

Drug pricing

Market access and reimbursement

The CEOs of seven big pharmaceutical companies recently appeared before Congress to discuss the prices they charge for their drugs. Their appearance comes at a time when President Trump and members of Congress continue to raise the issue of high drug prices. In this report we seek to add a little clarity on this area which is both complex and likely to remain an issue throughout the 2020 US presidential campaign.

A complex issue added to fragmented healthcare systems

Investors in biotech and pharma companies would clearly like the revenues of their companies to grow at a rate higher than inflation, particularly in a drug's launch phase. However, in a bid to boost profits, some companies have acquired drugs without incurring the cost of their development and immediately increased the price by up to 5,000%. Doctors treating cancer patients in the US have coined the phrase 'financial toxicity' in response to the finding that two years after a cancer diagnosis, 42.4% of US cancer patients had depleted their entire life's assets. In this article, we look at some of the dynamics of drug pricing and reimbursement across Europe and the US, the markets that do and do not allow free pricing, and the influence of co-pays, coinsurance and high deductibles in the US. We start with some definitions of drug pricing and how recent events have brought this into focus.

There are many drug prices

In all markets, there is more than one drug price. This starts with the list or gross price that the manufacture determines at launch. In some free-pricing markets like the US and Germany, payers for the drug may or may not be consulted before launch but in many others access to that market will hinge on a negotiated list price for national access with additional discounts determining the net price which can vary regionally. Once the drug starts its journey on the pharmaceutical value chain, the price of the product can rise and fall before it is eventually linked to a prescription. Even after the physician writes a prescription, in the US, the amount that a patient has to pay and the rebates that flow back through the pharmaceutical value chain continue to resonate after the patient receives the drug.

Likely winners from regulatory change

- Patients: in the US, their position could not get much worse
- Pharmaceutical and biotech companies such as AstraZeneca, GSK or Pfizer

Likely losers from regulatory change

- US pharmacy benefit managers (PBMs) if rebates are eliminated
- US health insurance companies

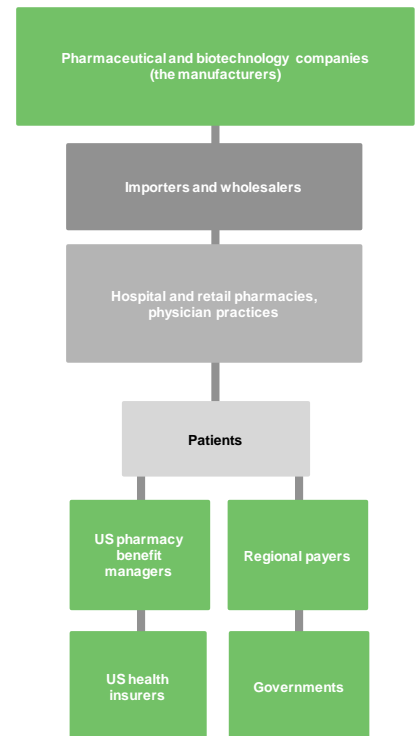
Winners and losers: The companies shown above do not translate into buys and sells as other themes (and valuation parameters) may conflict with this one.

Edison themes



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Pharmaceutical value chain



Edison themes

As one of the largest issuer-sponsored research firms, we are known for our bottom-up work on individual stocks. However, our thinking does not stop at the company level. Through our regular dialogue with management teams and investors, we consider the broad themes related to the companies we follow. Edison themes aims to identify the big issues likely to shape company strategy and portfolios in the years ahead.

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Edison conducts pricing and market access studies with payers on behalf of clients. After presenting and discussing the target product profiles of the drugs, we typically determine a pricing corridor using a Van Westendorp analysis and provide estimations of market penetration.

What's in a price?

This is not an easy question to answer because the benefits or value of a drug, the available healthcare budget and the drug's impact on a healthcare system all need to be considered when determining the price that the drug can command in negotiations between manufacturers and payers. Payers can be national or regional (and even in the UK, there are both) and in the US there is a highly fragmented and interconnected mix of public and private payers.

For any given drug, there are a number of prices – the list (or gross) price is the one that is made public and in recent times, the one that many big pharmaceutical companies have been increasing once or twice a year by about 9% in the US. The list price is frequently much higher than the price that payers pay, whether the payer is the NHS in the UK or a health insurance company in the US, but not if, as in some countries, the patient pays directly. In the recent congressional testimony, the seven pharmaceutical CEOs were at pains to point out that while list prices have been increasing, the net prices (that they receive) have been falling. The net price includes any rebates, subsidies and discounts paid to intermediaries such as wholesalers and PBMs in the pharmaceutical value chain. These typically reduce the net price to between 40% and 65% of the list price. The net price is rarely (if ever) quoted and can only be found out by asking payers. Between the list and net prices are a number of equally opaque prices that the payer or patient will not be aware of, but these prices follow the drug on its journey from manufacturer, wholesaler, pharmacy and even physician practice, to the patient. In the US the price can also be influenced by the organisations found towards the end of this journey along the pharmaceutical value chain, or even after the patient receives the drug. These commercial influences are from PBMs or the patients' health insurance companies (that administer the health plans of a majority of US patients, and are funded by the premiums paid by the employee and employer) and, to a much lesser extent, the Federal health programs may have already decided whether a patient can receive a branded or generic form of a drug before they are diagnosed. At each step in a drug's journey along the value chain, the prices paid between manufacturers, wholesalers and pharmacies can rise and fall and can include, for example, the average selling price or the wholesaler acquisition cost. Furthermore, at the patient end of the US value chain, depending on whether the patient has private health insurance or is covered by the public or Federal health programs (Medicare, Medicaid or veterans administration or VA), there are other payments, either regular, variable or one-off, that a patient may need to pay before they can receive their medicine. US patients with so-called high-deductible health insurance plans (with low annual premiums) pay out-of-pocket costs including close-to-list drug prices of up to \$6,550 per year before their health insurance starts to cover their healthcare costs. Typically, these plans encourage patients to shop around for their drugs although the imposition of a lower price cap on out-of-pocket costs was proposed during the recent congressional hearing.

US congress weighs in on drug pricing

The recent congressional hearing and the preceding political rhetoric on drug prices has exposed an interesting paradox in the US healthcare system. The US has some of the lowest prices for off-patent (generic) drugs of any high-income country but the highest branded prices anywhere in the world. In addition, over 90% of prescriptions in the US are for a cheap generic drug and there is intense competition amongst generic drug manufacturers. These generic price wars have severely damaged the investment proposition of those generic drug companies, driving US generic (net) drug prices down by around 5% per annum and resulting in regular profit warnings. If less than 10% of prescriptions in the US are for branded drugs, why is there such an intense debate on drug prices?

The answer is that there is such a substantial pricing differential between a high-volume small molecule generic drug, where pricing is literally pennies, and a recently approved very low volume large molecule (which is much more expensive to make) and is the first available treatment for that condition. The latter is either the typical orphan drug profile (to treat rare diseases) or a drug to treat cancer (one of the six protected Medicare drug classes in the US, which partly explains the higher prices for oncology drugs in the US compared to other markets). Orphan drugs and newer oncology drugs, whether they are small or large molecules, can have prices in the hundreds of thousands of dollars. In the past, these low volume specialist drugs for orphan diseases or the newest oncology drugs made up such a small part of the drugs budget that their impact was low and US insurance companies would cover patients with those diseases to increase the attractiveness of their health plans. Part of the drug pricing problem is the increasing number of high-value indications that are driving the US drug budget. However, the recent testimony from the pharmaceutical CEOs to Congress has centered on the role of the intermediaries between the drug manufacturers and the patients in making drugs more expensive. There is some truth in this as the CEO from one of the companies in the congressional hearings described the intense price competition between the three main branded insulin suppliers in the US. As a result of this competition the net price has fallen by 30% since 2012 with a consequential impact on insulin revenues. Despite this fall in net prices, the out-of-pocket costs to patients have increased by 60%. This has been associated with the deaths of US diabetic patients who were unable to afford their insulin injections. The cause of these increased list prices, while net insulin prices have been falling, has been laid at the door of the for-profit PBMs who retain a portion of the rebates that are meant for insurers, patients and manufacturers.

There is a profit motive linking list and net prices as the higher the list price, the higher the return to the participants in the channel, irrespective of what the final price net of rebates is to the manufacturer. In US hospitals, the structural issues of the mixed public/private healthcare system also compound these drug pricing issues as hospitals mark-up the list prices of the drugs their pharmacy dispense (having been acquired at a net price) by up to 500%. In addition, for products like oncology drugs that are administered in a physician's office or outpatient clinic under Medicare Part B in the US, the practice can currently charge the average selling price plus 6% (regardless of the net price paid). For patients with private insurance, these inflated drug prices may be invisible and negotiated down slightly but are ultimately paid for by increasing premiums.

It is no surprise therefore that the US Department of Health and Human Sciences (HHS) has proposed the elimination of rebates in order to lower the price of drugs that patients pay. The HHS proposals only apply to the Medicare Part D prescription drug benefit outside hospitals and outpatients (which is about 29% of all US retail drug spend), but the pharmaceutical CEOs who recently appeared before Congress were broadly supportive of this proposal. A more recent point of contention is at what point, and how much, of the rebates are passed onto patients. If rebates were passed on at the pharmacy counter rather than reducing list prices, the channel participants like the PBMs would retain the ability to determine formulary placement on the basis of (perhaps additional) rebates.

What is reimbursement?

The drug pricing issues in the US are also partially brought about by it being a market where the manufacturer is free to set a (list) price at launch. Germany is also a free pricing market, but only for the first year after launch. In most other high-income countries, the drug is only allowed to access that market at a price determined by a negotiation with the payer. Reimbursement is therefore the negotiation of a price between manufacturer and payer that allows the manufacturer access to that market. For single-payer markets like the NHS in England, its benefits and risks of a drug are appraised by a separate body – the National Institute for Health and Care Excellence, or NICE. NICE reviews the clinical and other data prepared by the manufacture in a submission that is

generically called a health technology assessment (HTA) and decides whether NHS England should reimburse the drug. Often, the decision to reimburse comes down to the price of the drug relative to the benefit it produces in treated patients. There have been some high-profile failures, not of a drug in clinical trials, but in the negotiation of the price that the NHS should pay in order to access the UK market. The manufacture of the disease-modifying drugs to treat the orphan disease cystic fibrosis is currently at such an impasse after NICE failed to recommend it for reimbursement in England.

In other European markets and even the UK and the US, national reimbursement is only the first step after which more regional negotiations, even down to the individual hospital group level are required for the drug to be included in, for example, a hospital's or an insurer's formulary. At the individual hospital or health insurer level, the clinical and outcome data will again be reviewed and if there is more than one manufacturer for a similar drug, a tender or contracting process can bring the net price down even further. All these discussions are confidential and there may be many net prices for a single drug. Without conducting primary market research with payers, the resulting net prices will never be known.

Price referencing

Most biotech and pharma companies launch their products in the US because of its size, the free pricing aspect and because over two thirds of people in the US have private health insurance. This means that the US has higher drug prices than most countries, which has emerged as a point of contention in the drug pricing debate. One often purported remedy for this price differential is to import drugs from lower-priced markets like Canada or Mexico. Other much smaller single-payer markets like the UK have been accused of 'freeloading' or benefitting from the US subsidising its high drug prices. US President Trump has proposed referencing US drug prices to an index of prices paid in other markets but only for the drugs administered under Medicare Part B (outpatient and physician office administration of drugs to the over-65s). Under Federal law in the US, Medicare is prohibited from negotiating the prices of the drugs it buys from manufacturers but relies on the negotiations of the many private health insurers who provide the part-privatised Medicare Part D plans. Other parts of the Federal health programs do have lower drug prices than, for example, Medicare Part D, as the VA requires that manufacturers charge them the lowest price paid in the private sector.

Ironically, drug price referencing is not new and is one of the most common payer pricing approaches globally. Even payers in the US will reference the price of the standard of care that probably comprises cheap generic drugs, to the proposed price of a new drug for the same indication to determine whether the additional value of the new drug can be justified. However, the most common use of price referencing is in southern Europe where countries will determine the price they will pay for a drug from an average of the lowest prices paid in other European countries.

Conclusion: No quick fixes

The price that a manufacturer charges for its drug is a balance between the costs of the drug's development, the associated failures of that company's other drugs, and the sales and earnings expectations of the company's investors. In addition, a further tension exists between payers with limited budgets, but their need to provide an adequate standard of care for their patients. Add to this the fragmented nature of the US healthcare system, global price differentials and, like Brexit, you have a range of issues that have developed over the years that have no single easy fix. The drug pricing debate will therefore continue.

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