IN THE HIGH COURT OF JUSTICE **CLAIM NO:**

QUEEN'S BENCH DIVISION

ADMINISTRATIVE COURT

BETWEEN:-

THE QUEEN

(on the application of GOOD LAW PROJECT LIMITED)

Claimant

- v –

SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE

Defendant

STATEMENT OF FACTS AND GROUNDS OF CLAIM

ESSENTIAL READING:

- N463 – APPLICATION FOR URGENT CONSIDERATION, DATED 25 FEBRUARY 2019 **[PB/1.1]**;
- WITNESS STATEMENT OF JANE HANNA OBE, DATED 25 FEBRUARY 2019 **[PB/2.45]**;
- WITNESS STATEMENT OF DEBORAH GOLD, DATED 25 FEBRUARY 2019 **[PB/2.149]**;
- WITNESS STATEMENT OF CHLOE ORKIN, DATED 25 FEBRUARY 2019 **[PB/2.168]**;
- WITNESS STATEMENT OF PETER WALSH, DATED 21 FEBRUARY 2019 **[PB/2.145]**;
- WITNESS STATEMENT OF TAMARA KATHERINE HERVEY, DATED 25 FEBRUARY 2019 **[PB/2.156]**;
- WITNESS STATEMENT OF JOLYON MAUGHAM QC, DATED 25 FEBRUARY 2019 **[PB/2.1]**;
- DEPARTMENT OF HEALTH AND SOCIAL CARE, CONSULTATION PAPER, DATED 5 DECEMBER 2018 **[PB/2.85]**;
- DEPARTMENT OF HEALTH & SOCIAL CARE, CONSULTATION RESPONSE, DATED 14 JANUARY 2019 **[PB/2.109]**;
- EXPLANATORY MEMORANDUM TO THE HUMAN MEDICINES (AMENDMENT) REGULATIONS 2019 **[PB/5.6]**;

ESTIMATED READING TIME: 4 HOURS

INTRODUCTION

1. This is a claim for judicial review by the Good Law Project Ltd (the "Claimant") challenging the making of Regulation 9 of the Human Medicines (Amendment) Regulations 2019 (the "2019 Regs"). This change has resulted in wholesale transformation to the framework by which patients will receive prescription-only

medicines. In particular, through the publication of a Serious Shortage Protocol – to be made at a later date as and when a shortage of medicines arises – pharmacists will be permitted to dispense medication in accordance with the Serious Shortage Protocol instead of in accordance with the prescription issued by "appropriate practitioners" (e.g. doctors and dentists).

2. The United Kingdom has never before had a Serious Shortage Protocol. In fact, it is currently a criminal offence for any person, including a pharmacist, to sell a patient medicine otherwise than as specified in a prescription issued by an "appropriate practitioner" (section 64 of the Medicines Act 1968) *or* (subject to exemptions) to sell or supply a prescription only medicine except in accordance with a prescription given by an "appropriate practitioner" (Regulations 214 and 255 of the 2019 Regs). These offences reflect the fact that prescription medicines can be dangerous and that safe prescription requires a personalised approach that is based on the patient, and their particular history and condition. That takes place in consultation with the patient. Accordingly, "*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*".[1] One avowed purpose of Regulation 9 of the 2019 Regs is that "*pharmacists and GPs…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*".[2]

3. The Claimant's case is that the Defendant does not have the power to make Regulation 9 of the 2019 Regs and that, even if he did, the process by which he made it was so rushed and inadequate so as to render it unlawful.

4. Regulation 9 of the 2019 Regs has expressly been made independently of, but prompted by, the possibility of the United Kingdom leaving the European Union ("Brexit") without a deal ("no-deal Brexit"). This cannot, however, pardon what would otherwise be a clearly unlawful enactment, bearing in mind that: the date for

[1] See §4 of the DHSC's Consultation Response, dated 14 January 2019 [PB/2.111].

[2] See the DHSC's Consultation email, dated 5 December 2018. [PB/2.85].

Brexit (29 March 2019) was fixed on, and has been public knowledge since, 29 March 2017; and, that Regulation 9, and the Serious Shortage Protocols it provides for, could have very serious adverse consequences for the health, welfare and even lives of certain vulnerable patients.

5. The Claimant accordingly seeks judicial review of Regulation 9 of the 2019 Regs on the following grounds:

    a. **Ground 1:** Regulation 9 of the 2019 Regs is *ultra vires*;

    b. **Ground 2:** The Defendant failed to comply with s149 of the Equality Act 2010 when making Regulation 9 of the 2019 Regs and his own s149 policy;

    c. **Ground 3:** The Defendant failed to take into account and act consistently with the NHS Constitution when making Regulation 9 of the 2019 Regs; and,

    d. **Ground 4:** The informal consultation carried out prior to making Regulation 9 of the 2019 Regs was unlawful.

6. As things currently stand, Brexit will take place on 29 March 2019. It is important that this claim be heard and decided before that date. This is to avoid the possibility of an unlawful Serious Shortage Protocol being issued and acted upon, in the event of a no-deal Brexit. The potentially very serious adverse consequences of Regulation 9 of the 2019 Regs, including the potentially fatal consequences, call for this exceptional approach. As the 2019 Regs came into force on 9 February 2019, it was not possible to bring this claim before now.

7. This Statement of Facts and Grounds is set out as follows:

    a. Procedure and expedition;

    b. Factual Background;

    c. Legislative Background;

    d. Grounds;

e. Costs Capping Order; and,

f. Conclusions and Relief.

PROCEDURE AND EXPEDITION

8. The Claimant and various patient-interest groups are concerned that the issuing of a Serious Shortage Protocol, with the legal effect set out in Regulation 9 of the 2019 Regs, could have severe consequences for certain patients, including potential loss of life[3]. The risk of a Serious Shortage Protocol being made is very significant in the event of a no-deal Brexit: Witness Statement of Tamara Katherine Hervey, dated 25 February 2019, §§4-9 **[PB/2.157]**. Otherwise, the risk is greatly reduced, but still exists. Consequently, as things stand, the Court is requested to expedite this claim so that it can be heard before exit day, which is on 29 March 2019: ss 1 and 20(1) of the European Union (Withdrawal) Act 2018.

9. The Claimant seeks an Order from the Court with the following directions:

   a. The Defendant shall file and serve an Acknowledgment of Service and Summary Grounds of Defence by 4pm on the 4 March 2019;

   b. Any legal submissions in response from the Claimant shall be limited to two sides of A4 paper and shall be filed and served by 4pm on the 5 March 2019;

   c. The Court shall endeavour to decide whether permission to apply for judicial review should be granted, and whether there should be a Costs Capping Order, by 4pm on the 6 March 2019;

   d. If permission to apply for judicial review and a Costs Capping Order are granted, then, subject to any further order the Court sees fit to make at that stage:

[3] Witness Statement of Jane Hanna, dated 25 February 2019, §§13-18 **[PB/2.51]**, Witness Statement of Deborah Gold, dated 25 February 2019, §§6-14 **[PB/2.151]** and Witness Statement of Professor Chloe Orkin, dated 25 February 2019, §§5-14 **[PB/2.170]**

i. The Claimant shall file and serve a skeleton argument and any further evidence by 4pm on the 13 March 2019;

ii. The Defendant shall file and serve a skeleton argument and any evidence by 4pm on the 19 March 2019;

iii. Any response from the Claimant shall be as concise as possible and shall be filed and served as speedily as possible;

iv. The Claimant and Defendant shall agree on a core and supplementary bundle of documents, and on a bundle of authorities, to be filed at Court as soon as possible and no later than 4 pm on the 22 March 2019;

v. There shall be a final hearing of the application for a judicial review listed for 2 days in the week starting the 25 March 2019.

e. If permission to apply for judicial review is refused on the papers or the Court wishes to have an oral permission hearing, that hearing to be listed for half a day by no later than the 13 March 2019.

FACTUAL BACKGROUND

(a) Good Law Project Ltd

10. Information about Good Law Project Ltd (the "Claimant") can be found in detail in the Witness Statement of Jolyon Maugham QC, dated 25 February 2019, §§2-7.

11. By way of summary, the Claimant is a not-for-profit organisation set up to help deliver practically beneficial outcomes through public-interest litigation. In particular, it looks for cases that provide checks and balances to executive power and which secure the rule of law. It has previously been successful in the case of *R (Good Law Project) v Electoral Commission* [2018] EWHC 2414 (Admin). It receives subscriptions from members and one-off donations for specific cases by way of crowdfunding.

(b) Impact of no-deal Brexit on medicines supply chains

12. Medicines supply in the United Kingdom is deeply integrated with the rest of the EU, supported by laws and multi-level regulatory arrangements. In the event of a no-deal Brexit, the absence of a legal framework for imports and exports is expected to have an immediate and drastic effect on supply chains. Shortages are likely as stockpiling arrangements cannot cope for more than a few weeks: Witness Statement of Tamara Katherine Hervey, dated 25 February 2019, §§4-9 **[PB/2.157]**.

13. Currently, the United Kingdom is set to withdraw its membership of the European Union on 29 March 2019.

(c) Consultation on 2019 Regulations

14. It was in the above context that the Defendant proposed to amend the Human Medicines Regulations 2012 so as to allow for the issuing of Serious Shortage Protocols.

15. The informal consultation commenced by way of an email to certain, targeted organisations: **[PB/2.85]**. It stated as follows:

> **"Informal consultation on urgent changes to the Human Medicines Regulation 2012 to ensure the continuity of supply of medicines (including in a 'no deal' Brexit)**
>
> Prompted by the preparations for the UK's exit from the EU, the Department of Health and Social Care is proposing some changes the Human Medicines Regulations 2012 to ensure the continuity of supply of medicines when the UK leaves the EU, including in a 'no deal' scenario. We have spoken to a number of representative bodies about the changes and would be happy to speak to others as well.
>
> Normally, we would consult publicly for 12 weeks before making any changes to the Human Medicines Regulations 2012. However, you will understand that any legislative changes in relation to the UK's exit from the EU need to be progressed quickly so that they are in force before the day that the UK leaves the EU. Therefore, we are seeking views of the relevant stakeholder representative bodies on the proposed changes by close on 12 December 2018."

16. It went on to ask for views on the following question: "*Question 1: Do you agree with the introduction of the provision for a 'serious shortage protocol' to deal with serious national shortages of medicines?*"

17. Under a sub-heading, titled "*Impact assessment*", it was stated that:

> "We expect that a 'serious shortage protocol' would have an impact on pharmacists and GP and on patients:
> • 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.
> • There will be a positive impact on patients who continue to have (quick) access to treatment.
> We have not yet quantified the impact."

18. Under a further sub-heading, titled "*Equality impact assessment*", it was stated that, "*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.*"

19. The email was sent on Wednesday 5 December 2018. The email concluded that responses had to be submitted "*by close on 12 December 2018*".

20. Outside of specially selected stakeholders, it is understood that there was no publication of the consultation nor communication explaining the proposal for Serious Shortage Protocols to many senior clinical and patient leaders: Witness Statement of Jane Hanna OBE, dated 25 February 2019, §3 **[PB/2.46]**. By way of example, SUDEP Action[4] first heard of the proposed Serious Shortage Protocols in a newsletter from the Neurological Alliance. National AIDS Trust did not hear about Regulation 9 and the proposal for Serious Shortage Protocols until the solicitors in this claim drew it to their attention on 18 February 2019. This is notwithstanding that Nationals AIDS Trust is formally registered as a stakeholder for Specialised Commissioning within NHS England: Witness Statement of Deborah Gold, dated 25 February 2019, §§15-18 **[PB/2.153]**. British HIV Association first heard about Serious Shortage Protocols on 18 February 2019, when contacted by National AIDS Trust: Witness Statement of Chloe Orkin, dated 25 February 2019, §15 **[PB/2.174]**.

[4] SUDEP stands for Sudden Unexpected Death in Epilepsy.

Similarly, Action against Medical Accidents first became aware when contacted by Jane Hanna OBE of SUDEP on 15 February 2019: Witness Statement of Peter Walsh, dated 21 February 2019, §8 **[PB/2.147]**. The Defendant did consult with National Voices (see further below) an "umbrella group" for a large number of patient representative groups but (see further below) National Voices complained that it was unable in the limited time available to consult with its members.

21. The sort of wide-ranging change envisaged in this consultation has tended to be consulted on *publicly* in the past: Witness Statement of Jane Hanna OBE, dated 25 February 2019, §25 **[PB/2.56]**.

(d) Outcome of consultation

22. The Consultation Response was published on 14 January 2019 **[PB/2.110]**. In describing the proposals, the Consultation Response stated that:

> "The proposal for the serious shortage provisions was prompted by the preparations for a 'no deal exit' from the EU. The provisions have however not been linked to a 'no deal' EU exit and have not been time limited (although any protocol itself would be time limited). Regardless of whether a shortage of a medicine is caused by a 'no deal' EU exit or something else, a serious shortage protocol can be a useful tool for managing any shortage and mitigating any impact on patients."

23. It stated that 47 responses had been received "*from across the NHS, industry, pharmacists', doctors' and patient representative bodies*": p2. It further stated that "*In addition to and separate from the consultation we received correspondence from some patient groups on the serious shortage protocol.*"

24. It stated that:

> "11. Consultation responses were broadly supportive of the proposal. However, patient groups and doctors' representative bodies raised concern about automatic therapeutic or generic substitution of medicines for high-risk patients, for example patients with epilepsy or transplant patients, without consulting the prescriber. Separate from the consultation, correspondence was received from further patient representative groups raising identical concerns.
>
> 12. Similar concerns were raised more generally about therapeutic or generic substitution where the MHRA requires prescribing by brand, including anti-epilepsy medicines or biological products.
>
> ...

14. Some respondents expressed concern about the short period of time that was given to respond to the consultation."

25. It noted the concerns about the inadequacies of the consultation and stated that:

> "18. To address concerns about the lack of public consultation and the provisions not being time-limited we have amended the regulation post-consultation to include a review clause. The Department will be required by law to review the serious shortage protocol provision as soon as is reasonably practical after the end of one year after the first protocol starts to have effect. The review will look at, specifically, any adverse consequences for either the market in prescription only medicines or patient safety."

26. Finally, the Consultation Response recognised the following:

> "23...Protocols for therapeutic or generic equivalents will not be suitable for all medicines and patients. For example, they will not be suitable for treatments for epilepsy or treatments requiring biological products where the medicines that are prescribed need to be prescribed by brand for clinical reasons. In these cases, patients would always be referred to the prescriber for any decision about their treatment before any therapeutic or generic equivalent is supplied."

(e) Risks inherent in Regulation 9 and Serious Shortage Proposals

27. The risks inherent in Regulation 9 of the 2019 Regs stem from a fundamental change in the relationship between the clinical prescriber, patient and pharmacist: Witness Statement of Jane Hanna OBE, dated 25 February 2019, §25 **[PB/2.56]**.

28. With respect to epilepsy, person-centred prescribing and medicines management is the most effective first-line of intervention to keep patients safe. In this context, bypassing the prescriber-patient relationship and altering treatment can risk breakthrough seizures and the worsening of anxiety and depression, which themselves increase the risk of fatality: Witness Statement of Jane Hanna OBE, dated 25 February 2019, §13 **[PB/2.51]**. This relates not just to the switching of medication, but also to reducing the dose, strength or form of epilepsy medication: Witness Statement of Jane Hanna OBE, dated 25 February 2019, §16 **[PB/2.52]**. Crucially, people with epilepsy will frequently have co-morbidities, such as depression, anxiety, dementia, heart-disease, peptic ulcers and arthritis. Changes to medicines prescribed for those other conditions could also have catastrophic impacts

on epilepsy sufferers: Witness Statement of Jane Hanna OBE, dated 25 February 2019, §17 and §33(j) **[PB/2.63]**.

29. With respect to HIV, there are various significant health risks and concerns in reducing the dose or strength of HIV medication: Witness Statement of Chloe Orkin, dated 25 February 2019, §§5-6 and §§8-11 **[PB/2.170]**; Witness Statement of Deborah Gold, dated 25 February 2019, §§7-10 **[PB/2.151]**. Co-morbidity is also a concern for HIV sufferers; 72% of people with HIV have at least one other long-term condition and 37% are taking at least one *other* prescribed medication: Witness Statement of Chloe Orkin, dated 25 February 2019, §7 **[PB/2.171]**; Witness Statement of Deborah Gold, dated 25 February 2019, §11 **[PB/2.151]**. Altering this *other* prescribed medication could reduce the effectiveness of the HIV medication itself. The only person safely able to alter an individual's HIV prescription is an HIV Consultant: Witness Statement of Chloe Orkin, dated 25 February 2019, §14 **[PB/2.173]**; Witness Statement of Deborah Gold, dated 25 February 2019, §12 **[PB/2.151]**.

30. These are just two groups that will be disproportionately impacted by Regulation 9 of the 2019 Regs. There are likely to be other such groups who will be similarly affected but who were, or still are, unaware of the changes made. This was a point made by the patient-interest group National Voices in their consultation response.

31. There are also concerns that particularly vulnerable groups will be affected to a greater degree when, at short notice, pharmacists offer them different medicine to that prescribed by their GP; they may feel less able to state their needs, medical history and co-morbidities: Witness Statement of Jane Hanna OBE, dated 25 February 2019, §18 **[PB/2.53]**. For example, HIV sufferers, historically stigmatised for their condition and having developed close relationships with their clinicians, may find it distressing to disclose their conditions to a pharmacist. This will disproportionately impact gay men and those of African origin: Witness Statement of Chloe Orkin, dated 25 February 2019, §§12-13 **[PB/2.173]**; Witness Statement of Deborah Gold, dated 25 February 2019, §14 **[PB/2.152]**. Further, risks are likely to be higher for patients with cognitive problems, mental health issues or learning

disabilities, who may be too confused or lack the confidence to challenge changes to their treatment by pharmacists: Witness Statement of Peter Walsh, dated 21 February 2019, §6 **[PB/2.147]**.

LEGISLATIVE BACKGROUND

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

33. The preamble **[PB/4.26]** 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."

34. Regulation 9 of the 2019 Regs **[PB/4.28]** provides 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.'."

35. Regulation 9 of the 2019 Regs refers to, and provides an exemption in respect of, Regulation 214 of the Human Medicines Regulations 2012 (the "2012 Regs") **[PB/4.19]**. This 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.

..."

36. Section 64 of the Medicines Act 1968 **[PB/4.11]** 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'."

37. Section 67(2) of the Medicines Act 1968 **[PB/4.13]** makes it a criminal offence to contravene s64 of the Medicines Act 1968. Regulation 255 of the 2012 Regs **[PB/4.24]** makes it a criminal offence to breach Regulation 214(1) of the 2012 Regs.

38. The Explanatory Memorandum to the 2019 Regs **[PB/5.6]** states as follows:

"7.11 Protocols for therapeutic or generic equivalents will not be suitable for all medicines and patients. For example, those types of protocols would not be suitable for treatments for epilepsy or treatments requiring biological products where the medicines that are prescribed need to be prescribed by brand for clinical reasons. In these cases, patients would always be referred back to the

prescriber for any decision about their treatment before any therapeutic or generic alternative is supplied.

...

8.1 This instrument does not relate to withdrawal from the European Union. However, if withdrawal from the European Union were a contributing factor to a serious shortage of prescription only medicines, a serious shortage protocol could be used in those circumstances.

...

10.4 DHSC separately consulted industry, pharmacy and general practitioner stakeholder representative bodies on the provision for the serious shortage protocol. Consultation responses were broadly supportive of the proposal. Concerns were raised about substitution of medicines for high-risk patients. However, any protocol would be developed with and signed off centrally by clinicians. Protocols for therapeutic or generic equivalents will not be suitable for all medicines and patients. For example, they will not be suitable for treatments for epilepsy or treatments requiring biological products where the medicines that are prescribed need to be prescribed by brand for clinical reasons. In these cases, patients would always be referred back to the prescriber for any decision about their treatment before any therapeutic or generic equivalent is supplied.

...

12.4 An Impact Assessment has not been prepared for this policy. The amendments to the 2012 Regulations providing for a serious shortage protocol are enabling and intended to be used when there is a recognised serious shortage. They do not create or impose significant costs on business, charities or voluntary bodies. There is also no significant impact on the public sector.

12.5 The main benefits of the protocol would be the NHS cost savings associated with GP time. There may be some risks to patients, and therefore costs associated with this but clinicians setting out the guidance will consider and minimise these risks when setting out the guidance.

12.6 Whilst costs savings from GPs are expected, the impact on community pharmacies is expected to be neutral. There will be cost savings from not having to liaise with GPs but community pharmacies will need to inform the GP when they dispense against a protocol and they may also be required to do some further checks that they would not do when dispensing against a prescription."

GROUNDS

Ground 1 – Regulation 9 of 2019 Regs is *ultra vires*

39. The Defendant does not have the power to make Regulation 9 of the 2019 Regs. It is, therefore, *ultra vires*.

40. Until the contrary is shown, the Court must proceed on the basis that the preamble to a statutory instrument sets out all the statutory enabling powers that are necessary for its validity: *Polestar Jowetts Ltd v Komori UK Ltd* [2006] 1 WLR 2472 (CA), §22 (Arden LJ). The preamble to the 2019 Regs relies solely on section 2(2) and (5) of the European Communities Act 1972. This appears to be correct for much of the 2019 Regs, which transpose the Falsified Medicines Directive (Directive 2011/62/EU) and give effect to Delegated Regulation (EU) 2016/161, which supplements the Falsified Medicines Directive.[5] Regulation 9 of the 2019 Regs does not, however, implement obligations or rights found in these instruments, nor any other instrument of EU law, nor does it deal with matters arising out of or related to relevant EU obligations or rights; it comprises a national measure. Accordingly, contrary to the preamble to the 2019 Regs, the European Communities Act 1972 did not authorise the Defendant to make Regulation 9 of the 2019 Regs.

41. Nor can any such authority be found elsewhere. For example, whilst section 58(4) of the Medicines Act 1968 empowers the Defendant to make exemptions to Regulation 214 of the 2012 Regs, that only allows the Defendant to make provision for pharmacists to sell what would otherwise be prescription-only medicine.

42. That there is no power to allow pharmacists to *alter* the contents of a prescription, however, is made clear from s64 of the Medicines Act 1968. Section 64(1) of the Medicines Act 1968, together with s64(5), prohibits any person from selling or supplying medicinal products which are not of the nature or quality specified in the prescription. There is no power for the Defendant to make exemptions to this provision. Acting contrary to s64 is a criminal offence: s67(2) of the Medicines Act 1968.

43. The Claimant's subsidiary point is that s58A(1) and (2) of the Medicines Act 1968 requires the Defendant to specify that certain medicines must be prescription only. For example, medicines that present a danger to human health, even when used correctly, if used without the supervision of a doctor or dentist; and medicines that

[5] See §2.1 of the Explanatory Memorandum to the 2019 Regs.

are frequently and to a very wide extent used incorrectly and as a result are likely to present a danger to human health. It is incompatible with s58A to exempt medicines falling within s58A(2) from the scope of Regulation 214 of the 2012 Regs when, by definition, these medicines require the close involvement of the patient's doctor or dentist.

44. In the premises, the Defendant had no power to enact Regulation 9 of the 2019 Regs, authorising pharmacists, as it does, 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. In addition, as a subsidiary point, the Defendant may not lawfully exempt from the scope of Regulation 214 medicine that is required to be prescription-only because it falls within one of the particularly dangerous categories of medicines in s58A(2).

Ground 2 – Failure to comply with Public Sector Equality Duty (s149 Equality Act 2010) and the Defendant's own PSED policy

45. The Defendant failed to comply with the public sector equality duty ("PSED") in s149 of the Equality Act 2010 by not conducting an equality impact assessment of his proposal to enact Regulation 9 of the 2019 Regs.

46. The Defendant provides a succinct summary of the PSED in "Equality duty in 2017: How the Department of Health and Social Care complies with the public sector equality duty" **[PB/5.31]**. As will appear, the Defendant acted in breach of every aspect of this duty and his own policy, as summarised by himself, below:

> "When working on policy, our officials are expected to look at the impact each option might have on people sharing the 9 protected characteristics. They also consider the need to avoid or mitigate against any negative impact on any group.
>
> Ministers are advised of the impact the proposed options may have on various groups of people, and this is taken into account when a policy decision is made. The standard ministerial submissions template that Department officials use specifically asks for equality considerations to be set out for decision-makers.
>
> We seek input from external stakeholders to gain a broader insight into our decisions, and share information about projects with major equality considerations with the Health and Wellbeing Alliance."

47. Section 149 of the Equality Act 2010 **[PB/4.3]** provides that:

> "(1) A public authority must, in the exercise of its functions, have due regard to the need to -
>
> (a) eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under this Act;
>
> (b) advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it;
>
> (c) foster good relations between persons who share a relevant protected characteristic and persons who do not share it."

48. "*Advancing equality*" means having due regard, in particular, to the need:

a. To remove or minimise disadvantages suffered by persons who share a relevant protected characteristic that are connected to that characteristic (s 149(3)(a));

b. To take steps to meet the needs of persons who share a relevant protected characteristic that are different from the needs of persons who do not share it (s 149(3)(b));

c. To encourage persons who share a relevant protected characteristic to participate in public life or in any other activity in which participation by such persons is disproportionately low (s 149(3)(c))."

49. As to "steps" that might be needed to meet the different needs of disabled people in particular (i.e. section 149(3)(b) above), section 149(4) states that:

> "The steps involved in meeting the needs of disabled persons that are different from the needs of persons who are not disabled include, in particular, steps to take account of disabled persons' disabilities."

50. The principles generally applicable here are set out in *R (Bracking) v Secretary of State for Work and Pensions* [2013] EWCA Civ 1345 ("***Bracking***" **[PB/6.48]**), §25 (McCombe LJ); approved in *Hotak v Southwark BC* [2016] AC 811 (SC), §§73-75 (Lord Neuberger) and *R (MA) v Secretary of State for Work and Pensions* [2016] UKSC 58, [2016] 1 WLR 4550, §24 (Lord Toulson). The PSED imposes a personal duty on the Defendant himself (*Bracking*, §26(3)). The Defendant, in exercising his power to make the 2019 Regs, was bound:

a. To inquire properly into and personally appreciate the full impact of the policy, which can include a duty to gather the relevant information:

Bracking, §25(8)(ii), §§62-63 (McCombe LJ), §70 (Kitchin LJ) and §§75-76 (Elias LJ);

b. Personally, to assess the risk and extent of any adverse impact on those affected by the policy, and the ways in which such risk might be eliminated or mitigated *before* adopting the policy "and not merely as a rear-guard action": *Bracking*, §26(4) (McCombe LJ);

c. To appreciate properly and address the full scope and import of the PSED "*in substance, with rigour, and with an open mind*": *Bracking*, §26(5)(iii) (McCombe LJ); and,

d. To carry out a structured analysis of the details of the equality issues such as the need to advance equality of opportunity and the specific matters set out in s 149(3)(a)-(c): *Bracking*, §61 (McCombe LJ).

51. The Court of Appeal in *Bracking* held that the PSED imposes a "*heavy burden*" on the Defendant to discharge these equality duties and to ensure that the necessary evidence is available; these issues must be at the *centre* of formulation of policy: *Bracking*, §59 (McCombe LJ). It was incumbent on officials reporting to Ministers to "*not merely tell the Minister…what he/she wants to hear but…to be "rigorous in both enquiring and reporting to them*".

52. In *Bracking*, the SSWP was found to have failed to discharge the PSED in deciding to abolish the Independent Living Fund for disabled people. This was because the material before the Minister did not disclose that she had had a focussed regard on the potentially very grave impact upon individuals affected by closure: McCombe LJ at §62. She did not have sufficient information to understand and assess the practical effect of the proposals on the particular needs of those affected and their ability to live independently: Kitchin LJ at §70.

53. As *Bracking* itself recognises, what the PSED requires is inevitably context specific, but the present context is one of nationally applicable legislation that poses a serious risk to the health, welfare and life of highly vulnerable persons; a heightened standard was required. Further, whilst the case-law deprecates attempts to use the PSED to

"micro-manage" public decision-making, and an excessively forensic approach, this is a case of wholesale breach of duty.

54. As far as can be seen from material in the public domain, the Defendant's officers did not advise the Defendant as to the existence and content of his duty under the PSED. Consequently and inevitably, therefore, the Defendant failed to have "due regard" to those matters that the PSED required him to have due regard to: there is, quite simply, nothing in any of the publicly available material that establishes that the Defendant had "due regard" to any of the matters that he was required to have regard to, under section 149(1), in the manner indicated by *Bracking*, or at all.

55. Further, the Explanatory Memorandum to the 2019 Regs accepts, at §12.4 **[PB/5.12]**, that "*An Impact Assessment has not been prepared for this policy*". As such, there was no equality impact assessment on the disparate effect of the proposals on, for example, the grounds of age, race, disability or sex. In fact, the evidence suggests that, at the very least, Regulation 9 of the 2019 Regs will disproportionately impact gay men and those of African origin: Witness Statement of Deborah Gold, dated 25 February 2019, §14 **[PB/2.152]** and Witness Statement of Chloe Orkin, dated 25 February 2019, §12 **[PB/2.172]**. This is due to those with HIV disproportionately belonging to those groups. There may well be other protected groups who will suffer disproportionately. Due to the lack of an equality impact assessment (and adequate consultation as set out below), the disparate impact on other protected groups is currently unknown.

56. This failure to conduct an equality impact assessment, in itself, and in the absence of the Defendant taking any other steps, is sufficient to indicate a breach of the PSED in light of the *Bracking* principles. The fact that Regulation 9 of the 2019 Regs has the potential adversely to affect the health outcomes of vulnerable groups in a significant and potentially fatal way, and impact disparately those with protected characteristics (see **§§27-31 above**) means that an equality impact assessment (or similar) was fundamental.

57. Further, the Explanatory Memorandum, at §12.5, states that "*There may be some risks to patients, and therefore costs associated with this but clinicians setting out the guidance will consider*

and minimise these risks when setting out the guidance". That is entirely insufficient given that: (a) the PSED is imposed on the Defendant personally and cannot be "delegated" to clinicians; (b) the PSED is required to be discharged at the time policy is *formulated*; (c) there is a major difference between the Defendant discharging the PSED and the much narrower role of clinicians addressing clinical risks – the latter is no substitute for the former; (d) Regulation 9 of the 2019 Regs will already be in force at that stage and the starting point for clinicians will therefore be that Regulation exists and is lawful in principle; (e) clinicians do not have the skills, resources or remit to consider the disparate impact of its guidance on those with protected characteristics - in the manner outlined in *Bracking*, or at all; and, (f) if a Serious Shortage Protocol becomes necessary, it will have to be done urgently; it will be far too late at that stage for anyone to employ the rigour required by s149 of the Equality Act 2010.

58. In this respect, the Defendant's breach of the PSED has some parallel with *Eisai Limited v The National Institute for Health and Clinical Excellence* [2007] EWHC 1941 Admin **[PB/6.18]**. In that case, Dobbs J held that the National Institute for Health and Clinical Excellence had been in breach of earlier versions of the PSED, in the Race Relations Act 1976 and Disability Discrimination Act 1995, when it issued guidance restricting the use of certain drugs, in some cases, for the treatment of Alzheimer's Disease. Dobbs J found such a breach, in part, on the basis that clinicians would, in appropriate cases, make a patient-specific decision that might diverge from the guidance and result in the drugs being prescribed. Dobbs J held, *inter alia,* at §92, that:

> "Rather than relying on what clinicians could do to eliminate the risk, and having regard to the need to eliminate discrimination, what could NICE itself do to reduce or eliminate any risk of disadvantage? No exercise of this kind was conducted. It is no answer to say that NICE does not deal with individuals and does not treat patients. As a public body, NICE is bound to ensure that its own duties are discharged, and that its Guidance complies with its own obligations under the anti-discrimination legislation."

59. These wholesale breaches of the PSED are plainly material. Although the consultation document states that the Serious Shortage Protocol will have a "*positive*

impact" on patients, this is an unsubstantiated assertion that simply underlines the extent to which the Defendant has failed to assess the risks.

60. Finally, Regulation 5 of the Equality Act 2010 (Specific Duties and Public Authorities) Regulations 2017 **[PB/4.18]** requires the Defendant to prepare and publish one or more objectives it thinks it should achieve to comply with the PSED. The Defendant's current, published objectives **[PB/5.31]** including the following:

> "• The Department of Health and Social Care will ensure that the public sector Equality Duty is embedded in Directorate business plans and reflected in our corporate priorities and is an integral part of any future priority setting for our organisation.
> • We will continue build and develop our relationships with stakeholders and the public, including those that represent groups with protected characteristics, to improve our functions and services.
> • We will ensure that it is clear, throughout the policy development process, how we have paid due regard to the public sector equality duty.
> • As guardians of the health and social care system, we will build on our strengths in knowledge and intelligence by improving the information we hold and collect. We will reflect back this intelligence to our partners, in order to improve the health and well-being of the whole population. .....
> • We will improve our internal business processes so that equality and diversity is an integral part of everything we do. Our drive to increase value, efficiency and productivity will always consider the needs of people with protected characteristics, internally in the Department and in our externally facing functions....."

61. The process by which the Defendant made Regulation 9 of the 2019 Regs was unlawful because it disregarded and diverged, without good reason, from the above policy objectives. This was in breach of the Defendant's public law duty to have regard to relevant considerations, including his own policies, and to act in accordance with his own policies except for good reason: *Mandalia v Secretary of State for the Home Department* [2015] 1 WLR 4546 (SC), §29 (Lord Wilson) **[PB/6.81]**; *R (Lumba) v Secretary of State for the Home Department* [2012] 1 AC 245 (SC), §26 (Lord Dyson).

62. In the premises, the process by which the Defendant made Regulation 9 of the 2019 Regs was in wholesale breach of the PSED and his own published equality objectives.

Ground 3 – Failure to take into account and act consistently with the NHS Constitution

63. In making Regulation 9 of the 2019 Regs, the Defendant was required to take into account the NHS Constitution: s1B(1) of the NHS Act 2006. This provides that, "*In exercising functions in relation to the health service, the Secretary of State must have regard to the NHS Constitution.*"

64. There is nothing in any of the documents produced by the Defendant to show that the NHS Constitution was taken into account in the process of making Regulation 9 of the 2019 Regs.

65. This is material due to the importance the NHS Constitution places on patients being involved at the heart of changes that affect them, such as Regulation 9 of the 2019 Regs. By way of example, the NHS Constitution provides as follows **[PB/5.15]**:

    i. Principle 4 of the "*Principles that guide the NHS*" is that "*The patient will be at the heart of everything the NHS does*". This states that:

> "It should support individuals to promote and manage their own health. NHS services must reflect, and should be coordinated around and tailored to, the needs and preferences of patients, their families and their carers. As part of this, the NHS will ensure that in line with the Armed Forces Covenant, those in the armed forces, reservists, their families and veterans are not disadvantaged in accessing health services in the area they reside. Patients, with their families and carers, where appropriate, will be involved in and consulted on all decisions about their care and treatment. The NHS will actively encourage feedback from the public, patients and staff, welcome it and use it to improve its services." (emphasis added)

    ii. The "*NHS Values*" include "*Working together for patients*". This provides that:

> "Patients come first in everything we do. We fully involve patients, staff, families, carers, communities, and professionals inside and outside the NHS. We put the needs of patients and communities before organisational boundaries. We speak up when things go wrong." (emphasis added)

iii. Under the section "*Patients and the public: your rights and the NHS pledges to you*", it is stated that:

i. "***Access to health services: Your rights*** - *You have the right to receive care and treatment that is appropriate to you, meets your needs and reflects your preferences.*"

ii. "***Nationally approved treatments, drugs and programmes: Your rights*** - *You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you.*"

iii. "***Involvement in your healthcare and the NHS: Your rights*** – *You have the right to be involved in planning and making decisions about your health and care with your care provider or providers, including your end of life care, and to be given information and support to enable you to do this.*"

66. Had the Defendant taken into account these parts of the NHS Constitution, there is a good chance that Regulation 9 would not have been made in the form it was. This is because the way in which it came into being, as well as its content, are antithetical to the principle of patient involvement: see **§20 above** and the Consultation Response of National Voices, dated 12 December 2018, pp1 and 5 **[PB/2.89]**.

67. In the premises, the Defendant failed to take into account these important Principles, Values and Pledges in the NHS Constitution in making Regulation 9 of the 2019 Regs, and failed to act in accordance with them, without good reason. These amount to clear breaches of the Defendant's statutory law duty to have regard to the NHS Constitution, and his public law duty to act in accordance with his own policies except for good reason: *Mandalia v Secretary of State for the Home Department* [2015] 1 WLR 4546 (SC), §29 (Lord Wilson) **[PB/6.81]**.

Ground 4 – Consultation was unlawful in extent and scope

68. It is trite law that, subject to any statutory provision, the duty to consult has to meet minimum standards of fairness, so that public authorities must:[6]

- undertake consultation when the proposals are still at a formative stage;
- give consultees sufficient reasons for the proposal, so as to permit intelligent consideration and response;
- give consultees adequate time for consideration and response;
- take the products of consultation conscientiously into account.

69. The Defendant acted unlawfully in: (a) not consulting publicly, or least a broader group of patient-interest groups as part of a formal consultation; and (b) confining the informal consultation to a period of 5 clear working days. Each of these errors was sufficient to have made the consultation unlawful. In combination, they render the informal consultation woefully inadequate.

(a) Obligation to consult

70. The obligation to consult at least a broad group of patient-interest organisations on Regulation 9 of the 2019 Regs derives from s1B(1) of the NHS Act 2006 **[PB/4.17]**. This is due to the importance placed in the NHS Constitution on listening to patients, as set out in Ground 3 above: *R (Juttla) v Hertfordshire Valleys CCG* [2018] EWHC 267 Admin, (2018) 21 CCLR 325, §§25-26 (Mostyn J) **[PB/6.92]**.

71. The obligation to consult also derives from s129(6) of the Medicines Act 1968 **[PB/4.15]**. Reg 9 of the 2019 Regs allows pharmacists *both* to sell prescription-only medicines and to alter the contents of a prescription. For the reasons set out in Ground 1 above, the Defendant acted *ultra vires* in providing for the latter. With respect to the former, however, the Defendant's power is set out in s58(4) of the Medicines Act 1968 **[PB/4.5]**.

72. Section 58 of the Medicines Act 1968 states that:

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[6] *R (Moseley) v Haringey LBC* [2014] UKSC 56, [2014] 1 WLR 3947, §25 (Lord Wilson) **[PB/6.67]**.

"58.— **Medicinal products on prescription only.**

(1) The Ministers may by order specify descriptions or classes of medicinal products as prescription only medicines.

...

(4) Without prejudice to regulation 223(1) of the 2012 Regulations, any order made by the Ministers for the purposes of this section may provide—

(a) that regulation 214(1) or (2) of the 2012 Regulations shall have effect subject to such exemptions as may be specified in the order or, in the case of an appropriate practitioner, other than a doctor or dentist, such modifications as may be so specified;

(b) that, for the purpose of regulation 214(1) of the 2012 Regulations, a medicinal product shall not be taken to be sold or supplied in accordance with a prescription given by an appropriate practitioner unless such conditions as are prescribed by the order are fulfilled.

...

(5) Any exemption conferred or modification made by an order in accordance with subsection (4)(a) or (4B) of this section may be conferred or made subject to such conditions or limitations as may be specified in the order.

(6) Before making an order under this section the Ministers shall consult the appropriate committee.

(7) In subsection (6) *"the appropriate committee"* means whichever the Ministers consider appropriate of—

(a) the Commission; or

(b) an expert committee appointed by the Ministers, or by one of them acting alone."

73. Section 129 of the Medicines Act 1968 provides that:

"(6) 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.

(7) Without prejudice to subsection (6) of this section, where any Ministers propose to make any regulations or order under Part III of this Act, or under

section 104 or section 105 of this Act, and they consult an expert committee appointed by themselves, or by one of them acting alone, or the Commission, with respect to that proposal, they shall take the advice of the committee or of the Commission into account before proceeding with those proposals."

74. In proposing Regulation 9 of the 2019 Regs, the Defendant was obliged to consult "*such organisations as appear to them to be representative of interests likely to be substantially affected by the regulations or order*". This is clear from s129(6) of the Medicines Act 1968, in combination with s129(7). It is an additional obligation to the duty to consult the Commission on Human Medicines (s58(7)(a)) or an appointed expert committee (s58(7)(b)).

(b) Scope of consultation

75. The Defendant's choice as to which organisations ought to be consulted as "*representative of interests likely to be substantially affected*" was subject to rationality constraints: see, for example, *Liverpool City Council v Secretary of State for Health* [2003] EWHC 1975 (Admin), §44 (Stanley Burnton J).

76. In this instance, the Defendant's decision not to consult *publicly*, or at least with a broader range of patient-interest groups, was irrational.

77. Given its informal and private nature, it is unclear at this stage exactly who the Defendant consulted. Nevertheless, the Defendant failed to consult at least the following groups:

i. SUDEP Action;
ii. The Neurological Alliance;
iii. National AIDS Trust;
iv. British HIV Association; and,
v. Action against Medical Accidents.

78. Regulation 9 of the 2019 Regs is of fundamental significance to those with some of the severest medical conditions, including those represented by the groups in the above paragraphs. The potential impact of Regulation 9 on health outcomes, as well

the technical complexity of the subject-matter being consulted upon, was substantial. In those circumstances, it was irrational not to consult publicly, or at least a wider group of patient-interest organisations, who could have given detailed evidence about the potential effect of Regulation 9 on those it represented.

79. The Witness Statement of Jane Hanna OBE, dated 25 February 2019, at §33 **[PB/2.59]**, sets out in detail what SUDEP Action would have said in response to the consultation. At the time of the consultation, it was not a member of National Voices. The Witness Statement of Deborah Gold, dated 25 February 2019, at §21 **[PB/2.154]**, sets out what the National AIDS Trust would have said in response to the consultation. The Witness Statement of Chloe Orkin, dated 25 February 2019, at §17 **[PB/2.174]**, sets out what the British HIV Association would have said in response to the consultation.

80. The Defendant did consult National Voices, self-described as a "*coalition of charities that stands for people being in control of their health and care*". National Voices was critical of Regulation 9, calling it "*unacceptable*"[7] in its current form and stating that "*the risks to patient safety could be serious*".[8] Nonetheless, in particular given the highly abridged time scale, National Voices, by itself, was not in a position to respond on behalf of all those patient-interest groups who had first-hand knowledge of how Regulation 9 would affect their members. National Voices made this concern clear, stating that:[9]

> "We would urge DHSC to find a better process to take this forward, enabling more discussion within and between stakeholders., [sic] to ensure patient interests are properly protected."

81. Furthermore, even though it was able to speak to a handful of other organisations to see how their members would be affected, it stated that:

> "The circumstances and period of the consultation have been too short for us properly to consult our members, or to hold discussions with professional bodies.

[7] National Voices, "Response to the informal consultation: Changes to the HMR2012 in relation to supply and the UK's exit from the EU" (12 December 2018), p5 **[PB/2.93]**.
[8] National Voices, "Response to the informal consultation: Changes to the HMR2012 in relation to supply and the UK's exit from the EU" (12 December 2018), p1 **[PB/2.89]**.
[9] National Voices, "Response to the informal consultation: Changes to the HMR2012 in relation to supply and the UK's exit from the EU" (12 December 2018), p1 **[PB/2.89]**.

> We have been able to work with a small number of member charities to understand the scenarios that could affect patients in relation to emerging shortages of supply. We include some of these below. These examples cover large numbers of patients; and we consider that there may well be comparable scenarios for many other patient groups."

82. These concerns, set out by one of the patient-interest groups consulted by the Secretary State, laid down a clear marker that consultation with other groups was essential in order to obtain the necessary information to proceed with Regulation 9.

83. The importance of consulting specific patient-interest groups is demonstrated by the Defendant's subsequent undertaking that an exception for epilepsy *treatment* will be granted.[10] The omission of such an undertaking with respect to other types of sufferers – who may be equally adversely affected as epilepsy sufferers – is notable and disturbing. It is the lack of proper consultation that has produced this inconsistent result.

(c) Length of consultation

84. Further and/or alternatively, the truncated nature of the informal consultation rendered it unlawful. The consultees were not given adequate time for consideration and response: R *(Moseley) v Haringey LBC* [2014] 1 WLR 3947 (SC), §25 (Lord Wilson) **[PB/6.67]**. This compounded the narrow scope of the consultation: those consulted groups who represented significant patient-interest groups, such as National Voices, did not have the time properly to confer with their members.

85. Those whom the Defendant describes as "informal consultees" were first notified of the consultation by an email on 5 December 2018. They were given until 12 December 2018 to respond. This amounted to 5 clear working days.

86. The Defendant's Consultation Paper **[PB/2.85]** states:

[10] This does not, in itself, solve the issue for epilepsy *sufferers*. This is because their concern is not just that the epilepsy medicine itself will be altered by pharmacists but that a whole host of medicines for co-morbidities that epilepsy sufferers also take will be altered, still liable to upset the delicate balance of medicine taken by such sufferers: see Witness Statement of Jane Hanna OBE, dated 25 February 2019, §17 and §33(b),(g) **[PB/2.60]**. See also the Witness Statement of Chloe Orkin, dated 25 February 2019, §16 **[PB/2.174]**.

"Normally, we would consult publicly for 12 weeks before making any changes to the Human Medicines Regulations 2012. However, you will understand that any legislative changes in relation to the UK's exit from the EU need to be progressed quickly so that they are in force before the day that the UK leaves the EU. Therefore, we are seeking views of the relevant stakeholder representative bodies on the proposed changes by close on 12 December 2018." (emphasis added)

87. The Cabinet Office guidance called *Consultation Principles* **[PB/5.38]** states "*E. Consultations should last for a proportionate amount of time. Judge the length of the consultation on the basis of legal advice and taking into account the nature and impact of the proposal. Consulting for too long will unnecessarily delay policy development. Consulting too quickly will not give enough time for consideration and will reduce the quality of responses*".

88. The Defendant has consulted most years on amendments to the Human Medicines Regulations 2012, and consultations have lasted for an extended period. By way of example **[PB/2.57]**:

    i. Human Medicines (Amendment) Regulations 2018: consultation took place between February and May 2015 for proposals on introducing independent prescribing for registered paramedics;

    ii. Human Medicines (Amendment) Regulations 2017: UK-wide public consultation took place during 10 March and 5 May 2017 – expressly in accordance with s129(6) of the Medicines Act 1968 – for the proposal to allow schools to hold stocks of Adrenaline Auto-Injectors for use in an emergency. There were over 500 response from parents, schools, education authorities, school nurses, GPs, pharmacists and key organisations;

    iii. Human Medicines (Amendment) Regulations 2016: consultation took place during February to May 2015 on the proposals for prescribing, selling, supplying and administering medicinal products by dietitians, radiographers and orthoptists. The proposals were circulated to the NHS, local authorities and a range of patient and representative bodies with 464 responses for dietitians, 984 for radiographers and 204 for orthoptists;

iv. Human Medicines (Amendment) (No 2) Regulations 2015: consultation took place between July and October 2014 on the proposal for electronic prescribing of drugs listed in Schedules 2 or 3 of the Misuse of Drugs Regulations 2001; and,

v. Human Medicines (Amendment) (No 2) Regulations 2014: UK-wide public consultation took place from 7 to 29 May 2014 – expressly in accordance with s129(6) of the Medicines Act 1968 – on the proposal to allow the supply of salbutamol asthma inhalers to schools for emergency use. Over 4000 responses were received;

89. Conversely, informal and targeted consultations have tended to be for minor changes. For example, the Explanatory Memorandum to the Human Medicines (Amendment) Regulations 2014 **[PB/5.1]** states that, "*8.1 As the amendments to legislation are minor and affected specific groups of health professionals, the MHRA carried out an informal targeted consultation exercise. There was only a limited response.*"

90. In any event, for the reasons set out below, in this case a consultation period of 12 weeks was the minimum that fair process required and/or, alternatively, that 5 days was grossly inadequate.

91. There is little case law on consultation periods because most public authorities take a prudential approach. However, such case law as the Claimant has been able to find, thus far, is as follows:

i. *R v Secretary of State for Education and Employment ex p National Union of Teachers* [2000] Ed CR 603 (QBD), 628-629 (Jackson J): a period of 4 days for consultation about regulations relating to the draft pay and conditions of teachers was held to be insufficient;

ii. *R v Devon CC ex p Baker* [1995] 1 All ER 73 (CA), 86 (Dillon LJ), 91 (Simon Brown LJ): a period of 5 days for consultation about the closure of a residential home for the elderly was found to be unlawful. Simon Brown LJ described this period as "*wholly insufficient*";

iii. *R v Birmingham City Council ex p Dredger* (1994) Admin LR 553 (QBD), 575-576 (Hutchison J): a period of just over a week for consultation relating to a large increase in rent to be paid by market stall holders was held to be inadequate. In the course of his judgment, Hutchison J stated that:

> "I am in no doubt that, given the length and complexity of the report, the fundamental changes that it proposed, the various different basis of change which it advanced, and the identity and number of the persons affected, the period was plainly wholly inadequate."

iv. *R (Boyejo) v Barnet LBC and Portsmouth CC* [2009] EWHC 3261, (2010) 13 CCLR 72: an 11-day consultation was not sufficient (Portsmouth) (§§72-73), but a 6-week consultation was (Barnet) (§68, HHJ Jarman QC), where what was proposed was significant changes to a sheltered housing service.

92. If these consultation periods were found to be inadequate, then the consultation period in the present claim was, *a fortiori,* inadequate given:

i. The significance of the policy change: Regulation 9 involves wholesale changes to a previously fundamental tenet of healthcare provision; medicines are to be prescribed by an appropriate practitioner, in consultation with the patient, and supplied by a pharmacist. Indeed, the previous policy position was that it was so dangerous for pharmacists to provide medicine other than as set out in a prescription that this amounted to a criminal offence (s64 and s67(2) of the Medicines Act 1968);

ii. The number of people it will affect: Regulation 9 could affect huge numbers of patients nation-wide;

iii. The potential adverse consequences: Regulation 9 could have serious, adverse effects on health outcomes, including loss of life; and,

iv. The complexity of the change: in order to make the proposal work, it requires thorough understanding of technical and complex subject matter. For example, slight alterations to a patient's prescription can have significant impact on those suffering from epilepsy to heart disease to

neurological illnesses, to name but a few. It was incumbent on the Defendant to be aware of and understand these ramifications before making Regulation 9;

v. The consultation was aimed at groups in the charity and voluntary sector, who do not have governmental resources, and who would, in turn, need to consult with their members, many of whom will be vulnerable and/or find it difficult to respond effectively;

vi. That National Voices – believed to be the only "informal consultee" representative of patients' interests - is an "umbrella" organisation, with over 150 charity and professional members. As National Voices itself pointed out to the Defendant **[PB/2.89]**:

> "The circumstances and period of the consultation have been too short for us properly to consult our members, or to hold discussions with professional bodies.
>
> We have been able to work with a small number of member charities to understand the scenarios that could affect patients in relation to emerging shortages of supply. We include some of these below. These examples cover large numbers of patients; and we consider that there may well be comparable scenarios for many other patient groups";

93. The importance of consulting publicly, alternatively at least with specific patient-interest groups, or affording National Voices adequate time to do so, is demonstrated by the Defendant's subsequent undertaking that an exception for epilepsy *treatment* will be granted. This was in response to subsequent representations by SUDEP Action, an epilepsy charity that learned of the proposals through a newsletter from the Neurological Alliance.[11] The omission of such an undertaking with respect to other types of sufferers – who may be equally adversely affected as epilepsy sufferers

[11] This does not, in itself, solve the issue for epilepsy *sufferers*. This is because their concern is not just that the epilepsy medicine itself will be altered by pharmacists but that a whole host of medicines for co-morbidities that epilepsy sufferers also take will be altered, still liable to upset the delicate balance of medicine taken by such sufferers.

– as well as for epilepsy *sufferers* in relation to co-morbidities is notable and disturbing. It is the lack of proper consultation that has produced this inconsistent result.

94. For all the above reasons, a 12-week period was the minimum in this case and/or, alternatively, 5 working days was inadequate.

COSTS CAPPING ORDER

95. The Claimant seeks a Costs Capping Order, pursuant to s88 of the Criminal Justice and Courts Act 2015, limiting its potential liability to pay the Defendant's costs of these proceedings to £15,000. The relevant evidential matters are set out in the Witness Statement of Jolyon Maugham QC, dated 25 February 2019, §§8-20.

96. First, these proceedings are public interest proceedings:

    a. The issue in dispute and the points of law expanded on above are of general public importance. Regulation 9 of the 2019 Regs could affect huge numbers of people all over the United Kingdom with significant consequences for their health. It involves transforming a long-established tenet of the NHS: "appropriate practitioners" prescribing medicines and pharmacists supplying them without alteration. Regulation 9 has caused grave concern amongst expert clinicians, patient-interest groups and the general public alike;

    b. The public interest requires the issues to be resolved; and,

    c. This claim will provide an appropriate means of resolving the issue.

97. Second, in the absence of a Costs Capping Order, the Claimant would withdraw this application for judicial review: Witness Statement of Jolyon Maugham, dated 25 February 2019, §14 and §21 **[PB/2.7]**.

98. Third, it would be reasonable for the Claimant to withdraw without a Costs Capping Order: Witness Statement of Jolyon Maugham, dated 25 February 2019, §14-18.

99. The other items to which the Court must have regard, as set out in s89(1) of the Criminal Justice and Courts Act 2015, are dealt with in the Witness Statement of Jolyon Maugham, dated 25 February 2019 **[PB/2.1]**. By way of summary;

a. The Claimant's assets, liabilities, income and expenditure are set out in the Witness Statement of Jolyon Maugham, dated 25 February 2019, §§8-11. The crowdfunding sought for this claim is set out in Witness Statement of Jolyon Maugham, dated 25 February 2019, §§12-18. At the moment, £14,176 has been raised;

b. In terms of benefits to the Claimant, its only interest is to deliver the public interest: Witness Statement of Jolyon Maugham, dated 25 February 2019, §19;

c. For working on this claim, the lawyers acting for the Claimant will be paid reduced fees (the equivalent Treasury rate) if the claim is upheld;

d. The Claimant is the appropriate person to bring this claim. Although various charities representing patients' interests are supportive of the case, they are not able to be a party largely due to the costs risk but also due to timing issues: Witness Statement of Jolyon Maugham, dated 25 February 2019, §20; Witness Statement of Jane Hanna OBE, dated 25 February 2019, §§4-5; Witness Statement of Deborah Gold, dated 25 February 2019, §5; Witness Statement of Chloe Orkin, dated 25 February 2019, §4; Witness Statement of Peter Walsh, dated 21 February 2019, §4.

CONCLUSIONS AND RELIEF

100. For the reasons set out above, the Claimant respectfully requests that the Court:

a. Expedite this claim so that it is heard before 29 March 2019;

b. Grant permission and consequential directions, as set out above at §9;

c. Grant a Costs Capping Order such that the Claimant does not have to pay the costs of the Defendant in excess of £15,000;

d. Quash Regulation 9 of the 2019 Regs;

e. Alternatively, declare that Regulation 9 of the 2019 Regs is unlawful;

f. Award the Claimant its costs; and,

g. Grant such further and other relief as the Court thinks fit.

STEPHEN KNAFLER Q.C.

YAASER VANDERMAN

Landmark Chambers

25 February 2019