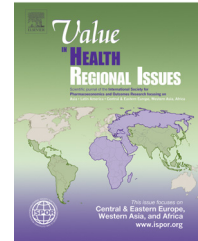




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## The Impact of a Pricing Policy Change on Retail Prices of Medicines in Egypt

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### ABSTRACT

**Objectives:** To describe the products with price changes and assess the impact of price changes on the products' price and affordability within the context of the Egyptian market. **Methods:** A descriptive pre-post observational study was conducted. We selected March through June 2013 as the post-change observation period. A matching pre-change observation period, one year earlier, was selected to be consistent with potential seasonal variation in product use. **Results:** It was found that 65.7% of the products with price changes were low-priced generic products. The overall average percent change in price was 24.7%. Before decree #499 implementation, the average affordability of the low-, medium-, and high-priced products

was 0.25 days' wage, 2 days' wage, and more than 100 days' wage, respectively. After the implementation, the cost increase for the low- and medium-priced products was less than 0.1 days' wage, whereas the high-priced products' cost decreased by 11 days' wage. **Conclusions:** The policy change resulted in both price decreases and increases without substantive implications on affordability. **Keywords:** decree #499 and direct price control, Egypt, external reference pricing, medicine, prices.

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### Introduction

In Egypt, approximately 70% of the total expenditures for health are paid out-of-pocket, and drug purchases at community pharmacies represent nearly half of these out-of-pocket expenses [1–3]. With this substantial burden of the cost of drug use falling on individual consumers, the Egyptian government has been keen on keeping drug prices as low as possible, especially because 22% of the population is categorized as being poor [1].

Egypt's pharmaceutical market is regulated centrally; prices are set solely by the government. The Ministry of Health and Population (MOHP), through the pricing committee at the Central Administration of Pharmaceutical Affairs (CAPA), sets compulsory product retail prices for medicines (and other related health products). Compulsory pricing was adopted in 1962 and prices, once set, are not changed unless the government issues a price certificate. Drugs must be sold at the compulsory retail price (stamped on the product package by the manufacturer), otherwise the pharmacist in charge can be sued for fraud. Wholesaler selling prices and ex-factory prices also are set by CAPA subsequently by serially subtracting fixed percentages off the retail prices.

Till 2012, MOHP followed a cost-plus method to set the retail prices on the basis of cost sheet reports from manufacturers when products were first introduced to the market to be sold in

Egypt. Once set, these prices rarely were re-evaluated to account for any changes in cost from inflation or exchange rate fluctuations experienced by manufacturers. Consequently, retail prices often remained constant over multiple years and have been considered very low by many [4,5]. In recent years, low prices have become one of the most problematic issues facing the Egyptian pharmaceutical sector, with concerns about shortages resulting from the low and stagnant prices for some products [2].

In June 2012, to mitigate some of the drawbacks of the cost-plus method, MOHP switched to a different pricing method for the pricing of innovator products via ministerial decree #499, effective October 2012. The new decree allowed the pricing committee to set the domestic retail price of an innovator product equal to the lowest retail price available worldwide for the exact same product, a method known as external reference pricing (ERP) [6]. The ex-factory and wholesaler selling prices continued to be set relative to the retail price. For generic drug products, decree #499 also specified that the price will be set at a fixed percentage markdown off the originator company's drug prices, 35% markdown for the first five generics and 40% off for those that follow.

The decree also included provisions to allow an increase in a product's price. A manufacturer could present the product's cost sheet and request a price to be set on the basis of the cost

Conflicts of interest: The findings of this study are the result of a dissertation work in partial fulfillment of the PhD degree in social and administrative sciences in pharmacy at the School of Pharmacy, University of Wisconsin-Madison. The views expressed in this article are those of the authors, and no official endorsement by the school is intended or should be inferred.

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reported. Each manufacturer would be allowed to request a price increase for not more than 5% of the firm's registered portfolio yearly, but MOHP would retain the right to accept or refuse any request for price increase.

When the new pricing policy was announced, MOHP emphasized that the new policy would reduce prices. Two waves of price changes were publicized by the MOHP, one effective October 2012 and the other effective January 2013. Announcements of the price changes included lists of products for which price changes would occur, covering 126 products (out of over 7400 products on the market) [3]. In many interviews, however, MOHP representatives mentioned that the prices of 500 products would be changed. After the announcements and changes, many practicing pharmacists claimed that prices were changed for more products than were announced publicly [7]. Furthermore, pharmacists reported that more products had price increases rather than price decreases, contrary to the emphasis on reducing prices that the MOHP stated when announcing the policy. MOHP did not reveal the rationale behind prices that changed or why prices of certain products were changed and not of others. After the second wave of price changes, MOHP put the new pricing decree on hold because of the struggle surrounding the decree. In 2014 and 2016, however, MOHP expanded the new pricing policy to additional products.

Given the controversy and conflicting information surrounding the decree, it seemed prudent to evaluate the impact of the decree on drug prices especially because present literature on similar pricing policies is inconsistent. Some studies reported decreases in prices after using ERP, and others concluded that the ERP impact depended on the pricing method that preceded it, the utilization control policies simultaneously applied, the basket of countries used as reference countries, and the frequency of price revisions [8,9]. Only one study compared the pharmaceutical prices in Middle East countries using ERP to price pharmaceuticals. It concluded that ERP resulted in higher pharmaceutical prices in lower income countries compared with nonpharmaceutical services [10]. The study, however, limited the evaluation to the comparison of public retail prices across countries and did not assess the pre-post impact of ERP on drug prices within the context of each country.

No evaluation of the impact of ERP or any price regulation policy has been done in any developing country in which most of the population is uninsured [6]. Therefore, the aim of this article was to describe and assess the impact of the policy change for setting retail prices for drugs within the context of the Egyptian market. We specifically focused on describing the products with price changes, whether price increases or decreases were more prevalent, what the overall impact on average retail price was for the products with price changes, and whether price changes were related to drug characteristics such as manufacturer type, brand or generic, and high- or low-price products. In addition, we estimated the impact of price changes on the affordability of these products.

## Methods

The study design was a pre-post observational descriptive study. The price changes were announced in two consecutive waves, October 2012 and January 2013. We selected March through June 2013 as the postchange observation period to allow for a sufficient washout period for product packages with updated prices to infiltrate the market, and to potentially capture enough product sales activity. A matching prechange observation period, a year earlier, was selected to be consistent with potential seasonal variation in product use.

An important initial step for the study was to identify products with price changes to include as a sample and we

sought to include a census of all products with price changes. Because product prices were set or changed by the CAPA pricing committee, and not through market competition, any price changes after decree #499 implementation would be the direct effect of the new pricing policy. Therefore, we used an iterative process to identify all products with price changes after decree #499 went effective.

The lists publicized when MOHP announced the price changes contained 126 products, but there were 38 redundant products in the two lists released later by MOHP, leaving 88 unique products identified for the sample from their lists. A second source of products with price changes was obtained from the Intercontinental Marketing Services (IMS) via a report compiled on the basis of a review of prices in December 2012 and June 2013. The IMS listing contained 500 products with price changes, including 367 nonpharmaceutical products such as medical accessories, and toothpastes. Among the 133 products remaining after excluding the nonpharmaceutical products from the IMS report, there were 39 products that were redundant with products already identified via the MOHP-released lists; thus, an additional 94 unique products with price changes were added to the sample from this source (62 prescription drug products and 32 over-the-counter drug products).

A final group of products with price changes were identified during an ex-post facto verification of the sample from the MOHP and IMS lists via the market data obtained for the analysis of price changes. Transaction data for all product purchases and sales during the pre- and postobservation time periods were obtained from a pharmacy chain in Alexandria, Egypt's second biggest city. These sales reports contained the product names, package sizes, number of packages sold, number of units (strips) sold, and retail prices for 6500 products. On comparing the data for the two study time periods, we identified 174 products with price changes, 152 already in the sample from MOHP and IMS lists and 22 additional products. Combining all the uniquely identified products from the three sources resulted in a sample of 204 products with price changes. Figure 1 presents a flowchart for identifying the study sample of products.

An iterative process was also used to obtain some key characteristics for each product. The 2013 Master on Therapeutic Drugs was searched to identify therapeutic class, manufacturer, brand or generic, and whether considered an essential drug. The Master on Therapeutic Drugs provides a list of all drugs available in Egyptian pharmacies. By name recognition, manufacturers were categorized by type (international, domestic, state-owned, etc.).

Two mobile applications recommended by practicing pharmacists, the Egypt Drugs Index and the Drug Index Egypt, were also consulted to supplement the Master on Therapeutic Drugs information. Four products were the first in that chemical class and eight products with price changes were not found in any of the references. Therefore, three community pharmacists (not practicing in the chain pharmacy from which price data were obtained) were consulted to identify the characteristics of the unidentified products. The pharmacists confirmed that no generics had entered the market after the 2013 Master on Therapeutic Drugs was issued and that the four first-in-class products were still under market exclusivity. They also reported that none of the eight unidentified products was sold in their pharmacies, and thus the products were retained in the sample with "missing" for the brand/generic and public/private manufacturer characteristics. On the basis of the per unit prices of products, they were also categorized into low ( $\leq 1$  Egyptian pound [EGP]), medium (1–5 EGP), and high ( $> 5$  EGP) price groups.

Pre- and postprices for all the products with price changes were obtained from the pharmacy sales transaction data. To assess the price changes after policy implementation, nominal

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