CASE STUDY: USING POLICY TOOLS TO MAKE MEDICINES MORE AFFORDABLE IN COLOMBIA

By April Harding and Barbara O'Hanlon

BACKGROUND

In the early 1990s, Colombia's health outcomes were poor; in particular, low income families experienced worse health outcomes compared to the general population. A contributing factor was limited access to essential, quality assured drugs. In principle, drugs should have been available for free in Ministry of Health (MoH) facilities, particularly for those who could not afford to purchase drugs. However, many Colombians did not have access to or did not utilize the public healthcare service network. And, those who did seek care in a public facility often didn't receive prescribed medicines due to frequent stock-outs. As a result, most Colombians used their own resources to buy drugs at private pharmacies.

While people could almost always find the drugs in stock in private pharmacies, drugs were very expensive. Almost half of private health expenditures was for drugs. Indeed, Colombians paid more for drugs than their neighbors: the percentage spent was much higher than the percentage spent on drug expenditures in the rest of Latin America.[1] The burden of these costs was especially high for the poor, who sometimes were impoverished by the cost of health services and drugs. Since most drugs were paid for out-of-pocket, people sometimes couldn't afford the drugs they needed.

Concerned about the financial barriers to drug use and the financial risk created by healthcare and drug spending, the government undertook a series of studies in early- to mid-1990s to better understand the health system supporting production, distribution and retail of drugs and to assess the different drug markets.

SITUATION WITHIN THE MARKET SYSTEMS

At that time, most prescription drugs sold were patented (originator). Drug sellers could charge high prices because there were few competing generic products in the market. Based on international experience, public officials concluded that large gains might be achieved by expanding production and use of generic drugs. Increased market penetration of generics had contributed to sizable price reductions in a number of countries.[2]

[1] Among 14 countries of Latin America and the Caribbean, drugs represented 35% of direct private expenditures on health. Figures ranged from slightly under 15% in the Cayman Islands and Uruguay to 44% in Peru, 45% in Guatemala, 46% in Colombia and 47% in El Salvador. (Bennett et al 1997).

[2] Data from price surveys in 36 low and middle-income countries (LMICs) show that in the private sector, prices of the lowest cost generic medicines were on average 2.6 times less expensive than the corresponding originator medicines. By using generic medicines, potential

The MoH officials dug deeper to discover what was causing the market systems related to drugs to operate the way were and to determine why so few generic products were imported, produced, and sold. They discovered that neither doctors, pharmacists nor patients had much faith in the quality of the drug supply in general; and the few generic products on the market, including those provided in public clinics, were not desired. There was an engrained culture of prescribing and trusting patented – branded - drugs.

The public officials also studied what caused so many poor people to buy expensive patented drugs when the government allocated sizable subsidies to procure and distribute drugs through government clinics. They found a variety of problems were undermining access, particularly among the poor, to free drugs. Problems in the public distribution system and inventory management resulted in frequent stock-outs throughout MoH facilities. The poor residing in rural and urban slum areas had limited access to public clinics for a variety of reasons. Finally, the consumers were not clear about which drugs they were entitled to receive for free.[3] As a result, almost all Colombians ended up purchasing their drugs in the private sector, who charged whatever price the market could bear.

High drug prices could present a business opportunity for a local manufacturer. They could produce a generic formula of a branded drug and successfully compete in the market by selling these generics at a lower-price. However, many factors discouraged local manufacturers from entering into this market. First and foremost, local drug manufacturing capacity in Colombia was weak. The manufacturing industry was fragmented and most producers were operating at such a small scale that their costs were high.[4] Few companies' were able to manufacture sufficient volume to offer competitive pricing and quality in order to sell their products abroad. Their size, volume and limited market potential restricted these companies from accessing equity financing or commercial loans needed to expand and grow their business.

Even if a local manufacturer had the capacity, initiating production of any new drug product was costly. Colombia produces few active pharmaceutical ingredients, requiring manufacturers to import most raw materials. Tariffs on these inputs were high, driving up production costs. Moreover, registering any new product was costly. But registering a generic product was even more costly because of the unclear guidelines for registering generic drugs. It was also unclear how generics would be treated under public purchasing and reimbursement. Estimating the size of the potential markets was difficult. Sales projections for generic products were extremely difficult because manufacturers, wholesalers, distributors and retailers were not clear exactly what constituted a generic product.

---

savings can be quite large [2]. For example, in the private sector of 17 countries, the average percentage savings for individual medicines (n = 4–12 medicines) ranged from 9% to 89% if private sector purchasers would switch from originator brands to the lowest-priced generic equivalents (Kaplan et al 2012).

[3] There was no defined package of drug coverage in the public healthcare network.

[4] For example, the purchase/import of raw materials in small quantities is much more expensive than in large quantities.

MARKET INTEVENTIONS AND SYSTEM CHANGES

Starting in 1992, the Colombian government initiated sustained efforts to bring down drug costs, aiming to reduce financial barriers to drug use as well as eliminate the risk of poverty caused by healthcare and drug spending. They also aspired to make it easier for people to get to a retail drug outlet where they could obtain drugs at subsidized prices. MoH officials' strategy focused on expanding production and use of generic drugs.

As a first step, the MoH passed a law clarifying the definition of generic drugs in the National Formulary.[5] The Law elaborated the policies and treatment of generics in production and sales, thereby reducing market uncertainty. The change in regulations intended to motivate local manufacturers and potential investors to produce locally generic equivalents of essential drugs, encourage wholesalers and distributors to purchase and carry generics listed in the National Formulary, and finally, incentivize retailers to stock and sell generic drugs.

In 1993, the government passed a National Health Law to remove the barriers to accessing drugs. The National Health Law created a framework for establishing subsidized social health insurance (SHI) coverage for poor people.[6] The new health law defined a basic package of services and the range drugs covered under the SHI scheme, effectively removing economic barriers for the poor. The law also facilitated geographic access by permitting those insured by SHI to obtain their drugs from any public or private pharmacy participating in the SHI network.

The SHI program also created a market for quality, generic drugs. The SHI clearly outlined the drugs eligible for reimbursement by listing them under their generic names (Gonzalez et al 2008). Moreover, these generic drugs had to be quality drugs. In the National Health Law, the MoH specified they would only reimburse suppliers and providers who dispensed drugs that were produced by companies with a quality certification.

The MoH moved quickly to put into place the necessary bodies (and capacity) to implement the regulations governing the overall quality of the drug manufacturing and supply in the Colombian health sector. In 1994, the MoH established a drug regulatory agency (INVIMA).[7] The following year, the government passed a decree establishing new standards for good manufacturing practices (GMP).[8]

Working with various government ministries, the MoH also introduced a series of regulations to reduce costs to local produce generic drugs. They worked with the Ministry of Finance to reduce tariffs on importation of needed raw materials to manufacture generic versions of essential drugs.

[5] República de Colombia, Ministerio de Salud (1992) . Decreto 709 de 1992. Por el cual se reglamenta la producción y expendio de los medicamentos esenciales del Formulario Nacional bajo su nombre genérico, Ministerio de Salud, Santa Fe de Bogotá.

[6] Coverage was gradually implemented as funds from savings within the health sector and other sectors became available

[7] Decree No. 1290 of 1994

[8] April 1995, Decree No. 677.

They also reduced the approval time required to register generics and similars. For example, it took three months to register and receive approval for a generic product compared to six months for an original and/or brand product (Homedes et al 2005). In addition, the MoH reduced fees to register a new generic drug product. The reduction in costs, as well as other incentives, enabled local companies to cover the costs of upgrading their manufacturing processes in order to meet GMP standards. GMP certification was very expensive (close to $US 3M 2001 - or 1/6 of annual turnover). Companies couldn't borrow to make these upgrades unless their business was in sound shape and they had predictable sales.

Working with various government ministries, the MoH also introduced a series of regulations to reduce costs to local produce generic drugs. The MoH and INVIMA worked with the local industry association (ASINFAR) to develop the GMP guidelines and to elaborate the inspection and certification process. INVIMA also held workshops and conducted training with local manufacturers on the GMP guidelines. From 1993 to 2000, INVIMA worked with the local pharmaceutical/manufacturing industry to phase in regulations (Rovira 2006). Private sector buy-in helped generate relatively good compliance with the new regulations; this, in turn, helped improve quality and reliability of pharmaceutical products. Gradual phase-in of the new rules helped consolidate the local manufacturing industry by weeding out low-price, low quality manufacturers while rewarding those who could increase scale and compete regional and internationally with affordable, quality products.

The MoH followed a similar consultative process to create transparency in pricing drugs - both brand and generics. Working with industry representatives, MoH built a process of collecting price information on an on-going basis. The MoH used this information to start publishing a price comparison guide. This guide helped make pricing information more available and understandable for consumers. As consumers became aware of the price advantage of locally produced generics compared to international drugs, the guide proved so popular that the local manufacturing association eventually took over regular publication of the price guidelines (Bennett 1997).

The MoH also passed a regulation permitting pharmacists to substitute generic if a prescription listed the branded medication. The MoH worked closely with the pharmacy chamber association to roll out the implementation and promote awareness of the new rules. [9]

As the market potential for generic drugs developed, The International Finance Corporation (IFC) invested in the expansion of one of Colombia's largest generic manufacturer, Tecnoquímicas, S.A. The IFC made a US $25 million equity investment (2008) and loaned US$20 million (2009) to support the company's acquisition plan.[10] Tecnoquímica has been successfully developed and produced products that reflect the preference of Colombian consumers. Leveraging its competitive

[9] Pharmaceutical Chamber, National Business Association of Colombia (Cámara Farmacéutica de la Asociación Nacional de Empresarios de Colombia)

[10] Economies of scale are significant in pharmaceutical production; hence, growth usually allows producers to lower their prices.

edge in research and marketing has helped Tecnoquímicas grow its market share (Mejía et al., 2009).

DID THE COLOMBIAN GOVERNMENT SUCCEED?

Impact in Generic Drug Market

Since 1993, substantial changes in the drug supply have occurred in Colombia. Following the IFC's investments, Tecnoquímicas launched more than thirty generic drugs in anti-infective, dermatology, respiratory, psychiatry and cardiovascular therapeutic areas. IFC received pricing data on seventeen of the top generic prescription drugs launched in 2010 and 2011. The prices of all these products were well below that of the equivalent originator drugs and were anywhere from as low as 6% and up to 45% of the originator price. As the scale of production increased, Tecnoquímicas and other manufacturers have been able to leverage their strong market position to shift from suppliers with higher quality assurance for inputs needed to manufacture generics.

The drive towards generics has also had positive spillover effects in drug manufacturing. Overall, drug manufacturers have improved their production processes and manufacturing standards significantly. And there has been a large increase in proportion of producers meeting GMP production quality standards. In fac,t many of the largest companies, who now mostly sell to the international market, also have ISO accreditation.[11]

The retail end in the supply chain has also experienced significant changes. The retail market moved from individual pharmacy owners and consolidated into several pharmacy chains. Product quality assurance and practices in pharmacy chains are better than in the independent pharmacies (Vacca, C. P., C. Y. Niño, et al. (2011).

With these changes, both providers and consumers now trust the quality of the drugs found in the health sector. Moreover, they have come to rely on and purchase generics. The percentage of generics purchased in the local market has increased significantly from less than 5% in 1992 to over 66% by 2009. By 2011, generics make up 90% of the market. Manufacturers have passed on the cost savings to consumer, resulting market prices of drugs dropping significantly. The cost of many drugs covered by SHI has also declined, contributing to the financial sustainability of SHI.

Impact on Access to Drugs

The new SHI had its intended effect: the number of people who benefited from social insurance coverage rose from 25% in 1993 (Glassman et al., 2010) to 86% in 2008 (DANE, 2008). As more poor people enrolled in SHI, they were better able to access public subsidies for drugs - mostly generics - in more outlets. Eligible consumers receive free generic drugs on the essential drug list where there are virtually no stock-outs in public facilities. Or they can access the same drugs for

[11] Also, growth of domestic industry: domestic producers portion of market grows from 10% (1993) to 35% in 2003; Export of drugs to countries of the Andean region and to the United States increased abruptly, from US $ 27.1m in 1991 to US $ 248.5m in 2002 (Gonzalez et al 2008).

free through a wide number private retail outlets, facilitated by the consolidation of drug stores into a number of retail drug chains. As a result, poor people pay less for drugs and are therefore at less risk of poverty drug costs.

Wider System Impact

Although the government's intention was to increase use of generic drugs, the government's sustained efforts over 15 years yielded results in other areas of the supply chain (Kaplan et al 2013). Overall, the supply chain is more reliable. The wide geographic reach if the wholesalers and distributors combined with heavily utilized retail pharmacy network are the key ingredients to the Colombian's supply chains success (Heimberger et al 2003).

The collaborative stewardship arrangements have helped the MoH introduce other changes in the pharma sector. For example, the successful effort to reduce excess use of antibiotics was attributed to the partnerships developed between the MoH authorities and other stakeholders while together to introduce generics.[12] This foundation has helped Colombia adopt other best practices and introduce life-saving drugs, such as emergency contraception, more rapidly than any other Latin American country.

Due to expanded insurance coverage and lower drug prices, private spending on health care went down from 3.3% of GDP in 1993 to 1.2% in 2003. Most of this decrease is related to drug spending (Genovese). Colombia now has among the lowest incidence of out-of-pocket payment in Latin America (Florez, 2013).

STUDY QUESTIONS

While reading the case, take note of the following questions:

1. What were the root causes contributing to the Colombian's poor access to affordable, quality drugs?

2. What policy tools did the government deploy in Colombia? Why?

[12] A study of antibiotic consumption in Latin America between 1997 and 2007, found that Colombia had the greatest reduction in the number of doses sold.