

21 January 2010

REF: SHA/15483

**APPEAL AGAINST NORFOLK PCT DECISION GRANT  
AN APPLICATION BY WEST NORFOLK HEALTH LTD  
FOR INCLUSION IN THE PHARMACEUTICAL LIST  
WITHIN 300 METRES OF TURBINE WAY, ECOTECH  
BUSINESS & INNOVATION PARK, SWAFFHAM,  
UNDER REGULATION 13(1)(d)**

**1 The Application**

By application dated 12 February 2009, West Norfolk Health Ltd (“the Applicant”) applied to Norfolk Primary Care Trust (“the PCT”) for inclusion in the pharmaceutical list within 300 metres of Turbine Way, Ecotech Business & Innovation Park, Swaffham under Regulation 13(1)(d). In support of the application it was stated:

- 1.1 In line with the NHS Pharmaceutical Regulations 2005 Part 2 Essential Services, the applicant will supply drugs to all patients requesting them. Prescriptions will be sent to the applicant via mail or collected from patients and in the future the applicant hopes to make full use of the Electronic Prescription Service. Prescriptions will be delivered to a place of convenience as requested by patients, within 48 hours of the applicant receiving the prescription.
- 1.2 The Pharmacist’s telephone number and an information leaflet will be attached to the prescription packages, thus allowing patients direct access to a pharmacist for information and advice in accordance with the Essential Services specification. Any unwanted drugs will be collected from patients at the time of delivery. There will be a secure audit trail for all prescriptions dispensed and delivered and a record of unwanted drugs will be kept.
- 1.3 The applicant will ensure that the pharmacy software is EPS compliant.
- 1.4 The pharmacist will be available on the telephone to provide advice regarding self-care and assistance with signposting.
- 1.5 All necessary Standard Operating Procedures will be in place and the pharmacy will comply fully with all Clinical Governance requirements including Significant Event monitoring, Complaints procedures. The Pharmacist will also maintain close contact with the prescribers and act as a resource for medicines management for the prescribers.

**2 The PCT Decision**

The PCT considered and decided to grant the application. The decision letter dated 2 October 2009 states:

Background

- 2.1 The application was submitted under regulation 13(1)(d) in relation to “premises at which essential services are to be provided but the means of providing those services are such that all persons receiving them do so otherwise than at those premises”. Under regulation 13(1) the application was exempt from consideration under regulation 12 (the necessary or expedient test) unless it related to premises “in a neighbourhood in which local pharmaceutical services are or are to be provided.

- 2.2 However, the location of the proposed premises is in a controlled locality and consequently the application was subject to determination in accordance with regulation 35(1) (the question of whether the area is a reserved location) and regulation and 18ZA (“the prejudice test”).
- 2.3 The application had been notified to interested parties in accordance with regulation 33 and representations arising from this were circulated to the applicant and other parties prior to determining the application. The Committee was satisfied that it could determine the application on the basis of the written evidence, and that an oral hearing was not required.

#### Consideration

##### General

- 2.4 The Committee noted that in practice, applications under regulation 13(1)(d) related to an internet or mail order pharmacy. Although such pharmacies could not provide “face to face” services this related to essential services only and there was no restriction within the regulations on the provision of directed services on a face to face basis.
- 2.5 The Committee was satisfied that following representations arising from the notification exercise the applicants had provided, in a letter dated 9 June 2009, an adequate description of how they would provide essential services.

##### Exemption criteria

- 2.6 Under regulation 13(1) exemption from the “necessary or expedient” test could not apply if the proposed premises were in a neighbourhood in which local pharmaceutical services are or are to be provided. In this regard the Committee noted that there is an Essential Small Pharmacies LPS (ESPSLPS) scheme in operation at Burnham Market which is approximately 25 miles by road from Swaffham. This pharmacy did not submit any representations on the application.
- 2.7 The ESPSLPS contract does not specify the area within which it operates and neither is there any record of a neighbourhood being defined in relation to this pharmacy, having been established well before the concept of neighbourhoods was introduced in 1992. For similar reasons there is no record of any neighbourhoods having been defined in Swaffham and, because neighbourhoods have relevance only in regard to the “necessary or expedient” test they are not normally defined in relation to pharmacies exempt from that test.
- 2.8 However, the Committee was satisfied that in normal circumstances a neighbourhood for a Swaffham based pharmacy was unlikely to extend beyond the town boundary, reflecting previous NHS Litigation Authority appeal decisions and other case law which had dismissed the sustainability of widely drawn neighbourhoods. They noted that there was nothing in the application to suggest that services would be specifically targeted towards Burnham Market or the catchment area of that pharmacy and their overall conclusion was that this ESPSLPS pharmacy was too remote for the restriction in regulation 13(1) to apply.

##### Regulation 17

- 2.9 The Committee noted that regulation 17 directs PCTs to refuse an application for a distance selling pharmacy if the premises are on the same site or in the same building as a doctor’s surgery. The Plowright Surgery (Dr Sorensen Pound & partners) is at 1 Jack Boddy Way, within the Ecotech Business and Innovation Park. The applicants had confirmed that the pharmacy will not be in the Plowright Surgery or any other NHS premises.
- 2.10 In this regard the Committee was satisfied that the location of the proposed pharmacy, notwithstanding its proximity to the Plowright surgery, did not breach regulation 17. In reaching this view the Committee considered that it was not reasonable to define “the site” as anything other than the curtilage of a surgery premises as this would represent an unfair and unsustainable restriction particularly in the case of a large retail or industrial park.

### The prejudice test

- 2.11 The Committee then considered the application under the “prejudice test” in regulation 18ZA, having noted that the number of registered patients within 1.6 kilometres of the proposed premises was in excess of 4,300 so that reserved location status under regulation 35 did not apply. Notwithstanding this, the operation of regulation 60(1)(c) meant that in the event of this pharmacy opening, any dispensing patient within 1.6 kilometres could continue to receive dispensing services from their doctor.
- 2.12 Prejudice is not defined in the regulations but Department of Health guidance states that in general “prejudice” means that nothing must be done which would have the result of preventing people in any controlled locality from having access to those primary medical and pharmaceutical services at the level of service which is provided for by NHS contractual arrangements and that a mere reduction in the total level of service is not of itself “prejudice”. The burden of proof is on the party alleging prejudice.
- 2.13 The Committee was satisfied that there was no evidence of prejudice to the proper provision of medical services. However, representations from the Norfolk Local Pharmaceutical Committee and Repeat Prescription Order Line Ltd (RPOL) both contained prima facie allegations of prejudice. The LPC had raised general concerns but did not provide sufficient specific detail to allow these to be substantiated, RPOL had referred to a threat to their financial commitment to establishing new pharmacies. In this regard it was noted that RPOL has one operational pharmacy at South Lynn and outstanding approvals for Hardwick Retail Park, King’s Lynn (both approximately 16 miles from Swaffham), and Marham (approximately 10 miles).
- 2.14 These pharmacies all had their own identifiable populations and in the case of the South Lynn pharmacy and the proposed pharmacy at Hardwick Retail Park were in a major urban area with other pharmacies close by. The proposed pharmacy at Marham was in a reserved location and the Committee considered that this was likely to present a greater threat to its sustainability than the establishment of a distance selling pharmacy elsewhere. There was no indication in the application that the pharmacy would be specifically targeted towards those populations and indeed by its very nature an internet pharmacy was available to any patient irrespective of where they lived (as was any NHS pharmacy) and, as a result of inclusion in a PCT list, could be accessed by a direct link from the NHS Choices website. The Committee therefore concluded, that any detrimental effect on existing pharmacies was likely to be spread over a wide area rather than being concentrated in a specific location or locations and that accordingly they could not be satisfied that the proper provision of pharmaceutical services in any locality would be adversely affected to the extent of prejudice within the definition in paragraph 2.12.

### Decision

- 2.15 The Committee concludes that there is no prejudice to the proper provision of medical or pharmaceutical services under regulation 18ZA and has granted approval under regulation 13.
- 2.16 The approval is for an area comprising a 300 metre radius from the midpoint of Turbine Way, Ecotech Business and Innovation Park, Swaffham, excluding any premises or site occupied by a provider of primary medical services with a patient list.

## 3 The Appeal

In a letter to the Family Health Services Appeal Unit of the NHS Litigation Authority (“the Appeal Unit”) received on 31 October 2009, Repeat Prescription Order Line Ltd appealed against the PCT’s decision. The grounds of appeal are:

- 3.1 The appellant would like to appeal against the PCT (Norfolk NHS) decision to allow the granting of a pharmacy license for a distant selling or Internet pharmacy in Swaffham. The appellant’s concerns come in regard to the prejudice it will cause their pharmacies. Clearly as

new pharmacies, the pharmacy must reach a minimum prescription volume under current government payment structures. Clearly as one of the appellant's pharmacies barely reaches that level and the other does not reach it at the moment, then clearly any loss of prescription volume will result in the figures falling below the threshold to get practice and establishment payments which will then result in the pharmacy being prejudiced. It must be noted in the last few days the threshold figure has been increased and the appellant will need to monitor their prescription volume to see if they are still able to achieve this new target figure.

- 3.2 Therefore as a loss of even a very small amount of prescription volume will have such a drastic impact on the appellant's income and ability to just cover their cost they believe this application should not be granted. The loss would result in pharmaceutical service no longer being able to be provided from those locations and would impact residents in around the locations of the pharmacies being able to access essential, enhanced and advanced services. The appellant is happy to provide all necessary financial details to the Appeal authority, but must specify that this information is commercially sensitive and would be alarmed if it was to become available for general circulation and ask the appeal authority how they would wish for the appellant to make submission of this information to be dealt with confidentially.
- 3.3 The appellant therefore ask that the Authority accept their appeal against this decision and refuse this application due to the prejudice that it will cause.

The appellant provided a page of confidential information as follows:

Confidential (all in Red and without authority for any further circulation without written authority from Hails The Chemist (Repeat Prescription Order Line Ltd) in brief Summary

Cost of Pharmacist	£# per annum
Rent Cost	£#per annum
Rates and Services Cost	£#
Staff Costs	£#per annum

Therefore the loss of establishment and practice payment, would lose approximately £# a year to the income of the pharmacy which would result in a loss being made in the yearly accounts and whilst one of the pharmacies is new, a business plan which allows a period when the prescription volume is below the threshold, but then managing to go above, which would result in the pharmacy being able to cover the cost of being in place, if now the prescription volume is diminished, the threshold may never be reached and then the service would need to be withdrawn. The distance and impact of a distance selling pharmacies, is normally spread over the UK but the appellant's understanding is the owners of the limited company are all the GP practices is the old west Norfolk PCT area).

#### 4 **Summary of Representations**

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

##### **West Norfolk Health Ltd (Applicant)**

- 4.1 In response to the appeal, there does not seem to be prima facie evidence of prejudice that will occur should the applicant's company open a Distance Selling Pharmacy. The case that Mr Damani puts forward is not backed up by any evidence beyond him saying that he may not qualify for the threshold for Establishment payments. As the Committee knows, the threshold for these payments has been increased by 60 prescriptions a months at the lowest payment, from 1 October 2009. The starting level for payments is now 2240 prescriptions a month.

- 4.2 It is highly unlikely that the applicant's Distance Selling Pharmacy will impact on Mr Damani's business in any way as he has 3 pharmacies throughout East Anglia, none of which are within 20 miles of the proposed site. Indeed, he has greater prejudice to his business from the 7 pharmacies within a 5 mile radius of his King's Lynn pharmacy. Any financial information provided by Mr Damani needs to be read in the context that he opened his South Lynn pharmacy in April 2009 and within the first year of opening, all financial return and projections should be analysed with great caution. Although his business seems to be improving dramatically over the last couple of months, this will only feed through to his financial statements in the next 3 months.
- 4.3 The nature of Distance Selling Pharmacies is that they provide a new service to patients who wish to use the internet to obtain their prescriptions. Patients throughout the country may use the Distance Selling Pharmacy and the applicant's customers will not necessarily know where they are based, as they will not be able to visit the premises. The additional services Mr Damani currently provides from his new pharmacies should in no way be affected by our Distance Selling Pharmacy.
- 4.4 In light of the above information, the applicant urges the Committee to reject this Appeal as there will clearly be no prejudice to the services available to all patients in the King's Lynn area.

#### **Repeat Prescription Orderline Ltd (Appellant)**

- 4.5 The appellant has enclosed the confidential projected costs of running their pharmacies which they believe will be prejudiced by this pharmacy application. The appellant is happy for the release of the information to the applicant upon signing of a suitable confidentiality agreement.
- 4.6 The appellant hopes the appeal unit will take on board their concerns and impacts this application will cause, particularly as the two pharmacies are only recently established are both bordering areas whereby patients are dispensed to by dispensing doctors. The decision for allowing these pharmacies to open was based on being able to provide pharmaceutical services for patients of the surrounding villages, this included, essential, enhanced and advanced services. Thereby allowing such patients to be able to access a healthcare professional, without the need for an appointment and to be able to benefit from a pharmacist and the services of a pharmacist and the pharmacy team.
- 4.7 Face to face consultations with a pharmacist are irreplaceable with a delivery service systems for example a patient presenting for self-care of a skin condition would need to show the pharmacist the area of concern for the appropriate diagnosis and recommendation to the patient, another example would be the measuring and fitting of compression hosiery,
- 4.8 Therefore the loss of establishment and practice payment alone, would lose approximately £# a year to the NHS income of each of the pharmacies which would result in a loss being made in the yearly accounts and whilst both pharmacies have only recently been established, a business plan which allows a period when the prescription volume is below the threshold, but then managing to go above, which would result in the pharmacy being able to cover the cost of being in place, if now the prescription volume is diminished, the threshold may never be reached and then the services would need to be withdrawn, Clearly in the second year, more patients would know that the pharmacy was present and the usage of the pharmacy would increase as patients incorporated the use of the pharmacy with their usual activities and this would grow the NHS Income and also the other income streams to result in year 2 being at a break even point. The loss of prescription volume even marginally would have drastic effect and would prejudice the pharmacies.
- 4.9 As pharmacist and pharmacy service providers the appellant is committed to undertaking their responsibilities to the NHS, under their terms of service and even under very difficult financial times, when they have met their responsibility to establish a pharmacy and provide service. The appellant would hope that factors which would impact on the viability of these

pharmacies would be taken seriously as they would jeopardise the pharmacies and the reason why these were proven to be needed in the first place. Please note that the appellant has not even included in their costing the amount for fitting out their pharmacy to allow it to undertake its function as a pharmacy, therefore clearly showing their long term commitment to community pharmacy in these areas.

4.10 The appellant hopes the appeal unit will refuse this application due to the prejudice that it will cause. The appellant would like to be kept informed of the processing of this application.

4.11 The following is our projected costs for the running of the Hardwick pharmacy for its 1 year period:

Pharmacist fees	£ #
Rent	£#
Rates and Services (water, elec, gas)	£#
Staff Salaries	£#
Insurance	£#
Cleaning and Repairs	£#
Printing & Stationary	£#
Software	£#
Telephone	£#
Postage & Packaging	£#
Bank Charges	£#
Delivery Vehicle RFL/insurance/Fuel/ Servicing/Repair	£#
Accountants Fees	£#
Professional Fees	£#
<b>Total Operating Expenses</b>	<b>£#</b>
Income NHS	£#
Private Prescription	£#
Standard Sales	£#
PCT Income	£#
Total Income	£#

**Therefore the first year is anticipated to make a loss of £#**

- 4.12 The following is our projected costs for the running of the South Lynn pharmacy for its 1 year period

Pharmacist fees	£ #
Rent	£#
Rates and Services (water, elec, gas)	£#
Staff Salaries	£#
Insurance	£#
Cleaning and Repairs	£#
Printing & Stationary	£#
Software	£#
Telephone	£#
Postage & Packaging	£#
Bank Charges	£#
Delivery Vehicle RFL/insurance/Fuel/ Servicing/Repair	£#
Accountants Fees	£#
Professional Fees	£#
<b>Total Operating Expenses</b>	<b>£#</b>
Income NHS	£#
Private Prescription	£#
Standard Sales	£#
PCT Income	£#
Total Income	£#

**Therefore the first year is anticipated to make a loss of £#**

## 5 Further Comments

### Repeat Prescription Orderline Ltd (Appellant)

- 5.1 In response to comment received during the consultation period. The appellant has provided evidence in regard to their financial situation, the appellant understands the NHS has access to prescription figures, but if there is a time lag for these coming through, which the appellant would be surprised about as they must submit their returns by the 5th of the following month meaning their prescription figures for December have already been submitted to the PPA. If direct information is required from the pharmacies then the appellant is more than willing to provide this to the Litigation Authority.

- 5.2 The distance referred to by West Norfolk Health Ltd, seems inaccurate and from the appellant's understanding, the distance between one of their pharmacies and the proposed location is around 13 miles as the crow flies and the road route follows a very similar line.
- 5.3 Clearly as one surgery has declared an interest in the ownership of the applicant limited company, the question needs to be asked how many other practices have an interest/part ownership of the limited company. If the case is that a significant number of practices are owners which the Litigation Authority should be aware of the ownership and therefore the fitness to practice of the owners of the limited company, they would be able to appreciate the area of impact if this application is allowed to be approved. In particular regard should be had to existing arrangements nationally, whereby GP practice consortia combine to form a limited company and initiate a distance selling pharmacy, and the impact to the local pharmacy network post opening of the distance selling pharmacy.
- 5.4 The appellant clearly believes that the application will prejudice their pharmacies, they have made representation and provided evidence to corroborate their position. If the Litigation Authority are minded to approve this application then the appellant formally requests that an oral hearing be called to allow the situation locally at first hand to be considered.
- 5.5 The appellant would like to end by saying that as there is evidence of the impacts to pharmacies where similar arrangements have been made nationally the Litigation Authority can utilise this information as the situation locally is almost identical. It would be a sad reflection if within 1 to 2 years of the distant selling pharmacy application being allowed, a number of communities were to be deprived of the ability to have face to face contact with their local community pharmacy and therefore are disadvantaged and lose the immediate access to excellent pharmaceutical services within their community. In all the appellant's years of working within the NHS, his belief has always been that the intention of the NHS is to provide an excellent service to the population of the United Kingdom, to improve and provide a service that is recognised World Wide for its excellence, forethought and development, never has the appellant considered it to have been short sighted or reckless.

## 6 Consideration

- 6.1 The Committee noted this was an application for inclusion in the PCT's pharmaceutical list within 300 metres of Turbine Way, Ecotech Business and Innovation Park, Swaffham, Norfolk.
- 6.2 The Pharmacy Appeals Committee appointed by the Family Health Services Appeal Unit of the NHS Litigation Authority, ("the Committee") had before it the papers considered by the PCT, together with a plan of the area showing existing pharmacies and doctors' surgeries and the location of the proposed pharmacy.
- 6.3 It also had before it the responses to the Authority's own statutory consultations. The Committee dealt with the application by way of reconsideration of all the issues and, on the basis of this information, the Committee considered it was not necessary to hold an Oral Hearing.
- 6.4 The Committee had regard to Regulation 13(1) of the National Health Service (Pharmaceutical Services) Regulations 2005 (as amended) ("the Regulations"). The application had been submitted to the PCT under Regulation 13(1)(d) '*premises at which essential services are to be provided but the means of providing those services are such that all persons receiving them do so otherwise than at those premises*'. Under Regulation 13(1) the application was exempt from consideration under Regulation 12 the 'necessary or expedient' test.

6.5 The Committee noted the location of the proposed premises is in a controlled locality but not a Reserved Location. These factors are not the subject of the current appeal.

6.6 Given the above, the Committee noted Regulation 18ZA applies to the application. Regulation 18ZA states:

*“the PCT shall refuse an application to the extent that it is of the opinion that to grant it would prejudice the proper provision of primary medical services, dispensing services, local pharmaceutical services or pharmaceutical services in any locality.”*

6.7 The Committee was aware of guidance issued by the Department of Health entitled ‘The NHS (Pharmaceutical Services) Regulations 2005 – Information for Primary Care Trusts’. The Committee noted Annex C, which states:

*‘The regulations do not provide any further definition of the concept of “prejudice”. In general, “prejudice” means that nothing must be done which would have the result of preventing people in any controlled locality from having access to those general medical and pharmaceutical services, at the level of service which is provided for by the National Health Service terms of service.*

*A mere reduction in the total level of service provided by either a pharmacist or a doctor is not of itself “prejudice”; prejudice arises where the service provided under the terms of service laid down by the National Health Service has in some respect to cease or otherwise be curtailed or withdrawn without proper substitution in the area.*

*In practice, the existence of “prejudice” involves, to a greater or lesser extent, making a judgement about events that will occur in the future. Inevitably, therefore, it can often be extremely difficult to judge whether or not there will be prejudice.*

*In considering questions of prejudice, it is important that decision-takers focus only on those services which have to be provided within the terms of service of the National Health Service. The fact that the provision of other non-NHS services or services provided above the level set by the NHS terms of service may be curtailed should not be regarded as relevant.’*

*The burden of proof is on the party alleging that prejudice will occur.’*

- 6.8 The Committee noted the appellant's assertion, that there would be prejudice to the proper provision of pharmaceutical services should the application succeed. There was no suggestion that the primary medical services, dispensing services or local pharmaceutical services in any locality would be prejudiced. The Committee considered the application on its own merits.
- 6.9 The Committee noted the appellant's concern that the proposed pharmacy threatened their 'new pharmacies'. For the appeal to succeed, the appellant would have to show there are people in a controlled locality(s) that would be prevented from having access to those pharmaceutical services, at the level of service which is provided for by the National Health Service terms of service.
- 6.10 The Committee noted information provided by the appellant, said to support their claims of prejudice to pharmaceutical services. In particular, financial information was provided for the Hardwick and South Lynn Pharmacies. The Committee noted the PCT's reference to the appellant's pharmacies having their own identifiable populations, the South Lynn and Hardwick Pharmacies being in a major urban area with other pharmacies close by. The proposed pharmacy at Marham was said to be in a Reserved location which the PCT regarded as being likely to pose a greater threat to its sustainability than the establishment of a distance selling pharmacy elsewhere. The Committee was mindful of the appellant's comments regarding the possibility of GP practices having an interest in the applicant's company. The Committee noted this was speculation on the appellant's part, and it had not been shown how that claim even if correct, would result in prejudice to pharmaceutical services.
- 6.11 If a finding of prejudice was to be made, the Committee had to be reasonably sure services provided under the terms of service laid down by the National Health Service would in some respect cease or otherwise be curtailed or withdrawn without proper substitution in the area(s). The Committee noted that the appellant had provided some financial information, but that the appellant had not provided any information to show how the granting of this application would directly affect the provision of pharmaceutical services by the appellant's pharmacies. Wherever within 300 metres of Turbine Way, the pharmacy is sited, the Committee considered the appellant's information fell short of demonstrating that any substantial impact of the application, would be on specific pharmacy(s) and that as a result services in any controlled locality, would likely cease, otherwise curtailed or withdrawn without proper substitution.

## 7 Decision

Accordingly the Committee has dismissed the appeal.

### **Ray Bushell** **Appeal Officer**

A copy of this decision is being sent to:

Dr P Koopowitz, West Norfolk Health Ltd – Applicant  
 Mr S Damani, Halls the Chemist Ltd – Appellant  
 Mr D Thorne – Anglia Support Partnership  
 Mr T Dean – Norfolk LMC  
 Ms S Payne – Norfolk LMC  
 Secretary – Suffolk LPC  
 Secretary – Suffolk LMC  
 Secretary – Cambs & Peterborough LPC  
 Secretary – Cambs LMC  
 Mr S K Morgan – The Co-operative Pharmacy

Mrs H Stanger – Boots UK Ltd  
Ms C Jarrett – Lloyds Pharmacy Ltd  
Mr M Rundle – The Campingland Surgery