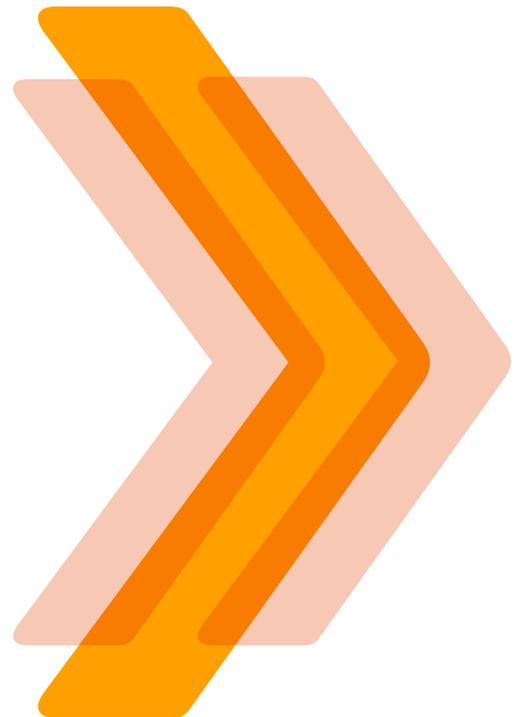


The rising cost of medicines to the NHS

What's the story?

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Key messages

- Estimated total NHS spending on medicines in England has grown from £13 billion in 2010/11 to £17.4 billion in 2016/17 – an average growth of around 5 per cent a year. These figures are uncertain due to gaps in data, but the rate of increase is substantially faster than for the total NHS budget over the same period.
- Much of the recent growth in medicines spending has been in the hospital sector, where estimated costs have grown at around 12 per cent a year on average since 2010/11. Today hospitals account for nearly half of total NHS spending on medicines.
- In primary care, spending growth has been much lower. Although the volume of prescription items provided to patients increased by almost half in the decade to 2016 (to 1.1 billion items), this was offset by a reduction of nearly a quarter in the average cost per prescription item (to £8.34).
- Policy on medicines in England aims to balance the competing goals of giving patients prompt access to effective treatments, incentivising the pharmaceutical sector to develop new products, and ensuring that expenditure on medicines is affordable for the NHS. Today it is becoming harder to balance these objectives.
- Over time the NHS has used a number of policies to promote value for money in spending on medicines, such as encouraging the widespread use of cheaper generic drugs. Opportunities to generate additional value remain, such as increasing the uptake of biosimilars (which resemble generics for biological products). But with growth in spending on medicines outstripping growth in funding, policy-makers have recently sought to exert greater control over medicines expenditure – for instance with the introduction of a controversial budget impact test for new products that will cost more than £20 million a year to provide.
- Given the founding principles of the NHS, policy options that are available in some other advanced health care systems, such as significantly increasing user charges for medicines, would be politically challenging to implement in England.
- Without a new funding settlement for the NHS, policy-makers are likely to face increasingly difficult choices. There is a risk of returning to the position of the 1990s, when funding pressures led to widespread concern about patients' access to medicines.



1 Introduction and context

Medicines are a vital part of modern health care. But in the face of rising costs, many advanced health care systems are grappling with how to provide access to them in an affordable way (van der Gronde *et al* 2017).

This is particularly true for the NHS in England today, for several reasons. Since 2010, health spending has been growing at around 1 per cent a year – substantially below the long-term trend ([The King's Fund *et al* 2017](#)) – putting pressure on the NHS budget. A growing number of older people is causing an increase in demand for medicines, with more patients taking multiple medicines at the same time ([Oliver *et al* 2014](#); [Duerden *et al* 2013](#)). Some short-term trends – for example, price spikes for certain generic products due to supply shortages (Smyth and Kenber 2017), and sterling's fall in value since the summer of 2016 pushing up prices of imported products ([Hazell 2016a](#)) – have compounded the challenge.

This context is bringing the competing objectives that policy-makers weigh up when developing medicines policy into greater focus, which can be summarised as:

- providing prompt access to effective treatments, including new ones
- making sure that spending on medicines is affordable for the NHS
- supporting long-term medicines innovation by promoting a thriving and sustainable pharmaceutical sector.

While these have not all been openly recognised as policy objectives, historically a compromise between them has been sought. Today, the Accelerated Access Review is a focal point of the government's efforts to improve patients' access to treatments and support long-term innovation in medicines development. But the NHS's tight funding settlement is also requiring additional measures to promote affordability. The risk is that over time the need to deliver affordability within a tough financial environment will result in patients' access to treatments being eroded.

Policy-makers have responded to these pressures with some controversial decisions. For example, access to a new high-profile treatment for hepatitis C was delayed

despite it being judged cost effective (Boseley 2015); and a ‘budget impact test’ has been introduced, meaning that new products that cost more than £20 million a year will be subject to commercial negotiation, with access potentially delayed if a deal to lower the cost cannot be reached (Timmins 2017).

In light of these developments, this briefing explores the NHS’s approach to managing its spending on medicines and aims to:

- describe the trends in NHS spending on medicines over recent years and explore what has been behind the trends
- outline the key policies that the NHS uses to control spending on medicines
- explore some of the choices about medicines that policy-makers are likely to face in the future.

The briefing is informed by a literature review, analysis of publicly available data and interviews with hospital providers and national bodies. It covers both generic drugs and branded medicines as well as policies used to control cost growth. In recent years, spending on branded medicines has been constrained by the Pharmaceutical Price Regulation Scheme, a new instalment of which is currently under negotiation.

The process of developing and introducing new medicines in England

This process involves numerous steps, which can be simplified into four stages (see Figure 1).

Figure 1 Simplified visualisation of the medicines development and introduction process



Source: Monitor Deloitte et al 2015

Within the development phase, products advance from basic research to clinical trials. At this point, the National Institute for Health Research, the UK government agency that

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The process of developing and introducing new medicines in England *continued*

funds clinical and health services research, monitors developments in research and makes policy-makers aware of products likely to need regulatory assessment in the near future.

Before products can be provided to patients, they are subject to regulatory approval by either the European Medicines Agency – an agency of the European Union – or the Medicines and Healthcare products Regulatory Agency – the UK medicines regulator. They assess products' safety, effectiveness (compared with an alternative, which may be a placebo) and the quality of the manufacturing process. Products that satisfy those requirements are approved for sale (often referred to as receiving a marketing authorisation). Today the two agencies work closely together. It is not yet clear how this relationship will function after the UK leaves the European Union, but there are reports that the UK will seek continued close partnership ([Withers 2018](#); [McKenna 2017](#)).

After regulatory approval, 'all new significant drugs and indications' ([National Institute for Health and Care Excellence 2014](#)) are assessed by the National Institute for Health and Care Excellence (NICE) to determine whether they will be provided by the NHS, based on clinical and cost effectiveness. This process of analysing the value that new products offer is often referred to as health technology assessment (discussed further below). Products are selected for assessment by NICE in consultation with the Department of Health and Social Care. Products that are not selected for assessment by NICE can be assessed by local commissioners, who can then decide whether they should be made available to patients.

If NICE recommends that a product be provided, commissioners – NHS England or clinical commissioning groups depending on the type of product – have a legal responsibility to make it available to patients. The normal requirement is that this happens within 90 days of NICE's decision.



2 How is NHS spending on medicines changing and why?

Establishing how much the NHS spends in total on medicines, and how this has changed over time, is complicated by a lack of comprehensive, publicly available data. In general, there is rich data on prescribing in primary care and only limited data on hospitals' use of medicines.

Primary care prescribing costs grew from £4 billion in 1996 to £8.2 billion in 2006 (NHS Information Centre 2007). This was driven by both an increase in the volume of items provided – from around 485 million in 1996 to 752 million in 2006 – and an increase in the average cost per prescription item – from £8.26 in 1996 to £10.90 in 2006 (NHS Information Centre 2007).

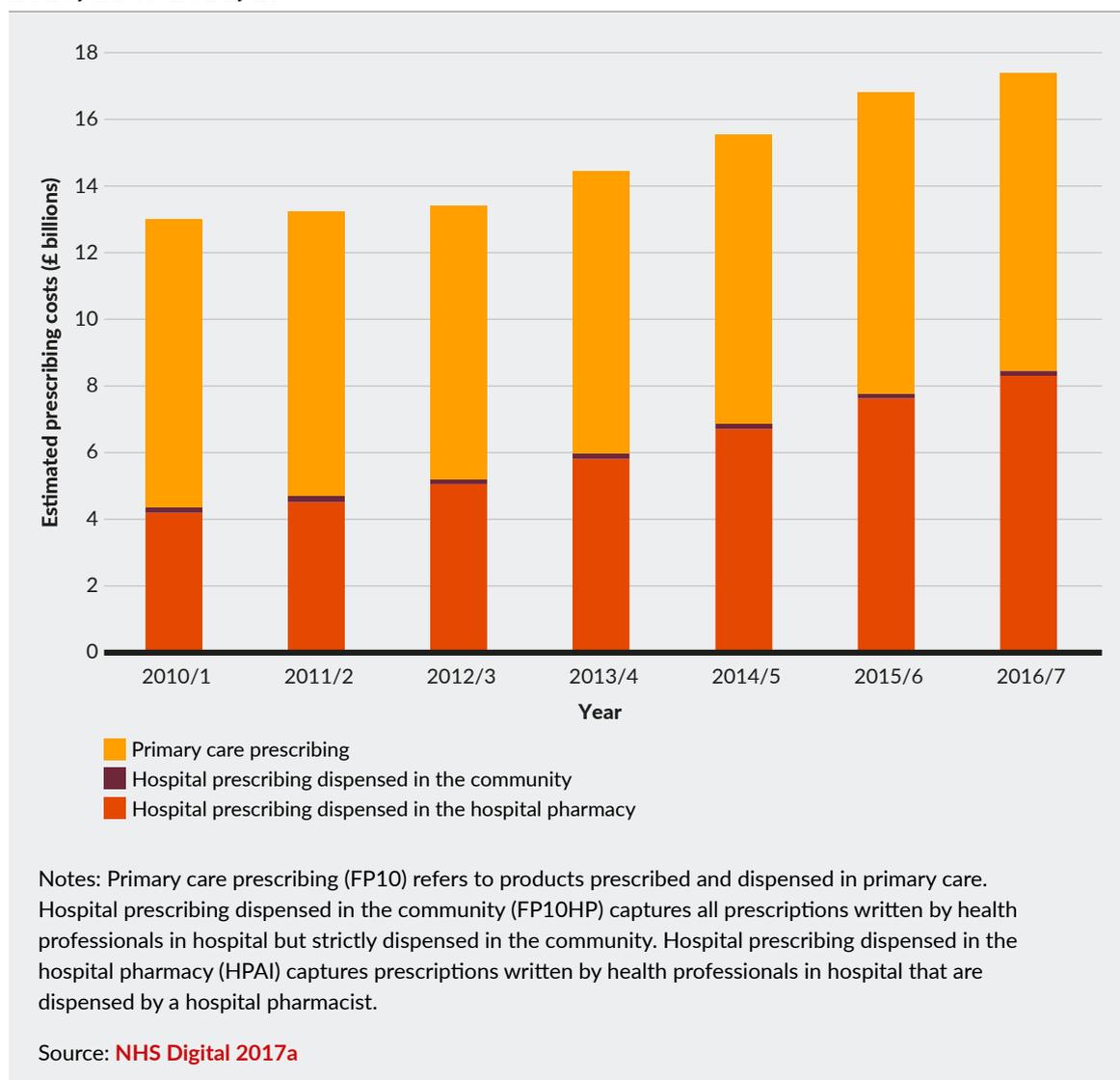
NHS hospitals' spending on medicines in the past is less well documented, but one analysis found that it grew from slightly less than £1.2 billion in 1990/91 to more than £1.5 billion in 1999/2000 (Audit Commission 2001).

These figures, while only offering an estimate of spending, highlight an important point: historically, primary care prescribing has been the largest component of the cost of NHS medicines by some margin. Recently, this has changed.

Spending on NHS medicines today

The most comprehensive snapshot of recent spending on NHS medicines shows that costs, based on list prices, rose from around £13.0 billion in 2010/11 to £17.4 billion in 2016/17 – an average growth of around 5 per cent a year (see Figure 2). This compares with an average growth of the total NHS budget (not adjusted for inflation) of around 1.5 per cent a year over the same period. However, for a number of reasons, it is not clear how closely the national figures for spending on medicines reflect reality (see the box on p 8).

Figure 2 Estimated prescribing costs (£ billions) by care setting, 2010/11 to 2016/17



Since 2010/11, the rate of prescribing cost increases has differed markedly between hospitals and primary care. Between 2010/11 and 2016/17, spending on hospital medicines nearly doubled, from around £4.2 billion to £8.3 billion – representing an average growth of 12.1 per cent a year. Meanwhile, the cost of primary care prescribing grew by a more sedate 0.6 per cent a year on average – from £8.6 billion to £9.0 billion. Consequently, the share of spending on NHS medicines that was attributable to hospital care grew from 32.1 per cent in 2010/11 to 47.6 per cent in 2016/17.



Measuring NHS expenditure on medicines

Estimates of total NHS expenditure on medicines give only an approximate indication of actual NHS expenditure, for a number of reasons.

First, products' list prices (which are set by manufacturers and sometimes known as ex-factory prices) do not reflect the prices that the NHS actually pays (often known as net prices) because confidential discounts are agreed, including via patient access schemes (discussed further below). Consequently, spending measured by list prices overstates the total cost of medicines.

Second, the figures for spending on NHS medicines do not include the cost of medicines dispensed by companies providing care to patients in their own home. While NHS providers or commissioners reimburse these home care providers for their services, it is not known what component of this spending is attributable to medicines. So there is some medicines expenditure, which it is not possible to quantify, that does not show up in the national figures.

Third, the spending figures do not factor in rebate income that the NHS receives from the pharmaceutical industry as part of the Pharmaceutical Price Regulation Scheme (PPRS) or income from prescription charges (both discussed further below).

Source: [NHS Digital 2017a](#)

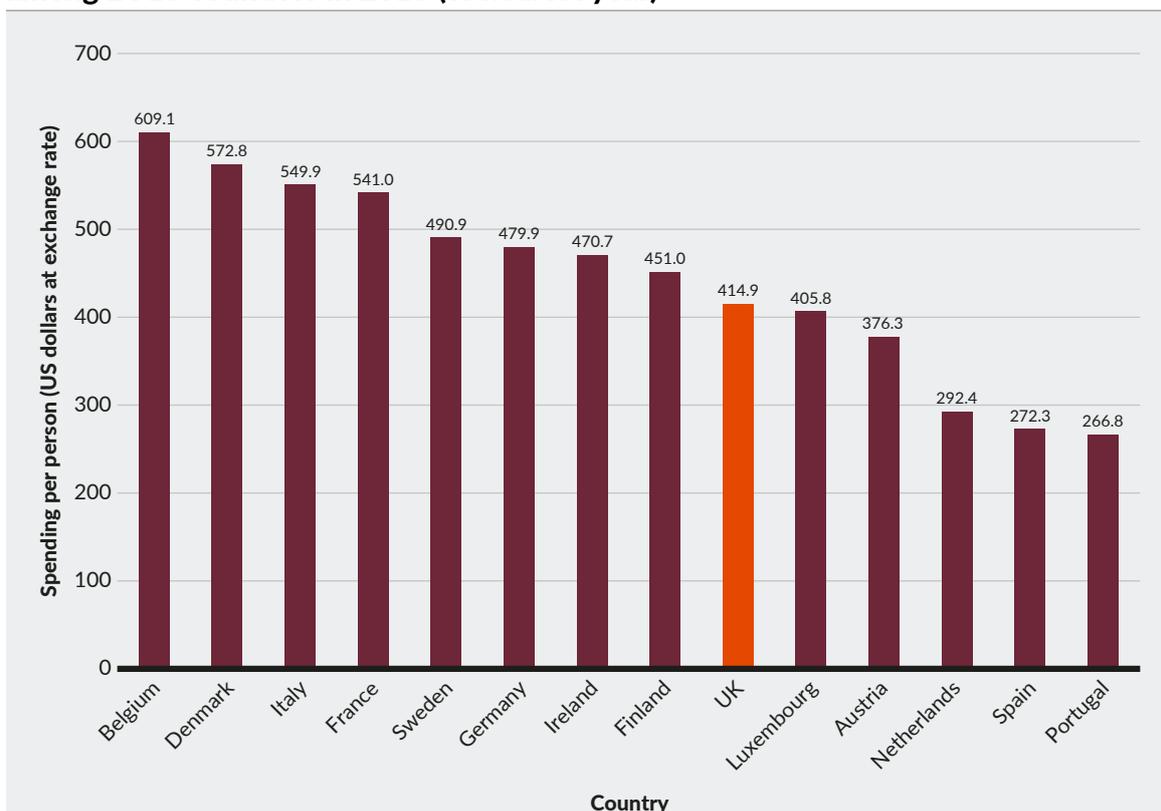
How does the UK's spending on medicines compare with that of other health systems?

International comparisons of expenditure on medicines are problematic. Both price and volume are difficult to compare because of confidential price agreements and variation in how health systems provide medicines to patients. Different approaches to recording out-of-pocket spending on medicines and hospital medicines further complicate the picture. For these reasons, care should be taken when interpreting comparative figures.

Notwithstanding these difficulties, data from the Organisation for Economic Co-operation and Development suggests that pharmaceutical spending per person in EU15 countries varies substantially (see Figure 3). In 2015, the UK spent US\$414.9 per person on medicines. This puts the UK in the lower half of the EU15 countries (for which data is available) and is slightly below the average of US\$442.4 per person.



Figure 3 Spending on medicines per person (in US dollars at exchange rate) among EU15 countries in 2015 (or nearest year) **K**



Notes: Data for France is from 2013 – the most recent available year. Greece was excluded from the analysis on the basis that the most recent data point available was from 2007. The Organisation for Economic Co-operation and Development’s measure of pharmaceutical sales in the UK includes drugs dispensed in hospitals; prices are list prices or the price in the Drug Tariff; over-the-counter purchases are not included. The following countries’ data does not include spending on medicines dispensed in hospital: Austria, Germany, Ireland, Luxembourg, the Netherlands, Portugal and Spain. The following countries’ data does not include spending on over-the-counter medicines: Austria, Ireland, Luxembourg, the Netherlands, Spain and the UK. Portugal includes some over-the-counter sales but not all.

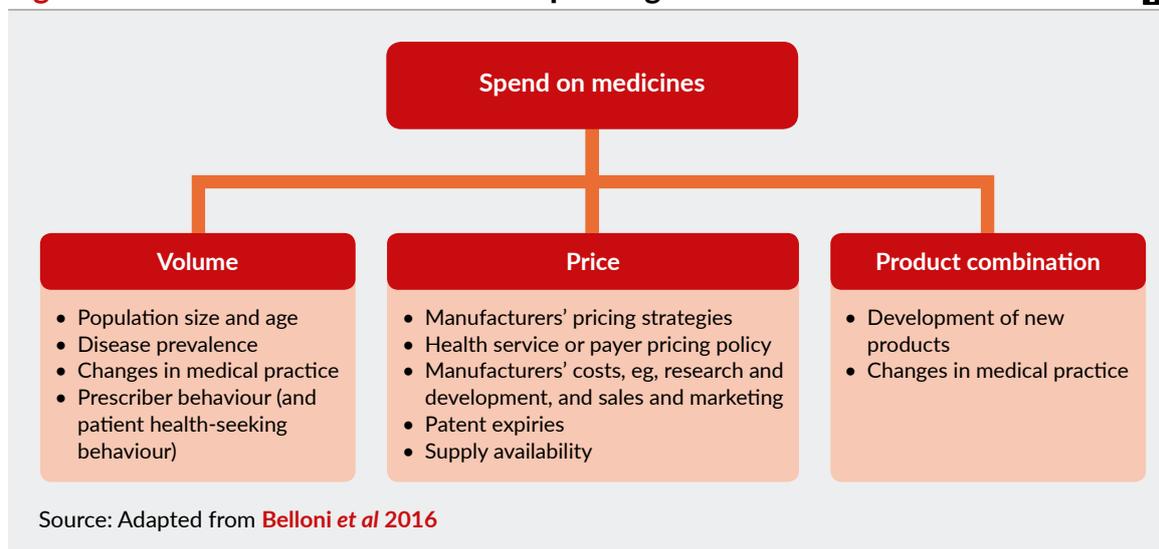
Source: [Organisation for Economic Co-operation and Development 2017](#)

What is driving expenditure on medicines in the NHS?

Expenditure on medicines is influenced by a number of factors, which can be simplified into three groups: the volume of products provided, the price of those products and the combination of products used (see Figure 4). These can interact in various ways in different clinical areas and may vary by region because how medicines are deployed is influenced by patient need and how services are organised.

Figure 4 Visualisation of the drivers of spending on medicines

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Population growth and increases in the numbers of older people push up the volume of medicines provided, partly due to older people being more likely to have long-term health conditions such as cardiovascular problems, arthritis or diabetes ([Duerden et al 2013](#)). Developments in medical practice – for instance due to new guidelines that adjust the recommended treatment per patient or which enlarge the population of patients who would benefit from treatment – often increase the volume of products prescribed. Antibiotics are an exception to this because there is a drive to reduce volumes in light of antimicrobial resistance (discussed further below) ([National Institute for Health and Care Excellence 2015a](#)).

Prescribers are the key decision-makers in the process and so their behaviour is a critical factor influencing the total volume of medicines provided (discussed further below). However, patients' help-seeking behaviour also plays a role. There is evidence that some GPs feel pressure from patients to provide them with prescriptions for medicines, for example for antibiotics ([Nesta 2014](#); [Carthy et al 2000](#)), although this is only one of many factors influencing their prescribing decisions ([Scoggins et al 2007](#)).

Product prices are influenced by a number of factors. Manufacturers' strategy, the type of product being priced and payers' policy on pricing all have an effect ([Eichler et al 2016](#)), as do manufacturers' development costs, including for products that never make it to market. Manufacturers have a responsibility to maximise profits



for their shareholders and this will also have an impact on prices. Estimates of how much it costs to research and develop a new product vary. One recent analysis put the cost at around \$2.5 billion in 2013 (DiMasi *et al* 2016) while a more-UK focused estimate was £1.15 billion (**Cancer Research UK 2016**). Meanwhile, prices in the UK also generally exhibit a pattern according to the stage in the life cycle of the medicine: medicines are most costly when they are launched and their price falls gradually over time (in nominal and real terms) (**Pistollato 2015**; Hoyle 2008).

A new product is usually protected by a patent, which means that no other company can manufacture an identical medicine. Once the patent expires, copies of the original product (called generic drugs/generics) can be made and competition begins (see the box below). Prices of generic products are subject to demand and supply pressures; if supplies of a particular product run short, prices can escalate, as has happened recently (**Iacobucci 2017**).

Patented versus generic medicines

Patent protection, which usually lasts 20 years from an application being submitted, gives a manufacturer a window of exclusivity to sell a product. The premium prices chargeable in that window help to create an incentive for manufacturers to invest in research and development.

Drug companies create brand names for patented products for marketing purposes. For example, 'Humira' is the brand name for a product manufactured by Abbvie for which the international non-proprietary name (INN) (generic name) is adalimumab. A product's brand can outlast its period of patent protection.

Generic products emulate a product for which the patent has expired and must demonstrate pharmaceutical equivalence. The product that a generic replicates is referred to as the originator or reference product.

Generics are usually cheaper than the reference product because the manufacturers have substantially lower development costs and competition for market share drives prices down. Switching patients from branded products to generics can therefore generate savings. In some cases the price of the reference product also falls once generics are available.

Confusingly, some generic products are also given brand names by their manufacturers to differentiate them and help secure premium prices.



The combination of products used (often known as product mix) generally refers to the arrival of new medicines on to the market. While these may offer therapeutic benefits for patients, including sometimes in clinical areas in which there was no prior effective treatment, their deployment pushes up spending. A recent example of this is the arrival of new treatments for hepatitis C (see the box below). Product combination also describes the process where new more expensive drugs replace older cheaper ones.

NHS provision of new treatments for hepatitis C

Hepatitis C is a virus that, if untreated, can lead to serious health conditions affecting the liver, for example cirrhosis and cancer. Public Health England estimates that around 160,000 people in England have the virus ([Public Health England 2017](#)).

In 2014, Gilead, a pharmaceutical manufacturer, launched a new treatment for hepatitis C called sofosbuvir (brand name Sovaldi). It was hailed as a step-change in treatment; where previously ongoing management was required, sofosbuvir offered a relatively short curative intervention. The UK list price for a 12-week course of sofosbuvir was nearly £35,000 (excluding VAT) and double that for a 24-week course ([National Institute for Health and Care Excellence 2015c](#)).

Notwithstanding the high price, in early 2015 sofosbuvir was recommended for funding based on its cost effectiveness. However, in light of the budget impact of the treatment, in the following months NHS England delayed consistent provision of sofosbuvir, instead phasing introduction through the use of quotas and prioritising patients with the most severe need (Gornall *et al* 2016).

Sofosbuvir has been followed by combination hepatitis C treatments manufactured by Gilead and others, which have also been recommended for NHS funding. Subsequently, the Department of Health and Social Care and NHS England have used competitive tendering to secure better prices for these treatments ([Staines 2018](#)).



What is happening in hospitals?

Hospitals' use of medicines is clearly leading to increases in NHS expenditure, but data on volume, prices and product mix in hospitals is not publicly available, so it is not possible to explore their interaction. By way of a hypothesis, increases in the number of patients that hospitals are treating each year ([Maguire *et al* 2016](#)) will be playing a role in pushing up volumes. The introduction of costly new treatments for conditions treated in hospital will also be a factor ([NHS Digital 2017a](#)); indeed many suggest that this is the main reason for escalating spending on hospital medicines. The number of products that each patient is provided with may be increasing as well (as is happening in primary care). But without robust data, these propositions cannot be tested.

What is happening in primary care?

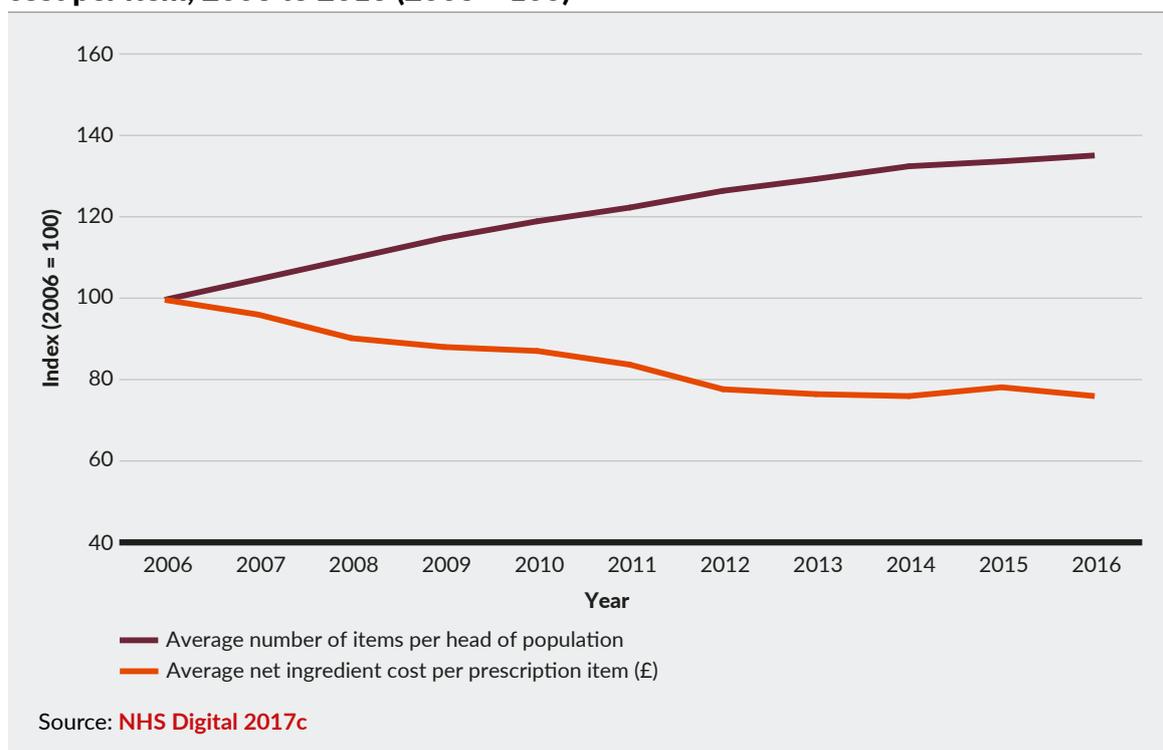
In primary care, data is much richer, making it possible to explore trends over recent years. At the headline level, the data shows that the volume of medicines provided is increasing and average prices are falling. In 2006, around 752 million prescription items were dispensed; by 2016 this had reached 1.1 billion – an increase of 46.8 per cent ([NHS Digital 2017c](#)).

Population growth of 8.4 per cent over the period accounts for some of the increase in volume ([Office for National Statistics 2017](#)). But the number of items dispensed per person per year also increased 35.4 per cent (see Figure 5) – from 14.8 to 20.0 – suggesting that changes to the age structure of the population, disease prevalence and developments in medical practice are also playing a role.

In relation to price, over the 10-year period the average net ingredient cost – the cost of the drug before discounts and not including dispensing costs – per prescription item fell by around 23.5 per cent (see Figure 5) – from £10.90 to £8.34.



Figure 5 Comparison of the average number of prescription items per head of population dispensed in primary care per year and the average net ingredient cost per item, 2006 to 2016 (2006 = 100)



Primary care prescribing is broken down into 21 clinical areas, of which four account for the bulk of volume and spend:

- the cardiovascular system, which includes medicines for combatting high blood pressure and high cholesterol, such as statins
- the respiratory system, which includes inhalers and treatments for asthma and chronic obstructive pulmonary disorder (COPD)
- the central nervous system, which includes medicines for depression, for pain and to help manage epilepsy
- the endocrine system, the largest component of which is treatments for diabetes.

In 2016, these four areas together accounted for 63.9 per cent of the total volume of items dispensed and 59.6 per cent of total cost.



In terms of explaining the growth in the number of medicines provided over the decade, volumes increased across most clinical areas, but the largest increases clustered in a few areas, in particular the cardiovascular system and the central nervous system. Between 2006 and 2016, the number of cardiovascular prescriptions grew by 36.2 per cent to around 320 million items, while the number for the central nervous system increased by 60.1 per cent to about 207 million.

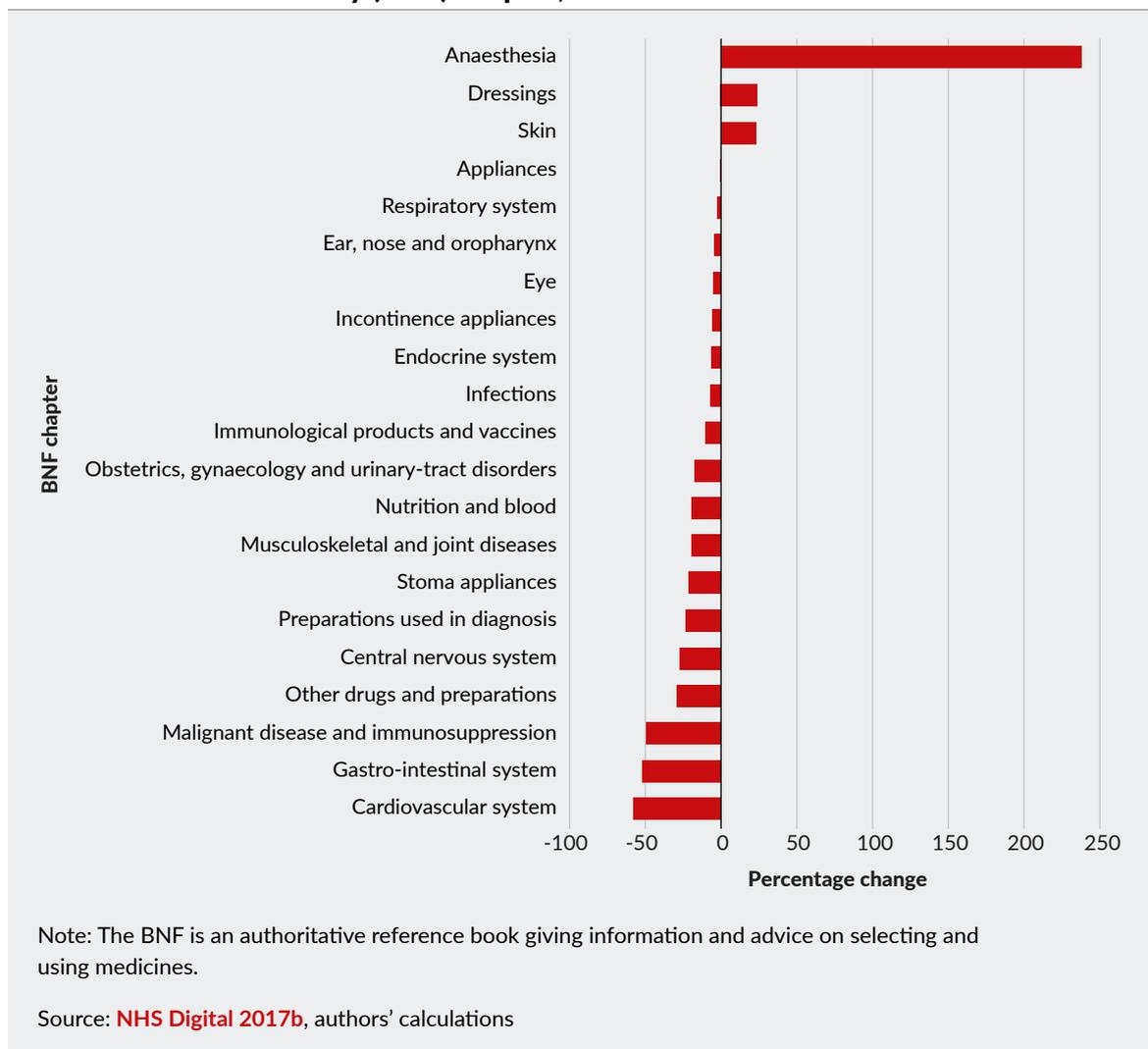
Within those clinical areas, products aimed at a few health conditions played a key role in volume increases. Prescriptions for lipid-regulating drugs (statins) increased 68.6 per cent and medicines for hypertension (high blood pressure) rose 49.7 per cent; together these accounted for around 62 per cent of the increase in cardiovascular prescriptions. Antidepressants, analgesics and anti-epileptic drugs were the reason for about 88 per cent of the volume increase in the central nervous system clinical area, with antidepressants seeing the largest numerical growth – the number of prescriptions issued in 2016 was up 33.7 million (108.5 per cent) on 2006.

These volume increases were offset by falls in the average net ingredient cost per item in 17 out of the 21 clinical areas (see Figure 6). The 57.7 per cent fall in the average cost of products used to treat the cardiovascular system was particularly important from a budget impact perspective. It generated the largest saving in total cost for any clinical area – around £799 million between 2006 and 2016. Consequently, cardiovascular products as a proportion of total spend fell from 23.0 per cent in 2006 to 11.8 per cent in 2016. To put this in context, the next largest fall in total cost for a clinical area was £94.4 million – in malignant disease and immunosuppression (which includes cancers and multiple sclerosis and for which much treatment takes place in hospital).

Not all clinical areas saw falls in average price per item though. The average cost of anaesthesia items increased 238.3 per cent between 2006 and 2016 (largely attributable to changes in the price of lidocaine hydrochloride). But because anaesthesia products are prescribed in relatively small volumes in primary care (0.16 per cent of total items in 2016), the increase only had a small impact on total expenditure – accounting for around £23 million of cost growth between 2006 and 2016.



Figure 6 Percentage change in average net ingredient cost per item by British National Formulary (BNF) chapter, 2006 to 2016 **K**



The fall in spending on cardiovascular treatments over the decade provides an example of how price changes help to moderate expenditure growth. Generic competition, particularly in statins (treatments for high cholesterol), played a key role in driving this fall in average cost per item.

Atorvastatin, a widely-used statin, was developed in the 1980s (under the brand name Lipitor) and its UK patent expired in 2012, allowing generic competitors to enter the market. Consequently, NHS spend on Lipitor prescriptions in primary care fell from around £310.5 million in 2011 to £105.8 million in 2012 and to



£3.3 million by 2014 as patients were switched to generic atorvastatin (see Figures 7 and 8). After that, the volume of generic atorvastatin prescribed grew rapidly – reaching over 32 million items in 2016 (see Figure 8). But the low unit cost of generic atorvastatin – around £1.50 per item in 2016 – helped to moderate growth in total spend.

Figure 7 Total net ingredient cost (£ millions) in primary care prescribing per year for Lipitor and generic atorvastatin, 2006 to 2016 **K**

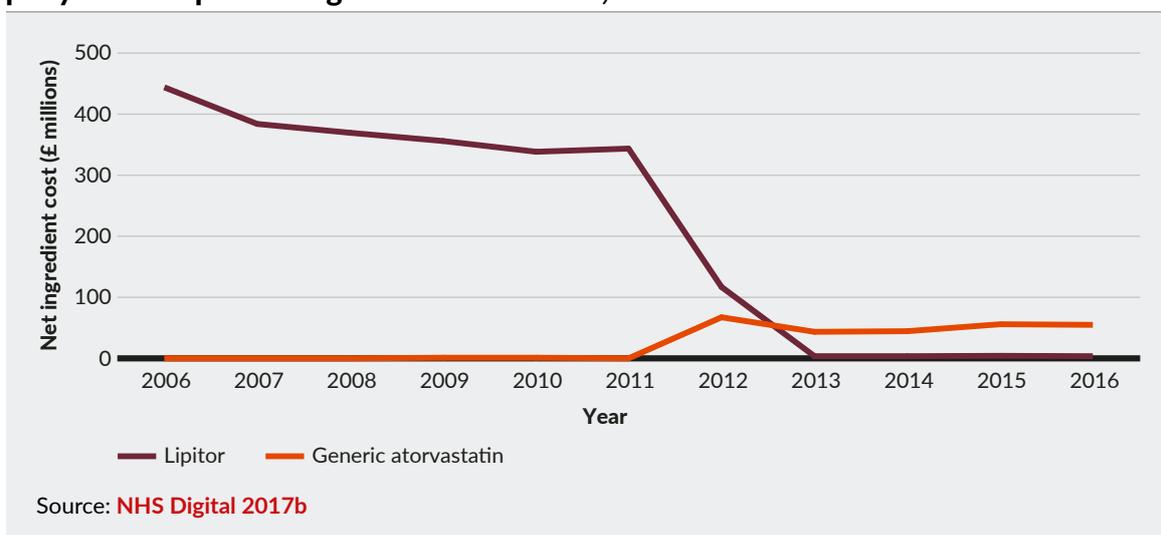
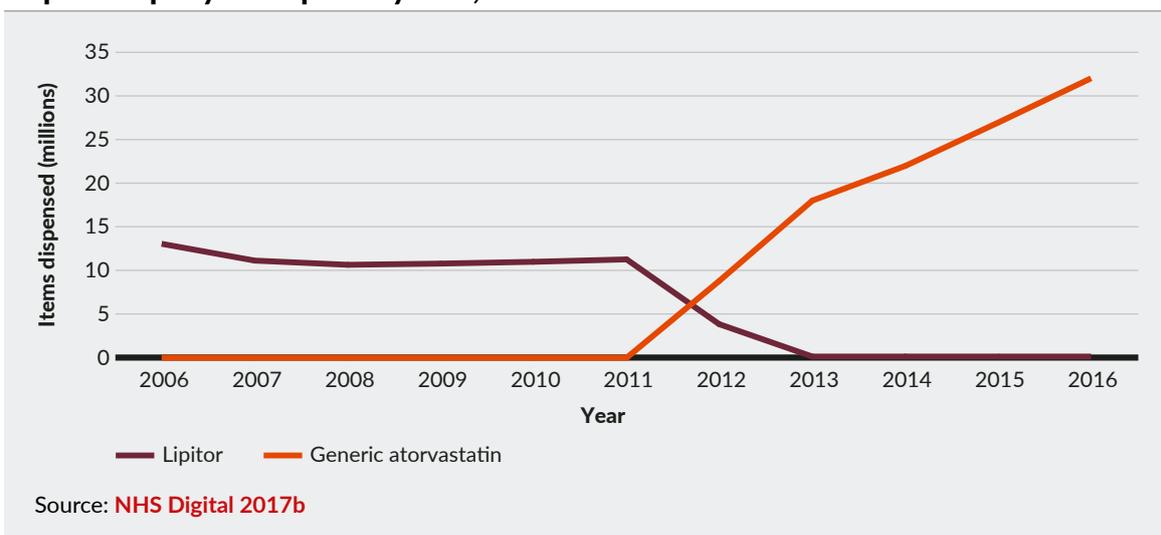


Figure 8 Number of Lipitor and generic atorvastatin prescription items dispensed per year in primary care, 2006 to 2016 **K**





The shift in the prescribing of statins is one example of a wider trend in primary care prescribing: thanks to concerted efforts from policy-makers (discussed further below), generic prescribing has grown substantially over the past 40 years, from less than one in five prescriptions issued in the mid-1970s to more than 80 per cent in recent years (*Alderwick et al 2015* pp 15–23).

Changes to the product mix – namely the arrival of new products – are important because they can create upward pressure on spending. This can be seen in the prescribing for diabetes over the decade up to 2016. The growing prevalence of diabetes increased the volume of products dispensed in primary care (up more than 80 per cent over the decade). However, the average net ingredient cost per item fell only 3.4 per cent over the period – from £19.78 per item to £19.11 – in part due to the arrival of new treatments, some of which are very costly and are being used in increasing volumes. By 2016, three relatively new treatments that made up only 8 per cent of the total volume of prescriptions for diabetes – linagliptin, liraglutide and sitagliptin – accounted for nearly a fifth of spending (18.2 per cent).

Overall, the picture in primary care shows that volume and price are exerting countervailing forces on spending on medicines. The total volume of prescription items dispensed grew around 47 per cent over the decade to 2016. Changing disease prevalence, an ageing population and changing practice are likely to be the cause of this. However, falls in the average price of products in all but four clinical areas have limited the budget impact of this volume growth. Reductions in the average cost of cardiovascular products, thanks to generic competition, have been particularly important in creating funding headroom.



3 How does the NHS control spending on medicines?

Policy-makers have a range of policy options to influence how medicines are used and thus overall medicines expenditure and value for money. This briefing identifies three categories of policy options: pricing, availability on the NHS, and influencing prescribing behaviour and pharmacy processes.

Before exploring the key measures that the NHS uses within each of these areas, it is worth acknowledging that some policies do not fit easily into this typology. For example, the Accelerated Access Review (see the box below), a key area of pharmaceutical policy activity in recent years, aims to improve patients' access to medicines and promote innovation among manufacturers by refining the process through which products are developed, appraised and rolled out. The goal is to improve access within the existing NHS funding settlement.

Accelerated Access Review

There is a longstanding view that the NHS, while it supports a lot of research, is slow to adopt and spread new products and techniques (Collins 2018). The government therefore commissioned an independent review – the Accelerated Access Review – to explore how to accelerate uptake (Accelerated Access Review 2016).

The government endorsed key aspects of the review and announced the introduction, from 2018, of a new accelerated access pathway for products that show potentially transformative impact (Department of Health and Department for Business, Energy & Industrial Strategy 2017). Up to five products a year will be selected for the pathway and by simplifying the development and approval process – regulatory approval, NICE's assessment and commercial negotiation will happen simultaneously – the government aims to bring forward access by up to four years.

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Accelerated Access Review *continued*

For products with an immature evidence base, NICE will also be able to provide conditional approval that allows for them to be provided on the NHS for a defined period of time. During that window, real-life evidence of effectiveness will be gathered before a full NICE appraisal will determine whether the NHS should continue to provide the product.

It is important to note that the government requires that the accelerated access pathway be cost-neutral (**Department of Health and Department for Business, Energy & Industrial Strategy 2017**, p 12). Any product introduced via the pathway that adds to NHS costs will need to be offset by another that reduces them. Others, including the Office for Budget Responsibility, have, however, observed that the introduction of new technologies is a key driver of cost in health care (**Licchetta and Stelmach 2016**).

The Accelerated Access Review sits within a wider government agenda focused on promoting the UK's life sciences industry. Since 2016 the government has embraced a more active industrial strategy whereby certain key sectors are supported by government action (**HM Government 2017**). In late 2017 a sector deal was agreed with the life sciences industry, which aims to make the UK a 'top tier global hub for biomedical and clinical research and medical innovation' (**Department for Business, Energy & Industrial Strategy and Office for Life Sciences 2017**, p 6). This forms the context for conversations about possible reform of medicines pricing in the UK.

Pricing

Pricing policy determines the basis on which manufacturers and the payer, in this case the NHS, set the price for products. There are a range of options for how to do this. The approach in England, which uses a number of instruments to influence prices of different categories of medicine, is relatively unusual (other advanced systems often use some form of external price benchmarking for example) (**Carone et al 2012**).

The Pharmaceutical Price Regulation Scheme

The Pharmaceutical Price Regulation Scheme (PPRS) is a voluntary UK-wide agreement between the Department of Health and Social Care and the Association of the British Pharmaceutical Industry (ABPI) to control expenditure on branded



medicines (generic products and those procured via ‘parallel trade’ – see the box on p 22 – are not included). Payments made by industry to the Department of Health and Social Care under the PPRS are distributed across the four health systems of the UK.

A version of the PPRS has been negotiated every five or six years since the mid-1950s. The current instalment (running from January 2014 to the end of 2018) ([Association of the British Pharmaceutical Industry 2014](#)) includes two key mechanisms for cost containment: rate-of-return regulation for companies (which assesses the income that companies generate from the NHS in relation to their expenditure on activities like research and development) and an overall envelope for NHS spending on branded medicines over the lifetime of the agreement – a departure from previous versions of the PPRS, which included mandatory price cuts. In the current instalment it is the overall envelope that is controlling spend. The agreement allowed for flat spending in 2014 and 2015 followed by growth of 1.8, 1.8 and 1.9 per cent in 2016, 2017 and 2018 respectively ([Department of Health and Association of the British Pharmaceutical Industry 2013](#), p 35).

If sales to the NHS exceed the agreed level of growth, the industry makes payments to the Department of Health and Social Care. Industry payments in recent years have ranged from £311 million in 2014 to £846 million in 2015 (see Table 1). In 2015/16, the Department of Health received an additional £205 million from the Treasury within the financial year, partly justified on the basis of lower-than-expected PPRS payments from industry ([Dunhill 2016](#)).

Table 1 Payments from industry to the Department of Health under the PPRS, 2014 to 2017

| | Calendar year | | | |
|---------|---------------|--------------|--------------|--------------|
| | 2014 | 2015 | 2016 | 2017 |
| Payment | £311 million | £846 million | £628 million | £386 million |

Note: The 2017 figure is still subject to audit.

Source: [Department of Health and Social Care 2018a](#)



Parallel trade in medicines

Parallel trade (also known as parallel imports) refers to importing units of medicines (in practice usually patented products) from other countries at lower prices than are available in the UK ([Kanavos et al 2005](#)).

Products can be imported thanks to the legal position that once a manufacturer places a product on the market in the European Union, purchasers can sell that product on without the consent of the patent holder ([Ganslandt and Maskus 2001](#)). The development of the European single market has facilitated the trade. The UK's decision to leave the European Union will therefore have implications for parallel trade, although the details will depend on the nature of the final deal.

Providers of care in the NHS – particularly pharmacies – source products independently and therefore try to benefit from the lower prices of products in other European countries stemming in part from varying approaches to price regulation ([Carone et al 2012](#)). The exchange rate is also an important factor in parallel trade: when the pound falls in value, products priced in euros become more expensive.

Parallel imports can cause problems for stakeholders in the UK. Manufacturers are resistant because they cut into their sales. Parallel imports are not included in the PPRS's financial envelope and can impede accurate measurement of total spending on medicines. Growth in parallel imports has been identified as one factor contributing to recent lower-than-expected payments from industry under the PPRS ([Barham 2016](#); [Hazell 2016b](#)). Parallel exports meanwhile can lead to supply shortages in the UK (as there have been in the past year).

The statutory scheme

The statutory scheme, for which the Department of Health and Social Care retains responsibility, regulates the prices of branded products manufactured by companies that are not signatories to the PPRS. Most large companies participate in the PPRS so only a relatively small volume of medicines fall within the scheme – around 6 per cent of total volume in 2014 ([Department of Health 2014a](#)).

In contrast to the current PPRS, the most recent version of the statutory scheme required a 15 per cent cut on the list price of branded medicines that were



launched before December 2013. However, the Health Service Medical Supplies (Costs) Act 2017 reformed the scheme to bring it more closely into line with the PPRS. In place of the price cut, the reformed scheme will require manufacturers to pay a percentage of their sales to the NHS – initially set at 7.8 per cent – to the Department of Health and Social Care (**Department of Health and Social Care 2018b**). Notably the statutory scheme will also be subject to annual review by the government where previously it was reviewed every seven years.

The pricing of generic medicines

The longstanding approach to regulating the prices of generic medicines in England has been to foster a market in which manufacturers compete on price to secure market share (**British Generic Manufacturers Association no date**). The way pharmacists are reimbursed gives them an incentive to source products as cheaply as possible, which helps to stimulate competition among manufacturers.

Alongside this, the government retains the right to intervene when competition does not function effectively. The Competition and Markets Authority, the market regulator, is responsible for investigating failures of competition. For example, in 2016 it fined Pfizer and Flynn Pharma for hiking the price of phenytoin (an anti-epilepsy product) (**Competition and Markets Authority 2016a**) and in another case it fined three companies for a deal that delayed the entry into the market of generic versions of an antidepressant (**Competition and Markets Authority 2016b**).

The Health Service Medical Supplies (Costs) Act 2017 has strengthened the government's hand in relation to generics as it has given it new powers to intervene in pricing (even for products manufactured by PPRS members), which had not been possible previously. The pricing of generic medicines has received increased attention in recent months due to supply shortages (see the box below) (**Brennan 2018b**).



Recent shortages of generic medicines

Generic medicines are subject to demand and supply pressures, similar to other commodities. If supply is insufficient to keep up with demand, prices can escalate as buyers chase dwindling stocks.

This has come to national attention over the past year as pharmacies in England, which are responsible for procuring their own products, have struggled to source a number of medicines and been forced to pay higher-than-expected prices. Treatments affected include drugs for migraines, epilepsy treatments, some mild painkillers and products that help to manage mental health disorders such as schizophrenia and bipolar disorder ([Croker 2017](#)).

NHS England estimates that these price increases cost the system around £362 million in 2017/18 ([Baumann 2018](#)).

Patient access schemes

In recent years the NHS has made increasing use of case-by-case negotiation with manufacturers of new branded products. In instances where products are not able to satisfy cost-effectiveness requirements based on their list price, companies may offer a discount or some form of commercial agreement – known as a patient access scheme – to enable the product to be provided to NHS patients. These agreements take different forms: some involve simple price discounts and, more rarely, others use more complex reimbursement mechanisms. Importantly, prices agreed via a patient access scheme remain confidential on the basis of commercial sensitivity.

The earliest schemes of this type were agreed in the early 2000s, a high-profile example being the 2002 agreement for multiple sclerosis treatments ([Raftery 2010](#)). Patient access schemes were subsequently codified as an option in the 2009 PPRS and have grown in number since then. As of January 2018, 140 schemes are listed on NICE's website (not including the agreed prices), of which 76 have been published since January 2016 ([National Institute for Health and Care Excellence no date](#)). Historically, the Department of Health was responsible for agreeing the schemes, but from early 2018 NHS England has taken on this responsibility (see the box on p 25 for a recent example).



NHS provision of trastuzumab emtansine

Trastuzumab emtansine (brand name Kadcyla) provides an example of how NHS England is using negotiation with pharmaceutical manufacturers to extend access to treatments. Developed by Roche, it is aimed at patients with a particular type of advanced breast cancer, of which NICE estimates there are around 1,200 people in England ([National Institute for Health and Care Excellence 2017b](#)).

NICE originally appraised the product in 2015 and concluded that it should not be routinely provided by the NHS, based on not meeting cost-effectiveness requirements (including those applying to end-of-life treatments) (Kmietowicz 2015). Its list price implied a cost of slightly more than £91,500 for an average treatment cycle of around 14.5 months ([National Institute for Health and Care Excellence 2017b](#)). The product was, however, made available to some patients via the Cancer Drugs Fund (discussed further below).

Since then, NHS England and Roche have successfully negotiated a commercial access agreement to make the drug available via routine NHS commissioning (Kmietowicz 2017). As with other arrangements of this type, the details, including the final price, remain confidential but NICE describes the deal as a 'simple discount' ([National Institute for Health and Care Excellence 2017b](#)).

Availability on the NHS

Availability refers to the group of policies that determine which products are made available to patients and the basis on which they are provided (that is, eligibility criteria and the extent to which patients are required to bear the cost).

The role of NICE

Since the establishment of NICE in 1999, health technology assessment has been used to decide which products should be provided by the NHS. NICE assesses all new significant products that have recently secured a marketing authorisation – from either the European Medicines Agency or the Medicines and Healthcare



products Regulatory Agency – using health economic evaluation and determines whether they should be provided based on their clinical and cost effectiveness (see the box below).

While NICE's role is to make availability decisions, in practice it also influences product prices. Manufacturers are aware of how NICE assesses cost effectiveness and the criteria it uses to judge what the NHS will fund and this informs their pricing strategies. It is also worth noting that moves to accelerate products through regulatory approval, particularly for diseases for which there are only limited therapeutic options, can cause problems for health technology assessment because the value that a new product offers is less well established at the point of assessment.

Background to NICE and its assessment methodology

A number of factors led to NICE being established during the first term of the recent Labour government. In particular, there was concern about local variation in the medicines that the NHS was making available to patients and that ministers in the Department of Health were sometimes being called on to decide whether a particular new product should be funded by the NHS (Timmins *et al* 2016). NICE aimed to bring analytical rigour to these availability decisions and greater national consistency to the NHS's provision of medicines.

At the heart of NICE's approach is a method for assessing the cost effectiveness of new products. It uses quality-adjusted life years (QALYs) to capture the health gain that a product offers (in terms of time and the quality of life that patients are likely to have as a result of treatment). This feeds into a calculation of a product's Incremental Cost Effectiveness Ratio (ICER), which captures how much the treatment costs per QALY gained (Poole 2008). Products offering substantial health gain at only marginally greater cost than existing NHS practice are more likely to fall within the cost-effectiveness threshold. NICE also draws on some other sources of insight, including patient engagement, to inform its appraisals.

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Background to NICE and its assessment methodology *continued*

Today, NICE effectively operates three cost-effectiveness thresholds, which represent the costs that the NHS is willing to bear for different categories of product:

- The default range is between £20,000 and £30,000, with products costing less than £30,000 per QALY generally recommended for funding and those costing more requiring additional justification (**Parliamentary Office of Science and Technology 2015**). The current PPRS stipulates that this threshold remains consistent for the lifetime of the agreement (**Department of Health and Association of the British Pharmaceutical Industry 2013**, p 19).
- In 2009 NICE increased the cost-effectiveness threshold for products aimed at patients in end-of-life situations. This was intended to reflect the priority that society affords to providing for these patients. This threshold has operated at around £50,000 per QALY.
- Most recently, NICE introduced a threshold for products that treat very rare health conditions (known as ultra-orphan drugs). (NICE considers diseases that affect fewer than 1,000 people in the UK to be very rare (**National Institute for Clinical Excellence 2004**.) After consultation in 2016, the threshold for these products was set on a scale from £100,000 to £300,000 per QALY for products that offer the most substantial health gains.

The budget impact test

In April 2017 NICE introduced the budget impact test, which has changed how the NHS makes availability decisions. NICE assesses the budget impact of new products against a threshold of £20 million (**National Institute for Health and Care Excellence 2017a**). If the cost of the product is projected to exceed that level in any of the first three years of use, a commercial negotiation will be triggered. NHS England will attempt to reach a deal with the manufacturer to bring the cost down. If successful, the normal 90-day requirement will apply. If not, NHS England will apply to NICE to delay the introduction of the product (usually by up to three years, and potentially longer in exceptional circumstances).

It is not yet clear what this will mean in practice for the availability of new medicines. Estimates based on previous experience suggest that 20 per cent of new treatments cost more than £20 million (**Timmins 2017**). However, NICE has



subsequently highlighted that the £20 million figure is not a hard cap and there may be circumstances in which treatments that exceed this cost are provided (Ogden 2017).

Reform of the Cancer Drugs Fund

In its original design, the Cancer Drugs Fund provided a dedicated funding stream for cancer drugs that NICE had rejected or was yet to appraise. However, following a number of developments (see the box below), the fund has recently been reformed in a way that provides more control over spending.

While the original version of the fund provided indefinite access to cost-ineffective medicines for patients on a case-by-case basis, the new fund operates as a so-called managed access fund. In this model, NICE identifies new cancer products with potential clinical value and they are made temporarily available with money from the fund. During that window, further evidence on the product's real-life effectiveness is gathered before a definitive appraisal by NICE to decide whether, based on its cost effectiveness, it should be provided via normal commissioning or no longer be available on the NHS (NHS England 2016). Early indications suggest that the new arrangement is providing greater control of the Cancer Drugs Fund budget (Brennan 2018a).

Origins and development of the Cancer Drugs Fund

Before 2010 a number of health care charities in the UK helped to initiate a public debate about NHS patients' access to drugs, particularly those for rarer cancers (Lowe 2015; Jack 2014). The government commissioned a report in that year exploring variation in the use of medicines among 14 advanced health systems which found that the UK ranked relatively low in relation to the use of new cancer drugs (Richards 2010).

Shortly before the 2010 general election, David Cameron raised the idea of a fund for cancer drugs (Timmins *et al* 2016, pp 93–113) and it was subsequently included in the coalition agreement (HM Government 2010, p 25). Clinicians were able to apply to the fund on behalf of their patients on a case-by-case basis. Initially the Cancer Drugs Fund was managed regionally but in 2013 responsibility moved to NHS England.

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Origins and development of the Cancer Drugs Fund *continued*

Originally the Cancer Drugs Fund was expected to be a temporary measure until the introduction of a new pricing policy – so-called value-based pricing (whereby prices reflect the clinical and wider benefits that products offer). However, consultation identified a number of practical challenges, which led to value-based pricing being postponed indefinitely and the fund continuing (Buxton *et al* 2014).

Maintaining control of spending in the original fund proved difficult (costs grew from £38 million in 2010/11 to £416 million in 2014/15) (Claxton 2016). Towards the end of the parliament, products were rapidly delisted from the fund to contain costs (Hawkes 2015). Following critical reports from the National Audit Office (2015) and Public Accounts Committee (2016) and widespread agreement that it was not a long-term solution, the Cancer Drugs Fund was reformed.

Delisting or reclassifying products

Since the 1980s the NHS has gradually stopped providing some older low-value products (Abraham 2009), for example those aimed at the relief of mild pain and indigestion, and cough and cold remedies. Today there is a 'black list' of products that should not be prescribed in primary care and a list of items that should only be prescribed in certain circumstances (both are included in the Drug Tariff) (Cylus *et al* 2015).

In recent months, NHS England has signalled a new push to reduce low-value prescribing in primary care. It has issued guidance on 18 products that are low value, are not cost effective or are deemed low priority (NHS England 2017e). Items include a small group of painkillers, herbal treatments, homeopathy, dietary supplements and antidepressants, on which the NHS spends around £141 million a year (NHS England 2017d). NHS England plans to recommend to the Department of Health and Social Care that some of these products, for example homeopathy, are blacklisted (NHS England 2017d, p 5). At the time of writing it was not clear whether the application to blacklist homeopathy had been made or considered by the Department.

In addition, NHS England plans to restrict the routine prescribing of products that are available on the general sales list, on which in the year to June 2017, the



NHS spent around £570 million ([NHS England 2017c](#)). To do this, NHS England has identified a group of around 33 conditions that are mild or self-limiting and for which guidance will advise that patients can effectively self-care using over-the-counter products, so prescriptions should not ordinarily be provided – examples include coughs and colds, indigestion and heartburn, mild acne and mild toothache ([NHS England 2017c](#)).

The Medicines and Healthcare products Regulatory Agency maintains a separate process for reclassifying products from the prescription-only category so that patients can purchase them from pharmacies without needing to see a doctor (see the box below). Between 1991 and 2016, 95 products were reclassified, including both products reclassified from prescription-only to pharmacy medicine and those moved from pharmacy medicine to the general sales list ([Freeman 2016](#)). A recent example is sildenafil citrate (brand name Viagra), a treatment for erectile dysfunction, which has recently been made available for purchase in pharmacies ([Medicines and Healthcare products Regulatory Agency 2017](#)). While reclassification has the effect of creating a new route by which patients can access treatments, it is not necessarily motivated by cost; the Medicines and Healthcare products Regulatory Agency makes a judgement on the safety of a product and the danger of it being abused.

Categories of medicines and routes to access

The way medicines are made available to patients in England varies based on which of three categories a product is classified into by the Medicines and Healthcare products Regulatory Agency.

- Prescription-only medicines must be prescribed by a qualified health professional (generally a doctor).
- Pharmacy medicines do not require a prescription but are only available for purchase from a pharmacy.
- General sale medicines can be purchased from retail outlets without clinical input.

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Categories of medicines and routes to access *continued*

The term 'over-the-counter' is often used to describe medicines that patients can purchase out of pocket. In England this term covers both pharmacy medicines and general sale products.

The bulk of NHS spending on medicines spend is on prescription-only products (although products in the pharmacy category and on the general sales list can also be prescribed for NHS patients). There is also private spending on medicines via out-of-pocket purchases and private prescriptions for which patients pay the full cost of the product. Prescription-only medicines are dispensed by pharmacies in the community (sometimes known as chemists) or in the hospital. Community pharmacies operate under a national contract, which pays them for dispensing medicines to NHS patients.

Prescription charges

First introduced in 1952 in response to concerns about spiralling NHS costs (before being subsequently abolished and reintroduced), prescription charges are one of the oldest pillars of the NHS's approach to medicines (Griffin 1996). Patients pay a fixed charge for each prescription item dispensed in primary care (items dispensed to inpatients in hospital are free), with the charge uprated each year; from April 2018 it will be £8.80 (**Department of Health and Social Care 2018c**). Prescription pre-payment certificates, for three or 12 months, are available to allow people who need regular prescriptions to cap the cost by paying a fixed amount for an unlimited number of items.

In practice only a relatively small proportion of prescription items are charged for due to broad exemptions that cover groups who are more likely to need medicines, for example, people aged 16 or under, people aged 60 or over, women who are pregnant or recently gave birth, people with certain medical conditions and people who are out of work (**NHS Choices no date**). In 2016 only around 9.9 per cent of all items dispensed in primary care incurred a charge or were covered by a pre-payment certificate. In the same year, 61 per cent of all items dispensed were to people aged 60 or over (**NHS Digital 2017c**).



In 2016/7, around £554.9 million was raised from prescription charges (see Table 2). Income from these charges is channelled into NHS England's budget (NHS Digital 2017c).

Table 2 Department of Health income from prescription charges per year, 2013/4 to 2016/7

| | Calendar year | | | |
|------------|---------------|-------------|-------------|-------------|
| | 2013/4 | 2014/5 | 2015/6 | 2016/7 |
| Amount (£) | 470,682,000 | 503,940,000 | 523,539,000 | 554,935,000 |

Note: The 2016/7 figure is still subject to audit.

Source: Department of Health 2017, 2016, 2015, 2014b

The NHS's approach to charging for medicines – a flat rate levied on a relatively small subset of prescriptions – is unusual. Other advanced health systems make more extensive use of user charges and in some cases these are designed to promote the use of cost-effective products (Barnieh *et al* 2014). While any changes would need to be given careful thought, the independent Barker Commission has suggested that reforms to prescription charges could both lower the charge and raise substantial amounts of money by reducing the exemptions available under the current system (Independent Commission on the Future of Health and Social Care in England 2014).

Influencing prescriber behaviour and pharmacy processes

Prescribers are the gatekeepers to prescription-only products on the NHS. Their decisions are therefore a key determinant of how much the NHS spends on medicines. If they can be encouraged to use the most cost-effective products, overall value can be improved. Likewise, how pharmacies use medicines, for example the extent of medication errors or waste, affects how efficiently resources are used.



The promotion of generic medicines

As The King's Fund has written about elsewhere, the NHS has deployed a number of policies over time to promote the use of generic medicines in primary care ([Alderwick et al 2015](#)). First, GPs in training are taught to prescribe using the generic name rather than the brand name, which allows pharmacists to dispense the lowest-cost product (Duerden and Hughes 2010). There are some exceptions to this though, for example in relation to inhalers for treating respiratory conditions and biological products, where best practice is to prescribe by brand name. Second, financial incentives have been used, for example through GP fundholding and community pharmacists being given incentives to dispense cheaper products. Third, GPs are subject to scrutiny and feedback over their prescribing (Hassali et al 2014). And finally, some general practices have introduced digital decision-support systems that prompt prescribers to use low-cost products ([Duerden et al 2011](#)).

This combination of measures has been effective. In 2016, 84.0 per cent of prescriptions in primary care were written using the generic name and 77.7 per cent were dispensed as generic (the difference is partly due to there being some clinical areas in which patents are yet to expire) ([NHS Digital 2017c](#)). (The calculation of the percentage of items dispensed generically excludes appliances and dressings.)

Widespread use of generics in the NHS has created headroom for growth in other areas – equivalent to £7.1 billion between 1976 and 2013 according to our recent analysis ([Alderwick et al 2015](#), p 19). But there remains scope to increase the proportion of products dispensed generically in the community, which would create headroom in the budget for further growth in volume. Tackling some of the variation in generic prescribing rates across GP practices would be an avenue for achieving this.

It is worth noting that encouraging prescribers to consider value for money in their decisions, as policy-makers have, can lead to volume increases and rising expenditure on medicines. This is because, in some cases, providing medicines, for example those that help to manage long-term conditions, is more cost effective than leaving patients untreated.



Biological medicines and biosimilars

An increasing number of new medicinal products are biological rather than chemical, meaning that they are derived from living entities. Examples include adalimumab, a treatment used in rheumatoid arthritis among other things, and interferon beta, which is used to treat people with multiple sclerosis. In 2014 there were more than 1,500 biological treatments going through clinical trials ([Otto et al 2014](#)). These are expected to have a particular impact on treatment for people with cancer and conditions of the immune system ([Rémuzat et al 2017](#)).

To secure regulatory approval for generic medicines, manufacturers have to demonstrate that they are identical to the reference product. This is not possible for biological medicines because their molecular composition is more complex and is subject to natural variation. So for biological medicines, drugs that are manufactured after the patent for the product expires only have to demonstrate *similarity* to the reference product and are called biosimilars.

As with generic medicines, national bodies are encouraging prescribers to use biosimilars. But while biosimilars are expected to help contain costs to some extent, it is likely that they will not generate the level of savings that generic medicines do. Evidence so far has shown price erosion of between 10 and 35 per cent for biosimilars ([Farfan-Portet et al 2014](#)) – substantially less than for many generics.

Nevertheless, NHS England has released a commissioning framework for biological treatments in which it estimates that consistent use of best-value biological and biosimilar products could save £200 to £300 million a year by 2020/21 ([NHS England 2017b](#)). It has set a target of 90 per cent of new patients being on the best-value biological or biosimilar medicine within three months of product launch and 80 per cent of existing patients within 12 months of product launch. Clinical commissioning groups have been asked to develop plans to ensure quick uptake and new regional medicines optimisation committees (discussed further below) are tasked with overseeing delivery.

Importantly, current guidance is that biological treatments should be prescribed by brand name (unlike chemical products) and patients should not be switched *automatically* on to biosimilar treatments once the patent has expired. Consequently, prescribers have to proactively switch patients.



Reducing waste and improving how medicines are delivered

Combatting medication waste is another way in which policy-makers can promote value in medicines expenditure. It has been estimated that prescription items worth around £300 million are wasted each year in primary care ([Trueman *et al* 2010](#)). Meanwhile, hospital admissions related to medication errors and adverse reactions could be costing the NHS £530 million a year ([National Institute for Health and Care Excellence 2015b](#)), with errors most likely to affect patients taking multiple medicines and contributing to 700 deaths a year ([Elliot *et al* 2018](#); [Duerden *et al* 2013](#), pp 9–10).

In light of these concerns, national bodies have initiated a range of activities to improve how the NHS delivers medicines to patients. The Carter Review of efficiency in hospitals ([Carter 2016](#)) led to the Hospital Pharmacy Transformation Programme, which aims to improve the productivity of hospital pharmacies through stronger data collection and smarter use of resources, partly through the better use of pharmacists' time. Following publication of the *Next steps on the NHS five year forward view* document in early 2017 ([NHS England 2017f](#)), which highlighted medicines as an important area of focus for improving efficiency, NHS England established four regional medicines optimisation committees. Their remit includes providing information to local providers and commissioners, monitoring the implementation of advice and guidance and identifying emerging medicines issues that would benefit from a national response ([NHS England 2017g](#)). Given that the committees' outputs are 'advisory', the extent to which they will be able to drive change is open to question.

Combatting the overuse of medicines

In recent years, the question of the overuse of medicines has risen up the agenda. In particular, antibiotics have been the focus of policy-makers' attention in light of concern about increasing antimicrobial resistance (AMR). A recent analysis found that antibiotic prescribing in English primary care is substantially higher than experts think appropriate for a number of common health conditions such as acute coughs, bronchitis and sore throats ([Pouwels *et al* 2018](#)).

A five-year national strategy for AMR was published in 2013 ([Department of Health and Department for Environment, Food & Rural Affairs 2013](#)). Following that,



the government commissioned an independent review of AMR. Its response set out a number of goals, including reducing inappropriate antibiotic prescribing by 50 per cent by 2020 (**HM Government 2016**). Since then, financial incentives have been developed to promote responsible prescribing at the front line, for example through AMR being included in the Commissioning for Quality and Innovation (CQUIN) scheme for hospitals and incorporated into the quality premium system for clinical commissioning groups. Also, Public Health England and the Royal College of General Practitioners have collaborated to develop a toolkit to encourage responsible antibiotic use in primary care (**Royal College of General Practitioners no date**).

While it is too early to offer an assessment of the impact that these activities are having, some early evidence suggests that progress is being made. NHS Improvement reported that the number of antibiotics prescribed fell 7.3 per cent in 2016 (**NHS Improvement 2016**) and in primary care, by 2016, the number of prescription items for broad-spectrum penicillin had fallen by around 20.7 per cent from a peak in 2012.



4 What next for medicines policy?

Through the ongoing refinement of the policies discussed above, the NHS has historically struck a balance between the three key objectives of medicines policy – access, affordability and innovation. Manufacturers have been able to sell products to the NHS, including new ones, where they have demonstrated cost effectiveness; patients have benefited from reasonable (although not perfect) access to innovative products; and the NHS's spending on medicines has risen but within the parameters of a growing overall budget.

Today, however, this carefully constructed compromise appears increasingly precarious, for a number of reasons:

- Demand for health care is rising due to increasing numbers of older people.
- Pharmaceutical companies are developing effective but increasingly costly products, for example sofosbuvir to treat hepatitis C and pre-exposure prophylaxis to prevent HIV.
- New biological treatments are emerging, which are providing therapeutic advances but in a form that is not amenable to traditional generic competition.
- There has been an unprecedented slowdown in NHS funding, which leaves very little headroom for growth in medicines expenditure.

Policy-makers have responded to these pressures with a range of measures:

- In pricing, the government now has the power to intervene in the pricing of generic medicines and more effectively manage prices for branded products made by companies outside the PPRS, and it is extending the use of case-by-case price negotiation for new products.



- In relation to availability, the Cancer Drugs Fund has stopped funding cost-ineffective treatments; the NHS has an affordability check for new products; and NHS England is bearing down on the prescribing of low-value products in primary care.
- National programmes are aiming to improve how medicines are used through cutting waste, reducing medication errors and promoting cost-effective prescribing. Regional medicine optimisation committees have been established to oversee delivery of those programmes.
- And the Accelerated Access Review could be seen as an attempt to find a way to improve access within the confines of the NHS funding settlement.

It is too early to know how impactful these measures will be. Careful monitoring of their impact – including how the measures interact and possible unintended consequences – will be important in the coming years. This would be helped by addressing data gaps, particularly data on the use of medicines in hospitals. Collecting and reporting data on volumes of products provided in hospitals and costs by clinical area would enable effective scrutiny of hospital prescribing (as happens in primary care). Given that hospitals today account for nearly half of NHS spending on medicines (based on list prices), this should be a priority.

If tight funding settlements for the NHS continue, further efforts to promote value for money will be needed. Looking across the key areas of medicines policy – pricing, availability and influencing prescriber behaviour – suggests that the policy options available to national leaders come with challenges and risks.

Measures to influence prescriber behaviour in favour of cost-effective products hold promise, although making change happen at the front line is rarely easy. There is room to go further in terms of generic prescribing in primary care, for instance through bearing down on variation between GP surgeries. The arrival of biosimilars presents an opportunity to improve value on which national leaders are keen to capitalise. Early signs from health care systems in Scandinavia suggest that substantial price erosion and widespread uptake is possible (**Generics and Biosimilars Initiative 2017**; **Welch 2016**). Encouraging prescribers to actively switch patients on to biosimilars will be crucial.



At first glance, the negotiation of a new PPRS ready for 2019 presents an opportunity to rethink the pricing of branded medicines. But the benefits of radical changes to control spending would need to be weighed against any impact on the long-term capacity for medicines innovation and the UK's reputation as a destination for pharmaceutical companies. The government's interest in economic performance, including of the life sciences sector, may make this trade-off difficult. In addition, the ongoing process of the UK leaving the European Union may mean that it is an inauspicious moment to attempt substantial reform of the pricing of medicines that is based on dramatically reducing expenditure.

Given the steps already taken, further measures to curtail the availability of medicines on the NHS would likely breed controversy among patients and clinicians if they undermined the aspiration to provide patients with good access to effective treatments. Patient groups and charities would campaign against such measures and media coverage would likely follow (Pace *et al* 2017).

While theoretically possible, raising additional revenue through increasing user charges for medicines – as some other advanced health systems have done in recent years (Vogler *et al* 2016) – would be politically controversial. The founding values of the NHS, including access to services being based on need and not on the ability to pay, continue to enjoy widespread public support (Evans and Wellings 2017). And even if increasing charges was politically possible, the new charges would need to be meticulously designed given the potential negative impact on health and equity (Lee *et al* 2015).

To conclude, in the absence of a change of fiscal policy from the government, the scope for policy refinements to allow the NHS to maintain a balance between access to medicines, affordability and long-term innovation seems increasingly limited. Difficult choices are coming more sharply into view.



Glossary

Biological medicines – medicines made from biological, rather than chemical, entities. These are living entities and consequently are more complex than chemical products and subject to natural variation. These characteristics make biological products unsuitable for generic replication.

Biosimilars – biological medicines that are very similar to a pre-existing biological product that has been licensed. They must pass the regulatory requirements of quality, safety and efficacy and can only be sold once the patent for the original product has expired.

Branded medicines – medicines that are subject to a patent, with the brand name being unique to the manufacturer.

British National Formulary (BNF) – a widely used information resource among NHS prescribers. Information includes product costs, indications that products can be used for and recommended doses.

Competitive tendering – a form of procurement in which suppliers submit bids to provide a service or product, with bids compared for the value they offer.

Drug tariff – the tariff, produced by the NHS Business Services Authority (an arm's length body of the Department of Health and Social Care), setting out how much pharmacies will be reimbursed for dispensing different drug products to NHS patients. It is updated regularly to reflect price changes. The tariff also includes lists of items that should not be prescribed and those that should only be prescribed in certain circumstances.

EU15 countries – European Union member states before the May 2004 expansion of membership: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the UK.



Generic medicines – products that emulate the chemical structure and clinical effect of a branded drug for which the patent has expired. They must be identical in quality, safety and efficacy to the original product and can only be brought to market once the patent for the reference product has expired.

Health technology assessment – an evaluation of the costs and benefits of a health intervention, including medicines. In England, NICE conducts a health technology assessment on the basis of clinical and cost effectiveness to determine whether a new pharmaceutical product should be provided by the NHS.

Indication – the particular health condition for which a treatment is used. Products are approved for use for a particular indication rather than simply being approved for general use, although products can be approved for use for multiple indications. Off-label use, which is possible in the NHS, refers to the use of an approved medicine to treat an indication other than that for which it was approved.

International non-proprietary name (INN) – an internationally recognised name for a product (also known as the generic name). Several products can have the same INN. Prescribing by INN therefore facilitates the dispensing of the most cost-effective treatment.

List price – the price of a product as set by the manufacturer (not including VAT). For a number of reasons – for example confidential discounts – this only gives an approximate indication of real NHS spending.

Net ingredient cost – the cost of a medicine as recorded in the national Drug Tariff or price list (not including VAT). This does not factor in any discounts and does not reflect whether a patient paid a prescription charge or held a prescription pre-payment certificate.

Orphan medicines – products that are targeted at rare diseases, which are often serious in their impact on health. The European Medicines Agency defines orphan products as those treating conditions that affect no more than five in 10,000 people among the population of the European Union.



Patented medicines – medicines that have patents, which are awarded to protect intellectual property and create an incentive for companies to invest in research. They provide manufacturers a window of exclusivity for their product during which competitors are not allowed to sell a product based on the same invention. In the UK, patents generally last for 20 years.

Patient access schemes – pricing agreements between manufacturers and NHS England (or previously the Department of Health and Social Care) to provide a product to the NHS at a set price, or more rarely with some type of outcome-based payment model, that satisfies cost-effectiveness requirements. The final price included in a patient access scheme remains confidential on the basis of commercial sensitivity.

Prescription item – one item is a single supply of a medicine, dressing or appliance on a prescription form (one form can list multiple items). The duration of treatment supplied by each item can vary.

Quality-adjusted life year (QALY) – a measure of health gain that a product offers, which includes both the duration of time offered and the quality of life the person will have, often based on the extent to which a person can perform activities.

Ultra-orphan drugs – products aimed at patients who have extremely rare health conditions. A consistent international definition does not exist. NICE considers diseases to be ultra-orphan if they occur in fewer than 1,000 people in the UK.

Value-based pricing – a system of pricing medicines in which the price paid reflects to some extent the value that a new product offers in terms of health gain for patients (and potentially other forms of value). The government consulted on introducing value-based pricing in 2010/11, but eventually it was not pursued.



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