
# Pricing & Reimbursement

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# United Kingdom

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**Abstract**

The UK has a large and complex healthcare system, under which the National Health Service ("NHS") funds the vast majority of medicines prescribed to patients.

The complexities of the system mean there is no single pathway to NHS reimbursement for a medicinal product, nor a universal reimbursement list. If and how the NHS funds a product often depends on the setting in which the NHS uses it. However, guidance from the National Institute for Health and Care Excellence ("NICE") plays an important role in determining whether the NHS will support the use of a product. The UK has price control policies for branded medicines but, in general, leaves the price of generic products open to market forces.

NHS drug expenditure continues to increase, albeit growth rates vary significantly depending on product-type. Reasons for this include a growing and ageing population, with specific needs, as well as the launch of costlier high-tech and rare disease medicines into the UK. Currently, the healthcare system faces significant financial pressure and this creates a challenging environment for product pricing and reimbursement. In light of this, there is a trend for the NHS and other state organisations to involve themselves directly and indirectly in drug pricing. Another trend is for suppliers and healthcare organisations to enter into innovative or bespoke commercial arrangements to facilitate the availability of a product in the NHS.

## Market overview

The UK comprises four constituent nations: England; Wales; Scotland; and Northern Ireland. The UK has a population of approximately 66 million people, with the vast majority (approximately 55.6 million) resident in England. There is a well-developed healthcare market in the UK, dominated by a large and sophisticated public healthcare system, the NHS. The NHS is almost entirely state-funded and mostly free to patients at the point of need.

When considering pricing and reimbursement in the NHS, it is important to keep two points in mind. Firstly, the structure and organisation of the NHS varies across the four nations of the UK, though many key concepts are similar. For the sake of simplicity, this chapter focuses primarily on the NHS in England, which is by far the largest market. Secondly, the way the NHS pays for medicines differs considerably between those supplied in "primary care" (i.e., prescribed by General Practitioners or other community prescribers and dispensed in a community pharmacy or by a dispensing doctor) and "secondary care" (i.e., in hospitals, clinics and similar settings). This distinction is relevant throughout this chapter.

In England, the NHS spent an estimated £18.2 billion on medicines in 2017/18, without taking discounts into account. That represents a 4.6% increase on the prior year and is broadly

consistent with an average 5% annual growth rate since 2010/11. That growth is almost entirely attributable to medicines dispensed in hospital settings (i.e., secondary care), the cost of which has more than doubled since 2010/11. The 2017/2018 year was the first on record in which hospital medicines consumed more than half of NHS England's total drugs budget.

By contrast, spending on medicines in primary care fell by 1% in 2017/18. The gross amount spent has broadly remained the same since 2010/11, despite the fact that the volume of medicines dispensed in primary care has risen by an average of 3.3% each year. This demonstrates the downward pressure on prices for medicines that are mainly dispensed by community pharmacies to non-hospitalised patients.

Historically, the NHS in England spends approximately three-quarters of its drugs budget on branded products.

## Pharmaceutical pricing and reimbursement

Regulatory classification

*Classification of medicinal products*

The Human Medicines Regulations 2012 create three broad regulatory classes of medicines:[1]

1. Prescription-only Medicines ("POMs");
2. "General Sale Medicines," which consumers may purchase without a prescription; and
3. "Pharmacy Medicines," which consumers may purchase without a prescription but only from a pharmacy.[2]

The regulatory classification of a new medicine will depend on a number of factors, including whether: (i) the marketing authorisation designates it as a POM, a General Sale Medicine or a Pharmacy Medicine; (ii) by statute the product must fall into a particular category; or (iii) the Medicines and Healthcare products Regulatory Agency ("MHRA") or the European Commission has allocated the product to a particular category.

In principle, NHS reimbursement is available to all three classes of medicines. However, the NHS increasingly focuses its expenditure on POMs and to that end, NHS England aims to dissuade clinicians from prescribing medicines available over the counter.[3]

*Eligibility for reimbursement*

In primary care, any medicinal product commercially available in the UK is, in principle, eligible for reimbursement (i.e., the NHS agrees to refund the cost of the medicine to the dispensing pharmacist/doctor). The main exceptions to this are where the NHS has "black-listed"[4] a product in the Drug Tariff (the monthly list of reimbursement prices in primary care) or has placed conditions on reimbursement (e.g., through the so-called "Selected List" in the Drug Tariff).[5]

In secondary care, eligibility for reimbursement is more localised and there is greater scope for variation. Prescription, treatment and supply often take place within a single NHS organisation (e.g., a hospital), which gives that organisation a degree of autonomy over the medicines it chooses to fund. CCGs (as defined in section "Who is/are the payer(s)?" below), NHS Hospital Trusts and other stakeholders often have their own policies and formularies setting out which products are and are not available to a clinician to prescribe. Prescribers in secondary care settings usually only deviate from these policies for clinically justified reasons, such as an individual patient's exceptional circumstances or requirements.

In both primary and secondary care settings, guidelines issued by NICE play an important role in determining whether the NHS funds a product and, in practice, whether clinicians

would prescribe the product to NHS patients (see section, "How is the reimbursement amount set?" below, which discusses NICE guidelines).

Who is/are the payer(s)?

The NHS ultimately funds the vast majority of POMs supplied to patients in the UK. In England only, it recovers a small fraction of its costs through flat-rate prescription charges, payable only by some patients (usually, adults aged under 60 in employment and earning over a certain threshold). The UK has a smaller – but growing – private healthcare market, funded by patients themselves or through private insurance.

Which NHS organisation is responsible for funding ("commissioning") a medicine and how it arranges that funding are complex questions, which often hinge on the type of treatment provided and the treatment setting (primary or secondary care). The main payers and payment structures in England are as follows:

- NHS England has responsibility for commissioning primary care in England, though these days many Clinical Commissioning Groups ("CCGs") (discussed further below) co-commission primary care services with NHS England. The reimbursement mechanism in primary care is largely centralised, under the Community Pharmacy Contractual Framework. Essentially, contractors who dispense products in primary care will receive a fixed reimbursement price for a particular product.
- Commissioning in secondary care is effectively the responsibility of approximately 200 local CCGs.[6] CCGs receive funding from the NHS and it is for them to obtain value for money in terms of the products and services they make available.
- NHS England commissions Specialised Services (which include treatments for certain cancers, genetic disorders or complex medical or surgical conditions) and Highly Specialised Services for rare diseases (typically to treat around 500 patients per year). These mechanisms allows NHS England to provide centralised funding for high-cost products that CCGs may be reluctant to fund.
- NHS England is also responsible for commissioning certain "public health" services (such as vaccination programmes).

What is the process for securing reimbursement for a new pharmaceutical product?

As noted above, the NHS funds treatments in a number of different ways. This means there is no single pathway to securing NHS reimbursement for a new product.

Nonetheless, NICE is often considered the gatekeeper to reimbursement, because a positive recommendation for a product or treatment from NICE obliges NHS England to make funding available for it, usually within three months of the recommendation.[7] A negative recommendation from NICE does not necessarily mean a product is ineligible for reimbursement. However, unless other funding arrangements are in place, it provides commissioners with a basis to resist or delay funding. As a matter of practice, NHS clinicians usually prescribe products according to NICE guidelines.

*NICE topic selection*

NICE does not appraise each and every new product. Its current aim is to evaluate all new significant drugs and indications launched in the UK. Manufacturers of new products may make suggestions for an appraisal though UK PharmaScan (an industry horizon-scanning directory).

From April 2019, NICE charges companies up to £126,000 for conducting technology appraisals.

*NICE assessment*

NICE evaluates whether the NHS should fund products or treatments (which NICE refers to as "technologies") based on clinical and cost-effectiveness assessments. As part of the Voluntary Scheme Agreement (see "How are drug prices set? What is the relationship between pricing and reimbursement?"), NICE has committed to reviewing its methodologies, with a public consultation expected in 2020.

Currently, NICE has a standard assessment methodology as well as variants for specific types of products (such as certain cancer or highly specialised drugs, see "NICE's Methodology for Certain Products – Cancer Drugs and Highly Specialised Technologies", below). The common thread is NICE's focus on a technology's incremental cost-effectiveness ratio ("ICER") against an existing reference based on the quality-adjusted life year ("QALY"). These are established health economic concepts that seek to quantify the relative utilities of a technology.

*NICE's Standard Assessment Methodology*

In most cases, NICE will issue a positive recommendation if it assesses a product to have an ICER, usually against an existing reference, of less than £20,000. NICE may apply its discretion to recommend technologies with ICERs between £20,000 and £30,000, where justified on certain grounds, such as the innovative nature of a drug. Under its standard methodology, it is rare for NICE to give a positive recommendation to a technology whose ICER exceeds £30,000. However, NICE has additional discretion where products are used in end-of-life scenarios. Nevertheless, NICE has yet to recommend a product using its standard methodology where the incremental cost-per-QALY was significantly in excess of £40,000.

NICE's cost-per-QALY thresholds have remained fixed for a number of years. Inflationary pressures, and an increased industry focus on rare diseases and other high-cost treatments, mean that it is increasingly difficult to bring certain new products below the thresholds in order to receive a positive recommendation.

*NICE's Budget Impact Test*

Introduced in April 2017, the "Budget Impact Test" is an additional step for NICE assessments. Any product that NICE has assessed to be cost-effective but is likely to cost the NHS more than £20 million in any of the first three years of its use must be subject to further negotiations between the supplier and NHS England to bring the overall cost down. If these negotiations are unsuccessful, NHS England may apply to NICE to delay funding the product by up to three years, or longer in exceptional cases. This has proven to be a controversial measure: in the second half of 2017, the Association of the British Pharmaceutical Industry ("ABPI") launched unsuccessful court proceedings to challenge the legality of the test.

*Patient Access Schemes*

When a product does not meet NICE's cost-effectiveness criteria, NICE may still give a positive recommendation subject to an agreed Patient Access Scheme. These are formal pricing agreements, provided for under the Voluntary Scheme (see section, "How are drug prices set? What is the relationship between pricing and reimbursement?", below) between a supplier and NHS England that make a product more affordable (e.g., by way of a price discount, rebates, free-stock or outcome-based pricing). The commercial details are usually kept confidential. NICE's Patient Access Scheme Liaison Unit advises NHS England on the feasibility of any proposed scheme.

*Managed Access Agreements*

Where the clinical data supporting a NICE application are uncertain, NICE may recommend a product subject to a Managed Access Agreement. These agreements enable NHS patients to access treatment, while allowing the company to collect real world data for a NICE re-appraisal. The commercial terms of these agreements are usually confidential, though they often contain an overall budget-impact cap.

*NICE's methodology for certain products – Cancer drugs and highly specialised technologies*

When evaluating specialist and high-cost technologies, NICE may depart from its standard methodology. For example:

- There is a specific assessment pathway for "Highly Specialised Technologies" ("HST"), which treat rare and specialist conditions. The HST process is only available to products that satisfy certain requirements, including:
  - The target patient group is distinct for clinical reasons and sufficiently small that treatment will usually be concentrated in very few centres in the NHS.
  - The condition is chronic and severely disabling.
  - The technology has the potential for lifelong use.

  For these products, the conventional NICE appraisal builds in certain allowances to accommodate likely higher-cost, and often more limited, clinical data. NICE will usually recommend HSTs that have an ICER of less than £100,000. It has discretion in certain circumstances to recommend products above that threshold, usually up to ICERs of £300,000. NICE has assessed a small number of products using the HST process and to date, has issued nine pieces of final guidance in more than five years.
- The Cancer Drugs Fund ("CDF"), is in place to enable faster access to promising new cancer treatments. Following its relaunch in 2016, the CDF aims for all new systemic cancer drugs to receive a fast-tracked NICE appraisal. NICE will recommend a product to receive funding from the CDF, at a negotiated price, if it has the potential to satisfy the criteria for routine commissioning, but there is clinical uncertainty that needs further investigation (i.e., through data collection in the NHS or clinical studies). The drug will remain available within the CDF while more evidence becomes available, at which point NICE will subject it to one of its standard technology-appraisal processes. A recent coup for the CDF was the landmark approval of certain CAR-T therapies through the fund.

*NICE appeals*

Generally, the manufacturer of the product under review, patient groups or clinician organisations who have participated in the assessment may appeal the outcome of a NICE assessment to the NICE Appeal Panel. There are three possible grounds for appeal, which mirror the grounds for judicial review in the English Courts:

1. that NICE has failed to act fairly;

2. the recommendation is unreasonable in light of the evidence submitted; and/or

3. NICE has acted unlawfully or has exceeded its legal powers.

Most appeals are under the first two grounds but, in recent years, some successful appeals against NICE determinations have invoked novel human rights' considerations of the affected patient groups (e.g., children), which are essentially claims that NICE has acted unlawfully.

If an appeal to NICE's Appeal Panel is unsuccessful, a party may challenge the decision by way of judicial review in the High Court.

How is the reimbursement amount set?

In primary care, the NHS usually reimburses products: (i) for the amount set out in the Drug Tariff (if the product is listed there); (ii) at the "NHS list price"; (iii) or in other cases for the net price at which the dispensing pharmacy/doctor purchased the product. The Drug Tariff lists the reimbursement amount for commonly used, mostly generic products. The NHS reviews Drug Tariff prices each month, based on a survey of the market. The NHS list price applies mainly to branded products and is set in accordance with the Voluntary or Statutory Schemes (see section, "How are drug prices set? What is the relationship between pricing and reimbursement?" below).

The concept of a "reimbursement amount" is less relevant in secondary care because the NHS operates a *payment by results* model. Under this model, providers receive an amount per patient treated, based on the treatment provided, the length of a patient's stay, the complexity of their needs, etc. In most cases, this does not take the price of individual products directly into account.

How are drug prices set? What is the relationship between pricing and reimbursement?

The Secretary of State for Health has a statutory power to limit the price of medicines supplied to the NHS (section 262, NHS Act 2006). However, significant price control mechanisms only really exist for branded products and not generics (whose prices are broadly controlled by market forces). Branded medicines supplied to the NHS are subject to one of two price control schemes: the Voluntary Scheme for Branded Medicines Pricing and Access ("Voluntary Scheme"), or the so-called "Statutory Scheme".

*Voluntary Scheme*

As the name suggests, the Voluntary Scheme is an opt-in arrangement, agreed between the innovative pharmaceutical industry body, the Association of the British Pharmaceutical Industry ("ABPI") and the Department of Health. In one form or other, the Voluntary Scheme has been running in the UK since 1957. The current scheme came into effect on 1 January 2019 and will run for five years. The current Voluntary Scheme builds on many of the principles set out in the previous "Pharmaceutical Price Regulation Scheme", which expired at the end of 2018.

The Voluntary Scheme contains complex arrangements for price and profit control. Below are some key features:

- The Voluntary Scheme aims to cap increases in the amount the NHS spends on branded medicines, which companies that have opted into the Scheme ("Members") supply, to 2% growth per annum. To stay within this cap, Members must pay the Department of Health a fixed percentage of their net sales of branded medicines supplied to the NHS ("Scheme Payments"), with certain exceptions. Scheme Payments are designed to offset anticipated growth above the agreed 2% limit. The fixed percentage applies scheme-wide and is 9.6% for 2019. For future years, the percentage will depend on the difference between the agreed growth rate and projected growth in sales (it is expected to be 14.2% in 2020).
- Members who are small companies (i.e., essentially, those whose sales of branded products to the NHS total less than £5 million in the previous year) are exempt from making Scheme Payments. For medium-sized companies (i.e., essentially, those whose sales of branded products to the NHS total between £5 million and £25 million in the previous year), the first £5 million of sales may be exempt from Scheme Payments.
- Importantly, not all branded medicines supplied by Members are subject to Scheme

Payments. Medicines containing new active substances sold to the NHS within 36 months of their marketing authorisation are outside the net of Scheme Payments. However, sales of those products will still contribute to calculating expenditure grown across the scheme.

- The Voluntary Scheme also contains pricing controls. A Member may not increase the list price of a product without the prior approval of the Department of Health, which (amongst other things) requires a justification for the increase and an assessment of the Member's profits. In order to avoid stifling innovation, Members have the freedom to set the list price of medicines containing new active substances launched in the UK within 36 months of the grant of a marketing authorisation. However, this still requires a Member to confirm that its intended selling arrangements to the NHS will take cost-effectiveness into account. In other words, very high prices would go hand in hand with significant NHS discounts.

As part of the Voluntary Scheme agreement, NHS England has made a number of commitments aimed at improving access to medicines. These include the aim that from 2020, all new innovative medicines will receive NICE appraisals unless there are clear reasons not to assess them. There is commitment to review NICE's methods for conducting assessments – albeit NICE's cost-effectiveness thresholds will not change for at least five years. There is also a commitment to increase commercial flexibility, giving NHS England scope to engage with industry and agree bespoke pricing and access deals with companies.

*Statutory Scheme*

Manufacturers or suppliers of branded medicines to the NHS who do not participate in the Voluntary Scheme are, by default, subject to the so-called "Statutory Scheme" (per sections 262–264 of the NHS Act 2006).

The Government revised the Statutory Scheme significantly in 2018 through the Branded Health Service Medicines (Costs) Regulations 2018 (the "2018 Regulations"). The 2018 Regulations came into force on 1 April 2018 and were subject to further significant amendments, which took effect on 1 January 2019. The re-cast Statutory Scheme includes the following features:

- Manufacturers or suppliers must pay a percentage of their net sales of branded products to the NHS on a quarterly basis. The percentage payable was 7.8% for the 2018 calendar year, 9.9% for 2019 calendar year, and will be 14.7% for 2020 and 20.5% for 2021.
- There are also pricing controls, such as:
  - The maximum price of a product that was on the market on 1 December 2013 is capped to the price at that date, subject to any agreed increases.
  - Price increases and the price of new presentations require the agreement of the Secretary of State, who must take into account factors including: (i) the clinical need for the product; (ii) the cost of therapeutically equivalent or comparable products (including in other European Economic Area countries); (iv) if the product contains a new active substance; and (v) estimated profits and other financial parameters, etc.
- From 1 January 2019, unless the Voluntary Scheme applies, the Statutory Scheme will encompass all biologic medicines supplied to the NHS, including biosimilars.

The revisions to the Statutory Scheme bring it more closely in line with the Voluntary Scheme, though there are some differences. Arguably, pricing arrangements for products containing new active substances are more straightforward under the Voluntary Scheme than the alternative.

Factors that affect pricing

A number of factors affect drug pricing in the UK, ranging from Government and NHS policies, commercial arrangements between companies and the NHS, and marketplace competition. Note, the UK list price is often a benchmark for countries that operate reference pricing systems. This can be an important consideration for companies, which encourages providing discounts to the NHS under agreements that do not affect the reference price.

As noted above, companies must price branded products in accordance with the Voluntary or Statutory Schemes. The schemes tightly control increases in the price of established branded medicines but provide more (though unlikely complete) flexibility when pricing new products. New, innovative products are very likely to be subject to a NICE appraisal and companies try to meet NICE's cost-effectiveness criteria, if at all possible. If that is not feasible, companies often consider methods to provide better value for money to the NHS, such as through Patient Access Schemes or Managed Access Agreements.

Even after companies have agreed a price under the Voluntary or Statutory schemes and a NICE appraisal has taken place, there are various forces within the NHS that can further reduce the price that a company actually charges for its products.

For example, NHS Hospital Trusts, CCGs and other NHS bodies rely heavily on tenders, rebate agreements and other commercial arrangements to purchase generic and branded products with additional discounts. In particular, the NHS increasingly uses Framework Agreements (structured agreements in which a consortium of NHS "buyers" can purchase products for centrally contracted prices), which can significantly affect the price a supplier receives. "Framework Agreements" are regulated under the UK Public Contracts Regulations 2015.

The NHS in England increasingly takes a joined-up approach to procurement and medicines optimisation. For example, the NHS has established several national and regional procurement groups to co-ordinate and support medicines procurement, sharing information and expertise. Similar groups exist to align local formularies and prescribing policies to the most cost-effective options available, which can stimulate companies to offer keener prices to remain locally recommended or on a preferred formulary.

As in most other markets, competition from generic and biosimilar products also affects the price of innovator products on the market. The NHS' policy, for some time, has been to encourage clinicians to prescribe most products by their International Non-proprietary Name (INN) to encourage generic prescribing and dispensing. Many NHS organisations (such as CCGs or Hospital Trusts) also run programmes to switch patients from innovative to generic or biosimilar products. These factors mean that once generic or biosimilar products enter the market, suppliers of innovative products can rapidly lose market share unless they reduce prices. Note, however, that the UK prohibits generic or biosimilar substitution in pharmacies for a brand-name prescription (save in certain hospitals). That situation may change, on an emergency basis, if the UK exits from the EU in a "no deal" scenario.

The NHS generally avoids intervening in the market for generic products, relying on market forces to regulate it. However, over the last two years, the NHS has experienced severe shortages in the supply of certain generic medicines. Reportedly, this is the result of a weakened currency affecting imports and a variety of other supply-side issues. These shortages have led to price increases and the NHS has, in some cases, reflected this by offering a higher reimbursement amount in the Drug Tariff, often on a temporary or *ad hoc* basis.

### Policy issues that affect pricing and reimbursement

The NHS' medicines policies aim to balance a number of interests, including:

- obtaining value for money for taxpayers;
- ensuring there is equitable access to treatment for NHS patients; and
- stimulating innovation in the life sciences industry by reimbursing new products that demonstrate clinical and cost-effectiveness.

However, demographic change, an increase in spending on prescription medicines, and budgetary pressure, make it increasingly difficult to maintain this balance.

The UK's population is growing as well as becoming older. The Office for National Statistics projects the UK's population to increase from approximately 65.6 million people in 2016 to approximately 69.8 million people by 2026. In that time, the proportion of the population over the age of 65 would increase from 18% to 20.5%. The rising number of older people has increased the demand for healthcare and the volume of products dispensed, particularly those to treat age-related conditions, such as cardiovascular disease and diabetes.

As noted above, the volume and cost of drugs used in and/or reimbursed by the NHS is on a steady upward trajectory. Population and demographic changes are major contributing factors. Another reason is an increase in high-cost innovative medicines available in the NHS (such as medicines for orphan and ultra-orphan conditions). It is unsurprising that while price-control mechanisms such as the Voluntary and Statutory Schemes have delivered savings and depressed prices of established medicines, the NHS has struggled to contain its overall drugs bill.

While NHS spending on medicines has risen by approximately 5% per annum over the past decade, investment into the NHS has struggled to keep pace, growing by approximately 1.5% *per annum* over the same period. Much of that is because of Government austerity and a challenging economic climate. In June 2018, the Government announced a plan to increase NHS spending by 3.4% *per annum* in real terms from 2019 to 2024. Despite this, many commentators still consider there to be an unsustainable funding gap.

### Emerging trends

The NHS is constantly evolving and there are a number of emerging trends that may affect pricing and reimbursement. Some of these are below:

- NHS budgets are likely to face continued pressure, which may lead to further measures to cut drugs spending. The newly re-cast Voluntary Scheme, combined with NICE's fixed cost-effectiveness criteria and Budget Impact Test, mean that some companies launching new products in the UK may need to offer the NHS sizeable discounts to achieve meaningful levels of uptake. NHS England's strengthened mandate to negotiate pricing deals with industry will probably make Patient Access Schemes and similar agreements more common. NHS England points to its reimbursement of CAR-T oncology therapies sooner than in most other EU countries as an example of its new access-oriented approach. However, not all cases have proven as successful, with NHS England and Vertex Pharmaceuticals deadlocked over the access price of Orkambi.
- The NHS is committed to speeding-up access to promising technologies in specific treatment areas, such as cancer, dementia and diabetes. The NHS has recently made improvements to its Accelerated Access Collaborative ("AAC"), which identifies

game-changing innovations and provides their manufacturers with advice and strategic support to ensure rapid uptake within the NHS. Recently, the AAC identified tumour-agnostic oncology drugs as a particular area of interest.

- The NHS is likely to continue using co-ordinated procurement (particularly Framework Agreements) to drive better value for money. This could lead to more medicines procurement litigation. A recent example from early 2019 involved an unsuccessful attempt to overturn an NHS procurement programme for products to treat and eliminate Hepatitis C, the largest drug tender the NHS has ever undertaken.
- The NHS' internal policies are likely to reinforce the cost-effectiveness message to clinicians. For example, NHS-organised Regional Medicines Optimisation Committees now provide targeted guidance to CCGs and clinicians about savings associated with switching to specific biosimilars. The overall aim is to switch 90% of new patients and 80% of existing patients to the cheapest available biological product within 3–12 months of its UK launch. NHS organisations that fall short of delivering value for money are potentially vulnerable to financial penalties or disincentives.
- Linked to this is the growing tendency for the NHS to support using unlicensed products (or licensed products off-label) for reasons of cost. Historically, the NHS respected the principle of using licensed products within their label wherever possible, which is consistent with the MHRA's position and professional guidelines for doctors. Similarly, NICE's position is that it cannot positively recommend unlicensed products or off-label use of licensed medicines in an assessment (though it sometimes takes this into account for cost-comparison purposes). Despite this, the NHS has in certain high-profile cases advocated using lower-cost, unlicensed or off-label products. This is highly controversial, having been the subject of recent High Court litigation in respect of reformulated bevacixumab for intra-ocular use. At the time of writing, the case is awaiting a Court of Appeal hearing.
- NHS organisations continue to seek increasing amounts of information from internal and external sources about product pricing (e.g., discounts). The Health Service Medical Supplies (Costs) Act 2017 gives the Secretary of State wide-ranging powers to demand a variety of information from all stages in the medicines supply chain. Authorities could use this information to derive better value for money in areas where there has traditionally been price opacity (e.g., generics). The controversy surrounding a Vertex product, Orkambi, has led to a Parliamentary enquiry and discussions about forcing companies to reveal their EU-wide prices. Similarly, there is a growing expectation that NHS bodies that enter into commercial agreements with suppliers will share this information within the NHS with a view to deriving the best value nationally.
- The industry continues to face growing scrutiny from the UK Competition and Markets Authority ("CMA"). In particular, the CMA has investigated alleged anti-competitive agreements and conduct and suspected excessive and unfair pricing. Largely, this concerns allegations that manufacturers of generic products have inappropriately increased prices of products for which there is no meaningful competition.
- Anecdotally, there are signs that the uncertainties concerning Brexit have had an indirect effect on pricing and reimbursement. Potential stockpiling and market uncertainties have led to price volatility and stock-shortages. In the longer term, a no-deal Brexit could see controversial laws enabling pharmacy substitution coming into force. Clearly, these could have a knock-on effect on the UK's branded products market.

### Successful market entry

Formulating a successful strategy for market entry will depend on the type of product in question and its place in the NHS' complex architecture. The following are some general points to consider:

- **NICE appraisal**. A company should investigate whether its product could be subject to a NICE appraisal and if so, whether it could meet NICE's cost-effectiveness criteria. The company could also explore qualifying for Highly Specialised Technology status or the Cancer Drugs Fund. For high-cost products, the company should consider the possibility of offering a Patient Access Scheme.
- **Specialised commissioning categories**. Falling within the scope of Specialised Services, Highly Specialised Services, the Cancer Drugs Fund or benefiting from Accelerated Access Collaborative Support would increase the likelihood of a high-cost product receiving NHS funding.
- **Commercial negotiations with the NHS customer base**. Companies should consider what their optimal pricing and discount strategy would be in the procurement space. This is particularly important if a product's main use is in secondary care.
- **Understanding NHS prescribing policies**. In the UK, market penetration is often a greater concern for companies than market entry. The NHS' prescribing policies (both local and national) have a significant impact on the uptake of a new product. Understanding these is therefore important.

* * *

### Endnotes

1. Regulation 5 of the Human Medicines Regulations 2012.
2. See also Regulation 220 of the Human Medicines Regulations 2012.
3. "Conditions for which over the counter items should not routinely be prescribed in primary care: Guidance for CCGs" NHS England, 29 March 2018.
4. Schedule 1 to the NHS (General Medical Services Contracts) (Prescription of Drugs, etc.) Regulations 2004.
5. Schedule 2 to the NHS (General Medical Services Contracts) (Prescription of Drugs, etc.) Regulations 2004.
6. Pursuant to the Health and Social Care Act 2012.
7. Regulations 7(2)-(3) of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 (SI 2013/259) and as set out in the NHS Constitution.

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