In the High Court of Justice
Queen's Bench Division
Administrative Court

CO Ref:
CO/771/2019

In the matter of an application for Judicial Review

THE QUEEN

on the application of

GOOD LAW PROJECT LIMITED

Claimant

-and-

SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE

Defendant

Application for permission to apply for Judicial Review
NOTIFICATION of the Judge's decision (CPR Part 54.11, 54.12)

Following consideration of the documents lodged by the Claimant and the Acknowledgement of service filed by the Defendant

Order by the Honourable Mr Justice Swift

1. Permission to apply for judicial review is refused.

2. The costs of preparing the acknowledgment of service are to be paid by the claimant to the defendant, summarily assessed in the sum of £8,000. This is a final order as to costs unless within 14 days the claimant notifies the court and the defendant, in writing, that he objects to paying costs, or objects to the amount now ordered to be paid, in either case giving reasons. If he does so, the defendant has a further 14 days to respond to both the court and the claimant, and the claimant the right to reply within a further 7 days, after which the defendant's claim for costs and any submissions in relation to it will be put before a judge to be determined on the papers, or at a hearing to reconsider the application for permission.

3. Where the claimant seeks a reconsideration of the application for permission the above order now made as to costs will be final unless the Claimant files the written representations referred to above or further order is made by the Court either at a permission hearing or as a consequence of the parties settling the claim and reaching agreement as to costs.

Reasons:

1. The challenge is directed to regulation 9 of the Human Medicines (Amendment) Regulations 2019 ("the 2019 Regulations") which amends the Human Medicines Regulations 2012 ("the 2012 Regulations") by insertion of a new regulation 226A. That regulation provides an enabling power for the Secretary of State to issue Serious Shortage Protocols ("SSPs"), and provides that where an SSP has been issued, the prohibition at regulation 214(1) of the 2012 Regulations (against the sale or supply of prescription only medicines other than in accordance with a prescription given by an

"appropriate practitioner") will not apply to the extent that the sale or supply is in accordance with the terms of the SSP, and other conditions specified in regulation 9 are met.

2. Four grounds of challenge are advanced.

3. The *first* is to the effect that regulation 9 was made ultra vires the enabling power (sections 2(2) and (5) of the European Communities Act 1972 and/or inconsistently with the provisions of sections 58A and/or 64 of the Medicines Act 1968. This ground is not arguable, for the reasons set out in the Summary Grounds at §§38 – 42.

4. The *second* is that the decision to make the 2019 Regulations was made without compliance with section 149(1) of the Equality Act 2010 (i.e., the public sector equality duty). The Claimant points to the absence of a formal equality impact assessment document ("EIA"). There is no such document, but compliance with section 149(1) does not require an EIA. The question is whether there is sufficient evidence to demonstrate that the "due regard" required by section 149(1) has been had. Annex C to the December 2018 Ministerial Submission is sufficient evidence of compliance with the section 149(1) Equality Act duty. In this regard it is significant that in large part, the new provision introduced by regulation 9 is an enabling power. In the event that the Secretary of State choses to issue any SSP under that provision, that act would itself attract the operation of the public sector equality duty. That being so, the points made at Annex C are sufficient; and the second ground of challenge is not arguable.

5. The *third* ground is that the decision to make regulation 9 was made without compliance with section 1B(1) of the National Health Service Act 2006, which requires the Secretary of State "to have regard to the NHS Constitution" when exercising functions in relation to the health service. The Claimant relies in particular on a principle of patient involvement. The Secretary of State's response (Summary Grounds at §§53 – 54) is that regard was had to the principles contained in the NHS Constitution. Having regard to the substance of the provision at regulation 9, there is no obvious inconsistency with the principle the Claimant relies on. To the extent that the Claimant contends that the principle of patient involvement required public engagement prior to making the 2019 Regulations, that point falls within the fourth ground of challenge.

6. The *fourth* ground of challenge alleges a failure to consult. I accept the Secretary of State's case that there was no statutory obligation to consult – see Summary Grounds at §§58 – 59. The Claimant refers to consultation exercises that preceded other amendments to the 2012 Regulations, but (correctly in my view) does not contend that those matters gave rise to any legitimate expectation as to the form or manner of consultation on this occasion. On this basis the consultation was undertaken voluntarily; the only matter arising is whether it was conducted fairly, and in good faith. The Claimant's challenge is directed to the 5 December 2018 email. The Claimant contends that this was sent to an irrationally narrow class, and that insufficient time was permitted for response. I do not consider that either point is arguable. In the absence of any statutory framework for the consultation, the Secretary of State could, subject to the usual public law principles, decide whose views to seek. The selection made by the Secretary of State was not (even arguably) irrational. The fact that other organisations which did not receive the email may have been able to provide relevant responses, does not of itself raise an arguable case that the selection made by the Secretary of State was irrational. Further, it is important to distinguish between the effect of the amendment affected by regulation 9 (in essence introduction of an enabling power), and the matters

of substance that might be addressed in due course in the event that the power to issue SSPs is exercised. The response period was short (7 days). However, having regard to the identity of the bodies consulted (all bodies with expertise) and the targeted nature of the questions posed, it is not arguable that it was unfair for the response period to be as short as it was.

7. The Secretary of State is entitled to an award of costs on *Mount Cook* principles. I have summarily assessed those costs in the amount of £8,000 taking into account (a) that it was not clear from the Schedule provided that the costs claimed related only to the preparation of the Acknowledgement of Service and Summary Grounds; and (b) that in any event, that amount is the amount that is fair and proportionate for the Claimant to pay, regardless of the actual costs incurred by the Secretary of State.

Signed

The date of service of this order is calculated from the date in the section below

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Sent to the claimant, defendant, and the claimant's, defendant's, solicitors on: 15 MAR 2019

Solicitors: DEIGHTON PIERCE GLYNN

Ref No. AH/3553/004/AH.

Notes for the Claimant

If you request the decision to be reconsidered at a hearing in open court under CPR 54.12, you must complete and serve the enclosed FORM (86B) within 7 days of the service of this order. A fee is payable on submission of Form 86B. ***For details of the current fee please refer to the Administrative Court fees table at*** https://www.gov.uk/court-fees-what-they-are. Failure to pay the fee or submit a certified application for fee remission may result in the claim being struck out. The form to make an application for remission of a court fee can be obtained from the Justice website https://www.gov.uk/get-help-with-court-fees