your ref
our ref

AH/3553/004
19 February 2019

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deighton pierce glynn

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Dear Madam/Sir

Judicial Review - Letter Before Claim

1. **To:** Secretary of State for Health & Social Care

2. **The Claimant:** Good Law Project Limited[1]

3. **Reference Details:** Unknown

4. **Details of the Matter being Challenged:** Regulation 9 of The Human Medicines (Amendment) Regulations 2019 ("Regulation 9")

5. **The Issue:**

Summary of Factual Background

Our understanding of the factual background to this proposed claim is as follows:

a) One potential consequence of the UK leaving the EU without a formal Withdrawal Agreement in place ("no deal Brexit") is the impact on medicines

[1] GLP is a non-profit, membership organisation that uses strategic litigation to deliver a progressive society. Its members have an interest in many areas, including healthcare and Brexit-related matters (see for example R(GLP) v Electoral Commission [2018] EWHC 2414 (Admin)). Further background can be found at https://goodlawproject.org/.

supply chains. The UK's medicines supply is deeply integrated with that of the rest of the EU. That integration is enabled by EU law on movement of products, in particular, in the case of medicines, shared regulatory standards and processes aimed in part to protect patients and ensure that medicines used in the national health systems of the Member States are effective and safe. The Withdrawal Agreement provides continuity of those rules, while the future EU-UK trading relationship is agreed. A no deal Brexit involves an abrupt legal rupture. The UK will immediately be treated as a 'third country' by the EU, with all that implies for (lack of) recognition of UK-produced products and regulatory processes. Medicines supply in the UK involves components and products crossing the UK-EU border, sometimes multiple times in the production process. Delays at the border in the EU (for instance in France or the Netherlands), while products are checked as involving a 'third country', are expected to disrupt these highly integrated supply chains, in potentially extreme and unpredictable ways. In the event of no deal, the Defendant would have to make provision for securing safe and effective medicines supplies to patients in the UK. Without such supply, patients who rely on medication for their continued health or even life, would be in jeopardy.

b) To try and prepare for this, from 4 October 2018 to 1 November 2018 the Defendant consulted on amendments that would have to be made to the Human Medicines Regulations 2018 in the event of a no deal Brexit. The consultation was published on the Consultation Hub part of the Defendant's website, and detailed the various regulatory measures that would be required. No mention was made of any proposals to issue 'Serious Shortage Protocols' (see further below).

c) Regulation 9 empowers the Defendant to issue a 'Serious Shortage Protocol' if there is or may be a serious shortage of a prescription-only medicine in England or Northern Ireland. The Protocol would enable pharmacists to replace the prescribed medication with an equivalent treatment, or with a reduced dose or strength, without a change in the prescription (ie; without the involvement of the treating/prescribing doctor). That is to say; patients could turn up at a pharmacy with a prescription, but be given different medication, of a different dose or strength, in order to ensure that stocks last. No such protocol has ever been made before, so neither the Department of Health, industry, clinicians, pharmacists nor patients have any experience of how to operate such a protocol in practice.

c) Despite the unprecedented nature of such a power, it was not consulted upon. Instead, Regulation 9 was first communicated privately by the Defendant to a small group of selected organisations ("stakeholders") in an email on 5 December 2018[2]. It is unclear on what basis those particular stakeholders were chosen.

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[2] https://www.the-pda.org/wp-content/uploads/Medicines-Shortages-Brexit-Consultation.pdf

d) The stakeholders were given until "close on 12 December" to respond to the proposal; only 4 clear working days.

e) The proposal became public knowledge on 7 December 2018 when it was leaked and reported in the Sunday Times[3] and the Pharmaceutical Journal[4].

f) On the basis of this coverage, at least two organisations that had not been consulted wrote to the Defendant setting out concerns about the proposal; the Neurological Alliance wrote on 17 December 2018 to highlight the risks to patients with neurological conditions[5], whilst SUDEP Action also wrote on 21 December 2018 to alert the Defendant to the potential risk to people living with epilepsy[6]. Other organisations that also focus on specific conditions did not have the opportunity to react, as they were not consulted, were not alerted to the proposal, and did not have sufficient time to do so after it was leaked.

g) On 21 December 2018 the Defendant published its EU Exit Operational Readiness Guidance[7] which stated that it "*is putting in place a "Serious Shortage Protocol". This will involve changes to medicines legislation that will allow flexibility in primary care dispensing of medicines. Robust safeguards will be put in place to ensure this is operationalised safely, including making authoritative clinical advice available*".

h) On 6 January 2019 the Sunday Times reported that epilepsy medication would be exempt from the Regulation's proposed Serious Shortage Protocols[8]. The news was welcomed by epilepsy-focussed organisations, who informed their members accordingly[9]. Others, such as the Neurological Alliance, emphasised that other conditions required similar consideration, for example "*not getting the right medication on time can have a hugely detrimental impact on the health of people with other neurological conditions such as Parkinson's or MS. At worst an individual may be left unable to move, eat or swallow, experience distressing psychological symptoms and uncontrolled movements."*[10]

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[3] https://www.thetimes.co.uk/article/ministers-will-order-pharmacists-to-ration-drugs-if-uk-crashes-out-kxd00jv9j

[4] https://www.pharmaceutical-journal.com/news-and-analysis/news/government-consults-on-giving-pharmacists-powers-to-substitute-drugs-during-shortages/20205873.article

[5] https://www.neural.org.uk/assets/pdfs/2018-12-brexit-prescriptions-letter.pdf

[6] https://sudep.org/sites/default/files/rt_hon_matt_hancock_mp_emergency_powers_epilepsy_0.pdf

[7] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/768077/eu-exit-operational-readiness-guidance.pdf

[8] https://www.thetimes.co.uk/edition/news/epileptics-exempted-from-brexit-prescriptions-plan-wxp2wzqmb

[9] https://sudep.org/article/epilepsy-medications-will-be-exempt-brexit-after-coalition-intervene

[10] https://www.neural.org.uk/news-06-01-19/

i) The outcome of the 'consultation' on Regulation 9 was circulated to some (but not all) stakeholders on 14 January 2019. Unlike most, if not all, other consultations the Defendant conducts, it was not published at the time, but a copy has now appeared online. It is unclear when it was posted or by whom[11].

j) At paragraph 17 the document produced by the Defendant following the 'consultation' states:

> "*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.* "

k) In other words, the document admits that the Regulation was prompted by Brexit, but that it has not been subject to the statutory and parliamentary safeguards provided for by the EU (Withdrawal) Act 2018, and will remain in place long after Brexit has concluded, yet it was not formulated following a public consultation, and was not developed in consultation with many significant patient representative organisations.

l) The Defendant published and laid the Regulations on 18 January 2019 pursuant to a negative resolution procedure. They came into force on 9 February 2019. It is unclear whether the Regulations were communicated to stakeholders in advance, and if so which ones and when.

m) The Explanatory Memorandum to the Regulations identifies epilepsy as a special case, but does not go as far as the Sunday Times report suggested it would. It states at paragraph 7.11 that "*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.*"

n) That is to say, it is recognized that it would not be appropriate to replace epilepsy medication, but it is silent on whether epilepsy patients could be issued with reduced dosage or reduced strength medication. No other condition is specified.

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[11] https://cached.offlinehbpl.hbpl.co.uk/NewsAttachments/PGH/DHSC_SSP_Consultation_Response.pdf

o) We understand that there are no plans for statutory guidance that might further detail the criteria by which the Defendant will determine whether there is or may be a serious shortage; or the method for selecting clinicians to consult before doing so.

If any part of this summary of the factual background is disputed or is believed by your authority to be inaccurate please identify in your response each part of the factual background that is disputed, please explain why it is disputed and please provide full details of the basis for this alternative factual account including copies of any reports or relevant contemporaneous records upon which it is based.

Grounds of Challenge

Ground 1 - Ultra Vires

p) The Human Medicines (Amendment) Regulations 2019 (the "2019 Regulations") are expressly said, in the preamble to the Statutory Instrument, to have been made in exercise of the powers in s2 of the European Communities Act 1972. Whilst this appears to be correct for many of the Regulations in the 2019 Regulations, it is not correct in respect of Regulation 9 of the 2019 Regulations (which inserts Regulation 226A into the Human Medicines Regulations 2012). There is no provision which empowers the Secretary of State to make Regulation 9 of the 2019 Regulations, which is therefore *ultra vires*.

q) Section 64 of the Medicines Act 1968 requires medicinal products to be sold of the nature or quality specified in any prescription. The Medicines Act 1968 does not entitle the Secretary of State to modify this duty or make exemptions. Insofar as Regulation 9 purports to do so, it is ultra vires.

r) Section 58(4) of the Medicines Act 1968 provides that the Secretary of State may make exemptions to Regulation 214 of the Human Medicines Regulations 2012. It does not, however, empower the Secretary of State to make lawful the otherwise unlawful action of a pharmacist supplying medicinal products specified in a prescription, contrary to s64 of the Medicines Act 1968.

s) Section 58A(1) and (2) requires the Secretary of State 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 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 section 58A to exempt medicines falling within section 58A(2) from the scope of Regulation 214 of the Human

Medicines Regulations 2012 when, by definition, these medicines require the close involvement of the patient's doctor or dentist.

Ground 2 - Unlawful scope and extent of consultation

t) For the reasons set out above, there is no power for the Secretary of State to make Regulation 9 of the 2019 Regulations. Nonetheless, at the very least the Secretary of State was required to consult with "*such organisations as appear to them to be representative of interests likely to be substantially affected by the regulations or order*", pursuant to s58 and s129(6) of the Medicines Act 1968.

u) It is unclear exactly who the Secretary of State consulted with and how/on what basis but there was a failure to consult with many substantially affected patient groups, such as SUDEP and the Neurological Alliance. The failure to consult properly with organisations representing specific patient interests was unlawful.

v) The importance of consulting specific patient-interest groups is demonstrated by the Secretary of State's subsequent undertaking that an exception for epilepsy sufferers will be granted. 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.

(x) The Secretary of State failed to provide consultees with sufficient information about Regulation 9/the proposed Serious Shortage Protocol, to enable them to make a properly informed response. For example, the consultation material failed to inform consultees what medicines might fall within the Protocol, how the Protocol would be implemented, how patient safety would be protected and what the alternatives were.

y) The truncated nature of the "informal consultation" – 4 working days – on a very complex, sensitive and life-endangering proposal was insufficient and unlawful. In addition to leading to a flawed outcome, the urgency of such a proposal is particularly hard to justify in circumstances where the Explanatory Memorandum states that, "*This instrument does not relate to withdrawal from the European Union*": §8.1.

z) The failure properly to consult with groups representative of patients is also inconsistent with section 1B of the NHS Act 2006 and key parts of the NHS Constitution (see below).

Ground 3 – Failure to comply with the Public Sector Equality Duty (s149 of the Equality Act 2010)

aa) Section 149 of the Equality Act 2010 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."

"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))."

bb) 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.*"

cc) The principles applicable here are set out in *R (Bracking) v Secretary of State for Work and Pensions* [2013] EWCA Civ 1345 ("*Bracking*"), §25 *per* McCombe LJ; approved in *Hotak v Southwark BC* [2016] AC 811, §73-75 *per* Lord Neuberger. They require the Secretary of State:

i. To inquire properly into and appreciate the full impact of the policy, which can include a duty to gather the relevant information: *Bracking,* §25(8)(ii), §§62-63 *per* McCombe LJ, §70 *per* Kitchin LJ and §§75-76 *per* Elias LJ;

ii. 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: *Bracking,* §26(4) *per* McCombe LJ;

iii. 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) *per* McCombe LJ; and,

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

dd) The Explanatory Memorandum to the 2019 Regulations expressly states, at §12.4, 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, disability or sex. The Explanatory Memorandum does state 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. If a Serious Shortage Protocol becomes necessary, it will have to be done urgently. It will be too late at that stage to employ the rigour required by s149 of the Equality Act 2010.

ee) The consultation document states that the Serious Shortage Protocol will have a "positive impact" on patients. This is no more than an assertion. The Secretary of State has failed to assess the already well-known risk, raised for instance in evidence to the House of Commons Health and Social Care Committee[12] that there will be shortages, the risks that this poses for different types of patients and how to mitigate them. The Secretary of State has also failed to assess the risks posed by the Protocol for different types of patients, and how to mitigate and monitor those risks.

Ground 4 - Failure to have regard to a statutorily relevant consideration

ff) The limited consultation undertaken by the Secretary of State, his failure properly to discharge the PSED, the form of Regulation 9 and the proposed Serious Shortage Protocol are all undermined by the Secretary of State's failure to take into account an important consideration that primary legislation required him to take into account. Section 1B(1) of the NHS Act 2006 provides that, "*In exercising functions in relation to the health service, the Secretary of State must have regard to the NHS Constitution.*"

gg) The NHS Constitution variously states as follows:

- **Principles that guide the NHS**
  Principle 4 - **The patient will be at the heart of everything the NHS does**

[12] See for example 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

"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."

- **NHS Values**
  Working together for patients
  "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."

- **Patients and the public: your rights and the NHS pledges to you**
  "Your rights
  You have the right to receive care and treatment that is appropriate to you, meets your needs and reflects your preferences."

- **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."

- **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."

hh) There is nothing in any of the consultation documents to suggest that the Secretary of State took these fundamental parts of the NHS Constitution into account in making Regulation 9 of the 2019 Regulations.

Ground 5 – Failure to comply with s2 of the Civil Contingencies Act 2004

ii) Section 2(1) of the 2004 Act imports a whole series of duties on the Defendant in the context of an "emergency". These duties apply in the present context because the conditions in s1 (which defines "emergency" as "*an event or situation which threatens serious damage to human welfare … in the United*

Kingdom", including "*loss of human life … human illness or injury … disruption of services relating to health*" and 2(2) (that *"(a) the emergency would be likely seriously to obstruct the person or body in the performance of his or its functions, or (b) it is likely that the person or body– (i) would consider it necessary or desirable to take action to prevent the emergency, to reduce, control or mitigate its effects or otherwise in connection with it, and (ii) would be unable to take that action without changing the deployment of resources or acquiring additional resources*" are satisfied.

jj) The Defendant has acted unlawfully by failing to provide information and advice to the public, with respect to health and medicinal issues, on what to do in the event of a no deal Brexit, as required under s2(1)(g) of the 2004 Act. Instead, he has provided misleading advice to the public, by assuring them that:

> *"if your doctor prescribes you with medicines or special equipment for a health condition, you should still be able to get the treatment you need from your GP or pharmacist.*
> *Occasionally we do experience temporary shortages of specific medicines. If this happens, your doctor will prescribe the best alternative to your usual medication – this is a tried and tested system.*
> *If there are any shortages of particular medicines after EU Exit, the same system will be in place – your doctor will advise you of the best alternative to treat your condition."*[13]

kk) That announcement was made on 18 January 2019, yet makes no mention of the power created by Regulation 9 which creates the very real possibility that it will be a pharmacist rather than the patient's doctor who decides what alternative should be used to treat the patient's condition.

ll) Furthermore, the Secretary of State has acted unlawfully by failing to publish any assessments of the risk of the emergency occurring and any plans to show that the Secretary of State will be able to perform his functions in preventing the emergency, reducing, controlling or mitigating its effects, or taking other action in connection with it, contrary to s2(1)(f) of the 2004 Act. Such publication is necessary or desirable in order that patients with certain conditions are informed as to what might happen and can prepare for the emergency.

mm) The absence of publicly available documentation in relation to the scheme establishes a *prima facie* failure on the part of the Defendant to comply with the obligations set out above.

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[13] https://www.gov.uk/government/publications/getting-medication/getting-medication

In your response please refer to each numbered point in turn and confirm whether the ground is conceded or disputed and, if it is disputed, please provide full details of the basis on which it is disputed.

6. **Details of the Action that the Defendants are Expected to Take:** Confirm, by 4.00pm on Monday 25 February 2019, that the Regulations will be withdrawn pending compliance with the Defendant's statutory obligations as set out above.

7. **Details of the Legal Advisors Dealing with this Claim:** Deighton Pierce Glynn, Unit 10C Whitefriars, Lewin's Mead, Bristol, BS1 2NT, reference AH/3553/004.

8. **Details of any Interested Parties:** None

9. **Documents and Information that you should provide with your Response:** You are reminded that in responding to this letter you must comply with your duty of candour.

   This duty requires due diligence in: (a) investigating what material is relevant to this claim; and, (b) disclosing that material where it is relevant or assists the Claimant, including on some as yet unpleaded ground. A failure to comply with the duty of candour when providing your response to this letter may result in costs sanctions.

   The duty of candour is reinforced by paragraphs 6 and 16(d) of the Judicial Review Pre-Action Protocol which provide that you must enclose any relevant documentation requested by the Claimant with your response and that where you ignore this requirement the court may impose sanctions, for example costs sanctions.

   Accordingly, in your response, you are asked to confirm that you have investigated what material is relevant to this claim and to disclose that material in or with your response. In addition, we would ask you to ensure that copies of the relevant documents are provided with your response in compliance with your pre-action disclosure duties.

   With this in mind, you are asked to provide the following information and documentation by 4pm on Monday 25 February 2019.

   a) A full list of consultees in relation to the Regulations, and details of how they were chosen and engaged with.

   b) All consultation responses received.

   c) Any assessments of the impact on equality of the Regulations.

d) Any assessments of the risk of a no deal Brexit on healthcare-related issues.

e) Any contingency plans in the event of a no deal Brexit in relation to healthcare issues.

f) Any information or advice provided to the public, with respect to health and medicinal issues, on what to do in the event of a no deal Brexit.

g) Any other documents on which the Defendant intends to rely in defence of this claim.

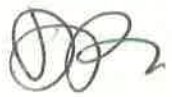
10. **Details of any Other Documents that are Considered Relevant and Necessary:** None other than those identified above.

11. **Alternative Dispute Resolution (ADR):** We do not consider that this matter is suitable for an alternative form of resolution because of the nature and urgency of the dispute. If you disagree, please let us have your reasons and your proposals.

12. **Address for Reply and Service of Court Documents:** Deighton Pierce Glynn, Unit 10C Whitefriars, Lewin's Mead, Bristol, BS1 2NT, reference AH/3553/004.

13. **Proposed Reply Date:** By 4.00pm on Monday 25 February 2019.

Yours faithfully



DEIGHTON PIERCE GLYNN