Working Paper 3: The Regulation of Mark-ups in the Pharmaceutical Supply Chain

Executive Summary

This paper reviews the literature on the regulation of pharmaceutical distribution mark-ups in low- and middle-income countries (LMICs) with a view to describing and analysing the current knowledge. A search was conducted of published literature indexed in PubMed and EconLit as well as grey literature.

Evidence of the regulation of mark-ups in the distribution chain in LMICs is sparse, not systematically collected, and often of poor quality where it exists.WHO pharmaceutical indicator survey data shows that around 60% of low-income countries report regulating wholesale or retail mark-ups in either the public or private sector. In middle-income countries, regulation in the public sector is of a comparable level. Data from medicine pricing and availability surveys undertaken using the WHO/HAI methodology suggest that fixed percentage mark-ups are most common in LMICs, with regressive mark-ups only applied in some higher income economies e.g. India, Iran.

Mark-up regulation is generally not used as a means to promote generic dispensing, and in LMICs it tends to include all medicines within the defined public or private sector. There is no reliable information available about the impact of mark-up regulation alone on medicine prices in LMICs. Enforcement of regulations is also seldom covered in the literature apart from a small number of accounts of varying degrees of lax enforcement in some countries.

There is limited information about the effect of mark-up regulation on the viability of distribution operations at importer, wholesale or retail level. However, in unregulated pharmaceutical settings, retail mark-ups in the private sector vary depending on distance from major urban centres. A fixed percentage mark-up appears the most common form of remuneration of retailers in LMICs and dispensing fees are uncommon. Apart from isolated mention of discounts and rebates, there was no evidence as to whether regulation of such commercial practices would be effective in reducing medicine prices.

The above information contrasts with the situation in high-income countries (HICs) where mark-ups or margins are commonly regulated in countries that have a national health system or other reimbursement mechanism for prescribed pharmaceuticals. This is usually part of comprehensive medicine price regulation which, as a whole, has been shown to reduce pharmaceutical expenditure in the short term. Retailer mark-ups appear more likely to be subject to regulation than wholesaler mark-ups in HICs and a variety of methods are used from simple flat percentage mark-ups through regressive scales combined with fixed fees or more complex formulae. High-income countries often focus their regulation on

prescription medicines or those which are reimbursed. It is assumed that high-income countries have rigorous enforcement mechanisms.

Based on the literature available, the following key points were identified:

- Regulation of mark-ups as part of a comprehensive price regulation strategy probably will lead to reduced medicine prices. However, regulation of mark-ups without regulation of either the manufacturer‟s selling price or the retail selling price is unlikely to lead to reduced medicine prices.
- Regulation of mark-ups will probably have an effect on the viability of some operators in the pharmaceutical supply chain and may adversely impact the viability of operations in more remote areas or other health services that are cross-subsidized through higher mark-ups.
- Regulation of distribution mark-ups can have unintended impacts or consequences. Incentives and disincentives need to be mapped and potential unexpected effects considered.
- A reliable mechanism for monitoring the prices and sales of medicines in the appropriate sector or market is essential to be able to judge the effects of pricing regulations, both intended and unintended.
- It is possible to use mark-up regulation as part of a generic medicine promotion policy, for example by providing higher remuneration for generic medicines or any other group of products, but this is not commonly practiced.
- Regulating mark-ups in the private sector is probably more complex than in the public sector. Improving efficiency of procurement and distribution in the public sector should be considered as a strategy to lower pharmaceutical costs.
- Regulating mark-ups without adequate enforcement is probably not effective and adequate enforcement in low-income countries appears challenging.
- Mark-ups that include a regressive component with or without fixed fees probably lead to better outcomes that fixed percentage mark-ups through their influence on financial incentives. However, fixed fee mark-ups can dramatically increase the price of otherwise low-cost medicines.
- While banning discounts, rebates and bonuses in the supply chain probably increases transparency in medicine pricing, there is insufficient evidence to say whether it leads to reduced prices.

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