NHS Resolution

24 October 2024

REF: SHA/26275

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APPEAL AGAINST WEST YORKSHIRE ICB DECISION TO GRANT AN APPLICATION BY ENHANCED CARE PHARMACY LIMITED FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 2A SCHOOL STREET, CLAYTON, BRADFORD, BD14 6AS UNDER REGULATION 25

1 Outcome

1.1 The Pharmacy Appeals Committee ("Committee"), appointed by NHS Resolution, quashes the decision of the Commissioner and redetermines the application.

1.2 The Committee determined that the application should be refused.

A copy of this decision is being sent to:
Enhanced Care Pharmacy Limited
Raj's Chemist
PCSE on behalf of West Yorkshire ICB
Community Pharmacy West Yorkshire

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1 The Application

By application dated 15 January 2024, Enhanced Care Pharmacy Limited ("the Applicant") applied to West Yorkshire ICB ("the Commissioner") for inclusion in the pharmaceutical list at 2a School Street, Clayton, Bradford, BD14 6AS under Regulation 25. In support of the application it was stated:

1.1 In response to "If you are undertaking to provide appliances, specify the appliances that you undertake to provide (or write 'none' if it is intended that the pharmacy will not provide appliances)" the Applicant left this box blank.

1.2 In response to why the application should not be refused pursuant to Regulation 31 the Applicant left this box blank.

1.3 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant left this box blank.

Further Information in Relation to Provision of Essential Services in Accordance with the Regulatory Requirements for Distance Selling Pharmacies

1.4 Please find below information to explain how the pharmacy procedures used within the premises will secure:

(a) the uninterrupted provision of essential services during the opening hours of the premises, to persons anywhere in England who request those services, and

(b) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or someone else's behalf, and the applicant or the applicant's staff.

1.5 Please describe the procedure that will be followed where a patient attends the premises and asks for one or more of the essential services.

1.6 If you are undertaking to provide advanced services at the premises please describe how you will do so without providing any element of essential services.

1.7 "See additional supporting information attached to this application."

1.8 "**NHS England Premises Standards**

1.9 The information contained in this section will outline how the premises will satisfy the requirements to fulfil paragraph 28 (2) (g) of Schedule 4 Part 4 to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (as amended). It should be noted that not all these requirements apply directly to distance selling premises, other than where a patient is accessing non-essential services.

1.10 We will ensure that, the area of the premises from which NHS services are provided functions properly as a healthcare environment. This will be achieved through:

1.10.1 Keeping the area where medicines are dispensed clean, implementing systems for maintaining cleanliness throughout the premises to ensure, in a proportionate manner, that the risk to people at the pharmacy of healthcare-acquired infection is minimized.

1.10.2 Ensuring the amount of space available allows staff to perform tasks safely.

1.10.3 Ensuring that there are arrangements in place that enable a person performing pharmaceutical services to communicate confidentially with a person accessing pharmaceutical services either by telephone or another live audio link, or via a live video link.

1.11 **GPhC Guidance**

1.12 The pharmacy will operate following the "Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet", the content of which is considered and replicated in part below but is not intended to exhaustively replicate the entirety of the GPhC guidance which will be followed.

1.13 Specifically, but not exhaustively, we will have in place, before opening the following which are GPhC requirements:

1.13.1 **Risk Assessment**

1.13.2 A Risk Assessment document and risk matrix to help identify and manage risks. The risk assessment will look at what could cause harm to patients and people who use the pharmacy services, and what the pharmacy needs to do to keep the risk as low as possible.

1.13.3 The risk assessment will be reviewed quarterly and when there are significant business or operational changes.

1.13.4 **Audit Procedures**

1.13.5 A regular audit program will be in place. The audit will be an important part of the evidence which gives assurance that the pharmacy continues to provide safe pharmacy services to patients. Any issues identified will be subject to a reactive review.

1.13.6 The audit will, at the very least, consider.

1.13.6.1 Staffing levels and the training and skills within the team.

1.13.6.2 Suitability of communication methods with patients, and between staff and other healthcare providers.

1.13.6.3 Use of specialized equipment and new technology.

1.13.6.4 Records of decisions to make or refuse a sale.

1.13.6.5 Systems and processes for receiving prescriptions, including EPS records of decisions to make or refuse a sale (note that our pharmacy SOPs will require more frequent analysis of refusals to sell).

1.13.6.6 Systems and processes for secure delivery to patients.

1.13.6.7 Any information about pharmacy services on the website.

1.13.6.8 Review of how the pharmacy adheres to the information security policy, Payment Card Industry Data Security Standard (PCI DSS), and data protection law.

1.13.6.9 Feedback from patients and people who use our pharmacy services.

1.13.6.10 Concerns or complaints received, and

1.13.6.11 Activities of third parties, agents, or contractors.

1.13.7 The Audit and review process will act as a Project Plan for the pharmacy to implement change and upgrades in service and training.

1.13.8 **Reactive Review**

1.13.9 A reactive review will take place if an audit identifies a problem, or if there is;

1.13.9.1 A change in the law affecting any part of the pharmacy service.

1.13.9.2 A significant change in any part of the pharmacy service provided, for example, an increase in the number of patients the pharmacy provides services to, or an increase in the range of services the pharmacy intends to provide.

1.13.9.3 A data security breach.

1.13.9.4 A change in the technology the pharmacy uses.

1.13.9.5 Concerns or negative feedback are received from patients or people who use the pharmacy services.

1.13.9.6 A review of near misses and error logs causes a concern about an activity.

1.13.10 **Accountability**

1.13.11 During opening hours there will always be a responsible pharmacist (RP) on site. Each area of work will have clear lines of accountability that will be set out by the superintendent pharmacist. We are aware that if we have an arrangement with or contract out any part of the pharmacy service to a third party, we are still responsible for providing said pharmacy service safely and effectively. Due diligence and careful consideration will be undertaken when selecting any contractors.

1.13.12 **Record Keeping**

1.13.13 Records in the pharmacy will be scanned into the pharmacy IT system (including but not limited to, patient consent forms, queries, complaints, customer logs, sale refusals, and dispensing). Records will be kept for a minimum period of 7 years or longer if specific legislation requires.

1.13.14 **Training**

1.13.15 We will ensure that all staff are properly trained and competent to provide medicines and other professional pharmacy services safely. The GPhC has produced guidance to ensure a safe and effective team, and this will form the basis of the training. Staff will be empowered to use their professional judgment

to act in the best interest of our service users. Patient-centred care will be at the forefront to ensure the health, well-being and safety of patients and the public are not compromised. In addition to this, extra training will be provided in the following areas:

1.13.15.1 Information security management – how data is protected, and cyber security.

1.13.15.2 Communication skills to support staff in managing effective non-face-to-face communications with pharmacy users and prescribers.

1.13.15.3 Using specialised equipment and new technology.

1.13.16 **Premises**

1.13.17 Premises will be registered with the GPhC before entry to the pharmaceutical list and will therefore comply with GPhC requirements for pharmacy premises.

1.13.18 **Website**

1.13.19 The only website used to sell P medicines will be the website associated with the pharmacy. The website will be secure and follow information security management guidelines and the law on data protection. The website will use secure facilities for collecting, using, and storing patient details and a secure link for processing card payments.

1.13.20 The website will display.

1.13.20.1 The GPhC pharmacy registration number.

1.13.20.2 The name of the owner of the registered pharmacy.

1.13.20.3 The name of the superintendent pharmacist.

1.13.20.4 The name and address of the registered pharmacy that supplies the medicines.

1.13.20.5 Details of the registered pharmacy where medicines are prepared, assembled, dispensed, and labelled for individual patients against prescriptions (if any of these happen at a different pharmacy from that supplying the medicines).

1.13.20.6 Information about how to check the registration status of the pharmacy and the superintendent pharmacist.

1.13.20.7 Details of specific services available and how to use them, i.e.

1.13.20.7.1 Return of unwanted medicines

1.13.20.7.2 Patient Lifestyle Questionnaire

1.13.20.7.3 How to register exemptions from NHS charges

1.13.20.7.4 Promotion of Health Lifestyles and details of campaigns being undertaken

1.13.20.7.5 Procedures for Emergency Supply

1.13.20.7.6 Explanation of rules on non-face-to-face contact

1.13.20.7.7 Annual patient survey

1.13.20.7.8 Patient Information Leaflet

1.13.20.8 The email address and phone number of the pharmacy

1.13.20.9 Details of how patients and users of pharmacy services can give feedback and raise concerns.

1.13.20.10 GPhC internet logo (linked to register entry)

1.13.20.11 The pharmacy will be registered with the Medicines and Healthcare Products Regulatory Agency (MHRA) and be on the MHRA's list of UK-registered online retail sellers.

1.13.20.12 EU common logo

1.13.20.12.1 The pharmacy will display the new EU common logo on every page of the website offering medicines for sale, even if they are already displaying the GPhC voluntary logo. The registered EU common logo will also be linked to the entry in the MHRA's list of registered online sellers.

1.13.20.13 The website will be regularly updated, clear and accurate and follow the GPhC guidance on websites.

1.13.21 **Transparency and Choice**

1.13.22 Our website and materials will specify the nature and type of services we provide and who provides those services. If any part of our pharmacy services is provided at different locations, we will explain clearly to people who use pharmacy services where each part of the service is based.

1.13.23 **Managing Medicines Safely**

1.13.24 The pharmacy standard operating procedures (SOPs) provide the procedures for all staff to follow to ensure that the sale and supply of medicines is done in such a manner as to minimise risk to patients. The supply or sale of any new medicine must be approved by the superintendent pharmacist as suitable for sale via distance selling.

1.13.25 **Supplying Medicines Safely**

1.13.26 The SOPs for the delivery of medicines contain detailed information on the safe and effective supply of medicines via the pharmacy's driver, Royal Mail and courier firms, including;

1.13.26.1 Assessing the suitability and timescale of the method of supply, dispatch, and delivery for all medicines particularly refrigerated medicines and controlled drugs.

1.13.26.2 Ensuring that the prescriber has robust processes to check the identity of the person to make sure the medicines prescribed go to the right person – for example, by keeping to the Identity Verification and Authentication Standard for Digital Health and Care Services, which provides a consistent approach to identity checking across online digital health and care services.

1.13.26.3 Assess the suitability of packaging (for example, packaging that is tamperproof or temperature-controlled).

1.13.26.4 Ensure appropriate safeguards for all online supplies of medicines.

1.13.27 The pharmacy will monitor third-party providers, including analysis of patient feedback about deliveries and delivery times and processes.

1.13.28 **Equipment and Facilities**

1.13.29 All equipment used in the pharmacy will be sourced from manufacturers that have designed the equipment to be used in the manner in which the pharmacy intends to operate. All equipment will be subject to annual performance testing and review, with specialist equipment (such as temperature monitoring) subject to monthly checks. IT equipment will meet the latest security specifications and be regularly updated including the use of encrypted networks for wired and wireless communication. Access to records will be dependent on any given employee's level of authority and clearance which shall be determined by the superintendent pharmacist.

1.13.30 **Standard Operating Procedures**

1.13.31 We have developed a draft suite of operating procedures that cover the operations of this distance-selling contract. If NHS England requires any further information about any aspect of the operation of the pharmacy, then the relevant SOP will be provided upon request. We have not provided all SOPs with this application as they contain commercially sensitive material.

1.13.32 It should be noted that NHS England's national policy document, "Policy for monitoring compliance with the terms of service for pharmacy and dispensing appliance contractors" (published 5 April 2013) contains a section on SOPs that states:

1.13.32.1 -2.11

1.13.32.2 "*The essential service and clinical governance specifications require pharmacies to have appropriate standard operating procedures for dispensing, repeat dispensing and support for self-care.*

1.13.32.3 Monitoring compliance requires only the determination of whether the pharmacy has an appropriate SOP.

1.13.32.4 It does not require NHS England to carry out a detailed analysis of the content of the SOPs. Indeed, it would be unwise for an NHS England employee to carry out any detailed examination because he or she will be unable to determine what is appropriate for the individual pharmacy concerned.

1.13.32.5 Any shortcomings not identified, or suggestions made which themselves cause problems in the delivery of the services could lead to NHS England itself being involved in litigation."

1.13.33 We however note that there may be occasions where NHS England would wish to see specific SOPs if particular concerns are raised and in any such instance, we would be happy to provide a copy of any requested SOPs.

1.13.34 **Pharmacy Systems and Procedures**

1.13.35 All Essential Services will be delivered in accordance with:

1.13.35.1 Company Standard Operating Procedures

1.13.35.2 NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

1.13.35.3 NHS Act 2006

1.13.35.4 Human Medicines Regulations 2012

1.13.35.5 GPhC – Professional Standards and Guidance on Distance Selling Pharmacies

1.13.35.6 Relevant Data Protection laws

1.13.36 This will ensure that we provide a safe, effective, and uninterrupted provision of all essential services to persons anywhere in England who request those services during the opening hours of the premises. Essential Services will be provided without face-to-face contact between anyone receiving the services, whether on their own or someone else's behalf, and the pharmacy staff.

1.13.37 Our wholly Internet/Delivery Pharmacy will operate from secure premises, with a controlled entry system, to which members of the public will not have access.

1.13.38 **If a patient attends the premises and asks for one or more of the essential services:**

1.13.38.1 Any patient who requests essential services to be provided at the premises will be informed that the pharmacy is not permitted to provide those services at the premises. They will be directed to our website or advised further on how to contact us where we can explain access to the provision of NHS Essential Services to them (see below).

1.13.39 Access to information about the provision of NHS Essential Services will be achieved by using:

1.13.39.1 Telephone

1.13.39.2 The website will enable patients or their carers to communicate remotely but directly allowing quick and easy access and providing clear unambiguous details of how safe, efficient, and uninterrupted NHS Essential Services will be provided by the Pharmacist and qualified, knowledgeable, experienced support staff on duty throughout the opening hours of the pharmacy premises without having 'face to face' contact with the patient or their representative.

1.13.39.3 Email

1.13.39.4 Postal services

1.13.40 All NHS services will be delivered free of charge in accordance with the NHS Act 2006.

1.13.41 Essential Services may be delivered using:

1.13.41.1 Telephone, including text messaging where appropriate.

1.13.41.2 Electronic Prescription Service (EPS)

1.13.41.3 Website

1.13.41.4 Email

1.13.41.5 Royal Mail postal service

1.13.41.6 Courier service

1.13.41.7 Specialist Waste Management Services

1.13.41.8 We also intend to promote the use of free video-conferencing services such as Skype or Zoom so that patients have a better chance of getting to know their pharmacy staff. Such services do not constitute 'face-to-face' contact under the Regulations and can be a particularly efficient way of interacting with patients and gaining rapport, as they are more personal than a basic telephone service. Many people now can use services like this via their mobile phones at any location where they can find a wireless internet signal. A video link service may also be integrated into the pharmacy website to further provide ease of access.

1.13.41.9 Specialist cold chain courier services will ensure the integrity of the cold chain and the maximum stability of thermo-liable drugs by packing, transporting, and delivering in such a way that their integrity, quality, and effectiveness are always preserved. This will be a dedicated, fully monitored and temperature-controlled delivery service.

1.13.42 **Provision of NHS Essential Services**

1.13.43 We will provide all the essential services as outlined in the NHS contractual framework. These are as follows:

1.13.43.1 Discharge medicine service

1.13.43.2 Healthy living pharmacies

1.13.43.3 Dispensing medicines

1.13.43.4 Disposal of unwanted medicines

1.13.43.5 Public health (promotion of healthy lifestyles)

1.13.43.6 Repeat dispensing

1.13.44 **Dispensing Medicines**

1.13.45 Prescriptions will be received by the EPS, post, and fax or where practicable, with the patient's informed consent, collected from a surgery. Prescriptions will be clinically and legally assessed to determine if they can be dispensed.

1.13.46 If they are not clinically or legally correct, pharmacists will follow Standing Operating Procedures to resolve clinical or legal issues before dispensing items. This may involve contacting the prescriber as soon as possible to make sure the patient receives their medication without delay.

1.13.47 When appropriate prescription interventions take place, for example, drug/drug interactions, suspected over/under prescribing, etc. the pharmacist on duty will telephone and discuss with the prescriber and patient prior to dispensing or delivering the medication. Appropriate records of clinical interventions will also be made before delivery of medication.

1.13.48 **Repeat Dispensing Services**

1.13.49 The Terms of Service require pharmacy contractors to ensure that appropriate advice about the benefits of repeat dispensing is given to any patient who—

1.13.49.1 (i) has a long-term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term), and

1.13.49.2 (ii) requires regular medicine in respect of that medical condition, including, where appropriate, advice that encourages the patient to discuss repeat dispensing of that medicine with a prescriber at the provider of primary medical services whose patient list the patient is on.

1.13.50 Such advice will be provided by the Pharmacy using its permissible methods of non-face-to-face contact with patients.

1.13.51 Dispensing of repeat NHS prescriptions including those dispensed in dosette boxes as may be required under the Equality Act 2010 will be carried out in partnership with patients, carers, pharmacists, and prescribers. It will cover requirements additional to those for dispensing, assessing the patient's need for repeat supply. Any clinical issues identified will be addressed to the prescriber. Where considered necessary by a pharmacist, the patient may be contacted by telephone and given verbal advice in addition to information delivered with the repeat prescription.

1.13.52 For a successful implementation, we will have SOPs relevant to the process of repeat dispensing for paper and electronic NHS prescriptions and private prescriptions respectively, to ensure that staff are appropriately trained in the entire repeat dispensing process. Training will also be supplemented by third-party resources e.g. CPPE e-Learning.

1.13.53 Before each delivery, the patient will be asked (over the phone) if there are any changes to their therapy if they are experiencing any side effects or taking any new medication over the counter. The pharmacist will then with this information make a judgement as to whether the medication is appropriate to supply or not. Or whether any changed to the patient’s health may indicate a review with the prescriber.

1.13.54 The pharmacy team will let the patient know, via text/email/phone call:

1.13.54.1 How often they are due medication (weekly, monthly, bi-monthly, etc.)

1.13.54.2 When the last batch of medication will be dispensed and when to arrange an appointment with their GP for a new batch of prescriptions to be authorized (a ‘last batch’ reminder slip will also be put into the patient's medication bag to further remind them and ensure they do not forget to arrange an appointment.

1.13.54.3 We will ask them how they are managing their condition and may refer them back to the GP.

1.13.54.4 They can stop at any time or change pharmacies at any point. All new patients to the service will receive an initial phone call explaining the repeat dispensing process and how it works.

1.13.54.5 The patient will be made aware of the different methods of contacting the pharmacy to manage their repeat dispensing should they need to.

For example, if they are to go on holiday and need an advance supply, or if they have any queries in general.

1.13.55 **Urgent Supply and Emergency Supply**

1.13.56 Whilst the Distance Selling nature of the pharmacy is such that Urgent Supply or Emergency Supply is unlikely to occur as often as in a retail pharmacy, all staff will be aware of the procedures to be followed in the event of such a request.

1.13.57 The request may be received from a Prescriber (Urgent Supply) or a Patient (Emergency Supply).

1.13.58 The following conditions must apply to the request made by a prescriber:

1.13.58.1 The Pharmacist must be satisfied that the request is from the appropriately authorized prescriber.

1.13.58.2 The Pharmacist is satisfied that a prescription cannot be supplied immediately due to an emergency.

1.13.58.3 The Prescriber agrees to provide a written prescription within 72 hours.

1.13.58.4 The medication is supplied following the prescriber's directions.

1.13.58.5 The medication is permitted to be supplied on an Emergency Supply basis.

1.13.58.5.1 An emergency supply cannot be provided for a Schedule 1, 2, or 3 CD except Phenobarbital for epilepsy by a UK-registered prescriber.

1.13.58.6 EEA prescribers cannot request an emergency supply of any Schedule 1 - 5 CD.

1.13.59 Full records of the supply will be kept as per the relevant SOP.

1.13.60 The following conditions must apply to the request made by a patient:

1.13.60.1 Interview

1.13.60.1.1 The Pharmacist must interview the patient. The interview may not be by way of face-to-face contact and must be by other means, e.g., telephone, Skype/video link.

1.13.60.2 Records

1.13.60.2.1 An entry must be made in the POM register on the day of supply and record all the relevant details. The label for the dispensed medicine must contain the words "Emergency Supply".

1.13.60.3 Faxed Prescriptions

1.13.60.3.1 A 'faxed prescription' does not fall within the definition of a legally valid prescription because it is not written in indelible ink and has not been signed by an appropriate practitioner. A

faxed prescription can confirm that at the time of receipt, a valid prescription is in existence.

1.13.60.3.2 Any pharmacist who dispenses a prescription-only medicine against a faxed prescription without sight of the original prescription must take steps to ensure that the original prescription will be in their possession within a short period and not more than 72 hours. Any concern as to the content of the original prescription due to the quality of the fax must be dealt with before the medicine is supplied by contacting the prescriber.

1.13.60.3.3 Other than in emergencies it is recommended that the pharmacist does not dispense against faxed prescriptions and instead uses the Emergency Supply procedures.

1.13.60.3.4 As it is possible to fax a prescription many times the pharmacist is advised to ensure that no dispensing against a fax takes place unless the system used for the sending or receipt of faxes is secure.

1.13.60.3.5 Schedule 1, 2, or 3 CDs (except Phenobarbital for the treatment of epilepsy) must not be supplied against a faxed prescription.

1.13.60.3.6 As detailed above the patient should be interviewed over the phone. Payment can be processed via the website or over the phone. The pharmacist may wish to consider the following before providing an emergency supply at the request of the patient:

1.13.60.3.6.1 **Delivery of Urgent Supplies**

1.13.60.3.6.2 Given the nature of a request of this type, the Pharmacy will prioritize delivery of the medication to the patient. For local deliveries the driver should be specially informed of the fact that the items are “URGENT” and for any items delivered by courier, the courier will be informed that items must be delivered ASAP by the quickest route possible. We will not charge additional fees to the patient even if these are incurred in the delivery process. Other than noting the urgent nature of the delivery, normal delivery SOPs apply.

1.13.61 **Disposal of Unwanted Medicines**

1.13.62 Patients will have several options for the disposal of unwanted medicines.

1.13.62.1 A specialist waste management company will provide safe and secure disposal of unwanted medicines by collecting unwanted medicines from patients and residential homes.

1.13.62.2 Patients wishing to return unwanted medicines to the pharmacy may do so by courier, which will be provided and paid for by the pharmacy.

1.13.62.3 Patients in the locality may contact the pharmacy by phone or email to arrange collection of unwanted medicines from their home or work by pharmacy staff.

1.13.63 Appropriate packaging will be sent to patients in advance and details of the service and how to book a collection will be available on the Pharmacy website.

1.13.64 Upon return to the pharmacy, unwanted medicines will be sorted and placed in disposal units ready for waste management services to collect. The disposal service will be advertised on the website/app and marketing leaflets.

1.13.65 **Promotion of Healthy Lifestyles**

1.13.66 Identification of patients for promotion of healthy lifestyles will take two forms, namely, passive, or active.

1.13.66.1 **Active patients** will be those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further information should be sent, or who should be called to follow up on the results and offer additional support and information.

1.13.66.2 **Passive patients** are those where the identification happens as part of another interaction with the patient, but where the patient does not appear to be actively seeking additional assistance. For example, the dispensing of a prescription that identifies the patient as having high blood pressure.

1.13.67 All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight, and lifestyle questions such as whether a patient is a smoker and how much exercise they normally carry out weekly.

1.13.68 Leaflets will be delivered to patients with their medication. Those identified (Active or Passive) as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc., or being at risk from them or other conditions will also receive targeted campaigns to increase the patient's knowledge and understanding of health issues relevant to them. The website will also be used to promote healthy lifestyles.

1.13.69 **Public Health Campaigns**

1.13.70 The Pharmacy will take part in national health campaigns to promote public health messages to our patients across England. This will be achieved by sending out leaflets with prescriptions during specific targeted campaign periods and providing additional advice and learning resources via the website.

1.13.71 Patients will be directed to the learning resources via email, text, and other non-face-to-face communication so that they are aware of the campaign.

1.13.72 Patients should also be assessed for participation in at least one clinical audit and whichever of the following that the NHSCB specifies—

1.13.72.1 (i) a clinical audit carried out in a manner that is compatible with the NHSCB's arrangements for the receiving and processing of data from the audit, or

1.13.72.2 (ii) a policy-based audit (to support the development of the commissioning policies of the NHSCB) carried out in a manner that is compatible with the NHSCB's arrangements for the receiving and processing of data from the audit.

1.13.73 **Signposting and Support for Self-Care**

1.13.74 The patient will be signposted to health and social care providers and/or any other assistance available whenever necessary. To assess whether patients require advice to minimize inappropriate use of health or social care services the pharmacist will use the same “Active and Passive” assessment tool already set out above.

1.13.75 Where it appears to the pharmacist, after reviewing the assessment and having regard to the need to minimize inappropriate use of health and social care services and of support services, that a person using the pharmacy would benefit from advice to help manage their medical condition then advice will be provided via non-face to face methods of communication and this will include advice on both treatment options, non-prescription medicines, and lifestyle advice.

1.13.76 If a patient.

1.13.76.1 (a) requires advice, treatment, or support that the pharmacy cannot provide; but

1.13.76.2 (b) another provider, of which the pharmacy is aware, of health or social care services or support services is likely to be able to provide that advice, treatment, or support, we will provide contact details of that provider to that person and will, in appropriate cases, refer that person to that provider.

1.13.77 **Referral for Certain Appliances**

1.13.78 Where, on presentation of a prescription form or repeatable prescription, the pharmacy is unable to provide an appliance or stoma appliance customization because the provision of the appliance or customization is not within the pharmacy’s normal course of business, the pharmacist will—

1.13.78.1 (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or an NHS appliance contractor; and

1.13.78.2 (b) if the patient does not consent to a referral, provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who can provide the appliance or stoma appliance customization (as the case may be) if these details are known to the pharmacist.

1.13.79 In appropriate cases, we will keep and maintain a record of any information given or referral made to facilitate auditing and follow-up care.

1.13.80 **Support for People with Disabilities**

1.13.81 This service will be provided per the Equality Act 2010. We will make reasonable pharmaceutical adjustments to ensure that those who qualify for help under the Act are provided with the right compliance aids.

1.13.82 We will conduct an initial assessment with the patient, carer, or representative to assess the support required to improve medication compliance. Such assessments will be carried out without patients having to access the pharmacy premises so that no face-to-face contact at the premises will take place.

1.13.83 Compliance aid systems such as blister packs/dosette boxes will be provided in compliance with both service levels 1 & 2 respectively.

1.13.84 **Clinical Governance**

1.13.85 We will be involved in and comply with all the components of clinical governance including, but not limited to, compliance with standard operating procedures, patient safety incident and near-miss reporting, demonstrating evidence of Pharmacists and Pharmacy Technician CPO, conducting clinical audits and patient satisfaction surveys, and drug recalls.

1.13.86 'How to Make a Complaint or Compliment' will be displayed and downloadable from the pharmacy website or upon request by telephone or post a copy will be posted.

1.13.87 All staff will be qualified or undergoing nationally accredited training. They will be competent to deliver the highest standards of Clinical Governance. All staff will receive individual and collective training, development and education provided in-house or from accredited external providers.

1.13.88 All staff will have an annual appraisal, and receive, and provide feedback.

1.13.89 The Pharmacy will conduct an annual Patient Satisfaction Survey / Community Pharmacy Patient Questionnaire ("CPPQ") based on the template recommended by the PSNC.

1.13.90 Details of the survey (as per the PSNC website) can be found at http://psnc.org.uk/contract-it/essentialservice-clinical-governance/cppq/

1.13.91 The survey will be adapted to reflect the operation of a distance-selling pharmacy, i.e.

1.13.91.1 Distributed via email, post, and with delivery drivers/couriers.

1.13.91.2 References to "visiting" the pharmacy changes to reflect non-face-to-face contact methods used.

1.13.91.3 Ratings for the pharmacy based on physical characteristics changed to reflect the actual method of use, i.e. ease of use of the website as opposed to "comfort and convenience of the waiting areas".

1.13.92 **Information Governance**

1.13.93 The Pharmacy will be registered and comply with the Data Protection Act and the General Data Protection Regulation (GDPR). It will also comply with the Access to Health Records Act 1990. It will publish its Freedom of Information Act Publication Scheme on its website and copies will be made available on request. All patient data will be kept private and confidential by NHS and legal obligations on data security, protection, and confidentiality.

1.13.94 **Delivering Medicines**

1.13.95 The Responsible Pharmacist (RP) has overall responsibility for ensuring the delivery of medicines to intended patients. Medicines must be delivered safely and with appropriate instructions.

1.13.96 The RP must take adequate measures to ensure that the delivery mechanism used is secure and that medicines are delivered to the intended user promptly, safely, and in a condition appropriate for use. If the delivery to patients is local,

this will be undertaken by the delivery driver. All other nationwide deliveries (other than fridge lines) will be delivered by Royal Mail special delivery or courier and signed for by the patient, their notified carer, or another patient-authorized representative. Fridge Lines will be delivered by courier (see further below).

1.13.97 Medicines will be packed, transported, and delivered in such a way that their integrity, quality, and effectiveness are preserved. The delivery mechanism used will provide a verifiable audit trail for medicine from the initial request through to its final delivery, or its return to the pharmacy in the event of a delivery failure. Packaging must maintain patient privacy and confidentiality.

1.13.98 The choice of packaging will depend on the nature of the items being delivered and the appropriate level of protection must be used to ensure that the item can withstand the normal rigours of the delivery process.

1.13.99 All packaging must have the tamper-proof seals provided in the pharmacy attached to the packaging so that any tampering with the packaging will be evident.

1.13.100 Medicine for local delivery which is not fragile and to be delivered by the delivery driver can be packaged using the pharmacy bags supplied for standard prescription items.

1.13.101 Medicines classified as non-flammable or non-toxic must be securely closed and placed in a leakproof container such as a sealed polythene bag (for liquids) or a sift proof container (for solids). Must be tightly packed in strong outer packaging and must be secured or cushioned to prevent any damage.

1.13.102 This means that for postal / courier items, either:

1.13.102.1 At the very least - padded envelopes even for non-fragile items will help to ensure the integrity of the manufacturer's packaging.

1.13.102.2 For most items - bubble wrap and where necessary, polystyrene filler, placed within a cardboard box. Cardboard boxes must be the re-enforced type.

1.13.102.3 Large or any fragile medicines should be packed into cardboard boxes with bubble packaging and filling material to protect from damage.

1.13.103 The patient, carer, or notified, authorized patient representative must always sign and date a receipt to prove safe receipt of the medicines. A patient who is not at home when delivery is attempted will be informed using a non-delivery notice and an alternative delivery date will be arranged.

1.13.104 A list of the approved cold chain couriers is available within the Pharmacy. Cold chain items should be stored in Styrofoam-filled cardboard boxes before being passed to the courier and marked with the “FRAGILE” and “FRIDGE LINE” stickers. Additional packing will not be required as the courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box and are fully monitored. Pharmacy staff will be aware that some thermolabile products can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in medicines which is damaging to them. The courier service is a dedicated, fully monitored and temperature-controlled delivery service. Any breach of the cold chain is automatically notified to the driver who will then follow the failed delivery procedure and notify the pharmacy accordingly so that re-delivery can be arranged. Where the cold chain breach notice is issued items will not be re-used.

1.13.105 **Controlled Drugs**

1.13.106 **Delivery of Controlled Drugs**

1.13.107 There is a provision within controlled drugs legislation to cover occasions when a controlled drug (CD) may temporarily be in the possession of a third party, e.g. a delivery person or postal carrier, while it is being transferred from one authorized person to another authorized person who is entitled to have the drug. Delivery of CDs will be carried out by couriers with pharma-grade specialist facilities to meet specific quality and validation requirements for healthcare products. This includes Home Office-licensed controlled drug stores. The couriers will have the following UK Licenses and Standards:

1.13.107.1 MHRA Wholesale Dealer License

1.13.107.2 MHRA Manufacturers importers License

1.13.107.3 MHRA IMP License

1.13.107.4 ISO 9001: 2000 Certified

1.13.107.5 Meet all Home Office safe custody and record-keeping requirements.

1.13.108 **Return and Destruction of CD**

1.13.109 Appropriate packaging will be sent to patients in advance with instructions for packaging any returned medicines and this will be provided and paid for by the pharmacy. The Superintendent Pharmacist will specify the appropriate method of collection depending on the items being returned and the distance from the pharmacy. Patients may also be signposted to alternate pharmacies if they prefer to return medicines to a different pharmacy. Any ‘returned’ Controlled Drugs must not be re-used or entered into the CD register. We will denature and render them irretrievable as soon as possible to avoid storage problems and an increased security risk.

1.13.110 Destruction must be witnessed by another member of staff. If not immediately destroyed, they should be segregated from main stock, clearly marked 'Patient Returns' to minimise the risk of errors and inadvertent supply and stored securely in a CD Cabinet waiting to be denatured. A record of destruction will be recorded in a separate CD Destruction Register designated for this purpose and will be available in the pharmacy for inspection.

1.13.111 **Cover for Breaks / Working Time Directive**

1.13.112 Any breaks in working time taken by the RP will be covered by a second pharmacist who will then assume the responsibility of the RP.

1.13.113 **Contingency Planning**

1.13.114 We will have accounts direct to pharmacy manufacturers and many full-line and short-line pharmaceutical wholesalers to try and increase the availability of stock and reduce Owings. A Contingency Plan will be in place to ameliorate the effects of any disruption to the provision of pharmaceutical services such as medicines shortage, postal strike, EPS systems failure, etc.

1.13.115 **Verification of Declarations of Prescription Exemptions**

1.13.116 The reverse of the prescription should be fully completed (other than age-exempt patients) in black ink.

1.13.117 Where evidence of exemption is required or provided by the patient it can be sent to the pharmacy for verification via the delivery driver and then returned to the patient. The PMR system will be updated to reflect that the necessary check has been carried out and a note of when the next check is required should be entered into the system. The Regulations require a patient to produce 'satisfactory evidence' to confirm exemption. Where appropriate (i.e. for deliveries made other than by the pharmacy's delivery driver), the patient may scan or fax copies of the evidence to the pharmacy (or use the postal / courier service) and the pharmacy can record that the evidence provided was not in the original format. It is for the pharmacist in charge to determine if the evidence is satisfactory or not and, if not, then cross the 'Evidence not Seen' box.

1.13.118 The type of exemption and date of expiry will be recorded in their Patient Medication Record. If they are not exempted prescription charge payments will be made using a secure online payment method.

1.13.119 Exemptions may be sent to the pharmacy by post and the pharmacy will pay for postage and return the exemption to the patient free of charge. Faxed and scanned email copies of exemptions are also acceptable. The nature of any exemption will be recorded on the PMR system with a copy attached to the patient's file.

1.13.120 Payment for prescription charges will be received via the secure payment portal on the website (e.g. Sagepay) and when payment is received the prescription will be marked as paid.

1.13.121 **Registration of the Premises with the GPhC**

1.13.122 We understand that it is not lawful to operate a Pharmacy without registering the premises and Superintendent Pharmacist with the GPhC. We will apply to register the premises with the GPhC following the grant of an NHS Contract application. The GPhC will send an inspector to inspect the premises for approval before commencement of any Pharmacy services.

1.13.123 **Practice leaflet**

1.13.124 Nothing in the Pharmacy's practice leaflet, or publicity material, including the website, will represent, either expressly or impliedly, that—

1.13.124.1 the essential services provided at or from the premises are only available to persons in particular areas of England, or

1.13.124.2 the Pharmacy is likely to refuse, for reasons other than those provided for in our terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms that are presented by categories of patients (for example, because the availability of essential services from the Pharmacy is limited to other categories of patients)."

2 The Decision

The Commissioner considered and decided to grant the application. The decision letter dated 9 July 2024 states:

[Any reference to 'Committee' in this section is not to be confused with the Pharmacy Appeals Committee of NHS Resolution]

2.1 “West Yorkshire ICB has considered the above application and I am writing to confirm that it has been granted. Please see the enclosed report for the full reasoning.”

PSRC report

2.2 “WY – Enhanced Care Pharmacy Ltd.

2.3 2a School Street, Clayton, Bradford, BD14 6AS.

2.4 SR presented a paper for a DSP in a non-controlled locality. The FtP was granted on the 31st of May 2024.

2.5 Regulation 31 does not apply as there is no pharmacy at the same or adjacent premises to the proposed site, nor is there any suggestion that any of the nearby pharmacies are in any way connected with this application. There are eight existing providers of Pharmaceutical Services within 1.3 miles of the application, with the closest being 0.1 of a mile away according to NHS.UK.

2.6 Regulation 25(2)(b) does not apply as the applicant has demonstrated how services will be provided remotely, and without interruption throughout the given opening hours. The applicant has provided assurance in the application form and the additional information that the specific conditions set out in Regulation 64 are met.

2.7 Representations were received from Boots UK Ltd, Gorgemead Ltd, CPWY and Raj’s Chemist. Boots UK Ltd and Gorgemead asked Committee members to be fully satisfied that the application meets the requirements of the Regulations. Representations made by CPWY refer to WY ICB being assured that Regulations 25(2)(a) and 25(2)(b) are met and ensure that all aspects of the Regulations are adhered to and feel assured that the applicant will be able to provide pharmaceutical services throughout the proposed contracted hours. Raj’s Chemist provided a four-page representation setting out why the application should not be granted. Although comprehensive, the issues raised by Raj’s Chemist do not illustrate that the application does not meet the required regulations. The applicant had addressed the issues raised in the representations.

2.8 SR recommended that the application is granted on the grounds that the applicant has met the requirements set out in Regulation 25 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and has demonstrated that they will comply with the specific conditions placed on DSPs as set out in Regulation 64.

2.9 The Committee considered the application. It was agreed that the supporting information and the applicant’s response to the representations given were robust. The Committee agreed that the contractor had met all regulatory requirements for a DSP application.

2.10 The Committee considered whether Raj’s Chemist had a right of appeal. The Committee unanimously agreed that Raj’s Chemist does have a right of appeal considering that they had submitted substantial comments against this application.

2.11 PSRC Decision: Having considered all the information provided by the contractors and the regulations, the PSRC granted this application.

2.12 Right of Appeal: Raj’s Chemist.”

Extract from the paper presented to PSRC

2.13 “This is an application (enclosed as Appendix A) [1.1 to 1.7 above] from 2a School Street, Clayton, Bradford, BD14 6AS for Distance Selling Premises. The applicant has submitted supporting information (enclosed as Appendix B) [1.8 to 1.13.124.2 above].

2.14 Regulation 31

2.15 Regulation 31 does not apply as there is no pharmacy at the same or adjacent premises to the proposed site, nor is there any suggestion that any of the nearby pharmacies are in any way connected with this application.

2.16 There are 8 existing providers of Pharmaceutical Services within 1.3 miles of the application the closest being 0.1 of a mile away according to NHS.UK. Attached at Appendix C is the interested parties list.

2.17 Regulation 25 Distance Selling premises applications

2.18 Regulation 25 (2) (a) - does not apply as no primary care provider with a patient list is present within the same premises as the proposed site.

2.19 Regulation 25(2)(b) - does not apply as the applicant has demonstrated how services will be provided remotely, and without interruption throughout the given opening hours.

2.20 Regulation 64 - Regulation 64 sets out the specific conditions to be met by applications for Distance Selling Premises:

2.20.1 The applicant must not offer to provide pharmaceutical services, other than directed services, to persons who are present or in the vicinity of the pharmacy premises.

2.20.2 The means by which persons receive services from the pharmacy must be otherwise than at the pharmacy premises.

2.20.3 The pharmacy premises must not be on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

2.20.4 The pharmacy procedures must ensure the uninterrupted provision of essential services, during the pharmacy opening hours, to persons anywhere in England who request the services and must ensure the safe and effective provision of essential services without face-to-face contact between the person receiving the services and the pharmacy staff.

2.20.5 The pharmacy must not produce any practice leaflet, publicity material or any other communication, which expressly or impliedly states that access to the essential services provided by the pharmacy are only available to persons in particular areas of England or that the pharmacy is likely to refuse to provide essential services or prescribed drugs or appliances to particular categories of patients.

2.21 The applicant has provided assurance in the application form (Appendix A) [1.1 to 1.7 above] and the additional information (Appendix B) [1.8 to 1.13.124.2 above] that the specific conditions set out in regulation 64 are met."

3 The Appeal

In a letter dated 5 August 2024, received 6 August 2024, Raj's Chemist ("the Appellant") appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "Please find below my statement of the grounds for my appeal to the granting of the above application.

3.2 Local data from the Integrated Care Board (ICB) regarding DSP's shows that out of 40 DSP's only 3 appear to offer a service to patients anywhere in the country during

opening hours and so must be considered before granting an application with regards to its intended purpose.

3.3 As stated, within a 1.3-mile radius of the application, there are 8 established Pharmaceutical Service providers, with the nearest one located just 0.1 mile away as reported by NHS.UK. The latest Pharmaceutical Needs Assessment shows that there is no additional need for pharmacy delivery services in the local area. There are existing DSPs in Bradford.

3.4 It is essential to ensure that the local pharmacies offering community pharmacy services in the area are not unduly burdened by the presence of pharmacies that operate under the guise of Distance Selling Pharmacies. It is imperative that patients local in the area are not misled into believing that a pharmacy they cannot physically access can adequately provide them with the personalized care and services that a truly local pharmacy can offer.

3.5 It has been stated that the pharmacy (a) must not produce any communication, which expressly or impliedly states that access to the essential services provided by the pharmacy are [sic] only available to persons in particular areas of England or (b) that the pharmacy is likely to refuse to provide essential services or prescribed drugs or appliances to particular categories of patients.

3.6 Regarding (a) above …this will have to be monitored and assurances that if the application is successful that any occurrences of this are dealt with swiftly and as a breach of contract terms of service.

3.7 Regarding (b) above … as an example, a category of patient common in the locality and throughout society are substance misuse clients receiving treatment, often supervised and they must not be refused yet may receive other prescribed drugs and this poses a threat to this critical continuous treatment. Drug dependency services rely on local pharmacies being physically accessible to provide methadone, buprenorphine etc. and its supervision to clients and the application cannot provide this in addition to offering DSP services to these patients.

3.8 It has been stated that DSPs must ensure the safe and effective provision of essential services WITHOUT face-to-face contact between the person receiving the services and the pharmacy staff.

3.9 Regarding this it must be taken to include any local delivery drivers as they are pharmacy staff and ensuring they not visit local patients face-to-face.

3.10 The NHS Act 2006 provides for remuneration for contractors to be directed in particular ways and these include: Section 165 – the desirability of promoting pharmaceutical services which are of an appropriate standard.

3.11 Regarding this, just as one example, there are many times when in an emergency a patient and / or their relatives must visit into their local pharmacy needing to discuss their medicines with staff, often presenting the medication for discussion not knowing what they are and to identify the presented medication. In these cases, being physically present is crucial and provides a high level of service of the appropriate standard expected which a DSP cannot provide. Another example would be the Discharge Medicines Service which is a complex service and often requires patients to be able to return to the pharmacy and the DSP without patient facing services cannot provide to high standards expected and so putting patients at risk.

3.12 Opportunistic health services, such as Stop Smoking, Blood Pressure checks etc are provided at point of contact with patients, the DSP minimises such opportunities within the community by preventing local pharmacies from dispensing services to patients who are registered with local GP services.

3.13 The introduction of a new distance-selling pharmacy will disrupt the local pharmacy market and result in decreased revenue for established pharmacies, from already reduced funding, potentially affecting the level of service and care the existing local services provided to patients.

3.14 In the public view a distance-selling pharmacy is not subject to the same urgent care expectations and responsibilities as bricks and mortar pharmacies and so devaluing the face of Pharmacy.

3.15 I wish my appeal against this application to be considered for the above reasons and in that the establishment of a distance-selling pharmacy will threaten the viability of existing local pharmacies, potentially limiting access to critical healthcare services for patients who rely on local pharmacies for their medication needs from a face-to-face service.

3.16 Face to face contact is vital in a community pharmacy where practicable and adds value, quality and safety to the provision of medicines and challenging this will have a negative effect on the community.

3.17 The pharmacies in the area service the community with no complaints plus provide extra support particularly with staff that engage with the public and customers with queries and concerns about their health and medicines and it is imperative that these services built up over many years are not undermined and that the integrity of the pharmacy services in the community are maintained.

3.18 The above points raise serious concerns regarding the potential impact of this application on the public, the community, local pharmacies and existing services. Preserving an accessible healthcare environment is essential for the well-being of our community and the quality of care provided to our patients.

3.19 In light of these grounds, I appeal against the granting of the application."

4 Summary of Representations

This is a summary of representations received on the appeal.

4.1 Community Pharmacy West Yorkshire

4.1.1 "Community Pharmacy West Yorkshire members still feel that their comments made in their letter to Sameena Arif on 11th March 2024 are valid. These were as follows.

4.1.2 In considering this application members were mindful of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

4.1.3 Community Pharmacy West Yorkshire members would like to make the following observations:

4.1.3.1 NHS England must be assured that Regulations 25(2)(a) and 25(2)(b) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 do not apply.

4.1.3.2 The applicant must give NHS England assurance that they will be able to provide pharmaceutical services throughout the contracted hours.

4.1.3.3 NHS England will be aware of the decision made by NHS Resolution with regard to the Pharmacy 2 U (P2U) application in Leicestershire (SHA/22233) [appendix A]. CPWY are sure that NHS England will want to reflect on the areas where the P2U application was felt to be

lacking and ensure that this application is not subject to the same or similar concerns.

4.1.3.4 NHS England makes reference to previous applications for Distance-Selling pharmacies that have been refused upon appeal including the West Yorkshire applications SHA/18299 - May 2016 [appendix B] and SHA/18727 - Sept 2017 [appendix C]."

4.2 The Applicant

4.2.1 "Please find below our response to the letter of appeal submitted by Mr. G of Raj's chemist. It is to be noted that Mr. G had initially made a representation against our application for inclusion in the pharmaceutical list. We provided a response to this representation by Mr. G, and our application was subsequently granted. It is of utmost importance to note that the points made by Mr. G in his recent letter of appeal (5th August 2024) are the exact same points raised in his initial representation against our application. The PSRC in their decision report (Appendix 1) [2.4 to 2.21 above] agree that our supporting information and response to the representation by Raj's Chemist (the points of which have now been repeated in this letter of appeal) are 'robust', thus concluding that we have met the requirements set out in Regulation 25 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and have demonstrated how we will comply with specific conditions placed on DSPs as set out in Regulation 64. The PSRC also state in the decision report that, '*Although comprehensive, the issues raised by Raj's Chemist do not illustrate that the application does not meet the required regulations*.'

4.2.2 Mr. G continues to make speculative comments without any substance in his letter of appeal, such as stating that DSPs 'devalue the face of Pharmacy'. Mr. G's grievances against DSPs in general are uncalled for. In light of the above facts, and due to Mr. G not having submitted any new information, please find below our response to his initial representation, the content of which also covers and responds to his letter of appeal.

4.2.3 Response to R G (Raj's chemist)

4.2.4 *'The premises are retail in nature – on a busy road, in a parade of other retail premises. There is currently a Tattoo shop; nail shop; tanning salon; take away and a barber along the same parade.'*

4.2.5 Our premises are based on a quiet, residential side street. There is low foot traffic, and our neighbouring units remain empty. Mr. G's reference to the current retail businesses present is of no significance, these businesses are based on a different, main road adjacent to our premises. NB: these businesses are based on Park Lane; our premises are based on School Street.

4.2.6 *'There will be an expectation of a retail service by the public.'*

4.2.7 This is a speculative comment of no value. For example, a DSP located in a trade park is still accessible to the public, as such there may still be a probable expectation of a retail service by the public.

4.2.8 *'Standard Operating Procedures have not been submitted so NHSE cannot possibly ascertain the procedure when members of the public invariably turn up. The explanatory notes to the application state 'This type of pharmacy is also referred to as 'distance selling premises' and operates under strict rules which means it is not able to provide services face to face at the premises. Given the 'strict rules' stated, NHSE will need to determine how it will enforce these 'strict rules'*

4.2.9 Submission of Standard Operating Procedures is not a requirement for an excepted application of a distance selling premises under regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. Processes to ensure adherence to Regulation 64(3)(a)(b) of the aforementioned are clearly detailed in the application and additional information.

4.2.10 The following is extracted from our additional information document (pg. 7-8) submitted with our application and made available to all interested parties:

4.2.10.1 Our wholly Internet/Delivery Pharmacy will operate from secure premises, with a controlled entry system, to which members of the public will not have access.

4.2.10.2 If a patient attends the premises and asks for one or more of the essential services:

4.2.10.3 Any patient who requests essential services to be provided at the premises will be informed that the pharmacy is not permitted to provide those services at the premises. They will be directed to our website or advised further on how to contact us where we can explain access to the provision of NHS Essential Services to them (see below).

4.2.11 *'No plan of the premises has been submitted.'*

4.2.12 *'Without a plan of the premises being submitted, NHSE cannot confirm that this application will NOT be retail in nature.'*

4.2.13 Where enhanced and/or advanced services will NOT be provided, submission of a floor plan is NOT a requirement for an excepted application of a distance selling premises under regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. We have made it clear in our application that we DO NOT intend to provide any enhanced and/or advanced services. NB: It is baseless to claim that not submitting a floor plan would effectuate a DSP to breaching the Terms of Service requirements.

4.2.14 Page 1 of the additional information document (made available to all parties) outlines how the premises will satisfy the requirements to fulfil paragraph 28 (2) (g) of Schedule 4 Part 4 to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (as amended). Furthermore, the premises will meet the General Pharmaceutical Council's requirements for a registered DSP premises. It will be inspected in person by a General Pharmaceutical Council inspector prior to achieving registration.

4.2.15 *'As SOP's have NOT been submitted NHSE cannot scrutinise the application to ensure it meets Reg64(3)d.'*

4.2.16 The additional information document (made available to all parties) covers in great breadth and depth how the pharmacy procedures used within the premises will secure:

4.2.16.1 Reg 64(3)(d)(i) - the uninterrupted provision of essential services during the opening hours of the premises, to persons anywhere in England who request those services, and

4.2.16.2 Reg 64(3)(d)(ii) - the safe and effective provision of essential services without face-to-face contact between any person receiving the services, whether on their own or someone else's behalf and the applicant or the applicant's staff.

4.2.17 *'There is currently ample provision in the area according to the Pharmaceutical Needs Assessment.'*

4.2.18 *'The latest Pharmaceutical Needs Assessment shows that there is no additional need for pharmacy delivery services in the local area. There are existing DSPs in Bradford.'*

4.2.19 The above statement is irrelevant to a DSP as we will provide a wholly national remote delivery service. As such, our patients would be drawn from a much wider catchment area, extending beyond the boundaries of any Primary Care Trust, therefore, a local Pharmaceutical Needs Assessment is of no relevance as we are not required to demonstrate a local need and our impact on the local market will be negligible.

4.2.20 *'If this application is granted it is highly likely that it will operate as a pseudo-DSP-'*

4.2.21 This is a highly speculative and baseless comment.

4.2.22 Mr. G further mentions proximity to other pharmacies, limiting access to such for patients who need a face-to-face service, and 'taking business away from local pharmacies'.

4.2.23 This is again, of no relevance. We will provide a wholly national service, patients wanting to access local brick and mortar pharmacies will still be able to do so. The additional information document (made available to all interested parties) clearly states procedures for emergency supplies and urgent delivery of medication, noting patients will not be charged extra for the fastest delivery method.

4.2.24 *'Discharge medicines services from hospitals are a complex service and may require patients to be able to return to the pharmacy with their medicines which are often in a Dossett box for checking, adjusting, face to face advice etc. and the DSP without patient facing service cannot provide putting patients at risk.'*

4.2.25 The procedure for return of medications to the pharmacy is covered in detail within the additional information document (made available to all parties).

4.2.26 *'Local Community Pharmacies are a source of advice, information, leaflets and posters advising on health and the application will have an impact on Community Health with reduced face to face contact in the community with pharmacy staff.'*

4.2.27 The additional information document (made available to all parties) covers in detail how the DSP will partake in promotion of healthy lifestyles and public health campaigns e.g. through posted leaflets, website, lifestyle questionnaires.

4.2.28 *'In the public view a distance-selling pharmacy is not subject to the same urgent care expectations and responsibilities as bricks and mortar pharmacies and so devaluing the face of Pharmacy.'*

4.2.29 This is incorrect. DSP patients are one and the same as bricks and mortar pharmacy patients. Both have the probable need for an urgent supply of medication and urgent care requirements e.g. urgent antibiotics. The additional information (made available to all parties) covers the processes for the urgent delivery of medications."

5 Summary of Observations

No observations were received by NHS Resolution in response to the representations received on appeal.

6 Consideration

6.1 The Pharmacy Appeals Committee ("Committee") appointed by NHS Resolution, had before it the papers considered by the Commissioner.

6.2 It also had before it the responses to NHS Resolution's own statutory consultations.

6.3 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 the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations").

Regulation 31

6.5 The Committee first considered Regulation 31 of the Regulations which states:

(1) A routine or excepted application, other than a consolidation application, must be refused where paragraph (2) applies.

(2) This paragraph applies where -

(a) a person on the pharmaceutical list (which may or may not be the applicant) is providing or has undertaken to provide pharmaceutical services ("the existing services") from -

(i) the premises to which the application relates, or

(ii) adjacent premises; and

(b) NHS England is satisfied that it is reasonable to treat the services that the applicant proposes to provide as part of the same service as the existing services (and so the premises to which the application relates and the existing listed chemist premises should be treated as the same site).

6.6 The Committee noted that the Applicant had not provided any information in the application form on this point but the Committee noted that the wording of the application form only required the Applicant to include information in the relevant section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee considered it reasonable to determine that the lack of information in the application form on this point when read with the wording of the application form allowed it to be reasonably satisfied that the Applicant considered that the proposed premises were not adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises.

6.7 In the decision letter, the Commissioner stated that *"Regulation 31 does not apply as there is no pharmacy at the same or adjacent premises to the proposed site, nor is there any suggestion that any of the nearby pharmacies are in any way connected with this application."* The Committee noted this had not been disputed by any party.

6.8 The Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

6.9 The Committee had regard to Regulation 25 of the Regulations which reads as follows:

"(1) Section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) does not apply to an application—

(a) for inclusion in a pharmaceutical list by a person not already included; or

(b) by a person already included in a pharmaceutical list for inclusion in that list in respect of premises other than those already listed in relation to that person,

in respect of pharmacy premises that are distance selling premises.

(2) NHS England must refuse an application to which paragraph (1) applies—

(a) if the premises in respect of which the application is made are on the same site or in the same building as the premises of a provider of primary medical services with a patient list; and

(b) unless NHS England is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure—

(i) the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and

(ii) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff."

6.10 The Committee also had regard to the provisions of Schedule 2 to the Regulations shown below:

Additional information to be included with excepted applications

8. *If the applicant (A) is making an excepted application, A must include in that application details that explain—*

(a) A's belief that the application satisfies the criteria included in one of the regulations in Part 4 which need to be satisfied if section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) are not to apply in relation to that application; and

(b) if the regulation includes reasons for which the application must be refused, why the application should not be refused for those reasons.

Nature of details to be supplied

10. *Where, pursuant to this Part, a person is required to provide details, that obligation is only discharged if the information or documentation provided is sufficient to satisfy NHS England in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that NHS England may need to make of the information or documentation when carrying out its functions.*

Regulation 25(1)

6.11 In relation to Regulation 25(1), the Applicant is applying for inclusion in the relevant pharmaceutical list, as a person not already included in a pharmaceutical list, and

paragraph (1)(a) therefore operates to disapply the specified provisions of section 129 of the National Health Service Act 2006, provided that paragraph (2) does not require the application to be refused.

Regulation 25(2)(a)

6.12 As far as Regulation 25(2)(a) is concerned, the Committee noted that the Applicant had not included any information in the relevant section of the application form that deals with this point. The Committee noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Commissioner it is decision report stated that "*Regulation 25 (2)(a) does not apply as no primary care provider with a patient list is present within the same premises as the proposed site."*

6.13 Based on the information available to it, which had not been disputed by any party, the Committee therefore determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

6.14 As far as Regulation 25(2)(b) is concerned, the Committee considered the information which had been provided by the Applicant in relation to its procedures for the provision of essential services, including the "additional info" document provided with its application.

6.15 The Regulations require the Committee to be satisfied as to a number of matters, including that essential services will be provided on an uninterrupted basis, in a safe and effective way, across England, and without face to face contact.

6.16 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicates that the obligation is only discharged if the information or documentation provided is sufficient to satisfy the Commissioner in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the Commissioner may need to make of the information or documentation when carrying out its functions.

6.17 The Committee has asked itself whether it has sufficient information and documentation which would address the criteria in Regulation 25(2)(b). If the Committee is to be satisfied of the matters in that paragraph, the Committee must be provided with evidence to demonstrate these matters. In this case, that evidence put forward has taken the form of the original application and the additional information document which includes extracts of the SOPs that the Applicant has prepared or commissioned.

6.18 It is not for the Committee to 'approve' or 'disapprove' these extracts (as they may contain matters not relevant to the Committee's consideration, and there are many ways an applicant can choose to organise itself in order to comply with the various requirements of the Regulations) and the Committee has not sought to do so. The Committee has sought evidence within the extracts of the SOPs, the application and the representations in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.

6.19 The Committee considered how the Applicant would provide essential services without interruption and noted the additional information document provided with the application form under the following headings:

6.20 Pharmacy Systems and Procedures

6.20.1 *"All Essential Services will be delivered in accordance with:*

6.20.1.1 Company Standard Operating Procedures

6.20.1.2 NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

6.20.1.3 NHS Act 2006

6.20.1.4 Human Medicines Regulations 2012

6.20.1.5 GPhC – Professional Standards and Guidance on Distance Selling Pharmacies

6.20.1.6 Relevant Data Protection laws

6.20.2 *This will ensure that we provide a safe, effective, and uninterrupted provision of all essential services."*

6.20.3 …"*The website will enable patients or their carers to communicate remotely but directly allowing quick and easy access and providing clear unambiguous details of how safe, efficient, and uninterrupted NHS Essential Services will be provided by the Pharmacist and qualified, knowledgeable, experienced support staff on duty throughout the opening hours of the pharmacy premises."*

6.21 Cover for Breaks / Working Time Directive

6.21.1 *"Any breaks in working time taken by the RP will be covered by a second pharmacist who will then assume the responsibility of the RP."*

6.22 Accountability

6.22.1 *"During opening hours there will always be a responsible pharmacist (RP) on site."*

6.23 With regard to services being available to persons anywhere in England, the Committee noted the additional information document provided with the application form under the following headings:

6.24 Pharmacy Systems and Procedures

6.24.1 *"All Essential Services will be delivered in accordance with:*

6.24.1.1 Company Standard Operating Procedures

6.24.1.2 NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

6.24.1.3 NHS Act 2006

6.24.1.4 Human Medicines Regulations 2012

6.24.1.5 GPhC – Professional Standards and Guidance on Distance Selling Pharmacies

6.24.1.6 Relevant Data Protection laws

6.24.2 *This will ensure that we provide a safe, effective, and uninterrupted provision of all essential services to persons anywhere in England who request those services during the opening hours of the premises."*

6.24.3 *… Access to information about the provision of NHS Essential Services will be achieved by using:*

6.24.3.1 Telephone

6.24.3.2 The website will enable patients or their carers to communicate remotely but directly allowing quick and easy access and providing clear unambiguous details of how safe, efficient, and uninterrupted NHS Essential Services will be provided by the Pharmacist and qualified, knowledgeable, experienced support staff on duty throughout the opening hours of the pharmacy premises without having 'face to face' contact with the patient or their representative.

6.24.3.3 Email

6.24.3.4 Postal services."

6.25 The Committee considered how the Applicant would provide essential services without face to face contact and noted the additional information document provided with the application form under the following headings:

6.26 Training

6.26.1 "*…extra training will be provided in the following areas:*

6.26.1.1 "communication skills to support staff in managing effective non-face-to-face communications with pharmacy users and prescribers."

6.27 Website

6.27.1 "*The website will display… Details of specific services available and how to use them, i.e…. Explanation of rules on non-face-to-face contact."*

6.28 Pharmacy Systems and Procedures

6.28.1 *"…uninterrupted NHS Essential Services will be provided by the Pharmacist and qualified, knowledgeable, experienced support staff on duty throughout the opening hours of the pharmacy premises without having 'face to face' contact with the patient or their representative."*

6.28.2 *"Our wholly Internet/Delivery Pharmacy will operate from secure premises, with a controlled entry system, to which members of the public will not have access. "*

6.28.3 *"Any patient who requests essential services to be provided at the premises will be informed that the pharmacy is not permitted to provide those services at the premises."*

6.28.4 *"Essential Services may be delivered using:*

6.28.4.1 Telephone, including text messaging where appropriate.

6.28.4.2 Electronic Prescription Service (EPS)

6.28.4.3 Website

6.28.4.4 Email

6.28.4.5 Royal Mail postal service

6.28.4.6 Courier service

6.28.4.7 …free video-conferencing services such as Skype or Zoom

6.28.4.8 Specialist cold chain courier."

6.29 The Committee was aware that when the pharmacy opens, it will be the responsibility of the Commissioner, in keeping with Regulation 64, to ensure that services are provided other than with face to face contact.

6.30 The Committee was satisfied that the provision of services would be without interruption, without face to face contact and would be available to persons anywhere in England. The Committee went on to consider whether safe and effective provision of essential services was likely to be secured.

6.31 The Committee considered each essential service in paragraphs 3 to 22 of schedule 4 of the Regulations ("Terms of Service") in turn.

6.32 The Committee paid particular attention to the following aspects of the essential services, which it considered were more difficult to provide safely and effectively in a distance selling context:

6.32.1 Dispensing of drugs and appliances

6.32.2 Urgent supply without a prescription

6.32.3 Preliminary matters before providing ordered drugs or appliances

6.32.4 Providing ordered drugs or appliances

6.32.5 Refusal to provide drugs or appliances ordered

6.32.6 Further activities to be carried out in connection with the provision of dispensing services

6.32.7 Disposal service in respect of unwanted drugs

6.32.8 Promotion of healthy lifestyles

6.32.9 Prescription linked intervention

6.32.10 Health campaigns

6.32.11 Signposting

6.32.12 Support for self-care

6.32.13 Discharge medicines service

6.32.14 Websites and health promotion zones

6.33 The Committee was of the opinion that the procedures adopted by the pharmacy were not likely to secure the safe and effective provision by the Applicant of the following essential services:

Providing ordered drugs or appliances

6.34 The Committee considered whether the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that (i) the 'cold chain' is maintained, where relevant, and (ii) that the requirements of the Misuse of Drugs Regulations 2001 and, in particular, Regulations 14 and 16, are met).

6.35 In relation to cold chain deliveries, under the following headings in the additional information document, the Committee noted:

6.36 Delivering Medicines

6.36.1 *"The RP must take adequate measures to ensure that the delivery mechanism used is secure and that medicines are delivered to the intended user promptly, safely, and in a condition appropriate for use. If the delivery to patients is local, this will be undertaken by the delivery driver. All other nationwide deliveries (other than fridge lines) will be delivered by Royal Mail special delivery or courier and signed for by the patient, their notified carer, or another patient-authorized representative."*

6.36.2 *"A list of the approved cold chain couriers is available within the Pharmacy.*

6.36.3 *Cold chain items should be stored in Styrofoam-filled cardboard boxes before being passed to the courier and marked with the "FRAGILE" and "FRIDGE LINE" stickers. Additional packing will not be required as the courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box and are fully monitored.*

6.36.4 *Pharmacy staff will be aware that some thermolabile products can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in medicines which is damaging to them. The courier service is a dedicated, fully monitored and temperature-controlled delivery service.*

6.36.5 *Any breach of the cold chain is automatically notified to the driver who will then follow the failed delivery procedure and notify the pharmacy accordingly so that re-delivery can be arranged. Where the cold chain breach notice is issued items will not be re-used."*

6.36.6 *"The delivery mechanism used will provide a verifiable audit trail for medicine from the initial request through to its final delivery, or its return to the pharmacy in the event of a delivery failure."*

6.37 Pharmacy Systems and Procedures

6.37.1 *"Specialist cold chain courier services will ensure the integrity of the cold chain and the maximum stability of thermo-liable drugs by packing, transporting, and delivering in such a way that their integrity, quality, and effectiveness are always preserved. This will be a dedicated, fully monitored and temperature-controlled delivery service."*

6.38 Equipment and Facilities

6.38.1 *"All equipment will be subject to annual performance testing and review, with specialist equipment (such as temperature monitoring) subject to monthly checks."*

6.39 The Committee noted that the above information was relevant to a specialist courier however it was also mindful that deliveries would also be made by its own delivery driver. With regard to local deliveries, the Committee noted that no information was provided to outline how the local delivery driver would audit and monitor the temperature whilst the medication is out for delivery. The Committee was therefore not satisfied that the cold chain would be maintained during local deliveries.

6.40 In relation to deliveries of controlled drugs, under the following headings in the additional information document, the Committee noted:

6.41 Delivering Medicines

6.41.1 *"The RP must take adequate measures to ensure that the delivery mechanism used is secure and that medicines are delivered to the intended user promptly, safely, and in a condition appropriate for use. If the delivery to patients is local, this will be undertaken by the delivery driver. All other nationwide deliveries (other than fridge lines) will be delivered by Royal Mail special delivery or courier and signed for by the patient, their notified carer, or another patient-authorized representative."*

6.41.2 *"A patient who is not at home when delivery is attempted will be informed using a non-delivery notice and an alternative delivery date will be arranged."*

6.42 Controlled Drugs

6.42.1 *"Delivery of Controlled Drugs*

6.42.2 *There is a provision within controlled drugs legislation to cover occasions when a controlled drug (CD) may temporarily be in the possession of a third party, e.g. a delivery person or postal carrier, while it is being transferred from one authorized person to another authorized person who is entitled to have the drug. Delivery of CDs will be carried out by couriers with pharma-grade specialist facilities to meet specific quality and validation requirements for healthcare products. This includes Home Office-licensed controlled drug stores. The couriers will have the following UK Licenses and Standards:*

6.42.2.1 MHRA Wholesale Dealer License

6.42.2.2 MHRA Manufacturers importers License

6.42.2.3 MHRA IMP License

6.42.2.4 ISO 9001: 2000 Certified

6.42.2.5 Meet all Home Office safe custody and record-keeping requirements.

6.42.3 *Return and Destruction of CD*

6.42.4 *Appropriate packaging will be sent to patients in advance with instructions for packaging any returned medicines and this will be provided and paid for by the pharmacy. The Superintendent Pharmacist will specify the appropriate method of collection depending on the items being returned and the distance from the pharmacy. Patients may also be signposted to alternate pharmacies if they prefer to return medicines to a different pharmacy. Any 'returned' Controlled Drugs must not be re-used or entered into the CD register. We will denature and render them irretrievable as soon as possible to avoid storage problems and an increased security risk.*

6.42.5 *Destruction must be witnessed by another member of staff. If not immediately destroyed, they should be segregated from main stock, clearly marked 'Patient Returns' to minimise the risk of errors and inadvertent supply and stored securely in a CD Cabinet waiting to be denatured. A record of destruction will be recorded in a separate CD Destruction Register designated for this purpose and will be available in the pharmacy for inspection."*

6.43 The Committee noted the procedure that would be followed if the patient made a request to return a controlled drug but there was very little information provided as to the procedure that would be followed by either the delivery driver or Royal Mail/courier if there was a missed or failed delivery. The Committee noted there was no information regarding a tracking system and an explanation given as to how this would allow the Applicant to ensure that it is aware on a regular basis of the safe progress of the dispensed items to the patient, whether over short distances or to further afield.

6.44 Further the Committee noted that "*the RP must take adequate measures to ensure that the delivery mechanism used is secure"* but no further assurance had been provided to outline the measures that will be in place to ensure controlled drugs are kept secure when out for delivery for example if the items will be stored in a locked delivery vehicle and not left unattended.

6.45 Based on the information before it, the Committee was not satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

Further activities to be carried out in connection with the provision of dispensing services

6.46 The Committee considered whether the Applicant had explained how appropriate advice about the benefits of repeat dispensing is given to any patient who (i) has long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term), and (ii) requires regular medicine in respect of that medical condition.

6.47 The Committee noted under the heading "Repeat Dispensing Services":

6.47.1 *"The Terms of Service require pharmacy contractors to ensure that appropriate advice about the benefits of repeat dispensing is given to any patient who—*

6.47.1.1 has a long-term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term), and

6.47.1.2 requires regular medicine in respect of that medical condition, including, where appropriate, advice that encourages the patient to discuss repeat dispensing of that medicine with a prescriber at the provider of primary medical services whose patient list the patient is on.

6.47.2 *Such advice will be provided by the Pharmacy using its permissible methods of non-face-to-face contact with patients.*

6.47.3 *Dispensing of repeat NHS prescriptions including those dispensed in dosette boxes as may be required under the Equality Act 2010 will be carried out in partnership with patients, carers, pharmacists, and prescribers. It will cover requirements additional to those for dispensing, assessing the patient's need for repeat supply. Any clinical issues identified will be addressed to the prescriber. Where considered necessary by a pharmacist, the patient may be contacted by telephone and given verbal advice in addition to information delivered with the repeat prescription.*

6.47.4 *For a successful implementation, we will have SOPs relevant to the process of repeat dispensing for paper and electronic NHS prescriptions and private prescriptions respectively, to ensure that staff are appropriately trained in the entire repeat dispensing process. Training will also be supplemented by third-party resources e.g. CPPE e-Learning.*

6.47.5 *Before each delivery, the patient will be asked (over the phone) if there are any changes to their therapy if they are experiencing any side effects or taking any new medication over the counter. The pharmacist will then with this information make a judgement as to whether the medication is appropriate to supply or not. Or whether any changed to the patient's health may indicate a review with the prescriber.*

6.47.6 *The pharmacy team will let the patient know, via text/email/phone call:*

6.47.6.1 How often they are due medication (weekly, monthly, bi-monthly, etc.)

6.47.6.2 When the last batch of medication will be dispensed and when to arrange an appointment with their GP for a new batch of prescriptions to be authorized (a 'last batch' reminder slip will also be put into the patient's medication bag to further remind them and ensure they do not forget to arrange an appointment.

6.47.6.3 We will ask them how they are managing their condition and may refer them back to the GP.

6.47.6.4 They can stop at any time or change pharmacies at any point. All new patients to the service will receive an initial phone call explaining the repeat dispensing process and how it works.

6.47.6.5 The patient will be made aware of the different methods of contacting the pharmacy to manage their repeat dispensing should they need to. For example, if they are to go on holiday and need an advance supply, or if they have any queries in general."

6.48 Whilst the Applicant had outlined the above, the Committee was of the view that the Applicant had not described how the benefits of this service would be provided to those patients who were not already in receipt of repeat dispensing.

6.49 The Committee was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.

Discharge medicines service

6.50 The Committee considered whether the Applicant had explained how it will provide advice, assistance and support to and in respect of a health service patient – (a) recently discharged from hospital who is referred to P for advice, assistance and support in respect of the patient's medication regimen by the staff of the hospital in which the patient stayed; or (b) who is otherwise referred to P for advice, assistance and support in respect of the patient's medication regiment by the staff of an NHS trust and NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.

6.51 The Committee noted the following under the heading "Provision of NHS Essential Services" in the additional information document:

6.51.1 "*We will provide all the essential services as outlined in the NHS contractual framework. These are as follows…Discharge medicine service."*

6.52 The Committee noted the Appellant's following statement in the appeal:

6.52.1 *"Discharge Medicines Service which is a complex service and often requires patients to be able to return to the pharmacy and the DSP without patient facing services cannot provide to high standards expected and so putting patients at risk."*

6.53 The Committee then noted the Applicant's response in their representations:

6.53.1 *"The procedure for return of medications to the pharmacy is covered in detail within the additional information document (made available to all parties)."*

6.54 The Committee had regard to the additional information document and could not see a section covering "Return of Medications" however it did note the information under the heading "Disposal of Unwanted Medicines" and assumed this was the section the Applicant was referring to. However, the information contained under this section as well as the other information in the document makes no reference to the procedure the Applicant will follow if a patient who has recently been discharged from hospital is referred to them for advice and support.

6.55 Further the Committee considered whether the Applicant had explained what procedures it has in place for checking referrals for the discharge medicines service.

6.56 The Committee noted that there was no reference in any of the supporting information provided by the Applicant either in the original application form or in their representations that refers to the procedures in place for checking referrals for the discharge medicines services.

6.57 The Committee was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

6.58 In relation to all other essential services, the Committee was, on balance, satisfied that procedures adopted by the pharmacy (and general adherence to the Terms of Service) would be "likely to secure" safe and effective provision.

Summary

6.59 On the information before it, the Committee could not be satisfied that there are procedures likely to secure safe and effective provision of essential services as required by Regulation 25(2)(b).

6.60 Pursuant to paragraph 9(1)(a) of Schedule 3 to the Regulations, the Committee may:

6.60.1 confirm the Commissioner's decision;

6.60.2 quash the Commissioner's decision and redetermine the application;

6.60.3 quash the Commissioner's decision and, if it considers that there should be a further notification to the parties to make representations, remit the matter to the Commissioner.

6.61 As the Committee had reached a different decision to the Commissioner, the Committee determined that the decision of the Commissioner must be quashed.

6.62 The Committee considered whether there should be a further notification to the parties detailed at paragraph 19 of Schedule 2 of the Regulations to allow them to make representations if they so wished (in which case it would be appropriate to quash the original decision and remit the matter to the Commissioner) or whether it was preferable for the Committee to reconsider the application.

6.63 The Committee noted that representations on Regulation 25 had already been made by parties to the Commissioner, and these had been circulated and seen by all parties as part of the processing of the application by the Commissioner. The Committee further noted that when the appeal was circulated representations had been sought from parties on Regulation 25.

6.64 The Committee concluded that further notification under paragraph 19 of Schedule 2 would not be helpful in this case.

7 Decision

7.1 The Committee concluded that it was not required to refuse the application under the provisions of Regulation 31.

7.2 Accordingly, the Committee:

7.2.1 quashes the decision of the Commissioner; and

7.2.2 redetermines the application as follows -

7.2.2.1 the Committee was satisfied that the proposed premises were not adjacent to or in close proximity to other chemist premises,

7.2.2.2 the Committee was satisfied that the premises of the Applicant are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list,

7.2.2.3 the Committee was satisfied that all essential services were likely to be secured without interruption during the opening hours,

7.2.2.4 the Committee was satisfied that all essential services were likely to be secured for persons anywhere in England,

7.2.2.5 the Committee was not satisfied that all essential services were likely to be secured in a safe and effective manner,

7.2.2.6 the Committee was satisfied that all essential services were likely to be secured without face to face contact;

7.2.3 The application is refused.

Case Manager
Primary Care Appeals