The 30-billion-dollar distribution and taxation cost of pharmaceuticals in Latin American countries: Impact, options and trade-offs.

Giovanny Leon, Eduardo Gonzalez-Pier, Panos Kanavos, Eva Maria Ruiz de Castilla, Gerardo Machinicki

Abstract

Objectives: The World Health Organization (WHO) provides 10 specific guidelines for managing the prices of pharmaceutical products. Many of those are widely known and used such as reference pricing, value based pricing, price transparency and tendering. Less attention and knowledge is concentrated in markup regulation across the pharmaceutical supply chain and distribution and in tax exemptions or reductions. This paper quantifies the impact of these price components in the Latin American (LatAm) region and places the findings in the context of economic theory and international policy experiences. **Methods:** 2020 retail pharmaceutical sales data from eight major LatAm markets covered in the IQVIA database were decomposed into ex-factory, distributor markups and taxes using price build up information and the Price Decipher Methodology developed by the Novartis Global pricing governance and negotiation team. The findings were reviewed by an international panel representing academia, health policy, health economics, patient and industry. **Results:** The ex-factory market value of the analyzed markets was USD49 billion. Distribution markups added USD20 billion and taxes a further USD10.5 billion. This represented a 63% increase over ex-factory prices, considered high if compared to 24% for an international benchmark of 35 ex-LatAm countries. Reducing markups

for these LatAm countries to 24% would represent up to USD19 billion in savings for payers and/or patients. **Conclusion:** there is potential for significant cost reductions associated with tax and distribution markup refinements in the Latin American retail pharmaceutical market. National policies should be informed by additional context-specific research for effective implementation.

Keywords: Pharmaceutical distribution; Ex-factory prices; Retail prices; Taxation of prescription pharmaceuticals; National pharmaceutical policy.

Introduction

Pharmaceutical pricing decisions are a fundamental component of pharmaceutical policy and require considerable attention by researchers and policy-makers. The pricing of pharmaceuticals is widely researched, for example in systematic reviews[1,2] and in particular policy topics[3,4], while orientation for policy-makers, including books[5] and guidance, is available. One such example is the WHO Guideline on Pharmaceutical Pricing Policies[6].

The WHO considers 10 policy options to determine and manage pharmaceutical prices. Although several of these policies are more widely known analyzed and discussed across policy roundtables, for example external reference pricing[7], internal reference pricing[8], value-based pricing[9], price transparency[10] and tenders[11], two of them need more visibility: markup regulation across the pharmaceutical supply chain and distribution[12] (recommendation #4) and tax exemptions or tax reductions for pharmaceutical products[13] (recommendation #10). These recommendations are to be carried out by countries with levels of priority; one (promotion of quality generics and biosimilars) is strongly recommended; 8 are conditionally recommended, and one (cost-plus pricing) is conditionally not recommended. Recommended policy options also vary on the size and strength of evidence that support them. Inspecting the technical documentation[14,15] behind the WHO recommendations, it is visible that some of these options have received more analytic attention than others.

The purpose of this research is to quantify the impact and policy options in Latin America (LatAm) regarding two relatively less visible recommendations that WHO conditionally

recommends: markup regulation across the supply chain and tax exemptions/tax reductions for pharmaceutical products. [1]

Methods

The quantitative analysis is based on 2020 retail pharmaceutical sales data from eight LatAm markets covered in the IQVIA database: Argentina, Brazil, Chile, Mexico, Peru, Central America & Caribbean (CAC) (covering six countries: Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras and Panama), Colombia and Ecuador. The analysis used the price build up information and the Price Decipher Methodology developed by the Novartis Global Pricing Governance and Negotiation team[16] in order to disaggregate pharmaceutical prices into three components: ex-factory prices, distribution (wholesale and retail) markups andtaxes. Sales data were obtained from IQVIA MIDAS (assessed via IQVIA PADDS on 15 Sept 2021). These data were combined with average markup information at the wholesaler and retail level, dispensing fee, and percentage of VAT collected from Novartis pricing experts from each country.

International comparisons using IQVIA data that have been presented elsewhere[17] have been used to create an international comparison benchmark. This updated research accounts for methodological improvements including: specific focus on relevant LatAm markets, comparisons to an international benchmark of thirty-five ex-LatAm markets, using the same methodology and data from the same calendar period.

A panel of experts was convened at an ISPOR 2021 panel meeting to discuss the findings and explore policy options and recommendations. The panel consisted of an academic expert in

[1] Instead of "markup regulation" some policy makers and economists may refer to competition policies to reduce distribution and dispensing costs of pharmaceutical products. For consistency with WHO recommendations, markup regulation is retained here.

pharmaceutical pricing policy (PK), a Latin American senior health economist with previous experience as a government officer (EGP), a Latin American leader regarding coalition forming and education facilitation for patient associations (EMR) and a pharmaceutical industry global pricing expert with experience in Latin America (GL). The discussion was reviewed and inputs were provided by another Latin American health economist (GM).

Results

The total sales of the analyzed markets at ex-factory price level were USD49 billion in 2020. More than half of this was accounted for by Brazil, followed by Mexico and Argentina. When information about markups of the distribution and delivery system and taxes were factored in, it was found that, on average, this represented a 63 percent increase in the ex-factory price.

The attribution of retail price increases associated with taxes and distribution markups over ex-factory prices showed wide variations amongst the study countries (Figure 1). Ecuador and Colombia had a 30 and 35% price increase, respectively, over the ex-factory price, attributable exclusively to markups; Central America Caribbean (CAC) and Peru had the same 44% increase in ex-factory prices (for CAC, almost exclusively due to markups, while in Peru, it was evenly distributed between markups and taxes); Mexico had a 47% markup and no taxes (in the institutional channel, the markup is absorbed by the pharmaceutical industry but not in the retail market); Chile had a 51% price increase over ex-factory (closely distributed between markups and taxes) ; finally, Brazil and Argentina had a 73% and 75% joint distribution and taxation cost, respectively, over ex-factory prices, of which the tax impact was 32% and 35%, respectively, the highest among the study countries.

These findings were compared against an international benchmark of thirty-five non-Latin American countries available through the research conducted by the London School of Economics (LSE) and Novartis. The modeled addition to ex-factory prices due to distributor markups and taxes was 19 and 5 percent, respectively, totaling 24% for both; the same component in this LatAm sample ranged between 2.16 and 4.40 times larger. If LatAm health systems could reduce their distribution and taxation cost to 24% over ex-factory price levels based on the international benchmark and if all markup and tax reductions were transferred to patients and institutional buyers, the potential saving to the health systems or patients could be as high as USD19 billion. Given that not all buyers face this full price (institutional buyers may get price discounts) and that some of the collected taxes may be already used to fund healthcare services, this potential saving should be considered a top estimate. It is, however, sufficiently large such that even smaller of savings amounts will warrant policy makers analysis and actions.

Discussion

These results presented in the previous section raise a number of important policy issues. These relate to both taxation of retail prescription pharmaceuticals and distribution markups. We explore these in turn.

First, there seems to be an inconsistency between fiscal policy (as it relates to revenue-raising ability) and health care policy imperatives. The former imply a maximization of revenue from all possible sources, while the latter focuses on utilizing allocated funds to yield maximum social benefit. Considering that health care systems in LatAm are underfunded, imposing high VAT rates on essential inputs to the health care system, such as prescription pharmaceuticals, deprives the health care system from valuable resources by acting as a stealth tax. Many countries have

recognized this and have exempted prescription pharmaceuticals from VAT altogether (e.g., Sweden and the UK), or subjected them to a low rate (e.g., France).

Second, a balancing act is needed in the context of LatAm, which takes into account fiscal efficiency, health system optimal funding through the achievement of universal health coverage, and out-of-pocket (OOP) spending on prescription pharmaceuticals. One of the main challenges to achieve Universal Health Coverage (UHC) and other sustainable development goals by 2030, is fiscal space[18] including an efficient and reliable tax structure. Fiscal efficiency favors minimizing distortions among economic sectors using uniform VAT rates[19,20]. Reducing VAT on prescription pharmaceuticals or altogether exempting them from VAT could have a significant redistributive effect if it increases the available resources to spend on health. If such reduction is able to reduce patients' spending, it will have significant equity implications particularly in settings where a significant number of low-income citizens purchase prescription pharmaceuticals OOP. OOP expenditure represent between 20 and 80 percent of total health expenditure[21] and large part of this spending relates to prescription pharmaceuticals . The re-distributive effect of VAT reduction for prescription pharmaceuticals needs to be balanced against fiscal revenue efficiency by raising taxes elsewhere. Alternative means to raise taxes would be for example via "sin taxes" (alcohol, tobacco, sugar sweetened beverages)[22], the revenue-raising effects of which have been modelled elsewhere[23]. Fiscal analysis needs to consider a broader set of supply and demand elasticities in the economic system to estimate the net fiscal impact of a reduction in VAT for prescription drugs including social welfare analysis that incorporates externalities[24].

Third, when considering tax reforms, it is important to recognize the heterogeneity in the LatAm region, where more mature health systems in terms of financing coexists with many that are

much less mature. Evidence based policy should be considered in regards to taxation of pharmaceutical products. The final effect of tax reductions on price is one of the areas where more research is needed. This effect is context dependent, as it has been shown empirically for different economic sectors[25], supply and demand elasticities will dictate how much of a tax reduction will be absorbed by the wholesaler and retail sector and how much will be passed onto buyers. For example, an analysis in South Africa indicated that only 40% of a VAT reduction on prescription and non-prescription pharmaceuticals will be passed to consumers[26]. Another example is provided by the elimination of sales taxes and VAT for antiretrovirals in Peru in 2001. Contrary to expected, there was no reduction in the prices, which was attributed to a lack of "accompanying conditions" such as a coordinated retail markup regulation[27]. Policy makers will aso need to minimize the possibility that much of the income redistribution through VAT exemptions benefits sectors of the population that are relatively well off (what is known as "leakage"[28]) and need to be attentive to research into the effects of VAT exceptions as aredistribution tool[29,30]. In addition, currency depreciation and instability, including persistently high inflation, can introduce distortions in economic systems leading to limitations in the ability of economic policies to produce their intended effect . This topic can be even more prevalent in low and middle income countries. This is an important dimension needing further study and attention in the design of policies such as the ones mentioned in this manuscript.

Fourth, with regards to pharmaceutical distribution, the structure of the distribution chain (wholesaling and retailing) involves complex issues related to market structure, wholesaling market models, system controls, market entry criteria based and degrees of freedom to horizontally or vertically integrate[31]. All these points highlight the value of appropriate regulation, intervention or oversight of the supply system. WHO considers affordability one of

the key components of a national drug policy and strengthening the supply systems therefore as very important since it has implications for access and for rational drug use. The retail sector is very complex with the need to consider remuneration, mark-up set-up (progressive, fixed or regressive, flat fees, etc.) and linkages of the retail dispensing function with other policies such as generic substitution or the effect of efficient procurement through discounting particularly for generic pharmaceuticals. Any proposal for reform in the retail sector is conditional upon an understanding of market structure to consider how wholesaling and retailing are linked to national drug policies, including competition, what are the issues around competition[32], horizontal and vertical integration, discounting and consideration to other factors such as the application of public service obligations to wholesaling, requiring them to have sufficient stock of medicines in a warehouse so that pharmacies can actually be supplied across the board. Table 1 indicates the components and objects of the national drug policy. Supply systems influence both the access but also rational drug use.

Fifth, in LatAm economies there is a generalized problem of lack of competition. Many oligopolies and monopolies prevail. With very few players in many countries (especially small ones), this can carry unjustified price increases that would be avoided in a more competitive scenario. At least in certain LatAm countries, pharmacies face few barriers to entry and the key need is to enhance the value of dispensing via its professionalization and efficiency. Overall, there is a need to come up with new distribution systems and pathways in order to enhance competition. One such model is the direct-to-pharmacy distribution (the agency model), whereby a wholealer supplies pharmacies or government warehouses. The wholesaler does not own the stock, and it is still owned by the manufacturer. The wholesaler becomes a logistics provider. The reduced wholesaler model (RWM) consists in a limited number of wholesalers (usually two

or three but this can be adjusted to national specifications) that can supply medicines in close to 100% percent of a national territory.

Sixth, merging activities of wholesalers or the activities of wholesalers and retailers would constitute ways of changing market structure and, potentially, increasing competition and efficiency. Horizontal integration has been frequently used to transform supply systems in the last 20 years (Table 2). Horizontal integration aims to reduce inefficiencies within a sector. If the wholesaling sector has significant discontinuities due to inefficiencies, if it is very fragmented, one way to create economies of scale is to promote horizontal integration among wholesalers or also amongst pharmacies and therefore creating pharmacy chains.

In vertical integration, wholesaler and retailer integrate (Table 2). There are some examples in the UK and in continental Europe. A significant decline in the acceptable margins charged by each part of that business will be expected because of reductions in operating costs, provided that markup regulations secure that efficiency-gains are translated to the patients or health-care system.

Finally, reforms in the distribution chain need to be checked against prevailing legal frameworks, the competition framework (to understand if different forms of integration enable sufficient competition), and payment frameworks (charges and markups). An option is to determine pharmaceutical prices centrally and regulate retail prices or the final price on the market via wholesaler and all retailer charges or fees. This can be done for a significant number of medicines but not necessarily for all. It can consider vaccines, very costly medicines directly distributable to hospitals and a significant part of the medicines consumed by the average patient community. In some cases, there will be significant geographical constraints that make distribution very difficult. Incentives could be provided for pharmacies or pharmacy chains to

open in major urban centers provided that that they also open branches in very poorly provided areas or in rural areas. WHO identified a paucity of research about the effect of markup regulations in low and middle income countries[33].

Conclusion

This research found that in key Latin American markets, distribution markups and taxes added a 63% increase in ex-factory price levels of prescription pharmaceutical products. Bringing these markups and taxes to a 24% ex-Latam international benchmark will carry significant reductions in out-of-pocket and/or payer expenditures.The savings could up to USD19 billion.

To achieve these savings, policy makers will need to consider tax exemptions, distributor and retail policies and improved competition. Careful policy design should also consider fiscal space trade-offs (including who will bear cost and benefits of differential taxation, its effect on social welfare and externalities) and adopt an evidence based policy that analyzes intended and unintended impacts of reforms, guided by economic theory, scenario analyses with local parameters, policy principles, sectoral interrelations and experiences in policy implementation.

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Policy Objectives **Components**	***Access***	***Quality***	***Rational Use***
Selection of essential drugs	X	(x)	x
Affordability	x		
Drug financing	x		
Supply systems	x		(x)
Regulation and quality assurance		X	x
Rational use			x
Research	x	X	x
Human resources	x	X	x
Monitoring and evaluation	x	X	x

x: Direct link (x): Indirect link

Source: Modified from Kanavos et al. Competition issues in the distribution of pharmaceuticals. Presented at OECD Global Forum on Competition; 2014; Paris, France. http://eprints.lse.ac.uk/id/eprint/56006

Table 1 – Components and objectives of a national drug policy

Horizontal integration (e.g., amongst wholesalers or amongst retailers)
• Extensive between 1990 and 2014 in Europe & led to a significant reduction of full-line wholesalers from around 600 to <120 • Further consolidation ongoing • Limitations by EU competition law for consolidation taking place in Europe, and/or national legislation
Vertical integration (e.g., wholesaler with retailer)
• Limitations by national legislation and regulation on pharmacy ownership • Limitations by EU competition law

Source: Modified from Kanavos, et al. The Pharmaceutical Distribution Chain in the European Union: Structure and Impact of Pharmaceutical Prices. European Commission; 2011. http://eprints.lse.ac.uk/id/eprint/51051

Table 2 – Wholesaling: consolidation and diversification in Europe