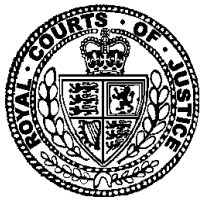

Neutral Citation Number: [2024] EWCA Civ 530

Case No: CA-2024-000663

**IN THE COURT OF APPEAL (CIVIL DIVISION)**
**ON APPEAL FROM THE HIGH COURT OF JUSTICE**
**KING'S BENCH DIVISION**
**ADMINISTRATIVE COURT**
**Mrs Justice Lang**
**[2024] EWHC 709 (Admin)**

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 15 May 2024

**Before:**

**LORD JUSTICE NUGEE**
**LADY JUSTICE ELISABETH LAING**
and
**LORD JUSTICE SNOWDEN**
- - - - - - - - - - - - - - - - - - - - -

**Between:**

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|---|---|
| **BRITISH STANDARDS INSTITUTION** | **Appellant** |
| **- and –** | |
| **THE KING** | **Respondent** |
| **on the application of** | |
| **RRR MANUFACTURING PTY LTD** | |
| **-and-** | |
| **THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY** | **Interested Party** |

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**Tim Johnston** (instructed by **DAC Beachcroft LLP**) for the **Appellant**
**Adam Heppinstall KC** and **Freya Foster** (instructed by **Dentons UK and Middle East LLP**) for the **Respondent**
**Tom Leary** (instructed by **The Treasury Solicitor)** for the **Interested Party**

Hearing date: 18 April 2024
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# Approved Judgment

This judgment was handed down remotely at 11.00am on 15 May 2024 by circulation to the parties or their representatives by e-mail and by release to the National Archives.

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## Lady Justice Elisabeth Laing:

*Introduction*

1. The respondent in this court ('RRR') markets a small, portable defibrillator ('the device'). The appellant in this court, the British Standards Institution ('BSI'), is an 'approved body' appointed by the Medicines and Healthcare Products Regulatory Agency ('the MHRA'). In short, under the relevant regulatory regime, RRR needs a certificate to sell the device in the United Kingdom. It had such a certificate. BSI decided to suspend that certificate ('the decision').

2. RRR applied for judicial review of the decision, and of two related decisions. It also applied for interim relief. Lang J, sitting in the Administrative Court ('the Judge'), made an order (1) restraining BSI from withdrawing or suspending the certificate, (2) requiring BSI, when the certificate expires on 26 May 2024, to extend or to renew the certificate until the determination of the application for judicial review (or further order) and (3) requiring BSI to pay RRR's costs of the application for interim relief ('the order').

3. This is my judgment after an expedited 'rolled-up' hearing of an application for permission to appeal (and, if permission is granted, of an appeal) from the order. BSI's three grounds of appeal challenge each of the three facets of the order. For the reasons given in this judgment, each ground of appeal is arguable. I would give permission to appeal, and, for those reasons, I would also allow the appeal. In brief, I accept BSI's submissions that in making each of the contentious parts of the order, the Judge erred in law.

4. I have much sympathy for the Judge, as, in a no doubt busy list, she was faced with a case which partly depends on technical issues. There are many documents which, as this court has discovered, are both difficult to read and hard to understand. She had to make a quick decision under considerable pressure. She was, perhaps understandably, influenced by the apparently significant commercial impact of the decision on RRR. I have also borne those circumstances in mind in my approach to the judgment. In interpreting it, I have given the Judge the benefit of any available doubt.

5. On this application, Mr Heppinstall KC and Ms Foster appeared on behalf of RRR, Mr Johnston for BSI and Mr Leary for the MHRA. I thank counsel for their written and oral submissions.

6. Paragraph references are, as the case may be, to the Judge's judgment, or to an authority, unless I say otherwise.

*The facts*

7. I have taken some of the facts from the judgment. The Judge recorded that RRR is an Australian company and that it had developed the device. The device was given a CE certificate in the European Union in May 2021.

8. The Judge described BSI as 'the UK's national standards body and the UK approved body which exercises its powers and acts pursuant to the Medical Devices

Regulations 2002…and the retained powers under Annex 11 of Council Directive concerning Medical Devices, 93/42/EEC'.

9. She described the MHRA as 'an executive agency sponsored by the Department of Health and Social Care, which regulates, inter alia, medical devices in the UK. It has investigatory and enforcement powers. It also designates approved bodies, such as the BSI, to assess the compliance of the manufacturers of medical devices'.

10. On 24 August 2022 BSI issued a certificate which enabled RRR to sell the device in the United Kingdom. The MHRA registered the device on 12 September 2022. RRR passed BSI's 'Continuing Assessment Surveillance Audit' in March 2023.

11. On 13 September 2023 the MHRA contacted RRR to tell it that, in the Judge's phrase (which might also, in part, have been the MHRA's) 'unidentified stakeholders' had expressed 'concerns'. RRR responded. The Judge said that 'These appear to have been the issues raised by Mr Fagan', that is, Martin Fagan of the Community Heartbeat Trust ('CHT') and of the Resuscitation Council UK ('RCUK'). Mr Fagan is said to have a commercial interest in RRR's competitors. The MHRA had not at that stage, and still has not, taken a decision to exercise any of its powers in relation to the device.

12. In September 2023, BSI started a review of the certificate, after the MHRA raised, it appears, Mr Fagan's concerns with BSI. The Judge did not describe those concerns in her judgment. A letter from BSI to RRR's solicitors dated 27 February 2024 explains that those concerns were described in an email which the MHRA sent to BSI on 19 September 2023. That email summarised concerns expressed to the MHRA by CHT and RCUK. They were that there was a 'lack of available clinical data to confirm safe and effective use', a 'lack of peer-reviewed clinical evidence'; that 'UK guidance on shock energy levels are 120-360 Joules', whereas the device delivered a maximum of 80 Joules; the 'power requirement and capacitor specifications to achieve the levels of charge [which RRR] claimed [were] difficult to follow', ('mathematics don't work out'); concerns about the use of the device on new-born babies, such that worried parents might end up killing a child, and that RCUK was concerned about advice given about the positioning of the pads. Officials at the MHRA had reviewed RRR's technical files, and were concerned that 'the available clinical data is sparse'. The letter to RRR's solicitors added that the device had a valid CE certificate from an EU body (DQS) based on RRR's assertion that the device was equivalent to the Philips HeartStart HS1.

13. After a 'technical surveillance review' on 9 January 2024, BSI issued a report ('decision 1'). Decision 1 'purported to identify', the Judge said, two major and three minor 'non-conformities'. BSI asked for 'corrective action plans' ('CAPs'). RRR exercised a right of internal appeal to BSI. One of RRR's grounds of appeal was that RRR's process had been unfair. On 20 February 2024, BSI dismissed the appeal. BSI gave further reasons on 27 February 2024 ('decision 2'). BSI had then decided, as a result of decisions 1 and 2, to suspend the certificate ('decision 3'). Decision 3 would be put before a panel, which would then decide whether or not to approve decision 3.

14. The points made in decision 1 were helpfully summarised by Mr Tunbridge in paragraph 51 of his first witness statement. They include five broad points.

i. The technical documents were not detailed enough to show 'sufficiently' that the device would work as expected 'in line with its intended performance'.
ii. Major safety failures such as sparking and burning were noted. They had not been sufficiently explored, nor had their causes been established.
iii. There was not enough information in the technical documents about the safety and performance of the device, including plans to monitor its performance over its lifetime, its shelf life, how it responded to being transported and its 'software architecture'.
iv. The clinical evaluation of the device did not follow 'commonly accepted scientific methods'. Mr Tunbridge criticised this in six respects in paragraph 51.c of his witness statement. Two of these were that meta-analyses of the published writing on similar devices 'which typically are considered to provide the highest level of evidence, were excluded from the literature analysis' for the device, and that 'The commonly accepted scientific principle …of "energy" (a mutual measure of current and voltage) being a determinant factor for defibrillation was discounted in favour of a comparison of "current" delivered by such devices'.
v. 'The clinical data collected did not support the clinical safety and performance of the device'. He gave four examples in paragraph 51.d. The first, which is linked with the point made at the end of paragraph iv., above, was that the device did not reach the energy levels reached by comparator defibrillators. In some cases the energy levels produced by those defibrillators were twice as high as the level produced by the device. The claim that the comparison should be based on 'current' rather than on energy for effective defibrillation 'was not accepted as it is not supported by commonly accepted scientific opinions from resuscitation councils in UK and EU'. The use of such low energy levels was novel. It needed support from clinical evidence 'of its use on human patients in a controlled environment which has not been conducted/provided'. The documents about the clinical evaluation referred to a study on pigs, but a report of that study was not provided. A study on pigs might provide pre-clinical evidence to show that the device could work on human beings, but it could not amount to 'clinical data'. The third and fourth points concerned clinical data arising from the actual use of the device. In short, there was no such data.

15. RRR passed a 'QMS' review: see the report dated 26 February 2024. 'QMS' stands for 'Quality Management Systems'. This was one aspect of the audit required for recertification of the device (as page 9 of that report explains). This report did not deal with the safety concerns which I have described in the previous paragraph. They were outside its scope, which was also described on page 9 of that report.

16. On 4 March 2024, RRR issued an application for judicial review, challenging decisions 1, 2 and 3. The Judge said that RRR had invited BSI to agree a stay and to refer their dispute to arbitration. She added that the court would be likely to agree a stay, if the parties had wanted to arbitrate. BSI declined to do so. She also added that BSI was 'entitled to defend its judicial review claim and decline arbitration if it wishes to do so'. Judicial review and arbitration are 'completely different' procedures

in 'their nature and scope'. It was for the parties to decide whether or not to have an arbitration, the Judge said.

17. I understand from counsel's oral submissions that BSI wishes to reserve its position on whether it is amenable to judicial review at all, on the basis that its relationship with RRR is purely contractual, and therefore only governed by private law. We have not heard argument on this point. I would only observe that if BSI was exercising public powers (which is the premise of the application for judicial review, and of the appeal) it would not be lawful for it to abdicate those functions to an arbitrator.

18. The Judge said that RRR had applied urgently for interim relief to prevent BSI from withdrawing its certificate on the grounds that 'suspension of the certificate on the basis of unlawful decisions would cause serious and potentially irreversible harm to RRR group, both in the UK and in other jurisdictions'. Chamberlain J adjourned that application to an oral hearing on 12 March 2024. On 21 March 2024, he gave directions for skeleton arguments and evidence. His view was that RRR's grounds of challenge 'disclosed a prima facie case that the decision was unlawful, sufficient to call for an answer'. At that early stage of the proceedings, there was no such answer from BSI, as it had not yet lodged its acknowledgement of service and summary grounds of defence.

*An outline of the legal regime*

19. The most significant aspect of the legal regime is domestic secondary legislation which implements an EU Directive. BSI's skeleton argument for this appeal summarised that regime. RRR's skeleton argument did not indicate any disagreement with that summary. In his oral argument Mr Heppinstall did no more than to draw our attention to one or two details. As the regime is apparently agreed in outline, it is not necessary for me to describe it in great detail.

20. Chapter 3 of Part 4 of the Medicines and Medical Devices Act 2021 ('the MMDA') gives the MHRA powers to take action about medical devices if they are a risk to public safety or do not comply with the relevant regulations. The MHRA may issue a safety notice to protect public health or safety, compliance notices if a person is not complying with regulations about medical devices, or a suspension notice, to restrict the supply of a product on the grounds of health or safety. Section 39 gives the MHRA powers to disclose information about medical devices. Those include a power to warn the public if the MHRA is concerned about the safety of a medical device.

21. The MHRA has power to appoint an 'approved body' to assess whether or not medical devices conform with the Medical Devices Regulations 2002 (2002 SI No 618) ('the relevant regulations'). A person who wishes to market a medical device in the United Kingdom must engage an approved body to assess whether or not that device conforms with the relevant regulations. That person can choose which approved body to approach for an assessment, and must pay for that assessment. The terms of the assessment are governed, at least in part, by a contract between the approved body and that person.

22. The domestic secondary legislation implemented Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended ('the Directive'). As is clear from

its recitals, the purposes of the Directive included harmonising national provisions for the safety and health of patients and users. Such devices should provide patients and users with 'a high level of protection', and should 'attain the performance levels attributed to them by the manufacturer'. There are three other references in the recitals to a 'high level of protection'. Two other purposes of the Directive are evident from the recitals. First, that the 'design and manufacture' of devices with a high 'risk potential' should be inspected by a 'notified body'. Second, that 'as a general rule' medical devices should bear a CE mark 'to indicate their conformity with the provisions of this Directive'.

23. The relevant regulations were expressed to be made under powers conferred by section 2(2) of the European Communities Act 1972, in the exercise, with the consent of the Treasury, of the powers conferred by section 56(1) and (2) of the Finance Act 1973, and in the exercise of the powers conferred by sections 11 and 27(2) of the Consumer Protection Act 1987 (and of all other relevant powers), after consultation in accordance with section 11(5) of the Consumer Protection Act 1987 with organisations appearing to the Secretary of State to be representative of interests substantially affected by the relevant regulations, with such other persons considered by him appropriate, and with the Health and Safety Commission.

24. The version of the relevant regulations in the bundle of authorities is over 200 pages long. I will only refer to a few of their provisions. 'Approved body' is to be construed in accordance with regulation A45 (see paragraph 30, below). 'Relevant essential requirements' means the essential requirements set out in Annex I of whichever of three potentially applicable Directives applies (regulation 9).

25. Regulation 7 is headed 'Classification of general medical devices'. There are four classes. We were told that the device is in Class IIb. The criteria for classifying medical devices are in Annex IX of the Directive, read with two earlier Directives (regulation 7(1)).

26. Regulation 7A is headed 'Registration of persons placing general medical devices on the market'. A person who places a medical device on the market in the United Kingdom must be established in Great Britain. A manufacturer based outside Great Britain must appoint a 'sole UK responsible person' who must satisfy the Secretary of State that he has the manufacturer's authority so to act, must describe the relevant device and must pay a fee (regulation 7A(1)). Regulation 7A(3) imposes duties on that person. He must ensure that there have been drawn up a declaration of conformity (for which, see Annex II, IV, V, VI and VII) and technical documentation (for which, see Annex II, III, or VII) (regulation 7A(4)), and where appropriate, that 'an appropriate conformity assessment procedure has been carried out by the manufacturer'. He must, 'in response to a request from the Secretary of State, provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of the device', and 'co-operate with the Secretary of State on any preventive or corrective action taken to eliminate, or, if that is not possible, to mitigate the risks posed by devices'.

27. The 'essential requirements for general medical devices' are provided for by regulation 8. Subject to regulation 12, regulation 8(1) prohibits anyone from placing

on the market any device which does not meet those 'essential requirements' in Annex I which apply to it and the requirements in Regulation (EU) No 722/2012, if it applies. Regulation 12(6) disapplies regulations 8 and 10 if the Secretary of State directs that a relevant device meets other requirements or standards, or if it is marked other than with a UK marking which the Secretary of State determines is equivalent to the requirements and standards imposed by regulations 8 and 10. The Secretary of State cannot make such a direction unless he is satisfied that 'the other standard imposes a degree of safety and quality equivalent to that imposed by those regulations' (regulation 12(7)).

28. Regulation 9(2) provides that where 'confirmation of conformity with the essential requirements must be based on clinical data, such data must be established in accordance with the requirements set out in Annex X' (see paragraph 36, below, for the requirement of Annex X on which BSI relied).

29. Regulation 13 provides for the process by which a UK marking is put on a general medical device. A device in Class IIb may only bear a UK marking if its manufacturer or UK responsible person meets those obligations in Annex II (apart from Section 4) Annex III, IV, V or VI which apply to the device, makes the necessary declaration, and 'ensures' that the device meets the provisions of this Part which apply to it (regulation 13(3)).

30. An 'approved body' means a 'conformity assessment body' which has been designated by the Secretary of State in accordance with the procedure described in regulation 45, or which, immediately before IP completion day, was a UK notified body, from which the Secretary of State has not withdrawn that designation (regulation A45(1)). 'UK notified body' is defined in regulation A45(2).

31. Regulation 47 provides for 'general matters' about approved bodies. Where a manufacturer has 'supplied information or data to an approved body' during a conformity assessment procedure, that body 'may, where duly justified' require the manufacturer to provide 'any additional information or data which it considers necessary for the purposes of that procedure' (regulation 47(2)). When an approved body has assessed a medical device, regulation 47(4) imposes a duty on it to inform all other approved bodies and the Secretary of State of 'all certificates suspended or withdrawn', and, 'on request, [of] all certificates issued or refused', and, if asked, to provide any further relevant information. Where an approved body finds, after inspecting a medical device, that the relevant requirements of the relevant regulations have not been met, or are no longer met or a certificate issued by it should not have been issued, it may '(having regard in particular to the principle of proportionality and the ability of the manufacturer to take appropriate corrective measures)', suspend or withdraw a certificate, and, where the Secretary of State may need to take action under regulation 61, it must tell the Secretary of State what it has done.

32. Annex I of the Directive is headed 'Essential Requirements'. Section 1 requires devices to be designed and made in such a way that they do not 'compromise the clinical condition or safety of patients, or the safety and health of users', with the proviso that 'any risks which may be associated with' their use 'constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high

level of protection of health and safety'. The rest of section 1 explains what is included in that stipulation.

33. Section 2 requires that 'The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art'. Section 2 then lists, in descending order of importance, the principles which manufacturers must apply when choosing those solutions. Risks must be eliminated or reduced as far as possible '(inherently safe design and construction)', the devices must achieve the performances intended by the manufacturer, and the characteristics and performances referred to in Sections 1, 2, and 3 must not, as a result of the stresses which can occur in normal use, be affected to such an extent that anyone's safety is compromised during the 'lifetime of the device as indicated by the manufacturer'. Section 6a. requires that 'Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X'.

34. Annex II is headed 'EC Declaration of Conformity (Full quality assurance system)'. Section 1 requires the manufacturer to 'ensure application of the quality system approved for the design, manufacture and final inspection of the products concerned…'. Section 2 explains that the declaration of conformity is 'the procedure' by which the manufacturer who meets the obligations imposed by Section 1 'ensures and declares that the products concerned meet the provisions of this Directive which apply to them'. Section 3 is headed 'Quality system'. Section 3.1 requires the manufacturer to make an application to a notified body for the assessment of its quality system. Section 3 also lists what such an application must include. It must include the procedures for 'monitoring and verifying the design of the products, including the corresponding documentation'. Some of the relevant documents are 'the design specifications, including the standards which will be applied and the results of the risk analysis, and also a description of the solutions adopted to fulfil the essential requirements which apply to the products if the standards referred to Article 5 are not applied in full', 'the pre-clinical evaluation', and 'the clinical evaluation'.

35. Section 4 of Annex V is headed 'Surveillance'. Paragraph 4.2 provides that the manufacturer authorises the notified body to 'carry out all the necessary inspections and must supply it with the relevant information, in particular…the technical documentation'.

36. Annex X requires, among other things, the provision of a 'compilation of the relevant scientific literature currently available on the intended purpose of the devices and the techniques employed, as well as, if appropriate, a written report containing a critical evaluation of this compilation; or the results of all the clinical investigations made, including those carried out in conformity with Section 2'.

*The Judge's reasoning*

*The Judgment*

37. In paragraph 14, the Judge said that 'The principles governing the grant of interim relief in judicial review proceedings are those in *American Cyanamid Co v Ethicon Limited* [1975] AC 396, modified as appropriate for public law cases'. She referred to the threshold test concerning the legal merits of the claim, and said that,

consistently with *R (Medical Justice) v Secretary of State for the Home Department* [2010] EWHC 1425 (Admin) ('the *Medical Justice* case'), the test was higher than the arguability test which applies on an application for permission to apply for judicial review.

38. The court should then consider whether damages would be an adequate remedy for either side if interim relief were granted or refused. Damages would 'rarely be an adequate remedy in the context of judicial review claims' (paragraph 15). The next step for the court was to consider whether the 'balance of convenience' favoured the grant of an injunction or not. The court had to balance 'the harm to the claimant and to any public interest which would be caused if interim relief is not granted and the claim later succeeds, against the harm which would be caused to the defendant, any third party and the public interest if interim relief is granted' and the claim later fails (paragraph 16).

39. In paragraph 17, she added that 'It is well established that the court will have regard to the principle that it is in the public interest that a decision of a public body should be respected unless or until it is set aside. The strength or weakness of the claim is likely to be a significant factor in assessing the balance of convenience'.

40. She summarised RRR's four grounds of claim in paragraph 18. They were illegality (by reference to paragraphs 72-79 of the statement of facts and grounds ('SFG')), procedural unfairness (paragraphs 80-87 of the SFG), irrationality (paragraphs 88-91 of the SFG), and fettering of discretion (paragraphs 92-93 of the SFG).

41. In paragraph 19, the Judge recorded a concession by BSI, in the light of the remarks of Chamberlain J (see paragraph 18, above) that RRR had 'passed the merits threshold, applying the *American Cyanamid* case' but that it submitted, nevertheless, that the claim was not a strong one, and reserved its position to argue, in due course, that permission to apply for judicial review should be refused. Mr Johnston explained to us during the hearing of this application that BSI had not lodged its acknowledgement of service by the date of the hearing of the application for interim relief.

42. The Judge then said (paragraph 20) that she had carefully considered BSI's evidence, the submissions in its skeleton argument and its response to RRR's criticisms in correspondence. She added, 'Whilst some of [RRR's] points are stronger than others, I am satisfied that [RRR] has demonstrated that there is a serious question to be tried.' Damages would not be an adequate remedy for either party. 'Therefore, I turn to consider where the balance of convenience lies'.

43. In paragraph 21, she accepted that RRR would suffer 'considerable commercial and reputational harm, both in the UK and in other countries, if its certificate is suspended, even if only up to the date of trial.' She accepted that news of the suspension would spread quickly and that other regulators would be likely to start their own investigations as a result. The device is RRR's only product 'and so its entire business could be threatened'. If, as RRR claimed, the device is a 'life-saving innovative product, it is not in the public interest to put it out of business'.

44. If BSI were restrained from suspending the certificate, it would be 'deprived of its power to prevent [RRR] from operating in the UK'. She acknowledged that 'public health and safety is obviously a paramount concern'. But, she added, 'there is no evidence that the device is a current risk on health and safety grounds'. She referred to paragraph 8 of Mr Tunbridge's witness statement for RRR. While he described 'fundamental and overarching concerns for public safety when using the device', 'BSI has not identified direct evidence that the device is unsafe, and it was content to allow the product to continue to be marketed during the implementation of its CAP requirements. The device has previously been certified and approved by BSI and it is certified and approved in other jurisdictions as well. Certification denotes that the requirements of safety and efficacy have been met' (paragraph 22).

45. She continued, in paragraph 23, that 'if a risk to public health and safety were to be identified, the MHRA has a suite of powers at its disposal to protect the public'. She listed some of those. The MHRA could also utter warnings about devices. It had said that if an injunction were granted, it would keep the matter 'under careful review'. It was suggested at the hearing that the MHRA might even take action because an injunction had been granted. 'In my view that would not be a proper exercise of its powers'.

46. She concluded, in paragraph 24, that the balance of convenience favoured keeping the status quo by restraining BSI from suspending or withdrawing the certificate until after a decision on the claim. She foreshadowed that she would consider the renewal of the certificate shortly.

47. Mr Tunbridge had helpfully told the court in his first witness statement that the existing certificate was, in any event, due to expire on 26 May 2024. Renewal was not automatic. The renewal of the certificate would have to be reviewed, and the device would have to be assessed again. In his second witness statement, Mr Tunbridge had said that BSI would not be able to renew the certificate 'in the light of the identified non-conformities which remain unaddressed'. He had also said, in his first witness statement, that he had assumed that RRR 'may also intend to seek a mandatory order compelling the BSI to renew the certificate' (paragraph 26).

48. In paragraph 27 the Judge expressed her view that 'it would defeat the object of the court's order if [RRR's] certificate was not renewed because of the decisions which are under challenge and before the court has had an opportunity to rule on their lawfulness'. She was '[t]herefore willing to extend the scope of the injunction to require [BSI] to maintain the certification in place until the determination of this claim'. She would hear submissions from BSI on the precise mechanism in due course.

49. She confirmed in paragraph 28 that the hearing was not listed as a hearing of the application for permission to apply for judicial review as neither BSI nor the MHRA has filed their summary grounds of resistance. She was not, therefore, able to consider the application for permission. She would give case management directions. Both the parties considered that it was an appropriate case for a 'rolled-up' hearing of the application for permission to apply for judicial review and, if permission were granted, of the application for judicial review (paragraph 29).

*The Judge's decision on costs*

50. There is no transcript of the Judge's decision on costs, but there is an agreed note of what she said. She is recorded as saying 'D has forced C to come to court to obtain interim relief to which I found it is entitled. D could have agreed to interim relief of this nature and must take the costs consequences. RRR claimed to have paid £30,000 for work on documents and for attending the hearing. The Judge described the costs as being 'incredibly high figures'. She ordered BSI to pay the costs but that the costs should be the subject of a detailed assessment.

*The Judge's refusal of permission to appeal*

51. The Judge refused permission to appeal. She did not think that the appeal had reasonable prospects of success or that there was a compelling reason for it to be heard. Her view was that it was 'significant' that BSI had conceded in its skeleton argument, on the basis of Chamberlain J's conclusion that RRR's grounds of challenge disclosed 'a prima facie case that the decision was unlawful, sufficient to call for an answer' that RRR had 'passed the merits threshold, for the purposes of the first stage of the test in *American Cyanamid*…'. She added that, in the light of that concession, she had been able to 'deal with the grounds relatively briefly. Whilst accepting that some of the grounds were stronger than others, I was satisfied that there was a serious question to be tried. The contentious issue was the balance of convenience'. She had weighed 'the competing considerations' and had concluded, in the exercise of her discretion, that the balance of convenience lay 'in favour of preserving the status quo by the grant of interim relief…' She had made the mandatory order requiring BSI to renew the certificate before it expired because the expiry of the certificate would 'defeat the objective' of the interim relief if the certificate were not renewed. BSI had not been able at the hearing, 'to confirm how it could best give effect to the Court's intention to preserve the status quo…'

*The parties' submissions*

*BSI*

52. BSI's case on this appeal was that several principles governing the grant of interim relief against a public body in a case were not in dispute before the Judge. That seems to be confirmed by paragraph 13 of RRR's skeleton argument for this appeal, which refers expressly to *R (Governing Body of X) v Office for Standards in Education* [2020] EWCA Civ 594; [2020] EMLR 22 (paragraph 66, per Lindblom LJ) ('the *OFSTED* case').

53. BSI submitted that there are three initial questions.
    i. Is there a serious issue to be tried?
    ii. Would damages be an adequate remedy if an injunction were refused/granted?
    iii. If not, what is the balance of convenience?

54. Three factors in particular are significant in the assessment of balance of convenience when a public authority exercises powers in a health-related context.
    i. The court will not readily restrain a public authority from exercising its powers in good faith (*R (Association of British Insurers) v Lord Chancellor* [2017] EWHC 106 (Admin) (paragraph 61) and *R v Ministry*

*of Agriculture, Fisheries and Food ex p Monsanto Plc* [1999] QB 1161 per Rose LJ at page 1173E).

ii. If the claim does not disclose a 'strong prima facie case' that will weigh against the grant of an injunction: the *OFSTED* case (paragraph 66, per Lindblom LJ).

iii. The protection of public health is 'a very important objective and must carry great weight' (*R v Secretary of State for Health ex p Eastside Cheese Co* [1999] CMLR 12, paragraph 43, per Lord Bingham LCJ; *R (British American Tobacco UK Limited) v Secretary of State for Health* [2016] EWCA Civ 1182; [2018] QB 149, paragraph 196, per Lewison LJ, and *R (Dolan) v Secretary of State for Health and Social Care* [2020] EWHC 3857 (Admin), paragraphs 26 and 27, per Swift J.

55. The court will be slow to grant a mandatory order to compel a public authority to act in a way which it considers to be contrary to public interest. A strong prima facie case must be shown: *De Falco v Crawley Borough Council* [1980] QB (CA) 460 at page 481. This is not part of the assessment of balance of convenience, but is a threshold test for the grant of a mandatory order against a public authority.

56. A court will not interfere with the exercise of the court's discretion to grant interim relief unless the judge has erred in law, misunderstood the evidence, or, occasionally, even if no express error can be detected, if the 'decision to grant or refuse the injunction is so aberrant that it must be set aside on the ground that no reasonable judge regardful of his duty to act judicially could have reached it' (*Hadmor Productions v Hamilton* [1983] AC 191 at page 220B-220 C-E, per Lord Diplock).

57. The first ground of appeal is that the Judge misunderstood both the burden of proof under the relevant regulations, and what it was that has to be proved. She was wrong to decide that 'there is no evidence that the device is a current risk on health and safety grounds'. That was an error of law. First, BSI does not have to satisfy the court that the device is unsafe; RRR, rather, has to satisfy BSI that the device is safe. Mr Johnston relied on regulations 8 and 9(2) of the relevant regulations and Annex X (see paragraphs 27, 28 and 36, above). He submitted that, at every relevant stage, the manufacturer must show that the essential requirements are met. If it cannot do so, that itself is a safety concern. BSI will not authorise the sale of a device unless the manufacturer has shown that the device works and is safe '(in the sense that all risks have been identified and minimised)'. BSI does not ask whether a device is unsafe; it asks whether the manufacturer has shown that it has met all the essential requirements. Had the Judge understood the burden of proof correctly, and what had to be shown, she would have reached the opposite conclusion on interim relief.

58. The subsidiary points on which the Judge relied do not remedy these linked errors. First, BSI had not said that it would allow the device to be sold for a further 90 days. It had said, instead, that if RRR provides the CAPs for which BSI has asked, it might allow RRR to sell the device. BSI has not made any decision about this, because RRR has refused to provide CAPs which would address the disputed issues.

59. Second, the fact that BSI had certified the device in the past is not material, or barely material. The original certificate was the result of a limited review because the device had been certified in Germany. BSI then did a detailed file review when the MHRA

identified serious concerns. BSI has now done a full review of the technical file and has decided that there is not enough clinical evidence to show that the device is effective and safe, or that it is clinically equivalent to other devices. The earlier certificate is, in effect, water under the bridge. The Judge overstated the significance of the earlier certificate. It does not show that the relevant requirements are met. The fact that the device is certified elsewhere is also irrelevant. RRR's case rests on the asserted equivalence of the device to another defibrillator which is on the market. That is something which must be shown by evidence. That certification, if relevant to the balance of convenience, points against the grant of an injunction, as it would enable RRR to sell the device elsewhere.

60. A speedy trial has been ordered, and it may well be listed for June. If BSI's decisions turn out to have been unlawful, RRR will only be prevented from selling the device in the United Kingdom for about two months. RRR could market the device under the CE certificate, unless the MHRA takes any steps in that regard, or RRR could apply to another approved body for a certificate. BSI's decisions will have a commercial effect on RRR, but if RRR is right, and those decisions are unlawful, it should be easy for RRR to dispel any doubts about the device which other regulators might have as a result of the decisions.

61. The Judge was also wrong to hold that the public interest would be damaged if 'a life-saving innovative product' were lost. The market in such devices is very competitive and there are other portable defibrillators on the market, including the device to which RRR claimed that the device is equivalent (the Philips HeartStart HS1). I add here that the MHRA agreed with that proposition at the hearing of this appeal.

62. Ground 2 is that the Judge was wrong to grant a mandatory injunction, for four reasons. First, the principle that a public authority should not be restrained from discharging its functions in good faith applies a fortiori to a mandatory order which requires a public authority to act in a way which it considers unsafe and contrary to the public interest. Second, the Judge did not find that RRR had a strong prima facie case. Third, the harm which RRR would suffer would be considerably less if its certificate is not renewed. Fourth, the mandatory order puts RRR in a better position than it would have been in without the litigation. It also puts BSI in an invidious position, because it forces BSI to renew the certificate when it is not currently satisfied that the device is safe.

63. The third ground of appeal challenges the order for costs. The order pre-empted the decision on the lawfulness of the BSI's decisions. RRR has not yet got all the relief it claims in the application for judicial review. The Judge should have reserved the costs of the interim application until the outcome of the claim was known. BSI relies on *M v Croydon London Borough Council* [2012] EWCA Civ 595; [2012] 1 WLR 2607 ('*M v Croydon*') and *R (Naureen) v Salford City Council* [2012] EWCA Civ 1795; [2013] 2 Costs LR 257) ('*Naureen*').

*RRR*

64. RRR submitted that BSI's appeal was an attempt to have 'the proverbial "second bite of the cherry"'. The Judge did not err in law and there was simply a disagreement

about where the balance of convenience lay. The need to show a 'strong prima facie case' is not a gateway test for the grant of interim relief: '…as this case illustrates, where the strength of the case is considered within the [balance of convenience], adding a gateway for mandatory relief adds nothing to the overall assessment' (skeleton argument, paragraph 15). RRR nevertheless accepted (skeleton argument, paragraph 22) that a judge should assess whether there is a 'strong prima facie case' in evaluating the balance of convenience, not as a 'condition precedent' or 'gateway' but when considering what relief to give, including mandatory relief.

65. RRR submitted that *De Falco* had been doubted in some first instance decisions. Lord Hoffmann said in *National Commercial Bank Jamaica Limited v Olint Corporation Limited* [2009] UKPC 16; [2009] 1 WLR 1405 that when a court considers the balance of convenience an attempt to distinguish between prohibitive and mandatory injunctions is 'barren': although 'the features which ordinarily justify describing an injunction as mandatory are often more likely to cause irremediable prejudice than' cases in which a defendant is stopped from doing something (paragraphs 19-21).

66. What is now the first ground of appeal, RRR argued, is based on a selective approach. It is an over-simplification of the claim and was rightly dismissed by the Judge. BSI had certified the device in 2022 and had unreasonably changed its position in 2024. It did not give RRR a fair opportunity to address it on the issue. Ground 1 is a disagreement with the Judge's assessment of the balance of convenience. It is factually accurate to say that BSI had not found any evidence that the device is unsafe. In any event, if there were any safety concerns, the Judge had rightly noted that they could be addressed by the MHRA.

67. Mr Heppinstall nevertheless accepted in oral argument that a manufacturer could only get a certificate if it met the obligations described in regulation 13(3) of the relevant regulations (see paragraph 29, above). He also submitted, by reference to Annex I of the relevant regulations, that the 'central test is whether there is a positive risk/benefit balance'. It is never possible to say that a device is 'safe' or 'unsafe'. Section 6.a, which requires a clinical evaluation in accordance with Annex X is 'central' to the dispute (see paragraphs 32-33, above). He accepted that if RRR made a claim under Annex I, that claim had to be true.

68. BSI had assumed that the device was equivalent to the Philips HeartStart HS1 and had then decided that it was not equivalent. The moment it was not equivalent, RRR had to 'reinvent the wheel'. It had relied on the data for the Philips HeartStart HS1 and now it had to provide its own data. The device was clinically equivalent because it generates the same clinically equivalent waveform as the rest of the devices on the market. The significant factor is the current generated by the device. The reason for certification by equivalence was to avoid testing the same product over and over again. The device generates the same clinically significant peak to peak current as the Philips HeartStart HS1. The market response to the loss of the certificate would be very significant.

69. The Judge was not there to decide whether or not RRR complied with the regulatory requirements, but simply to apply the test in *American Cyanamid*. That involves the exercise of an equitable jurisdiction. If the Judge had concentrated on the legal merits, she would have fettered her wide equitable jurisdiction. RRR's submissions showed

a 'category error'. Mr Heppinstall appeared to accept that the Judge had not assessed the strength of RRR's legal argument when considering the balance of convenience. His response was that that was not an error of law and the Judge could not be 'hide-bound' by the legal regime or by one concept of public safety when considering balance of convenience. '*American Cyanamid* cannot be that narrow'. If BSI was right, public safety would always be a trump card, even when the process, as here, was unlawful. RRR accepted that the strength of the claim is relevant to the balance of convenience. Mr Heppinstall also accepted that the Judge had not gone further than asking whether there was a serious issue to be tried. She had, in any event, accepted his submission that the device was 'life-saving'. This is not quite right, as the last sentence of paragraph 21 of the judgment is qualified by the phrase 'if, as Mr Heppinstall submits' (see paragraph 43, above).

70. He accepted that the public interest was relevant, and that if there is a 'weighty public interest' that is a 'trump card'. If there was evidence that the device 'kept electrocuting people, I would not be here'. RRR's 'equivalence stool had been kicked over and it does not have the clinical data', although that was 'on its way'. He used the phrase 'equivalence stool' more than once in his submissions.

71. The Judge was also entitled to make the mandatory order. Mr Heppinstall nevertheless accepted that the grant of what was, in effect, a mandatory quia timet injunction was a completely new step. It was 'utterly unreal' to suppose that RRR could 're-create the clinical evidence' in a short time. It was wrong to say that RRR had not supplied a CAP, as RRR had provided CAPs 'on some things'. RRR's preference was a confidential arbitration. Equivalence is 'designed' to get innovative products on the market while the manufacturer gets data. The purpose of the mandatory injunction was to support the prohibitive injunction. Without the mandatory injunction, the prohibitive injunction would be in vain. It was 'novel but appropriate'.

72. His submission on ground 3 was that costs generally follow the event. Decisions about costs are discretionary. The Judge was right to order BSI to pay the costs of the application for the reasons which she gave. Mr Heppinstall accepted, nevertheless, that the order was an 'unusual exercise of discretion'.

*The MHRA*

73. By the date of the hearing of the application for interim relief, the MHRA had not yet exercised any of its relevant powers. It had been keeping the device under 'active review'. By the time of the appeal, the MHRA had 'identified potential safety and performance issues with [the device]'. It had written to RRR on 9 April 2024 to ask it voluntarily to suspend sales of the device, while the MHRA considered those questions. It invited RRR to provide it with 'any data, relevant technical information, or interim clinical investigation data' on which it wanted to rely. In its skeleton argument, the MHRA described RRR's response to its letter of 9 April as 'ill-tempered', for the reasons given in paragraph 11 of that skeleton argument. It is not necessary for me to describe those reasons in this judgment. RRR did not agree voluntarily to suspend sales of the device. The MHRA's position is that it will keep the device under review.

*Discussion*

74. I have already indicated that I would give BSI permission to appeal. All the grounds of appeal are arguable.

75. There are three issues on this appeal.
    i. What is the nature of the court's jurisdiction to grant interim relief on an application for judicial review? Did the Judge apply the relevant principles (ground 1)?
    ii. What is the court's approach, on an application for judicial review, to the grant of a mandatory injunction requiring a decision-maker to make a particular decision? Did the Judge apply the relevant principles (ground 2)?
    iii. What is the court's approach to ordering a defendant who has unsuccessfully resisted an application for interim relief to pay the costs of that application in any event? Did the Judge apply the relevant principles (ground 3)?

*Ground 1*

76. Mr Heppinstall referred repeatedly during his submission to the court's equitable jurisdiction to grant an injunction. When the court grants an injunction in the course of an application for judicial review, it does not exercise an equitable jurisdiction. The court's jurisdiction in judicial review is derived from its powers in relation to the prerogative writs. It is now found in section 31 of the Senior Courts Act 1981 ('the 1981 Act'). It is true that, when considering whether or not to grant interim relief in an application for judicial review, the court applies the principles in *American Cyanamid* by analogy. That fact, does not, by a form of reverse logic, mean that when the court does so, it is exercising a free-standing equitable jurisdiction. It is exercising the powers described in section 31. It applies private law principles to that exercise by analogy.

77. I therefore reject Mr Heppinstall's submission that the Judge was not 'hide-bound' by the legal framework, or by a particular view of public safety. She was required to approach all the relevant questions in the context of the regulatory framework which applies to the sale of medical devices. She had to ask whether there was a serious legal issue to be tried in that framework, and if so, as part of the balance of convenience, she had to consider the strength of RRR's legal arguments, again, in that framework. Mr Heppinstall was right effectively to accept that the Judge had not answered the second of those questions. In failing to answer that question, she erred in law.

78. Two cases about the public interest and the balance of convenience were cited to the Judge (see paragraph 54.i., above). I note that the observations in the first case were obiter, as Andrew Baker J refused permission to apply for judicial review. The *Monsanto* case was a very different case from this case, and the relevant observations might also be considered to have been obiter.

79. Paragraph 12 of the judgment of Cranston J in the *Medical Justice* case is more clearly in point, other things being equal, even though it was a challenge to the lawfulness of an executive policy, not a challenge to a particular decision taken in the exercise of powers conferred by secondary legislation. It supports the obvious

proposition that the court will not readily restrain a public authority in the exercise of its functions. He clearly distinguished between the gateway to the assessment of the balance of convenience ('Is there a serious question to be tried?') and the issues which are relevant to the assessment of that balance. He pointed out that damages are not generally payable in applications for judicial review and that a public authority will not suffer financially if it is stopped from implementing its policy. He said 'The public interest is strong in permitting the public authority to continue to apply its policy when ex hypothesi it is acting in the public interest'. That interest cannot simply be measured by reference to 'financial or individual consequences to the parties'. He cited the judgment of Browne LJ in *Smith v Inner London Education Authority* at [1978] 1 All ER 411 at page 422h. He pointed out that the weight to be given to the public interest in part turns on the juridical basis of the policy, by reference to *R v Secretary of State for Transport ex p Factortame* [1991] AC 603 at page 674C-D. Lord Goff there referred to 'apparently authentic law'. He took three factors into account in his decision in that case to grant interim relief (judgment, paragraphs 15 and 16). A challenge to an executive policy is closer to a challenge to a particular decision than it is to a challenge to primary or delegated legislation.

80. The Judge accepted, in paragraph 17, that this consideration was relevant, but there is no sign that she took it into account in her assessment of balance of convenience, and in this respect, she also erred in law.

81. Mr Heppinstall accepted that RRR's claims in support of its application for a certificate had to be true. He was right to do so. I accept Mr Johnston's submission that the Judge reversed the burden of proof, and wrongly asked whether BSI had shown that the device was 'a current risk on health and safety grounds'. The question for her, rather, was whether, on the available material, it was arguable to the relevant extent that BSI had erred in law in suspending the certificate because it was no longer satisfied that the device met the essential requirements. That approach is supported by BSI's power to require relevant information from the manufacturer (regulation 47(2)), and the terms of the duty imposed on BSI by regulation 47(4) (see paragraph 31, above), by the duty imposed on the manufacturer by paragraph 4.2 of Annex V (see paragraph 35, above), and by the obligation imposed by Annex V which I describe in paragraph 36, above.

82. The Judge's approach was wrong in law in two respects. First, she gave decisive weight, in paragraph 21, to the commercial damage which the suspension of certificate would inflict on RRR. Second, she balanced, against that damage, BSI's 'power to prevent RRR from operating in the UK'. She relied on the lack of direct evidence that the device is unsafe, and on the facts that BSI had allowed the device to be sold while the CAP requirements were being implemented, and that it had previously been certified: 'Certification denotes that the requirements of safety and efficacy have been met'. She should have put, on the other side of the balance, BSI's concern, on the basis of a more detailed review, that RRR had not shown that it met the essential requirements. None of the factors on which the Judge actually relied was relevant to the correct balance. In fairness to the Judge, she might have meant was that there was no evidence that the device was actually dangerous. That might have been relevant on different facts, but in this case, I consider that she should have given that factor little or no weight, as there was an alternative device on the market which did meet the regulatory requirements.

83. It is true that in the *Eastside Cheese* case (see paragraph 54.iii., above), there was a direct link between cheese sold by the applicant and the admission to hospital of a child suffering from E-coli. It was also a case in which the effect of the measure which was challenged was to 'paralyse' the applicant's business, and to interfere with the business of other companies. I accept, also, that some risks to public health and safety are self-evidently more serious than others, and should be given greater weight in the balance of convenience than others. That case is not authority for the proposition, however, that, if there is commercial damage to a claimant, it is only where a regulator shows that there is a direct and serious risk to health that interim relief will be refused.

84. The underlying principles which apply to the facts of this case are, first, that great weight must be given to the protection of public health, and, second, in this regulatory framework, that the manufacturer must satisfy the approved body that a device is safe and effective. A third principle is that the court should also give great weight to the assessment of the relevant material by the expert regulator. Mr Heppinstall's oral submissions on this appeal came close to an acceptance that RRR did not have the material to satisfy BSI that the device was safe and effective.

85. The Judge's errors of law mean that this court must exercise the relevant discretion afresh. In short, the commercial damage which RRR feared was obviously outweighed by BSI's concern that RRR had not provided it with material to satisfy it that the device was safe and effective and that another relevant device was available (see paragraph 82, above). It follows that there should be no interim relief. I also consider, for what it is worth, that had the Judge assessed the balance of convenience correctly, she would have been bound to conclude that it favoured the refusal of interim relief.

*Ground 2*

86. There are three sub-issues in ground 2.
    i. Has *De Falco v Crawley Borough Council* been overruled in later cases?
    ii. What are the court's powers when it quashes a decision?
    iii. Did the Judge err in law in making a mandatory order?

*i. Has De Falco v Crawley Borough Council been overruled in later cases?*

87. Mr Heppinstall suggested that the approach in *De Falco* is no longer good law. He did not identify any case in which it had been overruled, but relied on some obiter observations in one case in this court, first instance decisions in the Administrative Court and two decisions in private law cases. One of the first instance decisions, which concerned a dispute about age assessment, is not relevant, as such disputes are a rare example of disputes in which the Administrative Court (or the Upper Tribunal) makes a factual decision on an application for judicial review, and, as a result, the test for granting permission to apply for judicial review in such cases is different from the test in most public law cases. I do not accept his submission that the cases on which he relied show that *De Falco* is no longer good law.

*ii. What are the court's powers when it quashes a decision?*

88. The position at common law, broadly, was that if the court quashed a decision, it would remit the case to the decision-maker for the decision-maker to reconsider the

case, even when the answer was obvious (*Barnet London Borough Council ex p Shah* [1983] 2 AC 309). Parliament has now somewhat changed that position. Section 31(5)(b) of the 1981 Act gives the court a limited power, when it makes a quashing order, to substitute its own view for that of the decision maker. The court may only exercise that power, however, when the quashed decision is that of a court or tribunal, and, without the error, the court or tribunal could only have reached one decision (section 31(5A)). On conventional principles of statutory construction, that express limitation means that it is not open to a court, when it makes its decision on the merits of an application for judicial review in cases in which the defendant is not a court or tribunal, to quash a decision and substitute its own view for that of the decision-maker.

*iii. Did the Judge err in law in making a mandatory order?*

89. Neither counsel could think of a case in which a court has, without deciding whether or not a public authority has acted unlawfully in relation to a decision which is challenged in existing proceedings, required a public authority to exercise a power on a future occasion in a particular way. As I have just explained, even when it has quashed a decision because it is unlawful, a court has limited powers to usurp the powers of a public authority by making a particular decision, which, in normal circumstances, it would be for the public authority to make in the future, after remittal by the court. A fortiori, a court has no such power when it has not even decided that the decision which is under challenge is unlawful. In this case, no future decision had been made, and no decision about its lawfulness could therefore be made. The Judge erred in law in making the mandatory order in this case. What is more, there are no circumstances in which such an order would be lawful.

*Ground 3*

90. When the Judge made the costs order, she did not yet know whether or not RRR would succeed in its challenge to the decisions. The only factor on which she relied was that BSI could have agreed to the application for interim relief and the hearing would then not have been necessary. With the exception of cases which are so urgent that the claimant does not have time to engage with the defendant before applying for interim relief, that is always a factor in applications for interim relief.

91. In *M v Croydon* this court rejected an argument that the general approach to costs in judicial review claims and in private law claims was different. The normal rule in judicial review is that a party who obtains the relief he seeks, whether by consent, or after a hearing, is the successful party and is entitled to his costs.

92. A successful application for interim relief is not, however, to be equated with success overall in an application for judicial review, so that if the claim is later withdrawn without any concession from the defendant, that success is not a reason for ordering the defendant to pay all the costs of the application for judicial review (*Naureen*, paragraph 44 per Jackson LJ, and see also *Shahi v Secretary of State for the Home Department* [2021] EWCA Civ 1676; [2021] Costs LR 1397). It is obvious that, on an application for interim relief, the court is not deciding the merits of the claim, and is in no position to assess them. Indeed the Administrative Court sometimes grants interim relief without deciding whether or not the claim is sufficiently arguable for the grant of permission to apply for judicial review (see, for example, *Naureen* and

*Shahi*). Nor had the Judge in this case decided to give permission to apply for judicial review.

93. As RRR had not succeeded in the claim overall, the Judge was wrong in principle to order BSI to pay the costs of the interim relief hearing in any event. She should, instead, have reserved those costs until the outcome of the application for judicial review.

*Conclusion*

94. For these reasons I would allow the appeal on all three grounds.

**Lord Justice Snowden**

95. I agree with Elisabeth Laing LJ and Nugee LJ that the appeal should be allowed. I agree with and have nothing to add to their judgments on Grounds 2 and 3. I would, however, wish to add my own observations on Ground 1 as to why I consider that the Judge erred in her evaluation of the balance of convenience.

96. The authorities to which Elisabeth Laing LJ has referred at [54] above highlight two factors that are particularly important in determining where the balance of convenience lies in a public law case,

a. that the court will not readily restrain a public authority from exercising its powers in good faith, so that even if a claim passes the threshold test of raising a serious issue to be tried, if there is not a strong prima facie case on the merits, this will be a significant factor in the balance of convenience against the grant of an injunction; and
b. that maintenance of public health is a very important objective and must carry great weight in the balancing exercise.

97. It is likely that the Judge had the first of these factors in mind at [17] of her judgment when concisely summarising the legal principles on determining the balance of convenience. However, I agree with Elisabeth Laing LJ that there is no obvious sign that the Judge then actually took the strength or weakness of RRR's challenge into account when carrying out the balancing exercise in the remainder of her judgment. In particular, there is no indication that the Judge gave any weight to the fact that under the relevant regulatory regime, it is RRR that carries the burden of satisfying BSI that the device meets the essential requirements in Annex 1 of Council Directive 93/42/EEC, so that it will be for RRR to make good its case that BSI acted unfairly or irrationally in not being satisfied that such requirements are met. It will not be for BSI to prove that the device is unsafe or does not work.

98. It is clear that the Judge did have the second factor identified in [96] above well in mind, since at the start of [22] of her judgment she stated that "Public health and safety is obviously a paramount concern".

99. I would readily accept that the absence of any evidence that the device was positively dangerous to use (e.g. that it would explode or electrocute the user) was a relevant factor in the balance of convenience pending the determination of RRR's challenge. If that is what the Judge meant by her comments in [22] that "… there is no evidence

that the device is a current risk on health and safety grounds", and "BSI has not identified any direct evidence that the device is unsafe", for my part I think that she was entitled to take that into account.

100. However, given the nature of the device, a proper evaluation of "public health and safety" in the balance of convenience pending determination of RRR's challenge should also have included the issue of whether the device is effective, coupled with whether there are alternative certified products available for purchase in the interim which have been demonstrated to work to the required standard.

101. In that regard, if the device had been the only defibrillator on the market, and there was no evidence that it was positively dangerous, then the fact that BSI was not satisfied that it would work when used might carry less weight in the balance. It might well be thought to be better in the interests of public health and safety for there to be a chance that the device might work and save a life, than for there to be no opportunity for a defibrillator to be used at all. But that is not this case.

102. The evidence before the Judge was that there are alternative certified products currently available, not least because the existing certification of the device was on the basis that it is equivalent to another approved defibrillator. As such, a weighty factor in the interests of public health and safety which was missing from the Judge's analysis is that until RRR's challenge is resolved, a would-be purchaser should only be able to buy a certified defibrillator that the BSI is satisfied will work to the required standard when needed, since a life may depend upon it.

**Lord Justice Nugee**

103. I am very grateful to Elisabeth Laing LJ for setting out the position so clearly, and I will adopt the same abbreviations as her. I agree that the appeal should be allowed for the reasons she gives. I add some comments on each of the grounds of appeal.

104. Ground 1 concerns the approach of the Administrative Court to the grant of interim relief in the form of a normal (prohibitory) injunction. In private law cases the three-stage approach of the Court to the grant of an interim injunction has been settled since *American Cyanamid v Ethicon Ltd* [1975] AC 396. The basic principle is that so long as there is a serious issue to be tried, the Court should take the course which seems likely to cause least irremediable prejudice if it turns out that the injunction should not have been granted (or withheld, as the case may be). This will depend on the extent to which the party who is ultimately successful can be compensated, either (if a successful claimant is not granted an injunction at the interlocutory stage) by an award of damages, or (if a successful defendant has an injunction granted against them at the interlocutory stage) under the cross-undertaking: see the summary by Lord Hoffmann in *National Commercial Bank Jamaica Ltd v Olint Corpn Ltd* [2009] UKPC 16, [2009] 1 WLR 1405 at [16]-[18]. In practice in many cases, at any rate in commercial disputes, the interests of both parties are ultimately financial ones, and the balance of convenience will involve assessing the respective risks to their financial interests accordingly.

105. Public law disputes are of course rather different. Those who exercise public law functions do not do so in their own commercial interests but in the public interest.

This is seldom capable of being quantified in money. Two things follow. First, as the Judge recognised, damages will rarely be an adequate remedy in the context of judicial review claims, and (assuming the case meets the threshold at the first stage) the grant or withholding of relief will turn on the balance of convenience. Second, in assessing the balance of convenience the risk of detriment to the public interest is seldom capable of being directly measured against the risk of prejudice to the claimant as the two are essentially incommensurable. These points were well expressed by Cranston J in the *Medical Justice* case at [12] as follows:

> "In judicial review, this consideration [ie the balance of convenience] varies from its application in private law, because generally speaking damages will not be payable in the event of an unlawful administrative act, nor will a public authority suffer financial loss from being prevented from implementing its policy. The public interest is strong in permitting a public authority to continue to apply its policy when ex hypothesi it is acting in the public interest. That wider public interest cannot be measured simply in terms of the financial or individual consequences to the parties, a point made by Browne LJ in his judgment in *Smith v Inner London Education Authority* [ie [1978] 1 All ER 411] at page 422h."

106. In those circumstances two principles are established by the authorities. First, as Cranston J says, there is a strong public interest in not restraining a public body from exercising its powers. Hence the Court will generally be reluctant to grant interim relief where there is not a strong prima facie case: see the *OFSTED* case at [66] per Lindblom LJ. And second, where the public interest concerned is that of public health and safety, this is a very important objective and one that must carry great weight: see the cases cited by Elisabeth Laing LJ at paragraph 54(iii) above.

107. The Judge duly accepted that "Public health and safety is obviously a paramount concern" (paragraph 22). But she went on to say that there was no evidence that RRR's device was a current risk on health and safety grounds, and that BSI had not identified direct evidence that the device was unsafe.

108. That I think underplayed the thrust of BSI's case, and the concerns identified by it. These were summarised in the executive summary of its assessment report as being that the technical documentation provided "fails to identify evidence in full of meeting all essential requirements which apply to the device". As has been explained by Elisabeth Laing LJ (see paragraph 24 and 27 above) the "essential requirements" are those set out in Annex I of the relevant Directive (in this case Council Directive 93/42/EEC). This includes a requirement that the device must achieve the performance intended by the manufacturer. In simple terms the device must be shown to work.

109. I think BSI is right that a failure to provide sufficient evidence that a medical device such as RRR's works as intended is a matter that engages the strong public interest in public health and safety. There was some debate before us as to the extent to which it is appropriate to describe a device that has not been shown to be effective as unsafe:

the Judge is clearly right that this is not the same as positive evidence that a device may actively harm someone in use, but I do not think that means there are no (or only minor) potential risks to public health and safety in a device which has not been shown to work effectively. The point was nicely illustrated by Mr Leary for the MHRA, who said that if an inflatable paddling pool fails to inflate it may be a disappointment, but if an inflatable life raft fails to inflate when needed, it is self-evidently rather more serious. Similarly a device such as RRR's is only likely to be used in an emergency in order to save life, and if it does not then work it is too late to obtain an alternative. RRR of course maintains that BSI's concerns are misplaced and that its device works perfectly well, but BSI has taken the view that that has not yet been adequately demonstrated, and at this stage of the proceedings it is impossible to resolve who is right.

110. In those circumstances I agree that the Judge's assessment of the balance of convenience was flawed as she appeared to attach no significant weight to the paramount concern of public health and safety. I would therefore allow the appeal on Ground 1.

111. On Ground 2, I agree that it is a novel proposition that the Administrative Court can require a body exercising public functions to exercise them in a particular way when that body has not yet made a decision, let alone made a decision that is said to be flawed. I am reluctant to say that this can *never* be done as it is seldom sensible to say never, and in the light of our decision on Ground 1 the question does not in fact arise in the present case. But it is not easy to envisage the circumstances in which such an order would be appropriate.

112. Quite apart from this point, I would have allowed an appeal on Ground 2. I agree with Elisabeth Laing LJ that *De Falco* requires that a "strong *prima facie* case" be shown for the grant of a mandatory order against a public authority; that this is a threshold requirement not simply a matter of the balance of convenience; and that we are not justified in treating *De Falco* as no longer good law (see paragraphs 55 and 86 above). In the present case the Judge did not find such a strong case before making the mandatory order. All she said about the merits of the judicial review was (at paragraph 20):

> "Whilst some of the claimant's points are stronger than others, I am satisfied that the claimant has demonstrated that there is a serious question to be tried."

That seems to me quite a long way short of what was required by *De Falco*.

113. So far as Ground 3 is concerned, I again agree with Elisabeth Laing LJ. A parallel can be drawn with the practice on the grant of interlocutory relief in private law. Where an interlocutory injunction is granted on the basis of the balance of convenience for the purpose of holding the ring until trial, the costs of the application will usually be reserved: see *Civil Procedure (The White Book) 2024* §44.2.15.1 and cases there cited, particularly the decision of Neuberger J in *Picnic at Ascot v Kalus Derigs* [2001] FSR 2, which has been approved by this Court more than once. This is not of course an absolute rule as costs are always discretionary and cases vary

infinitely, but a Court should have some reason for departing from the usual order. In the present case all that the Judge is reported as saying is that:

> "D has forced C to come to court to obtain interim relief to which I found it is entitled. D could have agreed to interim relief of this nature and must take the costs consequences."

That can always be said where a judge grants an interlocutory injunction and does not indicate any unusual feature which justified departing from the normal position. In those circumstances I would have allowed the appeal on Ground 3 as well, even without our decision on the other grounds.