

Executive Summary

Variation in per capita expenditure on pharmaceuticals is relatively low across OECD countries...

The average OECD country spent 401 USD [measured in purchasing power parities (PPPs)] per person on pharmaceuticals in 2005, and half of OECD countries had per capita spending within 20% of the average. The United States had the highest level of per capita expenditure, at 792 USD PPP, and Mexico the lowest, at 144 USD PPP, just 18% of the US amount.

Variation in the volume of pharmaceutical consumption and in pharmaceutical retail prices are similarly low

France and Spain had the greatest volume of pharmaceutical consumption (an estimate derived by adjusting pharmaceutical expenditures for cross-country differences in the average retail pharmaceutical price level) per person in 2005, followed by the United States and Australia. All of these countries had below-average retail pharmaceutical price levels in 2005, with the exception of the United States, which had retail prices about 30% above the OECD average. Canada and Germany had price levels similar to that of the United States, exceeded by Iceland (159%) and Switzerland (185%).

Mexico had the lowest volume of pharmaceutical consumption per capita – less than a quarter of the OECD average and less than half that of Poland, the second-lowest country – but was not among the countries with the lowest average retail pharmaceutical prices. The lowest-priced countries were Poland, Turkey, the Slovak Republic, the Czech Republic, Korea, Greece, Hungary, Spain and Australia, all of which had retail pharmaceutical price levels between 68% and 81% of the OECD average.

Cross-country differences in retail prices reflect factors other than differences in the prices manufacturers charge. They also include distribution costs and – in many countries – value-added tax, which together can account from only a small share to more than one-half of the price paid by the end purchaser.

A country's income per head affects its pharmaceutical consumption, retail prices and expenditure levels, but other factors are at work

In general, income per capita is positively correlated across countries with the volume of pharmaceutical consumption and expenditure per capita. However, income is not the whole story. In fact, per capita income explains only one quarter of the variability observed in per capita volumes of consumption across OECD countries, and even less of the variability in expenditure and retail price levels. This is consistent with findings from research indicating that pharmaceutical demand varies across countries and is relatively income-inelastic – meaning that expenditure changes with income, but not as fast as income does.

Despite rapid growth, spending on pharmaceuticals accounts for a minor share of health expenditure in most OECD countries, though there are a few exceptions

Growth in pharmaceutical expenditures greatly exceeded the rate of growth in other types of health expenditures throughout the 1990s. Although pharmaceutical growth has since slowed while other health expenditures have increased more rapidly in recent years, growth in pharmaceutical expenditures continues to exceed the average growth of OECD economies. Nevertheless, the pharmaceutical sector accounts for a minor (average 17%) share of total health expenditure in most OECD countries. However, pharmaceutical expenditure accounted for about one third of health expenditure and more than 2% of GDP (compared with an OECD average of 1.5%) in Hungary and the Slovak Republic.

Out-of-pocket payments are relatively important sources of financing for pharmaceuticals

Private sources play a bigger role in financing of pharmaceutical expenditures – accounting for 40%, on average – than of other components of health spending, although the bulk of pharmaceutical spending is publicly financed in all but four OECD countries (the United States, Canada, Poland and Mexico). Out-of-pocket spending is generally more significant than private health insurance, which is an important source of financing for drug spending in only a handful of countries (the United States, Canada, the Netherlands and France).

The pharmaceutical industry plays an important role in the economies of several OECD countries

All of the top-15 firms in terms of global pharmaceutical sales have their headquarters in OECD countries, with about half in the United States and half in Europe (France, Germany, Switzerland and the United Kingdom). Production and R&D activities are undertaken in many countries, not only (or even primarily) in the country where the firm has its headquarters. The United States accounts for 39% of global pharmaceutical production, slightly more than the 36% European share. Pharmaceutical production accounts for a notable share of national income in Ireland (11% of GDP) and Switzerland (3% of GDP), the

two biggest net exporters of pharmaceuticals. Pharmaceutical industry R&D activities are relatively more important to the economies of Sweden and Switzerland, accounting for about 0.5% of GDP in those countries.

Parallel and cross-border trade accounts for only a small fraction of the value of the market

The practice of importing pharmaceutical products from a lower-priced country to a higher-priced one, either for sale (so-called “parallel trade”) or for personal use (so-called “cross-border trade”), receives considerable policy attention. Parallel trade is most significant between EU countries, but even so only accounts for an estimated 2% of the EU market. Canadian cross-border trade with the United States peaked in 2004 at about 8% of total Canadian sales, which represented only 0.5% of the US market in terms of value.

The products of ten large firms account for much of the global pharmaceutical market

In 2006, the top ten pharmaceutical firms accounted for nearly half the value of global sales. The market for pharmaceutical products is increasingly a global one, with trade and policy practices making market segmentation and corresponding price differentiation by country difficult – particularly within Europe, where multinationals have encouraged their subsidiaries to set prices within narrow price corridors. New active ingredients are launched in an average of ten countries, although manufacturers often release multiple versions of their on-patent products in different markets to reflect consumer preferences and to reduce opportunities both for prospective buyers to make external price comparisons and for wholesalers to engage in parallel trade.

The United States is the predominant market in terms of pharmaceutical sales value

Nine OECD countries account for about 80% of the value of global sales of pharmaceuticals. The United States, with a 45% global share, is the world’s largest market, followed by Japan, which accounts for 9% of global sales, France (6%), Germany (5%), the United Kingdom (4%) and Italy (4%).

Most sales revenues derive from on-patent products, rather than generics, with value concentrated in a relatively small number of therapeutic classes and successful products

Just ten therapeutic classes of drugs accounted for 36% of total global sales in 2006, a year in which approximately 105 original products were considered “blockbusters,” i.e. each generating more than 1 billion USD in annual sales. By contrast, generic products accounted for just 14% of the global market in terms of value, although more than 40% of products sold in several large markets, including the United States, Germany and the United Kingdom, are generics. Generics have less than a 10% share of the market in terms of both volume and value in Italy, Belgium, Spain and Portugal.

The prices manufacturers receive for their products vary across countries, although there is less variation in prices for the most innovative products

Japan, Switzerland and the United States have been identified in the research literature as countries with particularly high ex-manufacturer prices for patented medicines. Japan and Switzerland also have high ex-manufacturer prices for generic products. Studies have found that ex-manufacturer prices vary according to national income per capita, although there were important exceptions. In particular, such prices were higher than expected in some low-income countries, including Mexico. Another study found that there is less cross-country variation in ex-manufacturer prices for those products representing significant innovation.

In spite of continuously increasing R&D investment, output of new drugs has declined and most pharmaceutical innovation has been incremental

Because most R&D initiatives are unsuccessful in bringing a new product to market, the total amount of investment per successful drug – an indication of the “productivity” of R&D spending in the pharmaceutical industry – is very large. A decline in productivity has been evident since the mid-1990s, as increased R&D investment has coincided with a decline in the number of new chemical entities approved for marketing.

As is true in other industries, most pharmaceutical innovation has been incremental, rather than radical. Most such innovation has little or no added therapeutic value over existing treatments.

The pharmaceutical industry uses a range of techniques to maximise profits over a product’s life cycle

Since marginal production costs are relatively low, maximising profits translates into maximising cash flows during the life of a product. In each market where sales would be expected to enhance a product’s global profitability, pharmaceutical firms endeavour to launch products quickly at the price that maximises prospective profits. Firms try to extend the period of market exclusivity and to engage in promotional activities that aim both to capture as large a market share as possible and to increase the potential market.

By some estimates, pharmaceutical marketing expenditures account for a share of firms’ outlays that exceeds that of R&D expenditures. Furthermore, the costs of doing business in different countries vary, depending on factors such as the burden imposed by regulatory compliance, the types of marketing and/or advertising activities permitted and the exposure to liability for safety or quality problems.

Prices are not the only factor determining profits

Because marginal costs of producing most pharmaceuticals are very low relative to the cost of research, development and bringing a product to market, firms can make volume-price trade-offs that result in equivalent sales revenue and profits for the industry, provided spillover to other markets can be prevented. Pharmaceutical firms have therefore made with public and private purchasers and third-party payers confidential agreements that provide discounts and rebates linked to the level of product sales.

Widespread health insurance coverage distorts the market for pharmaceuticals

The coverage schemes that subsidise the amount individuals spend on pharmaceuticals and protect them against the risk of incurring high out-of-pocket costs also distort the pharmaceutical market, affecting both prices and volumes of consumption. They define the degree to which the pharmaceutical market is subsidised, with greater subsidies resulting in relatively lower consumer price elasticity of demand. While there is great cross-country variation in cost-sharing requirements, individuals in OECD countries typically bear much less than half the cost of their pharmaceutical consumption, resulting in consumption that is greater than it otherwise would be if individuals paid the full cost. Beyond this, coverage schemes differ importantly in the extent to which they seek to manage the volume and mix of pharmaceutical consumption, with many coverage schemes having few restrictions on choice by physicians and patients while others are active in efforts to affect physician, pharmacist and/or patient decision-making.

The global market for original medicines is competitive

Unlike sellers of most health services in OECD countries, research-based pharmaceutical firms operate globally and thus do not face a single purchaser wielding monopsony power. Firms can and do choose not to launch their products in countries where doing so is not profitable. On the other hand, the manufacturer of an on-patent medicine normally has a monopoly on sales of a particular product in a particular market, although the product may be subject to competition from therapeutic alternatives.

Specific characteristics of the pharmaceutical market have given rise to pharmaceutical price regulation in most countries

The perceived potential for manufacturers to exploit a monopoly position when facing relatively inelastic demand for medicines has led many countries to regulate prices for at least some portion of the pharmaceutical market. Two countries with pluralistic coverage schemes – Canada and Mexico – have established price regulation for on-patent pharmaceuticals intended to assure that prices paid by any part of the population, insured or not, are not excessive. In most other OECD countries, coverage schemes require manufacturers to accept price limits in exchange for subsidisation through reimbursement schemes, which

act as *de facto* regulation for that part of the market covered by reimbursement. Even in the United States, manufacturers must submit to price regulation if they wish to be reimbursed under Medicaid and the Veterans Health Administration, the public schemes providing coverage to 19% and 2.6% of the US population, respectively.

Market-based or “free” pricing is common for products not subsidised by coverage schemes

Except in Mexico and Canada, where the prices of all on-patent medicines are subject to regulation, over-the-counter (OTC) products are normally not subject to price regulation unless their purchase is reimbursed by a coverage scheme. In a minority of OECD countries, including Denmark, Germany, the United Kingdom and the United States, firms are not constrained in setting either OTC or prescription drug prices at market entry, irrespective of the product’s reimbursement status.

Several types of practices are used to limit prices and define reimbursement amounts

Regulatory authorities use a common set of tools to limit the prices charged by pharmaceutical firms. The most commonly used methods involve comparing proposed prices for new products against those prices paid by other payers, a practice known as external price referencing, or against those prices already paid for products judged to be similar, a practice known as internal price referencing. Pharmaco-economic assessment is used by some schemes as a means of making a formal judgment as to value provided, in terms of benefits and costs. There are a limited number of other approaches used, including profit controls, which serve as an indirect form of price regulation. Pricing policies are not limited in focus to the payment received by pharmaceutical firms; regulation of the distribution chain is undertaken in many systems.

With the exception of profit controls, public and private payers and purchasers of pharmaceuticals use the very same approaches to define the acceptable payment or reimbursement price. In the context of reimbursement, so-called reference price systems are often used to set common reimbursement amounts for products judged to be equivalent or similar, leaving patients to pay any price difference out-of-pocket. In cases where generic substitutes or therapeutic alternatives are acceptable, purchasers in some markets obtain low prices using tendering processes that require sellers to bid for an agreed volume of sales.

Pharmaceutical prices are determined by the respective market powers of the parties involved

In the case of the pharmaceutical firm, market power is determined by the perceived value of the product and the extent of competition from alternative therapies on the market.

In the case of the buyer (or payer), market power is determined by the size of the market represented – as measured in terms of the number of persons and their willingness and ability to pay – provided that the payer has the ability to act in ways that influence the

volume of a product consumed. While most OECD countries have a universal scheme that maximises market power by representing all or nearly all of the country's consumers, a few countries, such as the United States, have pluralistic schemes. Several large publicly financed coverage schemes and private insurers in the United States have enrolments that exceed the populations of some OECD countries.

The extent to which prospective buyers or third-party payers have the power to walk away from a transaction varies. Either regulation or competition to provide comprehensive coverage can limit their ability to deny patients reimbursement for a product that is categorically eligible for coverage. In particular, the power to walk away from a transaction is limited when a drug is in a monopoly position in a therapeutic area and is used in the treatment of a life-threatening disease. In such cases, both public and private payers experience public pressure to cover the drug. Thus, the ability to obtain price concessions often rests instead with the ability to influence the volume of the product consumed, by limiting reimbursement to particular circumstances or identifying preferred products.

Price regulation does not necessarily result in lower prices

While private insurers universally face pressure to extract the best possible price which their relative market power will permit, regulators and public schemes seek to balance cost-containment objectives with others, such as public health improvement, as well as industry policy goals and considerations of support for future pharmaceutical innovation, which may mean that they fail to push their market power as far as they might to obtain the lowest possible price. For this reason, it is not necessarily the case that price regulation will always result in lower pharmaceutical prices than would be obtained in an environment characterised by competing private insurers.

Many other types of policies, other than those directly related to pricing, affect the pharmaceutical market

While pricing policies have been the focus of attention in terms of their impact on pharmaceutical markets, other types of policies are important in their prospective impact on the timely availability of products in the market, the adoption and diffusion of those products, and the level of consumption of the product over its life cycle. Chief among these policies are those that affect market authorisation and those that set standards for enforcement of intellectual property rights. In addition, coverage schemes routinely employ policies aimed at modifying patient demand (in particular, cost-sharing requirements), often employ policies aimed at influencing pharmacists' dispensing (such as policies to promote use of generic alternatives to off-patent original medicines), and occasionally employ policies aimed at altering physician prescribing (e.g., prescribing budgets).

Policy makers hold common objectives, but may weight them differently when trade-offs are required

Policy makers intervene in pharmaceutical markets to promote public health by fostering prompt, affordable access to effective medical treatments. But subsidising individuals' pharmaceutical consumption often results in pressure to contain overall costs. And payers are increasingly concerned with being able to demonstrate that they attain good value for money in their pharmaceutical expenditures. Trade-offs across these goals are required when conflicts arise among them and with industrial policy goals, as may occur depending on the economic significance of the pharmaceutical industry in the country in question.

There are shortfalls in access to effective medicines, even in OECD countries

Although the availability of medicines on the market varies considerably across countries, the implications for accessibility are unclear, since countries often grant exceptional access to drugs that have not (yet) been launched in a market. Heavy subsidies for pharmaceuticals provided by public coverage and private insurance, reasonable cost-sharing arrangements, exemptions of vulnerable patients and caps on out-of-pocket spending serve to limit the likelihood of access being threatened on affordability grounds in most OECD countries. More serious risks come from gaps in coverage, given that a few countries still have populations without adequate coverage to ensure affordable access to prescription medicines. Furthermore, access can be limited by decisions not to subsidise expensive drugs that are judged not to be affordable or cost-effective at the offered price.

Policy makers seek to restrain the rate of growth in pharmaceutical expenditures, although the optimal expenditure level is undefined

The variation in pharmaceutical expenditures across countries raises questions about whether and which countries may be over- or under-spending, although there are no agreed international benchmarks for making such assessments. Policy makers in OECD countries attempt to control pharmaceutical expenditures using a range of tools, including control of prices and/or volumes (e.g., benefits management strategies directed at physicians or pharmacists). Some countries use policies to control the level of spending for particular products (e.g., product-specific rebates) or for pharmaceuticals generally (e.g., claw-backs, patient cost-sharing).

Payers are experimenting with sophisticated approaches to purchasing and payment arrangements

There may well be scope to move to cost-control mechanisms, such as price-volume agreements, that focus on achieving the desired level of expenditure on pharmaceuticals. In France, for example, specific agreements are signed for some products with high risk of overuse or misuse, under which the pharmaceutical company will pay rebates when the

agreed volume of consumption is exceeded or when drugs have been misused. Risk-sharing arrangements, under which the price may be retroactively adjusted as information about utilisation and outcomes under normal use become available, have the potential to reduce the need to make a trade-off between the objectives of ensuring prompt access and getting good value for money, when faced with incomplete information about the relative efficacy and cost-effectiveness of a new product.

*Improvement in meeting public health objectives
may well be possible without sacrificing
cost control*

Efforts to improve value for money in public spending on pharmaceuticals could help free up resources that could be better spent enhancing the availability, accessibility and appropriate use of effective medicines. Many, if not all, countries have some room for improvement in this respect. They could get better value for their money by maximising the use of generic alternatives to off-patent original products, fostering erosion of the prices of off-patent products through greater competition, ensuring efficient distribution systems for prescription and OTC products, and becoming more sophisticated in their reimbursement pricing strategies.

*Reference pricing is a practice by which payers
seek to get good value for money
in pharmaceutical expenditure*

Under normal market conditions, informed consumers compare products to determine if added benefits are worth added cost. This is difficult in the case of pharmaceuticals, not only because information on relative benefits may not always be fully available at the time of decision making, but also because patients rely heavily on physicians to act as their agents in choosing appropriate medicines. The practice of setting a common reimbursement amount for similar products, leaving patients to pay the difference out-of-pocket if they use more expensive alternatives – a practice that is somewhat misleadingly known as “reference pricing” – is attractive in the sense that, theoretically, only those products valued by patients and their physicians should receive a premium price. In practice, however, manufacturers often prefer to price at the reference point rather than risk losing market share in imperfectly operating markets.

*Pharmaco-economic assessment can help
to ensure good value for money in pharmaceutical
expenditure*

A tool for evaluating a product's benefits relative to its costs, pharmaco-economic assessment can help achieve good value for money when incorporated into pricing and reimbursement decisions. Since its introduction into pricing and reimbursement processes by Australia and Canada in the 1990s, pharmaco-economic assessment has been incorporated in the pricing and reimbursement practices of many OECD countries in ways ranging from asking manufacturers to provide information on relative cost-effectiveness in support of applications for reimbursement to conducting original assessments of the

benefits that would be derived from use of a product and expected costs to payers or society generally. Experience from these countries demonstrates that pharmaco-economic assessment can be technically and politically feasible when employed in different types of health systems. It remains, however, a technically challenging and value-laden exercise, particularly when judgments about the value of a product for which there is no therapeutic alternative must be made.

Pharmaceutical pricing policies have an impact outside national borders

External price referencing (or international benchmarking) stands to affect the prices and availability of medicines outside the country undertaking the benchmarking practice by reducing manufacturers' willingness to set prices according to national market conditions. This may have a negative effect on affordability and availability of medicines in smaller markets and lower-income countries, including lower-income countries in the OECD. The practice of agreeing to confidential rebates can also have an external effect, in that other countries using external benchmarking may reference artificially high prices, resulting in list-price inflation. Claw-backs have a similar impact in that they mean the price is effectively changed post-purchase (after the list price has already affected the global price through external benchmarking). The convergence in list prices of pharmaceuticals that has been observed in Europe (including Switzerland) and between European countries and Canada is consistent with what would be expected in a market characterised by such practices.

Manufacturers have developed strategies to maximise profits in an increasingly global market

Even as globalisation has reduced opportunities to maximise profits through market segmentation and differential pricing, manufacturers have responded to the increasingly global market for their products in a strategic way. In response to external price referencing, they launch their products first in countries where they can set prices freely or can negotiate relatively high prices (often in the country where they have their headquarters), delay or refrain from launching in relatively lower-price countries and maintain artificially high list prices, even when they are willing to consent to confidential rebates. They use strategies to inhibit parallel trade, such as supply-chain management, litigation, lobbying and product proliferation (*e.g.*, release of products with different formulations, strengths and package sizes). The latter technique also serves to limit opportunities for international price referencing. The success of these strategies is evident in that the pharmaceutical industry continues to be one of the more profitable industries in the global economy.

Profits reward past investment in pharmaceutical R&D and serve as an incentive for future investment

As in other industries, private R&D investment in the pharmaceutical industry is motivated primarily by expected returns on the investments, given scientific opportunities

(the state of the art in a therapeutic area or in a mode of production) and the comparative advantages of firms. The pharmaceutical products that make it to market are those that are viewed by the pharmaceutical industry as most likely to be profitable in terms of the conditions they target and the level of innovation they represent over existing alternatives.

R&D investment incentives are distorted by characteristics of the pharmaceutical market

Important characteristics of the pharmaceutical market call into question whether it is possible to obtain a socially optimum level and direction of R&D investment. In the case of prescription medicines, the combined impact of insulating patients from the cost of the medicines they consume and providing firms that produce innovative medicines with the exclusive rights to sell their products distorts market signals, creating a risk of over-investment in the development of new products. On the other hand, cost-containment pressures may lead regulators, payers and purchasers to make pricing and reimbursement decisions that establish profit signals for under-investment.

Beyond this, purchasing decisions made in the absence of full information may well distort the incentives firms face as to how to direct their R&D investments. Information on the effectiveness of new medicines, relative to therapeutic alternatives, is often not available to patients and the physicians who act as decision-making agents, and neither may have incentives to consider whether any added benefits are worth the cost differential.

Pharmaceutical pricing policies are among several policy variables that influence the expected returns on investment in R&D that in turn serve as an incentive to finance new investment

Methods used to establish relative price levels, particularly techniques by which products are differentiated for price premia, provide market signals that steer investment towards particular types of innovation. The most commonly used practice, external benchmarking, encourages firms to differentiate their products across countries so as to limit price comparisons. Such practices yield no therapeutic benefit and may come at the expense of other types of innovation. The practice of referencing prices or reimbursement amounts to therapeutic comparators, on the other hand, provides incentives for innovation that offers demonstrably more value than existing therapies and acts as a disincentive for incremental innovation that offers little or no improvement over existing therapies. However, therapeutic referencing only provides an indication of the new product's value if the price of the comparator product is reasonably reflective of its own value. This is not necessarily the case in the current pharmaceutical market environment, where third-party payers and regulators predominantly use external benchmarking of prices paid elsewhere to limit or define the prices of products that have no therapeutic comparators.

Pharmaceutical pricing and reimbursement approaches using pharmaco-economic assessment establish incentives for investment in valued innovation

In the interest of encouraging valuable innovation, efforts to link the level of expenditure for a given pharmaceutical product to the value of the benefits offered by the new product are attractive in that they can be used by manufacturers to assess willingness to pay for future innovations and should thus provide incentives for investment in R&D leading to valued innovation. Pharmaco-economic assessment can be used to reward and foster innovation with the greatest value to patients and society. To the extent that pharmaceutical producers profit more from innovations that have the greatest value to patients and society, they will face incentives to invest more in R&D to produce such therapies.

Each country's policies will have only a marginal impact on future pharmaceutical innovation, except when there are spill-over effects

Pharmaceutical R&D investment decisions reflect the industry's assessment of the future market with a global perspective. Therefore, the marginal impact of any one country's policies will be proportional to market size and thus minor (with the important exception of that of the United States). Nevertheless, features of national markets and national policy practices may encourage firms to invest in R&D in order to differentiate products and segment markets, especially when national policy impacts have spill-over effects on other countries' price levels. The practice of external price benchmarking means that early-launch countries in particular (and those that are most often selected by other countries for price references) are likely to have an impact on incentives for investment that is disproportionate to the size of the market. This suggests that it is particularly important that the prices established in those countries present an accurate reflection of the product's value, both in absolute terms and relative to other products on the market.