Pricing & Reimbursement

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CONTENTS

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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.

Reflecting the complexities of the system, 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 context. 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 leaves the price of generic products open to market forces.

Despite price controls and other policies intended to contain spending, NHS drug expenditure continues to grow. This is because of a growing and ageing population, which has increased prescription volumes, as well as the introduction of costlier high tech and rare disease medicines into the UK. Currently, the healthcare system faces significant financial pressure and this creates an increasingly challenging environment for product pricing and reimbursement. In light of this, there is a growing tendency 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 65.6 million people, with the vast majority (approximately 55.2 million) resident in England.

The UK has a well-developed healthcare market, in which a large and sophisticated public healthcare system, the NHS, plays a dominant role. The NHS is almost entirely state funded and generally free to patients at the point of need. The structure and organisation of the NHS varies across the four nations of the UK, though most of the main principles and outcomes are very similar. For the sake of simplicity, this chapter focuses primarily on the NHS in England.

In England, the NHS spent an estimated £17.4 billion on medicines in 2016/17, which reflects an average 5% growth rate since 2010/11. Much of this growth is attributable to spending on medicines dispensed in hospitals, which has almost doubled between 2010/11 and 2016/17. Hospital medicines now account for almost half of all NHS drugs spending in England. Historically, the NHS in England has spent approximately three-quarters of its drugs budget on branded products.

When considering pricing and reimbursement in the UK, it is important to recognise the

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differences between medicines supplied in NHS "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). The distinction is relevant throughout this chapter, particularly because of the differences in the way the NHS pays for products in each setting.

Pharmaceutical Pricing and Reimbursement

Regulatory Classification

Classification of Medicinal Products

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

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

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 Pharmacy Medicine or a General Sale Medicine; (ii) the effect of legislation means the product must fall into a particular category; or (iii) the MHRA, or the European Commission for centrally authorised products, has allocated the product to a 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 has recently introduced prescribing guidance aimed at dissuading clinicians from prescribing medicines available over the counter (*i.e.*, General Sale Medicines and Pharmacy Medicines).[4]

Eligibility for Reimbursement

In primary care, any medicinal product commercially available in the UK and prescribed on an NHS prescription form 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 principle are where the NHS has "black listed"[5] a product in the Drug Tariff (the monthly list of reimbursement prices in primary care) or has placed restrictions on the circumstances in which it will reimburse a product (*e.g.*, through the so-called "Selected List" in the Drug Tariff).[6]

In secondary care, eligibility for reimbursement is more localised and there is greater scope for variation. Prescription, treatment and supply often take place within the same NHS organisation (*e.g.*, a hospital), which gives each of those organisations a degree of autonomy over the medicines it funds. CCGs (as defined in section "Who is/Who are the payer(s)?" below), 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 will fund a particular 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/Who 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,

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payable by some patients (usually, only adults aged under 60 in employment and earning over a certain threshold). The UK has a smaller 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 from 2015, many local CCGs (as defined below) have started to partner with NHS England to co-commission primary care services. 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 Clinical Commissioning Groups ("CCGs").[7] 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 also 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 to high-cost treatments that are not cost-effective in other contexts and may not have a NICE recommendation.

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. As a result, there is no single pathway to securing NHS reimbursement for a new product.

Nonetheless, NICE is often the gatekeeper to reimbursement because a positive recommendation for a product or treatment in NICE guidance obliges NHS England to make funding available for it, usually within three months of that recommendation.[8] 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 launched in the UK. NICE would conduct an appraisal if it considers a product is likely to be a significant benefit to patients and be at a significantly different price to the current treatment standard. Manufacturers of new products may make suggestions for an appraisal though UK PharmaScan (an industry horizon scanning directory).

NICE Evaluation

NICE recommends whether the NHS should fund products or treatments (which NICE refers to as a "technologies") based on clinical and cost-effectiveness assessments ("Health Technology Assessments" or "HTAs").

NICE's approach is to evaluate a technology's cost per quality-adjusted life year ("QALY"), a health economic concept that seeks to capture the clinical benefits of a technology. In general, NICE will issue a positive recommendation if the incremental cost per QALY

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("ICER"), usually against an existing reference, is 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. It is rare for NICE to give a positive recommendation to a technology whose ICER exceeds £30,000. NICE also has additional discretion where products are used in end-of-life scenarios. NICE has yet to recommend a product 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" provides that any product that NICE has assessed to be cost-effective, but that is likely to cost the NHS more than £20 million in any of the first three years of its use, must be subject to negotiations between the supplier and NHS England to bring the overall cost down. If these negotiations are unsuccessful, NHS England may apply to NICE for its approval 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 British Pharmaceutical Industry ("ABPI") launched unsuccessful court proceedings to challenge the legality of the test.

Patient Access Schemes

NICE may recommend a product that might otherwise not meet NICE's cost-effectiveness criteria, subject to the manufacturer offering a Patient Access Scheme. These are formal pricing agreements, provided for under the PPRS (see section "How are drug prices set? What is the relationship between pricing and reimbursement?" below) between a supplier and NHS England that make the product more affordable (*e.g.*, by way of a price discount, rebates, free-stock or outcome-based pricing). NICE's Patient Access Scheme Liaison Unit advises NHS England on the feasibility of any proposed scheme.

Managed Access Agreements

In some cases, NICE recommendations have also taken into account Managed Access Agreements. These agreements to allow 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 Approach to Cancer Drugs and Highly Specialised Technologies

NICE has certain measures in place to address the challenges of evaluating specialist and high-cost technologies. These include:

- The "Highly Specialised Technologies" ("HST") appraisal process. HST appraisals use standard NICE assessment procedures but with variations built-in to accommodate treatments for extremely rare conditions. NICE has established a principle that it will automatically recommend funding for HSTs with an ICER of less than £100,000. The HST process is only available to the small number of products that satisfy a number of requirements, including the following:
    - The target patient group for the technology in its licensed indication is so small that treatment will usually be concentrated in very few centres in the NHS.
    - The target patient group is distinct for clinical reasons.

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  - The condition is chronic and severely disabling.
  - The technology has the potential for lifelong use.
- Cancer Drugs Fund ("CDF"). Following a relaunch in 2016, the CDF operates through a partnership between NHS England, NICE, Public Health England and the Department of Health. It aims to enable faster access to promising new cancer treatments. NICE will recommend a drug for use in the CDF if it has the potential to satisfy the criteria for routine commissioning, but where there is significant 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.

NICE Appeals

Generally, the manufacturer of the product under review, patient groups or clinician organisations who have participated in the assessment may appeal NICE guidance to the NICE Appeal Panel. There are three grounds for appeal:

1. that NICE has failed to act fairly;
2. the recommendation is unreasonable in the 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, recently, 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 the appeal to the NICE appeal panel is unsuccessful, the 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" (for branded products) or in other cases; (iii) the net price at which the contractor purchased the product. The Drug Tariff lists the reimbursement amount mostly for generic products. The NHS reviews these amounts each month, based on a survey of market prices. The NHS list price is set in accordance with the PPRS or Statutory Scheme (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 *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 NHS for Health has a statutory power to limit the price of medicines supplied to the NHS (section 262, NHS Act 2006). Currently, the Secretary of NHS does not exercise these powers for generic medicines. By contrast, branded medicines supplied to the NHS are subject to one of two price control schemes: the Pharmaceutical Price Regulation Scheme ("PPRS") or the so-called "Statutory Scheme".

PPRS

The PPRS is a voluntary, non-contractual scheme between companies in the pharmaceutical sector and the Department of Health. The scheme regulates the growth of a company's sales to the NHS, the profits it makes from those sales, and (to an extent) product prices. In one form or other, the PPRS has been running in the UK since 1957. The current scheme runs for five years from January 2014. Negotiations for the 2019 PPRS are currently underway.

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The current PPRS focuses on limiting the overall growth of NHS expenditure on branded medicines that scheme members supply (0% in 2014–15; and 1.8%–1.9% in 2016–18). Members make quarterly rebates to the Department of Health to offset any growth above the agreed limits ("PPRS Payments"). Smaller companies with sales to the NHS of less than £5 million in the previous year are exempt from making PPRS Payments. In 2018, members' PPRS Payments were set at 7.8% of the value of their net sales of scheme-products.

Under the PPRS, a member may not increase the price of a scheme-product without the prior approval of the Department of Health, which (amongst other things) requires a reasoned justification for the increase and an assessment of the member's profits. That said, a company may "modulate" prices for specific products (*i.e.*, adjusting certain prices up or down), so long as the net effect is neutral. In order to avoid stifling innovation, members have the freedom to set the price of any "new" products (*i.e.*, those launched in the UK after 1 January 2014) at their discretion.

Statutory Scheme

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

Following a 2017 consultation, the Branded Health Service Medicines (Costs) Regulations 2018 (the "2018 Regulations") came into force on 1 April 2018. The 2018 Regulations amended the Statutory Scheme significantly, which now includes the following features:

- Manufacturers or suppliers must on a quarterly basis pay 7.8% of the net sales income from the supply of branded products to the NHS. This figure is subject to annual review.
- There are also a series of limits on product pricing and price increases, such as:
  - The maximum price of a product that was available to the NHS on 1 December 2013 is capped to the price at that date, subject to any increases agreed in accordance with the Statutory Scheme (including in its previous guise).
  - 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); (iii) if the product contains a new active substance; and (iv) estimated profits and other financial parameters, *etc*.

The revisions to the Statutory Scheme bring it more closely in line with the PPRS than before. Previously, some companies had left the PPRS because the Statutory Scheme offered a more favourable environment. At present, one of the main advantages the PPRS possesses over the revised Statutory Scheme is the ability to set prices with more freedom, particularly for new products or as part of price "modulation".

Factors that Affect Pricing

A number of factors affect drug pricing in the UK, ranging from pricing and reimbursement policies, commercial negotiations between companies and the NHS and marketplace competition. It is worth noting that the UK list price is often a benchmark for countries that operate reference pricing systems. This can sometimes be an important consideration for companies, particularly if there are opportunities to offer discounts to the NHS without affecting the headline price.

As noted above, companies must price branded products in accordance with the PPRS or the Statutory Scheme. Historically, the general effect of these schemes has been to restrict

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price increases for established branded medicines, but provide pricing flexibility for new products. Even so, when pricing new branded products, companies are often conscious to avoid jeopardising formulary listings or reducing uptake. In addition, if a product could be the subject of a NICE appraisal, companies try to fall within NICE's cost-effectiveness criteria, if at all possible. If it is not feasible to meet these criteria, companies might consider methods to provide better value-for-money to the NHS, such as through Patient Access Schemes.

The effect of NHS tendering and other commercial arrangements often reduces the prices that a company actually receives for its products. Hospitals, CCGs and other NHS bodies rely heavily on tenders and rebate agreements to purchase both generic and branded products at discounted levels (*i.e.*, below Drug Tariff and NHS list prices). In particular, there is an increasing use of 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. These "Framework Agreements" are regulated under the UK Public Contracts Regulations 2015.

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 products by their International Non-proprietary Names (INN), wherever possible. 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 rapidly face pressure to reduce their prices. Note, however, that the UK prohibits generic or biosimilar substitution in pharmacies (save for certain hospital pharmacies).

The NHS generally avoids intervening in the market for generic products, relying on market forces to restrict price inflation. However, in the last 12 months, the NHS has experienced severe shortages in 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 of many generic products and the NHS has in some cases reflected this by offering a higher reimbursement amount in the Drug Tariff, sometimes on a temporary 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.

The NHS' expenditure on medicines in England increased from approximately £13 billion

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in 2010/11 to £17.4 billion in 2016/17 (representing an average growth rate of around 5% *per annum*). It is well-accepted that prescription-volume growth linked to demographic change is a major contributing factor. Another reason is an increase in high-cost innovative medicines launched in the UK and reimbursed by the NHS (such as orphan, ultra-orphan and biologic medicines). As a result, while the price control mechanisms in the PPRS and Statutory Scheme have delivered savings on established medicines, it has proven difficult to contain the overall NHS drugs spend.

While NHS spending on medicines rose by approximately 5% *per annum* between 2010/11 and 2016/17, investment into the NHS has failed to keep pace, growing by approximately 1.5% *per annum* over the same period. This is largely because of Government austerity in response to a challenging economic climate. Many politicians and commentators consider that the funding gap is unsustainable and have called for a new funding settlement for the NHS.

Emerging Trends

The NHS is constantly evolving and there are a number of new initiatives, policies and other changes that will impact pricing and reimbursement in the future. Some of these are below:

- The severe pressure on NHS budgets is likely to result in additional policies to restrict the price the NHS pays for products. The renewal of the PPRS in 2019 will be a key milestone. NICE's Budget Impact Test will stimulate some companies to offer the NHS discounted prices for new products. The use of Patient Access Schemes is also likely to continue increasing, as fewer new products meet NICE's cost-effectiveness criteria.
- Linked to this, the NHS is likely to continue making greater use of tendering (particularly Framework Agreements) and other commercial arrangements to derive better value for money.
- In terms of commissioning, the NHS has recently introduced a new "Accelerated Access Review" pathway. In essence, this will mean that up to five products a year that have the potential for transformative impact will benefit from simplified and simultaneous regulatory approval, NICE assessment and commercial negotiation. The aim is for this pathway to be cost-neutral to the NHS.
- The NHS' prescribing policies are likely to continue to encourage clinicians to consider lower-cost treatments (such as generic and biosimilar medicines) and to restrict the prescription of products available over the counter. For example, NHS England's 2017 Commissioning Framework for Biosimilars sets a target to switch 90% of new patients and 80% of existing patients to the cheapest available biological product within three to 12 months of its UK launch.
- In future, the NHS is likely to demand far greater information from companies related to product pricing (*e.g.*, costs or wholesaler discounts). In particular, 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 are likely to use this information to derive better value for money in areas where there has traditionally been price opacity (e.g., generics).
- Recently, pharmaceutical product pricing has faced growing scrutiny from the UK Competition and Markets Authority ("CMA"). In particular, the CMA has investigated alleged anti-competitive conduct and suspected unfair pricing. This has primarily related to allegations that manufacturers of generic products that are not subject to pricing controls in the PPRS and Statutory Scheme have inappropriately increased prices of products for which there is no meaningful competition. Going forwards,

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competition law considerations are likely to affect the stance that suppliers take to pricing.

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, or the Accelerated Access Review 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 Polices.** 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. *Id.*
3. Regulation 5 and Regulation 220 of the Human Medicines Regulations 2012.
4. "Conditions for which over the counter items should not routinely be prescribed in primary care: Guidance for CCGs, NHS England, 29 March 2018.
5. Per Schedule 1 to the NHS (General Medical Services Contracts) (Prescription of Drugs, etc.) Regulations 2004.
6. Per Schedule 2 to the NHS (General Medical Services Contracts) (Prescription of Drugs, etc.) Regulations 2004.
7. Pursuant to the Health and Social Care Act 2012.
8. Per 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.

Acknowledgment

The authors acknowledge the contribution made to this chapter by Raj Gathani. Raj is an Associate in Covington & Burling LLP's London office. Raj's practice includes advising a variety of clients on UK pricing and reimbursement matters. He takes a particular interest regulation of UK pharmacy businesses, having spent eight years in that industry prior to joining Covington & Burling LLP.

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Mr. Kelly has advised and successfully represented a variety of clients in respect of NICE appeals. He has advised clients on establishing joint working and risk-sharing relationships with the NHS in England and Wales. Mr. Kelly has also successfully represented Life-Sciences clients in judicial reviews and other administrative proceedings in the UK in respect of NHS procurements.

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