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CHAPTER 9

Pharmaceutical pricing policy

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SUMMARY

In a market economy, the interaction of producers and consumers determines the price of goods and services. Understanding the theory of supply and demand helps explain how prices are determined, and this theory also explains how responsive (elastic) both supply and demand are to changes in price. For example, medicines that are not considered essential and that the buyer could credibly refuse to purchase will have more elastic prices, whereas the prices of medicines that are considered essential and that the buyer must obtain will be inelastic, meaning buyers will be less sensitive to higher prices.

Factors that interfere with the ability of the market to efficiently produce and allocate goods and services are said to result in “market failure.” An example of market failure is when buyers do not have the same level of knowledge; for example, some buyers might pay more than others for the same medicines because they are unaware of what everyone else is paying.

When buyers or sellers have market power (monopoly or monopsony), they can distort how the market price mechanism works. For example, in absolute monopolies (one seller) and oligopolies (a few sellers), the seller has significant ability to set prices, because the consumer has limited choices. This distortion allows the seller to command a price that is higher than would have prevailed under more competitive situations. In a monopsony, where the government has market power as the only large buyer in the market, the government acts on behalf of consumers to obtain better prices.

In addition to these economic theories of price determination, prices for medicines are influenced by the fact that medicines have certain traits that set them apart from other consumer products. For example, consumers need expert advice to make rational choices between using and not using a medicine and about what kind

of medicine to use. This advice is provided by prescribers, who may not know or even care about the price of medicines. Medicines also serve as an investment in future health, which may be difficult for the consumer to value.

The literature unanimously concludes that medicine price differences exist between countries, even when comparing between or within the strata of industrialized, middle-, and low-income countries. Price variation within countries is more likely in less price-regulated markets, such as the United States; however, prices vary in other countries, where public, private, and non-governmental (not-for-profit) sectors procure medicines separately. Variable prices for medicines within and between countries often result from—

- The pharmaceutical manufacturer selling the same product for different prices
- Intra- and intercountry differences in the margins charged in the postmanufacturing supply chain by wholesalers, distributors, and pharmacists, as well as taxes and co-payments levied by the state

Conducting pharmaceutical price comparisons is challenging, but such assessments can identify price variations and provide valuable information on their source and on interventions that can help reduce medicine prices. For example, margins and taxes charged along the pharmaceutical supply chain can add significantly to the final price of medicines; however, governments can control these markups by enacting price-control policies and eliminating tariffs and taxes. In addition, buyers of pharmaceuticals should assess their own position in the marketplace and use tactics such as price negotiations, pooled procurement, and information sharing to increase their market power.

9.1 The theory of determining prices

The history of economics, and therefore much of economic thought, is dominated by discussion of the theory of prices and how they are determined. This theory is underscored by the behavior of market participants—buyers and sellers. As noted in Chapter 10, a scarcity of resources requires that buyers and sellers make choices about how resources will be used, whereas abundance allows limitless production and consumption. However, resources *are* always limited, and using a resource in one way means it is no longer available for alternative uses.

In competitive markets, producers need to decide, for a given amount of resources, what and how much to produce, while consumers, with a given amount of income, need to choose what and how much they will buy. Producers and consumers come together in the marketplace, and under certain assumptions, their interaction determines market prices.

Demand and supply

Demand is generated by consumers, while the supply is provided by producers. Critical to the theory is an under-

standing of what drives each group, because consumers and producers are not driven by the same forces.

Demand: Market theory places the consumer in the lead role for determining what will be produced. Consumers want to maximize their welfare through the total bundle of goods and services they buy with their income. The bundles of goods that consumers choose to buy at given prices tell producers what to produce. In theory, consumers make rational choices as to what is included in the bundle of goods; however, nothing in the theory suggests that these preferences are equitable or socially desirable, only that they represent choices. Prices of complementary products or substitute products affect demand, as does the number of consumers in the market and their desire—for example, if a consumer prefers to buy a branded medicine over a generic and is willing to pay more. Associated with the role of creating demand is the consumer’s ability to vote—with money—on what will be produced. Therefore, individuals with greater income have proportionally more votes (Bannock et al. 1984).

Supply: Producers want to maximize their profit. Profits are determined by the cost of production and the firm’s total revenue (or sales). To maximize profit, the seller has an incentive to use resources in the production process in the least costly way. In a perfectly competitive marketplace, firms receive “normal profits”; that is, they cover the cost of all production costs plus the minimum return required to keep them in business. If the firms’ returns were greater than this minimum, new firms would be encouraged to enter the market, and the competition would drive profits downward until normal profits were reached. If the returns were less than the minimum, low profitability would encourage firms to leave the market, raising the profits of the remaining businesses until they achieved normal profits. Other factors that affect the supply curve include the number of producers, which increases competition; technology, which can initially represent a cost to the producer but ultimately increases efficiency; and the cost of inputs.

Elasticity of prices

The intersection of supply and demand provides the tool for understanding price determination. However, a further aspect of supply and demand helps explain behavior, that is, how responsive each is to changes in price.

Elasticity of demand: On the demand side, if consumers really need a product to the extent that a significant price increase has little effect on the quantity demanded, demand is nonresponsive to price and is said to be *price inelastic*. The reverse situation is where demand is very responsive to price, such that a slight rise in price causes a proportionally larger fall in demand. Pharmaceutical demand varies across countries. It is also relatively *income inelastic*, meaning that a person’s income affects pharma-

ceutical purchases less than other factors (OECD 2008). The four determinants of price elasticity of demand are substitutability, proportion of income committed to the purchase, whether the item is a luxury or a necessity, and market timing (see Box 9-1).

Elasticity of supply: On the supply side, if suppliers do not respond to price changes, they are price inelastic, whereas suppliers who do respond are said to be price elastic. The determinants of the price elasticity of supply depend on timing (Jackson and McConnell 1989). In the immediate market period, say on the day of a significant price rise, producers may not be physically able to increase production. However, over time and assuming demand is maintained, suppliers will seek to increase production by using existing excess capacity and ultimately by expanding their production capabilities by increasing capital and labor.

9.2 The reality of competition in a market-based economy

An *economic market* is defined as a trade of goods or services between two independent players: (a) buyers and (b) sellers or producers. Price carries information about the value of the goods or services, with the buyers’ willingness to pay defined as *demand*, and the sellers’ willingness to produce the goods being the *supply*. The market is where the buyers and sellers interact, and the interaction of supply and demand determines price.

Most economic theory starts with an assumption of a perfectly competitive market where buyers demand goods and services until the marginal value of each is equal to their price, and producers adjust the supply until the marginal cost of each unit is equal to the market price. This interaction allows demand and supply to fluctuate until they are in equilibrium. When price equilibrium exists between demand and supply, then the resulting allocation of resources for the goods or services of that market is also in equilibrium. Such a market is perfectly competitive. The necessary conditions of a perfectly competitive market include—

- A large number of buyers and sellers or suppliers to form the market
- Buyers that have excellent information, act rationally, and have the time and ability to compare the prices of various suppliers
- Suppliers or producers that have free entry and exit from the market
- Homogenous products of known quality offered by different producers

A review of these characteristics shows that health care is not an example of a perfectly competitive market. Buyers do not have perfect information—patients must rely on health

Box 9-1 Factors that influence elasticity of demand

The degree to which the product can be substituted with another

For example, aspirin is produced by many companies. In a situation where the consumer sees no major difference between each firm's brand of aspirin, a rise in price by one firm will result in a proportionally greater fall in the quantity purchased. For example, if firm A decides to increase its price by 20 percent, the level of demand for A's aspirin line is likely to fall by a larger proportion (by more than 20 percent) because consumers will purchase the equivalent and cheaper products from firms B, C, or D. This scenario exemplifies *price elasticity*. However, where the product has no or few direct substitutes, demand will be less responsive to price changes. For example, a newly patented, innovative medicine that has no therapeutic equivalent (a single-source drug), which is also considered to be essential, will have demand that is *price inelastic*: that is, a 20 percent rise in price might not affect demand at all.

Proportion of income

If a product costs only a small proportion of income, it is likely to be price inelastic. For example, if the price of over-the-counter analgesics sold by all sellers, such as

paracetamol and aspirin, increases by 20 percent, the level of demand is only likely to fall slightly, because the price represents a small fraction of the consumer's average weekly income.

Luxuries and necessities

As their names suggest, the demand for necessities is likely to be price inelastic because consumers cannot live without them, whereas the demand for luxuries will vary significantly with price. Essential medicines are necessities.

Time

Time makes demand more price elastic as information spreads about alternatives and because firms making alternatives find starting to produce identical or similar products profitable. For example, the manufacturer of a patented, innovative medicine that has no therapeutic alternative will be able to reap monopoly profits. However, these profits will encourage other manufacturers to look for other ways to obtain the same therapeutic outcome with a different (nonpatented) technique (such as the development of "me-too" drugs). The arrival of me-too drugs makes demand more elastic.

care providers to give them information about treatment. Furthermore, the suppliers—health providers—do not have easy market entry because of various factors such as licensing and regulatory requirements. Finally, health care is not homogenous in that quality varies among health providers. The result is often a noncompetitive market with market failures, as described in the remainder of this section.

The best possibility for the seller to charge higher prices and earn larger profits is in the extreme situation of an absolute monopoly. In an *absolute monopoly*, a product has only one seller with no alternative. This situation prevails with many patented medicines, particularly if no effective alternative treatments exist.

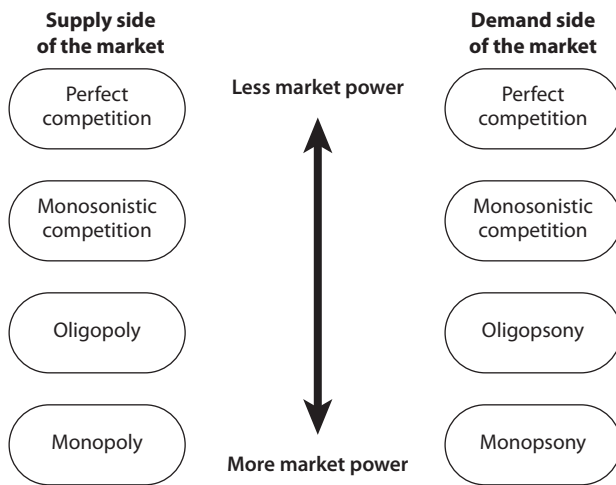
Oligopolistic competition occurs when only a few sellers operate in the market, so each seller can still influence price. *Monopolistic competition* involves multiple sellers, but they reduce the competition by allowing products to be differentiated (for example, by advertising); a single seller still has some influence over price or at least is able to vary prices without losing all sales. Similar descriptions apply to buyers in the market. Where a market has only one large buyer, which sometimes happens when governments purchase or subsidize pharmaceutical products, it is a *monopsony*. In this

case, the government acts on behalf of consumers to obtain better prices.

Figure 9-1 illustrates the range of buyer and seller market positions from perfect competition to monopoly and monopsony. Sellers in pharmaceutical markets are focused at the oligopoly and monopoly end of the supply spectrum. Depending on the influence of buyers, they can be located anywhere on the spectrum, from perfect competition to monopsony.

Market failure

Factors that interfere with the ability of the market to efficiently produce and allocate goods and services are said to result in market failure. Price distortions occur when the market fails to recognize and appropriately value important aspects of society, such as public goods. As noted in Chapter 10, public goods are those goods and services that people cannot be prevented from using, such as local roads, and goods and services whose costs do not vary if additional people use them, such as radio broadcasts. The price system cannot properly evaluate public goods because it has no means to value the level of each individual's demand for the

Figure 9-1 Market structures for buyers and sellers

Source: Jackson and McConnell 1989.

good or service and no means of excluding those who claim not to use the good or service.

For example, the evaluation of the safety of pharmaceuticals before human use, which is undertaken by a publicly funded body, is a public good because most individuals do not have the resources to conduct these assessments. Once the evaluation has been undertaken, the cost of sharing this information is almost zero: use of this information by one individual does not reduce anyone else's ability to use it. When consumers cannot be excluded from using the good or service, the market finds determining a price difficult, because potential consumers have an incentive to use the good or service without paying for it. Left alone, the free market would undersupply this information.

Pharmaceutical regulation, which can be considered a public good, can nevertheless contribute to market failure by creating a high barrier to companies that want to enter the market. Only large companies have the staff and resources to satisfy regulatory requirements, which reduce the number of companies that can compete in this market.

Market failure also occurs because of *externalities*, which are the benefits or costs associated with production or consumption that accrue to others. Immunization is one example: the benefits of disease prevention accrue not only to the person who is immunized, but also to others in the community who are exposed to a lower risk of infection. Externalities are not valued by the price mechanism because the individual who is to be immunized will assess only the benefit he or she directly receives, not the benefit received by others. When such externalities create public goods, governments may be willing to subsidize these prices.

Another type of market failure occurs when buyers do not have the same level of knowledge; buyers do not always know what others are paying for the same product, and the seller has an interest in keeping these prices hidden. That is, buyers pay more when they assume everyone else is paying the same price. For example, some large health care organizations in the United States negotiate deals with pharmaceutical manufacturers but do not make the purchase prices publicly available (Dougherty 2004). Alternatively, complex pricing arrangements can be set up that hide the ultimate price paid by the buyer (Country Study 9-1). In South Africa, the government has made such practices illegal in the private sector. Medicines have a single "exit price," which includes logistics fees; legislation also determines the markup and dispensing fee charged by the pharmacist. The intention is to make the pricing process transparent to consumers.

Country Study 9-1 Lack of transparency in medicine markets in New Zealand

Buyers commonly do not know the true price paid for individual products. For example, in New Zealand, a pharmaceutical company sells a range of medicines, including highly priced patented medicines. The public-sector buyer and the company negotiate a price for a bundle of medicines. The pharmaceutical company provides significant discounts to the buyer, but the company does not want other buyers to know that it will discount the patented medicines to make a sale. In the absence of an enforceable confidentiality agreement between the buyer and seller, what options does the pharmaceutical company have to maximize its profits? One way would be to make an agreement with the buyer to purchase the patented medicine at the stated market price in exchange

for a rebate at the end of some stipulated period. Alternatively, the company could hide the true price paid for a patented medicine by providing substantial discounts on other, possibly off-patent medicines sold by the company. This way, a buyer appears to be paying the market price requested by the company for the patented medicine, but in reality, the buyer is paying a much lower price for the basket of medicines. Naturally, the seller would prefer not to offer any discounts to anyone; however, if the buyer is in a position to exercise its own market power and negotiate lower prices, the seller will not want this price information to be freely available.

Source: McNee 2006.

So, to some degree, market failure in the pharmaceutical market is a price consumers pay for effective regulation. However, information asymmetry, high barriers to market entry, and monopolistic behavior have led to high prices for many patented medicines, which have made them unaffordable in many settings. Government intervention has been used to correct these distortions. Section 9.7 covers many approaches to price reduction.

Market power

Participants that exert market power can distort how the market price mechanism works. For example, in absolute monopolies (one seller) and oligopolies (a few sellers), the seller has significant ability to set prices, because the consumer has fewer choices. This distortion allows the seller to command a price that is higher than would have prevailed under more competitive situations (Jackson and McConnell 1989).

The same profit motive that drives sellers to seek new and more efficient means of production is also an incentive for them to form collectives where they can exert more power in the market. Antitrust and antimonopoly legislation aims to counter this anticompetitive tendency of markets. However, even strong, enforced legislation is no guarantee that firms will operate competitively. In 2006, five pharmaceutical companies were charged in Britain with colluding to set high prices (Dyer 2006). Despite the risk and cost of being caught, the large potential profits from price setting are a potent incentive to collude.

Sellers are not alone in their ability to influence the market. The strongest buying power is obtained from a monopsony buying position, that is, where a market has only one buyer. The most effective monopsony will have multiple sources for the product. In pharmaceutical markets, this situation translates into one buyer purchasing from several sellers of equivalent medicines. In this setting, the monopsonist can credibly purchase medicines from different sources, which creates a significant incentive for sellers to offer the best possible price. The least effective setting for a monopsony will be for patented, innovative medicines for which no alternatives are available (single-source medicines).

Negotiating with a monopoly removes some of the monopsonist's market power. However, even in this setting, the monopsony will have stronger buying power than several buyers (oligopsony) in negotiating with a single seller and even stronger power than when many buyers are negotiating with a single seller.

The extent to which the monopsony can offset monopoly pricing power will also depend on how necessary the medicine is. The offset will be strongest for medicines that are not considered essential and that the buyer could credibly refuse to buy. These medicines will have some elasticity of demand, and buyers will be price sensitive. The offset will be weak-

est for medicines that are considered essential and that the buyer must purchase. The demand for these medicines will be inelastic, and the need for the medicines will make buyers less price sensitive.

In some circumstances, a buyer emerges that has significant buying power. Examples of such large-scale buyers with purchasing power include health maintenance organizations in the United States (private sector) and, as shown in Country Study 9-2, the Pharmaceutical Benefits Scheme in Australia (public sector, monopsony). Although regulation is a critical factor influencing prices, compared to large procurement agencies, smaller buyers have little leverage and will likely pay higher prices. However, buyers can form cooperatives or join to increase their market power, which is the theory behind pooled procurement, discussed in Chapter 18.

It is intuitive to think that large buyers will have strong market positions to negotiate prices, if not by being the sole source of demand, then by the volume of the product they are expected to purchase. However, this association between a large buyer and low prices does not always hold true; the World Health Organization (WHO) reports that some government procurement operations are effective in obtaining low medicine prices, while others are not—usually because they purchase brand-name pharmaceuticals that are no longer under patent rather than lower-priced generic alternatives (Gelders et al. 2006). The buyer should be continually aware of the availability of generics entering the market.

The concern that a single large buyer can adversely affect producers appears uncommon in the area of pharmaceuticals but has been seen in some sectors of low-income countries. For instance, a large, powerful buyer can force down the prices of produce, such as fruit or coffee, to the extent that smaller producers suffer genuine hardship.

9.3 Economic characteristics of pharmaceuticals

Aside from the obvious characteristic of having health benefits, medicines have certain traits that set them apart from most other consumer products (see also Chapter 1).

First, when patients purchase a medicine, they do not gain an “asset” in an economic sense. In most countries, the patient cannot legally resell the medicine; its value rests in the knowledge that went into its development and the testing that determined the correct way to use it, such as dose, course of treatment, and contraindications. Particularly for recently introduced innovative medicines, the economic value of the pharmaceutical to the producer lies in this intellectual property rather than in the chemical constituents of the product.

Second, the patient is not a consumer in the traditional sense. She or he is usually directed by a third party, a doctor or other health professional, to purchase a medicine. The

Country Study 9-2 Australia's pharmaceutical benefits scheme

The Australian Pharmaceutical Benefits Scheme (PBS) requires consumers to make a maximum co-payment of 33.30 Australian dollars (AUD) for all medicines listed on the national formulary (as of 2010). Disadvantaged citizens in the community pay only AUD 5.40, and a safety net exists for people who exceed a maximum amount per year. Medicines not listed with the PBS may still be sold in Australia (provided safety and quality requirements are met), but at an unsubsidized price. However, since few patients will purchase full-price medications, particularly if a therapeutically equivalent medicine is available with a PBS subsidy, the Australian system operates as a monopoly, with the PBS as sole gatekeeper to medicines sold in the country. Pharmacists also receive an incentive each time they dispense a generic medicine to decrease the use of originator brands.

The Australian system of providing affordable access to medicines relies on public-private interactions. The public sector, through the PBS, determines what medicines will be subsidized by the government and at what level of subsidy. The government negotiates the agreed price with pharmaceutical manufacturers and the dispensed price with the Pharmaceutical Guild of Australia, including the markups and dispensing fees. Private-sector doctors are largely responsible for prescribing, and private-sector pharmacists are largely responsible for dispensing the medicine to the patient and collecting the co-payment at the point of sale.

The Australian Productivity Commission compared pharmaceutical prices in a range of industrialized nations. The commission found that—

- Prices for patented, innovative medicines in the United States were 104 percent higher than in Australia. While Australian prices were at the lower end of the price spectrum, prices in Spain were even lower.
- The price of me-too medicines was at least 57 percent more expensive in Canada, Sweden, the United Kingdom, and the United States than in Australia. However, Australian prices were similar to those in New Zealand and Spain.
- The price of generics was at least 40 percent more expensive in Canada, Sweden, the United Kingdom, and the United States than in Australia, but lower prices were recorded in New Zealand and Spain.

In general, countries with less price control (such as the United States) had higher medicine prices than those in the more controlled Australian system. Although the report could not identify specific causal factors explaining why prices tended to be lower in Australia, it was thought to be related to the policy environment and specific features of Australia's cost containment techniques—reference pricing, in particular. Overall, prices in Spain and New Zealand were close to those in Australia. All three countries have predominantly public coverage of medicines for all residents.

Sources: Australian Government Department of Health and Ageing 2010; Australian Productivity Commission 2001; Sansom 2004; Sweeney 2007.

doctor, as gatekeeper to the pharmaceutical market, does not pay for the medication and may not even know how much the prescribed medication will cost the patient. Thus, transmission of price signals between those who initiate demand for the medicine and those who supply it is blurred.

Third, without the expert advice of an intermediary, few consumers have sufficient information to make rational choices between using and not using a medicine, using a brand-name medicine versus a generic, or using a prescription medicine versus an alternative (nonpharmaceutical) therapy. This asymmetry of information affects the pricing mechanism because the consumer is not in a position to make informed choices. The pricing mechanism can be further distorted if the intermediary is influenced by pharmaceutical promotions.

Fourth, health services are a form of investment: investing in health services today is expected to have a return later (Grossman 1972; Johnson 2001). Medicines are a form of investment because people do not receive their benefits until some point in the future. Furthermore, some individuals' pharmaceutical investments may have no obvious return at all, as in the case of vaccines. These characteristics make estimating the monetary value of medicines difficult for the individual. For example, statin drugs can reduce the risk of heart disease in later life. In terms of seeing these medicines as an investment, individuals must assess the benefits of this protection without experiencing what the heart disease actually feels like, and they must judge the possible consequences of *not* taking the statin drugs.

The level of competition among different pharmaceutical product categories is important in understanding medicine pricing strategies. The three main product categories are patented medicines, generic medicines, and branded off-patent medicines.

Patented medicines

This group can be further categorized into—

- Patented, innovative, essential medicines, where no alternative medicine or intervention can provide the same therapeutic outcome, sometimes referred to as *single-source* medicines (such as Herceptin for the treatment of breast cancer)
- New medicines protected by patents, but for which alternative therapies are available (such as Tamiflu for the treatment of influenza)

The distinction between the two types is important because it reflects the degree of market power held by the seller and the price elasticity of demand. Demand for single-source medicines that are considered essential is likely to be inelastic, and combined with patent protection, the seller is in a strong market position compared to situations where alternative therapies are available.

A recent example is the breast cancer drug Herceptin. Because alternatives to this drug do not currently exist, the manufacturers have set a very high price in the knowledge that patients and their insurers (including governments) will be under heavy pressure to pay. This is a classic example of a single-source product with price inelasticity because of patent protection.

The effect of patents on the market stems from monopoly rights that, to varying degrees, are conferred for the life of the patent. These rights allow the monopolist to charge higher prices than would be possible under more competitive conditions, although the extent of the monopolist's price-setting power is not unlimited. For example, the state can counter the monopolist's price-setting power by establishing price regulations, forming a monopsony to purchase medicines on behalf of all residents, issuing a compulsory license to another producer, or using policy instruments such as restrictions on pharmaceutical company profits. More details on these techniques follow in Section 9.7.

Markets can also limit the monopolist's price structure. The potential profits the monopolist stands to make from an essential single-source patented medicine should stimulate other firms to develop medicines that have the same health outcome because patents are granted for the chemical compound rather than the therapeutic indication. The arrival of competitor products restricts the price-setting power of the monopolist, but their arrival on the market is not necessarily immediate. In the United States, competitor medicines

are estimated to arrive between one and six years after the original medicine is introduced to the market (Congressional Budget Office 1998).

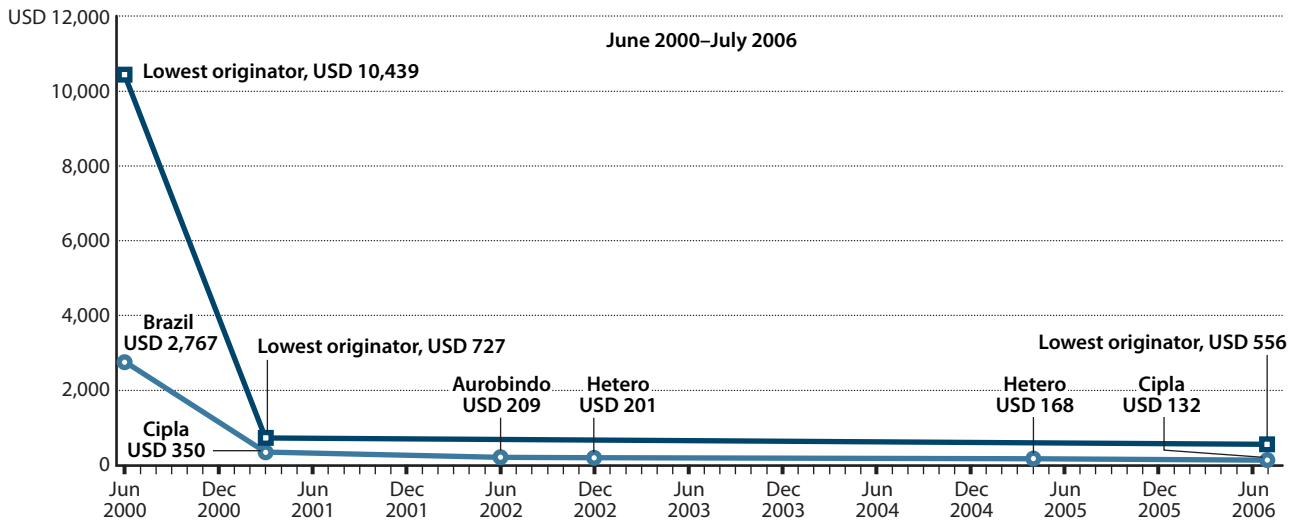
When a large number of competitor products enters a particular market segment—more than is needed to satisfy clinical need and introduce genuine price competition—the term *me-too* medicines is often applied. Many examples exist, including gastric acid inhibitors, statins, and angiotensin-receptor antagonists. Although a degree of competition is desirable, the development and aggressive marketing of patented me-too medicines may consume pharmaceutical budgets and divert resources and development efforts away from treatments for less common diseases. From a societal point of view, whether the incremental benefit from me-too medicines is worth the cost of development is questionable.

Generic medicines

Generic or multisource medicines are not under patent and can be produced using the same compounds found in the originator product using either the same or a different process. Multisource pharmaceutical products are pharmaceutically equivalent products that may or may not be therapeutically equivalent; products may not be therapeutically equivalent because differences in the excipients or the manufacturing process can lead to differences in product performance.

Because patents are country specific, some countries can produce generic medicines using compounds that are still protected by patents in other countries. Where patents operate, generic medicines are allowed to enter the market only when the patent expires. Under special circumstances, such as a public health emergency, countries are allowed to manufacture patented medicines under compulsory licenses, which are sanctioned by the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights. Producers may also enter into voluntary licensing agreements with local companies. (See Chapter 3.) Some countries in sub-Saharan Africa are using voluntary licenses to manufacture antiretroviral medicines to improve access to inexpensive treatment for HIV/AIDS.

In general, the absence of patent protection lowers the barrier to entry into the market because generic companies do not have to bear the high costs of research and development (R&D), including rigorous clinical trials to prove safety and efficacy of the medicine. Reduced R&D costs enable multiple companies to enter the market, resulting in a high level of competition. However, the expiration of patents does not mean that barriers to market entry disappear. As noted, the originator company develops significant marketing leverage while protected by the patent, which must be overcome by new generic medicines. Buyers may not always be aware of the availability of lower-priced generic medicines, they may be persuaded by promotional efforts not to change medicine

Figure 9-2 The effect of generic competition on the prices of antiretrovirals in Brazil

Source: MSF 2006.
USD = U.S. dollars.

brands, or they may view the generic product as inferior or of poor quality. For example, Malaysian buyers appear to prefer higher-priced branded medicines to cheaper generics (Babar et al. 2005).

Although the absence of patent protection can encourage the entry of generic medicines, strict regulation of medicine prices has been associated with a lower penetration of generic medicines into the market, because reduced profitability keeps generic firms from covering the costs of market entry. In countries with relatively little price regulation, such as Germany and the United States, generics have a greater market share than in the more heavily regulated markets of Australia (Lofgren 2004), France (Königbauer 2006), and Italy.

The entry of generics can be delayed for other reasons. Patent holders use a number of techniques to extend their period of market exclusivity, including making legal challenges to generic manufacturers trying to enter the market and developing minor variations in product characteristics that are sufficient to generate a new patent (known as *evergreening*). Another approach is for governments to grant data exclusivity rights to the manufacturers who introduced the pharmaceutical product. Such rights prevent pharmaceutical regulators from using the originator's data to make registration decisions about generic equivalents for a defined period (such as five years), thereby slowing the introduction of generic competition. Increasingly, such provisions are being guaranteed as part of bilateral trade agreements. Chapter 3 covers these issues in more depth.

The process of allowing generic medicines onto the market differs among countries. The United States passed a law designed to allow faster entry of generic medicines when patents expire. However, it also provides a significant pen-

alty if generic companies enter the market too early. In Europe, the entry of generics was made easier by forgoing the requirement of trials demonstrating safety and efficacy as long as the generic medicine is the bioequivalent of the originator and the originator is sold in the same market. Some patent-holding companies responded by removing the patented medicines from the market before the entry of the generic and then releasing a modified form of the original drug. This strategy effectively prevents generics from claiming bioequivalence of an existing medicine sold in the European market, thereby delaying entry of the generic product (Australian Productivity Commission 2001).

In general, introducing generic competition is the most effective way to lower medicine prices. The effect is not only because of the lower-priced generic products but also because originator companies often respond by lowering prices of their patented products. This effect has been very evident in the pricing trend of antiretroviral medicines for HIV/AIDS. According to Médecins Sans Frontières (MSF 2006), in 2000, when Brazil first introduced a generic antiretroviral medicine, the lowest originator price to treat one patient for a year was 10,439 U.S. dollars (USD). By July 2006, the generic version of the same drug cost USD 132, while the lowest price branded version cost USD 556 (see Figure 9-2). However, for increased competition to result in lower prices, purchasers must be informed about their medicine choices.

Branded off-patent medicines

A complicating issue in the generic market is when well-known branded medicines go off patent and the originator company produces generic versions of its own products

and retains the brand names that are recognizable through extensive marketing campaigns. Apparently, when the brand-name generic has a larger share of the generic market, the brand-name medicine will be more expensive; in addition, a higher market share held by the brand-name generic will result in higher generic medicine prices—among all companies (Hollis 2005). The market entry of brand-name generic medicines, if combined with a large market share for the manufacturer, will prevent prices falling to levels reached with more diverse competition. Therefore, by entering both branded and generic segments, large companies can exercise considerable market power.

9.4 Variable pricing for medicines

The literature unanimously concludes that medicine price differences exist between countries, even when the comparison is made between or within the strata of industrialized, middle-, and low-income countries. For example, price information compiled by WHO's Global Price Reporting Mechanism shows clear differences in prices paid by low- and middle-income countries for medicines treating HIV/AIDS. Importantly, low-income countries did not always obtain the lowest prices for medicines; as shown in Table 9-1, the 2009 cost of stavudine 30 mg in low-income countries was 37 percent more than the price paid in middle-income countries.

Price variation within countries is more likely in less price-regulated markets, such as the United States; however, prices vary in other countries, where public, private, and nongovernmental (not-for-profit) sectors procure medicines separately. An example is South Africa, where the public sector achieves low prices through tendering; in contrast, medical insurance funds and individuals paying out of pocket typically pay higher prices, although government legislation has been introduced that aims to control medicine prices in the private sector.

Variable prices for medicines within and between countries often result from one of the following—

- The pharmaceutical manufacturer sells the same product for different prices.
- The margins charged in the postmanufacturing supply chain by wholesalers, distributors, and pharmacists, as well as taxes, duties, and co-payments levied by the state, differ intra- and intercountry.

Differential pricing by the pharmaceutical company

Price differentiation (also known as tiered pricing) occurs when a firm sells the same product at a different price to different groups of people. It is known as *equity pricing* when the intention is to improve the affordability of medicines in

low-income settings. The groups of people could be populations in different countries or subpopulations within a single country. From the buyer's perspective, tiered pricing may appear to be a form of market failure, particularly for those who pay the higher prices, but for the seller, it is another method of maximizing profits by ensuring each buyer group pays according to its willingness and ability to pay.

A seller can price differentiate if—

- It has monopoly rights over the product.
- Willingness and ability to pay are different among groups of buyers (varying price elasticities).
- Buyers cannot trade the item among themselves. That is, buyers who negotiate a low price do not resell the item, thereby undercutting the seller in markets that are able and willing to pay a higher price (Wagner and McCarthy 2004).
- An agreement exists to achieve more equitable access to essential medicines through differential pricing for needy populations. Examples of such agreements exist for medicines for HIV/AIDS, some vaccines, insulin, oral contraceptives, and some antimalarial medicines.

A common misperception is that the price paid by consumers reflects the cost of production plus a margin. In reality, manufacturers want to charge the highest price that the consumer will pay to maximize profits. Therefore, in terms of upward movements in price, the price paid by the buyer need not have any relationship to the cost of production. Evidence confirms that the relationship between production costs and medicine price is tenuous (Loff and Heywood 2002). In Brazil, South Africa, and Thailand, pharmaceutical companies have responded to pressure from court actions, government interventions, and the introduction of generic medicines by significantly reducing their originator medicine prices, which suggests that little relationship exists between medicine prices and the cost of production.

Differential pricing caused by supply chain factors

The pathway from manufacturing, transporting, storing, and then distributing medicines to the patients who need them is complex. Margins and taxes charged along this supply path can add significantly to the final price of medicines. Therefore, a pharmaceutical pricing policy must acknowledge the potential for the supply chain to significantly reduce the affordability of essential medicines to consumers.

As an example, a pharmaceutical pricing study in Ghana (Sarley et al. 2003) showed that although government policy limited margins on pharmaceuticals in the public-sector supply chain to a cumulative 40 to 50 percent, the actual margins averaged 100 percent and in some cases exceeded 300 percent by the time the medicines got to the patients. High markups occurred throughout the supply chain, but

Table 9-1 Median price paid by low- and middle-income countries for selected first-line antiretroviral formulations, 2005 and 2009

Antiretroviral medicine	USD per patient per year, 2005		USD per patient per year, 2009	
	Low-income countries	Middle-income countries	Low-income countries	Middle-income countries ^a
Stavudine (d4Tt) 30–40 ^b mg	58	44	30	19
Lamivudine (3TC) 150 mg	73	80	38	—
Zidovudine (ZDV) 300 mg	153	146	100	94
Nevirapine (NVP) 200 mg	102	102	42	43
Efavirenz (EFV) 600 mg	346	372	132	103
3TC/ZDV 150/300 mg	241	241	114	153
d4T/3TC/NVP 30–40 ^b /150/200 mg	168	211	83	93

Sources: WHO/GPRM 2005; 2009.

Note: — = not available.

^a Upper-middle income.^b WHO recommendation changed from 30 mg to 40 mg.

dispensing facilities reported pricing their products slightly below those in private local pharmacies—no matter what the margin increase—because they perceived that patients would pay at least this amount.

Developing pharmaceutical pricing policies requires more than just an understanding of the supply chain, although that is clearly a good start. Prices, margins, and taxes change over time, and even unintentional adjustments throughout the supply chain can enormously affect medicine affordability. For this reason, stages in the supply chain should be continually monitored, so that changes in costs can be assessed and, if needed, acted upon to remedy unacceptable increases.

A key report from the advocacy group Health Action International (HAI) and WHO (Levison 2006) describes pricing throughout the pharmaceutical supply chain—

Supply chain, stage 1: the price from the manufacturer.

Called the manufacturer's selling price, if the manufacturer is located in the same country as the buyer, no further costs are added at this stage. If the medicine is imported, the price from this stage is the manufacturer's selling price, plus freight and transit insurance. The determinants of the price negotiated between the buyer and the manufacturer will be—

- The level of competition applying to the medicine (whether it is single source or multisource)
- The quantity sought by the buyer
- The number of alternative buyers in the same country for the same medicine (a single buyer will have stronger purchasing power than multiple smaller buyers)
- Pricing regulations and controls
- The price negotiated with the manufacturer

Supply chain, stage 2: the landed price. These are the fees and charges required to deliver the medicine to the

wholesaler. Determinants of the price at this stage will be—

- The fees, charges, and profits levied by transporters, insurers, and warehouses
- The level of taxes levied by the state (for example, stamp duty; value-added tax, or VAT; and goods and services tax, or GST)
- Tariffs on imported medicines and ingredients for locally manufactured medicines

Supply chain, stage 3: the wholesale selling price. This price is the landed price plus the wholesaler's costs of storage, transport, insurance, and profit margin. The wholesaler could be a private (for-profit) operation; a public operation; or a not-for-profit, nongovernmental organization. Increasingly, wholesalers are being replaced by distributors who have a relationship with suppliers and work with lower margins because they do not own the stock.

Supply chain, stage 4: the retail selling price. This is the wholesaler's price plus all costs associated with transporting medicines to the retailer, including transit insurance. Retailers could be a private, for-profit operation, a public operation, or a nongovernmental organization. After delivery to the retailer, storage and stock insurance are required. The retailer also adds a profit margin and sometimes a professional dispensing fee. Sizable mark-ups can occur in the retail stage, especially in the private sector and from dispensing doctors; a WHO study of thirty countries concluded that although pharmaceutical availability tended to be better in the private sector, it was also associated with higher medicine prices and therefore lower affordability (Gelders et al. 2006). Compared with international reference prices, private-sector prices were between three and one hundred times more.

Supply chain, stage 5: the dispensed selling price. The state can impose additional taxes such as VAT or GST on top of the retail price; such taxes are controllable by

the government. A European study of nine countries showed that nations applying VAT or GST to medicines ultimately had higher medicine prices, even if they had comparatively lower wholesale prices (Martikainen et al. 2005). Other studies have shown that significant reductions in price are possible with the removal of these taxes. For example, estimates for Peru indicate that the removal of VAT on medicines would reduce prices by 18 percent (Ewen and Dey 2006).

Country Study 9-3 describes an analysis of supply chain markups in Malaysia.

9.5 Monitoring medicine prices by performing price comparisons

Although the literature shows that price variation exists within and between countries (Wagner and McCarthy 2004; Scherer 2004; Waning et al. 2010), the methodology used for many of these comparisons has been criticized because of the difficulties in validating the results (Danzon 2004).

Challenges related to price comparisons

Comparing pharmaceutical prices between countries is complicated: The same medicine is often sold in different countries in different strengths, pack sizes, and with various modes of administration; in addition, any assessment must determine whether the product is being sold in the public or private health care system and account for differences in tariffs, taxes, and other markups. Comparability is even more of a problem if the assessment is based on a basket of medicines. For this reason, comparing individual medicines

that have high usage and limited ranges of doses and modes of administration may be better.

Selecting which price to use as the basis for comparison is critical. Should it be the price paid by the patient, the third-party insurer, or in the case of a state purchaser, the government? Some argue that the price paid by the consumer is the most important because it represents the patient's out-of-pocket expense (Wagner and McCarthy 2004). The advantage of using this payment is that it includes all of the add-on costs after manufacture, such as margins paid to wholesalers, distributors, and pharmacists. The final price paid by the consumer can be more than doubled by the additional costs encountered in the postmanufacturing supply chain (Ewen and Dey 2006). Moreover, understanding the components of the final price identifies potential targets for price reductions. However, a disadvantage of relying solely on price as a measure of affordability is that a low price for a medicine in a low-income country does not make it affordable. Sometimes, a further measure is required, such as the number of days the country's lowest paid worker must work to pay for the medicine. This is one of the measures used in studies conducted by HAI and WHO.

Determining which price to use for comparison will ultimately depend on the intended use of the analysis. In many comparisons, the manufacturer's or wholesaler's price is the basis for measurement, and this can be a useful tool to improve procurement practices. The common resource for international reference prices is the *International Drug Price Indicator Guide*, which provides an indication of pharmaceutical prices on the international market. The guide includes actual prices paid by government agencies, pharmaceutical suppliers, and international development organizations for almost a thousand pharmaceuticals (see Box 9-2). The Global Fund requires principal recipients to submit

Box 9-2

International Drug Price Indicator Guide

Produced in collaboration with the WHO, Management Sciences for Health's *International Drug Price Indicator Guide* provides an indication of pharmaceutical prices on the international market. Updated annually, the guide contains a spectrum of prices from pharmaceutical suppliers, international development organizations, and government agencies. The 2008 edition has more than 1,100 items and prices from 30 sources.

Lower prices can be obtained through bulk purchasing, competition, skillful price negotiations, and sound supply management. The guide makes price information more widely available to improve procurement of medicines of assured quality for the lowest possible price.

Readers can use the guide to—

- Locate new supply sources
- Assess the efficiency of their procurement systems
- Determine the probable cost of pharmaceutical products for their programs
- Compare current prices paid to those available on the international market
- Assess the potential financial impact of changes to a medicine list
- Support rational drug use education

The *International Drug Price Indicator Guide* can be accessed at <http://erc.msh.org/priceguide>.

Country Study 9-3 Examples of supply chain markups: Malaysia

A price survey in Malaysia using the WHO/HAI methodology compared median price ratios of medicines distributed in the private and public sectors with international reference prices. Despite the expectation that the prices of medicines in the public sector would be relatively low, in some cases, public-sector prices were higher than the international reference price. The study also found that the postmanufacture margins charged in the supply chain were significantly driving prices upward in both the public and private sectors. The authors concluded that the lack of a coherent government policy to regulate medicine prices allowed excessive profits and reduced medicine affordability.

The survey also found substantial price differences within the private sector between dispensing doctors and pharmacies. Compared with pharmacies, brand-name medicines tended to be cheaper when purchased from a dispensing doctor, but generic medicines were more expensive. Overall, the study found that dispensing doctors had excessive profit margins, particularly

on some lower-priced generic medicines. This finding has been consistent in the literature: dispensing doctors, who benefit financially from the consultation and the prescription, have perverse incentives to prescribe expensive medicines and then charge a higher margin on these products. Because patients have little information about medicines, they have little recourse about taking the doctor's advice about the choice of treatment. This asymmetry of knowledge supports the argument that without regulation, doctors should not be allowed to sell the medicines that they prescribe to their patients.

The following table illustrates the percentage of markups encountered after medicine was purchased from the manufacturer for the public sector and for retail pharmacies and dispensing doctors in the private sector. Overall, the data confirm an expectation that public-sector prices tend to be lower than those offered by the private sector. Yet the supply chain analysis highlights several critical points where application of taxes, charges, and margins causes medicine prices to increase dramatically.

Percentage supply chain markups for generic and branded atenolol in the public and private sectors

Supply chain stage	Generic	Branded
Public sector		
Stage 1 MSP + insurance and transport	Price paid in stage 1 = MYR 7.78	Price paid in stage 1 = MYR 33.63
Stage 2 Customs and port charges	+ 22.2%	+ 5.6%
Stage 3 Distributor wholesale markup	+ 20.0%	+ 20.0%
Stage 4 Retailer or dispensing doctor markup	NA	NA
Stage 5 Other charges	NA	NA
Total markup over stage 1 price	46.5%	26.7%
Private sector: retail pharmacies		
Stage 1 MSP + insurance and transport	Stage 1 price = MYR 9.62	Stage 1 price = MYR 40.05
Stage 2 Customs and port charges	+ 17.9%	+ 20.4%
Stage 3 Distributor wholesale markup	+ 5.8%	+ 19.1%
Stage 4 Retailer or dispensing doctor markup	+ 100.0%	+ 25.4%
Stage 5 Other charges	NA	NA
Total markup over manufacturer's price	149.5%	79.8%
Private sector: dispensing doctor		
Stage 1 MSP + insurance and transport	Stage 1 price = MYR 9.58	Stage 1 price = MYR 41.17
Stage 2 Customs and port charges	+ 18.0%	+ 18.0%
Stage 3 Distributor wholesale markup	+ 15.0%	+ 11.1%
Stage 4 Retailer or dispensing doctor markup	+ 146.2%	+ 76.0%
Stage 5 Other charges	NA	NA
Total markup over stage 1 price	234.0%	129.0%

Sources: Babar et al. 2005; Gelders et al. 2006.

Note: MSP = manufacturer's sale price; MYR = Malaysian ringgit; NA = not applicable.

prices paid for medicines purchased with fund resources, which are made public. Other multinational resources for price comparisons include Médecins Sans Frontières' guide to antiretroviral prices in developing countries (<http://utw.msffaccess.org>) and WHO's Global Price Reporting Mechanism and website for medicine price information (<http://www.who.int/hiv/amds/gprm/en>). A new resource focuses on prices and sources for children's medicines (UNICEF/WHO 2010).

The WHO/HAI methodology for monitoring medicine prices

The goals of conducting a pricing survey include the ability to compare home-country prices with international reference prices, and to make intracountry price comparisons of medicines provided by different sectors, such as the government, nongovernmental organizations, and private facilities. The WHO/HAI methodology for comparing medicine prices (outlined in WHO/HAI 2008a) is based on simple techniques that have been field-tested and validated in many countries (see Country Study 9-4 for some examples). The methodology is available to governments, nongovernmental organizations, and researchers and is designed to facilitate intra- and intercountry comparisons of medicine prices and ultimately to identify which sector delivers the best medicine prices to patients. Documentation in English is freely available from <http://www.haiweb.org/medicineprices>. Documentation in French, Russian, and Spanish is also available on the HAI website.

Selecting locations. The first location of the survey's sample is the major central urban center—usually the capital city. In addition, three other locations are randomly selected from a list of all areas that can be reached in one day of travel from the urban center. In each location, at least five public health centers are sampled, including the main public hospital. Five private-sector pharmacies are also included based on their proximity to the public health centers. If the country has private nongovernmental organizations or dispensing doctors that provide medicines to patients, five from each category are selected using the same methodology.

Selecting medicines. The surveyors collect price data at each facility for a list of core and supplementary medicines. WHO identifies the core medicines based on the global burden of disease, medicine availability and importance, and patent status. Supplementary medicines are selected based on the health issues in the survey country. To prevent the collected data from being distorted by medicines that might be counterfeit or of poor quality, the methodology stipulates the sampling of only registered medicines or those with market authorization.

Categorizing medicines. Price data are categorized by the innovator brand (which is or was under patent), the highest-volume generic sold, and the lowest-priced generic.

A generic drug can fall into both the highest-volume and the lowest-priced medicine categories. The brand name of the innovator product may vary by country, but unless licensed, generic equivalents cannot be labeled with brand names; for example, Valium is the name of the innovator product, and although generic medicines cannot use this name, they may use their own brand name or the nonproprietary name of the active ingredient, diazepam.

In countries where a medicine is under patent, only the innovator brand should be available. Exceptions might occur, for example, when the innovator brand is produced under license or where the country allows the sale of equivalent generics. If a patent is not in force, multiple generic equivalents for the innovator may be available. The WHO/HAI methodology defines generic medicines as those intended to be the equivalent of the innovator brand and that are produced after the expiration of patents or other exclusivity periods. The definition implies that the same active ingredient is used in the generic and the innovator. Medicines cannot be categorized as generic if they are produced under license to the innovator.

Analyzing price data. Prices are ultimately presented as a ratio of the median price in the surveyed country to the international reference price, provided by Management Sciences for Health's *International Drug Price Indicator Guide*. The ratio is called the median price ratio. To simplify data entry and analysis, WHO/HAI provide a computer program that facilitates data entry and automatically provides the outcomes from analysis. Apart from information on prices, the analysis reports on the availability, affordability, and components of medicine prices, which are the charges and markups that contribute to the final price. The methodology also provides instructions on presenting results so the findings can be effectively disseminated.

9.6 Obtaining value in pharmaceutical markets: buyer strategies

As mentioned in Section 9.1, the determination of price is related to factors influencing both supply and demand. Supply-side strategies target the seller and ensure the lowest possible medicine price is paid by the patient. The following strategies focus on the supply side with emphasis on pharmaceutical manufacturers and the pharmaceutical supply chain.

Demand-side strategies focus on the use of medicines: Are medicines being prescribed appropriately? Are generic medicines being substituted for more expensive brand-name products? Has promotion and advertising created patient demand that exceeds clinical demand? Demand-side questions are equally as important to medicine pricing as the supply-side pricing issues, but they are the topic of other chapters. Nevertheless, the development of a compre-

Country Study 9-4 Measuring medicine value: WHO/HAI survey methodology to compare prices and affordability in multiple countries

Price surveys using the WHO/HAI methodology have been undertaken in several countries, including China, India, Kuwait, Malaysia, the Philippines, Tajikistan, and Thailand. The surveys determined comparative prices in these countries and identified medicine prices that were different from the international reference price and by how much. Rather than using actual currency units for comparing prices, the surveys used ratios that identified the relative price in the target country compared with an international reference price.

Within each country, the surveys also compared prices in the public and private sectors, which facilitated policy recommendations, such as encouraging the use of generic medicines, increasing private-sector competition when only small price differences existed between innovator brands and equivalent generics, or reducing price markups in the supply chain.

Examples of medicine price survey findings for China's Shandong Province, Kuwait, the Philippines, Tajikistan, and Thailand follow.

Shandong Province, China

- In the private sector, innovator brands were 14 times more expensive than lowest priced generics.
- In the public sector, the difference was 4 times more than the lowest priced generics.
- Comparing public-sector procurement prices and public-sector patient prices for core medicines revealed that patients paid an additional 75 percent of the procurement price for generics and 22 percent for innovator brands.

Kuwait

- Private-sector procurement prices of medicines were 18.3 (innovator brands), 16.1 (most popular generic), and 15.9 (lowest priced generic) times the international reference price.
- Public-sector prices for innovator brands were 5

times the international reference prices and generic equivalents were 1.2 times the international reference prices.

Philippines

- Generic products markups ranged up to 355 percent at the retail level and 117 percent at the distributor level.
- VAT significantly increases the price of medicines in the country.

Tajikistan

In the private sector—

- Some innovator brands were 43 times the international reference price.
- The most popular generic equivalent and the lowest priced generic equivalent were 2.3 times the international reference price.

In the public sector—

- Prices tended to be slightly higher than those in the private sector: innovator brands in the public sector were 49 times the international reference price.
- The most popular generic equivalent and the lowest priced generic equivalent were 2.3 and 2.4 times the international reference price, respectively.
- The “brand premium” innovator product price was up to 20 times the price of the generic.

Thailand

- Public sector prices were higher than the international reference price: 32 percent for innovator brands and 75 percent for generics.
- In the private sector, patients paid 3.9 times more overall for originator brands than for the lowest price generics.

Sources: Ball et al. 2005; Drug Information Center Project ZdravPlus/USAID 2005; Qiang 2005; WHO/HAI 2006, 2008c.

hensive policy to contain the cost of medicines should consider strategies that correct distortions in both supply and demand as well as the government's role.

Assess the circumstances

The buyer strategies outlined below are used in different countries, with varying degrees of success. Any strategy

used on its own is unlikely to provide the best possible outcomes for reducing medicine prices. The best possible outcomes will require an assessment of which buying technique best suits the circumstances for each purchase of medicines and a clear understanding of the buyer's own position in the marketplace.

Examples of issues a buyer should address in an assessment include—

- The ability to join with others to purchase medicines (pooled procurement). Are cultural or political barriers preventing buyers from joining forces? Can these differences be resolved? Saving money can be a powerful motivator for tolerance.
- Whether the buyer is in the public or private sector and whether the buyer can influence government policy. For example, a public-sector buyer may be able to influence government policy to mandate the use of reference or differential pricing.
- The type and volume of medicine being purchased. Although the least powerful market position will be associated with buying single-source essential medicines compared to nonessential and multisource medicines, some large buyers have successfully negotiated price discounts on patented, single-source medicines. Successful negotiations can result from the size and certainty of the order and the effect on reducing the seller's risk (see maximizing buying power below). The seller's risk is reduced when the purchaser makes reliable payments.
- Whether the purchasing group has access to good advice on efficacy and cost-effectiveness of medicines in the country. A careful, independent assessment of the comparative performance of a new medicine can be a powerful tool when negotiating with a manufacturer or supplier.

Monitor prices

Knowing what prices other buyers paid for medicines helps buyers evaluate the value of their own medicine purchases. Although comparing medicine prices is not a straightforward task, without knowing what a medicine really costs to produce, comparing prices paid by other buyers is the next best measure. In addition, ongoing price monitoring is preferable to a one-time comparison, because markets continually change, and new products, new clinical data, or new treatments can mean that medicines that are a good value today can be overpriced tomorrow.

Analyze pharmaco-economics

Pharmaco-economic techniques, such as cost-effectiveness, cost-benefit, and cost-utility analysis, are of value to some pharmaceutical and health commodity buyers, but are labor intensive. The analyses do not set prices but assess the costs and outcomes from using certain medicines. The evaluator must decide whether the medicine or commodity represents good value at the price offered and then use this information in price negotiations. Pharmaco-economic and related medicine expenditure analyses, such as ABC and VEN (vital-essential-nonessential), are described in Chapters 10 and 40.

Maximize buying power

As identified in Figure 9-1, market power for sellers increases as the spectrum moves from a competitive market to an oligopoly and monopoly. Buyers can exert corresponding buying power as oligopsonies and monopsonies; therefore, buyers that pool their procurement can potentially lower prices by providing the seller more stable levels of demand, certainty of payment, and lower administrative costs compared with selling to multiple small buyers. In addition, the development of medicine insurance schemes that cover many members (such as the Australian PBS) and the use of a common formulary help shift the purchaser's buying power to this stronger market position.

Examples of organizations that combine buying power include the International Dispensary Association Foundation and the Clinton Health Access Initiative. For example, the Clinton initiative reports price reductions for antiretroviral medicines of 50 percent for first-line treatments and 90 percent for pediatric formulations (Clinton Health Access Initiative 2010).

Negotiate prices

Price negotiation models apply to large public- and private-sector buyers that have some degree of buying power. Examples are government programs purchasing medicines on behalf of the public and third-party payers, such as private health insurers. Formularies can be used as a bargaining tool (for example, lower prices exchanged for including more of a single pharmaceutical company's medicines on the formulary) and as a list used by prescribers to select the lowest-priced medicine available within a therapeutic class. Clearly, the formulary must include generics. The strength of these negotiation models might diminish when dealing with essential, single-source medicines, because there are no alternatives to negotiate.

Techniques used for price negotiations include—

Tendering, where the buyer issues a tender seeking price offers from different pharmaceutical suppliers. An initiative to introduce joint tendering in El Salvador resulted in lower medicine prices (SEAM 2007). Through improved tendering and other practices, New Zealand's Pharmaceutical Management Agency has saved; for example, the price of generic medicines in New Zealand is estimated at less than a quarter of the price of those in Canada (Cumming et al. 2010). However, supplier performance must be monitored to ensure the quality and reliability of supply. (See also Chapter 21.)

Package agreements, which comprise contracts negotiated for multiple products from one company. These arrangements can entail rebates on the entire package or large discounts on out-of-patent medicines in return for pur-

chasing full-price patented medicines. These agreements tend to work best when a credible alternative is available, such as another supplier from which the package could be purchased (McNee 2006). Package agreements that include hidden discounts are attractive to the purchaser because of the immediate cost savings; however, the true price of the medicine is hidden from the consumer making the final purchase. Such arrangements are open to abuse (including fraud), and they may hamper attempts to create a uniform pricing structure for a pharmaceutical class or to introduce genuine competition, if key information is hidden from other suppliers.

Price/volume agreements, which work when uncertainty exists about the level of demand for a medicine. Under these agreements, when a certain threshold volume is reached, the manufacturer's price falls. This threshold can be determined by population and economic modeling. For example, a medicine may appear to be a cost-effective treatment at a certain price for individuals with a severe form of a disease but be cost-ineffective when used to treat less severe cases. The estimated number of individuals with severe disease represents a threshold volume of use above which the price automatically falls to a level where the medicine is considered cost-effective for less severe cases. Australia uses this technique to maintain the cost-effective use of medicines and protect against unintended use that can be encouraged by excessive promotion of medicines (Sansom 2004).

Rebates, which are payments that the pharmaceutical manufacturers make to the buyer. Rebates can, for example, be related to sales volumes, so that when a certain volume is reached, the manufacturer provides a rebate to the buyer. Rebates are sometimes required by legislation, usually for public-sector buyers, or included in private-sector contracts with the pharmaceutical company. As is the case with discounting, such arrangements should be completely transparent.

9.7 Government intervention in the pharmaceutical market

Government intervention in pricing is a controversial topic because market economists feel strongly that the market should be left to its own devices. However, as noted previously, market failure is common in the pharmaceutical sector. In theory, the market can efficiently determine prices for many goods and services. However, the price of medications can determine quality of life or when or if people die. In reality, an uncontrolled market can lead to the most vulnerable people paying the most for medicines—if they can afford them at all. In general, and particularly for single- or limited-source medicines, an unregulated medicine market is

unlikely to provide acceptable outcomes in terms of achieving public health equity.

More general government intervention in pharmaceutical markets should include the establishment of an essential medicines list and the development of policies that encourage the purchase of low-priced, quality generic medicines. The government should encourage the entry of generic products into the market, even if legislative changes are required to streamline the registration process for these medicines. If generic competition is weak or nonexistent, as in the case of an innovator brand that is still under patent, governments can consider regulating prices or requiring compulsory licenses (Gelders et al. 2006).

Some countries favor minimal regulation of pharmaceutical pricing, allowing suppliers, health sectors, and patients to determine an equilibrium. Most industrialized countries favor more intervention, with governments either subsidizing medicines or providing them free to their citizens (Henry and Lexchin 2002). Other forms of governmental interventions include price controls or limits on pharmaceutical profitability. For example, several countries of the Organisation for Economic Co-operation and Development require manufacturers to limit prices in exchange for receiving subsidies through country reimbursement schemes, which can cover a large percentage of the population (OECD 2008).

Countries that intervene take the view that providing affordable medicines is too important to be left to the market—that medicines are more than just consumables to be traded for the highest possible price. However, instituting price-control regulations takes substantial political will and can produce unexpected consequences; for example, some claim that price control of medicines in the Philippines is thwarting the market for generics (Hookway 2010).

The arguments against government interventions tend to focus on the potential negative effect on R&D of new pharmaceutical products. Most notably, regulations that restrict market-determined prices reduce profitability, which, in turn, can restrict research into new and innovative medicines. Several studies have shown that regulation of medicine prices, differential pricing of medicines, and profitability of pharmaceutical companies are associated with the level of R&D undertaken by a pharmaceutical firm (Danzon and Towse 2003; Scherer 2001; Vernon 2005). However, these findings do not suggest that, in the absence of price controls, R&D will increase for medicines for neglected diseases that affect health in the developing world. Profitable medicine lines are those that sell in large volumes in industrialized nations, which can afford to pay more.

The ethical question is whether medicine prices should be the main determinant of pharmaceutical R&D. Incentives other than high medicine prices that are used to encourage R&D include tax concessions and public grants. These

incentives are discussed in Chapter 3 on intellectual property and access to medicines.

Government-imposed price controls can be used at different points in the supply chain, but probably the two most important broad stages can be defined as prices from the manufacturer and prices in the supply chain. Methods identified by the WHO that governments can use to influence the manufacturer's price (Dukes et al. 2003) are discussed in the following sections.

Price controls on the manufacturer

These price controls usually take the form of governments restricting medicine prices to the cost of production plus a profit margin (also called cost-plus pricing). However, accurate cost information from the manufacturer is difficult to obtain. The information might be more readily available from local manufacturers without production units in other countries, but the listing of R&D in the cost structure is likely to be controversial and almost impossible to obtain from multinational organizations.

As an example, under the United Kingdom's Pharmaceutical Price Regulation Scheme, the government has the right to refuse a pharmaceutical company's application to increase the prices of existing medicines. In addition, the government can (and has) demanded price reductions for medicines purchased by its National Health Service (ABPI and DOH 2009).

Profit controls on the manufacturer

Although profit controls are not widely used internationally, the United Kingdom caps the profits pharmaceutical companies can earn from sales to the National Health Service (ABPI and DOH 2009). Within this cap, companies are allowed to price freely. From a single country's perspective, multinational operations still have the ability to shift costs throughout their operations, leaving the reported profitability subject to a degree of manipulation. Profit controls in the United Kingdom have been criticized for being open to manipulation and having an allowable profit level that is set too high (Earl-Slater 1997).

Reference pricing and brand premiums

Reference pricing allocates a medicine to a therapeutic group of medicines that are considered equivalent on the basis of safety, efficacy, and outcome. Prices of all medicines in the group are tied to that of the lowest—or in some cases, the average—price. The reference price does not necessarily become the market price for all medicines in the same therapeutic class, but rather a benchmark price. Manufacturers can set prices higher than the reference, but in doing so, they need to compete against equivalent, lower-priced

medicines. Although typically a government intervention, large, private-sector buyers use it as well.

Brand premiums are often used in conjunction with reference pricing. They are used when a third party, such as an insurance company or the government, pays for medicines to which patients contribute a co-payment. The brand premium operates by reimbursing all medicines in a therapeutic class up to a certain amount—where the reimbursement is determined by the price of the least expensive generic (or an average of all medicines in the class). Patients pay the smallest co-payment if they purchase the medicine priced at the reference price, but if the patient buys a higher-priced medicine (say a branded generic), the patient pays the co-payment plus the difference between the reference price and the selected medicine's price (Sansom 2004). The two advantages of this technique are that price competition between supplying pharmaceutical companies is encouraged and patients have an incentive to switch to lower-priced medicines.

Comparative pricing controls (international benchmarking)

This technique compares the prices in one country with those in reference countries. The government limits price increases of existing medicines to the average increase recorded in a set of reference countries, and new medicines are priced at the average (or lowest) of the reference countries. The difficulties with comparative pricing are the same issues encountered when comparing prices in different countries. Strengths, pack sizes, and active ingredients tend to differ among countries, and unit prices are lowest when products are purchased in bulk. Additionally, the point in the supply chain at which the price is compared (manufacturer, wholesaler, retailer, patient) introduces further inter-country differences in terms of margins and taxes.

A given product may have several selling prices (public-tender price, private-sector uninsured price, etc.), so one has to be selected for the comparison. Choosing benchmark countries can also be difficult; for example, including countries at a similar stage of economic development may seem sensible, but such countries may not have an effective system for setting prices. Nevertheless, the Netherlands, Portugal, and Romania all use international benchmarking, and the Netherlands reported an average 20 percent decrease in the cost of pharmaceuticals when it introduced the comparative pricing technique in 1996 (Dukes et al. 2003).

Eliminating tariffs and taxes

As mentioned, sizable price increases can occur throughout the supply chain, some of which are imposed by governments in the form of taxes and tariffs. WHO estimates that high tariff structures in selected low-income coun-

tries increase the price of medicinal ingredients by 23 percent and the price of finished medicines by over 12 percent (WHO 2004). Although tariffs and taxes provide the opportunity for raising state revenue, their effect on medicines is to reduce affordability and substantially erode public health objectives. Sometimes the argument for tariffs is to protect emerging local industries until they become established; nonetheless, the effect on medicine affordability is the same. In terms of pricing policy, governments must minimize unnecessary add-on costs and should not impose revenue-raising charges on essential items such as medicines (Global Health Council 2007).

In addition to introducing price control measures and eliminating taxes and tariffs on pharmaceuticals, WHO has identified the following methods by which governments can influence medicine prices by controlling the margins charged by the retail pharmacy, and in some countries, by dispensing doctors (Dukes et al. 2003).

Fixed margins

These margins are a fixed percentage of the wholesale price. Commonly used in the United States and Europe, fixed margins tend to average about 30 percent of the wholesale price. Problems include the tendency for pharmacists to negotiate rebates and other discounts directly with the wholesaler that do not get passed on to the consumer. In some countries (for example, Denmark), these discounts are illegal (Dukes et al. 2003).

Digressive markups

These margins are a shifting percentage of wholesale prices: lower-priced medicines have a proportionally larger margin than more expensive medicines. This system tries to encourage the dispensing of less expensive medicines by using the pharmacist's profit-maximizing behavior as a driver.

Capitation systems

The pharmacist is reimbursed with a fixed sum based on the number of patients per year or a fixed fee per prescription. The system's goal is to keep pharmacists from benefiting from either the price or volume of medicines dispensed, but the system is open to manipulation if the pharmacist continues to add a margin on to the wholesale price.

9.8 Influence of globalization on pharmaceutical prices

As noted previously, the international system to protect intellectual property rights tends to keep the prices of patented medicines high. Countries can take some actions to

lower the cost of medicines under the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (see Chapter 3). For example, compulsory licenses can be used in national emergencies or when a country needs a supply of a medicine for government use. If the required medicine is under patent, the patent may be broken to allow the medicine to be locally manufactured. If the country does not have the capacity to manufacture the medicine, it can be imported from another country where it is not already protected by patent. The granting of the license requires that the patent holder be paid a "reasonable" fee. Compulsory licensing is not an option that is available only to low-income countries. During an anthrax emergency in 2001, the U.S. government considered invoking this right to bring down the price of ciprofloxacin (Bradsher and Andrews 2001).

Parallel importation is common in the European Union, although it represents only about 2 percent of the European market (OECD 2008). A branded medicine may be sold relatively cheaply in one member state and then be imported into another country and sold below the usual domestic selling price. Such arrangements are attractive to the importing country, but parallel importation can undermine efforts to achieve equitable international pricing of essential medicines when manufacturers shy away from offering cheaper versions of their products in low-income countries for fear they will appear on the European market and undercut those prices. In addition, a study concluded that the benefit of parallel trade goes to the traders themselves, rather than to patients in the form of cheaper medicines and better access (Kanavos et al. 2004).

Voluntary price reductions offered by major pharmaceutical corporations (often under pressure from advocacy groups) have reduced the cost of antiretroviral therapy available in low-income countries dealing with HIV/AIDS epidemics. These pricing structures have resulted in significant price decreases but have not necessarily translated into improved access. Other factors, such as the inability of health systems to deliver medicines to those who need them, also hinder access. For example, despite the reduction in prices of antiretroviral medicines for HIV/AIDS, only an estimated 31 percent of the world's low- and middle-income populations living with HIV have access to treatment (WHO/UNAIDS/UNICEF 2009).

The Affordable Medicines Facility–malaria (AMFm) initiative is piloting a program to increase access to artemisinin-based combination therapies (ACTs) by paying a large proportion of the cost of ACTs to the manufacturers so the public and private sectors can buy the products at a greatly subsidized price (about USD 0.05 per treatment). The idea is that the subsidy will trickle down to the end user, resulting in a price reduction from about USD 6–10 per treatment to about USD 0.20–0.50. At that cost, ACTs would be cheaper than monotherapies, which would theoretically be crowded

out of the market. Social marketing strategies have used similar approaches to increase the availability of products such as contraceptives and bed nets. Launched in 2010 by the Global Fund to Fight AIDS, Tuberculosis and Malaria, the AMFm will be independently evaluated in 2012 in the nine pilot countries.

9.9 Conclusion

The international and domestic systems that determine the selling prices of pharmaceutical products are extremely complex. Although covering all the issues in depth is difficult, one can draw a number of important conclusions—

- Patented medicine prices tend to be high, and a competitive market for generic products is the most important mechanism for ensuring the affordability of essential medicines.
- Governments can intervene effectively in the pharmaceutical market by becoming large purchasers on behalf of their communities and by regulating the different markups along the supply chain, which can greatly affect the costs to consumers. Governments can also eliminate or reduce taxes on important medicines. To encourage the supply of generic medicines, governments can work to minimize barriers to their entry into the market.
- Health insurance that covers a core list of essential medicines with minimal consumer co-payments can be a major force in improving access to essential medicines. An insurer can use purchasing power and other techniques that reduce medicine prices. Chapter 12 discusses different types of health insurance schemes.
- A number of mechanisms exist to control pharmaceutical prices, including tendering, generic substitution, reference pricing, international benchmarking, and pharmaco-economic analysis. No *one* mechanism will meet all of a country's needs, and the country must determine which mechanisms are best, based on assessing the context and monitoring it for change over time. Within a particular country, different methods may be appropriate for different market segments (for example, public versus private procurement).
- The total costs of medicines depend not only on selling prices but also on volumes of use. Unnecessary medicine use contributes to both costs and adverse clinical outcomes. The demand side of the pharmaceutical market is just as important as the supply side. ■

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- Describe the buyers and sellers in the pharmaceutical sector. Is there one dominant buyer? Does one dominant seller have negotiating power in the market?
- Does the government have a policy regarding the promotion of generic medicines?
- What is the regulatory process that allows generic medicines into the market?
- For the three categories of medicines in the market, patented, generic, and branded off-patent, what is their percentage of use by volume and value? Are prescribers and patients more likely to use generic products if they are available?
- Do any data exist showing the variation of medicine prices in the public, private, and nonprofit sectors? For innovator products and lowest price generics?
- How do pharmaceutical prices in public and private sectors compare to those in other countries or to international reference prices?
- What are the markups on medicines throughout the supply chain? Does the government regulate any of the markups? Does the government or other authorities impose markups in the form of tariffs or taxes?
- Have pharmaceutical buyers used any strategies to maximize their power in the market, such as monitoring prices, negotiating prices, or pooling procurement?
- Does the government impose price controls at the dispensing level, such as fixed margins or banning or regulating the practice of dispensing doctors?

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