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Judicial review and the life sciences and health sectors

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Status: **Published on 08-Feb-2021** | Jurisdiction: **United Kingdom**

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This note considers the application of the various grounds for judicial review in the life sciences and healthcare sectors.

What is judicial review?

Judicial review is a specialised form of litigation which allows the courts to supervise the exercise of power by public bodies in order to ensure that they act lawfully and fairly. Judicial review does not operate as an appeal against the merits of a public body's decision. Instead it is restricted to analysing flaws in the decision-making process and deciding its lawfulness. There are various ways to look at the grounds of judicial review, but a common method which has evolved through case law is a tripartite categorisation, namely where:

- A public authority has acted illegally or unlawfully by acting outside the scope of its powers.
- A public authority has taken an irrational or unreasonable decision.
- The process by which the public authority has come to its decision is procedurally unfair or improper.

Judicial review is a remedy of last resort, and as such, other adequate alternative remedies (such as an appeal process or statutory review) should be exhausted prior to or instead of initiating judicial review. So if there is, for example, an appeal mechanism against a licensing decision, then that should be pursued rather than judicial review.

Where judicial review succeeds, the most typical remedy is a quashing of the public authority's decision. However, depending on the terms of the court's judgment, when the public authority takes a fresh decision which rectifies the error identified by the court, it might arrive lawfully at the same ultimate result as the initial (flawed) decision.

While judicial review proceedings take place in the Administrative Court, which is part of the High Court, it is a more streamlined form of litigation than much other High Court litigation. There are short time limits. Also, for example, evidence will be limited to that which is relevant to the grounds on which the decision by the public authority in question is challenged and there is not usually any oral evidence at the hearing of the judicial review. For further information, see Practice note, Judicial review: an introduction.

Regulation in the life sciences and health sectors

The life sciences and healthcare sectors are heavily regulated. UK public authorities whose decisions can be challenged include:

- The Medicines and Healthcare products Regulatory Agency (MHRA), which regulates medicines and medical devices.
- The National Institute for Health and Care Excellence (NICE), which issues guidance to improve health and social care, such as guidance on the use of health technologies, such as medicines, medical devices and digital health technologies.
- NHS Clinical Commissioning Groups (CCGs), which adopt policies that influence prescribing decisions. CCGs can, for instance, issue directions to healthcare professionals to:
  - prescribe a specific generic medicinal product rather than a brand name product; and
  - use certain medicines "off-label". Off-label prescribing is when a drug is used for a disease which is outside the specified indication(s) or in an unapproved age group, dosage or route of administration. It usually arises because there are no existing treatments, but may also occur as an economic measure.

  CCGs therefore have a significant influence on the drugs which are prescribed.

In addition to UK legislation, the life sciences sector is also impacted by EU legislation that was applicable in the UK at the end of the post-Brexit transition period on 31 December 2020 and relevant EU case law.

Directive 2001/83/EC on medicinal products for human use is the key EU legislation dealing with medicinal products. It is implemented in the UK by the Human Medicines Regulations 2012 (SI 2012/1916). Since the Human Medicines Regulations 2012 were applicable in the UK at the end of the transition period, they remain on the statute book after the end of the transition period as a form of retained EU law (specifically, EU-derived domestic legislation, pursuant to section 2 of the European Union (Withdrawal) Act 2018). Previous EU case law will still have interpretative value in the UK post-Brexit, though going forward it is likely that the UK legislation will slowly begin to diverge from EU principles. For information on the rules in the European Union (Withdrawal) Act 2018 and other relevant Brexit-related legislation regarding the use of CJEU decisions by UK courts and tribunals after the end of the transition period when interpreting retained EU law, see Practice note, UK law after end of post-Brexit transition period: overview: Use of retained EU case law in interpretation of retained EU law.

Grounds for judicial review in the life sciences and health sectors

There are various ways to look at the grounds of judicial review but a common method which has evolved through case law is the tripartite categorisation of illegality, irrationality and procedural impropriety.

Illegality

In determining whether a decision of a public body is unlawful or ultra vires (that is, outside the scope of the decision-maker's power), a claimant should consider the following:

- Did the decision maker act outside of its powers?
- Did the decision maker fail to comply with its own statutory duties and make an error in applying the law, whether this is UK or EU law?
- Did the decision maker make an error in relation to uncontested facts of the case such as would render the decision unlawful?
- Has the decision maker acted in a manner that contravenes duties under the Human Rights Act 1998 or in relation to other legislation such as equality legislation?
- Has the decision maker made a decision for an improper purpose?

The application of the ground of illegality can be seen in, for example, in *R (Eisai Ltd) v National Institute for Health and Clinical Excellence [2007] EWHC 1941 (Admin)*. Eisai challenged NICE guidance to rely on Alzheimer patient's scores in a mini mental state examination to determine patients' eligibility to receive acetylcholinesterase inhibitors as a treatment. Eisai argued that NICE's exclusive reliance on such scores as the only test for determining the severity of the disease was illegal because it was unreasonable and discriminated against certain atypical groups (such as people with learning difficulties, people whose first language is not English, and people with a particularly high IQ) and was therefore contrary to equality legislation.

Dobbs J upheld this challenge because no proper consideration had been given to NICE's statutory duties as a public authority to promote equal opportunities and to have due regard to the need for eliminating discrimination. It was, therefore, unreasonable and unlawful for NICE to overlook its responsibility with respect to anti-discrimination.

In *Bayer Plc v NHS Darlington Clinical Commissioning Group [2020] EWCA Civ 449*, Bayer plc and Novartis Pharmaceuticals UK brought a case challenging the lawfulness of a policy adopted by 12 CCGs, asking NHS Trusts to use Avastin, in its compounded form "CB", as the preferred treatment option for wet age-related macular degeneration (WAMD). Novartis and Bayer sold Lucentis and Eylea which were licensed treatments for WAMD.

NICE's guidelines recommended the off-label use of Avastin, in its compounded form CB, as a cost-effective treatment for WAMD on the basis that there was no significant difference between the effectiveness of CB and licensed alternatives, Lucentis and Eylea. Accordingly, NICE's guidance had negative ramifications for Bayer and Novartis.

Bayer and Novartis argued that implementing NICE's policy would result in a breach of EU legislation regulating the marketing and manufacture of medicines and the associated implementing domestic legislation, and that therefore, the policy was unlawful. The Court of Appeal rejected the case on the basis that no marketing or manufacturing authorisation was required under EU law where no modification to the biological, chemical or physical attributes of the product was required and the compounding was carried out solely on the basis of individual prescriptions. Recommending the use of Avastin in its compounded form CB because there were no clinically significant differences in its effectiveness and safety as compared to its licensed counterparts, and it was cheaper than licensed alternatives, was therefore not unlawful. For more information, see Legal update, Court of Appeal upholds CCG policy recommending off-label use of Avastin (UK).

A number of judicial review cases in recent years have dealt with applications for marketing authorisations

and the use of competitor data in supporting such applications. An application for marketing authorisation must be accompanied by the results of:

- Pharmaceutical tests.
- Pre-clinical tests (toxicological and pharmacological).
- Clinical trials.

(Article 8(3), Directive 2001/83/EC and Regulation 50, Human Medicines Regulations 2012).

By way of derogation from Article 8(3) (or Regulation 50), an applicant is not required to provide pre-clinical tests and the results of clinical trials if it can demonstrate that "the medicinal product is a generic of a reference medicinal product" (*Article 10(1), Directive 2001/83/EC* and *Regulation 51, Human Medicines Regulations, 2012*). Where an authorisation is being sought on the basis of a medicine being a generic, a company will be able to receive authorisation by showing bioequivalence through bioavailability studies. This abridged procedure for obtaining a marketing authorisation can be used, provided that the authorisation is granted (in most circumstances) at least 10 years after the date of authorisation of the reference drug.

The Directive also provides, under Article 10(3), a procedure for the authorisation of drugs that are variants of drugs which are already authorised but are not generics. In this case, the authorisation can only be granted in the absence of bioequivalence if "appropriate pre-clinical tests or clinical trials are provided". Data provided under Article 10(3) is called bridging data. (The corresponding provision under UK legislation is Regulation 52 of the Human Medicines Regulations 2012.)

In *R (Napp Pharmaceuticals) v The Secretary of State for Health acting as the Licensing Authority [2016] EWHC 1982*, Napp Pharmaceuticals Ltd applied for judicial review of a decision by the MHRA relating to the application of Article 10(3). In 1992, Schering-Plough registered Buprenorphine as an opioid analgesic under the brand name Temgesic, which was a sub-lingual tablet. In 2005, Napp obtained a marketing authorisation from the UK authority for its product, Bu Trans, as a variant of Temgesic under Article 10(3). Bu Trans was administered through a trans-dermal patch as opposed to a sub-lingual tablet and was therefore not considered a generic version of Temgesic. Napp carried out 26 clinical trials and studies over a period of nine years to compile the bridging data demonstrating the clinical effectiveness of BuTrans and its bioequivalence with Temgesic. In 2016, Sandoz obtained a marketing authorisation for its product, Reletrans, a transdermal patch containing buprenorphine. Sandoz applied under Article 10(3) and referred to Temgesic as the reference medicinal product and relied on Napp's bridging data in support of its application. The only new material Sandoz supplied in support of its application was bioequivalence data which demonstrated that Reletrans was the bioequivalent of BuTrans.

Napp challenged the MHRA's decision to issue a marketing authorisation for Reletrans on the grounds that:

- Sandoz should have provided bridging data to establish the safety of its product by reference to the reference medicinal product, Temgesic.
- Article 10(3) did not permit Sandoz to rely on Napp's bridging data and then simply provide bioequivalence data to show that its product was the same as Temgesic

Whipple J concluded that Article 10(3) did not suggest that Napp's bridging data was exclusive, or that subsequent generic application must be supported by its own bridging data.

The overriding consideration was to demonstrate the safety and effectiveness of the product and where bridging data had already been provided to support the application of BuTrans, the data need not be repeated provided that Reletrans could be shown to be the bioequivalent of BuTrans. Whipple J rejected Napp's arguments that its bridging data could not be used as this would give Napp open-ended protection and would be inconsistent with the aim of the legislation which aimed to prevent unnecessary repeat testing. It would also be contrary to the public interest as it would act as a disincentive to the development of generic alternatives.

Validity of parallel importing licences is another area in which pharmaceutical companies have brought judicial review proceedings. In *Primecrown Ltd v Medicines Control Agency [1997] EuLR 657*, Primecrown Ltd sought judicial review of the Medicines Control Agency's (MCA's) decision to revoke its parallel importing licence (the MCA being the predecessor of the MHRA). Smith & Nephew Pharmaceuticals Ltd produced Ditropan in the UK (Ditropan 1), the active ingredient of which it obtained from MMD in the USA. Primecrown applied for a parallel importing licence to permit it to sell Ditropan in the UK, which had been authorised for sale in Belgium by MMD Belgium (Ditropan 2). The MCA's assessor concluded that Ditropan 2 had the same composition as Ditropan 1 and found that there was a link between Smith & Nephew and MMD Belgium for the purposes of satisfying the requirements of EU legislation. Primecrown was therefore granted a parallel importing licence for Ditropan 2. Following this, the MCA discovered that there was no actual commercial link between Smith & Nephew and MMD Belgium and withdrew Primecrown's parallel importing licence.

Primecrown sought judicial review of the MCA's decision to revoke its licence. The Administrative Court submitted a reference to the ECJ and the ECJ held that Ditropan 2 must be treated as being covered by the marketing authorisation for Ditropan 1:

This interpretation effectively led to a finding in Primecrown's favour (thereby rendering its licence valid).

In interpreting applicable legal provisions, courts are conscious that public authorities need to allocate scarce resources and to manage the costs associated with the public health sector. Therefore, courts are hesitant to take decisions which would result in them substituting their decision for that of the public authority.

The Association of the British Pharmaceutical Industry (ABPI) brought judicial review proceedings against the MHRA's policy that Primary Care Trusts (PCTs) (now CCGs) used financial incentives to influence doctors to prescribe lower-cost, specific-named medicinal products to control healthcare expenditure. In *R (Association of the British Pharmaceutical Industry) v Medicines and Healthcare products Regulatory Agency [2011] PTSR 391,* the ABPI argued that the financial incentive policy was inconsistent with Article 94(1) of Directive 2001/83/EC which provided that the promotion of medicinal products by gift, benefits or pecuniary advantage to doctors was prohibited unless they were inexpensive and relevant to the practice of medicine.

The MHRA argued that the Directive did not apply to non-commercial schemes, such as the instant case where a public authority was using the scheme to assist with reducing the overall public expenditure on medicinal products.

The Administrative Court referred the matter to the ECJ which concluded that the prohibition set out in Article 94(1) could not apply to national health authorities as they were responsible for defining the priorities for public health policy. Since the policy did not pursue any profit making or commercial promotion of medicinal products, it was permissible.

Judicial review proceedings may also be brought by charitable organisations involved in the healthcare sector where they may challenge and therefore indirectly affect the availability of particular drugs on the NHS. For instance in *R (National Aids Trust) v National Health Service Commissioning Board (NHS England) and others [2016] EWCA Civ 1100*, NHS England refused to consider commissioning pre-exposure prophylaxis (PrEP), an anti-retroviral drug to be used as a preventive measure by those at high risk of being infected with HIV. The National Aids Trust sought judicial review of NHS England's decision on the grounds that it had erred in law because NHS England was the appropriate public body responsible for dealing with HIV drugs.

NHS England submitted that under regulations promulgated by the Secretary of State, local authorities had assumed responsibility for preventative medicine in relation to sexually transmitted diseases and therefore were responsible for commissioning PrEP, which was a preventative medicine. The Court of Appeal found that, based on the applicable regulations, NHS England did have the power to commission PrEP. To avoid the fragmentation of responsibility in a highly specialised area, all treatment associated with HIV whether preventative or otherwise was found to be the responsibility of NHS England and therefore it had the power to commission PrEP. (For more information, see Legal update, Court of Appeal confirms NHS England has power to commission HIV preventative treatment.)

Additionally, a challenge can also be based on those provisions of the European Convention on Human Rights (ECHR), which have been effectively incorporated into domestic law through the Human Rights Act 1998. For instance in *Eisai*, the claimant sought to rely unsuccessfully on arguments based on Article 8 (right to respect for private and family life) and Article 14 (prohibition of discrimination, an article which can only be raised when in the ambit of another article).

Irrationality

Irrationality, or unreasonableness, is commonly regarded as the most difficult ground on which a judicial review challenge can succeed as the threshold for showing that a public body has acted unreasonably is very high.

In heavily regulated industries such as the health sector, where regulators enjoy statutory discretion, have staff with significant experience and obtain expert advice in making controversial decisions, the courts will be circumspect, and the rationale for the decision will need to be seriously flawed for the decision to be overturned.

Before bringing an action for irrationality, any claimant should ask itself the following questions:

- Is the decision so unreasonable that no reasonable person in the public authority's position could have made it?
- Has the decision maker taken into account all relevant considerations and ignored all irrelevant considerations?
- Has the decision maker improperly delegated its responsibilities?
- Has the decision maker acted in a way that has fettered its discretion?
- Has the decision made an insufficient inquiry into the issues in dispute?
- Has the decision maker acted in bad faith?

- Has the decision maker's conduct induced an expectation and has the decision maker then reneged on that expectation?
- In EU or human rights cases, is the decision disproportionate to the aim to be achieved?

The difficulty in successfully challenging a public body's decision on irrationality grounds is evidenced in *R (Pharma Nord (UK) Ltd) v Medicines Control Agency [1998] 3 CMLR 109*, which concerned the classification by MCA of melatonin as a medicinal product. Pharma Nord was importing melatonin contained in Bio-melatonin tablets into the UK and challenged the MCA's classification which resulted in Bio-melatonin requiring a marketing authorisation on the basis that it was flawed on (Wednesbury) unreasonableness grounds. The Court of Appeal dismissed the claim and held that the MCA's decision to classify melatonin as a medicinal product was not unreasonable. Lord Woolf MR said that the court should be wary of becoming involved in such issues given that the MCA was an expert body that had "accumulated experience in relation to other products which a court lacks" and has "to develop a consistent policy between similar products".

Similarly, in the recent case of *R (Cotter) v National Institute for Health And Care Excellence [2020] EWHC 435 (Admin)*, the High Court dismissed an application for judicial review of the decision of the National Institute for Health and Care Excellence (NICE) to assess the drug Kuvan under the Health Technology Appraisal (HTA) rather than Highly Specialised Technology (HST) process. If the HST process had been used, the upper limit of cost used by NICE to determine whether a drug could be prescribed on the NHS was £100,000 as compared to £30,000 under the HTA process. Therefore, using the HST process would have significantly increased the prospects of Kuvan being prescribed on the NHS.

The court held that although the relevant criteria to be applied by NICE did not involve highly technical scientific questions, the decision involved issues of judgement and NICE had particular experience and expertise to take it. The views of NICE, as decision-maker should be given proper respect. While this did not mean that the court should simply defer to NICE, the central question was whether the decision was irrational or perverse, which is a high threshold. NICE's decision was not irrational. The case was appealed to the Court of Appeal and although it differed on certain points from the analysis at first instance, the Court of Appeal agreed that consideration of the criteria required the exercise of expert judgement and the use of expert knowledge and that there is always a high threshold for irrationality cases. This case is also a good example of instances where individuals have claimed against a public authority for refusal to prescribe a drug for their use.

Judicial review proceedings have also been brought on the grounds that a body's decision was not proportionate (*R (Actegy) v The Advertising Standards Authority (ASA) [2019] EWHC 2374 (Admin)*). The High Court dismissed a judicial review challenge against a decision of the Advertising Standards Authority (ASA) that an advert for a medical device which made claims as to its therapeutic benefits could not be substantiated.

Actegy Ltd placed adverts for the device in The Daily Mail and The Times in early 2017 claiming that the device Revitive would boost circulation and alleviate pain or discomfort from swollen or aching legs, feet or ankles, especially for patients diagnosed with osteo arthritis, diabetes or muscle weakness.

The ASA received a complaint that the claim could not be substantiated. Actegy had obtained a Clinical Evaluation Report (CER) which it submitted to the British Standards Institute (BSI) pursuant to which the BSI issued a "CE certificate" and Actegy subsequently affixed the CE marking to the device. Notwithstanding the submission of the CER, the ASA upheld the complaint on the grounds that the evidence provided was not sufficient for the Unfair Commercial Practices Directive (2005/29/EC) (UCPD). Actegy sought judicial review of this decision on the ground that the ASA had acted disproportionately and/or unreasonably and that its conclusion was irrational.

The court stated that the proportionality and free movement aspects of the challenge must fail unless Actegy could show that the approach departed from the requirements of the UCPD in such a way as to interfere with Actegy's EU law rights. It considered that the ASA had acted proportionately and reasonably in considering the quality of evidence which was in the public interest and consistent with EU law. The court concluded that the ASA's conclusions were rational and there was expert support on the issues it identified.

While an irrationality challenge is difficult, it is not insurmountable as evidenced by *R (Blue Bio Pharmaceuticals Limited) v Secretary of State for Health [2016] EWCA Civ 554.* The claimants challenged the decision of the MHRA to classify its product, Dolenio (a glucosamine containing product or "GCP"), as a medicinal product while refusing to classify other GCPs, which the claimant effectively said had the same relevant characteristics, as medicinal products. The consequence was that Dolenio was heavily regulated while competitors marketing identical products as vitamin supplements were under a much lighter regulatory regime.

The Court of Appeal overturned the decision of the High Court, finding that the MHRA had not properly considered the evidence presented. The Court of Appeal held that to the extent a product has several significant

characteristics in common with other products it should be classified and marketed in the same way. In determining whether a product was significantly similar, the court clarified that national courts must proceed on a case by case basis taking account of all of the product's characteristics, in particular:

- Its composition.
- Its pharmacological properties.
- The manner in which it is used.
- The extent of its distribution.
- Its familiarity to consumers.
- The risks which its use may entail.

Here, the court concluded that other GCPs should be treated in the same way as Dolenio. Unless there were specific reasons not to do so, products containing significant similarities, should be classified in the same way. The MHRA's decision was unreasonable and the challenge therefore succeeded on *Wednesbury* grounds of unreasonableness.

Procedural impropriety

While the grounds of illegality and irrationality may effectively be used to attack the substance of a decision (albeit based only on the way in which it was taken, not on its merits), the ground of procedural impropriety or procedural unfairness is concerned only with the process leading to the decision. The basis for a procedural challenge can be a failure to adhere to an express procedural requirement (such as a statutory duty to consult specified groups before a decision is made) or breach of common law principles of procedural fairness. This includes the right to a fair hearing and the rule against actual or apparent bias.

Therefore, in determining whether a decision maker has acted in a manner that is procedurally unfair, the following questions should be considered:

- Has the decision maker breached an express procedural rule?
- If common law procedural fairness applies, has the decision maker both: let the company know the case against their position, and given a fair opportunity to make representations in response?
- Is this a case where the duty to consult arises or a consultation has been carried out in a flawed manner? (See Practice note, Duty to consult: when does it arise and what does it entail?)
- Is there actual or an appearance of bias?
- Has the decision maker pre-determined the issues without giving due consideration to the claimants' arguments or has it failed to give reasons for its decision?
- Has the decision-maker breached a procedural legitimate expectation?
- Does the duty to give reasons arise and has it been breached? (See Practice note, Duty to give reasons.)

One particular procedural issue is that, where the duty to consult arises, the consultation must be carried out in accordance with statutory requirements and follow four key common law principles:

- The consultation must take place while proposals are still at a formative stage.
- Sufficient explanation must be given to allow for intelligent consideration and response.
- Adequate time must be given for consideration and response.
- The decision maker must conscientiously take consultation responses into account.

For more information, see Practice note, Duty to consult: when does it arise and what does it entail?: Context specific with guiding principles.

The ground of procedural impropriety can be seen in action in the *Eisai* case. Eisai succeeded on the grounds of illegality in the High Court, but was unsuccessful on the grounds of procedural unfairness. In the Court of Appeal, Eisai successfully argued that NICE breached principles of procedural fairness by not providing to consultees during the consultation process a fully executable version of an economic model which had been developed to illustrate the cost effectiveness of the inhibitors. The model was provided in "read-only" format which, Eisai argued, had prevented Eisai from checking the accuracy of the formulae. Richards LJ held that NICE's failure to disclose a fully executable version of the economic model was a breach of the principles of openness and transparency. In particular, NICE had placed the consultees at a significant disadvantage in challenging the reliability of the model and limited their ability to make an intelligent response during the appraisal process. (See Practice note, Duty to consult: when does it arise and what does it entail?: Sufficient information to permit intelligent response.)

While NICE, as the decision maker, was responsible for checking the reliability of the model, fairness required consultees to be given the opportunity to test the reliability of the model themselves. Tuckley LJ stated that limiting "the extent to which consultees can engage in the legitimate task of testing such an important element in the appraisal process does seem to be unfair".

However, in *R (Bristol-Myers Squibb Pharmaceuticals Ltd) v National Institute for Health and Clinical Excellence [2009] EWHC 2722 (Admin)*, Bristol-Myers Squibb (BMS) brought a judicial review on the basis that NICE did

not allow BMS to see the amendments made by the review group to BMS's model failed. Blake J found that BMS had been able to make informed representations regardless of not having sight of the model because BMS was the author of the model and had been provided with alternative figures which it could input into the model during the consultation process. The court distinguished the position from *Eisai* where the claimants could not test the sensitivities of the model without receiving a fully executable version.

In *R (Servier Laboratories Ltd) v National Institute for Health and Clinical Excellence [2010] EWCA Civ 346,* Servier applied for judicial review of two final appraisal decisions (FADs) made by NICE which recommended Servier's drug, Protelos (strontium ranelate) only for a defined and limited group of patients on the basis that it was insufficiently effective and too expensive for its wider use to be recommended. The economic model which was commissioned by NICE was not disclosed to consultees owing to reasons of confidentiality. Servier challenged the consultation process leading to NICE's FADs on the ground that fairness required full disclosure of the final executable version of the economic model. Holman J held that where NICE had given undertakings of confidentiality, it remained under a positive duty to take all reasonable steps to obtain permission to disclose the confidential information and NICE had failed to take such reasonable steps. Accordingly, Holman J held that NICE should seek to be released from its obligation of confidentiality for the limited purpose of disclosure to consultees upon appropriate terms with a view to giving them an opportunity to respond.

Servier also challenged NICE's rejection of data derived from a post-hoc subgroup analysis before arriving at its FADs. Servier argued that the post-hoc analysis demonstrated that Protelos was as efficacious as alendronate in the prevention of hip fractures and that NICE failed to give adequate reasons for its rejection of the data. These arguments failed at first instance. On appeal the Court of Appeal held that NICE's failure to give reasons as to why the post-hoc analysis was rejected was such as to require that NICE take a fresh decision.

Points of practical guidance when considering judicial review in the life sciences and health sectors

Since the courts recognise public authorities as having specific expertise in the healthcare sector and that there are competing interests that need to be balanced, judicial review where the aim is to attack the substance of a decision in this area can be difficult. There are a number of practical considerations for claimants who wish to bring judicial review proceedings including the following:

- Judicial review is aimed at considering questions of law, not the merits. The same issue can sometimes be presented in terms of both illegality and irrationality. It might be helpful to look at a case in both ways but cases based on illegality tend to have greater prospects of success because courts will be willing to interpret questions of law but may be more willing to defer to public authorities on questions such as whether a public authority's judgement was reasonable.
- If the only workable ground of challenge in judicial review is irrationality, the point should be presented as simply and starkly as possible. It is also worth considering whether the regulator asked itself the right question and took steps to acquaint itself with relevant information to be able to answer the question (*Eisai*).
- The courts are less likely to defer to the public authorities in procedural challenges than in irrationality challenges. In particular, consider whether a consultation process has been carried out appropriately (*Eisai* and *Servier*). However, note that procedural cases can effectively be a Pyrrhic victory because they can simply lead to a public authority making the same decision again without the procedural error.
- There are limited circumstances in which new expert evidence can be adduced in a judicial review. Where possible ensure that the material is before the public authority, because it will be easier to justify deploying it in a judicial review than if there is a need to submit it afresh.