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Pharmaceutical Pricing Policies and Interventions
POLICY BRIEF NUMBER 3

REGULATION OF MARK-UPS IN THE PHARMACEUTICAL SUPPLY CHAIN

As part of the joint World Health Organization (WHO) / Health Action International (HAI) Project on Medicine Prices and Availability, a series of in-depth reviews have been published on pharmaceutical pricing policies and interventions that may improve medicine availability and affordability. This policy brief summarises the key points from the review on the regulation of distribution mark-ups, which included a systematic literature review and analysis of policy issues and options.

Page references to the review paper are given in parentheses.

WHAT IS THE BASIS FOR THIS POLICY BRIEF?

WHO/HAI Review Series on Pharmaceutical Pricing Policies and Interventions. Working paper 3: *The regulation of mark-ups in the pharmaceutical supply chain* by Douglas Ball. www.haiweb.org/medicineprices/policy/index.html

SUMMARY CONCLUSIONS

What are the main advantages of mark-up regulation?

If part of a comprehensive price regulation strategy, mark-up regulation can reduce prices and help to control expenditure. Mark-up regulation alone is unlikely to reduce prices.

What are the main disadvantages of mark-up regulation?

Poorly designed mark-up regulation can reduce availability of low-priced medicines and make rural pharmacies unviable. Those in the distribution chain can often find ways to evade regulations or recoup lost profits by increasing other fees and prices.

What is the most appropriate form of mark-up regulation?

Regressive mark-ups and fixed fees can avoid perverse incentives to dispense high priced medicines and encourage dispensing of lower-priced generics.

Should mark-up regulation be applied to all medicine prices?

Selective regulation within a sector risks unintended effects on the availability of regulated products, but countries may regulate mark-ups only for the public sector or only for reimbursement prices for social health insurance. Low-priced generics may be exempt.

Is mark-up regulation appropriate for all countries?

Countries that lack monitoring and enforcement capacity are unlikely to be able to implement mark-up regulation effectively.

Are there any complementary policies that should accompany mark-up regulation?

Additional policies may be needed to ensure medicine availability in remote areas. Promotion of generics and rational use can complement regressive mark-ups and fixed fees.

Are there any key prerequisites for implementing mark-up regulations?

Systems for consulting stakeholders, monitoring prices, sales and medicine availability are vital. Mark-up levels should be informed by intelligence on costs in the distribution chain.

Studies of medicine price components in low- and middle-income countries (LMICs) show variable and often high cumulative mark-ups, from 17%-84% in the public sector and 11%-6,894% in the private sector. The level of mark-ups among Organization for Economic Coorperation (OECD) countries also varies widely, from 2%-21% for wholesale mark-ups and from 4%-50% for retail mark-ups (pp.17,19). It is therefore important to find ways of improving efficiency and controlling costs in the pharmaceutical distribution chain.

Defining distribution 'mark-ups'

Distribution mark-ups are the additions to the medicine manufacturer's or importer's supply price to cover the costs of wholesale and retail activities, including overheads, distribution costs and profit margins for wholesalers or other distributors and retailers. In traditional supply chains, the wholesale mark-up (expressed as a percentage add-on to the manufacturer's sale price) can be distinguished from the retail or pharmacy mark-up (expressed as a percentage add-on to the wholesaler's price or pharmacy purchase price). However, there can be diversity in how supply chains are organized, for example, pharmacy chains may carry out their own wholesaling functions, manufacturers may distribute directly to hospitals and pharmacies, or products pass through multiple wholesalers and distributors before reaching the retailer. Each adds a mark-up, leading to high cumulative mark-ups and prices. Importers also apply mark-ups. Because these mark-ups are applied early in the supply chain they will be compounded by the addition of distribution mark-ups, so their effect on the final patient price can be substantial. (p.2)

Policy objectives

Price regulation usually has the objective of reducing medicine prices and containing pharmaceutical expenditure, while ensuring prices are sufficient to achieve availability and assure product quality. Mark-up regulation creates incentives and disincentives throughout the supply chain. Some forms of mark-up regulation seek to influence these incentives for policy purposes, for example, to promote dispensing of generics, to encourage price competition, to discourage non-transparent commercial practices that may be anti-competitive (e.g. volume rebates or bundling), or to support locally manufactured products. (p.14)

What is the policy?

Mark-up regulation may be applied to the private sector and the public sector, and also used as part of a system for setting the reimbursement prices paid by social health insurance or public health systems. There are many variants in the way countries regulate mark-ups, corresponding to differences in policy objectives, including product-oriented approaches (e.g. cost + fixed or regressive percentage), or patient-oriented approaches (e.g. fixed dispensing fees, capitation payments per patient per year).

Patient-oriented approaches delink pharmacy profit and the price or quantity of medicines dispensed, encouraging more rational, efficient, patient-responsive pharmacy practices. In high-income countries (HIC) a combination of the two is often used. Table 1 provides an overview along with potential advantages and disadvantages. (p.15)

Some countries have separate regulation of wholesale and retail mark-ups. Wholesale mark-ups can be limited by setting a maximum allowable mark-up or a maximum price for resale. Some countries ban discounting and rebates by manufacturers and wholesalers to increase transparency of pricing and prevent commercial practices that may contribute to irrational use of medicines.

How and where has mark-up regulation been implemented?

LMICs most commonly use fixed percentage mark-up regulation. Some control prices either by regulating final retail prices or regulating manufacturer/importer price plus wholesale and retail mark-ups, while others use mark-up regulation alone. WHO/HAI data show some LMICs (India, Iran, South Africa, Syria, Tunisia) apply regressive mark-up regulation (higher priced products incurring lower percentage mark-ups to defined cost thresholds), and Indonesia, Iran, and South Africa use dispensing fees. A few LMICs use selective mark-up regulation for some essential medicines in an attempt to improve affordability. For example, India regulates prices of a small "scheduled" list and Indonesia regulates prices and mark-ups for around 450 unbranded generic medicines, though prices of branded originator and generic products are unregulated. (p.16)

Most OECD countries regulate mark-ups as one component of a comprehensive pricing strategy which also involves setting the manufacturer's or importer's selling price, or profit control or setting the final retail price. Some HICs only regulate prices for reimbursed prescription medicines, while prices and mark-ups for non-reimbursed medicines, over-the-counter medicines and/or hospital medicines are unregulated or subject to different mark-up regulation. Among HICs, all of the options for regulating mark-ups listed in Table 1 can be found, with many variants.

Table 1. Advantages and disadvantages of mark-up remuneration strategies

REMUNERATION/MARK-UP (cost price +)	ADVANTAGES / INCENTIVES	LIMITATIONS / DISINCENTIVES
Fixed fee, fees for services	• No/reduced incentive to sell higher value items • Relatively easy to enforce	• No incentive to sell lower-cost items • Adds significantly to the patient price of low-cost medicines
Regressive flat fee/amount	• Reduces incentive to dispense high cost medicines	• Reduces incentive to carry high value stock • Adds significantly to the patient price of low-cost medicines
Fixed percentage	• Relatively simple to implement and enforce	• Disincentive to sell lower-cost items • Encourage stocking and sale of more expensive items
Regressive percentage	• Easy to implement • Reduces incentive to dispense high-cost medicines	• High-cost items may still attract large value mark-ups • May not create incentive to dispense less expensive items
Differential percentage or fixed fee	• Incentives can be created for particular groups of medicines (e.g. essential medicines list, generics)	• More complex to implement and enforce
Fixed maximum fee / percentage	• Incentive for competition	• May lead to reduced service quality or product range in drive to lower costs • Disincentive to sell lower-cost items if fixed percentage and inadequate competition or room to reduce costs • Incentives exist for retailers to sell more expensive drugs
Combined mark-up to be divided after negotiation	• Reduces regulation	• Retailers may bypass wholesalers and increase margins/mark-up
Capitation fees	• No link to the sale or cost of the medicines • No incentive to sell high-cost items	• Sophisticated administration systems required
Capping of mark-ups	• Reduces incentive to dispense very high-cost items	
Combinations of above	• Combinations of above	• Combinations of above

Key aspects of designing mark-up regulation policies

Consider the incentives and disincentives created

Fixed percentage mark-ups tend to encourage stocking and sale of higher priced products. Regressive mark-ups are one method to counter this. Patient-oriented approaches seek to separate pharmacists remuneration from the price of the product. Fixed or differential dispensing fees create incentives for dispensing lower-priced products but also create incentives to dispense more items and can disproportionately increase the price of very low-priced products. The benefits of regressive margins or fixed or differential fees can be negated by discounts or other trade schemes which increase the actual profit margin earned by retailers and/or wholesalers. (pp.23-24 and 61-62)

The magnitude and calculation of regulated mark-ups

What constitutes a reasonable mark-up will differ within and across countries because of differences in geography, level of development, urbanisation, health system structure, procurement price and other factors that affect distribution costs. International comparisons of mark-up levels are not a useful guide. Country-specific cost accounting studies of distribution and pharmacy costs and monitoring of the impact of mark-up regulation can help inform policy. It is important to also consider the effects of mark-up policies on availability, particularly for low-priced medicines, and the viability of pharmacies in remote, sparsely populated areas where distribution costs are high and product turn-over is low. Low-priced generics may be cheaper than their branded equivalents even with high mark-ups. (pp.45-46)

Complementarity and integration with other policies

Mark-up regulation needs to be part of a comprehensive regulatory strategy covering manufacturer and importers price, or it is unlikely to control prices effectively. Countries may need to design policies to ensure availability of medicines in remote rural areas where distribution costs are high, such as higher permitted mark-ups, exemption from regulation for low-priced generics, pharmacy subsidies, mobile services, or limited dispensing rights for rural healthcare workers. Promotion of generics and rational use can complement regressive mark-ups and fixed fees. (p.44)

What capacity and information is required to implement the policy effectively?

Mark-up regulation requires intelligence on costs and profitability in the distribution chain and economic, statistical, medical, pharmaceutical and legal expertise. It requires mechanisms for consulting stakeholders and for monitoring and analysing prices, sales and availability of regulated products, together with resources for enforcement. Studies in a number of LMICs report regulations not being implemented or enforced, and there can be widespread deviations of actual prices from the regulated level in both public and private facilities. (*1, 2*) (p.47)

Are there risks associated with mark-up regulation?

If the regulated mark-up is set at an unprofitable level, the availability of regulated medicines may be adversely affected. If most or all medicines are regulated, the commercial viability of some wholesalers or retailers will be reduced, particularly in rural and poor areas with high distribution costs and low product turnover. Fixed percentage mark-ups create incentives for pharmacists to shift stocking and sales to higher priced products and may reduce availability of low-priced generics. Selective regulation of only essential list medicines may lead manufacturers and pharmacists to shift production and sales to more profitable non-essential products. Dispensing fees can add significantly to the prices of low-priced medicines, making them unaffordable for poor patients. Unintended effects can also arise when those in the distribution chain try to recover lost profits.

Regulated companies can be expected to lobby or litigate to overturn the policy, so consultation, involvement of civil society and political support are needed to sustain it. Manufacturers, importers and wholesalers may collude to inflate landed costs. Wholesalers and retailers may introduce additional fees on top of mark-ups. Hospitals may increase other patient fees to make up lost revenue. Unless regulation of mark-ups is part of a comprehensive regulatory process that also covers manufacturers, importers and all agents involved in procurement and distribution, substantial loopholes will exist through which actual mark-ups and medicine prices can be manipulated. Countries can address this by setting a total distribution mark-up or by regulating final patient prices and then using separate regulation or competition or negotiation among firms in the supply chain to determine the actual split between importers, wholesalers, distributers and retailers. (pp.25-27)

How has the policy been monitored and evaluated?

Monitoring data and evaluation of the regulation of mark-ups in LMICs is sparse and often of poor quality. Countries with better data availability are mostly middle income countries and those with more resources and infrastructure. (pp. 35, 38, 41)

What effect does the policy have on prices and availability?

Evidence from HICs show that a comprehensive system of price regulation – in which mark-up regulation is one component – can reduce prices and expenditure in the short term (3). Evidence in LMICs is conflicting and mostly anecdotal. South Africa reported reduced prices of hospital medicines when mark-ups were eliminated (4). Jordan reported price increases, while Kenya reported price reductions, after removal of price controls (5,6). Ecuador and Panama perceive that they have more uniform prices and reduced speculation as a result of mark-up regulation, while Honduras believes it leads to over-invoicing (7). Use of fixed percentage mark-ups have been found to create incentives for the sale of higher priced medicines in some countries, including China (8). In China and Mali, selective regulation reportedly has resulted in adverse effects on availability of price-regulated medicines (8,9). There is no reliable information available about the impact of mark-up regulation alone on medicine prices. No evidence is available on whether regulating discounts and rebates leads to lower prices. (pp.25-27)

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OTHER USEFUL RESOURCES

A list of useful links and resources, other reviews and policy briefs in this series, and a glossary of terms used in the policy briefs can be found at: www.haiweb.org/medicineprices/policy/index.html