



OUTER HOUSE, COURT OF SESSION

[2023] CSOH 65

P919/22

OPINION OF LORD HARROWER

in the petition of

COMMUNITY PHARMACY SCOTLAND

Petitioner

for

judicial review of decisions of Fife Health Board and Lothian Health Board dated 2 September 2022 that it is lawful for a pharmacy contractor to install and operate automated collection points, such as prescription collection lockers, from premises that are not included in their pharmaceutical lists

Petitioner: Lindsay KC; CMS

First and second respondents: J MacGregor KC, S Dundas; Central Legal Office

First interested party: Crawford KC, D Blair; MacRoberts LLP

Minuter: S Donnelly; SGLD

26 September 2023

The issues

[1] From a purely practical point of view, it is no longer necessary to attend a local pharmacy in order to pick up prescription drugs. Some pharmacy contractors in Scotland, and indeed throughout the United Kingdom, deliver pharmaceutical services from so-called prescription collection lockers. These may be located outwith the pharmacy's premises, and may be made accessible at any time by or on behalf of patients provided with a unique PIN code. The lockers may be used in order to deposit prescriptions given by a doctor, dentist or other prescriber, and also to collect prescription drugs and appliances, once they have been

prepared or dispensed in accordance with such a prescription at a registered pharmacy by or under the supervision of a pharmacist.

[2] In terms of the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009 (“the 2009 regulations”), which are the regulations governing the provision of pharmaceutical services in Scotland, such arrangements are called “collection and delivery arrangements”. The principal question in this petition for judicial review concerns the circumstances in which such arrangements are lawful. Specifically, do the 2009 regulations require the premises in which the lockers are situated to be included in the pharmaceutical list maintained by every health board in Scotland of the names of persons who undertake to provide pharmaceutical services, and the addresses of the premises within the board’s area from which they undertake to provide them?

[3] The petitioner says that they do. It is a company called Community Pharmacy Scotland, whose objects include the representation of pharmacy contractors. It seeks to challenge the decisions, separately made by the respondent health boards (Fife Health Board and Lothian Health Board) that such lockers do not require to be so listed. The boards’ position is supported by the first interested party, Barrie Dear Limited, trading as Dears Pharmacy, a pharmacy contractor operating prescription collection lockers in Scotland.

[4] The respondents and Dears Pharmacy have also raised a subsidiary issue concerning the lawfulness of the 2009 regulations themselves. If the petitioner’s argument were correct, they say, then it would mean that the 2009 regulations purport to regulate the place at which medicinal products may be supplied to the public. However, the place at which medicinal products may be supplied to the public is a matter falling within the scope of the Medicines Act 1968, and as such is a reserved matter in terms of paragraph J4 of Schedule 5 to the Scotland Act 1998. Therefore, so the argument runs, any provision of the 2009 regulations

requiring the listing of the premises at which prescription collection lockers are located would be outside the legislative competence of the Scottish Ministers and “not law”.

[5] The whole matter came before me at a substantive hearing, at which I heard oral submissions supplementing the written notes of argument from all parties. I also heard from counsel for the Lord Advocate, who had lodged a helpful minute of written submissions confined to the devolution issue.

The relevant legislation

Arrangements

[6] Every health board in Scotland is required to make arrangements as respects its area, and in accordance with the relevant regulations, for the provision of pharmaceutical services (National Health Services (Scotland) Act 1978, s27, which defines pharmaceutical services as including the provision of drugs, medicines, appliances and services in accordance with such arrangements). The relevant regulations are the 2009 regulations.

The pharmaceutical list

[7] The health board must maintain a list of the names of persons who undertake to provide pharmaceutical services, and the addresses of the premises within the board’s area from which they undertake to provide them. The list must also state the nature of the services to be provided, and the days and hours during which the premises are open (reg 5(1)).

The scheme

[8] In addition, the health board is required to prepare a scheme for securing that one or more places on the pharmaceutical list in its area shall at all reasonable times be open (reg 11(1)). The scheme must specify the days and hours during which such premises shall be open, and the arrangements for dispensing medicines urgently at other times. Schemes prepared under paragraph (1) are subject to the approval of the Scottish Ministers (reg 11(2)). Regulation 11(5) permits the board to agree with any person whose name is included in the pharmaceutical list that the provisions of a scheme prepared under paragraph (1) shall not apply to that person for the duration of an emergency requiring flexible provision of pharmaceutical services (reg 11(5) actually refers to “a scheme prepared under paragraph (3)” but this is clearly an error, since paragraph (3) is simply a dispute-resolution provision).

Terms of service – pharmacy contractors

[9] The arrangements entered into by a health board with pharmacy contractors who undertake to provide pharmaceutical services in its area must incorporate the terms of service set out in Schedule 1 to the regulations (reg 3(2)). Paragraph 6 of Schedule 1 is at the very heart of this dispute and requires to be set out in full.

“6-(1) Subject to regulation 11(5), pharmaceutical services shall be provided from the premises specified in the application made by the pharmacy contractor for inclusion in the Board's list, and the premises shall be open for the supply of pharmaceutical services during the hours specified in the scheme to be made by the Board for that purpose under the Regulations.

(2) At every premises from which pharmaceutical services are provided there shall be exhibited a notice to be provided by the Board in the form prescribed in Schedule 2. There shall also be exhibited at such premises, at times when those premises are not open, and in such a manner as to be visible at such times, a notice in a form approved by the Board, indicating the facilities available for securing the dispensing of medicines urgently required.

(3) Pharmaceutical services shall not, except with the consent of the Board, or on appeal, of the Scottish Ministers, be provided by a pharmacy contractor in premises occupied by a doctor other than at a health centre.

(4) Subject to regulation 6 [a provision dealing with temporary relocation during an emergency] and sub-paragraph (4A), no pharmacy contractor shall provide pharmaceutical services from any pharmacy or other premises which are not included in the pharmaceutical list in respect of that pharmacy contractor.

(4A) Sub-paragraph (4) does not apply to the provision of pharmaceutical services which form part of a collection and delivery arrangement.”

[10] The inclusion of sub-paragraph (4A) was a consequence of regulation 3 of the National Health Service (Pharmaceutical Services) ((Scotland) Amendment Regulations 2021 (“the 2021 regulations”), which adopts the following definition of a “collection and delivery arrangement” from regulation 248(2) of the Human Medicines Regulations 2012 (“the 2012 regulations”):

“In this regulation ‘collection and delivery arrangement’ means an arrangement whereby a person may —

(a) take or send a prescription given by a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber, physiotherapist independent prescriber, podiatrist independent prescriber, therapeutic radiographer independent prescriber, paramedic independent prescriber or optometrist independent prescriber to premises other than a registered pharmacy and which are capable of being closed by the occupier to exclude the public; and

(b) collect or have collected on his or her behalf from such premises a medicinal product prepared or dispensed in accordance with such a prescription at a registered pharmacy by or under the supervision of a pharmacist.”

Terms of service - pharmacists

[11] Schedule 1 also imposes obligations on pharmacists, compliance with which must be secured by the pharmacy contractor (Sch 1, para 2). Paragraph 4(1) of Schedule 1 requires a pharmacist to supply with reasonable promptness certain prescription drugs and appliances to any person presenting the appropriate signed prescription form, unless he reasonably

believes the order is not a genuine order for the patient, in which case he must refuse to supply them (Sch 1, para 4(9)). In addition, paragraph 4 contains the following provisions:

“(12) Subject to sub-paragraph (13A), a relevant pharmacist shall not, except for the duration of an emergency requiring the flexible provision of pharmaceutical services, accept for dispensing any prescription form or serial prescription transmitted from or received at a registered pharmacy which is not included in the pharmaceutical list.

(13) Subject to sub-paragraph (13A), a relevant pharmacist shall not, except for the duration of an emergency requiring the flexible provision of pharmaceutical services, supply any drugs or listed appliances ordered on a prescription form or serial prescription other than at a registered pharmacy which is included in the pharmaceutical list.

(13A) Sub-paragraphs (12) and (13) do not apply to the acceptance of a prescription form or serial prescription, or to the supply of medicinal products ordered on such a form or serial prescription, which form part of a collection and delivery arrangement.”

[12] The disapplication of sub-paragraphs (12) and (13), where the acceptance of a prescription form, or the supply of medicinal products ordered thereon, form part of a collection and delivery arrangement was introduced by the 2021 regulations (reg 4). A registered pharmacy has the meaning given by section 74 of the Medicines Act 1968, being premises for the time being entered in the register maintained by the General Pharmaceutical Council in terms of article 19 of the Pharmacy Order 2010 (reg 2 of the 2009 regs).

Payment

[13] Regulation 12 and paragraph 10 of Schedule 1 make provision for payment to pharmacy contractors included in the pharmaceutical list in respect of the provision of pharmaceutical services.

Submissions

The petitioner

[14] The petitioner's submissions can be summarised quite briefly. The definition of "collection and delivery arrangements" makes it clear that prescription collection lockers do not require to be "registered premises". It says nothing about whether they require to be premises included in the pharmaceutical list. The amendments to the 2009 regulations left paragraph 6(1) of Schedule 1 untouched. It continues to provide that pharmaceutical services shall be provided from the premises included in the pharmaceutical list.

Accordingly, prescription collection lockers must be included in the pharmaceutical list. To hold otherwise would undermine the viability of other pharmacies within the board's area.

[15] The petitioner sought decree of reduction of the boards' decisions dated 2 September 2023 that it was lawful for prescription collection lockers, that were not included in the pharmaceutical list, to be used for the collection of drugs under an NHS prescription. It also sought decree of declarator that such lockers may only be located within premises included in the pharmaceutical list in the name of the pharmacy contractor operating the lockers. Finally, it sought decree of declarator that it would be unlawful for the boards to make any payments under regulation 12 and paragraph 10 of Schedule 1 in respect of drugs or applications collected from such lockers, and to interdict the boards from making any such payments.

The boards

[16] The boards' argument was rather more complex, but can be summarised as follows. Paragraph 6(1) of Schedule 1 created no more than a "general rule" that pharmaceutical services require to be provided from premises included in the pharmaceutical list. This

general rule was, they said, subject to “exceptions”, one such exception being the provision of services that form part of a collection and delivery arrangement (note of argument, paras 6c-6e).

[17] The objective meaning of the legislation required to be interpreted as a whole, having regard to the surrounding circumstances and the legislative purpose (*R (Quintavalle) v Secretary of State for Health* [2003] 2 AC 687; *R (on the application of Spath Holme Limited) v Secretary of State for the Environment, Transport and the Regions* [2001] 2 AC 349). The clear intention of regulation 6(4A) was to allow collection and delivery arrangements to take place on unlisted premises. The explanatory note to the 2021 regulations supported the boards’ interpretation, since it stated that the purpose of the amendment was “to make provision for the collection of prescriptions for, and supply of medicinal products in accordance with a collection and delivery arrangement as defined by [regulation 248(2) of the 2012 regulations]”. The petitioner’s interpretation would frustrate the purpose of the 2021 regulations, and would mean that collection and delivery arrangements operated differently in Scotland compared to the rest of the United Kingdom.

[18] Senior counsel for the boards also invited me to take into account, as part of the relevant context, an earlier petition raised by Fife Health Board against Dears Pharmacy concerning its use of prescription collection lockers. In that litigation, the Scottish Ministers had apparently accepted that the 2009 regulations, prior to the 2021 amendments, purported to regulate the place at which medicinal products were supplied and were thus outside the legislative competence of the Scottish Ministers. This was the “mischief” which the 2021 regulations were intended to address (note of argument, para 6j). On the petitioner’s interpretation, however, the amendment would have failed to achieve that purpose, since

the regulations would continue to specify the place where medicinal products may be supplied to the public, namely, at listed premises.

[19] If, contrary to the boards' submissions, the 2009 regulations as amended did require prescription collection lockers to be included in the pharmaceutical list then this would mean that the regulations were outside the legislative competence of the Scottish Ministers and "not law". Sections 52 and 53 of the Medicines Act 1968 regulated the place where medicinal products could be supplied to the public (see now regulations 220 and 221 of the 2012 regulations). Specifically, section 52 required medicinal products not on the general sale list to be supplied from a registered pharmacy, while section 53 specified the conditions under which a medicinal product on the general sale list may be permitted to be supplied other than at a registered pharmacy. The petitioner's interpretation of paragraph 6(1) of Schedule 1, requiring collection and delivery arrangements to be carried out from listed premises, if correct, would regulate the place where medicinal products are to be provided. At the very least, the regulations would have more than a loose or consequential connection with the 1968 Act. Accordingly, they would relate to a reserved matter and be "not law" (*Martin v Most*, 2010 SC (UKSC) 40, para 49; *Imperial Tobacco Ltd v Lord Advocate*, 2013 SC (UKSC) 153, para 16, *In re UK Withdrawal from the European Union (Legal Continuity) (Scotland) Bill* [2019] AC 1022, para 27; *Reference by the Lord Advocate of Devolution Issues under paragraph 34 of Schedule 6 to the Scotland Act 1998* 2022 SLT 1325, para 75).

Dears Pharmacy

[20] Dears Pharmacy made submissions closely corresponding to those made on behalf of the boards. In particular, it too submitted that paragraph 6(1) of Schedule 1 was merely a general term in the pharmacy contractor's conditions of service. It permitted exceptions,

such as that provided by Schedule 1, paragraph 6(4A), and indeed Schedule 1, paragraph 4, particularly sub-paragraph (13A). The petitioner's interpretation would lead to absurd or futile results, which it must be presumed the legislator did not intend (*R (Noone) v Governor of Drake Hall Prison* [2010] UKSC 30). If it were correct, the 2021 amendments would be deprived of any practical effect. The petitioner's interpretation would also mean that delivery of pharmaceutical services to a patient's home would fall foul of paragraph 6(1) of Schedule 1. Senior counsel also agreed with the boards' submission regarding the previous litigation involving Fife Health Board and Dears Pharmacy being part of the relevant context to the 2021 regulations. She also agreed with the boards' alternative submission that the 2009 regulations as amended, assuming the petitioner's interpretation were correct, would be outside the legislative competence of the Scottish Ministers.

The Lord Advocate

[21] In a brief intervention, the Lord Advocate submitted that the 2009 regulations were within the devolved competence of the Scottish Ministers. They did not purport to regulate the place at which medicinal products may be supplied to the public. Rather, they regulated the conditions under which NHS pharmaceutical services may be provided and be eligible for reimbursement at public expense.

Decision

[22] Paragraph 6(1) of Schedule 1 to the 2009 regulations was central to the petitioner's argument. It provides that, subject to regulation 11(5), which I will discuss presently, pharmaceutical services shall be provided from the premises specified in the application made by the pharmacy contractor for inclusion in the pharmaceutical list. But it does not

say that pharmaceutical services may *only* be provided from such premises. The petitioner's argument involved reading paragraph 6(1) as though it had said that "all pharmaceutical services" or "the pharmaceutical services" provided by the pharmacy contractor shall be provided from listed premises.

[23] The submissions for the boards and Dears Pharmacy were similarly misconceived. They misconstrued paragraph 6(1) as containing a "general" prohibition on pharmaceutical services being provided elsewhere than at a listed pharmacy, with paragraph 6(4A) being considered as some sort of "exception" to that general prohibition in the case of collection and delivery arrangements. In my view, paragraph 6(1) is no such thing. What it does is to require the pharmacy contractor, as a bare minimum, to provide pharmaceutical services from the premises stated in his application. Provided he does that, he is not prevented by paragraph 6(1) from providing them elsewhere. Paragraph 6(4) does, of course, prevent him from providing pharmaceutical services elsewhere, but that is precisely the requirement that has been disapplied by paragraph 6(4A) to pharmaceutical services forming part of a collection and delivery arrangement. Moreover, the disapplication effected by paragraph 6(4A), in respect of pharmacy contractors, is mirrored in the disapplication by sub-paragraph (13A) of sub-paragraphs (12) and (13), prohibiting pharmacists from accepting prescription forms transmitted from or received at an unlisted pharmacy, or from supplying drugs and appliances other than at a listed pharmacy. It is simply misleading to characterise this, as senior counsel for Dears Pharmacy did, as an "exception" to paragraph 6(1) (note of argument, para 15).

[24] The second part of paragraph 6(1) provides that the pharmacy contractor's premises "shall be open for the supply of pharmaceutical services during the hours specified in the scheme to be made by the Board for that purpose under the Regulations". The reference to

“the scheme” means the scheme to be prepared by the board under regulation 11(1) “for securing that one or more places on the pharmaceutical list in its area shall at all reasonable times be open”. Of course, regulation 11(5) allows the board and a pharmacy contractor to agree that the scheme shall not apply to that contractor during an emergency. But the fact that regulation 11(5) qualifies the whole of paragraph 6(1) makes it clear that the first part of that paragraph, requiring pharmaceutical services to be provided from listed premises, must also be read in the light of the provisions relative to the scheme to be prepared by the board. In my view, the clear purpose of paragraph 6(1) of Schedule 1, when read together with regulation 11, is to secure rather than to restrict the supply of pharmaceutical services to the public from listed premises. And while paragraph 6(1) is directed at the pharmacy contractor, its concern with securing supply is mirrored by paragraph 4(1), requiring the pharmacist to supply drugs and appliances when presented with a signed prescription form, unless he reasonably believes it not to be a genuine order for the patient.

[25] Collection and delivery arrangements require the use of premises that are “capable of being closed by the occupier to exclude the public”. In that sense, delivery to a prescription collection locker is more like a home delivery, in both cases, the premises are capable of being closed by the occupier to exclude the public. Of course, the advantage of the locker, over both the high street pharmacy and home delivery service, is that it can be accessed 24 hours a day, 7 days a week. In my view, it would be odd if paragraph 6(1) of Schedule 1, together with regulation 5, required the opening hours of prescription collection lockers to be listed. I am prepared to accept, as senior counsel for the petitioner submitted, that the take-up by the public of prescription collection lockers may have consequences for the viability of high street pharmacies. However, I reject the submission that the 2009 regulations seek to control entry to the market by requiring the listing of such lockers

as premises, any more than they require the listing of homes to which prescription drugs may be delivered.

[26] I would underline two matters for the avoidance of doubt. Firstly, and putting whatever arrangements that may be required during an emergency to one side, my interpretation of the 2009 regulations would not permit a pharmacy contractor to deliver pharmaceutical services *only* by way of prescription collection lockers. Paragraph 6 of Schedule 1 permits the use of such lockers complying with the definition of a collection and delivery arrangement, provided the pharmacy contractor provides pharmaceutical services from the premises referred to in his application for inclusion in the pharmaceutical list. Secondly, while the definition of a “collection and delivery arrangement” permits a prescription form to be taken to premises “other than a registered pharmacy”, provided it is capable of being closed to the public, it nevertheless requires the relevant preparation and dispensing of medicinal products to be carried out at a registered pharmacy. The disapplication by paragraph 4(13A) of the requirements of paragraphs 4(12) and 4(13) of Schedule 1 must be read with that important qualification in mind.

[27] For similar reasons, in my view, no devolution issue arises. Broadly speaking, it is necessary to distinguish the board’s responsibility for securing the adequate supply of pharmaceutical services in its area from the General Pharmaceutical Council’s responsibility for setting standards for the safe and effective practice of pharmacy. The latter is governed by the requirement to register premises in accordance with article 19 of the Pharmacy Order 2010 and section 74 and 74A of the Medicines Act 1968. The former is governed by the 2009 regulations insofar as they require the inclusion in the pharmaceutical list of registered premises from which pharmaceutical services are to be supplied. Even if I were wrong in my interpretation of paragraph 6(1), such that the premises in which prescription

collection lockers were situated required to be included in the pharmaceutical list, then I would have held that any connection between that requirement and the Medicines Act 1968 or the 2012 regulations was no more than loose or consequential.

Disposal

[28] I shall repel the petitioner's second plea-in-law and refuse to grant the remedies it seeks of reduction, declarator and interdict. I shall also repel the boards' fifth plea-in-law and Dears Pharmacy's fourth plea-in-law, insofar as directed at the 2009 regulations being *ultra vires* and outside the devolved competence of the Scottish Ministers. I shall reserve any question of expenses.