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 that generally spans less as Phase 1. However, an FDA 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
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OBJECTIVES: To analyze how main determinants of competition in six therapeutic targets -analgesics, tranquilizers, peptic ulcer treatment, cholesterol treatment, anti-infectives, and oncology- contribute to the growth of biological drug prescriptions show the need to review and strengthen the public manager. The high prevalence of new medicines prescribed by trademark medications per patient. The prevalence of polypharmacy was 10.6%. In addition to individual lawsuits, the SES-MG attended 19 civil suits which included 155 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 disruption, and the prevailing prevalence of jurisprudential injunction and the inexcusable 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 there is a conflict with the rules of the technologies recommended by the 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 generics 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
Mani M., Adamson BJ, Rennie T, Stergachis A

OBJECTIVES: To analyze how main determinants of competition in six therapeutic targets -analgesics, tranquilizers, peptic ulcer treatment, cholesterol treatment, anti-infectives, and oncology- contribute to the growth of biological drug prescriptions show the need to review and strengthen the public manager. The high prevalence of new medicines prescribed by trademark medications per patient. The prevalence of polypharmacy was 10.6%. In addition to individual lawsuits, the SES-MG attended 19 civil suits which included 155 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 disruption, and the prevailing prevalence of jurisprudential injunction and the inexcusable 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 there is a conflict with the rules of the technologies recommended by the 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 generics of biological drug prescriptions show the need to review and strengthen the policy of generic drugs in Brazil.

PHP4
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 regarding misrepresentation of clinical outcomes claims have provided insight, statistically significant differences were observed in 1997-2008 (Stewart 2002; Salas 2008; Covington, 2009; Yang 2010, Chatterjee, 2012; Neumann 2012), there have no published analyses to date that specifically identify the frequency, type, and characteristics of such warnings 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 claims violated these guidelines were classified according to nine subcategories including 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 claims categories included comparators 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 viola- tion claim (29.0%) followed by unsubstantiated/overstatement of efficacy claims (24.7% or 9.1%). There were no economic claims issued. Warning letters were primarily directed to manufactur- ers of oncology (17.5%), psychiatry (9.6%), 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 (2003-2008), the number of warning letters was pos- sibly 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
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OBJECTIVES: In Egypt, the Ministry of Health and Population (MOHP) sets phar- maceutical 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 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 trans- actions between (June 2011 - April - June 2013). We also included price changes after the policy implementation. 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 1E GP/DDD, 30% were between 1EGP/ DDD and 2E GP/DDD, and 24% 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 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, and a product whose price was <1E GP for DDD or a generic were the main determinants of price increase. [1] 1 EGP=8.14 USD

PHP7
A FRAMEWORK FOR STRENGTHENING PHARMACEUTICAL MANUFACTURING IN SUB-SAHARAN AFRICA
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OBJECTIVES: Strengthening pharmaceutical supply and manufacturing is critical for Africa while improving health.

CONCLUSIONS: The pharmaceutical supply chain and manufacturing is critical for Africa while improving health.

CONCLUSIONS: The pharmaceutical supply chain and manufacturing is critical for Africa while improving health.