

23 February 2010

REF: SHA/15557

APPEAL AGAINST SUFFOLK PCT DECISION TO REFUSE THE CONSTABLE COUNTRY MEDICAL PRACTICE APPLICATION TO PROVIDE PHARMACEUTICAL SERVICES UNDER REGULATION 61(1) OF THE NHS (PHARMACEUTICAL SERVICES) REGULATIONS 2005 (AS AMENDED) TO ELIGIBLE PATIENTS IN THE VILLAGES OF HOLTON ST MARY, BRANTHAM, STRATFORD ST MARY, HOLBROOK, RAYDON AND EAST BERGHOLT

1 The Application

By application dated 15 June 2009, The Constable Country Medical Practice ("the Applicant") applied to Suffolk Primary Care Trust ("the PCT") for outline consent in accordance with Regulation 61(1). The applicant intended to dispense to eligible patients from 36 The Street, Capel St Mary, to eligible patients in the villages of Holton St Mary, Brantham, Stratford St Mary, Holbrook, Raydon and East Bergholt. In support of the application it was stated:

- 1.1 It is our intention to provide these services from our dispensary located within the surgery premises at 36 The Street, Capel St Mary, IP9 2EE. There is currently no community pharmacy within 1.6km of this site.
- 1.2 We believe that the provision of dispensing to these patients will provide a genuine enhancement to the service by increasing patient choice and improving access by means of a delivery service, which will be of real benefit to patients living in rural villages.

2 The PCT Decisions

The PCT's considered and decided to refuse the application. The decision letter dated 19 November 2009 states:

- 2.1 NHS Suffolk has delegated decisions in respect of pharmacy and dispensing applications to the Pharmacy and Dispensing Committee.
- 2.2 At a meeting on 12 November 2009 the Pharmacy and Dispensing Committee gave careful consideration to the written representations in respect of an application by the Constable Country Medical Practice for outline consent to dispense.
- 2.3 The Committee noted that the National Health Service (Pharmaceutical Services) Regulations 2005 paragraph 61(1)(a) and (b) states:

'A doctor wishing to be granted the right to provide pharmaceutical services ... to patients residing in the area, may apply to the PCT in writing for:

- (a) *consent specifying the area in relation to which he wishes the outline consent to be granted: and*
- (b) *approval of any premises from which he wishes to dispense*
 - (i) *the premises for which he wishes to be granted premises approval and whether those premises are listed premises in relation to a different area ...'*

- 2.3.1 The Committee determined that the practice had complied with this regulation and had specified both the area in respect of the outline consent to dispense and the premises from which it wishes to dispense. It was noted

that the premises specified in the application were The Street, Capel St Mary which under regulation 67 were listed as premises in relation to the area which the practice have dispensing rights immediately prior to 1 April 2005.

2.3.2 However, the National Health Service (Pharmaceutical Services) Regulations 2005 paragraph 18(2)(c) states:

*'...the Primary Care Trust –
(c) shall refuse an application under 61 in relation to any premises from which the doctor wishes to be authorised to dispense and which are within 1.6 kilometres of any pharmacy'*

2.3.3 The premises from which the Constable Country Medical Practice wishes to dispense from are in the same location as Villapharm Ltd's pharmacy and therefore fell within the definition of regulation 18(2)(c).

Decision

2.3.4 The Committee, on behalf of NHS Suffolk, refused the application.

3 The Appeal

In a letter to the Family Health Services Appeal Unit of the NHS Litigation Authority dated 11 December 2009, Mr Morley on behalf of Constable Country Medical Practice, appealed against the PCTs decision. The letter stated:

3.1 I have been instructed by The Constable Country Medical Practice to represent the practice and to appeal against the decision of Suffolk PCT dated 12 November 2009 to refuse our application because of Pharmaceutical Services Regulations (2005) paragraph 18 (2)(c).

3.2 We wish to make the following comments:

3.3 In our opinion the PCT have misdirected itself as Regulation 18(2)(c) is not applicable and therefore the PCT had no option but to grant this application to dispense for patients in additional locations in controlled areas who reside more than 1.6km from a pharmacy.

3.4 We adduce that the committee noted:

"that the National Health Service (Pharmaceutical Services) Regulations 2005 paragraph 61(1)(a) and (b) states:

'A doctor wishing to be granted the right to provide pharmaceutical services ... to patients residing in the area, may apply to the PCT in writing for:

- (d) consent specifying the area in relation to which he wishes the outline consent to be granted: and*
- (e) approval of any premises from which he wishes to dispense*
 - (ii) the premises for which he wishes to be granted premises approval and whether those premises are listed premises in relation to a different area ...'*

The Committee determined that the practice had complied with this regulation and had specified both the area in respect of the outline consent to dispense and the premises from which it wishes to dispense. It was noted that the premises specified in the application were The Street, Capel St Mary which under regulation 67 were listed premises in relation to the area within which the practice have dispensing rights immediately prior to 1 April 2005."

- 3.5 Since at the date of our application, 1st June 2009 [sic], there was no pharmacy within 1.6km of the site which enjoyed previous approval, therefore regulation 18(2)(c) did not apply. The current pharmacy in Capel St Mary opened on 1st September 2009.
- 3.6 We would further adduce that Pharmaceutical Services Regulations 18(1) applies in that the PCT has not made a determination under regulation 35.
- 3.7 There is no mention of regulation 18(1) or regulation 35 in the PCT determination letter and therefore any determination under 18(2)(c) is ultra vires.
- 3.8 We would therefore respectfully ask you to grant their appeal and grant their application for additional online consent for the areas specified.

4 **Summary of Representations**

This is a summary of representations received on the appeal. A summary of those representations made to the PCTs are only included in so far as they are relevant and add to those received on the appeal.

4.1 PRIMARY CARE SERVICES ON BEHALF OF THE PCT

- 4.1.1 Constable Country Medical Practice had dispensing consent prior to 1st April 2005 for a number of areas covered by the practice. Under regulation 67 their surgery at The Street, Capel St Mary was registered as listed premises in respect of those areas.
- 4.1.2 The application for outline consent made on 17th June 2009 specified additional areas within which the practice wished to dispense and the surgery at The Street, Capel St Mary was named as the premises from which they wished to dispense to those areas. To that extent the PCT was satisfied that the application was made in accordance with regulation 61.
- 4.1.3 Regulation 61(2) states that, amongst others, regulations 18 and 62 apply to the determination of the application. It is clear therefore that paragraph (2)(c) of regulation 18 does apply and it is the Committee's contention that it is the situation pertaining at the time of determination that is material to its decision rather than the situation at the time the application was made, in line with established principles throughout the regulations (unless there are specific exceptions, where there are not in these circumstances).
- 4.1.4 At the date of determination on 15th October 2009 a pharmacy was in operation by Villapharm Ltd at 36 The Street, Capel St Mary which is within 1.6 kilometres of the surgery at The Street, Capel St Mary. This pharmacy had been granted approval on 22nd January 2009 and commenced service provision on 31st August 2009.
- 4.1.5 Under regulation 18(2)(c) the presence of this pharmacy prevented approval from being granted for the premises at The Street, Capel St Mary in respect of the areas specified in the application, notwithstanding that those premises were listed in respect of the areas for which the practice had dispensing consent at 1st April 2005. As it was not possible to grant premises approval the need to consider "prejudice" under regulation 18(2)(a) fell away as the regulations do not appear to allow dispensing consent to be granted for specific areas in isolation from consent for the premises from which the practice wishes to dispense to those areas.
- 4.1.6 Whilst we agree that at the time the application was made there was no a pharmacy in operation within 1.6 kilometres of the surgery premises, there was an "outstanding application" within the meaning of regulation 62(5) (i.e. in respect of the pharmacy at 36 The Street, Capel St Mary). As a result of

this, if the application for outline consent had been determined before that pharmacy commenced service provision and approval granted, the PCT would have had to determine, under regulation 62(1) when the consent was to take effect. However, any such consent would have lapsed, in accordance with regulation 62(10) when the pharmacy commenced service provision. The final outcome of the application would, therefore, have been the same.

4.2 DEDHAM PHARMACY

4.2.1 In our opinion the PCT's decision is correctly based upon section 18(2) since the pharmacy at Capel St Mary was open at the time of the application's determination.

4.2.2 Furthermore, Capel St Mary was determined not to be a reserved location since the committee noted that the number of individuals on all the patient list for the area, which is 1.6km from the proposed relevant location is approximately 2960 (210 patients more than the 2,750 threshold). Therefore regulation 35 is not valid in this case.

4.2.3 Since the position remains unchanged we would respectfully request you to reach the same decision as the PCT and reject this application.

4.3 SUFFOLK AND GREAT YARMOUTH LPC

4.3.1 Suffolk and Great Yarmouth LPC believe that NHS Suffolk made the correct decision not to grant outline consent and appropriately followed the regulations. The PCT did consider if the area was a reserved location and determined that it was not.

4.3.2 The Capel St Mary pharmacy was open at the time the application was determined. We believe that this appeal should be rejected.

5 Observations on Representations

5.1 MR MORLEY on behalf of COUNTRY CONSTABLE MEDICAL PRACTICE

5.1.1 We would further adduce that nothing in the responses leads us to believe that our letter of 11 December 2009 does not fully support our appeal in general, and in particular we would state that none of the responses, including the response from David Thorne of NHS Primary Care Services, shows any evidence or indeed mentions why regulation 18(1) should not apply. It is quite clear the PCT have not made any determination under regulation 35 (in any case, any determination made under regulation 35 would be appealable in the normal way).

5.1.2 We would therefore respectfully ask you to grant my clients appeal and grant the application with additional outline consent for the areas specified.

6 Consideration

6.1 The Pharmacy Appeals Committee appointed by the Family Health Services Appeal Unit of the NHS Litigation Authority, ("the Committee") had before it the documents considered by the PCT, a map of the area showing the doctors' surgeries in the area, together with the areas from which they wish to provide dispensing services, the pharmacies in the area, dispensing figures from the pharmacies, list sizes and dispensing list sizes together with the number of prescriptions issued by the practice and the responses to the Authority's own statutory consultations. On the basis of this information, the Committee considered it was not necessary to hold an oral hearing.

- 6.2 The Committee noted the application had been made in accordance with Regulation 61(1) (Outline consent and premises approval) of the NHS (Pharmaceutical Services) Regulations 2005 (as amended).
- 6.3 Regulation 61(1)(a) requires that the applicant doctors, specify in writing, the area in relation to which they wish outline consent to be granted.
- 6.4 The Committee noted approval of “any premises from which he wishes to dispense” (Reg 61(1)(b)) was sought in relation to the applicant’s branch surgery at 36 The Street, Capel St Mary. The premises are not listed in relation to a different area, nor had the application arisen because there has been a practice amalgamation.
- 6.5 The Committee noted Regulation 61(2) states an application under paragraph (1) shall be determined in accordance with paragraph (3), and regulations 18, 20(2), 33 to 38 and 62.
- 6.6 The Committee noted the proposed ‘area’ and ‘premises’ referred to on appeal, are in a controlled locality.
- 6.7 The Committee noted the comments from the appellant with regard to Regulations 18(1) and 35. The Committee noted that the PCT, following the application for a pharmacy in the area, had considered if the area was a reserved location in accordance with regulation 35. The PCT had determined that the area was not a reserved location. The Committee noted that the instant application was for outline consent for dispensing services. The Committee noted that regulation 35 deals with pharmaceutical services in reserved locations. The Committee were of the view that under the regulations the definition of dispensing services is different to that of pharmaceutical services.
- 6.8 The Committee noted the comment in the appeal with regard to Regulation 35, Reserved Location. The Committee noted in the representations the comment that Capel St Mary is not a reserved location and noted that this had not been disputed by the appellant. The Committee had no reasons to believe that the population in Capel St Mary had dropped to below the threshold for a reserved location and concluded that 36 The Street, Capel St Mary, being the location of the premises from which the applicant wishes to provide pharmaceutical services, is not in a reserved location.
- 6.9 The Committee noted regulations 18(2)(b) & (c) and noted that the PCT had refused the application for outline consent as the applicant’s named premises are within 1.6km of a pharmacy, as per regulation 18(2)(c).
- 6.10 The Committee mindful of regulation 34(1)(a) and 34(1)(d), had no reason to believe that any application had been finally refused within a period of 5 years immediately preceding the making of the current application.
- 6.11 The Committee noted that the appeal centred on the question of Regulation 18(2)(c) in respect of a pharmacy being within 1.6km of the premises for which outline consent was applied for. The Committee noted the argument from the applicant that there was no pharmacy open at the time of the application for outline consent in June 2009. The Committee noted however that the regulations are silent on whether it is the situation at the time of the application or at the time of the determination. The Committee noted however that in certain parts of the regulations it is specifically stated that it is “at the time of the application” as per Regulation 35, reserved location. The Committee were of the view that in the absence of such a specific statement, it is the situation at the time of the determination of the application. The Committee noted that the existing pharmacy was granted approval in January 2009 and commenced service provision on 31 August 2009. The Committee was therefore satisfied that there was a pharmacy within 1.6km of the premises for which outline consent was applied for.

6.12 The Committee noted regulation 38(14) states :

On an appeal under this regulation, the Secretary of State—

- (a) may allow the appeal;
- (b) may, in a case where the Primary Care Trust, on determining the application, considered the question whether to impose conditions to postpone the making or termination of arrangements under regulation 60 (or equivalent provision under the GMS Regulations or PMS Regulations) for the provision by a doctor or GMS contractor or PMS contractor of pharmaceutical services or dispensing services to patients on the relevant patient list, himself impose conditions to postpone for such period as he thinks fit, the making or termination of such arrangements;
- (c) shall, in a case where that question was not considered by the Primary Care Trust when it determined the application, remit the question to the Primary Care Trust for determination;
- (d) shall, where he allows an appeal against a refusal of the Primary Care Trust as mentioned in paragraph (2)(b), remit the application to the Primary Care Trust and direct that regulation 34(1) shall not apply; or
- (e) may dismiss the appeal.

7 Decision

The Committee determined that as there is a pharmacy within 1.6km of the premises the PCT was correct to refuse the application for outline consent from 36 The Street, Capel St Mary in accordance with Regulation 18(2)(c). Accordingly, the appeal is dismissed.

Jill Jackson
Appeal Officer

A copy of this decision is being sent to:

Mr N Morley, Surelines Limited on behalf of The Constable Country Medical Practice
Dedham Pharmacy
Boots UK Ltd
Suffolk and Great Yarmouth LPC
North & South Essex LMC
Anglia Support Partnership on behalf of Suffolk PCT