



Neutral Citation Number: [2019] EWHC 800 (Admin)

Case No: CO/771/2019

IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION
ADMINISTRATIVE COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 29 March 2019

Before :

THE HONOURABLE MR JUSTICE SUPPERSTONE

Between :

THE QUEEN
(on the application of
GOOD LAW PROJECT LIMITED)
- and -
SECRETARY OF STATE FOR HEALTH
AND SOCIAL CARE

Claimant

Defendant

Richard Drabble QC and Yaaser Vanderman
(instructed by Deighton Pierce Glynn) for the Claimant
Sir James Eadie QC, Sarah Wilkinson and Saara Idelbi
(instructed by GLD) for the Defendant

Hearing date: 26 March 2019

Approved Judgment

Mr Justice Supperstone :

1. This is a renewed application for permission to challenge the making of regulation 9 of the Human Medicines (Amendment) Regulations 2019 (“the 2019 Regulations”), which came into force on 9 February 2019. Permission was refused on the papers by Swift J.
2. Regulation 9 amends the Human Medicines Regulations 2012 (“the 2012 Regulations”) by insertion of a new regulation 226A. Regulation 226A permits Ministers to issue a Serious Shortage Protocol (“SSP”) in circumstances where any part of the UK is in their opinion experiencing or may experience a serious shortage of a prescription-only medicine.
3. Where an SSP has been issued, the prohibition of regulation 214(1) of the 2012 Regulations (against the sale or supply of prescription-only medicines other than in accordance with the 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.
4. The Claimant’s case is that the Secretary of State does not have the power to make regulation 9 and that, even if he did, the process by which he made it was so rushed and inadequate as to render it unlawful.
5. Mr Richard Drabble QC, for the Claimant, identified two areas of concern that he said were raised by this application. First, the duty to prescribe. The Claimant contends that the making of the 2019 Regulations has resulted in a wholesale transformation to the framework by which patients will receive prescription-only medicines. In particular through the publication of a SSP pharmacists will be permitted to dispense medication in accordance with the SSP instead of in accordance with the prescription issued by “appropriate practitioners” (which includes a doctor, dentist or other independent prescriber).
6. The second concern is that the Secretary of State has acted in breach of the public sector equality duty and the duty to consult.
7. These concerns give rise to four grounds of challenge. The first ground (focussing on the first concern) is to the effect that regulation 9 was made *ultra vires* the enabling power (ss.2(2) and (5) of the European Communities Act 1972 (“the 1972 Act”)) and/or inconsistently with the provisions of ss.58A and/or 64 of the Medicines Act 1968 (“the Medicines Act”).
8. The remaining grounds of challenge relate to the second concern. The second ground is that the decision to make the 2019 Regulations was made in breach of s.149(1) of the Equality Act 2010 (the public sector equality duty). The third ground is that the decision 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 the principle of patient involvement. The fourth ground of challenge alleges a failure to consult.

9. What, as Sir James Eadie QC, for the Secretary of State, observes is not in issue between the parties is the need for the creation of the power to issue a SSP in appropriate circumstances (or the nature of the conditions set out in regulation 9). This is plainly an important legislative measure designed to enable the Secretary of State effectively to address serious drug shortages, including any potential drug shortages that may occur in the event of a no-deal Brexit.
10. On the first ground, the *vires* issue, the Claimant contends that contrary to the preamble to the 2019 Regulations which relies solely on s.2(2) and (5) of the 1972 Act, the 1972 Act does not authorise the Secretary of State to make regulation 9 of the 2019 Regulations. The reason for that is that regulation 9 does not implement obligations or rights found in instruments of EU law, nor does it deal with matters arising out of or related to relevant EU obligations or rights. It, Mr Drabble submits, comprises a national measure.
11. Mr Drabble refers to s.64, in particular s.64(5), of the Medicines Act, which provides that pharmacists shall not sell or supply any medicinal product other than as specified in the prescription. The Claimant contends that the Secretary of State has unlawfully created an exemption to s.64(1) and (5) by making regulation 9.
12. Regulation 214(1) of the 2012 Regulations provides that a person may not sell or supply a prescription-only medicine except in accordance with a prescription given by an appropriate practitioner, as defined in regulation 214(3). Whilst s.58(4) of the Medicines Act empowers the Secretary of State to make exemptions to regulation 214, that only allows him to make provision for pharmacists to sell what would otherwise be prescription-only medicine.
13. The Claimant's subsidiary point is that s.58A of the Medicines Act 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. It is, the Claimant contends, incompatible with s.58A to exempt medicines falling within s.58A(2) from the scope of regulation 214 when, by definition, these medicines require the close involvement of the patient's doctor or dentist.
14. Directive 2001/83/EC on the Community Code relating to medicinal products for human use ("the 2001 Directive") has been transposed into UK legislation through the 2012 Regulations. However, there is, Mr Drabble submits, nothing in Article 71, and in particular Article 71(4), to justify, as he put it, the insertion of a pharmacist in between a medical provider and the ultimate user of a medicinal product as permitted by regulation 9. That regulation is not in furtherance of Articles 70 and 71 of the 2001 Directive as permitted by s.2(2)(b) of the 1972 Act. These Articles require the Secretary of State to specify "dangerous" medicinal products as prescription-only unless, under Art.71(4), he finds it appropriate not to do so, exceptionally. However, under Arts.1(19) and 70 and 71, prescription-only products may only be issued by a professional person qualified to do so; in the UK that is by doctors and the other appropriate practitioners referred to in regulation 214, and not pharmacists.
15. Section 2 of the 1972 Act, so far as is material, provides:

"2 – General implementation of Treaties

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

(2) Subject to Schedule 2 to this Act, at any time after its passing Her Majesty may by Order in Council, and any designated Minister or department may by order, rules, regulations or scheme, make provision—

(a) for the purpose of implementing any EU obligation of the United Kingdom, or enabling any such obligation to be implemented, or of enabling any rights enjoyed or to be enjoyed by the United Kingdom under or by virtue of the Treaties to be exercised; or

(b) for the purpose of dealing with matters arising out of or related to any such obligation or rights or the coming into force, or the operation from time to time, of sub-section (1) above;

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

16. It is s.2(2)(b) of the 1972 Act that is relied on by the Secretary of State. The question is whether regulation 9 is “for the purpose of dealing with matters arising out of or related to any such obligation”. In my view it plainly is. In short, I agree with Sir James that management of shortages of prescription-only drugs is a matter arising out of and related to the EU obligations under the 2001 Directive to classify certain drugs as prescription-only and to control their supply. The power to make SSPs in regulation 9 was made for that purpose.

17. Part 6 of the Explanatory Memorandum to the 2019 Regulations is titled “Legislative Context”. So far as is material it states:

“Implementation of the Falsified Medicines Directive and the Delegated Regulation

6.2 The EU has created a comprehensive code for the marketing, manufacturing, packaging, distribution, advertising and monitoring of human medicines. The framework for this is set out in Directive 2001/83/EC. This has been transposed into UK legislation through the 2012 Regulations.

Serious shortage protocol

6.5 Under Part 12 of the 2012 Regulations, medicines which are classed as prescription-only medicines (POM) can only be sold or supplied in accordance with an appropriate practitioner's prescription. An appropriate practitioner includes a doctor, dentist or other independent prescriber. This instrument makes provision for a 'serious shortage protocol' to be issued by Ministers where there is or may be a serious shortage of a prescription only medicine. This would enable pharmacists to sell or supply against the protocol rather than a prescription."

18. Regulation 226A(1) provides that 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. Regulation 226A(2) provides Condition A which 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)". It follows that pursuant to regulations 226A(1) and (2), prescription-only medicines are not sold or supplied "in pursuance of a prescription" as would be required for s.64 of the Medicines Act to be engaged.
19. I do not accept that SSPs are an unlawful exemption to s.64. It seems to me that, as Sir James describes them, they are a parallel system to prescriptions which will only operate if, pursuant to regulation 226A(5)(a), Ministers decide that the UK or any part of the UK is experiencing or may experience a serious shortage of prescription-only medicines of a specified description.
20. The Claimant's contention that regulation 9 is incompatible with s.58A is similarly incorrect because regulation 226A does not exempt any medicines from the categories listed in s.58A(2) from being prescription-only. The effect of regulation 226A is to maintain the classification of the medicine to be supplied as "prescription-only" but to change, in the circumstances set out in regulation 226A(2), the instrument by which that medicine is supplied from "prescription" to "serious shortage protocol".
21. To conclude on the first ground of challenge: it was not necessary for the Secretary of State to identify a power in the Medicines Act to do what he has done. The effect of the 2001 Directive and s.2(2)(b) of the 1972 Act is to create a separate *vires* scheme which enabled regulation 9 to be lawfully made.
22. Mr Drabble made no submissions in relation to the third ground, namely that the Secretary of State failed to take into account the NHS constitution. That leaves Grounds 2 and 4.
23. As for Ground 2, at the forefront of the Claimant's pleaded case is the submission that the Secretary of State failed to comply with the public sector equality duty ("PSED") by not conducting an equality impact assessment ("EIA") of his proposal to enact regulation 9 (Statement of Facts and Grounds of Claim, para 45).
24. The Claimant contends that the evidence suggests, at the very least, regulation 9 will disproportionately impact on gay men and those of African origin, as those with HIV disproportionately belong to those groups. There may be other protected groups who

will suffer disproportionately, but due to the lack of an EIA (and adequate consultation) the disparate impact on other protected groups is currently unknown.

25. However, Mr Drabble accepts that compliance with s.149(1) and of the Equality Act 2010 does not require a formal EIA.
26. The real question is whether there is sufficient evidence to demonstrate that the “due regard” requirement has been fulfilled, having regard to the well-known principles set out by the Court of Appeal in *R (Bracking) v Secretary of State for Work and Pensions* [2013] EWCA Civ 1345.
27. In *Bracking* McCombe LJ cited with approval (at para 26(8)) the statement of Elias LJ in *R (Hurley and Moore) v Secretary of State for Business, Innovation and Skills* [2012] EWHC 201 (Admin), at para 78:

“The concept of ‘due regard’ requires the court to ensure that there has been a proper and conscientious focus on the statutory criteria, but if that is done, the court cannot interfere with the decision simply because it would have given greater weight to the equality implications of the decision than did the decision maker.”

28. I consider that the analysis of the impact of the proposals for the power in regulation 9 as set out in Annex C to the December Submission is sufficient evidence of compliance with the s.149(1) duty. Annex C stated:

“11. We considered the implications for each of the three equality objectives in relation to the proposed framework. Our assessment is that there is no detrimental impact on particular protected groups. Whilst some of the groups are likely to use medicines more often, the protocol should have a positive impact on anyone taking medicines, including those with protected characteristics.

12. A serious shortage protocol would support pharmacists and GPs when there are serious shortages of medicines. The protocol would help manage available stocks and ensure patients have continued and quick access to medicines or any suitable alternatives if no stock is available. This benefits all patients, including those with protected characteristics. Even if on a particular occasion one patient might experience the detriment of, for example, receiving a smaller amount of a medicine than had been prescribed, that would be to the benefit of another patient who might not have received any of the medicine, had the rationing scheme not been in place. That is, the arrangements will be to the benefit of patients overall even if though underpinning this will be individual losses and gains.”

29. Annex C was accompanied by an economic and social Impact Assessment which was put in a submission to the Secretary of State dated 7 January 2019 (“the January Submission”), in the Explanatory Memorandum to accompany the 2019 Regulations,

and also in Annex B to a submission to the Secretary of State dated 20 December 2018 (“the December Submission”).

30. Further, officials included a question on the PSED impact of the proposals in an e-mail dated 5 December 2018 sent to 24 stakeholder bodies including pharmacists, doctors and patient groups, and NHS bodies, who were invited to submit written answers to four questions. The draft regulations for the SSP power were attached to that consultation invitation. Question 3 asked: “Do you have views on the principles outlined above which are informing our assessment of impacts?”. Those principles were as follows: (1) There will be a positive impact on pharmacists and GPs who will save time and resource by not having to liaise with each other for each individual patient who has been prescribed a medicine for which a protocol is available. (2) There will be a positive impact on patients who continue to have (quick) access to treatment. We have not yet quantified the impact. (3) We expect that both proposals will help secure the continuity of supply of medicines and allow patients, including those with protected characteristics, continued access to medicines.
31. What in my view is of particular significance when considering this issue of compliance with the PSED is that regulation 9 in large part contains an enabling power to make SSPs subject to a broadly expressed set of conditions. That is the context in which the “due regard” duty should be considered. It is contemplated that further work will be needed to produce and implement an effective, operational scheme (including guidance for pharmacists) which will need to be considered and approved by the Secretary of State. That being so, Sir James acknowledges that further analysis of PSED will be needed and will be undertaken by the Secretary of State before the process is complete. The intention is that any SSP issued will relate to specific drugs in short supply, will be agreed by clinicians and will set out what action can be taken by the retail pharmacy, under what circumstances, for which patients, and during which period.
32. I am satisfied that the “due regard” requirement in s.149(1) of the Equality Act 2010 has been fulfilled.
33. Finally, the fourth ground: the allegation of a failure to consult. The Claimant alleges that the Secretary of State acted unlawfully by not consulting publicly or at least a broader group of patient interest groups as part of a formal consultation, and by confining the “informal consultation” to a period of 5 clear working days.
34. Mr Drabble submits that the obligation to consult at least a broad group of patient-interest organisations on regulation 9 derives from s.1B(1) of the National Health Service Act 2006 (“the 2006 NHS Act”), and also from s.129(6) of the Medicines Act which required the Secretary of State to “consult such organisations as appear to [him] to be representative of interests likely to be substantially affected by the regulations or order”.
35. The Secretary of State did consult National Voices, self-described as “a coalition of charities that stands for people being in control of their health and care”, nonetheless the Claimant contends, in particular given the highly abridged timescale, that 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. Sudep Action, the Neurological Alliance, National AIDS Trust, British HIV Association, and Action against Medical Accidents are some of the groups that the

Claimant contends the Secretary of State failed to consult. The Secretary of State's decision not to consult publicly, or at least with a broader range of patient interest groups, was, Mr Drabble submits, irrational. The Claimant suggests that 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.

36. It is said that the consultees were not given adequate time for consideration and response. The Claimant contends that in this case the consultation period of 12 weeks was the minimum that fair process required (having regard to the significance of the policy change, the number of people whom it will affect, the potential adverse consequences and the complexity of the change). Five days was, it is said, grossly inadequate.
37. I do not accept that any statutory obligation to hold a formal consultation in relation to regulation 9 can be derived from s.1B(1) of the 2006 NHS Act; and the obligation in s.129(6) of the Medicines Act does not apply to the making of regulation 9, which was made under the 1972 Act.
38. The question is whether in the circumstances the consultation that has occurred so far on the point of principle in regulation 9 was fair and adequate.
39. The 12-week public consultation that the Secretary of State would normally undertake before making any changes to the 2012 Regulations was not, the Secretary of State contends, feasible because of the need to move speedily so that proposed changes were in force before the day that the UK was due to leave the EU.
40. The consultation exercise that was conducted commenced on 23 November 2018 when the Secretary of State consulted the EU Medicines Supply Industry Collaboration Group. On 25 and 26 November officials contacted various bodies informing them about the proposals and offering to meet to discuss them. Meetings were subsequently held on 27 November with the National Pharmacy Association, the Royal Pharmaceutical Society, the Association of Independent Multiple Pharmacies, the Company Chemists Association and the Pharmaceutical Services Negotiating Committee ("PSNC"). On the same day officials also met with NHS England and the devolved administrations to discuss the proposals. On 29 November a meeting was held with the General Pharmaceutical Council, and on 30 November with the British Medical Association ("BMA"). Also on 30 November officials attended the Community Pharmacy Brexit Forum organised by the PSNC, which brought together all relevant community pharmacy stakeholders, and provided an update on the proposals.
41. On 3 December the offer of a meeting was made to the Royal College of General Practitioners ("RCGP"), which led to communication in writing with them over the next few days.
42. On 5 December 24 stakeholder bodies were invited to submit written answers to four questions, it being explained that the consultation was considerably shorter than usual because of the need to legislate before 29 March 2019 and responses were requested by 12 December 2018. The questions asked were (1) whether they agreed with the introduction of the provision for a "serious shortage protocol" to deal with serious national shortages of medicines by a proposed amendment to the 2012 Regulations

- (Question 1); (2) whether they agreed with the introduction of a regulation-making power in relation to serious shortages in case of a “no-deal” Brexit by a proposed amendment to the 2012 Regulations (Question 2); (3) Question 3 is set out at paragraph 30 above; and (4) whether they had any comments on the draft provisions (Question 4).
43. On 7 December 2018 the Director of New Business Models and Primary Care Contracts Groups at NHS England discussed the proposals with the Chair of the BMA’s General Practitioners’ Committee. On the same day the Director of Primary Care at NHS England discussed the proposals with the Chair of the RCGP.
 44. Forty-seven responses to these consultation measures were received, which were summarised in the Consultation Response dated 14 January 2019. The Consultation Response noted that officials had continued to consult with the stakeholder representative bodies after 12 December and noted that it had also received correspondence from some patient groups on the SSP. The Consultation Response noted six principal points and that the Secretary of State had taken certain actions in response to the responses received.
 45. The December Submission set out the outcome of the consultation and asked for agreement to the proposed amendments to the 2012 Regulations.
 46. On 7 January 2019 the January Submission was put to the Secretary of State. It set out the further discussions with key stakeholders that had taken place since the December Submission, noting the next stage of the process that would be required to develop the operational detail of SSPs, including the fact that SSPs would be approved by clinicians and that SSPs might not be suitable for some high-risk patients or medicines which would always be referred back to the prescriber.
 47. I do not consider it arguable that it was irrational for the Secretary of State not to have consulted a wider group of patient interest organisations or, in the circumstances, having regard to the identity of the bodies consulted, and the time constraints involved, unfair for the length of consultation to be as short as it was. The consultation that took place was, in my view, fair and adequate.
 48. The consultation exercise that has occurred has focussed on the principle of Ministers having a power to issue SSPs, not on the operational detail of SSPs. Consultation in stages is a permissible approach (see *R (Breckland District Council) v Boundary Committee for England* [2009] EWCA Civ 239, at para 49). The Secretary of State has made clear that engagement on operational detail and the necessary amendments to the NHS Terms of Service is ongoing through liaison with clinical and pharmacist bodies.
 49. One final point: Sir James submits that in any event the Claimant does not have standing to bring this claim, not having a sufficient interest in the matter to which the application relates. It has no direct interest in and knowledge of the matters relating to SSPs. There are innumerable other organisations with a direct interest in and knowledge of such matters.
 50. I consider it would be wrong to refuse permission on the basis of lack of standing in the absence of full argument from the parties, which I have not had.

51. In my judgment regulation 9 of the 2019 Regulations was lawfully made. For the reasons I have given, I do not consider this claim to be arguable. Accordingly, permission is refused.