IN THE COURT OF APPEAL **APPEAL NO:**
ON APPEAL FROM THE
HIGH COURT OF JUSTICE **CO/771/2019**
QUEEN'S BENCH DIVISION
ADMINISTRATIVE COURT
(MR JUSTICE SUPPERSTONE)

IN THE MATTER OF PERMISSION TO APPLY FOR JUDICIAL REVIEW

BETWEEN:-

THE QUEEN

(on the application of GOOD LAW PROJECT LIMITED)

Appellant

- v –

SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE

Respondent

SKELETON ARGUMENT

FOR PERMISSION TO APPEAL – 4 APRIL 2019

ESSENTIAL READING:

- STATEMENT OF FACTS AND GROUNDS, DATED 25 FEBRUARY 2019 **[3.7]**;
- RESPONDENT'S SUMMARY GROUNDS OF DEFENCE, DATED 8 MARCH 2019 **[3.48]**;
- APPELLANT'S REPLY, DATED 11 MARCH 2019 **[3.76]**;
- ORDER OF SWIFT J, DATED 15 MARCH 2019 **[3.96]**;
- ORDER OF SUPPERSTONE J, DATED **[2.1]**;
- JUDGMENT OF SUPPERSTONE J, DATED 29 MARCH 2019 **[2.2]**;
- WITNESS STATEMENT OF JOLYON MAUGHAM QC, DATED 25 FEBRUARY 2019 **[3.100]**;
- SECOND WITNESS STATEMENT OF JOLYON MAUGHAM QC, DATED 11 MARCH 2019 **[3.81]**;
- DEPARTMENT OF HEALTH AND SOCIAL CARE, CONSULTATION PAPER, DATED 5 DECEMBER 2018 **[3.183]**;
- DEPARTMENT OF HEALTH & SOCIAL CARE, CONSULTATION RESPONSE, DATED 14 JANUARY 2019 **[3.208]**;
- EXPLANATORY MEMORANDUM TO THE HUMAN MEDICINES (AMENDMENT) REGULATIONS 2019 **[3.287]**;

ESTIMATED READING TIME: 2 HOURS

INTRODUCTION

1. This is a claim for permission to appeal the Decision of Supperstone J, on 29 March 2019, refusing permission to apply for judicial review at an oral hearing, permission having been refused on the papers by Swift J, on 15 March 2019.

2. CPR 52.8 applies; the Court may grant permission to appeal, or permission to apply for judicial review and, if it grants permission to apply for judicial review, it may direct

the case to proceed in the High Court, or in the Court of Appeal. The Appellant is neutral as to forum but continues to seek expedition, in particular so long as there remains a risk of a no-deal Brexit, for the reasons at §8 of the Statement of Facts and Grounds **[3.10]**.

3. The Appellant seeks a judicial review of the making of Regulation 9 of the Human Medicines (Amendment) Regulation 2019 ("Regulation 9").

4. Regulation 9 enables the Respondent to publish a Serious Shortage Protocol whenever he deems there to be a serious shortage of a particular medicine. This authorises pharmacists to dispense medication in accordance with the Protocol, rather than in accordance with the patient's prescription.

5. The Appellant no longer seeks a judicial review on the basis of the Respondent's rushed and inadequate process of consultation and assessment of the risks to vulnerable groups of patients, created by the Serious Shortage Protocol machinery. It continues, however, to seek a judicial review on the basis that Regulation 9 is ultra vires:

    a. European Union law; and,

    b. the Medicines Act 1968.

6. In construing EU and national law, the Court will no doubt assess the language of the enactments in the light of their purpose and the "*factual matrix"* at the time.

7. In that regard, it is notable that, not only has the United Kingdom never before had a Serious Shortage Protocol, or the like, such a Protocol runs flat contrary to long-standing and accepted safe medical practice in this country, and within the EU. This accepted medical practice is that: (a) potentially dangerous medicine is categorised as "*prescription-only"* and, consequently, may only be prescribed by an appropriately qualified professional person, such as a doctor or dentist;[1] and, (b) once that clinical

[1] The list of "*appropriate practitioners"* is found at Regulation 214 of the Human Medicines Act 1968. It does not include the Respondent or any pharmacist, unless they have attained the status of being a "pharmacist independent prescriber". It is common ground that

judgment has been made by a qualified professional person, it cannot be interfered with by an unqualified person, e.g. a pharmacist.

8. The existence of a Serious Shortage Protocol poses obvious dangers for patients. Uniquely in this jurisdiction, it allows an existing clinical judgment made by qualified persons (doctors and other properly qualified professional persons) to be substituted or interfered with by an unqualified person (a pharmacist); each and every pharmacist may supply a prescription-only medicine to a patient they know little or nothing about, do not have the means to assess and are not qualified properly to assess, at the behest of the Respondent and in contradiction of the prescription issued by the patient's doctor. The dangers are summarised in the Appellant's Judicial Review Grounds at **[3.7]**.

9. One issue that arises, given the long-standing arrangements in the UK, and in the EU, whereby the prescription of potentially dangerous medicines is the exclusive province of persons who are professionally qualified to do so, and who have a close relationship with their patient is this: could national or EU law possibly have intended to authorise such a marked departure as in a Serious Shortage Protocol?

10. Finally, by way of introduction, it may be that Mr Justice Supperstone was influenced by the supposed urgency of the situation and the Respondent's submissions as to the beneficial intention of the Serious Shortage Protocol. With respect, he should not have been. Shortages of medicinal products are a common occurrence and, according to the Respondent himself, there is a long-standing method of dealing with them: "*Currently, if a pharmacy cannot dispense what is on a prescription, it will either send the patient back to the prescriber or if there is an urgent need contact the prescriber, discuss an alternative and then get the prescription changed by the prescriber*".[2] There is no need to fix that which is not broken. It is, furthermore, obvious that, if he considered it to be necessary, in the

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Serious Shortage Protocols are aimed at pharmacists who are not pharmacist independent prescribers.

[2] See §4 of the DHSC's Consultation Response of the 14 January 2019 **[3.208]**.

event of a serious shortage of a particular medicinal product, the Respondent could issue guidance for doctors about alternative, available medicinal products.

11. If permission is granted, the Court is also respectfully requested to make a Costs Capping Order in the terms set out in section 8 of the Claim Form and §§95-99 of the Statement of Facts and Grounds.

LEGISLATIVE BACKGROUND

12. The prescription of medicines is governed currently by Directive 2001/83/EC ("*on the Community code relating to medicinal products for human use*")("the Directive") **[3.436]**.

13. Title VI of the Directive is titled "*Classification of Medicinal Products*". Within this section, Article 70 of the Directive **[3.457]** provides, *inter alia*, that:

> "70.1 When a marketing authorisation is granted, the competent authorities shall specify the classification of the medicinal product into:
>
> - a medicinal product subject to medical prescription,
> - a medicinal product not subject to medical prescription.
>
> To this end, the criteria laid down in Article 71(1) shall apply."

14. Article 71 of the Directive **[3.458]** provides as follows:

> "71.1 Medicinal products shall be subject to medical prescription where they:
>
> - are likely to present a danger either directly or indirectly, even when used correctly, if utilised without medical supervision, or
>
> - are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health, or
>
> - contain substances or preparations thereof, the activity and/or adverse reactions of which require further investigation, or
>
> - are normally prescribed by a doctor to be administered parenterally.

2. Where Member States provide for the sub-category of medicinal products subject to special medical prescription, they shall take account of the following factors:

- the medicinal product contains, in a non-exempt quantity, a substance classified as a narcotic or a psychotropic substance within the meaning of the international conventions in force, such as the United Nations Conventions of 1961 and 1971,

- or the medicinal product is likely, if incorrectly used, to present a substantial risk of medicinal abuse, to lead to addiction or be misused for illegal purposes, or

- the medicinal product contains a substance which, by reason of its novelty or properties, could be considered as belonging to the group envisaged in the second indent as a precautionary measure.

3. Where Member States provide for the sub-category of medicinal products subject to restricted prescription, they shall take account of the following factors:

- the medicinal product, because of its pharmaceutical characteristics or novelty or in the interests of public health, is reserved for treatments which can only be followed in a hospital environment,

- the medicinal product is used in the treatment of conditions which must be diagnosed in a hospital environment or in institutions with adequate diagnostic facilities, although administration and follow-up may be carried out elsewhere,

- or the medicinal product is intended for outpatients but its use may produce very serious adverse reactions requiring a prescription drawn up as required by a specialist and special supervision throughout the treatment.

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.

5. If a competent authority does not designate medicinal products into sub-categories referred to in Article 70(2), it shall nevertheless take into account the criteria referred to in paragraphs 2 and 3 of this Article in determining whether any medicinal product shall be classified as a prescription-only medicine."

15. Article 1(19) of the Directive **[3.442]** defines "*Medicinal Prescription"* as "*Any medicinal prescription issued by a professional person qualified to do so".*

16. The above provisions were effectively transposed (and elaborated upon) by a combination of Part 12 of the Human Medicines Regulations 2012 (the "2012 Regs") and Part III of the Human Medicines Act 1968. By way of example, Regulation 214 of the 2012 Regs **[3.431]** states that:

> **"214.— Sale or supply of prescription only medicines**
>
> (1) A person may not sell or supply a prescription only medicine except in accordance with a prescription given by an appropriate practitioner.
>
> (2) A person may not parenterally administer (otherwise than to himself or herself) a prescription only medicine unless the person is—
>
> (a) an appropriate practitioner other than an EEA health professional; or
>
> (b) acting in accordance with the directions of such an appropriate practitioner.
>
> (3) The following are appropriate practitioners in relation to any prescription only medicine—
>
> (a) a doctor;
>
> (b) a dentist;
>
> (c) a supplementary prescriber;
>
> (d) a nurse independent prescriber; and
>
> (e) a pharmacist independent prescriber.
>
> …"

17. Regulation 255 of the 2012 Regs **[3.434]** makes it a criminal offence to breach Regulation 214(1) of the 2012 Regs.

18. Further provision is made by ss58 and 58A of the Medicines Act 1968 **[3.419]**. Indeed, section 58A of the Medicines Act 1968 is materially identical to Article 71 of the Directive.

19. An important part of this coherent domestic framework is section 64 of the Medicines Act 1968 **[3.425]**. This provides that:

> **"64.— Protection of purchasers of medicinal products.**
>
> (1) 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.
>
> (2) For the purposes of this section the sale of a medicinal product shall not be taken to be otherwise than to the prejudice of the purchaser by reason only that the purchaser buys the product for the purpose of analysis or examination.
>
> (3) Subsection (1) of this section shall not be taken to be contravened by reason only that a medicinal product contains some extraneous matter, if it is proved that the presence of that matter was an inevitable consequence of the process of manufacture of the product.
>
> (4) Subsection (1) of this section shall not be taken to be contravened by reason only that a substance has been added to, or abstracted from, the medicinal product, if it is proved that—
>
> (a) the addition or abstraction was not carried out fraudulently, and did not injuriously affect the composition of the product, and
>
> (b) the product was sold having attached to it, or to a container or package in which it was sold, a conspicuous notice of adequate size and legibly printed, specifying the substance added or abstracted.
>
> (5) 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'."

20. Section 67(2) of the Medicines Act 1968 **[3.427]** makes it a criminal offence to contravene s64 of the Medicines Act 1968.

21. So far as material, section 2 of the European Communities Act 1972 **[3.429]** provides as follows:

> **"2.— General implementation of Treaties.**

(1) All such rights, powers, liabilities, obligations and restrictions from time to time created or arising by or under the Treaties, and all such remedies and procedures from time to time provided for by or under the Treaties, as in accordance with the Treaties are without further enactment to be given legal effect or used in the United Kingdom shall be recognised and available in law, and be enforced, allowed and followed accordingly; and the expression "enforceable EU right" and similar expressions shall be read as referring to one to which this subsection applies.

(2) Subject to Schedule 2 to this Act, at any time after its passing Her Majesty may by Order in Council, and any designated Minister or department may by order, rules, regulations or scheme , 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 or the coming into force, or the operation from time to time, of subsection (1) above;

and in the exercise of any statutory power or duty, including any power to give directions or to legislate by means of orders, rules, regulations or other subordinate instrument, the person entrusted with the power or duty may have regard to the objects of the EU and to any such obligation or rights as aforesaid."

22. The Human Medicines (Amendment) Regulations 2019 came into force on 9 February 2019: Regulation 1 of the 2019 Regs.

23. The preamble **[3.278]** states that:

"The Secretary of State and the Department of Health in Northern Ireland make the following Regulations. They do so in exercise of the powers conferred by section 2(2) and (5) of the European Communities Act 1972, having been designated for the purposes of section 2(2) of that Act in relation to medicinal products."

24. Regulation 9 of the 2019 Regs **[3.281]** provides an exemption to Regulation 214 of the Human Medicines Regulations 2012. It states as follows:

"9. Insertion of regulation 226A (sale etc by a pharmacist in accordance with a serious shortage

protocol)

After regulation 226 (emergency sale etc by pharmacists: pandemic disease), insert—

'226A.— Sale etc by a pharmacist in accordance with a serious shortage protocol

(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 judgement, 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 (either of them acting alone or both of them acting jointly) in circumstances where the United Kingdom or any part of the United Kingdom is, in the opinion of the Ministers (either of them forming the opinion alone or both of them forming the opinion jointly), 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.

(6) As soon as is reasonably practical after the end of one year beginning on the day on which the first protocol issued under this regulation has effect, the Ministers must—

(a) review the operation of this regulation with a view to evaluating whether there have been any adverse consequences for the market in prescription only medicines or for patient safety as a consequence of the operation of this regulation;

(b) set out the conclusions of the review in a report; and

(c) publish the report.'."

25. There are other exemptions to Regulation 214 contained within Part 12 of the 2012 Regs. Regulation 226A is the only exemption, however, that allows for a pre-existing and specific clinical judgment to be interfered with by an unqualified person.

FIRST SUBMISSION – SSPs ARE IN BREACH OF DIRECTIVE

26. At the outset, it is important to highlight that the Respondent has not at any stage – whether in his Summary Grounds or at the oral hearing before Supperstone J – sought to particularise which *specific* wording in the Directive grants *vires* for Regulation 9. Rather, as echoed in §16 of Supperstone J's judgment, the Respondent

relies on the Directive, and the management of prescription-only drugs, *in general*. That is not a lawful approach.

27. Articles 1(19), 70 and 71 of the Directive 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 - i.e. when they are "*dangerous*".

28. Article 71(4) offers the only exception but the Respondent has never sought to rely on Article 71(4) and rightly so: it applies only where it is appropriate not to classify a medicinal product as prescription-only having regard to the particular ways in which the product will be used (e.g. a very small amount in a pill for headaches to be taken no more than 4 times daily).

29. Regulation 9 is *ultra vires* Articles 1(19), 70 and 71 of the Directive for the following reasons:

    a. It allows the Respondent to issue a Serious Shortage Protocol and thereby to authorise each and every pharmacist in the UK 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;

    b. This is because neither the Respondent, nor pharmacists (unless they are a "pharmacist independent prescriber"), are professional persons qualified to prescribe medicinal products;

    c. Therefore, the sale of prescription-only medicinal products, under a Serious Shortage Protocol, is a sale to patients of prescription-only products, otherwise than in accordance with a prescription issued by a professional person qualified to do so;

    d. Consequently, far from providing the power to make Serious Shortage Protocols, Articles 1(19), 70 and 71 of the Directive expressly prohibit them. These Articles clearly provide that, if a medicinal product is

prescription-only, that means that it can only be sold or supplied in accordance with a prescription issued by an appropriately qualified professional.

SECOND SUBMISSION – SSPs OUTSIDE S2(2)(B) ECA 1972

30. In any event, the Respondent cannot rely on s2(2)(b) of the European Communities Act 1972 to provides the *vires* for Regulation 9.

31. The Respondent's case is that Regulation 9 is authorised by section 2(2)(b) of the European Communities Act 1972, i.e. that it is "*for the purpose of dealing with matters arising out of or related to any [EU obligation of the United Kingdom] or rights*….". Nonetheless, it is again important to emphasise that the Respondent has not at any stage sought to particularise which *specific* wording or obligation in the Directive Regulation 9 is said to arise out of or relate to.

32. Whilst the precise ambit of section 2(2)(b) remains unclear, what is clear is that it only applies to domestic legislation that can properly be described as implementing, or dealing with matters arising from or related to EU obligations and rights. As it was put by Lord Mance in *USA v Nolan* [2015] UKSC 63, [2016] AC 463:

> 60 Fourth, section 2(2) authorises the making of provisions for two differently expressed purposes. In the case of paragraph (a), the purpose expressed is implementing or enabling the implementation of any EU obligation (or the enabling the exercise of any EU right enjoyed by the United Kingdom). In the case of paragraph (b), it is "dealing with matters arising out of or related to any such obligation or rights or the coming into force, or the operation from time to time, of" section 2(1) . It is not in my view appropriate to get too involved in a linguistic debate about whether these paragraphs should be read entirely disjunctively or whether there may be some overlap. But Jacob LJ was, I think, right in saying that "the wider section 2(2)(a) , the narrower section 2(2)(b) is likely to be"—that is so, because the language of paragraph (b) introduces bottom line limitations of the power it confers.
>
> 61 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 (or the

> coming into force, or operation, of section 2(1)). The words "arising out of" limit the power to provisions dealing with matters consequential on an EU obligation or right (or the coming into force, etc, of section 2(1)). 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, as they did to Waller and May LJJ, 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.
>
> 62 A fifth and final point is that it is, in the light of the above, possible to describe section 2(2) as both wide and confined in scope. It is wide because it authorises almost every conceivable provision required to fulfil the United Kingdom's obligations under article 4.3EU (or to give effect to any EU right) subject only to the restrictions in Schedule 2 . It is confined because any such provision must be for the purpose of implementing, or dealing with a matter arising from or related to, such an obligation or right.

33. It is implicit in the above and, in any event, implicit in section 2(2)(b), that section 2(2)(b) only authorises regulations "*for the purpose of … dealing with a matter arising from or related to"* an EU obligation when those regulations are in furtherance of, consistent with and closely connected with the relevant EU obligation; Regulation 9 is none of those things; first, because it contradicts Article 71; secondly, because although, in the Respondent's view, it creates a scheme "*it would be good policy or convenient to have"*, it has a different aim and covers matters significantly beyond the scope of the Directive (cf. Lord Mance at §61 above).

34. In the premises, Mr Justice Supperstone was wrong to conclude, at §16, that "*The question is whether regulation 9 is "for the purpose of dealing with matters arising out of or in related (sic) to any such obligation". In my view plainly it is. In short, I agree with Sir James that management of shortages of prescription-only drugs is a matter arising out of and related to EU obligations under the 2001 Directive to classify certain drugs as prescription-only and to control their supply. The power to make SSPs in regulation 9 was made for that purpose".*

THIRD SUBMISSION – SSPs CONTRARY TO DOMESTIC FRAMEWORK

35. Sections 64(1) and (5) of the Medicines Act 1968 provide that, where a medicinal product is sold or supplied in pursuance of a prescription given by an "*appropriate practitioner*", no person shall, to the prejudice of the person for whom the product was prescribed, sell to that person any medicinal product which is not of the nature or quality specified in the prescription. Acting contrary to section 64 is a criminal offence by virtue of section 67(2) of the Medicines Act 1968.

36. Regulation 9 is *ultra vires* section 64 of the Medicines Act 1968, in that it authorises pharmacists to sell medicine to patients which is not of the nature or quality specified in the patients' prescription: the patient's "*appropriate practitioner*" must sanction any change.

37. Mr Justice Supperstone was wrong to hold, at §20, that this submission was unarguable because "*The effect of [Regulation 9] is to maintain the classification of the medicine to be supplied as "prescription-only" but to change, in the circumstances set out in [Regulation 9], the instrument by which that medicine is supplied from "prescription" to "serious shortage protocol"*". There are 2 reasons why:

    a. The sale is still, despite the existence of a Serious Shortage Protocol, "*in pursuance of a prescription"*; there would not be a sale, or a Serious Shortage Protocol, were there not a prescription. In other words, a prescription is a condition precedent to dispensation of medicine under the Serious Shortage Protocol;

    b. Mr Justice Supperstone, and the Respondent, place weight on the expression "*in pursuance of a prescription"* that it was not intended to, and cannot, bear. The obvious purpose of section 64(5) was to prohibit and, ultimately, to criminalise, the sale of medicinal products otherwise than in accordance with a prescription, where they are prescription-only. In using the expression "*in pursuance of a prescription*", Parliament was simply indicating that, where there is a prescription, but the pharmacist for whatever reason sells the patient different medicine, that is a sale "*in pursuance of a prescription"*. Parliament cannot have had in mind, or intended to authorise, something that could not possibly have been in contemplation in 1968, namely, a totally new kind of

"*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 GP as to what alternative medicine should be prescribed. Indeed, this is contrary to the long-standing convention in the UK, and the factual matrix on which the Act was based, that doctors and other appropriately qualified professional persons, and only they, authorise the sale of prescription-only medicines.

CONCLUSION

38. Consequently, the Court is respectfully requested:

a. To expedite the consideration of this appeal in light of the risks of a no-deal Brexit;

b. To grant permission for Judicial Review;

c. To grant a Costs Capping Order such that the Appellant does not have to pay the costs of the Respondent in excess of £15,000;

d. In the event that the claim proceeds in the Court of Appeal:

i. To quash Regulation 9;

ii. Alternatively, to declare that Regulation 9 is unlawful;

iii. To award the Appellant its costs; and,

iv. To grant such further and other relief as the Court sees fit.

STEPHEN KNAFLER Q.C.

YAASER VANDERMAN

Landmark Chambers

3 April 2019