Case No: C1/2019/0779

Neutral Citation Number: [2019] EWCA Civ 1211
IN THE COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE QUEEN'S BENCH DIVISION
ADMINISTRATIVE COURT
(MR JUSTICE SUPPERSTONE)

The Royal Courts of Justice
Strand, London, WC2A 2LL

Friday, 10 May 2019

Before:

LORD JUSTICE HICKINBOTTOM
and
SIR STEPHEN RICHARDS

- -

Between:

THE QUEEN ON THE APPLICATION OF GOOD LAW PROJECT LIMITED **Applicant**

- and -

SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE

Respondent

- -

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(Official Shorthand Writers to the Court)

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Mr Stephen Knafler QC, and Yaaser Vanderman appeared on behalf of the **Applicant (instructed by Deighton Peirce Glynn Solicitors)**

Sir James Eadie QC, Sarah Wilkinson and Saara Idelbi appeared on behalf of the **Respondent (instructed by the Government Legal Department)**

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Judgment

(As Approved by the Court)

SIR STEPHEN RICHARDS:

1. This is an application for permission to appeal the order of Supperstone J made on 29 March 2019 by which he refused permission to apply for judicial review of the making of regulation 9 of the Human Medicines (Amendment) Regulations 2019 ("the 2019 Regulations"). Regulation 9 amends the Human Medicines Regulations 2012 ("the 2012 Regulations") by the insertion of a new regulation 226A concerning the sale or supply of prescription only medicines by retail pharmacists in accordance with a Serious Shortage Protocol ("SSP") which ministers may issue in circumstances where the UK or any part of it is in their opinion experiencing or may experience a serious shortage of such medicines. Although not formally linked to Brexit, the amendment is said to have been made in preparation for the possibility of a no-deal Brexit.

2. The essence of the SSP arrangements is that where a prescription only medicine prescribed by a doctor is subject to a serious shortage, a pharmacist can dispense a different strength, quantity or pharmaceutical form of the medicine, or a different prescription only medicine, as indicated in the protocol and subject to the professional skill and judgment of the pharmacist as to the reasonableness and appropriateness of what is dispensed.

3. The concerns underlying the present challenge relate to the risks said to arise from replacing or interfering with the clinical judgment of the prescribing doctor, and bypassing the relationship between doctor and patient, through the supply of medicine by the pharmacist in accordance with a centralised protocol rather than by the pharmacist contacting the doctor for the doctor to prescribe an alternative. The issues before the court relate, however, only to the lawfulness of the regulation, not to the

substantive merits of the measure. Moreover, the regulation establishes only the principle of supply in accordance with SSPs. The development of the operational detail has been left to the next stage of the process. It is contemplated, for example, that SSPs will be developed with, and signed off by, clinicians and that they may not be suitable for some high risk patients or some medicines.

4. Four grounds of legal challenge were advanced before Mr Justice Supperstone. Only one of them is still pursued. The single ground of appeal is that regulation 9 is ultra vires Directive 2001/83/EC of the 6 November 2001 on the Community code relating to medicinal products for human use ("the Directive") as well as the Medicines Act 1968. Under the umbrella of that ground it is contended first that regulation 9 is prohibited by the Directive; secondly that the Regulation falls outside the scope of section 2(2) of the European Communities Act 1972 pursuant to which it was made; and thirdly that the regulation is prohibited by section 64 of the Medicines Act 1968.

5. The application for permission to appeal was directed into open court by my Lord, Hickinbottom LJ. We have heard today from Mr Stephen Knafler QC for the applicant. The Secretary of State has chosen to be represented at the hearing, though not directed to do so. In the event it has not been necessary to hear from Sir James Eadie QC on the Secretary of State's behalf.

The legislative framework

6. The 2012 Regulations consolidate most of the previous UK legislation regulating the authorisation, sale and supply of medicinal products for human use. They give effect to, and elaborate upon, the Directive and a number of other EU directives.

7. This case concerns medicinal products classified as prescription only medicines. The classification of medicinal products is governed by Title VI of the Directive. Within that title, article 70 provides that when a marketing authorisation is granted for a medicinal product, the competent authorities must specify the classification of the product into (i) a medicinal product subject to medical prescription or (ii) a medicinal product not subject to medical prescription. A medicinal prescription (which I take for today's purposes to be the same as a medical prescription) is defined by article 1(19) as "any medical prescription issued by a professional person qualified to do so". The process of classification is governed by the criteria laid down by article 71: for example, medicinal products are to be subject to medical prescription where they are likely to present a danger if utilised without medical supervision. I will refer to further provisions of article 71 when considering the first issue.

8. The classification requirement is transposed into UK national law by regulation 5 of the 2012 Regulations. Regulation 5(3) provides that references in the Regulations to a prescription only medicine are to a medicinal product that is covered by an authorisation of which it is a term that the product is to be available only on prescription, or to a medicinal product that is classified as prescription only by various other routes.

9. Part 12 of the 2012 Regulations is headed "Dealings with medicinal products". Chapter 2 of Part 12 concerns the sale and supply of medicines. It provides by regulation 214(1) that: "A person may not sell or supply a prescription only medicine except in accordance with a prescription given by an appropriate practitioner". By paragraph (7), however, "This regulation is subject to Chapter 3 (exemptions)".

10. Prior to the amendment made by the 2019 Regulations, Chapter 3 of the 2012 Regulations already contained numerous exemptions, including various exemptions for emergency supply by pharmacists and exemptions for supply in accordance with a patient group direction.

11. The challenged regulation 9 of the 2019 Regulations inserts a new regulation 226A into the list of exemptions. It reads as follows:

> "(1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business if conditions A, B and C are met.
>
> (2) Condition A is that the prescription only medicine is sold or supplied for the purpose of being administered to a person in accordance with a serious shortage protocol (SSP).
>
> (3) Condition B is that the requirements of the SSP are satisfied in respect of to whom, and subject to what conditions, the prescription only medicine may be sold or supplied for the purpose of being administered.
>
> (4) Condition C is that the sale or supply of the prescription only medicine is by or under the supervision of a pharmacist who is of the opinion, in the exercise of his or her professional skill and judgment, that—
>
> (a) in a case to which paragraph (5)(b)(i) applies, the sale or supply of a different strength, quantity or pharmaceutical form of the prescription only medicine to the strength, quantity or pharmaceutical form of the prescription only medicine ordered by the prescriber is reasonable and appropriate; or
>
> (b) in a case to which paragraph (5)(b)(ii) applies, the sale or supply of—
>
> (i) a prescription only medicine other than the prescription only medicine ordered by the prescriber is reasonable, and

(ii) the substituted prescription only medicine, in accordance with the directions for use that he or she specifies, is appropriate.

(5) For the purposes of this regulation, a SSP is a written protocol that—

(a) is issued by the Ministers … in circumstances where the United Kingdom or any part of the United Kingdom is, in the opinion of the Ministers … experiencing or may experience a serious shortage of a prescription only medicine or prescription only medicines of a specified description;

(b) provides for the sale or supply by or under the supervision of a pharmacist and subject to such conditions as may be specified in the SSP—

(i) of a different strength, quantity or pharmaceutical form of the prescription only medicine to the strength, quantity or pharmaceutical form ordered by the prescriber, or

(ii) of a prescription only medicine other than the prescription only medicine ordered by the prescriber;

(c) provides, in a case to which sub-paragraph (b)(ii) applies, that the other prescription only medicine is to be—

(i) a generic version of the prescription only medicine being substituted, or that both products are generic versions of another prescription only medicine,

(ii) in the case of a biological medicinal product, a similar medicinal product to the prescription only medicine being substituted, or that both products are similar medicinal products to another biological medicinal product, or

(iii) a prescription only medicine that has a similar therapeutic effect to the prescription only medicine being substituted; and

> (d) specifies the period for which, and the parts of the United Kingdom (which may be all of the United Kingdom) in which, the protocol is to have effect."

12. I will take the main issues in the order in which they are set out in Mr Knafler's written skeleton argument, although they have been developed in a slightly different way in his oral submissions.

Compatibility with the Directive

13. The first main issue is whether regulation 9 is in breach of the Directive. The judicial review grounds claimed do not themselves allege such a breach. They contend only that regulation 9 does not implement any obligations or rights found in an EU instrument and is not otherwise within the *vires* of section 2(2) of the European Communities Act 1972 (a separate point to which I will turn next). A breach of the Directive was however raised in the applicant's reply to the Secretary of State's summary grounds of resistance to the claim. It appears to have been touched on in argument before Mr Justice Supperstone (see paragraph 14 of his judgment), and in any event no objection has been taken to it being advanced before us in the form set out in the grounds of appeal and the accompanying skeleton argument.

14. Mr Knafler's submission may be summarised as follows. Articles 70 and 71 of the Directive, taken with the definition of medicinal prescription in article 1(19), require the UK to classify medicinal products as being subject to prescription and thereby only issuable by a professional person qualified to prescribe them when any of the criteria in article 71 are satisfied. Regulation 9 is in breach of those provisions because it allows the Secretary of State to issue an SSP and thereby to authorise pharmacists to sell

patients prescription only medicinal products otherwise than in accordance with a prescription issued by a professional person qualified to do so, such as a doctor. Neither government ministers nor pharmacists, unless they are a pharmacist independent prescriber, are professional persons qualified to prescribe medicinal products. The sale of prescription only medicinal products under an SSP is a sale to patients of such products otherwise than in accordance with a prescription issued by a professional person qualified to do so. That, in Mr Knafler's submission, is in breach of the Directive.

15. The fundamental difficulty about that line of argument is that articles 70 and 71 of the Directive lay down requirements as to the *classification* of medicinal products into those subject to medical prescription and those not so subject, not as to the conditions on which medicinal products classified as subject to medical prescription may be sold or supplied. It may be inherent in the Directive that medicinal products subject to medical prescription are as a general rule to be supplied to the public only in pursuance of a prescription, but Articles 70 and 71 do not impose either expressly or impliedly an obligation on Member States to prohibit all supplies of such products otherwise than in pursuance of a prescription. To read these classification provisions as imposing such an obligation and as depriving Member States of any discretion or flexibility in the matter would in my view be to read far too much into them.

16. Indeed, the articles themselves point to the existence of a considerable degree of discretion in this area. Whilst article 71(1) sets out the criteria governing, for the purpose of article 70(1), the classification of medicinal products that are subject to medical prescription, and article 71(2) and (3) provide for sub-categories of medicinal

products subject to special medical prescription and those subject to restricted prescription, article 71(4) states as follows:

> "4. A competent authority may waive application of paragraphs 1, 2 and 3 having regard to:
>
> (a) the maximum single dose, the maximum daily dose, the strength, the pharmaceutical form, certain types of packaging; and/or
>
> (b) other circumstances of use which it has specified."

If such a discretion exists in the competent authority of a Member State in relation to the classification of a medicinal product as subject to prescription in the first place, it would in my view be very surprising if no discretion existed for the Member State in relation to the conditions of supply of such a product.

17. In reaching my conclusion on this issue, I have also taken into account the wider context as it appears from the Directive. Recital (29) states that the conditions governing the supply of medicinal products to the public should be harmonised. Recitals (31) and (32) show that the classification provisions are themselves an aspect of harmonisation. Recital (35) states that it is necessary to exercise control over the entire chain of distribution of medicinal products from their manufacture or import into the community through to supply to the public, though the stated purpose of that recital is to guarantee that such products are stored, transported and handled in suitable conditions. Against the background of those and other recitals and the substantive provisions in the Directive, it is accepted in the Secretary of State's summary grounds of resistance that the UK must have an effective and proportionate scheme for enforcing the prescription of any medicines to the public. But it is said that this is achieved through Part 12 of the 2012 Regulations, with its basic prohibition upon the

sale or supply of prescription only medicine except in accordance with a prescription, and its list of exemptions from that basic provision, including now the exemption inserted by regulation 9. The Directive cannot in my view be read as precluding that balanced approach, and although Mr Knafler says that the exemption inserted by regulation 9 is the only exemption to allow for a pre-existing specific clinical judgment to be interfered with by a pharmacist, I see no difference of principle, so far as concerns compatibility with articles 70 and 71of the Directive, between the regulation 9 exemption and at least some of the other exemptions in the 2012 Regulations that allow sale or supply of prescription only medicines otherwise than in accordance with a prescription where carefully defined conditions are met: for example, regulation 247, which exempts supply of a medicinal product in the event or anticipation of a pandemic when the supply is in accordance with a protocol approved by the ministers or an NHS body. I accept that the lawfulness of those other exemptions is not an issue for these proceedings, but I attach weight to the fact that the impugned regulation forms part of, and is in line with, wider regulatory arrangements that have not been challenged, and I find it difficult to accept that the Directive can have the effect of prohibiting arrangements of this kind altogether.

18. Having regard to the various points to which I have referred, I would reject as unarguable the applicant's case in relation to the first main issue.

The European Communities Act 1972

19. The second main issue is whether regulation 9 is within the *vires* of section 2(2) of the European Communities Act 1972, which provides so far as material that a designated minister may make provision:

> "(a) for the purpose of implementing any EU obligation of the United Kingdom, or enabling any such obligation to be implemented, or of enabling any rights enjoyed or to be enjoyed by the United Kingdom under or by virtue of the Treaties to be exercised; or
>
> (b) for the purpose of dealing with matters arising out of or related to any such obligation or rights …"

20. The Secretary of State relies on section 2(2)(b) as the enabling power. Supperstone J found that regulation 9 plainly fell within it, on the basis that the management of shortages of prescription only medicines is a matter arising out of and related to EU obligations under the Directive to classify certain drugs as prescription only and to control their supply (see paragraph 16 of his judgment).

21. Mr Knafler submits that the judge was wrong to reach that conclusion. He cites the judgment of Lord Mance in *United States of America v Nolan* [2015] UKSC 63; [2016] AC 463, at paragraphs 59-62. In particular, at paragraph 61 Lord Mance described the relationship between subsections (2)(a) and (2)(b) of section 2, and the effect of subsection (2)(b), in these terms:

> "What can in my view be said, from the wording and positioning of these two paragraphs, is that paragraph (a) is the main vehicle for implementation of EU obligations and rights which are not directly enforceable. Paragraph (b) goes further, in authorising provision for different purposes, but those purposes are limited by reference to

> the United Kingdom's EU obligations or rights … The words 'arising out of' limit the power to provisions dealing with matters consequential upon an EU obligation or right … The further phrase 'related to any such obligation or rights', must, unless redundant, go somewhat further. But the relationship required must exist objectively; and the positioning of the phrase and its conjunction with the earlier wording of section 2(1) suggest to me … that by speaking of a 'relationship' the legislature envisaged a close link to the relevant obligation or right. A relationship cannot on any view arise from or be created by simple ministerial decision that it would be good policy or convenient to have domestically a scheme paralleling or extending EU obligations in a field outside any covered by the EU obligations. That would be to treat paragraph (b) as authorising a purpose to implement policy decisions not involving the implementation of, not arising out of and unrelated to any EU obligation."

22. In the light of those observations, Mr Knafler submits that section 2(2)(b) only authorises regulations "for the purpose of dealing with matters arising out of or related to" an EU obligation when those regulations are in furtherance of, or consistent with and closely related to, the relevant EU obligation. He refers also to the expression "tidying things up" which was used by May LJ as a partial statement of the effect of section 2(2)(b) in an earlier case as quoted by Lord Mance at paragraph 57 of his judgment in *Nolan*. Mr Knafler submits that regulation 9 is none of these things: first, because it contradicts or is inconsistent with Article 71 of the Directive, and secondly because although it creates a scheme that in the view of the Secretary of State would be good policy or convenient to have, it has a different aim and covers matters significantly beyond the scope of the Directive. The regulation therefore falls outside the powers conferred by the subsection. Mr Knafler emphasizes the constitutional point that any legislation going beyond the limits of the subsection is a matter for Parliament to decide.

23. I have held already that regulation 9 does not contradict or involve any inconsistency with the Directive. Equally in my view it does not have a different aim from the Directive or cover matters significantly beyond the scope of the Directive. The matters covered by regulation 9, namely the conditions governing supply of prescription only medicines in times of serious shortage, are in my view plainly within the field covered by the Directive and are indeed closely related to the obligations contained in the Directive. I am satisfied that the close link required by section 2(2)(b) exists in this case and that the judge was correct to dismiss as unarguable the contention that the regulation is *ultra vires* section 2(2) of the 1972 Act

The Medicines Act 1968

24. The third main issue is whether regulation 9 is prohibited by section 64 of the Medicines Act 1968. Section 64(1) reads:

> "No person shall, to the prejudice of the purchaser, sell any medicinal product which is not of the nature or quality demanded by the purchaser."

25. This must be read, however, together with subsection (5) of the same section, which reads:

> "Where a medicinal product is sold or supplied in pursuance of a prescription given by an appropriate practitioner, the preceding provisions of this section shall have effect as if—
>
> (a) in those provisions any reference to sale included a reference to supply and (except as provided by the following paragraph) any reference to the purchaser included a reference to the person (if any) for whom the product was prescribed by the practitioner, and

> (b) in subsection (1) of this section, for the words 'demanded by the purchaser', there were substituted the words 'specified in the prescription'."

26. Supperstone J held that regulation 9 does not involve any breach of section 64. Under the exemption inserted by regulation 9, one of the conditions to be satisfied is that "the prescription only medicine is sold or supplied for the purpose of being administered to a person in accordance with a serious shortage protocol" (condition A in paragraph 2 of the inserted regulation 226A). The judge held (at paragraph 18 of his judgment) that where a prescription only medicine is sold or supplied for the purpose of being administered to a person "in accordance with a serious shortage protocol", it is not sold or supplied in pursuance of a prescription and does not therefore fall within the prohibition in section 64. He accepted (at paragraph 19) the description of SSPs given by counsel for the Secretary of State, as "a parallel system to prescriptions which will only operate if, pursuant to regulation 226A(5)(a), Ministers decide that the UK or any part of the UK is experiencing or may experience a serious shortage of prescription only medicines of a specified description". He also observed at paragraph 20 that the effect of regulation 226A "is to maintain the classification of the medicine to be supplied as 'prescription only' but to change, in the circumstances set out in regulation 226A(2), the instrument by which that medicine is supplied from 'prescription' to 'serious shortage protocol'".

27. Mr Knafler submits that the judge was wrong so to hold. He says that despite the existence of an SSP, the sale is still in pursuance of a prescription and that section 64 is therefore engaged. There would not be a sale or an SSP were there not a prescription. In other words, a prescription is a condition precedent to the dispensing of medicine under the SSP. The judge placed a weight on the expression "in pursuance of a

prescription" that it cannot have been intended to bear. Where there is a prescription but the pharmacist for whatever reason sells the patient a different medicine, Parliament must have intended that to be a sale in pursuance of a prescription. Parliament cannot have had in contemplation or have intended to authorise an instrument interposing itself between the doctor's prescription and the pharmacist's sale, rendering the prescription a dead letter and rendering irrelevant the professional opinion of the patient's doctor as to what alternative medicine should be prescribed. The judge's reading, in Mr Knafler's submission, drives a coach and horses through the protection that section 64 was intended to provide. And here too he raises the constitutional point that if the protection conferred by section 64 is to be overridden, that must be done by means of legislation made by Parliament.

28. I do not find Mr Knafler's submissions on this issue at all persuasive. It seems to me that the sale or supply of a prescription only medicine on the conditions laid down in the inserted regulation 226A, including that it is sold for the purpose of being administered to a person in accordance with an SSP, falls clearly outside the mischief at which section 64 of the 1968 Act is directed, even though Parliament will not have had the specific situation in contemplation at the time of enactment of that Act. It is of course true that in an SSP case the process starts with a prescription of a medicine which ex hypothesi is or may be in serious shortage, so that the prescription is in a sense a condition precedent to the rest of the process. But the judge was in my view plainly correct to draw the distinction he did and to hold that a sale or supply that meets the conditions of regulation 226A and is therefore made in accordance with an SSP is not a sale of supply in pursuance of a prescription within the meaning of section 64 of the 1968 Act. Again, I consider the contrary to be unarguable.

Conclusion

29. I have borne in mind throughout that we are concerned ultimately in this case with the threshold of arguability for a judicial review challenge. However, for the reasons I have given in relation to each of the main submissions advanced under the umbrella of the single ground of appeal, I take the view that an appeal against the refusal of permission to apply for judicial review would have no real prospect of success and that permission to appeal should for that reason be refused.

LORD JUSTICE HICKINBOTTOM:

30. I agree.

Order: Application refused