

21<sup>st</sup> January 2010

REF: SHA/15478

**APPEAL AGAINST BARNET PCT DECISION TO REFUSE AN APPLICATION BY THE GREEN PHARMACY FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 41 FRIERN PARK, NORTH FINCHLEY, LONDON N12 9DE UNDER REGULATION 13(1)(d)**

**1 The Application**

By application dated 20<sup>th</sup> May 2009, The Green Pharmacy ("the Applicant") applied to Barnet Primary Care Trust ("the PCT") for inclusion in the pharmaceutical list at 41 Friern Park, North Finchley, London N12 9DE under Regulation 13(1)(d). In support of the application it was stated:

- 1.1 Although clinical governance & CPD are the base of which any pharmaceutical services are provided essential services will be provided by:-
  - 1.1.1 Internet; mail – provision of dispensing / promotion healthy lifestyles / signposting / support self care.
  - 1.1.2 Home delivery & collection – dispensing / disposal unwanted medicines.

The Applicant wishes to apply for this exemption for the following reasons:

- 1.2 In order to provide an NHS pharmaceutical service via a remote source, to provide best all round pharmacy internet service.

**2 The PCT Decision**

The PCT considered and decided to refuse the application. The decision letter dated 5<sup>th</sup> October 2009 states:

- 2.1 DECISION: Not approved
- 2.2 REASONS:
- 2.3 The applicant was unable to provide adequate assurance for delivery of all essential services. In particular,
  - 2.3.1 The applicant stated that he would only be able to supply medicines from a restricted list, excluding most refrigerated and controlled drug products.
  - 2.3.2 The applicant has stated that he would be unable to offer adequate support to patients with medication under the disability discrimination act.
  - 2.3.3 The applicant has not been able to demonstrate that the pharmacy can comply with legal obligations on data protection and confidentiality, especially in relation to the use of modern technology to contact patients when away from the pharmacy.

**3 The Appeal**

In a letter to the Family Health Services Appeal Unit of the NHS Litigation Authority (“the Appeal Unit”) received on 29<sup>th</sup> October 2009, the Applicant appealed against the PCT’s decision. The grounds of appeal are:

- 3.1 Barnet PCT has provided three main reasons for exclusion.
- 3.2 The applicant stated that he would only be able to supply medicines from a restricted list, excluding most refrigerated and controlled drug products.
  - 3.2.1 Firstly, the restricted list is a list of medicines that the pharmacy would not be able to supply via postal delivery or couriers. The Applicant would be able to supply all other medicines NOT on the restricted list, as a “traditional” community pharmacy would.
  - 3.2.2 The medicines in the list are controlled drugs and refrigerated items. There are safety and security issues associated with controlled drugs, as well as potential issues with requirements for safe custody. At present, a cold chain supply is not feasible, although with growth in the business this would become a possibility in the future.
  - 3.2.3 For local deliveries, the Applicant would be able to deliver all medicines, including those from the restricted list.
  - 3.2.4 The list provided to Barnet PCT is one currently utilised by an already operating Internet Pharmacy, as a result it seems there would be a disparity if this would be a reason for exclusion.
- 3.3 The applicant has stated that he would be unable to offer adequate support to patients with medication under the disability discrimination act.
  - 3.3.1 At no point has the Applicant stated that they would not be able to offer adequate support to patients under the DDA. The fact is that this would be an Internet based pharmacy, and as a result, patient contact would not be face to face. This obviously will affect how the Applicant would be able to offer support - the Applicant has stated that they can offer reasonable support whenever possible, e.g. supply non-CRC caps, medication administration records charts etc.
  - 3.3.2 A website link was provided to Barnet PCT to an article in the Pharmaceutical Journal of examples of how help would be provided by the Applicant freely. The link is also provided below  
  
[http://www.pharmj.com/pdf/cpd/pj\\_20051217\\_disability.pdf](http://www.pharmj.com/pdf/cpd/pj_20051217_disability.pdf)
- 3.4 The applicant has not been able to demonstrate that the pharmacy can comply with legal obligations on data protection and confidentiality, especially in relation to the use of modern technology to contact patients when away from the pharmacy.
  - 3.4.1 The pharmacy itself would utilize a standard pharmacy computing system such as Nexphase used in any standard Pharmacy. As a result storage of data and back up of the data should not be an issue, as these would be to the same standard as a traditional community pharmacy.
  - 3.4.2 The methods of concern the Applicant believes relate to the access of the data by other means whilst away from the pharmacy.

- 3.4.3 The data on the pharmacy computer itself relating to patient information and medication would not be able to be accessed without access to the pharmacy computer.
- 3.4.4 However, email to the internet pharmacy could be accessed away from the pharmacy premises. This is a possibility for any Internet Pharmacy in operation at present as requests would be sent mainly by email, and also to that of a normal pharmacy with an email address. Any person from the pharmacy could access the emails simply with a computer or mobile phone from anywhere (provided they have the right password). The same would apply for the forwarding of telephone calls from the pharmacy, as these are processes that already happen in a non-internet pharmacy. The Applicant must stress that only emails would be able to be accessed away from the pharmacy (to help facilitate communications with patients and clients) and that actual personal patient data (i.e. data in the patient medication record system) would be confined to the pharmacy premises only.
- 3.4.5 If it is felt that such use of access away from the pharmacy is an issue of concern it would simply not be used in the business model, and should not be a reason for refusal of the contract.
- 3.4.6 Although the Applicant believes that modern technology is already used within the NHS such as requests made to a surgery for repeat prescriptions, and a lack of understanding of how it could be utilized should not be a reason for not using it.
- 3.4.7 Finally the Applicant would lack to close (*sic*) by stating that, Internet Pharmacy is a new means of providing access to patients to Pharmacy services.
- 3.4.8 It is hoped that the application is not refused on appeal through the lack of communication on how these issues would be resolved in order to provide the best healthcare to patients.

## **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.

### **4.1 BARNET PCT**

- 4.1.1 Firstly, the PCT would like to point out that the decision was based upon information available to the Barnet, Enfield and Haringey Pharmacy Practices Panel at the time of the application. This included the application form and some supplementary information provided by the applicant in response to routine queries. The PCT has enclosed a copy of this for the Appeal Unit's information.
- 4.1.2 In reaching its decision that panel worked to the principle that 'patients are entitled to the same quality of pharmaceutical care irrespective of whether the service is provided on-line or face to face on pharmacy premises' as cited in the Code of Ethics document - Professional Standards and Guidance for Internet Pharmacy Services, published by the Royal Pharmaceutical Society of Great Britain (RPSGB). An internet pharmacy would also be expected to abide by the same contractual obligations and standards as a pharmacy offering face to face services to patients. The guidance is clear in its expectations that all internet pharmacy applications would be expected to provide the full range of NHS services specified Nationally.

- 4.1.3 The panel felt that the application did not provide adequate evidence of an understanding of the contractual obligations required and that some areas of responsibility could be avoided or displaced to other contractors.

#### Restricted List

- 4.1.4 The first point for refusal of the application is based on the applicant's continued assertion that the pharmacy will only supply some, but not all, medicines that a patient may require. The applicant has drafted what he calls a 'restricted list' that would indicate its intention to not supply the range of medication needed to fulfil the essential service requirements of the existing contract.
- 4.1.5 Whilst the PCT acknowledge that there are safety and security implications involved in dispensing and delivering such items adoption of such a system would immediately put the pharmacy in a position where it is not compliant with the clause of the National Health Service (Pharmaceutical Services) Regulations 2005 which states that (subject to certain provisions) *a pharmacist shall, with reasonable promptness, provide the drugs so ordered (on a prescription or electronic prescription), and such of the appliances so ordered as he supplies in the normal course of his business.*
- 4.1.6 In relation to refrigerated products, the applicant noted in his letter to the appeal authority dated 29.11.09 that 'at present a cold chain supply is not feasible, although with growth in the business this would become a possibility in the future'. This gives an acknowledgement that a cold chain supply can be arranged but has financial implications for the pharmacy. The RPSGB (Code of Ethics) document - Professional Standards and Guidance for Internet Pharmacy Services includes information on delivery of medicines ordered via on-line routes and specifically notes that care should be taken with thermo-labile products. This gives an indication that the RPSGB are of the opinion that, professionally, such products should be included in the scope of service provision for internet pharmacies. As profitability of a pharmacy is not a consideration for determination of an application, it should not be used as a reason to offer pharmaceutical services lower than the expected standards for patients.
- 4.1.7 The applicant has stated that the list that he has supplied has been sourced from another pharmacy operating in such a manner and therefore represents a disparity. As the PCT are not party to the specific pharmacy's identification and were not able to find other examples of such lists during their research, they found no evidence that this is a common practice. The PCT would also comment that even if another Internet pharmacy does operate in this manner, it would not necessarily follow that service provision is in keeping with the expected standards. The manner in which other applications were granted and are monitored is a matter for the commissioning PCT.

#### Support to Patients under the Disability Discrimination Act

- 4.1.8 Pharmacy contractors have an existing and ongoing responsibility under the Disability Discrimination Act 1995 to make reasonable adjustments to their services for people with disabilities. PSNC Guidance for Pharmacy Contractors Disability Discrimination Act 1995 - Support for people with disabilities (updated 5 December 2005) sets out the PSNC's position with respect to the DDA 1995. It makes clear that it is unlawful for a contractor to discriminate against a disabled person by failing to comply with a duty in which the effect of that failure is to make it impossible or unreasonably difficult for a disabled person to make use of any services provided. The funding negotiated to recognise the costs of providing

support to such patients is being distributed to all contractors, based on volume of prescriptions dispensed.

- 4.1.9 Although, it is for the pharmacy contractor to determine how he manages the service, it follows that some form of discussion or assessment (face to face or otherwise) must take place to understand the specific needs of the patient and to identify what reasonable adjustments the pharmacist should offer to patients who request support.
- 4.1.10 In the additional information supplied to the PCT at the time of the application the applicant stated that *'the DDA currently means that face to face contact is initially required for an assessment to be made. However, this contact would not be possible due to the nature of internet pharmacy. We can re-direct patients to other providers who can do this and the website would be easy to use for all patients and comply with the DDA'. Adjustments can be made, should patients inform us of any specific problems'*.
- 4.1.11 The panel's opinion was that the comments were indicative of a lack of understanding of the applicant's role and obligations under the DDA. It is inadequate to only provide the service to patients who already understand and request their reasonable adjustments. Routine referral of patients to another pharmacy for such support is inappropriate and represents an attempt to negate himself of his legal and contractual obligations. This is especially relevant and contractual funding has been negotiated nationally to reflect the activity.

#### Legal obligations on Data Protection and Confidentiality

- 4.1.12 The panel were concerned regarding the security and confidentiality of data in response to the following statement in the applicant's supplementary information - *'contact with the pharmacy using modern technology would be continuous throughout the day. I would be able to receive calls or emails from the pharmacy anywhere. Also there is the potential of live chat forums with the pharmacist anywhere, without the constriction of being at the pharmacy'*. Taking into account the listed core/opening hours of the pharmacy (8pm-midnight on Monday to Wednesday and 9am-11pm on Thursday and Friday) the usage of such an approach could be extensive.
- 4.1.13 The expectation is that all patient data should be managed in a manner that is compliant with both professional and contractual requirements. The Professional Standards and Guidance for Internet Pharmacies published by the Royal Pharmaceutical Society of Great Britain gives a clear outline on the standards required and notes that all patient data transmissions are encrypted to prevent the possibility of an internet service provider or any other unauthorised party for accessing patient data either accidentally or deliberately. Contractually the pharmacy would be expected to comply with legal obligations on data protection and confidentiality. This includes the Data Protection Act 1998, The Human Rights Act 1998 and the common law of confidentiality. They should also conform to the NHS Code of Confidentiality. It would therefore be essential that safeguards are in place to ensure that patients/clients understand how their data is being managed and that it is being managed appropriately. Caution would need to be employed in using accessing and responding to patients queries away from the pharmacy premises without consent.
- 4.1.14 The PCT notes with interest that the applicant has stated that he could remove the use of such technology from his business model. The PCT would see this a sensible short-term solution until adequate safeguards could be established, if the application were granted. To support this, additional standards have become

available since the application, in the form of the 'Information Governance, Standard of Compliance'. It should also be noted that contractually the pharmacy need only comply with the 40 core hours listed and therefore access to patient information outside of this time frame should be unnecessary.

4.1.15 In summary, the above representations clarify further the view of the Barnet, Enfield and Haringey Pharmacy Practice panel in refusing the application on the grounds that the applicant was not able to demonstrate that he could offer the full range of essentials services to the expected standard. It should also be noted that in addition to the areas discussed above, further areas of similar misunderstanding were noted in the application (e.g. in relation to waste management and core hours) where the applicant felt that it was reasonable to fall short of the expected standards. These are noted in the minutes of the panel meeting. The panel adopted a balanced view in focussing on areas of significant contractual irregularity or patient safety, whilst considering the possibility of conditions or further discussion with the applicant on other matters.

4.1.16 The PCT, respectfully, hope that the appeal committee will uphold the decision of NHS Barnet.

## **5 Consideration**

5.1 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 site of the proposed pharmacy.

5.2 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.

5.3 The Committee had regard to Regulation 13 of the National Health Service (Pharmaceutical Services) Regulations 2005 (as amended) ("the Regulations").

5.4 The Regulations state that as regards to an application for 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 ("distance selling premises"), if the application is granted it is a condition of the applicant's inclusion in a pharmaceutical list (and so a term of service) that

a) he does not offer to provide pharmaceutical services to persons who are present at the premises to which the application relates; and

b) the means by which he provides pharmaceutical services are such that the person receiving them does so otherwise than at the premises to which the application relates,

and the Primary Care Trust may not vary or remove these conditions.

5.5 In the Committee's view, where an applicant indicates that it 'intends' to comply with a particular exemption then any breach of the terms of service could only be established following the commencement of providing pharmaceutical services. However, where an applicant specifically restricts the provision of pharmaceutical services in the application, and thereby would in effect be seeking to breach a term of service, the Committee concur with the PCT that it would be wrong to knowingly permit such a breach. In this case, the applicant has sought to restrict delivery of controlled drugs and refrigerated items to local deliveries, with a restricted list of medication being available by post outside the local

area. The Committee were of the view that Schedule 1, Part 2, Paragraph 4 (Dispensing Services) would not be complied with and therefore the application could not satisfy the requirement in that paragraph even on a 'non-face-to-face' basis.

## **6 Decision**

Accordingly the Committee dismisses the appeal.

**Abby Richards**  
**Appeal Officer**

A copy of this decision is being sent to:

The Green Pharmacy  
Barnet PCT