

**THE HIGH COURT  
JUDICIAL REVIEW**

2018 No. 455 J.R.

BETWEEN

DARASTREAM LIMITED

APPLICANT

AND  
HEALTH SERVICE EXECUTIVE

RESPONDENT

JUDGMENT of Mr Justice Garrett Simons delivered on 7 December 2018

**INTRODUCTION**

1. In these proceedings, the Applicant seeks to challenge the legality of a decision by the Health Service Executive ("HSE") to refuse to enter into an agreement with it. More specifically, the Applicant contends that a decision made by the HSE on 16 April 2018 to refuse to enter into a Community Pharmacy Contractor Agreement with it was *ultra vires*. The Applicant also contends that the HSE took into account irrelevant considerations in reaching its decision, by having regard to (i) the existence of an ongoing investigation into two related pharmacies, and (ii) the role of the *superintendent* pharmacist (as opposed to a *supervising* pharmacist).

2. The resolution of the dispute between the parties will turn, to a large extent, on the correct interpretation of section 59 of the Health Act 1970 (as amended). The Applicant contends that the discretion, if any, which the HSE enjoys under this section is very limited. Reliance is placed in this regard on the fact that the Minister for Health has a role, under section 59(1E), in specifying conditions for the provision of community pharmacy services. The inference here seems to be that the role of the Minister precludes the HSE itself from specifying conditions.

3. Conversely, the HSE contends that it has a broad discretion under section 59 of the Health Act 1970; and that this discretion must—consistent with section 7 of the Health Act 2004—be exercised in such a way as to ensure that the HSE uses the resources available to it in the most beneficial, effective and efficient manner.

4. In order to determine which of these rival submissions is correct, it will be necessary to consider the legislative—as opposed to the parliamentary—history of section 59 of the Health Act 1970. It is also necessary to consider the case law which has examined that section. Before turning to that task, however, it is appropriate first to set out the factual background leading up to the current dispute between the parties.

**FACTUAL BACKGROUND****(i) Community Pharmacy Contractor Agreement**

5. Section 59 of the Health Act 1970 provides that the HSE shall make arrangements for the supply without charge of drugs, medicines and medical and surgical appliances to persons with full eligibility. A person with full eligibility is referred to colloquially as a medical card holder.

6. In practice, one of the ways in which the HSE seeks to discharge its duty under section 59 is by entering into contracts with individual pharmacists. A standard form agreement has been negotiated between the Minister for Health and the representative of the pharmacists, the Irish Pharmaceutical Union. The standard form agreement is entitled "*Community Pharmacy Contractor Agreement for Provision of Services under the Health Acts*". For ease of reference, I will use the shorthand "*CPC Agreement*" to refer to this standard form agreement. It should be noted that at the time the agreement was negotiated, the Minister still had a wide power to make regulations under section 59(4) as originally enacted.

7. The current version of the CPC Agreement was, seemingly, negotiated in 1996, and remains largely unchanged since then. A copy of this version of the CPC Agreement has been exhibited in the proceedings by Anne Marie Hoey on behalf of the HSE in her affidavit of 19 July 2018.

8. The history of the CPC Agreement is set out as follows in Ms Hoey's affidavit.

"7. The CPC Agreement is the key agreement between the HSE and pharmacists regulating the manner in which they provide services to the public on behalf of the HSE. The terms of the CPC Agreement are standard for all pharmacists and were agreed with the representative organisation of pharmacists, the Irish Pharmaceutical Union, in July 1996. The CPC Agreement places considerable emphasis on the professional role of the pharmacist, on the quality of community pharmacy services expected and on accountability.

8. Medicines are the most common healthcare intervention within the health system and both the use and the complexity of medicines are increasing – in 2017, payments to pharmacies totalled over €1.4 billion. The HSE is the State body overseeing the disbursement of these monies by way of the CPC Agreement and it is essential that high standards should be expected from, and maintained by, pharmacists who operate the agreement on behalf of the State and for the benefit of the public. I beg to refer to a copy of the CPC Agreement which can be found at Tab 1 of the Book."

9. Clause 19 of the CPC Agreement provides as follows.

"19(1) This agreement shall terminate forthwith on the pharmacy contractor, or in the case of a body corporate, the supervising pharmacist ceasing to be entitled to practice as a pharmacist or upon his/her ceasing to keep open shop for the compounding and dispensing of medical prescriptions or on the cessation of the said contractor's entitlement so to do.

(2) The pharmacy contractor may terminate the agreement on giving three months notice in writing or such shorter period of notice, in writing, as may be agreed by the chief executive officer.

(3) This agreement is to be construed as contingent upon the terms agreed or to be agreed between the Minister and the Pharmacies Contractors' Committee regarding arrangements for the provision of pharmaceutical services under the provisions of the Health Act. The pharmacy contractor and the HSE agree that any changes in the terms of such arrangements, which may be agreed between the Minister and the Pharmacy Contractors' Committee, shall be

incorporated into this agreement and the terms of this agreement shall be construed accordingly, following the issue of a notification of such agreed changes by the Minister.

(4) Nothing in this agreement shall interfere with the statutory functions prescribed from time to time of the Minister or of the chief executive officer.

(5) The terms and conditions of this agreement between the Pharmacy Contractors' Committee and the Minister may be subject to review after a period of five years. In default of agreement and any such review, the matters of disagreement shall be subject to mediation and recommendation by third party appointed by the Minister."

10. As discussed presently, each of the parties to the proceedings attaches significance to certain clauses in the CPC Agreement as advancing their case. It will be necessary, therefore, to consider the terms of same in some detail. For introductory purposes, however, it is sufficient to note that the CPC Agreement (i) expressly addresses the issue of beneficial ownership of a pharmacy and allows for termination of the agreement in the event of a change in beneficial ownership; and (ii) does not address the position of a *superintendent* pharmacist (as opposed to *supervising* pharmacist).

**(ii) Application of January 2017**

11. An application for a CPC Agreement is made pursuant to a standard application form. Again, as in the case of the CPC Agreement itself, the standard application form addresses the beneficial ownership of the pharmacy, and does not address the position of the superintendent pharmacist.

12. The application form completed and submitted on behalf of the Applicant in the present case has been exhibited as part of Jack McPolin's affidavit verifying the statement of grounds. The application form was submitted on or about 5 January 2017.

13. As appears therefrom, the application was made on behalf of Darastream Ltd. and was made in respect of a new pharmacy located at Quarry Road, Cabra. Darastream Ltd. is the Applicant in these judicial review proceedings. The directors of Darastream Ltd. are Jack McPolin and Mary McPolin. The beneficial owner of Darastream Ltd. was identified in the application form as Jack McPolin.

14. Mr McPolin is also the beneficial owner of two other companies which operate pharmacies, namely Fair Street Pharmacy Ltd. and Lynnmoy Ltd. These two pharmacies are located at Main Street, Blanchardstown, and North Circular Road, respectively. These pharmacies are referred to in the HSE documentation as the "Blanchardstown" and "North Circular Road" pharmacies, and I will adopt the same shorthand in this judgment.

15. These pharmacies have entered into CPC Agreements with the HSE. The HSE has invoked clause 15 of the CPC Agreement, which allows for the carrying out of an investigation pursuant to clauses 16 to 18. This has been described in the documentation as the "clause 15 procedure", and I will use the same shorthand in this judgment. The clause 15 procedure is ongoing, and no final decision has been made in respect of same. It is the interaction between this ongoing investigation and the Applicant's application for the pharmacy at Cabra that gives rise to much of the complaints in these proceedings.

16. The HSE wrote to Mr McPolin, on behalf of the Applicant, by letter dated 16 March 2017. The content of this letter assumes a particular significance in light of subsequent events, and, accordingly, it is necessary to set out the key passages from the letter in full.

"I refer to your applications for a new pharmacy contractor agreement at Smith's Pharmacy, 1 Long Mile Road, Dublin 12 and Smith's Pharmacy, 2B Quarry Rd., Cabra Dublin 7.

I understand that you are registered with the Pharmaceutical Society of Ireland and are awaiting the HSE to finalise a contractor agreement at these locations.

However, we have received multiple complaints in relation to your offering inducements to place orders for medicines at your new PSI registered pharmacies.

Furthermore, we have conducted two inspections at other Pharmacies, for which you hold beneficial ownership, with HSE contractor agreements. These inspections support our concerns in relation to inducements offered. There will be separate communications forthcoming on those inspections as various claiming and practice issues arise at those locations.

It was most unsatisfactory to be informed that at North Circular Rd. a significant amount of High Tech Stock was ordered in the absence of Nominated High Tech Patients. I refer you to previous circulars in relation to High Tech Stock. Please ensure that in future, you only order High Tech Stock for patients who have nominated your pharmacy as their dispensing pharmacy.

In the circumstances outlined, we are not satisfied to finalise contractor agreements at new locations until these matters are addressed to the satisfaction of the HSE."

17. This letter of 16 March 2017 marked the start of a lengthy exchange of correspondence between the HSE and the solicitors acting on behalf of the Applicant. In brief, it was indicated on behalf of the Applicant that it required the HSE to complete its application for a CPC Agreement without further delay. The Applicant ultimately issued legal proceedings seeking mandatory relief as against the HSE in this regard (High Court 2017 No. 7834 P.). A plenary summons was issued on 28 August 2017. It seems that in response to this, the HSE resolved to determine the application for the CPC Agreement notwithstanding its preference to await the outcome of the ongoing investigation in respect of the two other related pharmacies.

18. The decision-making process in respect of the application for a CPC Agreement involved two steps: first, the issuing of what was described as a "preliminary recommendation", and, secondly, the making of a final decision having regard to any representations which the Applicant made to the "preliminary recommendation".

19. The HSE issued the "preliminary recommendation" on 9 February 2018. This preliminary recommendation was prepared by Kate Mulvenna, Head of the Pharmacy Function at the Primary Care Reimbursement Service of the HSE.

20. The preliminary recommendation identified that, in addition to being the beneficial owner of the relevant retail pharmacy business, Mr McPolin is also the beneficial owner of a number of pharmacies trading as Smiths pharmacies ("the Smith group") that currently have CPC Agreements with the HSE. In particular, Mr McPolin is the beneficial ownership of Fair Street Pharmacy Ltd. (trading as

Smith's pharmacy) in Blanchardstown, and Lynnmoy Ltd. (trading as Smith's pharmacy) on the North Circular Road. It was later noted that Mr McPolin was the superintendent pharmacist of these two pharmacies, and was to be the superintendent for the Cabra pharmacy also.

21. The preliminary recommendation records that complaints had been received by the HSE in respect of the premises at Blanchardstown and North Circular Road, and, further, that inspections had been conducted by the HSE at those premises. The inspections were conducted pursuant to Clause 7(1) of the CPC Agreements between the HSE and the Blanchardstown and North Circular Road pharmacies.

22. The Applicant was afforded a period of time (seven days) within which to make representations in response to the preliminary recommendation. In the event, the Applicant did not, in fact, submit a substantive response, but rather indicated instead that it wished to rely on the submissions made in the context of the parallel investigation in respect of the two other related pharmacies.

23. On 16 April 2018, the HSE made a final decision to refuse to enter into a CPC Agreement with the Applicant. A revised version of this final decision, which corrected a number of typographical or clerical errors in the original version, issued in May 2018. No issue was taken in these proceedings as to these amendments.

24. The final decision was made by a different person than the person who had prepared the preliminary recommendation. The final decision-maker, Anne Marie Hoey, holds the position of Assistant National Director of the Health Service. Ms Hoey swore an affidavit in the judicial review proceedings verifying the HSE's statement of opposition.

25. The final decision is a comprehensive document, running to some thirty pages. I have carefully considered same in preparing this judgment. The key elements of the final decision are set out in an appendix hereto.

### **(iii) Clause 15 Procedure**

26. It is necessary to refer briefly to the process which was being carried out in respect of the pharmacies at Blanchardstown and North Circular Road, respectively.

27. Clause 15 of the CPC Agreement provides as follows.

66. Where the chief executive officer of the HSE has reason to believe that a pharmacy contractor has failed to comply with any of the terms of the agreement, or is conducting himself/herself or his/her business in such a way as may present a danger to public health, or if the pharmacy contractor, or any person employed by the pharmacy contractor, has been convicted of an offence which is considered by the chief executive officer to be serious in the context of the practice of pharmacy, the chief executive officer shall notify the pharmacy contractor of the reasons for such belief by registered post and inform him that he will consider any representations in regard to the matter which may be received by him from the pharmacy contractor within fourteen days of the date of the notification. The chief executive officer may, if he is satisfied, after consideration of any representations which the pharmacy contractor may make in regard to the matter, that the pharmacy contractor has not complied the terms of the agreement and if he so thinks fit, either –

(a) issue a warning to the contractor or otherwise communicate appropriately with him, or

(b) arrange for the reference of the matter to a committee established under clause 16 of this Agreement for the purpose of investigating such a matter.”

28. Clauses 16 and 18, then, set out a procedure for (i) the establishment of a committee and (ii) the conduct of an inquiry by such a committee. Clause 18 provides that the Chief Executive Officer may, after consultation with the chairman of the committee, or in his/her absence the vice-chairman of the board, suspend an agreement pending a decision following a reference to a clause 16 committee where, in the opinion of the Chief Executive Officer the circumstances are sufficiently serious to warrant such suspension in the public interest.

29. The Chief Executive Officer of the HSE issued a letter pursuant to clause 15 in respect of the Blanchardstown pharmacy on 19 December 2017. This letter was accompanied by a witness statement relating to the findings from an inspection of the pharmacy.

30. The nature of the allegations are summarised as follows at paragraphs 12 to 14 of the witness statement.

12. I believe that the investigation demonstrates various instances in which the Pharmacy has claimed for reimbursement from the PCRs for multiple dispensings of the same medication across a number of pharmacies within the Smith's Pharmacy group on foot of obsolete/defunct or invalid prescriptions harvested within the Smith's Pharmacy group. It is also alleged that appropriate records were not maintained within the pharmacy including but not limited to the maintenance of appropriate and accurate patient medication records. Finally, it is alleged that the statutory prescription fee is not being applied such as to provide an inducement to place an order for medicines, a breach of Clause 4 (4) of the CPC agreement.

Suspected breaches of the CPC agreement by Fair St., Pharmacy Limited trading as Smiths pharmacy.

13. The investigation revealed that Smith's pharmacy had been engaging in a number of activities and practices that appear to be in contravention of the CPC agreement held by Fair Street Pharmacy Ltd. The following breaches are outlined below:

- i Duplicate Cross Pharmacy Claiming
- ii Owings
- iii DPS claims without copy prescriptions in the pharmacy
- iv Failure to maintain appropriate Pharmacy records
- v Failure to maintain Appropriate Patient Medication Records (PMRs)

14. Suspected Breaches of the CPC Agreement by Smiths pharmacy Blanchardstown.

14.1 Duplicate Cross Pharmacy Claiming

A complaint was made in relation to inducements being offered to place an order for medicines – an apparent breach of clause 4 (4) where a CPC agreement is in place. In reviewing pharmacy activity across the Smith's Pharmacy Group, it was noted that there appeared to be multiple claims entered for the same people in pharmacies some distance apart within a short timeframe i.e. within a shorter timeframe than would be necessary in accordance with the prescriber's instructions.

It was established, through medical card records held in the PCRs that some patients who appeared to attend Smith's Pharmacy Blanchardstown also appeared to attend other Smith's pharmacies in the same month (October 16) to access a duplicate supply of medicines. Upon further investigation, an examination of a number of patient reimbursement histories showed that some patients within Smith's Pharmacy, Blanchardstown had duplicated claims associated with them in the month of October 2016 and November 2016 in other pharmacies within the Smith's pharmacy group.

Two pharmacies, Smith's pharmacy, 409 North Circular Road, Dublin 7 & Smiths Pharmacy, Leixlip, Co. Kildare were identified within the Smith's pharmacy group as being involved in duplicate cross pharmacy claiming. Smith's Pharmacy Blanchardstown was among the pharmacies identified."

31. A similar letter pursuant to clause 15 was also issued in respect of the North Circular Road pharmacy. Again, this was accompanied by a witness statement.

**THE CASE AS PLEADED**

32. The Applicant was granted leave to apply for judicial review on an *ex parte* basis by the High Court (Noonan J.) on 11 June 2018. The proceedings ultimately came on for hearing before me on 27 November 2018.

33. The principal relief sought in the proceedings is an order of *certiorari* quashing the HSE's decision of 16 April 2018 refusing to enter into a contract with the Applicant. A declaration is also sought to the effect that the HSE has acted *ultra vires* its powers in refusing to enter into a contract for services with the Applicant.

34. The statement of grounds includes a claim for damages, but I was informed at the hearing that this was not a matter which was to be argued before me.

35. Part E of the statement of grounds commences with a narrative of the events leading up to the decision of 16 April 2018.

36. The legal grounds of challenge are set out at paragraphs E.18 to E.21. Given that there is some controversy as to the precise arguments which the Applicant is entitled to pursue in light of these pleas, it may be useful to set same out in full.

"18. The administration of the statutory scheme under the Health Act 1970 was carried out in an arbitrary and unjust manner and the Respondent erred in law and acted *ultra vires* in refusing the Applicant's application for a Community Pharmacy Contractor Agreement.

19. The Respondent in refusing to enter into an agreement for the provision of services has acted *ultra vires* its powers under the legislation which powers provide that it enter into such agreements pursuant to conditions determined by the Minister.

20. The Respondent in refusing to enter into the said agreement did so for a purpose other than that envisaged by the legislation granting it the power to enter into said agreement.

21. In the premises, the Respondent's decision is arbitrary, irrational and lacking in proportionality."

37. I will return to consider whether all of the arguments sought to be advanced at the hearing before me fall within the scope of the pleadings (see paragraphs 84 and 94 below).

**RELEVANT LEGISLATION**

**(i) Health Act 1970**

38. Section 59 of the Health Act 1970 as originally enacted provided as follows.

"59.—(1) A health board\* shall make arrangements for the supply without charge of drugs, medicines and medical and surgical appliances to persons with full eligibility.

(2) When a person with limited eligibility, or a person with full eligibility who does not avail himself of the service under subsection (1), satisfies the chief effective officer of the health board that, in respect of a period and to an amount determined by regulations made by the Minister, he has incurred expenditure on drugs, medicines and medical and surgical appliances which were obtained on the prescription of a registered medical practitioner and were for the treatment of that person or his dependants, the health board shall make arrangements to meet the balance of the cost, or a proportion thereof (as may be prescribed) of the person's being supplied in respect of that period with such drugs, medicines and medical and surgical appliances.

(3) A health board may make arrangements for the supply without charge of drugs, medicines or medical and surgical appliances to persons suffering from a prescribed disease or disability of a permanent or long-term nature.

(4) Regulations relating to the service under this section shall be made with the consent of the Minister for Finance."

\*The functions of health boards were transferred to the HSE under the Health Act 2004

39. The Minister for Health in the exercise of the power conferred upon him under section 59(4) made regulations on 30 May 1996, namely the Health (Community Pharmacy Contractor Agreement) Regulations 1996 (S.I. No. 152 of 1996) (hereinafter "*the 1996 Regulations*"). The 1996 Regulations were ultimately repealed on 31 January 2002, and have not been replaced. (See Health (Community Pharmacy Contractor Agreement) Regulations, 1996 (Revocation) Regulations 2002 (S.I. No. 28 of 2002)).

40. For the purpose of these proceedings, there are two aspects of the 1996 Regulations which are of interest. First, the 1996 Regulations purported to prescribe the criteria against which a decision to enter into a community pharmacy contractor agreement (as defined under regulation 1) was to be made. In particular, regulation 5(1) provided that no community pharmacy contractor agreement shall be granted or offered unless the Chief Executive Officer is satisfied *inter alia* of the following conditions.

- "(i) that there is a definite public health need for the supply of community pharmacy services in the particular catchment area to which an application relates;
- (ii) the premises have free and direct access to the public road at all times;
- [...]
- (vi) the proposed pharmacy practice has a reasonable prospect of being viable in the context of the pharmacy services to be provided and that there is a long term commitment to the catchment area which it is intended to serve."

41. The second respect in which the 1996 Regulations are of interest to these proceedings is that the Regulations purported to prescribe the form in which an application for a community pharmacy contractor agreement was to be made. In particular, regulation 7 provided that an applicant shall be required to make a detailed application in writing to the Chief Executive Officer of the health board, in whose functional area the community pharmacy is to be located, in the manner determined by the Chief Executive Officer. Regulation 7 went on to prescribe what might be colloquially characterised as the minimum information to be provided. This minimum information included items directed towards the substantive criteria specified in regulation 5 (discussed above). Thus, for example, an application was to include evidence to demonstrate that there is a *definite public health need* for the supply of community pharmacy services in the particular catchment area to which the application relates. An application was also to include evidence of the *viability* of the pharmacy practice in respect of which a community pharmacy contractor agreement was being sought.

42. As appears from the above summary, the 1996 Regulations purported (i) to prescribe qualitative criteria by reference to which the decision to grant or refuse an application for an agreement would be made; and (ii) to prescribe the procedure to be followed in the making of an application. Put shortly, the 1996 Regulations addressed both matters of substance and matters of procedure.

43. As discussed at paragraph 80 below, one of the complaints made by the Applicant in these proceedings is that there is no express reference in the impugned decision of April 2018 to matters such as whether there is a definite public health need for the supply of community pharmacy services in the particular catchment area. This complaint is made by way of analogy with the content of the 1996 Regulations. Counsel for the Applicant accepts, of course, that the 1996 Regulations are not directly relevant as same have been revoked since January 2002.

#### **(ii) Health (Amendment) Act 2010**

44. The provisions of section 59 of the Health Act 1970 were subject to significant amendment by the Health (Amendment) Act 2010. The principal purpose of these amendments was to allow for the imposition of what is colloquially known as a "prescription charge". Notwithstanding the provisions of section 59(1)—which, it will be recalled, provide for the supply of drugs, medicines, and medical and surgical appliances *without charge*—a person with full eligibility shall be charged an amount per item supplied to that person on prescription. The amount payable is determined by the Minister for Health by way of regulations made pursuant to an amended section 59(4). The amount is to be collected by the community pharmacy contractor.

45. The current amount is two euro per item, but this is subject to a monthly cap of twenty euro; and certain persons are exempted entirely. (See Health Services (Prescription Charges) Regulations 2017 (S.I. No. 553 No. 2017)).

46. The prescription charge has been given effect to by way of the introduction of a number of new subsections, ss. (1A) to (1E), to section 59 of the Health Act 1970.

47. Relevantly to the present proceedings, these amendments introduce a definition of the term "*community pharmacy contractor*". The term is defined under section 59(1E) as follows:

"'community pharmacy contractor' means a registered pharmacist, company or other body corporate that provides services to the Health Service Executive under an agreement made in accordance with conditions specified by the Minister in 1971 or 1996, as amended from time to time, for the provision of community pharmacy services to eligible persons under subsection (1)".

48. As discussed at paragraph 54 below, the Applicant places great emphasis on the fact that the Minister for Health has a role in specifying conditions for the provision of community pharmacy services under section 59(1E). The inference here seems to be that the role of the Minister *precludes* the HSE itself from specifying conditions.

49. The 2010 amendments also involved a recasting of the Minister's power to make regulations. This power is much more limited than under section 59(4) as originally enacted. The power is now confined to matters related to the prescription charge.

50. The amended section 59(4) reads as follows.

- "(4) (a) The Minister may make regulations—
  - (i) subject to paragraph (b), varying either or both of the amounts referred to in subsections (1A) and (1B)(a),
  - (ii) subject to paragraph (c), specifying other classes of persons who shall not be charged the amount referred to in subsection (1A) either in respect of all items supplied to persons of that class or specified categories of such items, and

(iii) where the Minister considers it necessary to do so, in relation to the refund, credit or other relief of amounts in excess of the maximum aggregate amount referred to in subsection (1B).

(b) The Minister shall make regulations under paragraph (a)(i) only where he or she is of opinion that such a variation is desirable, having regard to such of the following as he or she considers appropriate:

- (i) information on the consumer price index made available by the Central Statistics Office from time to time;
- (ii) recent information on the aggregate of the amounts expended, and the number of items in respect of which those amounts were expended, by the Health Service Executive in providing the service under subsection (1);
- (iii) the medical needs of, and the financial burden on, persons who avail themselves of the service under subsection (1);
- (iv) the necessity of controlling expenditure in relation to the provision by the State of health services.

(c) The Minister shall make regulations under paragraph (a)(ii) only where he or she is of opinion that not to charge the amount referred to in subsection (1A) to such a class is just and equitable in the circumstances, having regard to such of the following as he or she considers appropriate:

- (i) the particular medical condition, disability or medical needs of persons of that class;
- (ii) the number of prescription items required in respect of the condition, disability or medical needs referred to in subparagraph (i);
- (iii) recent information on the aggregate of the amounts expended, and the number of items in respect of which those amounts were expended, by the Health Service Executive in providing the service under subsection (1), either generally or in respect of persons of that class;
- (iv) the necessity of controlling expenditure in relation to the provision by the State of health services;
- (v) whether the overall financial situation of all, or substantially all, of the persons of that class is significantly worse than that of other persons who are charged amounts under subsection (1A).

(d) Regulations under this section shall be made with the consent of the Minister for Finance."

### **(iii) Health (Miscellaneous Provisions) Act 2001**

51. For the sake of completeness only, it should be noted that a much more elaborate power to make regulations under section 59 of the Health Act 1970 had been enacted—but never commenced—under the Health (Amendment) Act 2001. This defunct version of section 59(4) expressly provided that regulations could address matters such as (i) the need for community pharmacies, and (ii) the viability and permanence of pharmacies.

52. The 2001 amendment was revoked, without ever having been commenced, by the Health (Pricing and Supply of Medical Goods) Act 2013.

### **(iv) Health Act 2004**

53. Section 7(1) of the Health Act 2004 provides that the object of the Executive, i.e. the HSE, is to use the resources available to it in the most beneficial, effective and efficient manner to improve, promote and protect the health and welfare of the public. Section 7(5) provides that in performing its functions, the Executive shall have regard to inter alia the need to secure the most beneficial, effective and efficient use of those resources.

## **CONSIDERATION OF THE APPLICANT'S CASE**

### **(i) Role of the HSE under Section 59, Health Act 1970**

54. One of the principal complaints made by the Applicant is to the effect that the HSE exceeded its statutory jurisdiction under section 59 of the Health Act 1970. This was described at the hearing before me as the *ultra vires* argument.

55. As pleaded in the statement of grounds, the argument centres on the respective roles of the HSE and the Minister under section 59. See paragraph E.4 of the statement of grounds as follows.

"4. Section 59(1E) of the *Health Act 1970* as inserted by Section 1 of the *Health (Amendment) Act 1970* [recte *Health (Amendment) Act 2010*] provides that the Respondent enter into agreements for the provision of services with registered pharmacist, company or other body corporate for the provision of community pharmacy services in accordance with conditions specified by the Minister for Health. Such a service provider is referred to as '*Community Pharmacy Contractor*'. There are [recte no] conditions specified by the Minister under the Act or any Regulations."

56. The argument is put thus in the Applicant's written legal submissions.

"27. Section 59(1E) of the 1970 Act evidently bestows the sole power to formulate such conditions upon the Minister. To imply a power on the Respondent's part to create novel conditions in the apparent absence of any communication with the Minister would be completely at odds with the wording and legislative intent of section 59(1E).

[...]

30. In respect of the third limb of the test [*Magee v. Murray* [2008] IEHC 371], the Applicant submits that the purported power on the Respondent's part to impose conditions for the granting of a CPC Agreement and the manner in which it has

done so is inconsistent with the statutory scheme. While they have since been revoked, the 1996 Regulations clearly suggest that the decision as to whether a CPC Agreement should be awarded should not be entirely dependent on the identity of the beneficial owner and superintendent pharmacist. As stated above, the statutory scheme does not provide any basis for the Respondent to arbitrarily impose such novel preconditions.”

57. As appears from the foregoing, the gist of the argument is that the fact that the legislation confers a role in prescribing conditions upon the Minister carries with it the inference that the HSE is precluded from setting conditions. It is then argued that since the Minister has not, in fact, prescribed any conditions, the HSE is not entitled to refuse to enter into an agreement with a pharmacy by reference to factors such as the identity of the beneficial owner or superintendent pharmacist.

58. This argument overlaps to some extent with the “irrelevant considerations” argument discussed under the next heading below. The *ultra vires* argument goes further, however, in that it suggests that the HSE has no right to rely on any criteria other than those, if any, specified by the Minister.

59. With respect, the *ultra vires* argument is flawed for a number of reasons. First, it appears to be based on a misunderstanding of the use of the term “conditions specified” in the definition of “community pharmacy contractor” under section 59(1E) of the Health Act 1970 (as amended in 2010). The term is referring to the standard form agreements of 1970 and 1996, and not to the now defunct 1996 Regulations. Secondly, the argument is based on a misconception of the legal status of an arrangement entered into by the HSE pursuant to section 59. In particular, the argument overlooks the careful analysis of section 59 carried out by the Supreme Court in *Collooney Pharmacy Ltd. v. Minister for Health* [2005] 1 I.R. 134. That judgment makes it clear that an agreement under section 59 retains its character as a contractual agreement, and does not represent a form of quasi-legislation. The HSE is not under a *duty* to enter into an agreement with any particular pharmacist. These themes are elaborated upon below.

60. The legislative—as opposed to the parliamentary—history of section 59 has been summarised earlier. In brief, the Minister for Health enjoyed a broad discretion under section 59(4) as originally enacted to make regulations. This power had been invoked to make the 1996 Regulations which, again as discussed above, addressed both substantive and procedural aspects of an application to enter into an arrangement under section 59.

61. The legislative background against which these proceedings are to be determined is very different. First, the 1996 Regulations were revoked in their entirety in 2002. Secondly, the Minister’s power to make regulations has been severely curtailed by the Health (Amendment) Act 2010, and, in effect, is now confined to setting the level of, and possible exemptions to, the prescription charge. There is no question of the Minister relying on his power under the amended section 59(4) to regulate the manner in which an arrangement can be entered into by the HSE for the purposes of section 59(1).

62. The Applicant has sought to seize on the use of the word “condition” under section 59(1E) to advance an argument that it is the Minister—and the Minister alone—who is empowered to decide what criteria govern an application to enter into an agreement under section 59(1).

63. The term “conditions specified” is used in a definition section for the purposes of identifying the class of pharmacist to whom a prescription charge is to be paid. It may be useful at this point to recall the statutory language used.

“‘community pharmacy contractor’ means a registered pharmacist, company or other body corporate that provides services to the Health Service Executive under an agreement made in accordance with conditions specified by the Minister in 1971 or 1996, as amended from time to time, for the provision of community pharmacy services to eligible persons under subsection (1)”

64. It is clear that the reference to “an agreement made in accordance with conditions specified by the Minister in 1970 or 1996” under section 59(1E) is intended to refer to the standard form agreement which, as averred to by Ms Hoey in her affidavit, has most recently been revised in 1996. It is not intended to refer to the detailed type of conditions which the Minister had previously been entitled to make under section 59(4) as originally enacted.

65. Put shortly, the reference under section 59(1E) is to the conditions in the CPC Agreement rather than to any conditions (more properly, criteria) governing the threshold decision as to whether to enter into an agreement with any particular individual pharmacist.

66. There is, however, a more fundamental flaw in the Applicant’s case. The logic of the Applicant’s case, when pursued to its conclusion, seems to be that—absent the prescription of any conditions by the Minister—the HSE has little to no discretion to refuse to enter into an agreement with a pharmacist. This argument comes close to suggesting that there is a *duty* upon the HSE to enter into an agreement with an individual pharmacist.

67. The legal status of the CPC Agreement has been considered in some detail by the Supreme Court in *Collooney Pharmacy Ltd. v. Minister for Health* [2005] 1 I.R. 134. The applicants in those proceedings had sought to argue that the agreement represented a form of quasi-legislation. This argument was rejected by the Supreme Court. The judgments emphasise the voluntary and contractual nature of the agreement.

68. (It should be noted that the judgments in *Collooney Pharmacy Ltd.* were decided prior to the enactment of the Health (Amendment) Act 2010, and the reference to regulations below is to regulations permitted under the original unamended version of section 59(4)).

69. Kearns J. (as he then was) put the matter as follows at page 144 of the Irish Reports.

“50 I would be of the view that great value and importance attach to the process of securing uniformity, so far as is possible, in terms and conditions applicable to the supply of drugs and medicines to eligible persons under s. 59 of the Act of 1970. It would be both impracticable and, indeed, undesirable, to have a process of individual negotiation or to have a situation where different pharmacies were subject to materially different terms and conditions in respect of the provision of the same services. In the circumstances the fact that the respondents were not in a position to negotiate with the applicants in relation to amending the terms of the contract gives rise to no valid complaint on the applicants’ part and, still less, does it provide any basis for impugning the contract or any of its provisions.

51 However, this still leaves the point whether such a contract is ‘permissible’ under s. 59 of the Act of 1970. The applicants sought to distinguish the case of *Association of General Practitioners Ltd. v. Minister for Health* [1995] 1 I.R. 382 on the basis that the statutory provision at issue there - namely, s. 26(1) of the Act of 1979 - expressly authorised

the health boards to enter into contracts of that kind. However, s. 26(1), like s. 59, refers to 'arrangements' being made by health boards. Secondly, and perhaps more importantly, s. 26(1) is equally applicable to the provision of pharmacy services to eligible persons as it is to the provision of general practitioner services. It seems to the court, therefore, that any supposed distinction is non-existent.

52 I am of the view that s. 59 creates both a power and a duty to make 'arrangements' whereby the objective of s. 59 is effectively achieved. Once it can be said that any contract made does not go beyond what is reasonably necessary in this regard, or contain conditions which could properly be said to be outside the scope of s. 59, it follows that the respondents are entitled to include such terms as may be required to secure the provision of a high quality and reliable service to eligible persons. The fact that certain provisions of the contract, such as clause 6(2), address issues which could also have been addressed in regulations made for the purposes of s. 59 is not determinative of the issue. The contract is not expressed to be dependent on the existence of regulations. Nor should s. 59 be interpreted in such a way as to circumscribe the respondents in making such arrangements as appear appropriate in order to achieve the statutory objectives of s. 59."

70. I respectfully adopt this as a correct statement of the law in respect of the status of the CPC Agreement. The duty imposed on the HSE pursuant to section 59(1) is one which is directed to the recipients of the service, namely the eligible persons. It is a duty to ensure the supply of drugs, medicines, and medical and surgical appliances. In order to discharge this duty, the HSE has a corresponding power to enter into contractual arrangements with individual pharmacists. It is a *non sequitur* for the Applicant to contend, as it appears to do, that this gives rise to some sort of *duty* in favour of the individual pharmacists. No such duty exists. The arrangement between the Minister for Health and an individual pharmacist is primarily a matter of contract.

71. Of course, the fact that the contract arises in the context of the discharge by the HSE of a statutory duty, i.e. to supply drugs, medicines, and medical and surgical appliances; and the fact that the refusal to enter into an agreement with a particular pharmacist may have financial implications for the pharmacist, does mean that there is a public law element to these contracts. It may well be, therefore, that the HSE is not entirely at large in this regard, and that its actions are, in principle, amenable to judicial review. To adapt the extreme example posited in *Associated Property Picture House Ltd. v. Wednesbury Corporation* [1948] 1 K.B. 223, if the HSE were to decide to refuse to ever enter into an agreement with any red-headed pharmacists, such unreasonable behaviour might well be challenged by way of judicial review. This would not be because there is a *duty* to enter into agreement, but rather flows from the more general principle that statutory powers must be exercised in a reasonable manner.

72. To extrapolate from the language used by Kearns J. in *Collooney Pharmacy Ltd.* in respect of the terms of the CPC Agreement, the HSE is entitled under section 59(1) to apply threshold criteria which are reasonably required to secure the provision of a high quality and reliable service to eligible persons.

73. Finally and for the avoidance of any doubt, it should be noted that there was no argument before me as to whether a decision to refuse to enter into an agreement is amenable to judicial review. Rather, the HSE was prepared to defend the case on its merits. Nothing in this judgment should, therefore, be taken as deciding this issue, or from precluding the HSE from raising such an objection in a future case.

#### **(ii) Irrelevant considerations**

74. The Applicant seeks to argue that the HSE erred in law in taking into account irrelevant considerations in deciding to refuse to enter into a CPC Agreement with it. In particular, it is alleged that the HSE should not have had regard to the common beneficial ownership as between the Applicant and the two other companies which were under inquiry pursuant to clause 15 of the CPC Agreements governing their operation.

75. The point is pleaded as follows in the statement of grounds at E.17.

17. "It has been the Applicant's consistent position that the Respondent's investigations into the Blanchardstown and North Circular Road pharmacies should not influence its decision on the Applicant's application for a Community Pharmacy Contractor Agreement."

76. With respect, I cannot accept the Applicant's argument in this regard. The HSE has, correctly in my opinion, submitted that section 59 must be read in the light of the overarching obligation on the HSE pursuant to section 7 of the Health Act 2004 to seek to ensure the most effective use of its resources. This is also consistent with the language used by Kearns J in his judgment in *Collooney Pharmacy Ltd* (above). The HSE must be entitled to have regard to the fact that other pharmacies with the same beneficial ownership are under inquiry pursuant to clause 15 of their CPC Agreements. Without in any way wishing to pre-empt the outcome of those inquiries, it is sufficient to note that the issues raised, if proved to be correct, are serious matters, and could lawfully ground a decision to refuse to enter into a CPC Agreement. For example, if it were to be established that a pharmacy were claiming on the double for prescriptions then this is something which, self-evidently, adversely affects the beneficial, effective and efficient use of the HSE's resources.

77. It will be recalled from the chronology as set out above that the HSE's preferred approach was to defer making a decision on the Applicant's application until such time as the clause 15 inquiries were concluded. It was only after the Applicant insisted that a decision be made in advance, and went so far as to issue plenary proceedings in this regard, that the HSE proceeded to make a decision on the application. Further, the impugned decision expressly states that the HSE remain willing and open to consider any future application that may be made by the Applicant following the conclusion of the clause 15 procedure and subject to the outcome of the clause 15 procedure. The approach of the HSE in first, seeking to defer a decision, and secondly, then agreeing to make a decision at the insistence of the Applicant but leaving open the possibility of a subsequent application, was lawful.

78. I also note that both the standard form application form and the standard CPC Agreement make express reference to beneficial ownership. In fact, clause 22 of the agreement indicates that the HSE has an automatic right to terminate an agreement in the event of a change in beneficial ownership.

22. (1) This agreement is personal to the holder thereof and relates only to the premises specified in the agreement and the professional practices, including the dispensing and compounding of medical prescriptions conducted therein. It is non-transferable.

(2) Where the holder of an agreement is a body corporate and a change in the ownership or in the beneficial ownership of the said body corporate takes place, the agreement shall automatically terminate and a new agreement shall be required by the said body corporate.



(3) Without prejudice to the foregoing, the pharmacy contractor shall notify the chief executive officer immediately in writing of any change in the ownership or in the beneficial ownership of the community pharmacy in respect of which the agreement relates.

[...]"

(See also judgment of the High Court (Ó Caoimh J.) in *Collooney Pharmacy Ltd.* where this issue is discussed).

79. Whereas the nature and extent of relevant considerations under the statutory provision cannot, of course, be expanded upon by reference to the documentation prepared, it is nevertheless relevant to the Applicant's inchoate fair procedures/transparency argument that it was aware at all times that beneficial ownership was something which the HSE took into account.

80. Counsel for the Applicant, Mark Harty, SC sought to make an argument, by reference to the now revoked 1996 Regulations, that the sort of thing which should be considered on an application to enter a CPC Agreement was whether there was a public need for a pharmacy in the particular location. The implication here being that matters which had not been identified in the 1996 Regulations were not relevant considerations.

81. With respect, reference to the 1996 Regulations does not advance the case at all. First, the regulations were revoked in 2002. Secondly, and perhaps more importantly, the statutory basis on which the 1996 Regulations were made has itself been revoked. As discussed earlier, the broad power under the original section 59(4) has been repealed, and the Minister's regulation-making function is now confined to the prescription charge.

### **(iii) Superintendent pharmacist**

82. Counsel on behalf of the Applicant, Mr Harty, SC, attached particular significance to the fact that—whereas the standard application form seeks details in relation to proposed *supervising* pharmacists—it does not require any information in relation to a *superintendent* pharmacist. The omission of any express reference to a superintendent pharmacist is, or so it is argued, significant, and indicates that the identity of the superintendent pharmacist is not a relevant consideration for the purposes of an application to enter into an agreement.

83. Ms Eileen Barrington, SC, on behalf of the HSE, explained that the term "superintendent pharmacist" is a statutory one, and was first introduced under the Pharmacy Act 2007. It seems that the standard form agreement, which it will be recalled was last substantially negotiated in 1996, has not yet been revised to take account of this.

84. I have real reservations as to whether this issue in respect of the superintendent pharmacist is one which properly arises on the pleadings. Order 84, rule 20(3) (as amended in 2011) places an onus on applicants to plead their case with some particularity.

"(3) It shall not be sufficient for an applicant to give as any of his grounds for the purposes of paragraphs (ii) or (iii) of sub-rule (2)(a) an assertion in general terms of the ground concerned, but the applicant should state precisely each such ground, giving particulars where appropriate, and identify in respect of each ground the facts or matters relied upon as supporting that ground."

85. There is no reference in the statement of grounds to the superintendent pharmacist issue. Notwithstanding these reservations, I am prepared to deal with the matter on a *de bene esse* basis.

86. The distinction between a supervising and a superintendent pharmacist is evident from the following definitions provided under the Retail Pharmacy Business Regulations 2008.

"superintendent pharmacist" means a registered pharmacist acting in the capacity specified in section 27(b), 28(a) or 29(b) of the Act and which may be in respect of a single retail pharmacy business or in respect of a number of such businesses;

"supervising pharmacist" means a registered pharmacist acting in the capacity specified in section 27(c), 28(b) or 29(c) of the Act and who is in whole-time charge of carrying on the retail pharmacy business at the premises of the said business;"

87. The role of the superintendent pharmacist is discussed in some detail at paragraph 92 of the final decision (set out in the appendix to this judgment).

88. Given the importance of a superintendent pharmacist in the statutory regime, I am of the view that it was lawful for the HSE to take into account the fact that the proposed superintendent pharmacist is also the superintendent pharmacist of two related pharmacies which are subject to the clause 15 procedure. Again, this is in no way to pre-empt the outcome of the investigations, or to purport to express any view on the correctness of the allegations made. Nevertheless, it must be the case that the HSE is entitled to have regard to the fact that there is an ongoing investigation, and either (i) to defer making a decision, or (ii) to refuse the application (subject always to a right to reapply in the event that the inquiry is resolved in favour of the superintendent pharmacists). Put shortly, the existence of unresolved allegations against a superintendent pharmacist is clearly a relevant consideration.

89. I do not think that any weight can be attached to the fact that there is no express reference to the role of a superintendent pharmacist in either the application form or the agreement. The determination of what factors the HSE is entitled to take into account under section 59 is one of statutory interpretation. The discretion which the HSE enjoys under this section can neither be expanded nor reduced by the content of a non-statutory document which it has drawn up itself.

### **(iv) Fair procedures / Transparency**

90. In theory, the omission from the standard agreement or from the standard form application of an express reference to the role of a superintendent pharmacist might be relevant to a *fair procedures* argument. At the hearing before me, counsel on behalf of the Applicant has sought to agitate this issue. It was suggested that there is an (undisclosed) policy on the part of the HSE to have regard to the role of a superintendent pharmacist, and that this policy should have been made public.

91. Reference is made in this regard to the well-known judgment of the House of Lords in *Lumba v. Secretary of State for the Home Department* [2011] UKSC 12. The Applicant relied *inter alia* on paragraph [35] of the judgment as follows.

"The precise extent of how much detail of a policy is required to be disclosed was the subject of some debate before us.

It is not practicable to attempt an exhaustive definition. It is common ground that there is no obligation to publish drafts when a policy is evolving and that there might be compelling reasons not to publish some policies, for example, where national security issues are in play. Nor is it necessary to publish details which are irrelevant to the substance of decisions made pursuant to the policy. *What must, however, be published is that which a person who is affected by the operation of the policy needs to know in order to make informed and meaningful representations to the decision-maker before a decision is made.*"

\*My emphasis.

92. With respect, I think the Applicant's argument is misplaced. The only potential significance of the omission of express reference to the superintendent pharmacist in the standard application form is that, in theory, a party *might* be taken by surprise by this issue. It is difficult, however, to imagine how an experienced pharmacist could be unaware of the importance of the superintendent pharmacist in the regulatory regime for pharmacies. At all events, on the facts of this case, the Applicant was put on notice as to the HSE's concerns in respect of the common superintendent pharmacist at an early stage in the process. The Applicant was afforded an opportunity to comment on same. In all the circumstances, the mischief which the judgment in *Lumba* (above) is intended to address simply does not arise. For the same, the approach of the HSE does not offend against the principle identified in *A.M.M. v. (Somalia) v. Minister for Justice and Equality* [2013] IEHC 68.

93. I should also add that, in any event, this issue in relation to fair procedures has not been properly pleaded in the statement of grounds. Accordingly, even if I were to have found in favour of the Applicant on this issue—which I do not for the reasons set out above—it is not a ground upon which judicial review could have been granted in accordance with the order granting leave.

94. There was also an argument raised to the effect that even if the HSE was entitled to take into account its concerns in relation to the superintendent pharmacist, it was not entitled to rely on this factor to refuse the application outright. Rather, or so it was argued, the HSE should have amended the terms of the contract so as to provide that a different person was to act as the superintendent pharmacist. There is no such obligation on the HSE. The position of the superintendent pharmacist is a relevant consideration in the context of a decision to enter into a CPC Agreement. The HSE was, accordingly, entitled to take the same into account, and to rely on it as a factor to refuse to enter into the agreement. The HSE was not obliged to rewrite the terms of its standard contract so as to attempt to facilitate the Applicant in this regard. The desirability of a standard form contract has been confirmed by the Supreme Court in its decision in *Collooney Pharmacy Ltd*. The same sentiment applies by analogy here. Moreover, and in any event, this is not an issue which was properly pleaded in the statement of grounds.

## CONCLUSION

95. Section 59 of the Health Act 1970 (as amended) does not impose a *duty* on the HSE to enter into a contractual arrangement with any particular individual pharmacist. Rather, the HSE enjoys a discretion to do so. In exercising this discretion, the HSE is entitled to have regard to *inter alia* the financial probity and professional qualifications of the party seeking to enter into a contract with it. This is consistent with the overarching obligation of the HSE under section 7 of the Health Act 2004.

96. In circumstances where the party seeking to enter into a contract is a company, the HSE is entitled to have regard to the financial probity of the beneficial owners of that company. The character of a company can only be assessed by reference to that of its controlling shareholders.

97. As a result of the amendments made to section 59 of the Health Act 1970 under the Health (Amendment) Act 2010, the Minister's power to make regulations is confined to issues related to the prescription charge. The Applicant's argument that the absence of regulations addressing the CPC Agreement in some way affects the HSE's discretion to enter into contractual arrangements is thus misconceived.

98. On the facts of the present case, the HSE was entitled to have regard to the existence of the ongoing clause 15 procedure in respect of the two related pharmacies. It was also entitled to have regard to the fact that all three pharmacies would have a common superintendent pharmacist.

99. There was no breach of fair procedures or transparency: the Applicant was put on notice as to the HSE's concerns in respect of the common superintendent pharmacist at an early stage in the process.

100. Accordingly, the application for judicial review is dismissed in its entirety.

## Appendix

### Extracts from Decision of 16 April 2018

#### "Discussion

84 As set out in the Preliminary Recommendation, the HSE would prefer to make a decision on the Application following the outcome of the Clause 15 Procedure. However, given the Applicants insistence that a decision is required at this juncture, I now make this decision.

85 At this juncture, I agree with the position adopted in the Preliminary Recommendation that the issues raised above in respect of the Blanchardstown and North Circular Road are substantial issues, which require to be addressed before the Application can be approved

86. The issues arising are being considered in the ongoing Clause 15 Procedure by the HSE. They have also reached the point where the Director General of the HSE has reason to believe that the conditions set out in Clause 15 are satisfied.

87. The HSE has concerns regarding Mr McPolin and regarding the administration of the responsibilities of pharmacies under his management under existing CPC Agreements with the HSE. The HSE has concerns that the Applicant is not managed effectively.

88. These concerns have been evidenced in the investigations undertaken to date and have been communicated to Mr McPolin in correspondence from the Director General in the Clause 15 Procedure.

89. The Applicant has the same beneficial owner as Blanchardstown and North Circular Road.

90. The Applicant is trading as '*Smith's pharmacy*' and is part of the same pharmacy group – namely, that Smith Group – about which serious concerns have arisen as a result of the Inspections.

91. The Applicant also has the same superintendent pharmacist as Blanchardstown and North Circular Road, namely Mr McPolin.

92. As is set out in the Preliminary Recommendation, the superintendent pharmacist of a pharmacy perform is an extremely significant role:

- (1) The concept of a 'superintendent pharmacist derives from the pharmacy act and the superintendent pharmacist is held to accountable for pharmaceutical practice throughout the pharmacy under their scope of responsibility.
- (2) A superintendent pharmacist sets out the framework processes and protocols across all pharmacies within a pharmacy group.
- (3) Importantly, a superintendent pharmacist is the person who signs off on the Standard Operating Procedures across the pharmacy group.
- (4) As has already been outlined above, the Standard Operating Procedures in respect of Owings appear to not be what the HSE expects.
- (5) The superintendent pharmacist can have an active role day-to-day in the pharmacy and can have complete access to every pharmacy in the Group.
- (6) The superintendent pharmacist has managerial responsibility for the entire pharmacy group.
- (7) The superintendent pharmacist has an authoritative role as to what should happen in a Pharmacy Group.
- (8) The superintendent pharmacist is central to the management and control of the Pharmacy Group.

93. In the circumstances arising here, the Clause 15 Procedure clearly raises concerns in respect of Mr McPolin, who is the superintendent pharmacist of Blanchardstown and North Circular Rd and the Applicant.

94. I do not therefore accept that the Applicant cannot be affected by the Clause 15 Procedure merely because it is a separate legal entity from the pharmacies that are involved in the Clause 15 Procedure.

95. Rather, I am of the view that that the role of Mr McPolin in the Applicant renders the Clause 15 Procedure in respect of Blancherstown and North Circular Rd relevant to consideration of the Application.

96. I fully appreciate that, as I have noted above, the concerns raised in the Clause 15 Procedure are disputed by the Applicant. I reiterate that no concluded view is reached in this decision in respect of the concerns arising and that the HSE is not resolving these concerns at this stage.

97. However, as I have already outlined above, when performing its functions, the HSE is obliged pursuant to Section 7(1) and Section 7(5) of the 2004 Act to have regard to the resources, wherever originating, that are available to it for the purpose of performing its functions and to the need to secure the most beneficial, effective and efficient use of those resources.

98. In my view, it would be incompatible with the HSE's obligation to secure the most beneficial, effective, and efficient use of those resources to enter into a new CPC agreement with the Applicant prior to the conclusion of the ongoing Clause 15 Procedure.

[...]

### **Decision**

133. Overall, while I have carefully considered the Applicant's submissions, I do not find them to be such as to persuade me to depart from the Preliminary Recommendation.

134. In all the circumstances, therefore, it is my view that the Preliminary Recommendation should be adopted and the HSE should refuse to approve the Application and to enter into a CPC Agreement with the Applicant until such time as the concerns arising from the Clause 15 Procedure have been resolved.

135. However, I emphasise that I also endorse the position proposed in the Preliminary Recommendation that the HSE remain willing and open to consider any future application that may be made by the Applicant following the conclusion of the clause 15 procedure and subject to the outcome of the clause 15 procedure."