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An Overview of Medicine Pricing Policies that May be Applicable to Low-and Middle-Income Countries

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Abstract

Escalating medicine costs pose a risk to medicine access, particularly in low-and middle-income countries. Several high-income countries have instituted and documented the effects of pricing interventions to address this risk. Low- and middle-income countries, however, usually have less regulated pharmaceutical markets, with scant documented evidence to support successful policy interventions. Policy options for low- and middle-income countries should be transparent, individually tailored based on a country-specific context and cognisant of the associated risks.

The lack of empirical evidence of pharmaceutical policy interventions in low- and middle-income countries is a hindrance to understanding the challenges, successes and lesson these countries face in policy implementation. In addition to regular research and monitoring of pharmaceutical policies, low- and middle-income countries require strengthening of several other aspects of the market, with a focus on infrastructure and human capacity development; resource improvement and appropriate application of the legal systems necessary to support instituted policies.

Keywords: Pharmaceutical pricing policies; low-and middle-income countries; medicine prices; manufacturers price; regulation; medicine access

Introduction

In the past few decades, the societal importance attached to improved health has been met by a fast rise in the demand for health care [1]. Key to attaining optimal health outcomes is the accessibility to safe, effective and quality medicines for much of the population. Access however in low-and middle-income countries (LMIC), is hampered by high prices such that patients cannot afford to purchase the medicines that could improve, extend or potentially save their lives [2].

Medicines expenditure in LMIC's account for 20–60% of health spending, in comparison to the 18% spent in countries of the Organization for Economic Co-operation and Development (OECD) [2]. High medicine costs also deter health ministries from improving patient quality of life using newer and safer medicines. Additionally, out-of-pocket spending on medicine procurement is high and remains the largest family expenditure item after food in developing countries [3]. This implies that considerable proportions of the population would be pushed into poverty as a result of medicine procurement, hence affordability of treatment in several countries is low [2]. The growing burden of communicable and non-communicable diseases in developing countries, also contributes to high medicine expenditure, further impinging on restricted government budgets.

Increased fiscal spending on medicines consequently results in less money being available to spend on other essential health-care and non-healthcare services. It is amongst these reasons that several governments have embarked on introducing tighter control over medicine pricing, as it has been historically noted that, unregulated pharmaceutical markets particularly in developing countries are unlikely to provide acceptable outcomes in achieving equitable public health [4]. This article sought to review some of the existing pharmaceutical pricing being used globally to control the ex-manufacturers price of medicines and identify issues for their application in LMICs to improve their pharmaceutical pricing and purchasing systems.

Discussion

To Regulate or Not to Regulate?

The regulation of the pharmaceutical market through government interventions that limit profit, prices or total spending on medicines remains a controversial topic. Many economists favour limited medicine pricing interventions, and prefer allowing suppliers, health sectors and patients to achieve their own equilibrium. Arguments exist that wide scope government regulations are often responsible for the absence of

price competition in the pharmaceutical market [4]. Alternatively, healthcare lobbyists contend that, medicines, particularly essential medicines are not luxury commodities, and should not be reserved for just the wealthy. Their concern with having an unregulated market is that the most vulnerable populations would end up paying the most for medicines – if they can afford them at that.

Highly regulated markets may also become unattractive as it may limit competition for generic medicines; delay the launch of new medicines and hence limit the availability of new medicines [5] In due course pharmaceutical regulations may have negative consequences for the patients and thus constitute a trade-off between lowering current medicine costs, at the expense of having fewer medicines to treat future generations. It should also be noted that price interventions do not guarantee reduced prices, and can sometimes lead to unexpected consequences, as was the case in the Philippines where interventions were hurtful to the generic market [6]. Thus, the most difficult step in developing pricing interventions is to ensure a reasonable balance between sustaining pharmaceutical innovation whilst ensuring access to medicines.

Pharmaceutical company's assertion against governmental interventions centers on the negative effect they will have on Research and Development (R&D), as limited profit restricts research into new and innovative medicines [7]. The high costs and risks associated with R&D, has for decades been the industry's rationale for charging high prices in the developed countries, and is often the basis for claims that companies cannot afford research into diseases that feature in developing countries, where high prices cannot be charged [8]. Despite this, the ethical dilemma remains, whether medicine prices should be the primary determining factor of R&D.

Should governments not consider alternatives incentives, such as tax concessions and public grants to encourage R&D other than high prices or patent incentives? When considering any alternatives however, governments need to be vigilant that incentives that are publically funded reward companies that are developing clinically significant and required medicines (like for orphan diseases, or for conditions prevalent in that country) at lower prices, as opposed to those that develop new medicines of little advantage [9]. Consideration should also be given to where interventions should be made in the supply chain. These are explained further in the text that follows.

Addressing Medicine Prices from a Manufacturers Price Setting Point of View

The manufacturers price relative to the end user price varies widely across countries (ranging from 24% in Kenya, to over 64% in the Netherlands); therapeutic class intervals; as well as between medicines of different patent status [10]. The manufacturer's share of the medicine price build-up is dependent on either government regulations or the level of trade discounting. Trade discounts which are offered by manufacturers to wholesalers or pharmacies are negotiated individually in business to business transactions [10].

Hence, they vary depending on the purchasing power of the buyer and level of competition. It has been observed that generic manufacturers often offer much larger discounts in order to secure volume share. An example of this is in Brazil where generic manufacturers may offer discounts of over 50% from list prices, while originators may offer discounts in the range of 10-15%. The confidentiality attached to negotiated discounts, means that the gross manufacturer prices are often not reflective of the true price received, and hence introduces an element of non-transparency in the manufacturer's price.

Regulations that target the manufacturer's price have been implemented in several developed countries with success. However, there is very little literature that demonstrates similar scenarios in LMIC's. In response to the need to improve access to affordable medicines particularly in LMICS countries, and to aid national policy-makers and other stakeholders in identifying and implementing policies to manage pharmaceutical prices, the World Health Organisation (WHO) produced and published the WHO Guideline on Country Pharmaceutical Pricing Policies [11].

Essentially, there are no standalone or universal policies to attain affordable medicine prices, and the challenges in implementing policies vary from country to country. The common challenge that does exist however is the lack of technical capacity to analyse and interpret the relationship between price data and local policies and to respond effectively to high prices or unusual price variations [11]. Furthermore, the lack of published systematic data makes it difficult to gauge the effectiveness of policies in LMICs that would allow these countries to learn or emulate from each other. Some of the government interventions that target the manufacturer price include price or profit controls on the manufacturer; reference pricing and international benchmarking.

Price or Profit Control

Price controls on the manufactures price involve restricting prices to the cost of production plus a profit margin. Evidence of its application in LMIC's is scant and anecdotal in nature [11], with the main challenge being the difficulty in obtaining accurate costing information from the manufacturer. Additionally, it is dependent on a country having the technical ability and resources to obtain this information from manufacturers. Hence despite this approach being attractive in that it may be relatively straightforward to implement, it unfortunately can be manipulated to the advantage of manufacturers and disadvantage of patients. Cost-plus pricing may be beneficial to stabilize medicine prices and reduce out-of-pocket payments in unregulated settings, but ideally should be complemented with other polices to strengthen its outcome.

Profit controls which are not widely advocated, involve capping the profits manufacturers earn from sales, where companies can price freely within the cap. The challenges that arise is that it may be difficult to ascertain a fair price cap, and this method has often

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been criticized for being open to manipulation and having an allowable profit level that is set to high [4]. Although applied in other segments of the supply chain, no accounts of its application to the manufacturers price in LMIC's has been published.

Reference Pricing

Reference pricing allocates a medicine to a therapeutic group of interchangeable medicines which are considered equivalent based on safety, efficacy and outcome. Reference price systems set a benchmark price which is tied to the mean of the various prices or may reflect the price of one of the lowest-cost items in the class or an average of various low prices; alternatively, it may be the price of the product considered to be the most cost-effective in its category [1]. The reference price is not necessarily the market price for all medicines in a therapeutic class, and manufacturers can set prices higher than the reference, however in doing do they need to compete against interchangeable lower-priced medicines. The methodology employed in setting reference prices need to take into consideration, the country specific context of price competition and the volume of generic medicine use. Setting the reference price at the average price level of generic medicines in the reference group, coupled with stimulating the demand for generic medicines incentivizes these companies to compete, thereby driving down prices of medicines. Another option, that would be beneficial to LMIC's, who are still developing their generic medicines markets, would be to set the reference price at a higher level to encourage generic medicines market entry.

This system, which was employed in Portugal (2003), can be introduced as a temporary measure to boost the generic medicines market until it reaches an optimal level of competition [4]. For reference price systems to remain relevant, the process requires a country to have the technical capacity for regularly monitoring and updating to include new treatment options and medicines within a reference group. This policy option is best applied in conjunction with other measures such as official approval of price increases, compulsory generic substitution or compulsory price reductions [12]. This would prevent the phenomenon of lower priced medicines adjusting their prices upward toward the reference price.

International Benchmarking

International benchmarking refers to the practice of using the price of a pharmaceutical product (generally manufacturer) in one or several countries to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country [11].The literature suggests that this method of price regulation is one of the more popular efforts used in developing countries, employed as a means of price negotiation, setting, and verification. The benefits attached to international benchmarking include the relative simplicity in applying the system; however, its success is dependent on the availability of price information and price components from comparator countries as well as choosing appropriate comparator countries. Despite claims of price lowering effects of international benchmarking, the literature provides no supporting evidence of this in LMIC's. The possible negative effects of this system which have been observed in developed countries include launch delays and non-availability of new medicines in "low price" countries.

The Use of Generic Medicines

The promotion of quality assured generic medicines has been identified as a complementary strategy to the above-mentioned price regulations that can increase access and medicine affordability. This approach requires several additional policy options that should be combined to promote the use of generics. This begins with legislative and administrative measures to facilitate generic entry; legislation to allow generic substitution by dispensers; legislation that target prescribers as well as consumer and professional education regarding the quality and price of generics.

Local Production of Medicines

WHO recommendations also encourage local production of medicines through voluntary licensing and transfer of technology by the originator companies. Local production can result in increased accessibility to medicines through, introducing competition and lower prices as well as increased economies of scale and/or simple geographical access [13]. Further to this, the obvious and long term perceived benefits of local production include saving on foreign exchange; job creation and human capacity development; stimulation of exports and enhanced self-sufficiency in a country's pharmaceutical supply, thus prospectively alleviating poverty in LMIC's. The success of this mechanism however is reliant on the willingness of patent-holders to grant voluntary licenses and hinges on the availability of technical experience and infrastructure. The often-weak pharmaceutical regulations operating in LMIC's; poor implementation of Good Manufacturing Practices/ quality control standards; high cost of product development, and underdeveloped supporting industries; frequently represent barriers for countries to venture into local production.

Health Technology Assessment

As previously noted, the lack of reliable healthcare information systems in LMICs also contribute to the poor implementation, monitoring and evaluation of pharmaceutical pricing policies [12]. WHO recommends the use of Health Technology Assessments (HTA) in evaluating price setting or pricing policies, as they assist in addressing both the direct and indirect as well as intended and unintended consequences of policy implementation. In addition to using HTA as a tool to support price setting/negotiation, LMIC's should combine HTA with other policies and strategies, particularly those adopting reference pricing.

Despite its advantages, the lack of capacity, local data and qualified researchers to conduct HTAs in LMIC's resonates throughout the literature, making it a difficult strategy to implement. Governments should invest in developing the human capital required to conduct and utilize assessments particularly

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for HTA's that aid in determining fair and appropriate medicine prices. This is particularly important, since pharmaceutical expenditure is a function of medicine price. Hence better informed HTA's would assist in improved budget decisions.

Summary

It should be noted that government pricing regulations alone do not guarantee reduced prices or increased medicine accessibility. Price control measures are just one of the tools available to contain the costs of the health care and should remain just one facet of a more multi targeted (industry, wholesalers, retailers, consumers, doctors, etc.) comprehensive strategy. Strategizing price control measures should be an ongoing process, monitored regularly, researched and published timeously. Monitoring should have a far-reaching focus to include trends in medicine expenditure, medicine utilization, medicine consumption and pricing data. Collecting, analyzing and publishing reliable and valid data on process and outcomes over a period makes it possible to determine the overall effect of price controls policies, and to detect adverse effects such as medicine shortages.

This information is also important for other countries looking to contain costs as very often stakeholder's oppositions to proposed policies stems from fears and misunderstanding of the probable outcomes and adverse effects to their business should said policy be implemented. This could be allayed with sound information, where it has been proven that similar measures have been successful, without detriment, earlier in another country in a situation like one's own [4].

Implementing pricing regulations in any country requires significant planning and monitoring, and governments need to be aware of what is most suited to their national objectives and feasibility for any intervention to be successful. Ensuring that interests of the pharmaceutical industry be considered when planning to introduce new regulations are also essential. It is not always realistic to assert, over-zealous price controls that are generally likely to push prices down to levels that are too low to deliver a profit and to finance research and development. Such controls may be particularly harmful to local firms in developing and transitional countries, and have a reverberating effect on employment, income, exports and economic activity at large [11]. Currently there is a lack of research indicating which policies are preferred over others; as well as under what conditions certain policies fail to work in LMIC's, and thus represents a crucial first step to developing price regulations.

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