Medicines with one seller and many buyers: strategies to increase the power of the payer

Andrew Rintoul and colleagues argue that collaboration and transparency increase the market power of buyers who face a monopoly

ealth system budgets face increasing pressures from ageing populations, epidemiological transitions, and technological innovation. One area for buyers to find savings is in questioning whether the price they negotiate for a medicine is fair.

This challenge of high prices is particularly acute for medicines that are available from a single source, where there is no alternative with a similar indication. Monopolies can use several techniques to consolidate their market power and maintain a high price. For example, they may emphasise slightly different indications of their medicine from those of competitors, marketing small differences in benefits and risks that may not be clinically meaningful.

Health systems face consequences when markets fail because of a lack of competition: budgets need to increase, the needs of some patients are prioritised over others, out-of-pocket spending increases, and some patients do not receive treatment.²⁻⁴

KEY MESSAGES

- Achieving fair pricing of medicines is particularly acute for single source medicines—that is, medicines lacking an alternative with a similar indication (monopoly)
- Price negotiations deliver mixed results, particularly when anchored by discounts from a "list price" ceiling set by the seller, with no transparency about the true costs of development and production that could anchor a negotiating floor
- In the absence of transparent data, the closest that buyers can get to fairer pricing is to impose regulations and policies that attempt to assert their buying power
- Ultimately, a successful strategy to achieve fair pricing necessitates cooperation, both among buyers and among other stakeholders

A lack of affordability for patients is a unique type of market failure. Patients usually have limited power to select the medicine they need as this is usually the domain of doctors or other health workers. Patients also rarely negotiate the price of medicines, as this is usually the responsibility of governments and third party payers. The final price can also be increased by wholesaler and pharmacy mark-ups, or reduced by rebates and discounts. A lack of transparency distorts the market for medicines, where demand does not tend to depend on the price.

Yet even when there is only one supplier, buyers are not powerless. Health systems have used several approaches to negotiate a fairer price for medicines. These include strategies for improving the selection process for which medicines to cover in their health system, and benchmarking to determine a fair price to pay for those medicines. This article provides a review of several common strategies undertaken by countries in developing their pharmaceutical pricing policies, outlining their benefits and risks to buyers seeking to achieve fairer pricing for medicines. Ultimately a successful strategy to achieve fair pricing requires transparency and cooperation, both among buyers and among other stakeholders.

Improving strategies for selection and coverage

Buyers have developed several tools to ensure that a new single source medicine reaches appropriate patients. Budget and systems planning can ensure that price negotiations begin with an accurate forecast of the need for, and potential benefit of, a new medicine within a population. Many clinical benefits of a new medicine are common across countries, although their manner of use may need to be adapted to national situations. Thus, strategies for selection and coverage are an area ripe for improvement through additional collaboration and transparency.

Many health systems use horizon scanning for early awareness of medicines

that could enter a market. In this way, buyers gain sufficient lead time to analyse the potential effect of a new medicine on the health system and develop strategies to cope with its introduction. Medicines can be prioritised for further review based on criteria such as potential health benefit, potential to trigger system changes, and unit cost or effect on the budget. Horizon scanning is administratively burdensome, but information gathering can be a collaborative effort. For example, nine European countries to date are collaborating in establishing the International Horizon Scanning Initiative.

The World Health Organization recommends that countries use health technology assessment as a tool to support decision making about reimbursement, price setting, and negotiation. The assessment is a multidisciplinary process that uses explicit and scientifically robust methods to weigh up the value of using a health technology, such as at launch, when additional real world evidence about its use is available, and once competitor products reach the market. However, health technology assessment requires significant resources, including staff with training in health economics who can critically assess technical dossiers. Countries looking to introduce such assessment should take a stepwise approach to developing legislative and technical capacity to take full advantage of it in pharmaceutical price setting and reimbursement. National academic institutions can help in developing capacity and can serve as external reviewers and train health technology assessors.

Buyers can extract larger discounts from manufacturers by threatening to offer only limited coverage for a medicine, or to leave it out of a benefit package, national list, or formulary. Without an agreement there is no market. In the US, both the Veterans Health Administration and the Department of Defense negotiate lower prices directly with manufacturers, using formularies to manage which medicines they cover.

For high cost medicines with uncertain benefits, healthcare systems can put

conditions on how a medicine is used or paid for using a managed entry agreement. Conditions can be financial discounts and rebates, or more complex arrangements based on outcome. 10 Managed entry agreements often specify collection of additional data to enable future decision making about new products with limited current evidence. 11 Technical and practical challenges exist with such arrangements. Implementation can be limited by technical factors—for example, data collection in routine care can be costly and might yield less evidence than expected. In addition, delisting a treatment can raise objections from patients, who consider that they are being denied treatment, despite efforts to explain that a medicine is less effective than expected.

Buyers can use a variety of tools to improve their spending forecasts. Some can be used while research and development are still under way, as in the case of horizon scanning. Other tools, such as formularies and health technology assessment, allow buyers to select medicines once approved for marketing. In recent years managed entry agreements have reduced financial risk, particularly for medicines with uncertain benefits. Recognition that each of these processes is improved with better data reporting has led to an increased push for transparency and collaboration.

Improving strategies for price benchmarking

An important factor in determining a fair price for a medicine is the price a buyer is willing to pay for a given clinical benefit. Buyers have used several different methods to benchmark medicine prices and facilitate purchasing. None of these strategies alone will achieve lower prices, but the recent drive for additional transparency and collaboration has made buyers more active purchasers in determining what is fair in their goal of achieving access for their populations.

Setting a benchmark using price information from other countries, with similar socioeconomic status, is one method that buyers have used to control costs—known as external reference pricing. This method generally uses a declared list price that can differ substantially from the actual price paid, given confidential discounts and rebates. 12 13 The widespread use of external reference pricing, particularly in Europe, 14 has been criticised because of its reliance on list price. The interconnected web of countries referencing each other's prices has potentially affected launch sequencing

across countries, thereby directly affecting patient access. 15

Some countries are increasingly interested in developing tiered or differential pricing, whereby different prices are charged to buyers according to their income levels. In theory, it offers the possibility of simultaneously increasing profits and expanding access to a medicine for a larger population. Several criticisms have been raised about tiered pricing, particularly the potentially arbitrary nature of determining tiers, whether it will improve access in lower income countries or small markets, and the lack of transparency or public input into pricing primarily set by sellers-a phenomenon known as price discrimination.¹⁶

An alternative case has been made for expensive medicines offsetting longer term costs, leading to the development of value based pricing. Value based pricing follows the principle that price should reflect the value to the buyer rather than the actual costs of production plus a margin.17 18 It has emerged as a way of agreeing what will be considered during negotiations. Two stages are common: firstly, an agreement of what is included in the value assessment and secondly, how it is valued. Definitions of value can vary across stakeholders and contexts, however, with some arguing that the design of such models can be manipulated to demonstrate a desired outcome. 19 Some countries have experimented with permitting several prices for a single medicine with multiple indications according to the value of each indication. Others, such as Germany, account for such potential differences in value across indications by setting its price according to an average weighted by the population treated in each indication. This strategy, however, may disincentivise applications for new indications with minimal added benefit over comparators, instead relying on off-label prescribing or reformulation of medicines.²⁰

Pooled procurement, or joint purchasing, can reduce the power of a monopoly. This allows several buyers to agree to purchase certain medicines exclusively through the group. Joint purchasing increases buyers' power because it provides access to several markets and increases the volume of product included in the tender. ^{21 22} Pooled procurement has been shown to reduce the price of medicines drastically and improve access globally and regionally as suppliers and buyers both benefit from economies of scale. ^{23 24} For example, the Organisation of Eastern Caribbean States Pharmaceutical

Procurement Service negotiated an average cost savings of 37% for 25 selected pharmaceuticals over a five year period (1998-2002).^{25 26} Pooled procurement is not a perfect solution, however, as constraints owing to differences in national process or legislation may need to be resolved before implementation and may exceed the expected savings²⁷ or lead to unintended consequences for the supply.²⁸

Improving strategies for price benchmarking gives buyers additional information to inform their purchasing. The strategies outlined above are not new, but their efficacy has improved with the global push towards transparency. Pooled procurement takes such benchmarking a step further and allows joint purchasing at larger, more steady volumes—an improvement for both buyer and seller.

The case for collaboration

Achieving fair pricing of medicines is particularly important for medicines that are only available from a single source (a monopoly). Price negotiations can deliver mixed results where negotiations are based on discounts from a "list price" ceiling set by the seller, rather than a negotiating floor that reflects the cost of production.

No single strategy or policy can lead to a fair price for medicines. Each policy has its benefits and drawbacks, and thus it is important that it is not used in isolation. For buyers a robust strategy would make use of elements of each policy and be adapted to country characteristics.

In the absence of transparent data, buyers need to maximise their market power (monopsony power) to rival the monopoly they are confronting, otherwise an imbalance in market forces can lead to market failure. By imposing some of the strategies outlined above, payers have asserted their buying power and come closer to achieving a fair price.

Buyers seeking fairer prices benefit from both transparency and collaboration, but this requires strong commitment from decision makers. International commitment is emerging, with a recent World Health Assembly resolution on improving the transparency of markets.²⁹ Ultimately, a successful strategy to achieve fair pricing necessitates cooperation, both among buyers and among other stakeholders.

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