IN THE HIGH COURT OF JUSTICE **CLAIM NO: CO/771/2019**
QUEEN'S BENCH DIVISION
ADMINISTRATIVE COURT
B E T W E E N

THE QUEEN on the application of
GOOD LAW PROJECT LIMITED

Claimant

- and –

THE SECRETARY OF STATE
FOR HEALTH AND SOCIAL CARE

Defendant

SUMMARY GROUNDS OF RESISTANCE

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*References to pages in the Claimant's Application Bundle are given as [CB/Section**/Tab**/Page**] and to its Statement of Facts and Grounds as [C/SFG/**]. References to pages in the Defendant's Exhibit to these Summary Grounds are given as [D/SGExh/Doc No**/Page**/Para**]*

INTRODUCTION

1. The target of this claim is Regulation 9 of the Human Medicines (Amendment) Regulations S.I. 2019/62 ("the 2019 Regulations") which came into force on 9 February 2019. It inserted Regulation 226A into the Human Medicines Regulations S.I. 2012/1916 ("the 2012 Regulations"). Regulation 226A permits Ministers to issue a Serious Shortage Protocol ("SSP") in circumstances where any part of the UK is in their opinion experiencing or may experience a serious shortage of a prescription-only medicine.

2. It is to be noted at the outset that Regulation 9 provides the high level empowering framework and conditions for the issue of an SSP. The creation of that legislative power (including the specified conditions for its exercise set out in Regulation 9) is the first stage of the process of creating and implementing such a scheme. The operational detail of SSPs, including content, guidance for pharmacists and template documents, is not yet finalised, and is still subject to engagement with stakeholders and final approval by the Secretary of State. However, the intention is clear and, given the Regulation 9 power, unsurprising: it is that any SSP issued would relate to specific drug(s) in short supply, would be agreed by clinicians and would clearly set out what action could be taken by the retail pharmacy, under what circumstances, for which patients and during which period. If the requirements for each drug set out in the SSP are met, then the pharmacist may, using their professional judgement, supply prescription-only medicines of a different strength, quantity or

pharmaceutical form or a different prescription-only medicine to that ordered by the prescriber. However, even if all the conditions of the SSP are met, a pharmacist using their professional judgement may consider that the SSP action is not appropriate for a patient and will refer the patient back to the prescriber rather than make a supply according to the SSP. SSPs will not be suitable for all drugs, conditions or patients (such as a protocol enabling a change of medicines for epilepsy).

3. This is accordingly a thoroughly important legislative measure designed to enable the Secretary of State effectively to address serious drug shortages, including any potential drug shortages that might occur in the event of a no deal Brexit. The existence of such a power is supported by pharmacists and clinicians to protect patient safety. The Claimant does not even seek to challenge the need for the creation of the power to issue an SSP in appropriate circumstances (or the nature of the conditions set out in Regulation 9).

4. It is submitted that none of the grounds of challenge that the Claimant does make is properly arguable for the reasons set out below. In any event (and again as developed below), the Claimant seeks a quashing order in respect of Regulation 9 before 29 March 2019. It does so despite not challenging the clear and pressing need for the basic power conferred by Regulation 9. It also does so despite not even seeking to make a serious case that, if any of the procedural duties said to have been breached had been complied with, the basic power would or should have either not been made or should have been made in different form. If the relief sought were to be granted, the consequences would be highly unfortunate: the UK will be left without an important tool by which the Secretary of State can address any serious drug shortages arising, including post Brexit. In these circumstances, (a) s.31 of the Senior Courts Act 1981 is engaged (no difference); and (b) in any event, there is no realistic prospect of the Court exercising its discretion to grant the remedy to which this claim is directed.

5. Finally, it is denied that the Claimant has any standing to bring this claim.

THE RELEVANT FACTS

6. The Secretary of State takes action to manage supply issues as part of everyday business, sometimes up to 200 times each year. In many cases pre-emptive action will prevent an actual shortage but, in some cases, a shortage may still occur and has to be managed[1]. At the same time as the recent Epipen shortage (see footnote 1), several stakeholders called for additional measures to ensure the continuity of supply (referring to the possibility of such shortages in particular in the event of a no deal Brexit): see, for example, the interview

[1] The most significant recent example was a shortage of Epipen and Epipen Junior (adrenaline auto-injector devices) in September 2018 *[D/SGExh/1 and 2/1-9]*. On 18 October 2018, the Secretary of State issued an '*Interim Protocol on Dispensing of Adrenaline Auto-Injectors, 150micrograms*.' That Protocol provided a flow chart to be followed by pharmacists to enable them to determine on the basis of clinical indications whether the pharmacist needed to contact the prescriber to discuss adjusting the prescription or could exercise their own judgment to delay or reduce supply of the devices prescribed to the patient.

given by Professor Ash Soni, president of the Royal Pharmaceutical Society, on 21 October 2018, in which he called on the government to give pharmacists the same powers that they would have during a pandemic i.e. to choose a different drug if the usual prescription were unavailable;[2] and Martin Sawer, Chief Executive of the Healthcare Distribution Association making a similar point in evidence to the '*Impact of a no deal Brexit on health and social care*' inquiry by the Health and Social Care Committee on 23 October 2018.[3]

7. The need for powers effectively to manage serious shortages generally and concerns about such shortages in the context of Brexit thus converged in October 2018. The Secretary of State initiated an exercise involving officials and the Medicines and Healthcare Products Regulatory Agency ("MHRA") to explore what measures, in addition to stockpiling, could be taken to ensure continuity of drug supplies in the event of a no deal Brexit. They concluded that many of the measures identified could be taken within the existing framework of the 2012 Regulations. However, two measures were identified as needed, which required amendment to the 2012 Regulations. The first was an enabling power to make an SSP; and the second a separate power to make regulations solely to modify the application of the 2012 Regulations to deal with serious shortages of medicinal products in the event of a no deal Brexit.

8. A submission was made to the Secretary of State dated 20 November 2018 setting out those proposed high level changes to the 2012 Regulations and proposing that there should be consultation with the relevant representative bodies ("the November Submission"). The Secretary of State already had a slot in the busy legislative timetable for regulations to amend the 2012 Regulations to further transpose the Falsified Medicines Directive. It was recommended that this should be used to add the SSP Regulation to those proposed regulations in order to ensure that the necessary powers were in force, and available for use in the public interest, as soon as possible. By an email dated 22 November 2018, the Secretary of State indicated his approval to progress those proposals, also indicating that the Association of the British Pharmaceutical Industry ("ABPI") should be content with the proposals.

9. From 23 November 2018 to early January 2019, officials therefore engaged with stakeholders, including industry, pharmacists, doctors and patient groups, to inform them about these high level proposals and to offer them a meeting to discuss them. Thus, on 23 November 2018, the Secretary of State consulted the EU Medicines Supply Industry Collaboration Group. On 25 and 26 November 2018, officials contacted the following bodies to inform them about the proposals and to offer them a meeting to discuss them: British Medical Association ("BMA") *[D/SGExh/5a/20]*; General Pharmaceutical Council *[D/SGExh/5c/22]*; National Pharmacy Association *[D/SGExh/5e/24]*; Royal

[2] https://www.thetimes.co.uk/article/pharmacists-in-plea-to-beat-brexit-shortfall-38w8gv8g5
[3] http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/health-and-social-care-committee/impact-of-a-no-deal-brexit-on-health-and-social-care/oral/92043.html

Pharmaceutical Society *[D/SGExh/5i/28]*; National Voices (a coalition of charities representing a wide variety of patient interest and condition-specific groups) *[D/SGExh/5h/27]*; Health Watch (the national champion for those receiving health and social care) *[D/SGExh/5g/26]*; Pharmaceutical Services Negotiating Committee *[D/SGExh/5f/25]*; Company Chemists Association *[D/SGExh/5e/24]*; Association of Independent Multiple Pharmacies *[D/SGExh/5e/24]*. Officials asked Healthwatch, and National Voices whether they thought there were any other patient groups that they should contact.

10. The invitations stressed the need to move quickly, not least because of the potential need to have legislation in place before 29 March 2019. For example, the email to the BMA stated *[D/SGExh/5a/20]:*

> '*For changes to the Human Medicines Regulations, we would normally consult publicly. However, you will understand that any legislative changes in relation to the UK's exit need to be progressed quickly so that they are in force on the day that the UK leaves the EU or preferably before that. Therefore, we are seeking views of the relevant bodies on these changes and you may also have further thoughts on what we could do additionally to ensure continuity of supply in a 'no deal' scenario*.'

11. The same email set out the subject of the consultation which was the high level proposal that SSPs should be available, in effect in principle, as a tool to assist in managing serious drug shortages:

> *'There are some actions that we have identified that may require changes to the legislation to be able to:*
>
> 1. *Provide dispensers with more flexibility in case of serious shortages by introducing a 'national shortage protocol';*
> 2. *Ensure we can continue to amend the Human Medicines Regulations 2012 to ensure the continuity of supply in case of a 'no deal.'*

12. Of those, seven bodies accepted the offer of a meeting. Those meetings were held as follows:

    12.1. BMA (30/11)

    12.2. General Pharmaceutical Council (29/11)

    12.3. National Pharmacy Association (27/11)

    12.4. Royal Pharmaceutical Society (27/11)

    12.5. Association of Independent Multiple Pharmacies (27/11)

    12.6. Company Chemists Association (27/11)

    12.7. Pharmaceutical Services Negotiating Committee ("PSNC") (27/11).

13. On 27 November 2018, officials also met with NHS England and the devolved administrations to discuss the proposals.

14. On 30 November 2018, officials attended the Community Pharmacy Brexit Forum organised by the PSNC, which brought together all relevant community pharmacy stakeholders, and provided an update on the proposals.

15. On 3 December 2018, officials contacted the Royal College of General Practitioners ("RCGP") to offer a meeting *[D/SGExh/5j/29]*. No immediate response was received, but RCGP then engaged substantively over the next few days in writing.

16. By an email dated 5 December 2018, 24 stakeholder bodies including pharmacists, doctors and patient groups, as well as relevant NHS bodies, were invited to submit written answers to the four questions set out below; *[D/SGExh/6/30-35]*, *[D/SGExh/7/36-7]*. It was explained that the consultation was considerably shorter than usual because of the need to legislate before 29 March 2019 and responses were requested by 12 December 2018. The draft Regulations for the SSP power were attached to that consultation invitation. The four questions asked whether respondents were in favour of the principle of both the SSP power and also the regulation-making power:

    16.1. **Question 1**: do you agree with the introduction of the provision for a 'serious shortage protocol' to deal with serious national shortages of medicines via proposed Amendment 1 to the HMR 2012?

    16.2. **Question 2**: Do you agree with the introduction of a regulation making power in relation to serious shortages in case of a 'no deal' Brexit via proposed Amendment 2 to the HMR 2012?

    16.3. **Question 3**: Do you have views on the principles outlined above which are informing our assessment of impacts? Those principles were as follows:

        16.3.1. There will be a positive impact on pharmacists and GPs who will save time and resource by not having to liaise with each other for each individual patient that has been prescribed a medicine for which a protocol is available.

        16.3.2. There will be a positive impact on patients who continue to have (quick) access to treatment. We have not yet quantified the impact.

        16.3.3. We expect that both proposals will help secure the continuity of supply of medicines and allow patients, including those with protected characteristics, continued access to medicines.

    16.4. **Question 4:** Do you have comments on the draft provisions?

17. On 7 December 2018, the Director of New Business Models and Primary Care Contracts Groups at NHS England discussed the proposals with the Chair of the BMA's General

Practitioners' Committee. On the same day, the Director of Primary Care at NHS England discussed the proposals with the Chair of the RCGP.

18. 47 responses to these consultation measures were received. They are summarised in the Consultation Response dated 14 January 2019 *[D/SGExh/8/38-42]*. The Consultation Response noted that officials had continued to consult with the stakeholder representative bodies after the 12 December 2018 and noted that it had also received correspondence from some patient groups on the SSP (see §3). The Consultation Response noted six principal points raised:

    18.1. Responses were broadly supportive but patient groups and doctors' representative bodies raised concerns about automatic therapeutic or general substitution of medicines for high risk patients without consulting the prescriber, e.g. epilepsy or transplants *[D/SGExh/8/40/11]*.
    18.2. Similar concerns were raised more generally about therapeutic or generic substitution where the MHRA required prescribing by brand *[D/SGExh/8/40/12]*.
    18.3. Industry representative bodies queried the role of manufacturers and suppliers and considered that the amendments should be time limited or linked to a 'no deal' exit from the EU *[D/SGExh/8/40/13]*.
    18.4. Some expressed concern about the short consultation period *[D/SGExh/8/41/14]*.
    18.5. Operational issues were raised including informing a prescriber when the SSP had been used, communication with patients and with pharmacists by the Secretary of State *[D/SGExh/8/41/15]*.
    18.6. Pharmacy representative bodies expressed a concern that supply in accordance with an SSP would be a breach of s.64 of the Medicines Act 1968 *[D/SGExh/8/41/16]*.

19. The Consultation Response noted that the Secretary of State had taken the following actions in response to the responses received:

    19.1. The power to issue SSPs was not time limited (although individual SSPs are time limited) and it was made clear that they could be used to manage any serious drug supply shortage, not simply any occasioned by a no deal Brexit *[D/SGExh/8/41/17]*.
    19.2. A review clause (one year after the first SSP comes into effect) was included in the amendments to address the short consultation period, including a stakeholder consultation *[D/SGExh/8/41/18]*.
    19.3. An addition was made to the amendments to clarify that SSPs could cover medicines of different strengths *[D/SGExh/8/41/21]*.
    19.4. The development of SSPs by clinicians would be described in the Explanatory Memorandum to the 2019 Regulations *[D/SGExh/8/41-2/23]*.

20. On 20 December 2018, a submission was made to the Secretary of State setting out the outcome of the consultation and asking for agreement to the proposed amendments to the

2012 Regulations ("the December Submission") *[D/SGExh/9/43-56]*. The December Submission noted:

20.1. that both the BMA and RCGP were broadly supportive of the proposal (§9) *[D/SGExh/9/47]*;

20.2. that whilst the proposals had been prompted by EU exit work it was also helpful to manage shortages in general (§1a) *[D/SGExh/9/46]*;

20.3. that patient organisations cited concerns about risk to patients in certain cases e.g. epilepsy (§3) but that it was thought this was because it had not been clear that any SSP would be signed off by clinicians and would have undergone significant scrutiny in order to avoid any such risks *[D/SGExh/9/46]*.

21. Annex C of the December Submission contained an assessment of the impact of the Public Sector Equality Duty ("PSED") on the proposal to introduce the power to make an SSP. Annex C stated *[D/SGExh/9/56]*:

> *'11. We considered the implications for each of the three equality objectives in relation to the proposed framework. Our assessment is that there is no detrimental impact on particular protected groups. Whilst some of the groups are likely to use medicines more often, the protocol should have a positive impact on anyone taking medicines, including those with protected characteristics.*
>
> *12. A serious shortage protocol would support pharmacists and GPs when there are serious shortages of medicines. The protocol would help manage available stocks and ensure patients have continued and quick access to medicines or any suitable alternatives if no stock is available. This benefits all patients, including those with protected characteristics. Even if on a particular occasion one patient might experience the detriment of, for example, receiving a smaller amount of a medicine than had been prescribed, that would be to the benefit of another patient who might not have received any of the medicine, had the rationing scheme not been in place. That is, the arrangements will be to the benefits of patients overall even if though underpinning this will be individual losses and gains.'*

22. By an email dated 7 January 2019, approval from the Secretary of State was received, provided in summary that there was a stringent set of conditions to be met before the power was used and that approval was forthcoming from the ABPI and BIA *[D/SGExh/10/57-8]*.

23. On 4 January 2019, Liz Woodeson, Director of Medicines and Pharmacy at the Department for Health and Social Care ("DHSC"), had engaged with the ABPI and the RCGP to discuss concerns, including the introduction of a review clause into the proposed amendments.

24. On 7 January 2019, a further submission ("the January Submission") was put up to the Secretary of State *[D/SGExh/11/61-111]*. It set out the further discussions with key stakeholders that had taken place since the December Submission, noting the inclusion of a review clause, and the next stage of the process that would be required to develop the

operational detail of SSPs, including the fact that SSPs would be approved by clinicians and that SSPs might not be suitable for some high risk patients or medicines which would always be referred back to the prescriber *[D/SGExh/11/63-4/9]*. The Secretary of State was again provided with the December Submission PSED analysis in the January Submission *[D/SGExh/11/98-9]*. Approval was received on 9 January 2019 *[D/SGExh/12/112-3]*.

25. On 9 January 2019, a further meeting was held with the ABPI as a result of which a revised version of the Explanatory Memorandum to the 2019 Regulations was sent to the Secretary of State for approval, together with a letter to be sent to the ABPI. Approval for both was received on 11 January 2019 and the letter was sent on the same date *[D/SGExh/13/114-126]*.

26. On 18 January 2019, the 2019 Regulations were laid before Parliament. The 2019 Regulations came into force on 9 February 2019, which is the conventional 21 days after laying, according to the negative resolution procedure.

27. Since that date, the Secretary of State has been working closely with stakeholders on the stages of the process beyond the creation of the necessary legislative power – namely, the detail of the operational and implementation measures for SSPs. Thus, for example:

    27.1. On 18 January 2019, officials updated the EU Exit and Medicines Supply Industry Collaborative Group on progress.

    27.2. On 22 January 2019, officials attended the Community Pharmacy Brexit Forum organised by the PSNC, which brought together all relevant community pharmacy stakeholders and updated the group on progress and operationalisation of SSPs.

    27.3. On 30 January 2019, meetings with representative stakeholder bodies have been ongoing to discuss operationalisation of SSPs:

        27.3.1. BMA, Royal College of Physicians and RCGP.

        27.3.2. Association of Independent Multiple Pharmacies, Company Chemists Association, National Pharmacy Association, PSNC, Royal Pharmaceutical Society, General Pharmaceutical Council and Healthcare Distribution Association.

        27.3.3. ABPI, Bioindustry Association and British General Manufacturers Association.

    27.4. On 21 January and 1 February 2019, officials met with NHS Specialist Pharmacy Service to discuss the development of a template protocol and draft guidance to accompany SSPs. That template has also been shared with NHS England, the devolved administrations and the PSNC.

    27.5. On 5 February and 19 February 2019, officials met with the PSNC to discuss amendments to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations and the National Health Service (Charges for Drugs and Appliances) Regulations 2015 ("the Pharmacy NHS Terms of Service") to enable pharmacists to be reimbursed for products supplied in accordance with an SSP rather

than a prescription. There has also been further engagement by email with the BMA on consequential amendments to the Dispensing Doctors Terms of Service.

28. Further submissions to the Secretary of State are being prepared seeking approval for these changes to the Pharmacy NHS Terms of Service. It was originally intended that these amendment regulations would come into force on or by 29 March 2019. The submission seeking approval of the proposed changes to the Terms of Service (already discussed with the PSNC and the BMA) will again contain analysis, in respect of these more detailed operational proposals, of the Secretary of State's PSED duties and duties under the National Health Service Act 2006 ("the NHS Act 2006") including s.1 (comprehensive NHS), s.1A (improvement in quality of service), s.1B (NHS Constitution), s.1C (reducing inequalities) and the Family Test. Work is also continuing to create a departmental governance structure for the issue and content of SSPs.

LEGISLATIVE FRAMEWORK

The EU legislative scheme

29. The 2019 Regulations were made pursuant to ss.2(2)(b) of the European Communities Act 1972 ("the 1972 Act") *[CB/4/22/4.1]*. That section provides:

> *'(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] 2 , make provision— …*
> *(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; …'*

30. The EU has created a comprehensive code for the marketing, manufacture, packaging, distribution, advertising and monitoring of human medicines. The 2012 Regulations repealed or revoked most existing UK legislation regulating the authorisation, sale and supply of medicinal products for human use and consolidated their effect in one place and in rationalised form: see §2.1 of the Explanatory Memorandum to the 2012 Regulations. Most of the topics covered by UK legislation prior to the 2012 Regulations had become the subject of EU enactments, most notably Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use ("**the 2001 Directive**"): see §4.1 Explanatory Memorandum to the 2012 Regulations. Only very limited parts of the Medicines Act 1968 remained in force after the 2012 Regulations came into force.

31. Regulation 9 was made for the purpose of dealing with matters arising out of and related to the obligations in the 2001 Directive pursuant to ss.2(2)(b). Article 70.1 of the 2001 Directive requires a classification decision (whether a medicine is prescription-only or not)

to be made by the competent authority when medicinal products are authorised. That requirement has been transposed into national law in Regulation 5 of the 2012 Regulations. Recital (29) of the 2001 Directive further states that the conditions governing the supply of medicinal products to the public should be harmonised. Recitals (31), (33) and (35) emphasise that the supply chain runs from manufacture to supply to the public. Consequently, the UK must also have an effective and proportionate scheme for enforcing the supply of prescription-only medicines to the public. That requirement was transposed into national law in Part 12 of the 2012 Regulations, which is titled '*Dealings with medicinal products*.'

32. Regulation 214 of the 2012 Regulations provides that prescription-only medicine may only be sold or supplied in accordance with a prescription subject only to the exemptions set out in Chapter 3 of Part 12 of the 2012 Regulations (emphasis added) *[CB/4/27/4.19]*:

> *'**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.*
> *...*
> *(7) This regulation is subject to Chapter 3 (exemptions).'*

33. Regulation 9 of the 2019 Regulations amends the 2012 Regulation by inserting Regulation 226A. Regulation 226A falls within Chapter 3 of Part 12 of the 2012 Regulation which is titled, '*Exemptions relating to supply in specific circumstances*' *[CB/4/27/4.20]*:

> *'**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.".

34. Other parts of the 2019 Regulations amending the 2012 Regulations were made in order to deal with matters arising out of and related to the obligations in the Falsified Medicines Directive 2011/62/EU: see §§2.1 and 6.3 of the Explanatory Memorandum to the 2019 Regulations *[CB/5/29/5.1]*.

The surviving national legislation

35. Section 58A of the Medicines Act 1968 (see *[C/SGF/43-44)]*) provides that the Secretary of State must specify certain products as prescription-only medicines *[CB/4/24/4.5ff]*:

'Requirement to specify certain products as prescription-only products.
(1) The Ministers shall … so exercise their powers under section 58(1) of this Act as to secure that every product- … (c) to which subsection (2) of this section applies … is specified as a prescription only medicine.
(2) This subsection applies to any product which-
(a) is likely to present a direct or indirect danger to human health, even when used correctly, if used without the supervision of a doctor or dentist; or
(b) is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health; or
(c) contains substances or preparations of substances of which the activity requires, or the side-effects require, further investigation; or
(d) is normally prescribed by a doctor or dentist for parenteral administration. …'

36. Section 64 of the Medicines Act 1968 provides that pharmacists shall not sell or supply any medicinal product other than as specified in the prescription (emphasis added) *[CB/4/24/4.5ff]*:

*'**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".

37. Section 67 of the Medicines Act 1968 makes it a criminal offence to contravene s.64:

*'**Offences under Part III.***
[…]
(2) Any person who contravenes any of the following provisions of this Part of this Act, that is to say, sections 63 and 64, or who contravenes [...] any order made under section 62 of this Act, shall be guilty of an offence.
[…]
(4) Any person guilty of an offence under [subsection (1A), (1B), (2) or (3)] of this section shall be liable—
(a) on summary conviction, to a fine not exceeding [the prescribed sum];
(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.'

GROUND 1: *ULTRA VIRES [C/SFG/39-44]*

The EU point

38. Regulation 9 was lawfully made pursuant to ss. 2(2)(b) of 1972 Act:

38.1. Management of shortages of prescription-only drugs is a matter arising out of and related to the 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. That purpose was clear and express: see e.g. §§6.2 and 6.5 of the Explanatory Memorandum to the 2019 Regulations. The requisite connection to the EU legislative scheme is equally plain.

38.2. Regulation 9 was not made to transpose the Falsified Medicines Directive 2011/62/EU, nor does the Preamble or Explanatory Memorandum to the 2019 Regulations allege that it was. Other parts of the 2019 Regulations were made to transpose the Falsified Medicines Directive; see §§2.1-2.3 and 6.3 of the Explanatory Memorandum to the 2019 Regulations.

39. The effect of the EU Directives and ss.2(2)(b) of the 1972 Act is thus to create a parallel, and free-standing, *vires* scheme. There is no need to seek any such power in the surviving provisions of the Medicines Act 1968.

The s.64 point

40. The Claimant contends that the Secretary of State has unlawfully created an exemption to ss.64(1) and (5) by making Regulation 9. The Secretary of State has not done so.

41. The effect of ss.64(1) and (5) is that it is illegal for a pharmacist to sell or supply *'in pursuance of a prescription'* any medicinal product which is not specified by the prescription. Regulation 226A(1) (inserted by Regulation 9) provides for the sale or supply of prescription-only medicines *'in accordance with a serious shortage protocol'* subject to the fulfilment of three conditions (A) to (C). Regulation 226A(2) provides that Condition A is that the prescription-only medicine is sold or supplied *'in accordance with a serious*

shortage protocol.' Pursuant to Regulations 226A(1) and (2), prescription-only medicines are not, therefore, sold or supplied '*in pursuance of a prescription,'* as would be required for s.64 to be engaged, but are sold or supplied *'in accordance with a serious shortage protocol.'* Sections 64(1) and (5) are not, therefore, engaged and no exemption to them has been created.

42. As already noted, the *vires* for Regulation 9 is to be found in the free-standing EU regime and the related power in the 1972 Act. SSPs are not an unlawful exemption to s.64 but 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 medicine(s) of a specified description.

The section 58A point

43. The Claimant contends that the effect of Regulation 9 is to exempt medicines falling within s.58A from the prohibition in Regulation 214 and that this is incompatible with s.58A. That is also wrong.

44. Regulation 226A is an exemption to Regulation 214 because it falls within Chapter 3 of Part 12 of the 2012 Regulations which is titled '*Exemptions to supply in specific circumstances*' (see above). Regulation 226A(1) provides for the sale or supply of prescription-only medicines *'in accordance with a serious shortage protocol'* rather than *'in accordance with a prescription'* pursuant to Regulation 214. The exemption thereby created is not incompatible with s.58A because it does not exempt any medicines in the categories listed in s.58A(2) from being prescription-only. 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'*.

GROUND 2: PSED *[C/SFG/45-57]*

45. Regulation 9 contains a power to make SSPs subject to a broadly expressed set of conditions. It is plain, and evidently contemplated by Regulation 9 given its high level nature, that considerable further work will be needed to produce and implement an effective, operational scheme. As already noted, work in fact continues on the operational detail and content of SSPs (and other matters). The scheme produced by this work will need to be considered and approved by the Secretary of State. Two points flow:

    45.1. The high level and basic nature of the Regulation 9 power forms the essential context in which compliance with the PSED duty under challenge in this claim is to be assessed.

45.2. Moreover, this stage of creating the basic, necessary power is part of a process that will need to be followed (with other policy decisions along the way) before arriving at the final scheme. Further analysis of PSED (and other duties) will be needed and will be undertaken by the Secretary of State before the process is complete.

46. In any event, contrary to the Claimant's assertion that the Secretary of State's officials did not advise him as to the existence and content of his duty under the PSED *[C/SFG/54]*, an analysis of the impact of the proposals for the basic power in Regulation 9 pursuant to the PSED was set out in Annex C to the December Submission, as noted above[4]. Annex C was accompanied by an economic and social Impact Assessment which was put to the Secretary of State in the January Submission in the Explanatory Memorandum to accompany the 2019 Regulations and also in Annex B to the December Submission. Further, officials included a question on the PSED impact of the proposals in the consultation invitation sent on 5 December 2018 (see paragraph 16.3 above, Question 3) *[D/SGExh/6/31]*. Respondents therefore had the opportunity to comment on DHSC's PSED analysis before it was submitted to the Secretary of State.

47. The matters set out in *R (Bracking) v Secretary of State for Work and Pensions* [2013] EWCA Civ 1345 at §25 by McCombe LJ were dealt with, as appropriate to the context, by the analysis in Annex C *[D/SGExh/9/55-56]*:

47.1. It was stated that all patients, including those with protected characteristics would benefit from the use of an SSP in the event of shortages by the management of stocks (e.g. dispensing in smaller quantities than prescribed) and by supplying suitable alternatives than prescribed (§12);

47.2. The three equality objectives were set out (§9);

47.3. It was acknowledged that some of the protected groups would be likely to use medicines more often (i.e. including but not limited to the disabled) (§11);

47.4. It was noted that SSPs would not be suitable for some medicines, some conditions and some patient groups, such as epileptics or anti-depressants (paragraph 4) and that those groups would be referred back to their prescriber in the event of a shortage (§12);

47.5. It was noted that an SSP would include criteria that would need to be fulfilled before a supply could be made, for example, it might only apply to adults or to people stabilised on the medicine for a minimum of three months in order to ensure higher risk patients received more oversight from their GP (§5(a));

47.6. Any alternative to be supplied in accordance with an SSP would be agreed at national level and the views of senior clinical advisors would be sought on the substitutions. In England, it was expected that NHS England clinical experts would lead on developing the individual protocols (§7).

[4] It is to be noted that there is no statutory duty to carry out a formal equality impact assessment (EIA).

48. Thus, the PSED was considered by the Secretary of State personally through the provision to him of Annex C (to be read with Annex B *[D/SGExh/9/47/52-3]*). It will continue to be so considered in future submissions on the amendments to the NHS Terms of Service and on operational policy for SSPs.

49. The Secretary of State denies that Regulation 9, as a power, will disproportionately impact gay men and those of African origin because sufferers of HIV disproportionately belong to those groups *[C/SFG/55]*. HIV sufferers would only be impacted at all if any drugs relating to their treatment were in short supply and were the subject of an SSP. In the event that this occurred, the safeguards for the treatment of individuals set out in Annex C of the December Submission would be put in place by the clinicians that developed the SSP. The impact on any patient group suffering from a particular condition would be considered by those clinicians if drugs relating to that condition, or required as a result of that condition, were to be the subject of an SSP.

50. There is no parallel with *Eisai Limited v The National Institute for Health and Clinical Excellence* [2007] EWHC 1941 Admin (see *[C/SFG/58] [CB/6/34/6.18]*). In that case, Dobbs J found at §91 that there was no discussion whatsoever about the legal duties and obligations placed on the public authority under the anti-discrimination legislation then in force and no reference to that legislation in any detail. That is manifestly not the case here, as Annex C of the December Submission demonstrates. Further, there has been no attempt to delegate the PSED duty to clinicians by the Secretary of State, as Dobbs J suggested in *Eisai* in the quoted paragraph *[C/SFG/58]*. The Secretary of State has clearly fulfilled his duty to consider the impact of the SSP policy as a whole on groups with protected characteristics in the decisions taken to date and will continue to do so in those in the future. It is simply the case that the nature of an SSP will require specific consideration of groups with protected characteristics at a clinical level as well when the terms of the protocol is being agreed.

51. The Claimant further contends that the Secretary of State disregarded and diverged from its current published objectives (numbered here 1-5 in the order set out in *[C/SFG/60]*) in enacting Regulation 9. The Claimant does not specify which of those objectives have been disregarded. In any event:

    51.1. The PSED was addressed in the December Submission (Objectives 1 and 5);
    51.2. Stakeholders were consulted on the proposals (Objective 2);
    51.3. The impact of the proposals under the PSED was set out in the email sent to stakeholders on 5 December 2018 inviting them to comment on the SSP proposal (Objective 3);
    51.4. The SSP was self-evidently designed to improve the health and well-being of the whole population in the event of a serious drug shortage (Objective 4);

GROUND 3: FAILURE TO TAKE INTO ACCOUNT THE NHS CONSITUTION *[C/SFG/63-67]*

52. The Claimant contends that the Secretary of State was required by s.1B(1) of the NHS Act 2006 to take into account the NHS Constitution in enacting Regulation 9. Section 1B(1) provides *[CB/4/25/4.17]*:

> *'**Duty as to the NHS Constitution***
> *(1) In exercising functions in relation to the health service, the Secretary of State must have regard to the NHS Constitution.*
> *(2) In this Act, "NHS Constitution" has the same meaning as in Chapter 1 of Part 1 of the Health Act 2009 (see section 1 of that Act). '*

'*NHS functions*' are not defined in the 2006 Act[5].

53. **First,** the Secretary of State had those matters relied upon by the Claimant in this respect derived from the Constitution *[C/SFG/65]* well in mind. The Secretary of State's performance of these duties under the 2006 Act involves the exercise of substantial discretion, judgement and assessment since there may be tension between the duties in question; *R (PSNC) v Secretary of State for Health* [2018] EWCA Civ 1925 at §81. In this context also, it is important to recognise that the consideration of such matters arises at this stage in relation simply and only in relation to a decision about, in effect, the principle of having a power to make SSPs to manage serious drug shortages.

54. Specifically:

54.1. ***Principle 4 of the Principles that Guide the NHS (patient involvement in decisions about care and treatment) and NHS Values 'Working together for patients' [C/SFG/65(i) and (ii)]***: in so far as these principles/values can be applied to the creation of the power to make SSPs, the Secretary of State was aware of the consultation responses that raised the issue of patient consent (§6 December Submission). The Secretary of State was advised that this issue, amongst other operational issues, would need further communication and additional legal instruments to make SSPs operational (§6 December Submission). Any challenge to the consideration of this duty is clearly premature. The short Impact Assessment also

[5] No concession is made that the Secretary of State was exercising functions in relation to the health service when making Regulations pursuant to s.2(2)(b) of the 1972 Act when dealing with matters arising out of and related to the classification of medicines as governed by the 2001 Directive (see Ground 1 above). The classification of medicines probably belongs to the EU vires scheme, rather than an NHS scheme. As an illustration of the contrast between the two schemes, MHRA take licensing decisions permitting the placing on the market of medicinal products in the UK but the National Institute for Health and Care Excellence (NICE) recommends products for NHS use; see National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013. However, at this stage this issue does not need to be determined.

discussed risks from not reverting to the original prescriber and possible means of mitigating those risks (Annex B to the December Submission).

54.2. ***Patients and the public: your rights and the NHS pledges to you [C/SFG/65(iii)]****:* again, in so far as these principles/values can be applied to the creation of the power to make SSPs, the Secretary of State was aware of the consultation responses from patient organisations that were concerned about dispensing of different products without liaison with the prescriber (§3 of the December Submission). The Secretary of State was advised that it had not been clear from the consultation so far, which only dealt with the principle of the power to issue SSPs, that it was intended that any protocol would be signed off by clinicians and would have undergone significant scrutiny to avoid such risks (§3 of the December Submission). Further, the Secretary of State was advised that concerns could be addressed going forward by explaining in the next stage of policy development and engagement with stakeholders how protocols would work (§4 of the December Submission).

55. **Secondly,** these sorts of issues will continue to be considered as the process progresses towards a final, implementable scheme – for example, in relation to the amendments to the NHS Terms of Service and in relation to operational policy for SSPs.

GROUND 4: CONSULTATION *[C/SFG/68-94]*

56. The Claimant alleges that the Secretary of State acted unlawfully (a) by not consulting publicly or at least a broader group of patient interest groups, as part of a formal consultation and (b) by confining the 'informal consultation' to a period of 5 clear working days.

57. The target of the consultation that has so far taken place has been to ascertain stakeholder views as to the principle of Ministers having a power to issue SSPs, not on the operational detail of SSPs. As set out above, the operational detail remains the subject of ongoing policy development and engagement.

Obligation to consult

58. **First**, there was no statutory obligation to hold a formal consultation in relation to Regulation 9 derived from s.1B(1) of the NHS Act 2006 via *'the importance placed in the NHS Constitution on listening to patients, as set out in Ground 3 above' [C/SFG/70]*. This description of the alleged obligation by the Claimant falls far short of an obligation to hold a public consultation.

59. **Secondly,** the obligation in s.129(6) of the Medicines Act 1968 does not apply to the making of Regulation 9 because it was not made under s.129(6) or any other provision of

the Medicines Act 1968 but under ss.2(2)(b) and (5) of the ECA 1972, (see Ground 1 above).[6]

Scope and length of consultation

60. The Secretary of State would normally consult publicly for 12 weeks before making changes to the 2012 Regulations. However, that is not an immutable position; and this was plainly not a normal situation. The need for the power created by Regulation 9 was obviously important and obviously pressing – both generally (see the Epipen example) and in the context of Brexit (and the particular risks of shortages to which that might give rise). As noted above, the Secretary of State already had a slot in the legislative timetable for regulations to amend the 2012 Regulations to further transpose the Falsified Medicines Directive. He decided to add the SSP Regulation to those proposed regulations, in order to ensure that it was in force in good time. That was a rational decision properly open to him – and indeed, having identified the clear and pressing need for the power, an obviously appropriate one.

61. Consultation in stages is a permissible approach in principle and when, as here, there are good reasons for that approach: see, for example, *R (Bard Campaign) v Secretary of State for Communities & Local Government* [2009] EWHC 308 (Admin) at §§128 and 139 per Walker J; *R (Breckland District Council) v Boundary Committee for England* [2009] EWCA Civ 239 [2009] PTSR 1611, CA at §49 per May LJ (P).

62. The consultation that has occurred so far on the point of principle in Regulation 9, judged in the round as it must be, was fair and adequate and was not undermined by the required timetable. In summary, as noted above, it had the following main elements and periods:

    62.1. November 2018 to December 2018: engagement by way of meetings and phone calls with industry, clinical, pharmacist and patient representative bodies.
    62.2. 5 December to 12 December 2018: request by email to 24 stakeholder groups including industry, clinical, pharmacist and patient representative bodies inviting written comments on the draft Regulations.
    62.3. 9 January 2019: meeting with the ABPI.

63. Engagement on operational detail and the necessary amendments to the NHS Terms of Service is ongoing via liaison with clinical and pharmacist bodies to develop operational

[6] Section 129(6) provides: *' Before making any regulations under this Act and before making any order under this Act (except an order made in accordance with any provision of this Act under which, in case of urgency, an order can be made with immediate effect) the Ministers proposing to make the regulations or order shall consult such organisations as appear to them to be representative of interests likely to be substantially affected by the regulations or order.'*

guidance and templates for SSPs and on changes to the NHS Terms of Service (see paragraph 27 above).

64. In addition, Regulation 226A(6) provides for a review of the operation of SSPs as soon as reasonably practical after the end of one year beginning on the day that the first SSP is issued.

65. As to the Claimant's allegation that it was irrational for the Secretary of State not to have included the five bodies set out in *[C/SFG/77-78]* and/or not to have consulted publicly or consulted a wider group of patient interest organisations at the initial stage of consulting about the principle of a SSP power in November 2018 to January 2019:

    65.1. There was no statutory obligation to do so (see paragraph 58 above).

    65.2. The Secretary of State chose to consult National Voices, which represented a much larger range of patient interest groups in order to achieve a broad overview of opinion on the proposals. National Voices responded by saying that there would be specific interest groups that would be affected by SSPs and this was acknowledged in §11 of the Consultation Response *[D/SGExh/8/40]*.

    65.3. Clinical bodies were consulted that could and did highlight the significance of SSPs to those with the severest medical conditions, such as those represented by the groups set out in *[C/SFG/77]*.

    65.4. The Secretary of State included the review clause in Regulation 226A, acknowledging that some respondents to the consultation were concerned about the duration of the consultation.

REMEDY

66. Section 31 of the Senior Courts Act 1981 provides for consideration by the Court of whether the outcome for the Claimant would have been substantially different if the conduct complained of had not occurred both when considering the grant of permission and when determining what relief, if any, should be ordered if a claim succeeds:

> *'31. Application for judicial review.*
> *[…]*
> *(2A) The High Court—*
> *(a) must refuse to grant relief on an application for judicial review, and*
> *(b) may not make an award under subsection (4) on such an application,*
>
> *if it appears to the court to be highly likely that the outcome for the applicant would not have been substantially different if the conduct complained of had not occurred.*
>
> *(2B) The court may disregard the requirements in subsection (2A)(a) and (b) if it considers that it is appropriate to do so for reasons of exceptional public interest.*
> *(2C) If the court grants relief or makes an award in reliance on subsection (2B), the court must certify that the condition in subsection (2B) is satisfied.*

[…]
(3C) When considering whether to grant leave to make an application for judicial review, the High Court—

(a) may of its own motion consider whether the outcome for the applicant would have been substantially different if the conduct complained of had not occurred, and
(b) must consider that question if the defendant asks it to do so.

(3D) If, on considering that question, it appears to the High Court to be highly likely that the outcome for the applicant would not have been substantially different, the court must refuse to grant leave.
(3E) The court may disregard the requirement in subsection (3D) if it considers that it is appropriate to do so for reasons of exceptional public interest.
(3F) If the court grants leave in reliance on subsection (3E), the court must certify that the condition in subsection (3E) is satisfied.
[…]

(8) In this section "the conduct complained of", in relation to an application for judicial review, means the conduct (or alleged conduct) of the defendant that the applicant claims justifies the High Court in granting relief.'

67. There is no challenge in this claim to the justification, indeed the pressing need, for the power in Regulation 9.

68. As to Ground 2 (PSED), the Claimant does not assert that heightened scrutiny of the PSED would have made a substantial difference to the Secretary of State's decision to approve Regulation 9. In any event, the Secretary of State will consider PSED again when reviewing the proposed amendments to the Pharmacy NHS Terms of Service and the operational guidance and documents that will accompany the SSP power and there are no grounds for asserting that there would have been substantial difference to the decision to approve Regulation 9.

69. As to Ground 3 (NHS Constitution), the Claimant asserts that there is a good chance that Regulation 9 would not have been in the form that it was because the way it came into being as well as its content, are antithetical to the principle of patient involvement. As set out above, the Secretary of State had the principles and values the Claimant identifies in mind when approving the power to issue SSPs and it was identified that any concerns arising from those principles and values would be addressed, as they had to be, at the stage of creating operational policy. There are no grounds for asserting, therefore, that Ground 3 would have made a substantial difference to the decision to approve of Regulation 9.

70. As to Ground 4 (Consultation), the Claimant does not assert that if the consultation had been broader in scope or longer in duration, SSPs would not have been enacted or would or should have been enacted in a substantially different form. The Claimant's only contention in this regard is that, whilst an exception has been acknowledged for epilepsy

sufferers as a result of the consultation, other affected patient groups have not received similar reassurances *[C/SFG/83]*.

71. In response to that limited contention:

    71.1. There is no exception in Regulation 226A for epilepsy. SSPs may not be suitable for certain medicines, such as some epilepsy medicines, which have been used as an illustration in the Consultation Responses document and Explanatory Memorandum.

    71.2. Any SSPs issued will be agreed with clinicians and the interests of patients with specific conditions will therefore be protected.

    71.3. Patients will be able to refuse to have their treatment substituted under an SSP and to be referred back to their prescriber.

72. There are again, therefore, no grounds for the assertion that increased consultation as to the power to make SSPs would have made a substantial difference to the decision to approve Regulation 9.

73. There are no reasons of exceptional public interest pursuant to s.31(3E) for disregarding s.31(3C).

74. Pursuant to s.31(3C), (3D) and (3E) the Court is, therefore, invited to refuse permission or, pursuant to s.31(2A) and (2B), to refuse to grant any relief if the claim should ultimately be successful, in relation to Grounds 2, 3 and 4.

STANDING

75. The test for standing is set out in s.31(3) of the Senior Courts Act 1981: *'the Court shall not grant permission unless it considers that the applicant has a sufficient interest in the matter to which the application relates.'*

76. There are myriad other organisations with a direct interest in and knowledge of the matters relating to SSPs which could bring this claim to challenge the basic provision of power (or any future claim relating to an SSP that had been issued). The Claimant is not performing a role that no other body could do and is not well-placed to assist the court in relation to the issues it raises (see *R v Somerset County Council ex parte Dixon* [1998] Env LR 111 at 121 per Sedley J).

77. The importance of the issue is not sufficient in principle for the test to be met, *R (Chandler) v Secretary of State for Children, Schools and Families* [2009] EWCA Civ 1011, [2010] LGR 1 at [72], *'It would drive a coach and horses through the requirement for standing if the importance of the issue justified standing in such circumstances. It would mean that people with no real interest in the question could bring judicial review proceedings.'* In

any event for the reasons given above the issues raised are not within the important category anyway. The claim seeks to quash Regulation 9. However, it does so in circumstances in which there is no challenge to the utility of and need for such a power. Nor could there sensibly be such a challenge.

78. Some asserted interest in Brexit (which appears to be the only candidate for subjects in which the Claimant's members are said to be interested) is (a) not sufficient interest; and (b) not what this claim is about anyway. Brexit merely provides an important part of the context in which pressing focus was placed on the absence of a power to manage serious drug shortages.

CONCLUSION

79. For the reasons set out above, the Court is invited to refuse permission; and to award *Mount Cook* costs (a Schedule is attached). If, contrary to the submissions above, permission is granted on any part of the claim, the Claimant seeks a CCO. The Secretary of State opposes this application for the reasons set out in the Annex hereto.

SIR JAMES EADIE QC
SARAH WILKINSON
SAARA IDELBI

8 March 2019

ANNEX ON THE APPLICATION FOR A COST CAPPING ORDER ("CCO")

1. In a recent order refusing to grant a CCO to the Claimant, Ouseley J noted *'Regular crowdfunded public law litigation, brought by one particular Claimant for which a costs capping order is always sought, may require some closer examination for costs capping order purposes';* Order dated 22 May 2018 in *(R) Good Law Project v Electoral Commission* CO/4908/2017 *[D/SGExh/14/127-8]*. The Claimant's model for litigation depends on crowdfunding *[Witness statement of Jolyon Maugham §4, 8] [CB/2/5/4.1/2.3-2.5]*.

Power to make a CCO

2. Section 88 of the Criminal Justice and Courts Act 2015 ("CJCA 2015") provides a discretion for the Court to make a costs capping order if certain conditions are fulfilled:

*'**Capping of costs***
(1) A costs capping order may not be made by the High Court or the Court of Appeal in connection with judicial review proceedings except in accordance with this section and sections 89 and 90.
(2) A "costs capping order" is an order limiting or removing the liability of a party to judicial review proceedings to pay another party's costs in connection with any stage of the proceedings.
(3) The court may make a costs capping order only if leave to apply for judicial review has been granted.
(4) The court may make a costs capping order only on an application for such an order made by the applicant for judicial review in accordance with rules of court.
(5) Rules of court may, in particular, specify information that must be contained in the application, including—
(a) information about the source, nature and extent of financial resources available, or likely to be available, to the applicant to meet liabilities arising in connection with the application, and
(b) if the applicant is a body corporate that is unable to demonstrate that it is likely to have financial resources available to meet such liabilities, information about its members and about their ability to provide financial support for the purposes of the application.
(6) The court may make a costs capping order only if it is satisfied that:
(a) the proceedings are public interest proceedings,
(b) in the absence of the order, the applicant for judicial review would withdraw the application for judicial review or cease to participate in the proceedings, and
(c) it would be reasonable for the applicant for judicial review to do so.
(7) The proceedings are "public interest proceedings" only if—
(a) an issue that is the subject of the proceedings is of general public importance,
(b) the public interest requires the issue to be resolved, and
(c) the proceedings are likely to provide an appropriate means of resolving it.
(8) The matters to which the court must have regard when determining whether proceedings are public interest proceedings include—
(a) the number of people likely to be directly affected if relief is granted to the applicant for judicial review,

(b) how significant the effect on those people is likely to be, and
(c) whether the proceedings involve consideration of a point of law of general public importance.'

3. The Secretary of State opposes the application for a CCO. The statutory requirements for the making of a CCO are not met:

    a. These are not 'public interest proceedings' within the meaning of s.88(7) CJCA 2015.
    b. There is no evidence that the Claimant would have to withdraw its application for judicial review if a CCO is not granted.
    c. If the Claimant choses to withdraw if a CCO is not granted, it would not be reasonable for it to do so within the meaning of s.88(6)(c).

4. In accordance with s.88(8) CJCA 2015, the Court must have regard to three factors when determining whether proceedings are 'public interest proceedings':

    a. The number of people likely to be directly affected if relief is granted to the applicant for judicial review;
    b. How significant the effect on those people is likely to be; and
    c. Whether the proceedings involve consideration of a point of law of general public importance.

5. In addition, s.89(1) CJCA 2015 provide a non-exhaustive list of matters to which the Court must have regard when considering whether to make a CCO and what the terms of such an order must be:

    (a) the financial resources of the parties to the proceedings, including the financial resources of any person who provides, or may provide, financial support to the parties;

    (b) the extent to which the applicant for the order is likely to benefit if relief is granted to the applicant for judicial review;

    (c) the extent to which any person who has provided, or may provide, the applicant with financial support is likely to benefit if relief is granted to the applicant for judicial review;

    (d) whether legal representatives for the applicant for the order are acting free of charge;

    (e) whether the applicant for the order is an appropriate person to represent the interests of other persons or the public interest generally.

6. By s.89(2) CJCA 2015, a CCO that limits or removes the Claimant's costs liability in the event that relief is not granted must also limit or remove the Defendant's costs liability in the event that it is.

Public interest proceedings

7. In enacting the CCO provision, "*the intention of Parliament was to restrict costs capping orders to cases where the highest public interest was engaged in claims for which permission had been or was to be granted"; see* R (Hawking) v Secretary of State for Health and Social Care [2018] EWHC 989 (Admin), [2018] ACD 41 at [14]. Further, in the context of a protective costs order, *'just because there is public interest in issues illustrated by and surrounding this case does not mean that the issues actually raised in these proceedings are themselves of general public importance, at least in the sense intended by the Court of Appeal in Corner House.'* Jolyon Maugham v Uber London Ltd [2019] EWHC 391 (Ch) at [56].

8. That test for cases of the highest public interest is not met in this case for the reasons given in the body of the Summary Grounds.

9. As to ss.89(1)(b) and (c) (benefit to Claimant and to those funding the Claimant if relief granted), there will be no benefit to the Claimant or those who have contributed to its crowdfunding or to the population generally if relief is granted – on the contrary, there would be no SSP power to manage serious drug shortages.

10. As to s.89(1)(d), the Claimant's legal representatives are not acting free of charge but their fees are capped at Treasury rates; *[Witness statement of Jolyon Maugham §13] [CB/2/5/2.7]*.

11. As to s.88(8)(b) (the effect on those directly affected if relief granted) and s.89(1)(e) (appropriateness of Claimant to represent public interest), the Claimant has no particular expertise in drug shortages or health care generally, although it has a published interest in Brexit.

12. As to s.88(8)(c), the claim does not present any issue of law of wider application than this case.

Reasonable to withdraw in absence of a CCO

13. This test is not met:

    a. The Claimant is a limited company operating on a not for profit basis with reserves of approximately £50,000 which regularly applies for cost-capping

orders for its crowd-funded litigation *[Witness Statement of Jolyon Maugham QC/6, 10] [CB/2/5/2.4-2.6]*. It therefore has reserves estimated to be £50,000 with which it could meet an adverse costs order. Mr. Maugham's explanation that he has been *'trying to build up reserves to enable me to hire staff'* is wholly inadequate as a justification for not using company reserves to meet an adverse costs order.

b. It has brought a claim with a self-imposed cap of £20,000 of liability for any one case *[Witness Statement of Jolyon Maugham QC/14] [CB/2/5/2.7]*.
c. As at the date of these Summary Grounds, it has crowdfunding of £31, 755 with which to meet an adverse costs order.
d. It therefore has at least £80,000 with which it could meet an adverse costs order in circumstances where it (rightly) estimates that the Secretary of State's costs will not be more than £80,000. Where a claimant has financial resources in excess of the defendant's projected costs, it will not be reasonable for the claimant to withdraw their claim because a CCO has not been granted; see ***R (Litvinenko) v Secretary of State for the Home Department*** [2013] EWHC 3135 (Admin) [2014] ACD 25.
e. The Claimant's application for a CCO asks for an order capping its liability in essence at the level of its crowdfunding (at the time of the application £14, 176). The choice that it would be faced with if a CCO is not granted, is therefore, whether to use its own resources to fund the claim or withdrawing the claim but still paying its own legal team. There is nothing unreasonable in this choice for the Claimant.
f. The purpose of a CCO is to introduce certainty where there would otherwise be an uncertain litigation risk, not to protect a Claimant from a litigation risk that it has chosen and can reasonably afford to take.

Level of any CCO

14. Even if the statutory requirements for the making of a CCO were met in this case, which they are not, the level of the CCO sought by the Claimant is wholly inappropriate in light of the increase in crowdfunding received by the Claimant since the claim was filed and in light of its overall assets. Under s.89(1)(a) CJCA 2015, the Court is required to take into account the financial resources of the Claimant and of any person who provides, or may provide, financial support to it (i.e. its crowd funders).

15. Given the Claimant's assets and crowdfunding set out above, £15,000 is unreasonably low. In ***Hawking***, the Claimant's costs liability was fixed at the total amount it had already raised through crowdfunding (£160,000) even though it was anticipated that it would incur substantial legal costs itself (£115-140,000). In this case, the amounts are currently £31, 755 and £100,000. On that basis, if a CCO is made, the Claimant's costs liability should not be fixed at a sum lower than the amount of its crowdfunding at the date on which the CCO is made. Further, in this case, the Secretary of State submits that the Court should consider raising the amount ordered to take account of the costs

cap imposed by the Claimant on itself (£20,000) and its estimated reserves (£50,000). That self-imposed costs cap is entirely self-interested and takes no account of the interests of other parties to the litigation.