19 December 2024

REF: SHA/ 26337

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APPEAL AGAINST NHS WEST YORKSHIRE ICB DECISION TO GRANT AN APPLICATION BY ALCHEMY ENTERPRISES LIMITED FOR INCLUSION IN THE PHARMACEUTICAL LIST AT UNIT 4 DRUMHILL HOUSE, CLAYTON LANE, CLAYTON, BRADFORD, WEST YORKSHIRE, BD14 6RF 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:
Alchemy Enterprises 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 1 June 2024, Alchemy Enterprises Limited ("the Applicant") applied to West Yorkshire ICB ("the Commissioner") for inclusion in the pharmaceutical list at Unit 4 Drumhill House, Clayton Lane, Clayton, Bradford, West Yorkshire, BD14 6RF 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 stated:

1.2.1 *"Not applicable as no pharmacy in same or adjacent premises."*

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 Attached document (schematic file) not to scale."*

1.8 NHS England has published premises standards that the Pharmacy will comply with. But not all these standards apply directly to distance selling premises.

1.9 The pharmacy will be a Healthy living Pharmacy and comply with ensuring premises and facilities are fit for purpose and engaging with the community to deliver consistently high quality health and well being services.

1.10 The pharmacy will be [sic] have facilities to allow for both phone (or other live audio link) and live video communication with patients in a manner which maintains patient confidentiality.

1.11 **GPhC Guidance**

1.12 The pharmacy will apply the current GPhC guidance for registered pharmacies providing pharmacy services at a distance, including on the internet.

1.13 We will have in place, prior to opening the following;

1.14 **Risk Assessment**

1.15 A Risk Assessment document to help identify and manage risks. The risk assessment will look at possible causes of harm to patients and what the pharmacy needs to do to minimise risk.

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

1.17 **Audit Procedures**

1.18 A regular audit programme will be in place. This will provide 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.

1.19 The audit will, at the very least, consider;

1.19.1 staffing levels and the training and skills within the team,

1.19.2 communication methods with patients, and between staff and other healthcare providers, including between hubs and spokes and with collection and delivery points (if applicable),

1.19.3 use of specialised equipment and new technology,

1.19.4 records of decisions to make or refuse a sale,

1.19.5 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),

1.19.6 systems and processes for secure delivery to patients,

1.19.7 any information about pharmacy services on the website,

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

1.19.9 feedback from patients and people who use the pharmacy services,

1.19.10 concerns or complaints received, and

1.19.11 activities of third parties, agents or contractors.

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

1.21 **Reactive Review**

1.22 This will be done if an audit identifies a problem:

1.22.1 if there is a change in the law,

1.22.2 a significant increase in the number of patients the pharmacy provides services to, or an increase in the range of services the pharmacy intends to provide,

1.22.3 a data security breach,

1.22.4 a change in the technology the pharmacy uses,

1.22.5 concerns or negative feedback are received from patients,

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

1.23 **Responsible pharmacist (RP)**

1.24 There will always be a responsible pharmacist (RP) on site during opening hours. Each area of work will have clear lines of accountability that will be set out by the superintendent pharmacist.

1.25 **Documentation and Records**

1.26 Records in the pharmacy will be scanned into the pharmacy IT system (including patient consent forms, queries, complaints, customer logs, sale refusals, and dispensing).

1.27 Records will be kept for a minimum period of 7 years or longer if specific legislation requires.

1.28 **Education and training**

1.29 The pharmacy will ensure that all staff are properly trained and competent to provide professional pharmacy services safely.

1.30 **Facility**

1.31 The facility will be registered with the GPhC prior to entry to the pharmaceutical list and will therefore comply with GPhC requirements for pharmacy premises.

1.32 **Internet site**

1.33 The website will be secure and follow information security management guidelines and the law on data protection.

1.34 The website will use secure facilities for collecting, using and storing patient details and a secure link for processing card payments.

1.35 The website will display;

1.35.1 the GPhC pharmacy registration number,

1.35.2 the name of the owner of the registered pharmacy,

1.35.3 the name of the superintendent pharmacist,

1.35.4 the name and address of the registered pharmacy that supplies the medicines,

1.35.5 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),

1.35.6 information about how to check the registration status of the pharmacy and the superintendent pharmacist,

1.35.7 details of specific services available and how to use them, i.e.

1.35.7.1 Return of unwanted medicines,

1.35.7.2 Patient Lifestyle Questionnaire,

1.35.7.3 How to register exemptions from NHS charges,

1.35.7.4 Promotion of Health Lifestyles and details of campaigns being undertaken,

1.35.7.5 Procedures for Emergency Supply,

1.35.7.6 Explanation of rules on non-face to face contact,

1.35.7.7 Annual patient survey,

1.35.7.8 Patient Information Leaflet,

1.35.7.9 The email address and phone number of the pharmacy,

1.35.7.10 Details of how patients and users of pharmacy services can give feedback and raise concerns,

1.35.7.11 Ensuring that robust identity check processes are in place to ensure that the medicines dispensed are delivered to the correct person,

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

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

1.35.7.14 GPhC internet logo (linked to register entry).

1.35.8 Where any medicines are sold online, the pharmacy will be registered with the appropriate agency for online pharmacies.

1.35.9 The pharmacy will display any required logo on every page of the website offering medicines for sale, even if they are already displaying the GPhC voluntary logo. The website will be regularly updated, clear and accurate and follow the GPhC guidance on websites.

1.35.10 The pharmacy will allow the public to access pharmaceutical services from the pharmacy premises via a website on which there is an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues. NOTE - this is a new requirement under the Regulations and does not allow access to essential pharmaceutical services in a face to face manner at the premises and only applies to access via the website.

1.36 **Availability and transparency**

1.37 The website and materials will specify the nature and type of services the pharmacy provides and who provides those services.

1.38 **Safe Management and supply of medicines**

1.39 The pharmacy SOPs provide the procedures for all staff to follow to ensure that the sale and supply of medicines in carried out in such a manner as to minimise risk to patients.

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

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

1.41 **IT and equipment**

1.42 All equipment will be provided from manufacturers that have designed the equipment specifically for pharmacy purposes. Monthly checks will be done with specialist equipment (such as temperature monitoring). All equipment will have annual performance testing and review.

1.43 IT equipment will comply with relevant security specifications and be regularly updated. Records access, will depend on the employee's level of authority and clearance which is assigned by the superintendent pharmacist.

1.44 **Standard Operating Procedures**

1.45 There will be Standard Operating Procedures that cover the procedures of this distance selling contract. If NHS England requires any further information about any aspect of the workings of the pharmacy, then the relevant SOP will be provided upon request.

1.46 **Pharmacy Systems and Procedures**

1.47 All Essential Services will be delivered in accordance with:

1.47.1 Company Standard Operating Procedures.

1.47.2 NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

1.47.3 NHS Act 2006.

1.47.4 Human Medicines Regulations 2012.

1.47.5 GPhC – Professional Standards and Guidance on Distance Selling Pharmacies.

1.47.6 Relevant Data Protection laws.

1.48 All essential services will operate without face to face contact between anyone receiving the services, whether on their own or someone else's behalf, and the pharmacy staff.

1.49 We will provide safe, effective and uninterrupted provision of all essential services to persons anywhere in England who request those services during the opening hours.

1.50 The distance selling pharmacy will operate from secure premises, incorporating a restricted entry system. No member of the public will have access.

1.51 The facility is located within a unit, of a former school, secluded from the public.

1.52 Any patient that requests essential services to be provided at the premises, we will apologise, and stipulate that the pharmacy is not permitted to provide those services at the premises and sent away. Entry will be refused at the door. If they require the medication urgently they will be signposted to other pharmacies.

1.53 Further, there will be a clear sign on the door advising that if a patient does not have an appointment they will not be seen for non-essential/ advanced or private pharmaceutical services. Patients with pre-booked appointments will be advised that the pharmacist will contact them through internet, telephone or video link.

1.54 Information pertaining to NHS Essential Services will be achieved by using:

1.54.1 Telephone , Live Video Call, Email, Postal services and free of charge (as stipulated in the NHS Act 2006).

1.55 The website will enable patients or their carers to communicate remotely but directly allowing quick and easy access and provide clear unambiguous details of how safe, efficient, 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.

1.56 Essential Services may be delivered using a variety of methods:

1.56.1 Telephone, including text messaging if needed, Electronic Prescription Service (EPS), Website, Email, Royal Mail postal service, Courier service, Specialist Waste Management Services and Live video services.

1.56.2 Cold chain courier services will transport and deliver medication. This will ensure the integrity of the cold chain and the maximum stability of thermo-liable drugs by packing, including the quality and effectiveness. This will be a dedicated, fully monitored and temperature controlled delivery service.

1.57 **Provision of NHS Essential Services**

1.58 **Dispensing Services**

1.59 Prescriptions will be received by the EPS, post, and fax. If the patient requests, we can collect from a surgery.

1.60 Each prescription will be clinically and legally assessed.

1.61 The pharmacist will follow Standing Operating Procedures if there are any issues with the prescription. The problems maybe either clinically or legally.

1.62 To resolve these issues before dispensing items, contacting the prescriber, may be involved.

1.63 If this is the case, speaking to the clinician may be needed as soon as possible, to make sure the patient receives their medication without delay.

1.64 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.

1.65 **Repeat Dispensing Services**

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

1.66.1 has a long term, stable medical condition, and

1.66.2 requires regular medicine in respect of that medical condition.

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

1.68 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.

1.69 It will cover requirements additional to those for dispensing, assessing the patients' 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.

1.70 Medicines will only be supplied where the pharmacist is satisfied that the patient is taking and is likely to continue to take the drug appropriately and is not suffering from any side effects which indicate the need or desirability to review the patient's treatment.

1.71 Methods that will be used to promote the repeat dispensing service will involve:

1.71.1 Discussion over the phone/ video link with the patient and explaining the following benefits:

1.71.1.1 improves access to regular medicines,

1.71.1.2 simplified one stop process for obtaining next supply of medicines,

1.71.1.3 regular contact with pharmacist to discuss medicines-related issues,

1.71.1.4 pharmaceutical support for self- care and the management of long-term conditions.

1.71.2 Online

1.71.3 Patient information leaflets. For potential patients identified through the screening process (see below) A leaflet will be added to the prescription bag with their medication entitled 'A new way to get your regular prescriptions' or 'do you get regular medicines?' published by NHSBSA.

1.72 **Screening process**

1.73 The screening process will be conducted during the clinical and accuracy checking of prescriptions.

1.74 Particulars that will be looked for will be the following:

1.74.1 patients on single, stable therapy, for example, levothyroxine,

1.74.2 patients with stable long term conditions on multiple therapy for example, hypertension, diabetes, asthma,

1.74.3 patients that can appropriately self manage seasonal conditions in preparing for, and during, a flu pandemic.

1.75 **Urgent Supply and Emergency Supply**

1.76 In the event of an Urgent Supply or Emergency Supply request, all staff will be aware of the procedures to be followed.

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

1.78 The request made by a prescriber must ensure the following:

1.78.1 The Pharmacist is satisfied that the request is from the appropriate authorised prescriber.

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

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

1.78.4 The medication is supplied in accordance with the prescriber's directions.

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

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

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

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

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

1.79.1 Interview

1.79.1.1 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.

1.79.2 Records

1.79.2.1 Any supply must be entered in the POM register on the day and record all the relevant details.

1.79.2.2 The words "Emergency Supply" should be on the label.

1.80 **Faxed Prescriptions**

1.81 A 'faxed prescription' or other forms of scanned prescriptions do 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 / scanned prescription can confirm that at the time of receipt a valid prescription is in existence, but no medicines should be supplied until the original prescription is received.

1.82 The pharmacist should not dispense against faxed prescriptions and instead should use the Emergency Supply procedures.

1.83 **Delivery of Urgent Supplies**

1.84 Given the nature of a request of this type, the Pharmacy will prioritise 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. The pharmacy will not charge any delivery fees to the patient.

1.85 **Disposal of Unwanted Medicines**

1.86 Patients will have a number of options for disposal of unwanted medicines.

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

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

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

1.90 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.

1.91 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.

1.92 Those medications that are not suitable for return via royal mail (eg sharps) or not suitable for them, then should be returned to an appropriate local pharmacy of their choice. A list of providers will sent to the patient.

1.93 **Promotion of Healthy Lifestyles**

1.94 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 also lifestyle questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.

1.95 Leaflets will be delivered to patients with their medication. Those identified 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.

1.96 **Active patients**

1.97 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.

1.98 **Passive patients**

1.99 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 which identifies the patient as having high blood pressure.

1.100 **Health Campaigns**

1.101 The Pharmacy will take part in national health campaigns to promote 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.

1.102 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.

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

1.103.1 a clinical audit carried out in a manner which is compatible with the NHSCB's arrangements for the receiving and processing of data from the audit, or

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

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

1.105 Patient will be signposted to health and social care providers and/or any other assistance available whenever necessary.

1.106 Where it appears to the pharmacist, 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, nonprescription medicines and lifestyle advice.

1.107 If a patient requires advice, treatment or support that the pharmacy cannot provide; but another provider, of which the pharmacy is aware, of health or social care services or of support services, the pharmacy will provide contact details of that provider to the patient.

1.108 **Referral for Certain Appliances**

1.109 Where the pharmacy is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within the pharmacy's normal course of business, the pharmacist will refer the prescription form or repeatable prescription to another NHS pharmacist, if the patient consents.

1.110 If the patient does not consent to a referral, Then the pharmacy will provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who can provide the service.

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

1.112 **Support for People with Disabilities**

1.113 This service will be provided in accordance with the Equality Act 2010. The pharmacy will make reasonable pharmaceutical adjustment to ensure that those who qualify for help under the Act are provided with the right compliance aids.

1.114 The pharmacy 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.

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

1.116 **Clinical Governance**

1.117 Although not an essential service, the pharmacy will be involved in and comply with all the components of clinical governance.

1.118 There will be compliance with standard operating procedures, patient safety incident and near miss reporting, demonstrating evidence of Pharmacist and Pharmacy Technician CPD, conducting clinical audits, patient surveys, and drug recalls.

1.119 '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.

1.120 All staff will be qualified or undergoing nationally accredited training.

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

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

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

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

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

1.125.1 Distributed via email, post and with delivery drivers / couriers,

1.125.2 References to “visiting” the pharmacy changes to reflect non face to face contact methods used.

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

1.127 **Information Governance**

1.128 The pharmacy will be registered and comply with Data Protection Act and the General Data Protection Regulation (GDPR) and with the Access to Health Records Act 1990.

1.129 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 in accordance with NHS and legal obligations on data security, protection and confidentiality.

1.130 The pharmacy will receive support from the PMR provide to ensure that continuous access to the Electronic Prescription System is maintained.

1.131 Two members of staff will have the ability to login to the PMS system on all days (where there are 2 or more staff members working) and the NHS mail system will be checked every day for both general emails and also for any referrals under the Discharge Medicines Service.

1.132 **Discharge Medicines Service ("DMS")**

1.133 When NHS patients are discharged from hospital or there is, for other reasons, a transfer of care of them between different providers of NHS services, community pharmacies may be asked to perform a three stage service in respect of the patient, principally linked to changes in medication.

1.134 The second and third stages of this service are linked to the first prescription presented post-discharge or post transfer. Issues of concern may be raised by the pharmacy contractor not only with the patient or their carer but also with their general practitioner.

1.135 **Pandemic Treatment Protocol ("PTP")**

1.136 The pharmacy will provide medicines properly requested under any PTP arrangements.

1.137 The RP should (and if requested to do so by the person being supplied must):

1.137.1 Provide an estimate of the time the drug will be ready and delivered.

1.137.2 If the drug is not ready by the time then provide a revised estimate of when the drug will be ready and continue to update the patient on this time should the estimate change.

1.137.3 Contact the patient to confirm dispatch of the medication.

1.137.4 In addition to the normal requirements, the dispensing label on the packaging of the product supplied must also contain the additional wording shown below;

1.137.4.1 THIS PRODUCT IS BEING SUPPLIED IN ACCORDANCE WITH THE [INSERT NAME] PANDEMIC TREATMENT PROTOCOL.

1.137.4.2 And insert the name of the relevant protocol.

1.138 Refusal to Supply under PTP

1.139 The pharmacy may refuse to provide an order for a drug in accordance with a PTP where—

1.139.1 1 The RP reasonably believes it is not a genuine order.

1.139.2 2 The RP or other persons are subjected to or threatened with violence by the person who requests the provision of the drug.

1.139.3 3 The person who requests the provision of the drug, commits or threatens to commit a criminal offence.

1.140 The pharmacy must refuse to provide, pursuant to a PTP, an order for a drug, where the RP is not satisfied that it is in accordance with the PTP.

1.141 Any refusal to supply must be noted on the patient and / or pharmacy record system.

1.142 **Delivering Medicines**

1.143 Medicines must be delivered safely and with appropriate instructions. The Responsible Pharmacist (RP) has overall responsibility.

1.144 The RP must 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.

1.145 Local deliveries will be done by the delivery driver. In the case of fridge lines, these must be sent by courier. 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 other patient authorised representative.

1.146 Fridge Lines will be delivered by courier (see further below).

1.147 Medicines will be packed, transported and delivered in a way that the integrity, quality and effectiveness is preserved. The delivery mechanism will use a verifiable audit trail for medicine from the initial request through to its final delivery or return to the pharmacy, due to a failed delivery. At all times, packaging must maintain patient privacy and confidentiality.

1.148 The material chosen to package, will depend on the nature of the items being delivered. Whichever packaging is used, it should be able to withstand the normal rigours of the delivery process.

1.149 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.

1.150 Medicine for local delivery which is (A) not fragile and (B) is to be delivered by the delivery driver can be packaged in the using the normal pharmacy bags supplied for standard prescription items.

1.151 Medicines classified as non-flammable or non-toxic must be securely closed and placed in a leak-proof container, for example a polythene bag (for liquids) or a sift proof container (for solids). It must be tightly packed in strong outer packaging and must be secured or cushioned to prevent any damage.

1.152 At the very least - padded envelopes even for non-fragile items as this will help to ensure the integrity of the manufacturers packaging.

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

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

1.155 The patient, carer or notified, authorised patient representative must always sign and date a receipt to prove safe receipt of the medicines.

1.156 A patient who is not at home when delivery is attempted will be informed using a non-delivery notice, stating the date and time of the attempted delivery along with details of how to contact the courier to arrange the redelivery.

1.157 The patient can then rearrange delivery for a convenient time by telephone or Internet and an alternative delivery date will be arranged.

1.158 A list of the approved cold chain couriers is available within the Pharmacy.

1.159 Coldchain items should be stored in styrofoam filled cardboard boxes prior to being passed to the courier and marked with the “FRAGILE” and “FRIDGE LINE” stickers.

1.160 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.

1.161 Pharmacy staff should 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.

1.162 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 may not be re-used.

1.163 **Controlled Drugs**

1.164 **Delivery of Controlled Drugs**

1.165 There is 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 authorised person to another authorised person who is entitled to be in possession of the drug. Delivery of CD 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.

1.166 **Return and Destruction of CONTROLLED DRUGS**

1.167 Appropriate packaging will be sent to patients, with instructions for packaging any returned medicines. There will be no cost to the patient.

1.168 Patients may also be signposted to alternate pharmacies if they prefer to return medicines to a different pharmacy.

1.169 No ‘returned’ Controlled Drugs must not be re-used or entered into the CD register.

1.170 The pharmacy will denature and render them irretrievable as soon as possible.

1.171 Destruction must be witnessed by another member of staff.

1.172 If not immediately destroyed, they should be separated from main stock.

1.173 They should be clearly marked 'Patient Returns' to minimise the risk of errors and inadvertent supply and stored securely in a CD Cabinet waiting to be denatured.

1.174 A record of destruction will be recorded in a separate CD Destruction Register.

1.175 **Cover for Breaks / Working Time Directive and ensuring the uninterrupted provision of essential services.**

1.176 Any breaks in working time taken by the Responsible Pharmacist (RP) will be covered by a second pharmacist who will then assume the responsibility of the RP.

1.177 As a distance selling pharmacy, we need to ensure an RP is available on site to ensure the uninterrupted service throughout the opening hours. If the RP has not turned up on

the day or has left the premises before closing time, the superintendent needs to be informed immediately.

1.178 There will be a small bank of regular locum pharmacists who are willing to be the RP on some days.

1.179 The locum pharmacist will be aware that if they are unable to attend, then informing the superintendent pharmacist the day before is vital. This is to ensure that appropriate pharmacist [sic] cover can be arranged. If this is not achievable, then the locum agencies will be contacted to provide cover. We will have several agencies to call upon. Finally if this is still not possible, then as the superintendent pharmacist, I will be the RP for the day.

1.180 If in the event that the pharmacist is called away, then this will be done after the pharmacy has closed, if possible.

1.181 However, if this is not achievable, then the pharmacist must inform the superintendent pharmacist immediately, so that appropriate cover can be arranged.

1.182 The pharmacist must remain at the pharmacy until the new pharmacist arrives. Should all avenues not result in a replacement pharmacist, then I will be the RP, ensuring there is no interruption of essential services.

1.183 After I arrive, then the pharmacist can leave.

1.184 I will be the superintendent pharmacist and will be present on some days during the week, ensuring no interruption of essential services during the opening hours of the pharmacy. However, if this is not possible due to ill health or an appointment then the above protocol of contacting locum pharmacists and locum agencies will be done to arrange cover and I will not leave the site until the new pharmacist arrives at the facility.

1.185 If there are any unforeseen circumstances for example a car accident, then the pharmacist booked for the day, should inform the superintendent pharmacist immediately, so that an appropriate replacement pharmacist can be arranged. If this is not achievable then the locum agencies will be contacted. If this is still not achievable then myself, as the superintendent pharmacist, will be the RP.

1.186 **Website**

1.187 To remain active 24 hours per day, 365 days per year. Any down time must be reported to the superintendent so it can be rectified immediately. Website will be available nationally for anyone to access.

1.188 As you can see this explanation will form part of the SOP and will cover the needs of Regulation 25(2)(b) and Regulation 64, ensuring there is a pharmacist on site at all times during operational hours, ensuring uninterrupted provision of service.

1.189 **Contingency Planning**

1.190 The pharmacy 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 reduce the effects of any disruption to provision of pharmaceutical services such as medicines shortage, postal strike, EPS systems failure, etc.

1.191 **Verification of Declarations of Prescription Exemptions**

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

1.193 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.

1.194 The PMR system should be updated to indicate the check has been carried out and a note of when the next check is required should be entered onto the system.

1.195 The Regulations require a patient to produce 'satisfactory evidence' to confirm exemption.

1.196 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, but see NOTE below) 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.

1.197 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 on-line payment method.

1.198 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.

1.199 Payment for prescription charges will be received via the secure payment portal on the website and when payment is received the prescription will be marked as paid.

1.200 **Pharmacy Profile**

1.201 The pharmacy profile will be properly maintained in the NHS Digital Directory of Services Central Alerting System.

1.202 The pharmacy will maintain access to the MHRA Central Alerting System using the premises specific NHS mail email address which will be checked on a daily basis.

1.203 Registration of the Premises with the GPhC

1.204 The pharmacy 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 and will be regularly monitored and inspected.

1.205 **Practice Leaflet**

1.206 Nothing in the practice leaflet, or publicity material in respect of the listed chemist premises, will imply that the essential services provided at or from the premises are only available to persons in particular areas of England, or the pharmacy is likely to refuse, for reasons other than those provided for in the terms of service, to provide drugs or appliances.

1.207 **Advanced or Enhanced Services**

1.208 The pharmacy will provide services that are commissioned and provided remotely. They will not have to attend the pharmacy."

1.209 [A floor plan was also provided, see appendix A].

2 **The Decision**

The Commissioner considered and decided to grant the application. The decision letter dated 4 September 2024 states:

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.

2.2 The report details the conditions that will be placed upon your inclusion in the relevant pharmaceutical list should a valid notice of commencement be received. Enclosed is a form confirming acceptance of these conditions. It should be completed by an authorised person and returned to me with your notice of commencement.

2.3 Also enclosed is a template of the notice of commencement which you are required to submit to us. Please note that if this is submitted before the end of the 30 day appeal period and a valid notice of appeal is then received by the Secretary of State, the notice of commencement will cease to have effect. This means that if you have opened your new premises then you will be required to close with immediate effect.

2.4 Please note that you must submit the notice of commencement no fewer than 30 days before the date you intend to start service provision. If it is received fewer than 30 days in advance it is not a valid notice of commencement and will not be accepted by West Yorkshire ICB unless you successfully ask to give a shorter notice period. Should you wish to ask to give a shorter notice period please complete the enclosed application form."

PSRC Report

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

2.5 WY – Alchemy Enterprises Ltd - Unit 4 Drumhill House, Clayton Lane, Clayton, Bradford, West Yorkshire, BD14 6RF.

2.6 SR presented a paper for a DSP in a non-controlled locality. The FtP was granted on the 26th of July 2024. The applicant had provided the required application form and comprehensive information in support of their application.

2.7 Summary of Representations received:

2.8 Representations were received from Boots UK Ltd, Community Pharmacy West Yorkshire (CPWY), Raj's Chemist, Station Road Pharmacy and YORLMC.

2.9 Boots UK Ltd asks committee members to be fully satisfied that the application meets the requirements of the Regulations and note that there are several references to "Local" deliveries and the collection of prescriptions from GP surgeries and ask that the ICB are satisfied that the applicant will be offering services to anyone within the UK and not focusing purely on the local patient.

2.10 Representations made by CPWY refer to West Yorkshire ICB being assured that Regulations 25(2)(a) and 25(2)(b) are met and that the applicant will be able to provide pharmaceutical services throughout the proposed contracted hours.

2.11 Representations made by Rajesh Gautam of Raj's Chemist. Mr Gautam does not support the granting of this application and sets out his reasons concluding that the application: 'raise(s) 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 wellbeing of our community and the quality of care provided to our patients. Considering these concerns, we object to the application for the new distance-selling pharmacy business.'

2.12 Representations from Station Road Pharmacy did not support the application citing the applicant had not provided clear instructions on delivery procedures; cold chain supply; CD delivery; non entry compliance.

2.13 Representations made by Bradford and Airedale branch of YORLMC voiced general opinions regarding the increasing numbers of applications for internet /distance selling pharmacies and asks 'that PCSE monitors closely the internet pharmacies in this area to ensure that they abide by the regulations.

2.14 The applicant provided a response to representations by clarifying and reiterating information already included within their application and supporting information.

2.15 The committee considered all information presented and agreed that:

2.16 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 six existing providers of Pharmaceutical Services within 1.6 miles of the application, the closest being 0.3 miles away from the proposed site.

2.17 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. 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.

2.18 Regulation 64, which sets out the specific conditions to be met by applications for Distance Selling Premises:

2.18.1 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.

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

2.18.3 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.

2.18.4 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.

2.18.5 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.

2.19 Committee members concluded that, the applicant had provided robust information to enable the committee to decide that the contractor had 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.

2.20 In response to the two representations made objecting to the application, the committee noted that, the applicant had addressed the concerns raised by Station Road Pharmacy

and, although comprehensive, the issues raised by Raj's Chemist did not illustrate that the application did not meet the required regulations.

2.21 PSRC Decision: Having considered all the information provided and assessed it against the requirements of the Regulations, the PSRC GRANTED this application.

2.22 Right of Appeal: Raj's Chemist."

3 **The Appeal**

In a letter received 2 October 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 in the granting of the above application.

3.2 The applicant is a GP working in the area and the Superintendent Pharmacist for the application of this Distance Selling Pharmacy (DSP) in the area. The applicant has stated that other pharmacists will be on site and a bank of locum pharmacists, and he will be the backup should there be no pharmacist available. This should be taken into consideration if the applicant is working as a GP in the area as a conflict of interest.

3.3 A DSP provided by locum GP raises cause for concerns particularly when local pharmacy services are close by and assurances against prescription direction would need to be monitored closely and sanctioned.

3.4 The application is near local pharmacy services particularly Cohens Chemist and a current application exists for a DSP - reference ME3057 - CAS-268940-V9T8Z9 on School Street, Clayton which are both a few minutes' walk from the application.

3.5 DSP's offer (contractually) a 'strictly' national service to anyone in England.

3.6 The applicant has stated that a local delivery service will be provided by their delivery driver for example collecting medicines returns, collecting prescriptions from surgeries, local deliveries etc. This indicates that the application is aimed at providing a local service operating on a different model which is contrary to the strictly national service. 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. 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.

3.7 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.

3.8 The latest Pharmaceutical Needs Assessment shows that there is no additional need for pharmacy delivery services in the local area. Additionally, there are existing DSPs in Bradford.

3.9 NHS England will be aware of the decision made by NHS Resolution regarding the Pharmacy 2 U (P2U) application in Leicestershire (SHA/22233) and 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. The premises are not registered with the GPhC as per regulation 64.

3.10 The premises explanatory notes 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.' Without an accurate representation of a plan of the premises being submitted, NHS England cannot confirm that this application will not appear retail in nature or adequate for providing safe working environment for

dispensing medicines. Given this application is for a DSP a premises plan becomes necessary to verify that face to face services are not able to be provided.

3.11 SOP's have not been submitted NHS England cannot scrutinise the application to ensure it meets Reg 64(3)d.

3.12 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 (i) economic and efficient, and (ii) of an appropriate standard. Funding an additional DSP undermines the local bricks and mortar pharmacies and runs counter to the act above as it is not economic and efficient.

3.13 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: If this application is granted statistics suggest that it will operate as a pseudo-DSP and offer a local service as the ICB data shows above. This will undermine local bricks and mortar pharmacies and potentially deprive patients of access to local pharmaceutical services. Please also consider that local GP surgeries have patients only in the local area and not nationwide.

3.14 Urgent care of patients needs are a priority and often patients are requiring emergency supplies of their medicines immediately or palliative care services. A patient safety risk is to be considered when there are delays in relaying any prescriptions to a local service for emergencies, palliative care and more and this provides a huge risk to accessibility and delay of medical provision in these cases.

3.15 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. 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.

3.16 I kindly request that my appeal regarding this application to be considered based on the reasons outlined above."

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 [SS] on 1st July 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 B]. 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 C] and SHA/18727 -Sept 2017 [appendix C].

4.1.4 Members wish these comments to be taken into consideration by the Authority and wish to be notified of the decision."

4.2 The Applicant

4.2.1 "Thank you for your correspondence. I have some additional comments supporting the application after appeal.

4.2.2 **Regulation 31**

4.2.3 There is no person on a pharmaceutical list trading from the proposed facility or adjacent to the site. The dispensary is in a room within a former school. Other businesses in the building are not related to pharmacies. I am not on any pharmaceutical list. This has been verified by the initial granting of the application by NHS England.

4.2.4 **Regulation 25**

4.2.5 The distance selling pharmacy is not on the same site or building of a provider of primary medical services. The location is within a former school. This has been verified by the initial granting of the application by NHS England.

4.2.6 As stipulated in the original application there is a robust mechanism in place to ensure the uninterrupted provision of essential pharmaceutical services.

4.2.7 Medication will be delivered through the fasted rout [sic] possible. However, patient choice will always be maintained with no direction of essential services in anyway.

4.2.8 There will be no face to face interaction with patients as the facility is an isolated room in a former school.

4.2.9 I have attached a schematic of the room [appendix E] and pictures to provide evidence that this DSP does not resemble a retail unit at all.

4.2.10 There will be no advertising on the window either.

4.2.11 Highlighted part is the front external door and window.

4.2.12 Main dispensary.

4.2.13 Highlighted internal door to the dispensary and side room door to consultation room.

4.2.14 Corridor from the front external door. Immediately after the doors visible, is the internal door to the dispensary, as shown by the arrow.

4.2.15 Schematic representation".

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, in its application form, had stated "*not applicable as no pharmacy in same or adjacent premises".* 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.

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

Regulation 25

6.8 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."

6.9 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)

6.10 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)

6.11 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 also noted that the Applicant, in its representations, stated *"the distance selling pharmacy is not on the same site or building of a provider of primary medical services".* The Commissioner in its 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."*

6.12 Based on the information available to it, which had not been disputed by any party, the Committee 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)

6.13 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 "supporting info" document provided with its application.

6.14 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.

6.15 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.

6.16 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, the representations received on the appeal and the additional information document which includes extracts of the SOPs that the Applicant has prepared or commissioned.

6.17 It is not for the Committee to 'approve' or 'disapprove' of 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, application and representations in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.

6.18 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:

6.19 Pharmacy Systems and Procedures

6.19.1 *"We will provide safe, effective and uninterrupted provision of all essential services to persons…*

6.19.2 *…The website will enable patients or their carers to communicate remotely but directly allowing quick and easy access and provide clear unambiguous details of how safe, efficient, 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."*

6.20 Website

6.20.1 *"To remain active 24 hours per day, 365 days per year. Any down time must be reported to the superintendent so it can be rectified immediately. Website will be available nationally for anyone to access.*

6.20.2 *As you can see this explanation will form part of the SOP and will cover the needs of Regulation 25(2)(b) and Regulation 64, ensuring there is a pharmacist on site at all times during operational hours, ensuring uninterrupted provision of service."*

6.21 Cover for Breaks / Working Time Directive and ensuring the uninterrupted provision of essential services.

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

6.21.2 *As a distance selling pharmacy, we need to ensure an RP is available on site to ensure the uninterrupted service throughout the opening hours. If the RP has not turned up on the day or has left the premises before closing time, the superintendent needs to be informed immediately.*

6.21.3 *There will be a small bank of regular locum pharmacists who are willing to be the RP on some days.*

6.21.4 *The locum pharmacist will be aware that if they are unable to attend, then informing the superintendent pharmacist the day before is vital. This is to ensure that appropriate pharmacist cover can be arranged. If this is not achievable, then the locum agencies will be contacted to provide cover. We will have several agencies to call upon. Finally if this is still not possible, then as the superintendent pharmacist, I will be the RP for the day.*

6.21.5 *If in the event that the pharmacist is called away, then this will be done after the pharmacy has closed, if possible.*

6.21.6 *However, if this is not achievable, then the pharmacist must inform the superintendent pharmacist immediately, so that appropriate cover can be arranged.*

6.21.7 *The pharmacist must remain at the pharmacy until the new pharmacist arrives. Should all avenues not result in a replacement pharmacist, then I will be the RP, ensuring there is no interruption of essential services.*

6.21.8 *After I arrive, then the pharmacist can leave.*

6.21.9 *I will be the superintendent pharmacist and will be present on some days during the week, ensuring no interruption of essential services during the opening hours of the pharmacy. However, if this is not possible due to ill health or an appointment then the above protocol of contacting locum pharmacists and locum agencies will be done to arrange cover and I will not leave the site until the new pharmacist arrives at the facility.*

6.21.10 *If there are any unforeseen circumstances for example a car accident, then the pharmacist booked for the day, should inform the superintendent pharmacist immediately, so that an appropriate replacement pharmacist can be arranged. If this is not achievable then the locum agencies will be contacted. If this is still not achievable then myself, as the superintendent pharmacist, will be the RP."*

6.22 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:

6.23 Practice Leaflet

6.23.1 *"Nothing in the practice leaflet, or publicity material in respect of the listed chemist premises, will imply that the essential services provided at or from the premises are only available to persons in particular areas of England, or the pharmacy is likely to refuse, for reasons other than those provided for in the terms of service, to provide drugs or appliances".*

6.24 Pharmacy Systems and Procedures

6.24.1 *"…We will provide safe, effective and uninterrupted provision of all essential services to persons anywhere in England who request those services during the opening hours…*

6.24.2 *…Information pertaining to NHS Essential Services will be achieved by using:*

6.24.3 *Telephone , Live Video Call, Email, Postal services and free of charge (as stipulated in the NHS Act 2006)*

6.24.4 *The website will enable patients or their carers to communicate remotely but directly allowing quick and easy access and provide clear unambiguous details of how safe, efficient, 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".*

6.25 Health Campaigns

6.25.1 *"The Pharmacy will take part in national health campaigns to promote health messages to our patients across England".*

6.26 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:

6.27 Internet site

6.27.1 *"The website will display;…*

6.27.2 *Explanation of rules on non-face to face contact."*

6.28 Pharmacy Systems and Procedures

6.28.1 "*All essential services will operate without face to face contact between anyone receiving the services, whether on their own or someone else's behalf, and the pharmacy staff…*

6.28.2 *The distance selling pharmacy will operate from secure premises, incorporating a restricted entry system. No member of the public will have access.*

6.28.3 *The facility is located within a unit, of a former school, secluded from the public.*

6.28.4 *Any patient that requests essential services to be provided at the premises, we will apologise, and stipulate that the pharmacy is not permitted to provide those services at the premises and sent away. Entry will be refused at the door. If they require the medication urgently they will be signposted to other pharmacies.*

6.28.5 *Further, there will be a clear sign on the door advising that if a patient does not have an appointment they will not be seen for non-essential/ advanced or private pharmaceutical services. Patients with pre-booked appointments will be advised that the pharmacist will contact them through internet, telephone or video link…*

6.28.6 *...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."*

6.29 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, would be 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 noted that in response to the question as to whether they were undertaking to provide appliances, the Applicant left this box blank. In the additional information document under the heading "Referral for Certain Appliances", the Committee noted the following:

6.33.1 *"Where the pharmacy is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within the pharmacy's normal course of business, the pharmacist will refer the prescription form or repeatable prescription to another NHS pharmacist, if the patient consents.*

6.33.2 *If the patient does not consent to a referral, Then the pharmacy will provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who can provide the service".*

6.34 In the event that the application is granted, the Applicant would not therefore, be able to provide such appliances to patients.

6.35 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

6.36 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).

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

6.38 Delivering Medicines

6.38.1 *"The RP must 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.*

6.38.2 *Local deliveries, will be done by the delivery driver. In the case of fridge lines, these must be sent by courier. 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 other patient authorised representative.*

6.38.3 *Fridge Lines will be delivered by courier (see further below)...*

6.38.4 *…A list of the approved cold chain couriers is available within the Pharmacy.*

6.38.5 *Coldchain* [sic] *items should be stored in styrofoam filled cardboard boxes prior to being passed to the courier and marked with the "FRAGILE" and "FRIDGE LINE" stickers.*

6.38.6 *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.*

6.38.7 *Pharmacy staff should 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.*

6.38.8 *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 may not be re-used."*

6.39 Pharmacy Systems and Procedures

6.39.1 *"Cold chain courier services will transport and deliver medication. This will ensure the integrity of the cold chain and the maximum stability of thermo-liable drugs by packing, including the quality and effectiveness. This will be a dedicated, fully monitored and temperature controlled delivery service."*

6.40 Whilst the Committee noted the above, no information had been provided to outline the procedure that would be followed in the event of a failed and/or missed delivery or breach of the cold chain. It noted the reference to "*the failed delivery procedure*" but this had not been provided. The Committee could therefore not be satisfied that the cold chain would be maintained if either of these situations occurred.

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

6.42 Controlled Drugs

6.42.1 *"Delivery of Controlled Drugs*

6.42.2 *There is 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 authorised person to another authorised person who is entitled to be in possession of the drug. Delivery of CD 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.*

6.42.3 *Return and Destruction of CONTROLLED DRUGS*

6.42.4 *Appropriate packaging will be sent to patients, with instructions for packaging any returned medicines. There will be no cost to the patient.*

6.42.5 *Patients may also be signposted to alternate pharmacies if they prefer to return medicines to a different pharmacy.*

6.42.6 *No 'returned' Controlled Drugs must not be re-used or entered into the CD register.*

6.42.7 *The pharmacy will denature and render them irretrievable as soon as possible.*

6.42.8 *Destruction must be witnessed by another member of staff.*

6.42.9 *If not immediately destroyed, they should be separated from main stock.*

6.42.10 *They should be clearly marked 'Patient Returns' to minimise the risk of errors and inadvertent supply and stored securely in a CD Cabinet waiting to be denatured.*

6.42.11 *A record of destruction will be recorded in a separate CD Destruction Register."*

6.43 Safe Management and supply of medicines

6.43.1 *"The pharmacy SOPs provide the procedures for all staff to follow to ensure that the sale and supply of medicines in carried out in such a manner as to minimise risk to patients.*

6.43.2 *The SOPs for delivery of medicines contain detailed information on the safe and effective supply of medicines via the pharmacy's own driver, Royal Mail and courier firms, including; assess the suitability and timescale of the method of supply, dispatch, and delivery for all medicines and particularly refrigerated medicines and controlled drugs."*

6.44 Delivering Medicines

6.44.1 *"The RP must 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.*

6.44.2 *Local deliveries, will be done by the delivery driver. In the case of fridge lines, these must be sent by courier. 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 other patient authorised representative…*

6.44.3 *…The delivery mechanism will use a verifiable audit trail for medicine from the initial request through to its final delivery or return to the pharmacy, due to a failed delivery…*

6.44.4 *… A patient who is not at home when delivery is attempted will be informed using a non-delivery notice, stating the date and time of the attempted delivery along with details of how to contact the courier to arrange the redelivery.*

6.44.5 *The patient can then rearrange delivery for a convenient time by telephone or Internet and an alternative delivery date will be arranged."*

6.45 Audit Procedures

6.45.1 *"A regular audit programme will be in place. This will provide evidence which gives assurance that the pharmacy continues to provide safe pharmacy services to patients… systems and processes for secure delivery to patients."*

6.46 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, for example what would happen to the medicines. The Committee noted there was no information regarding a tracking system or 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.

6.47 Further the Committee noted that *"the RP must ensure that the delivery mechanism used is secure" and "…systems and processes for secure delivery to patients"* 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.

6.48 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.

Discharge medicines service

6.49 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.

6.50 The Committee noted the information in the additional information document under the following headings:

6.51 Information Governance

6.51.1 *"Two members of staff will have the ability to login to the PMS system on all days (where there are 2 or more staff members working) and the NHS mail system will be checked every day for both general emails and also for any referrals under the Discharge Medicines Service."*

6.52 Discharge Medicines Service ("DMS")

6.52.1 *"When NHS patients are discharged from hospital or there is, for other reasons, a transfer of care of them between different providers of NHS services, community pharmacies may be asked to perform a three stage service in respect of the patient, principally linked to changes in medication.*

6.52.2 *The second and third stages of this service are linked to the first prescription presented post-discharge or post transfer. Issues of concern may be raised by the pharmacy contractor not only with the patient or their carer but also with their general practitioner."*

6.53 Whilst the Committee noted the reference to the "three stage service", there was no explanation as to what this entails or the process that the Applicant will follow in relation to patients who have recently been discharged from hospital.

6.54 The Committee was 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

6.55 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

6.56 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).

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

6.57.1 confirm the Commissioner's decision;

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

6.57.3 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.

6.58 In those circumstances, given that the Committee reached a different decision to the Commissioner, the Committee determined that the decision of the Commissioner must be quashed.

6.59 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.

6.60 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.

6.61 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