general, 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 share.

In general, 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 share.

In general, 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 share.

In general, 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 share.