12 January 2024

REF: 26087

8th Floor
10 South Colonnade
Canary Wharf
London
E14 4PU

Tel: 0203 928 2000
Email: nhsr.appeals@nhs.net

APPEAL AGAINST SOUTH YORKSHIRE ICB DECISION TO GRANT AN APPLICATION BY REX PHARMA LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 64 HIGH STREET, MALTBY, ROTHERHAM S66 8LA UNDER REGULATION 25

1 Outcome

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

1.2 The Committee determined that the application should be granted.

A copy of this decision is being sent to:

Rushport Advisory LLP on behalf of Rex Pharma Ltd (the Applicant)
South Yorkshire ICB
Templebright LLP on behalf of H I Weldrick Ltd (the Appellant)
Community Pharmacy South Yorkshire

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1 The Application

By application dated 1 May 2023, Rex Pharma Ltd ("the Applicant") applied for inclusion in the pharmaceutical list at 64 High Street, Maltby, Rotherham S66 8LA 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 stated:

1.2 Drug Tariff part IX – except items that require measuring or fitting.

1.3 In response to why the application should not be refused pursuant to Regulation 31 the Applicant stated:

1.4 Not applicable as no other pharmacy in same or adjacent premises.

1.5 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant stated:

1.6 Application is not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

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

1.8 The Information contained within this document has been approved by the applicant prior to submission.

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

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

1.9.2 (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.

NHS England Premises Standards

1.10 NHS England has published premises standards that the Pharmacy will comply with, however, it should be noted that not all these standards apply directly to distance selling premises other than where a patient is accessing non-essential services.

1.11 The pharmacy will be a Healthy Living Pharmacy and comply with the change management and organisational development criteria, ensuring premises and facilities are fit for purpose and engaging with the community to deliver consistently high quality health and wellbeing services.

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

GPhC Guidance

1.13 The Applicant will operate the pharmacy in accordance with current GPhC guidance for registered pharmacies providing pharmacy services at a distance, including on the internet. Current guidance, the content of which is considered and replicated in part below, is not intended to exhaustively replicate the entirety of the GPhC guidance which will be followed.

1.14 The Applicant will have in place, prior to opening the following;

Risk Assessment

1.15 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 minimise risk.

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

Audit Procedures

1.17 A regular audit programme 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.

1.18 The audit will, at the very least, consider:

1.18.1 staffing levels and the training and skills within the team

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

1.18.3 use of specialised equipment and new technology

1.18.4 records of decisions to make or refuse a sale

1.18.5 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)

1.18.6 systems and processes for secure delivery to patients

1.18.7 any information about pharmacy services on the website

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

1.18.9 feedback from patients and people who use our pharmacy services

1.18.10 concerns or complaints received, and

1.18.11 activities of third parties, agents or contractors.

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

Reactive Review

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

1.20.1 a change in the law affecting any part of the pharmacy service

1.20.2 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

1.20.3 a data security breach

1.20.4 a change in the technology the pharmacy uses

1.20.5 concerns or negative feedback are received from patients or people who use the pharmacy services

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

Accountability

1.21 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.

Record Keeping

1.22 Records in the pharmacy will be scanned in to 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.

Training

1.23 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.

Premises

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

Website

1.25 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.

1.26 The website will display;

1.26.1 the GPhC pharmacy registration number

1.26.2 the name of the owner of the registered pharmacy

1.26.3 the name of the superintendent pharmacist

1.26.4 the name and address of the registered pharmacy that supplies the medicines

1.26.5 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)

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

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

1.26.7.1 Return of unwanted medicines

1.26.7.2 Patient lifestyle Questionnaire

1.26.7.3 How to register exemptions from NHS charges

1.26.7.4 Promotion of Health Lifestyles and details of campaigns being undertaken

1.26.7.5 Procedures for Emergency Supply

1.26.7.6 Explanation of rules on non face to face contact

1.26.7.7 Patient Information Leaflet

1.26.8 the email address and phone number of the pharmacy

1.26.9 details of how patients and users of pharmacy services can give feedback and raise concerns

1.26.10 GPhC internet logo (linked to register entry)

1.26.11 Where any medicines are sold online, the pharmacy will be registered with the appropriate agency for online pharmacies (NOTE FROM 1 JANUARY 2021 THE MHRA SCHEME DOES NOT APPLY BUT ANY EQUIVALENT UK SCHEME INTRODUCED Will BE FOLLOWED)

1.26.12 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. (The EU Common logo is no longer a requirement post Brexit - any equivalent scheme introduced will be complied with).

1.27 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.

Transparency and Choice

1.28 Our website and materials will specify the nature and type of services we provide and who provides those services.

1.29 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.

Managing Medicines Safely

1.30 The pharmacy SOPs will 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.

Supplying Medicines Safely

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

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

1.31.2 ensuring that robust identity check processes are in place to ensure that the medicines dispensed are delivered to the correct person.

1.31.3 assess the suitability of packaging (for example, packaging that is tamperproof or temperature controlled)

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

Equipment and Facilities

1.33 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.

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

1.35 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.

Standard Operating Procedures

1.36 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.

1.37 PHARMACY SYSTEMS AND PROCEDURES

1.38 All Essential Services will be delivered in accordance with:

1.38.1 Company Standard Operating Procedures

1.38.2 NHS (Pharmaceutical and local Pharmaceutical Services) Regulations 2013

1.38.3 NHS Act 2006

1.38.4 Human Medicines Regulations 2012

1.38.5 GPhC - Professional Standards and Guidance on Distance Selling Pharmacies

1.38.6 Relevant Data Protection laws

1.39 This will ensure that the Applicant provides 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.

1.40 The Applicant's wholly Internet/Delivery Pharmacy will operate from secure premises, with a controlled entry system, to which members of the public will not have access. Any patient that 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.

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

1.41.1 Telephone

1.41.2 Live Video Call

1.41.3 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.

1.41.4 Email

1.41.5 Postal services

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

1.43 Essential Services may be delivered using:

1.43.1 Telephone, including text messaging where appropriate

1.43.2 Electronic Prescription Service (EPS)

1.43.3 Website

1.43.4 Email

1.43.5 Royal Mail postal service

1.43.6 Courier service

1.43.7 Specialist Waste Management Services

1.43.8 Live video services.

1.43.9 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 is always

preserved. This will be a dedicated, fully monitored and temperature controlled delivery service.

1.44 Provision of NHS Essential Services

Dispensing Services

1.45 Prescriptions will be received by the EPS, post, 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.

1.46 In the event of any clinical or legal issues with the prescription, the pharmacist will follow Standing Operating Procedures to resolve these issues before dispensing items. This may involve contacting the prescriber as soon as possible to make sure the patient receives their medication without delay.

1.47 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.

Repeat Dispensing Services

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

1.48.1 (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

1.48.2 (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.

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

1.50 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 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.

1.51 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.

Urgent Supply and Emergency Supply

1.52 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.

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

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

1.54.1 The Pharmacist must be satisfied that the request is from the appropriate authorised prescriber, see list above.

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

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

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

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

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

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

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

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

1.56.1 Interview

1.57 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.

1.57.1 Records

1.58 An entry must be made in the POM register on the day of supply and record all the relevant details.

1.59 The label for the dispensed medicine must contain the words "Emergency Supply".

1.59.1 Faxed Prescriptions

1.60 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.

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

Delivery of Urgent Supplies

1.62 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 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 procedures will apply.

Disposal of Unwanted Medicines

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

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

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

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

1.64 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.

1.65 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.

Promotion of Healthy Lifestyles

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

1.67 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.

1.68 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.

1.69 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.

1.70 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.

Health Campaigns

1.71 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.

1.72 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.

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

1.73.1 (i) 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

1.73.2 (ii) 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.

Signposting and Support for Self-Care

1.74 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 minimise inappropriate use of health or social care services the pharmacist will use the same "Active and Passive" assessment tool already set out above.

1.75 Where it appears to the pharmacist, after reviewing the assessment and having regard to the need to minimise 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.

1.76 If a patient;

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

1.76.2 (b) another provider, of which the pharmacy is aware, of health or social care services or of support services is likely to be able to provide that advice, treatment or support,

1.77 The pharmacy will provide contact details of that provider to that person and will, in appropriate cases, refer that person to that provider.

1.78 Referral for Certain Appliances

1.79 Where, on presentation of a prescription form or repeatable prescription, 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-

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

1.79.2 (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 are able to provide the appliance or stoma appliance customisation (as the case may be) if these details are known to the pharmacist.

1.80 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.

Support for People with Disabilities

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

1.82 The Applicant will conduct an initial assessment with the patient, care 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.

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

Clinical Governance

1.84 Note: Clinical Governance is not an 'essential service' and is therefore dealt with briefly in this submission.

1.85 The Applicant 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 Pharmacist and Pharmacy Technician CPO, conducting clinical audits, workforce survey and drug recalls.

1.86 '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.

1.87 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.

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

Information Governance

1.89 The pharmacy will be registered and comply with 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 in accordance with NHS and legal obligations on data security, protection and confidentiality.

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

1.91 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.

Discharge Medicines Service (“DMS”)

1.92 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. The second and third stages of this service are linked to the first prescription presented post-discharge or post-transfer.

1.93 Issues of concern may be raised by the pharmacy contractor not only with the patient or their carer but also with their general practitioner.

1.94 Under the DMS the pharmacy must provide assistance and support to, and in respect of, an NHS patient

1.94.1 (a) recently discharged from hospital who is referred to the pharmacy 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

1.94.2 (b) who is otherwise referred to the pharmacy for advice, assistance and support in respect of the patient's medication regimen by the staff of an NHS trust or NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.

1.95 The service allows and requires the pharmacy to help not only the patient directly, but also (within the bounds of confidentiality) their carers and also provide them with assistance and support.

1.96 The service is designed in 3 Stages, where each Stage builds on the last to provide additional support if required to the patient or, where appropriate their carer.

1.97 The pharmacist must use their clinical judgement when considering their actions and recommendations in respect of the service and consider the duty of confidentiality to the patient when involving a carer in discussions about the patient and their medication regimen.

1.98 If the DMS referral requesting that the pharmacy provides the DMS includes circumstances in which the pharmacy is not to provide, or is to cease to provide the DMS service, then the Pharmacy is not to, or is to cease to, provide the DMS in those circumstances (for example, X's or Y's admission or readmission to hospital).

Pandemic Treatment Protocol ("PTP")

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

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

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

1.100.2 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.

1.100.3 Contact the patient to confirm dispatch of the medication.

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

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

1.102 And insert the name of the relevant protocol.

Refusal to Supply under PTP

1.103 The pharmacy may refuse to provide an order for a drug that is or is purportedly in accordance with a PTP where-

1.103.1 (a) The RP reasonably believes it is not a genuine order for the person who requests ,or on whose behalf is requested, the provision of the drug;

1.103.2 (b) providing it would be contrary to the RP's clinical judgement;

1.103.3 (c) The RP or other persons are subjected to or threatened with violence by the person who requests the provision of the drug, or by any person accompanying (see footnote re "accompanying"') that person; or

1.103.4 (d) the person who requests the provision of the drug, or any persona accompanying (see footnote re "accompanying") that person, commits or threatens to commit a criminal offence.

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

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

Delivering Medicines

1.106 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.

1.107 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.

1.108 If the delivery to patients is local, this will be undertaken by the delivery driver except fridge lines which 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. Fridge Lines will be delivered by courier (see further below).

1.109 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.

1.110 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.

1.111 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.

1.112 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.

1.113 Medicines classified as non-flammable or non-toxic must be securely closed and placed in a leak-proof 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.

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

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

1.116 For most items - bubble wrap and where necessary, polystyrene filler, placed within a cardboard box.

1.117 Cardboard boxes must be the re-enforced type.

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

1.119 The patient, carer or notified, authorised 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.

1.120 A list of the approved cold chain couriers will be maintained within the Pharmacy. Coldchain items will be stored in styrofoam filled cardboard boxes prior to 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. 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 and will therefore not be used in direct contact with any medicine. The courier service will be a dedicated, fully monitored and temperature controlled delivery service. Any breach of the cold chain will be 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.

Controlled Drugs

Delivery of Controlled Drugs

1.121 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.

Return and Destruction of CONTROLLED DRUGS

1.122 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. The Applicant will denature and render them irretrievable as soon as possible in order to avoid storage problems and an increased security risk.

1.123 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.

Cover for Breaks / Working Time Directive

1.124 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.

Contingency Planning

1.125 The Applicant 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 provision of pharmaceutical services such as medicines shortage, postal strike, EPS systems failure, etc.

Verification of Declarations of Prescription Exemptions

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

1.127 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 should be updated to reflect that necessary check has been carried out and a note of when the next check is required should be entered onto the system. The Regulations require a patient to produce 'satisfactory evidence' to confirm exemption. Where appropriate (ie for deliveries made other than by the pharmacy's delivery driver), the patient may scan 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.

1.128 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.

1.129 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. Scanned email copies of exemptions are also acceptable.

1.130 The nature of any exemption will be recorded on the PMR system with a copy attached to the patient's file.

1.131 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.

Pharmacy Profile

1.132 The pharmacy profile will be properly maintained in the NHS Digital Directory of Services

Central Alerting System

1.133 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.

Registration of the Premises with the GPhC

1.134 It is not lawful to operate a Pharmacy without registering the premises and Superintendent Pharmacist with the GPhC. The Applicant 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. The GPhC has a team of inspectors who undertake the routine monitoring and inspection of premises.

Practice Leaflet

1.135 Nothing in the Applicant's practice leaflet, or publicity material in respect of the listed chemist premises, in material published on behalf of the Applicant publicising services

provided at or from the listed chemist premises or in any communication (written or oral from the Applicant or the Applicant's staff to any person seeking the provision of essential services will represent, either expressly or impliedly, that-

1.135.1 (i)the essential services provided at or from the premises are only available to persons in particular areas of England, or

1.135.2 (ii)the Applicant is likely to refuse, for reasons other than those provided for in the Applicant's terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (for example, because the availability of essential services from the Applicant is limited to other categories of patients).

Advanced or Enhanced Services

1.136 The pharmacy will only offer services that can be delivered remotely and do not require patients to attend the premises."

2 **The Decision**

South Yorkshire ICB considered and decided to grant the application. The decision letter dated 8 September 2023 states:

2.1 "South 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 South 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."

2.5 South Yorkshire ICB Committee Report

[Please note that all references to "the Committee" in this section refers to the Committee of South Yorkshire ICB.]

2.6 "Re: Application for inclusion in a pharmaceutical list at 64 High Street, Maltby, Rotherham, S66 8LA in respect of distance selling premises by Rex Pharma Ltd

2.7 The Committee first considered Regulation 31 and determined that it did not apply. 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.

2.8 The Committee then proceeded to consider Regulation 25. The Committee was satisfied that the proposed premises 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. Therefore, the Committee determined that Regulation 25(2)(a) had been met.

2.9 Having regard to Regulation 25(2)(b), the Committee was satisfied that the provision of services would be without face to face contact and available to persons anywhere in England. The Committee was satisfied that the provision of services would be without interruption. Based on the information provided, the Committee was satisfied that the pharmacy procedures for the premises are likely to secure the safe and effective provision of all essential services. Therefore, the Committee determined that Regulation 25(2)(b) had been met.

2.10 Having considered the information provided by the applicant and the representations received, the Committee granted the application.

2.11 As the application is in respect of distance selling premises, by virtue of regulation 64(3) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, if the applicant is subsequently included in the pharmaceutical list for the area of Rotherham Health and Wellbeing board in respect of the premises included in the application that inclusion will be subject to the following conditions:

2.11.1 The applicant must not offer to provide pharmaceutical services to persons who are present at (which includes in the vicinity of) the proposed premises;

2.11.2 the means by which the applicant provides pharmaceutical services must be such that any person receiving those services does so otherwise than at the proposed premises;

2.11.3 the proposed 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;

2.11.4 the pharmacy procedures for the premises must be such as to secure:

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

2.11.4.2 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; and

2.12 nothing in the applicant's practice leaflet, in the applicant's publicity material in respect of the proposed premises, in material published on behalf of the applicant publicising services provided at or from the proposed premises or in any communication (written or oral) from the applicant or the applicant's staff to any person seeking the provision of essential services from the applicant must represent, either expressly or impliedly, that:

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

2.12.2 the applicant is likely to refuse, for reasons other than those provided for in the applicant's terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (for example, because the availability of essential services from the applicant is limited to other categories of patients).

2.13 Rights of appeal: H I Weldrick Ltd."

3 The Appeal

In a letter dated 4 October 2023 HI Weldrick Limited, represented by Templebright LLP appealed against South Yorkshire ICB's decision. The grounds of appeal are:

3.1 "I act for HI Weldrick Limited which is included in the pharmaceutical list in respect of premises at the Maltby Services Centre, Braithwell Road, Maltby, Rotherham, S66 8JE.

3.2 On behalf of my client, I write to appeal a decision of NHS England to grant an application by Rex Pharma Limited for inclusion in the pharmaceutical list at 64 High Street, Maltby, Rotherham, S66 8LA in respect of distance selling premises. The decision was notified to my client by letter dated 8th September 2023.

3.3 My client's ground of appeal is that NHS England failed to give any reasons for its decision to grant this application. NHS England stated in its decision report that it was "satisfied" that the requirements of regulation 25(2)(b) were met by the applicant but did not explain, in the context of the representations made by my client, why it was so satisfied.

3.4 By way of background, my client submitted representations to NHS England in respect of this application by letter dated 17th July 2023. I attach a copy of that letter for NHS Resolution's ease of reference. My client does not know whether the applicant responded to those representations, and NHS England's decision makes no reference to any such response.

3.5 On behalf of my client, I do not intend to repeat the contents of the letter of 17th July 2023 but, in summary, my client made the following representations:

3.6 1) The applicant company appears to have been formed after the date on which the application was submitted, making the application invalid.

3.7 2) The applicant relied on a generic document produced by Rushport Advisory LLP which did not explain how the applicant itself intended to provide NHS pharmaceutical services in the distance selling context.

3.8 3) The proposed premises themselves raised specific challenges, in particular in relation to the risk that patients may receive, or be offered, the provision of pharmaceutical services whilst present at, or in the vicinity of, the listed premises contrary to regulation 64(3). The applicant's generic supporting information did not address this in the context of the location of its proposed premises.

3.9 By reason of the matters raised in my client's representations to NHS England dated 17th July 2023, NHS England should have refused this application. Since none of those matters are addressed in NHS England's decision, my client asserts that NHS Resolution cannot be satisfied that this application meets the requirements of regulation 25 for those same reasons.

3.10 On behalf of my client, I therefore invite NHS Resolution to uphold this appeal and to refuse the application."

Letter to South Yorkshire ICB and regarding original application (dated 17 July 2023).

3.11 "Maltby Services Centre, Braithwell Road, Maltby, Rotherham, S66 8JE.

3.12 On behalf of my client I write further to your letter of 7th June 2023 and in order to submit representations to NHS England in respect of an application by Rex Pharma Limited for inclusion in the pharmaceutical list for premises at 64 High Street, Maltby, Rotherham, S66 8LA.

Legal status of the applicant

3.13 As NHS England will be aware, regulation 10 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations") provides that each Health and Wellbeing Board must prepare, maintain and publish 2 lists of persons who undertake to provide pharmaceutical services from premises situated in the HWB's area.

3.14 Regulation 10(7)(a) of the Regulations provides that those who are seeking inclusion in the pharmaceutical list must provide the information contained within schedule 2 to the Regulations.

3.15 Paragraph 2 of Schedule 2 to the Regulations provides that applications for inclusion in the pharmaceutical list may be made by an individual or partnership (where the individual or partners must be a registered pharmacist or registered pharmacists) (paragraph 2(2)) or a body corporate (paragraph 2(3)).

3.16 Where the applicant is a body corporate, paragraph 2(3) requires that the body corporate must provide the applicant's "registered name", "company registration number" and the body corporate's "registered office".

3.17 With regard to the application form provided with your letter of 7th June 2023, the applicant has provided the following details in respect of the information required by paragraph 2(3) of the Regulations:

3.18 The applicant is "Rex Pharma Limited"

3.19 The applicant is stated to be a "body corporate"

3.20 The applicant's registered office is given as 36 Rencliffe Avenue, Rotherham, S60 2RP.

3.21 No company registration number is provided with the application form provided by NHS England but, it is assumed, this information was provided with the fitness information form that has not been circulated to interested parties.

3.22 The application form is dated 1st May 2023 and has been signed by Mamoon Ali, who is stated to be a director of Rex Pharma Limited.

3.23 I have carried out a search through Companies House in respect of the applicant, Rex Pharma Limited. Whilst no company registration number is provided on the application form, it is assumed that the applicant is the company with Companies House registration number 14840905.

3.24 A copy of that search entry can be found here – REX PHARMA LTD overview - Find and update company information - GOV.UK (company-information.service.gov.uk). I attach the Certificate of Incorporation for Rex Pharma Limited. [See Appendix A for Committee].

3.25 As can be seen from the Companies House records, Rex Pharma Limited was incorporated on 2nd May 2023. This appears to be the day after the application form was completed and signed by the applicant's director.

3.26 Since, at the time the application form was completed and signed, the applicant did not exist as a legal entity, the application is invalid. In short, it was impossible for Rex Pharma Limited to apply for inclusion in the pharmaceutical list (or to complete the application form) on 1st May 2023 when the applicant did not exist until 2nd May 2023.

3.27 As such, this application must be refused as being invalid.

Regulation 25

3.28 Notwithstanding the above, as NHS England will be aware, regulation 25 of the Regulations requires the applicant to satisfy NHS England that the pharmacy procedures for the pharmacy premises are likely to secure:

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

3.28.2 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.

3.29 It is for the applicant to demonstrate that its application meets the requirements of regulation 25. That is, the burden of proof rests with the applicant.

3.30 The applicant has provided, with its application form, a document titled "Further Information in Relation to Provision of Essential Services in Accordance with the Regulatory Requirements for Distance Selling Pharmacies".

3.31 This document appears to have been produced by "Rushport Advisory LLP". It is generic in nature and does not even refer to the applicant by name or reference the applicant's premises.

3.32 The document repeatedly refers to how services "may" be provided but provides no information about how the applicant, itself, will provide all essential NHS services in the distance selling context.

3.33 Purely by way of example:

3.33.1 The document states that the pharmacy "will be equipped with facilities to allow for both phone (or other live audio link) and live video communication with patients in a manner which maintains patient confidentiality" but does not state how patient confidentiality will be maintained.

3.33.2 The document repeatedly refers to SOPs in the future tense (ie with the inference that those SOPs do not currently exist, such that NHS England cannot be assured that the pharmacy's procedures are likely to secure the safe and effective provision of pharmaceutical services). For example, the document states as follows:

3.33.2.1 "The pharmacy SOPs will provide the procedures for all staff to follow…"

3.33.2.2 "The SOPs for delivery of medicines will contain detailed information…"

3.33.3 The document states that "robust identity check processes are in place" but fails to explain what these processes are.

3.33.4 The document states that essential services may be delivered using a variety of methods but does not say how essential services will actually be delivered by the applicant.

3.33.5 The document states that prescriptions may be sent to the pharmacy by post, but does not explain how patients will be able to post prescriptions to the pharmacy free of charge.

3.33.6 The document refers to an "app" in relation to the return of unwanted medicines, but does not mention an app anywhere else. No information is provided about this "app" and how services will be provided through it.

3.33.7 My client is also concerned about the nature of the proposed premises, which are on a “high street” location surrounded by shops and other commercial buildings.

3.34 I have included, below, a google maps street view image which shows the proposed unit on the right hand side with the “to let” board affixed to the first floor.

3.35 As NHS England can see from this image, the proposed premises are “retail” in nature. There must, therefore, be an inherent risk that patients will seek to obtain pharmaceutical services whilst present at, or in the vicinity of, the premises. Despite this obvious risk, the applicant’s documentation makes no mention of the nature and location of the proposed premises and how this inherent risk will be sufficiently mitigated.

3.36 [See Appendix A – photograph for Committee]

3.37 In conclusion, for the reasons given above and on behalf of my client I invite NHS England to refuse this application.”

4 Summary of Representations

This is a summary of representations received on the appeal.

4.1 REX PHARMA LTD REPRESENTED BY RUSHPORT LLP (THE APPLICANT)

4.1.1 “Thank you for your letter of 17 October 2023 enclosing details of the above appeal.

4.1.2 As the Appellant relies on their previous correspondence to NHSE we have attached our previous reply to this submission in reply.

4.1.3 We look forward to hearing from you in due course.”

Rushport LLP comments to NHS England dated 28 July 2023

4.1.4 “Thank you for your letter of 27 July 2023. I act for Rex Pharma Limited in the above application and have been instructed by my client to submit the following reply to comments provided by interested parties.

4.1.5 The comments from the LPC are also contained within the comments from Weldricks and are dealt with below.

4.1.6 Weldricks questions the legal status of my client. As the Committee will be aware, the decision on whether to grant this application is yet to be taken. The Committee will consider the information and facts as they are at the time of the decision being made and not at any historical point in time. My client is properly incorporated as a body corporate and this is evidenced by the several pages of attachments provided by Weldricks representative.

4.1.7 Irrespective of the point above, my client submitted their application on 16 May 2023, ie more than 2 weeks after the company was incorporated. My client simply did not update the date on the form from previous draft versions. The company registration number is required with the application and was provided in separate documentation. The company registration number is not issued until after a company is incorporated and the company therefore existed prior to the application being made.

4.1.8 Therefore;

4.1.8.1 1. The application was submitted after the company was incorporated and

4.1.8.2 2. When the Committee makes its decision on this application the Applicant will be noted as being properly incorporated.

4.1.9 Weldricks representative then makes a number of submissions under the heading “Regulation 25”

4.1.10 Weldricks representative states;

4.1.11 *The applicant has provided, with its application form, a document titled “Further Information in Relation to Provision of Essential Services in Accordance with the Regulatory Requirements for Distance Selling Pharmacies”.*

4.1.12 *This document appears to have been produced by “Rushport Advisory LLP”. It is generic in nature and does not even refer to the applicant by name or reference the applicant’s premises.*

4.1.13 *The document repeatedly refers to how services “may” be provided but provides no information about how the applicant, itself, will provide all essential NHS services in the distance selling context.*

4.1.14 What Weldricks representative has failed to appreciate is that the information provided in support of the application is submitted by the Applicant and it is their information and evidence. This is clear from the fact that on every page it states “*Rushport Advisory LLP – Client Approved Service Description*”. In other words, my client (in this case Rex Pharma Limited) has approved the information. The fact that an Applicant engages an external advisor to assist in preparing their application is neither unlawful nor unusual and Weldricks representative is unable to direct the Committee to any rule, regulation or guidance that supports their argument – as none exists. This argument has been made by Weldricks representative on many occasions in the past and rejected on every occasion.

4.1.15 Weldricks representative then provides 6 bullet points which they appear to claim are examples of my client’s application not meeting the legal test, but as the Committee will see, none of these has any merit. Taking each of the points in turn;

4.1.15.1 *The document states that the pharmacy “will be equipped with facilities to allow for both phone (or other live audio link) and live video communication with patients in a manner which maintains patient confidentiality” but does not state how patient confidentiality will be maintained.*

4.1.16 As per the requirements of the Terms of Service, the pharmacy will have a separate room for such consultations to take place in the same manner as any other pharmacy has a consultation room that allows for discussion to take place privately.

4.1.16.1 *The document states that “robust identity check processes are in place” but fails to explain what these processes are.*

4.1.17 My client will require approved identification such as passport or driving licence prior to delivering any medication that requires identity checks to be in place (such as controlled drugs).

4.1.17.1 *The document states that essential services may be delivered using a variety of methods but does not say how essential services will actually be delivered by the applicant.*

4.1.18 The wording of the document is perfectly clear and the pharmacist will choose the most appropriate non face to face method for dealing with each patient. The pharmacist "may" (ie is permitted and indeed required) to use their judgement when considering a patient's needs.

4.1.18.1*The document states that prescriptions may be sent to the pharmacy by post, but does not explain how patients will be able to post prescriptions to the pharmacy free of charge.*

4.1.19 There is no requirement for the Applicant to pay for patients to post prescriptions to the pharmacy, however stamped and addressed envelopes will be provided and many pharmacies already provide these to patients and, in particular, GP surgeries so that prescriptions can be sent to them via post.

4.1.19.1*The document refers to an "app" in relation to the return of unwanted medicines, but does not mention an app anywhere else. No information is provided about this "app" and how services will be provided through it.*

4.1.20 The information provided states (page 8) "*The disposal service will be advertised on the website/app and marketing leaflets.".* If my client develops or provides the facility of an app to patients then the information will be contained within that app, but they do not yet have an app in place.

4.1.21 Weldricks also state that they are "concerned" by the location of the premises and that;

4.1.21.1*"There must, therefore, be an inherent risk that patients will seek to obtain pharmaceutical services whilst present at, or in the vicinity of, the premises"*

4.1.22 As the Committee will be aware, the requirements of the Regulations in relation to providing services are that;

4.1.22.1a. X must not offer to provide pharmaceutical services, other than directed services, to persons who are present at (which includes in the vicinity of) the listed chemist premises;

4.1.22.2b. the means by which X provides pharmaceutical services, other than directed services, must be such that any person receiving those services does so otherwise than at the listed chemist premises;

4.1.23 My client cannot prevent a patient from "seeking" to obtain a service. However Weldricks are wrong to say that my client has failed to consider this possibility as page 5 of the information provided by my client clearly states;

4.1.23.1*The Applicant's wholly Internet/Delivery Pharmacy will operate from secure premises, with a controlled entry system, to which members of the public will not have access.*

4.1.23.2*Any patient that 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.*

4.1.24 My client already has SOPs and has provided them with this reply so that the Committee can consider them along with his reply. [Appendix B for Committee]

4.1.25 We look forward to hearing from you in due course."

ADDITIONAL INFORMATION FROM THE APPLICANT DATED 26 OCTOBER 2023

4.1.26 "Please accept my apologies for this late email but my client has just informed me of an error on the application form.

4.1.27 My client was originally going to use a different pharmacist as the superintendent but at the last minute changed it to Mr Momoon Ali. My client updated all the forms (which are attached for reference) but did not change the superintendent's GPhC registration number on the main application form, but did on the other forms.

4.1.28 The superintendent section should therefore state Momoon Ali with registration number 2224021. All ftp checks were carried out for Mr Mamoom Ali with the correct registration number and were passed.

4.1.29 We provide this information in compliance with Schedule 2 Part 1 Para 9(a) and have copied in PCSE so that they can inform NHSE."

4.1.30 [Copy of updated application form - Appendix C for Committee].

ADDITIONAL INFORMATION FROM THE APPLICANT DATED 27 OCTOBER 2023

4.1.31 "Apologies – that should say Mr Mamoon Ali (not Momoon)."

5 Summary of Late Representations

5.1 COMMUNITY PHARMACY SOUTH YORKSHIRE

5.1.1 "Thank you for sending Community Pharmacy South Yorkshire the appeal documents for the above application with regards to an application for a distance selling pharmacy. Community Pharmacy South Yorkshire (LPC) would like to make the following comments:

5.1.2 The LPC believes the comments it made in its response to the application originally along with those from other commentators, Weldrick remain valid and should be considered by NHSR. The comments are below.

5.1.2.1 The LPC would like to request that NHSE will ensure that they are satisfied that procedures of the proposed pharmacy premises will allow for the uninterrupted provision of essential services during the opening hours stated on the application from anywhere in England, without face to face contact, and that promises made by the applicant are adhered to.

5.1.2.2 Also it was noted that Rex Pharma Ltd were not incorporated until a day after the date on the application form and we trust that NHSE will make the relevant company checks (enclosed is a screen shot of the companies house page) [Appendix D for Committee].

5.1.3 Please keep Community Pharmacy South Yorkshire (LPC) informed of progress. The LPC may like to comment further should the opportunity arise including attending and commenting at any oral hearing."

6 Summary of Observations

This is summary of observations received.

6.1 HI WELDRICK LIMITED, REPRESENTED BY TEMPLEBRIGHT LLP

6.1.1 "I write further to your letter of 21st November 2023 and in order to respond to representations made by the applicant in response to my client's letter of appeal. Taking each point raised by the applicant's representative in turn, my client comments as follows.

6.1.2 It appears to be accepted that, at the time the application form was completed and signed by the applicant's director, the applicant company did not exist. The applicant's representative states that the application was submitted on 16th May 2023, although no evidence is provided to support this assertion.

6.1.3 Irrespective of when the application was submitted, and irrespective of the fact that Rex Pharma Limited now exists as a legal entity, it is, of course, a matter of common sense that a company which has not yet been formed cannot complete an application to NHS England, such that the application is void.

6.1.4 In relation to the generic information provided by the applicant in support of its application, the response from Rushport Advisory LLP merely underlines the point being made by my client: the information provided in support of this application is identical to information provided by Rushport Advisory LLP in support of dozens of other applications across England.

6.1.5 Whilst it is accepted that Rushport Advisory LLP may assist its clients to prepare their supporting information, the information provided must reflect the way in which the applicant, itself, proposes to provide essential pharmaceutical services in the distance selling context.

6.1.6 Since it is inherently unlikely that every pharmacy applicant that Rushport Advisory LLP has licensed its generic SOPs to intends to provide essential services in an identical way, it is self-evident that the supporting information provided by Rex Pharma Limited does not detail how the applicant, itself, intends to provide pharmaceutical services. It therefore cannot possibly be sufficient to satisfy NHS Resolution that the requirements of regulation 25 are met.

6.1.7 Rushport Advisory LLP states that "a separate room for such consultations to take place" will be available. This is inconsistent with the applicant's application form, which states that the pharmacy will have "a private area where phone calls and video consultations can take place". This demonstrates the generic nature of the information provided by the applicant and how the information provided does not appear to reflect how the applicant, itself, intends to provide essential pharmaceutical services.

6.1.8 In relation to how essential services will be provided, the applicant's original supporting information stated that essential services "may" be delivered using a variety of methods. This list appears to have been provided to include every possible option as to how a distance selling pharmacy "may" provide services. However, nothing in the document assists NHS Resolution to understand how services will, in fact, be delivered.

6.1.9 NHS Resolution is reminded that regulation 25 requires NHS Resolution to be satisfied that "the pharmacy procedures for the pharmacy premises are likely to secure…the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and 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".

6.1.10 It is asserted on behalf of my client that the provision of generic information listing how essential services "may" be provided does little to satisfy NHS Resolution that the pharmacy's procedures are "likely" to secure the requirements of regulation 25(2)(b).

6.1.11 It is a requirement of section 1(4) of the National Health Service Act 2006 that patients must receive NHS services free at the point of care. Since patients would only be able to access pharmaceutical services from the applicant's proposed pharmacy remotely, patients must be able to access dispensing services from the proposed pharmacy free of charge. Provision of a dispensing service does, of course, require patients to be able to get their prescriptions to the pharmacy. It is therefore incumbent upon a distance selling pharmacy to facilitate the receipt of paper prescriptions by the pharmacy from the patient free of charge to the patient. The applicant's representative is therefore wrong to assert that "there is no requirement for the Applicant to pay for patients to post prescriptions to the pharmacy".

6.1.12 Rushport Advisory LLP state, in their letter of 28th July 2023, that "stamped and addressed envelopes will be provided" by the applicant. However, neither the applicant's supporting information document which was provided to NHS England nor its SOPs which are provided in response to this appeal make any mention of pre-paid envelopes being provided. Since, according to Rushport Advisory LLP, the SOPs are "submitted by the Applicant and it is their information and evidence", it is reasonable to assume that because that information makes no reference to pre-paid envelopes, the applicant has no intention of providing pre-paid envelopes.

6.1.13 It would therefore appear that patients with paper prescriptions have no way of getting those prescriptions to the applicant's proposed pharmacy free of charge to the patient, meaning that patients cannot access this essential service no matter where in England they live.

6.1.14 The position in relation to whether or not the applicant intends to use an "app" remains unclear. The generic information provided with the application to NHS England referred to an app, but the SOPs now provided do not appear to refer to an app. If the applicant does not intend to use an "app", why was there reference to it in its supporting information document?

6.1.15 If the applicant does intend to use an "app", why is there no reference to it in the applicant's SOPs? In relation to the proposed premises, my client remains of the view that there are inherent risks in terms of the premises proposed by the applicant that are not properly addressed in the generic information that has been provided the applicant.

6.1.16 For the reasons given above and those given in my client's letter of appeal, on behalf of my client I invite NHS Resolution to uphold this appeal and to refuse the application.

6.1.17 I look forward to hearing from you."

7 **Request for additional information**

NHS Resolution requested that PCSE on behalf of South Yorkshire ICB confirm the date that it received the application form from the Applicant. It responded:

7.1 "The application was received by email on the 16th May 2023."

8 **Comments on additional information**

8.1 REX PHARMA LTD REPRESENTED BY RUSHPORT LLP (THE APPLICANT)

8.1.1 “Thank you for your letter of 12 December 2023.

8.1.2 I note that NHS Resolution has now confirmed that date that the application was submitted and this date, 16 May 2023, is the same as I had previously notified to you when replying to the letter of appeal and was 2 weeks after the company was incorporated.

8.1.3 For the sake of completeness I wish to point out that whilst the Appellant’s representative also makes the claim that the application form was signed prior to the company being formed, this claim is also false as I sent the final form of unsigned documents to my client for review and signature on 11 May 2023, ie 9 days after the company was incorporated.

8.1.4 I look forward to hearing from you in due course.”

9 **Consideration**

9.1 The Pharmacy Appeals Committee (“Committee”) appointed by NHS Resolution, had before it the papers considered by the Commissioner.

9.2 It also had before it the responses to NHS Resolution’s own statutory consultations.

9.3 On the basis of this information, the Committee considered it was not necessary to hold an Oral Hearing.

9.4 The Committee had regard to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (“the Regulations”).

Preliminary matter

9.5 The Appellant, in its appeal states “*The applicant company appears to have been formed after the date on which the application was submitted, making the application invalid*.” The Appellant provided information in the form of an entry from Companies House, in Appendix A for Committee. This shows that the Applicant’s company was registered by Companies House on 2 May 2023. The Committee noted that the Appellant had raised its concerns to NHS England at the application stage however South Yorkshire ICB did not address this aspect in its decision. On appeal, the Appellant has commented with regard to Regulation 10(7) which states:

(7) Schedule 2, which has effect, contains provisions with regard to—

(a) the information to be supplied by a person—

(ii) seeking inclusion in a pharmaceutical list who is not already included in it, or

(iii) who is included in a pharmaceutical list and who is seeking—

(aa) to open, within the area of the relevant HWB, additional premises from which to provide the same or different pharmaceutical services,

(bb) to relocate to different premises, and at those premises to provide the same or different pharmaceutical services, or

(cc) to provide, from the person's listed chemist premises, services that are in addition to those already listed in relation to that person; and

(b) the procedure to be followed by persons as mentioned in sub-paragraph (a) when making a routine application or an excepted application; and

(c) other related matters.

9.6 The Committee noted the reference to paragraph 2 of Schedule 2 which states:

Information to be included in all routine and excepted applications for inclusion in a pharmaceutical list

2.— (1) The information mentioned below in this paragraph must be included in all routine and excepted applications for inclusion in a pharmaceutical list.

…..

(3) If A is a body corporate—

(a) A's registered name and any other name under which A trades;

(b) A's company registration number;

(c) A's registered office and any fixed line telephone number relating to that office;

(d) the private address and date of birth of A's superintendent (if A is seeking entry in the list mentioned in regulation 10(2)(a));

(e) the name and date of birth of each director of A (who is not A's superintendent), and if any director of A (who is not A's superintendent) is a registered pharmacist, that director's registration number in the GPhC register;

(f) a declaration that A is, or is entitled to be, lawfully conducting a retail pharmacy business in accordance with section 69 of the 1968 Act, if A is seeking entry in the list mentioned in regulation 10(2)(a); and

(g) if A is already included in Part 3 of the GPhC register in respect of any premises, A's registration number in that Part of the GPhC register, if A is seeking entry in the list mentioned in regulation 10(2)(a).

9.7 In response to the Appeal, the Applicant stated "*my client submitted their application on 16 May 2023, ie more that 2 weeks after the company was incorporated. My client simply did not update the date on the form from previous draft versions. The company registration number is required with the application and was provided in separate documentation. The company registration number is not issued until after a company is incorporated and the company therefore existed prior to the application being made*."

9.8 The Committee further noted that NHS Resolution had requested that PCSE on behalf of South Yorkshire ICB confirm the date that it received the application form from the Applicant. PCSE responded "*The application was received by email on the 16th May 2023*."

9.9 The Committee is of the view that despite the date on the application form being 1 May 2023, the application form was not received by South Yorkshire ICB until 16 May 2023, some 2 weeks after the company was registered at Companies House. The Committee is unsure why South Yorkshire ICB chose not to address this matter until requested to do so by NHS Resolution. However that aside, the Committee was of the view that the application was made correctly and in accordance with the Regulations. The Committee therefore went on to consider the substantive application.

Regulation 31

9.10 The Committee 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) the NHSCB 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).

9.11 The Applicant, in its application states "*Not applicable as no other pharmacy in same or adjacent premises*". The Committee noted that South Yorkshire ICB had concluded that Regulation 31 did not apply. The Committee also noted that this had not been disputed either on appeal or in subsequent representations. On the basis of the information before it, the Committee determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

9.12 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) The NHSCB 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 the NHSCB 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.

9.13 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 the NHSCB in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the NHSCB may need to make of the information or documentation when carrying out its functions.*

Regulation 25(1)

9.14 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)

9.15 As far as Regulation 25(2)(a) is concerned, the Committee had regard to the application form in which the Applicant states the "*application is 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 Committee noted that this had not been disputed and that it had not been provided with any information to persuade it otherwise. The Committee was therefore satisfied 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)

9.16 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 its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.

9.17 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.

9.18 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 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.

9.19 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 SOPs which the Applicant has prepared or commissioned.

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

9.21 The Appellant, in its Appeal states it "*is also concerned about the nature of the proposed premises, which are on a "high street" location surrounded by shops and other commercial buildings*." The Committee noted in the SOPs provided by the Applicant that SOP 1 'Introduction and Background to SOPs' point 1.3 states that the pharmacy must provide:

> "*The uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services*. *The safe and effective provision of essential service without face-to-face contact between any person receiving the services, whether on their own or on someone else's behalf, and the owner of this pharmacy or any member of staff either on or in the vicinity of the premises."*

9.22 Further, SOP 3 'Procedures for NHS Essential Services' point 3 states:

> *"NHS Essential Services will be provided to any patient living in England who requests such services, this is made clear on the website and in the Practice leaflet."*

9.23 In its SOP 31 'The Responsible Pharmacist' point 31.9, the Applicant states:

> *"As a Distance Selling pharmacy, we must provide uninterrupted service throughout the opening hours of the pharmacy. For this reason, the RP is not allowed to leave the premises in the same way as a RP at a non-Distance Selling pharmacy is allowed to (for up to 2 hours per day)* ***unless another pharmacist is present.*** [Emphasis added by Applicant.]
>
> *The Pharmacy will have a second pharmacist available during the core and any additional hours that it operates. If, for any reason, the RP is required to leave the premises or wishes to take a break (as per Working Time Directive) then the second pharmacist must sign in as the RP."*

9.24 The Committee noted that throughout the SOPs the Applicant states that essential services will be provided without face to face contact between any service user and the pharmacy staff. SOP 1 'Introduction and Background to SOPs' point 1.3 states:

"*All staff must be made aware that face to face contact between patients (or their representatives) is prohibited in respect of any and all Essential Services either on or in the vicinity of the premises*.

Face to face contact with patients or their representatives either on or in the vicinity of the premises is only allowed in respect of the provision of services other than Essential Services.

Any reference to 'contact' with or 'contacting' a patient in relation to these SOPs means contact other than face-to-face contact either on or in the vicinity of the premises." [Emphasis added by the Applicant.]

9.25 The Committee noted, as per SOP 3 'Procedures for NHS Essential Services', that service users would be able to utilise multiple methods to contact the pharmacy that did not result in face to face communication. The SOP, under the heading 'Communication Channels' point 3.1 states:

"All communication regarding NHS Essential Services should be carried out using the most suitable non face to face method for the patient and the service being provided with particular consideration to maintaining confidentiality. This may be telephone, email, video-conferencing or other types of non-face to face communications such as text messages."

9.26 The Committee noted the concerns raised by the Appellant on appeal and in its observations regarding "*a generic document*" and "*the risk that patients may receive, or be offered, the provision of pharmaceutical services whilst present at, or in the vicinity of, the listed premises*". The Committee noted that the cover page of the SOPs has the Applicant's Pharmacy name on it. The Committee considered the information provided in the SOPs, alongside the information submitted with the application, were sufficient to provide assurance that the Applicant, if granted, would be offering pharmaceutical services without face to face contact.

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

9.28 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.

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

9.30 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:

Dispensing of drugs and appliances

9.31 The Appellant, in its appeal states "*the document states that prescriptions may be sent to the pharmacy by post, but does not explain how patients will be able to post prescriptions to the pharmacy free of charge*."

9.32 The Committee considered whether the Applicant had explained how non-electronic prescriptions will be presented by the patients and how products would be provided.

9.33 The information contained in the SOPs provided by the Applicant, SOP 3 'Procedures for NHS Essential Services' in the first paragraph states:

"Patients who wish to send paper prescriptions to the pharmacy by post should be sent stamped addressed envelopes to enable them to do so."

9.34 From the information contained in the SOPs provided by the Applicant, SOP 6 'Online Order Receipt & Exemption Checking', point 6.2 under the heading 'Scope' states:

"… Requests to collect and dispense NHS Prescriptions.

Requests to dispense a prescription received in the post.

Any requests from the "contact us" section of the website."

9.35 The Committee had regard to SOP 17 'Order Delivery' which under the heading 'Choice of Delivery Method' at point 17.6 states:

"For items other than cold chain / "fridge line" items, local deliveries (up to 30 miles radius, but may be extended at the discretion of the RP) the delivery driver should deliver medication. Outside this area Royal Mail should be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier should be used (see SOP for Delivery of Controlled Drugs), or the items are fridge lines, in which case the cold chain courier should be used." [Emphasis added by the Applicant.]

9.36 The Committee was satisfied that the Applicant was proposing to offer the service to all of England, as per the information contained in the SOPs, and was of the view that the Applicant would not be just serving the immediate locality using a local delivery driver. The Committee was satisfied that the Applicant's SOPs had explained how patients could post their paper prescriptions free of charge.

9.37 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 5(2)(3) of Schedule 4.

Urgent supply without a prescription

9.38 The Committee considered whether the Applicant had explained how it proposes to safely and effectively receive requests from prescribers for urgent supplies of drugs and appliances.

9.39 The Committee had regard to SOP 14 'Emergency Supply and Urgent Supply' which describes how the Applicant will process such a request. The Committee noted that the SOPs refer to Essential Services being delivered by several means of non-face-to-face communication including telephone and email, and considered that it was reasonable to infer that these methods would be used to receive requests from prescribers for the urgent supply of drugs.

9.40 Based on the information before it the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.

Preliminary matters before providing ordered drugs and appliances

9.41 The Appellant, in its Appeal states "*The document states that "robust identity check processes are in place" but fails to explain what these processes are*."

9.42 The Committee considered whether the Applicant had explained how evidence will be sought and obtained about the patients' entitlement to exemption or remissions from NHS Charges.

9.43 The Committee noted SOP 6 'Online Order Receipt & Exemption Checking' and in particular the heading 'Exempt NHS Prescriptions' point 6.11 which states:

> *"…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 should be updated to reflect that necessary check has been carried out and a note of when the next check is required should be entered onto 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, but see NOTE below) and the pharmacy can note that the evidence provided was not in 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."*

9.44 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.

9.45 The Committee then considered whether the Applicant had explained how charges will be paid.

9.46 The Committee noted SOP 6 'Online Order Receipt & Exemption Checking' under the heading 'Paid NHS Prescription' point 6.14 which states:

> *"…Check to see if any fees have been paid and if so, was the correct amount paid?*
>
> *Contact the patient to arrange payment using the secure payments system using the "customer not present" option.*
>
> *If no fees have been paid or there is a discrepancy between fees paid and those due, the patient should be contacted and directed to pay the appropriate fees via the online payment system."*

9.47 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(5)(b) of Schedule 4.

Providing order drugs and appliances

9.48 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).

9.49 The Committee noted that SOP 17 'Order Delivery' under the heading 'Transfer to the Delivery Driver' at point 17.10 states:

> *"Ensure that the pharmacist on duty is available to supervise the handing over of all items for delivery.*
>
> *Ensure that any special instructions for the delivery are included with the packaging.*
>
> *Ask the delivery driver to check the details on the delivery sheet correspond to the deliveries.*
>
> *Ensure the delivery driver completes all the sections on the delivery sheet including their name and the date.*

Ensure that any deliveries for fridge items and CDs are taken out of storage when appropriate.

Ensure the delivery driver is notified of any messages for the patient or representative.

Make and retain a copy of the delivery sheet until the original has been returned by the delivery driver. The original must be returned to the pharmacy on the same day.

Ensure the deliveries are placed in the delivery vehicle and are stored securely and out of sight. The delivery vehicle must be locked at all times when left unattended."

9.50 Further SOP 17 at point 17.4, under the heading 'Delivery of a prescription via Royal Mail (Not for cold chain or CDs) states:

"Follow preparation for delivery process. The pharmacist should contact any patients for whom there are relevant messages or counselling required.

Ensure that the pharmacist on duty is available to supervise the handing over of all items for delivery.

Print and attach relevant Royal Mail Signed For delivery labels using the Royal Mail online business account and attach securely to outer packaging.

Ensure a return address is printed clearly on the outer packaging.

Confirm details of all prescriptions to be delivered.

Make a note of all Tracking numbers for prescriptions being delivered by Royal Mail on Delivery Log sheet.

Ensure Royal Mail driver signs Delivery Log sheet for all prescriptions being accepted for delivery. Store Delivery Log sheet for a minimum of 3 months from dispatch date.

Email patients dispatch confirmation with their Tracking number when the prescriptions have left the premises.

All deliveries will require a signature from the patient to confirm receipt of their prescription."

9.51 The Committee noted that the SOP then, under the heading 'Cold chain delivery via courier', at point 17.16 states:

"All cold chain deliveries must be carried out by couriers with verified and approved cold chain procedures. A list of approved cold chain couriers is available within the Pharmacy and will be updated from time to time. Each approved courier meets stringent criteria to ensure a fully monitored and dedicated cold chain service.

Specialist cold chain courier service 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 is a dedicated, fully monitored and temperature controlled delivery service.

Any breach of cold chain conditions will be notified to the driver and any affected delivery will be cancelled with the pharmacy informed of the cold chain breach. ……

Ensure any items for cold chain delivery via courier are stored in the fridge and accompanying items are appropriately marked with a fridge line sticker. Accompanying items should include a note to explain that fridge items will be delivered separately to the rest of their items to enable the cold chain to be maintained.

A delivery should be booked using the couriers specified Cold Chain Services (refer to booking procedure with courier in the "cold chain courier" folder),

Select a delivery maintaining 2– 8°C unless the item requires shipping at a different temperature.

The cold chain item should be kept in the fridge until the courier arrives to accept the delivery.

Confirm with the courier that the delivery will be maintained at the booked temperature range. ……

Unsuccessful cold chain delivery via courier

In the event of an unsuccessful delivery, the courier will leave a 'Missed Delivery' card, stating the date and time of the attempted delivery along with details of how to contact the courier to arrange the redelivery. The patient can then rearrange delivery for a convenient time by telephone or Internet.

We operate to a 48 hour maximum window for cold chain deliveries and the courier will keep the cold chain intact until successful delivery for up to 48 hours. After 48 hours the items will be returned to the pharmacy and the pharmacy will contact the patient to rearrange delivery.

Breach of Integrity of Cold Chain

….. The cold chain service is a dedicated, fully monitored and temperature controlled delivery service. However, in the event of any breach in the integrity of this service, the system automatically alerts the delivery driver that the cold chain has not been kept intact.

Where such an event occurs, the courier is instructed to leave a 'Missed Delivery' card and also inform the pharmacy that the delivery was unsuccessful due to a breach of the cold chain. The pharmacy must arrange for immediate re-delivery of the items via courier and the return of the items that have failed to be delivered to the pharmacy by the courier. Items subject to a cold chain breach may not be re-used and must be segregated from the pharmacy stock."

9.52 The Committee noted that SOP 21 'Controlled Drugs: Delivery' under the heading 'Delivery of Schedule 2 & 3 CDs' at point 21.5 states:

"A robust audit trail is essential when controlled drugs are involved. The delivery can be made to a person who is not the patient (the patient must have given authorisation for a representative to take receipt of CDs on their behalf). A Controlled Drugs Delivery Sheet must also be filled in for CD deliveries in addition to the Delivery Log sheet.

CDs should be in a separate bag to any other medication being delivered and the bags should be attached together. ….

The delivery van must be kept locked at all times when the driver is not in the vehicle.

The delivery driver/courier should sign the back of the prescription as the representative when accepting the CD for delivery.

The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative (passport, driving licence or government approved photo ID card are acceptable forms of ID). A delivery cannot be left with anyone who is not the patient or their authorised representative. …..

All entries in the CD register should be made when the medication leaves the pharmacy premises. The delivery driver/courier should be entered as the 'person collecting'.

The prescription should be retained in the pharmacy until the delivery driver returns the appropriate paperwork signed by the patient or representative to confirm successful delivery or the patient signature is confirmed online if delivered by courier.

Successful Schedule 2 & 3 Delivery

…. For all successful deliveries the Controlled Drug delivery sheet signed by the patient or online courier delivery record should be cross-referenced with the prescription and CD register prior to the prescription being processed as part of the end of day procedure.

Unsuccessful Schedule 2 & 3 Delivery via pharmacy driver

Unsuccessful deliveries sent with a pharmacy driver must be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate.

Unsuccessful Schedule 2 & 3 Delivery via courier

Unsuccessful deliveries sent with a courier should be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate. Where the time of attempted delivery means that the return cannot be made on the same day, the courier will store the drugs at their approved warehouse overnight.

When a failed delivery occurs, the tracking service will notify the pharmacy and the patient of the failed delivery so that delivery can be re-arranged for the patient at the next convenient time or returned to the pharmacy.

Note re Use of Couriers for Controlled Drugs Deliveries

The courier has pharma grade specialist facilities to meet specific quality and validation requirements for healthcare products. This includes Home Office licensed controlled drug stores."

9.53 Based on the information before it, the Committee was satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

9.54 The Committee considered whether the Applicant had explained the arrangement which would ensure that, for appliances which require fitting/measuring, a registered pharmacist measures/fits them.

9.55 In relation to appliances, the Applicant confirmed in its application form that it will undertake to provide:

> *"*Drug Tariff part IX – except items that require measuring or fitting.*"*

9.56 The Committee noted the relevant SOPs with regard to Appliances which were contained within the information provided by the Applicant and in particular SOP 7 'Pharmaceutical and Legal Assessment' under the heading 'Items requiring measuring and fitting' at point 7.9 where the Applicant states:

> *"Where a prescription is received for an item that requires measuring or fitting the patient should be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients should be signposted to at least two other providers of the service in their area. (see signposting SOP)"*

9.57 SOP 24 'Support for Self-care, Signposting and Health Promotion' point 24.14 states under the heading 'Items Requiring Measuring and Fitting':

> *"Where a prescription is received for an appliance or stoma appliance customisation or any item that requires measuring or fitting the patient should be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients should be signposted to at least two other providers of the service in their area. (see signposting SOP)"*

9.58 In the event that the application is granted, the Applicant would therefore not be able to provide those appliances as listed in the application form to patients.

9.59 Based on the information before it, the Committee was satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(4) of Schedule 4.

9.60 The Committee next considered whether the Applicant had explained what containers would be suitable for posted/delivered items.

9.61 The Committee noted that SOP 16 'Bagging Up' under the heading 'Choice of Packaging' at point 16.7 states:

> *"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.*
>
> *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.*
>
> *Medicine for local delivery which is not fragile and to be delivered by the delivery driver can be packaged in the using the pharmacy bags supplied for standard prescription items.*
>
> *DO NOT use normal cardboard boxes. When cardboard boxes are required ALWAYS use the re-enforced boxes that are purchased for delivery purposes.*
>
> *For postal items, either:*

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

*For most items - bubble wrap and where necessary, polystyrene filler, placed within a cardboard box. **use the re-enforced cardboard boxes**use the re-enforced cardboard boxes***

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

Coldchain items should be bubble wrapped and placed in Styrofoam filled re-enforced cardboard boxes and kept in the DELIVERIES FRIDGE (rather than the storage fridge) with the "FRAGILE" and "FRIDGE LINE" stickers attached. The courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box ("cold ship" packaging) and are fully monitored – typically at 2 to 8 degrees Celsius range- (see delivery SOP). 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 and such items must not be used." [Emphasis added by the Applicant.]

9.62 Based on the information placed before it, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(15) of Schedule 4.

Refusal to provide drugs or appliances ordered

9.63 The Committee asked itself how the Applicant will be satisfied that when dispensing a repeatable prescription other than on the first occasion, that the patient is still using the medication, is not suffering from any side effects, the medicine regimen has not changed in any way and there has been no changes to the patient's health, which may indicate the desirability of reviewing the patients treatment.

9.64 The Committee noted that SOP 33 'Repeat Dispensing' states under the heading 'Pharmaceutical & Legal Assessment' at point 33.11:

"The pharmacist should telephone and speak with the patient before issuing a repeat and ensure:

They are taking or using, and likely to continue to take or use the medicine or appliances appropriately

Advise the patient that they should only order items that they need

Check that the patient is not suffering any side effects which may suggest they need a review of their medication

Check that the patient's regimen has not been changed since the prescriber authorised the repeatable medication.

Check that there has not been any change to the patient's health since prescription was authorised

Provide advice and encourage patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber

Any interventions, referrals (to the patient's GP or otherwise) or refusal to supply decisions which are deemed to be clinically significant should be

recorded on the Intervention and Referral Form which must be shared with the patient's GP."

9.65 The Committee further noted SOP 33 under the heading 'Prescription Reception' at point 33.10 states:

> *"…. The pharmacy record card must be completed and attached to a RA and an entry made on each occasion a dispensing takes place.*
>
> *Any amendments to the RD, e.g. items not issued or change to expected interval must be recorded in the comment section of the pharmacy copy of the card."*

9.66 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 9(4) of Schedule 4.

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

9.67 The Committee considered whether the Applicant had explained how appropriate advice about the benefits of repeat dispensing to be given to any patient who (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 (ii) requires regular medicine in respect of that medical condition.

9.68 The Committee noted SOP 33 'Repeat Dispensing' under the heading 'Prescription Reception' at point 33.10 states:

> *"Appropriate advice about the benefits of repeat dispensing must be given to any patient who:*
>
> > *has a long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term); and,*
> >
> > *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.*
>
> *Such advice will be provided by the Pharmacy using its permissible methods of non-face-to-face contact with patients."*

9.69 Further, the Committee noted SOP 33 goes on under 'Pharmaceutical and Legal Assessment' at point 33.11 to state:

> *"Provide advice and encourage patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber."*

9.70 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.

Disposal service in respect of unwanted drugs

9.71 The Committee considered whether the Applicant had explained how it will safely and effectively accept and dispose of unwanted drugs presented to it for disposal.

9.72 For the return of controlled drugs, the Committee noted that in SOP 22 'Controlled Drugs: Collection and Disposal of Patient Returns', particularly under the heading 'Patient Returned Medication', at point 22.5 states:

"*This service is available to <u>all</u> patients living in England.*

Patients or their representatives <u>may not</u> return and medicines directly to the pharmacy and must follow the procedures set out in this SOP.

Patients should be referred to the 'Returning unwanted medication' page on the website for information.

To arrange the return of unwanted medicines to the Pharmacy the patient must telephone and speak to a member of the dispensary team. For controlled drugs this should always be the pharmacist on duty.

The process for returning medication should be explained to the patient.

Each return will be made by booking an appointment for the pharmacy's driver to visit the patient's home to collect the returned medication or by sending the appropriate packaging to the patient to arrange for return by Royal Mail…"

9.73 The Committee notes that SOP 22 goes on under the heading 'Return by Royal Mail' to state at point 22.7:

"*The pharmacist must*

Speak to the patient about the return and clarify the items being returned.

Assess the items for suitability for return by Royal Mail

If items are suitable for return by Royal Mail then make a note on the PMR and arrange to send the appropriate packaging to the patient for safe return (refer to bagging up SOP for appropriate packaging)

If items are not suitable for return by Royal Mail (eg clinical or contaminated waste) then provide the patient with details of their local procedures for disposal.

Send the packaging to the patient along with the instructions for appropriate packing of the goods

Contact the patient to ensure that the packaging has been received

Provide signposting to other pharmacies where the patient prefers to dispose of unwanted medicines locally."

9.74 The Committee noted that SOP 22 under the heading 'Handling Patient-Returned CDs from Delivery Driver' states at point 22.8:

"Drivers need to:

Be aware that they cannot accept patient returns from patients without prior arrangement. The driver should notify the patient to follow the "returning unwanted medication" process as set out on the website.

Ensure that appropriate packaging is within the van prior to starting the journey as the patient may not have requested the correct type or there may be a requirement for additional packaging."

9.75 The Committee noted that SOP 23 'The Safe and Effective Receipt and Disposal of Medicines' under the heading 'Process for Patients to Return Medication' at point 23.6 states:

"*Patient Returned Medication*

Patients or their representatives MAY NOT return and medicines directly to the pharmacy and must follow the procedures set out in this SOP.

This service is available to all patients living in England.

Patients can be referred to the 'Returning unwanted medication' page on the website for information.

To arrange sending medication back to the Pharmacy the patient must telephone and speak to a member of the dispensary team.

Patients may

Arrange collection by the Pharmacy driver at an appointed time, or

Send unwanted medication back to the Pharmacy via courier (at the pharmacy's cost), or Royal Mail (subject to risk assessment of contents by the RP in advance) or,

The Pharmacy can arrange for medication to be collected by our specialist waste management contractor.

Advise patient of their other options to dispose of unwanted or expired medication if none of these options is suitable for them (signposting to local pharmacies)."

9.76 The Committee noted that SOP 23 goes on under the heading 'Process for accepting patient returns by the Driver' at point 23.7 to state:

9.76.1 *"Confirm that a collection of unwanted medication for disposal has been booked. Returns without a booking should only happen in exceptional circumstances as this increases the chance that the proper process for segregation of medicine has not been followed. …..*

Identify any controlled drugs (check with the pharmacist if necessary); segregate these and place in a labelled clear bag for the pharmacist for denaturing and disposal. For further guidance read SOP Controlled Drugs: Disposal of Patient returned medication'.

Identify any sharps and ask the customer to take these back if it safe to do so, signposting to the most appropriate route of disposal.

Identify any cytotoxic or other hazardous waste (check with the pharmacist where necessary).

Identify any flammable waste and store separately until this can be removed by the waste contractor.

Complete the 'Patients Returns Sheet' detailing the patients name and address, also if relevant their representatives name.

Store returned medicines in the quarantine area of the van for transport.

The returnable items can be taken back to the pharmacy for destruction."

9.77 The Committee noted that the SOP, under 'Disposal of returned medicines' at point 23.10, states:

> *Use the specialist waste management company to provide safe and secure disposal of unwanted medicines by collection of unwanted medicines from patients and residential homes.*
>
> *Unwanted medicines collected by the driver must be sorted and placed in disposal units / containers provided by the NHSCB or a waste contractor retained by the NHSCB ready for waste management services to collect."*

9.78 The Appellant, in its appeal also states "*the document refers to an "app" in relation to the return of unwanted medicines, but does not mention an app anywhere else. No information is provided about this "app" and how services will be provided through it*."

9.79 The Committee noted that the Applicant, in representations on the appeal states "*The information provided states (page 8) "The disposal service will be advertised on the website/app and marketing leaflets.". If my client develops or provides the facility of an app to patients then the information will be contained within that app, but they do not yet have an app in place*." The Committee was of the view that currently there was no App in place as confirmed by the Applicant. However, patients are able to dispose of unwanted medications as considered in 9.73 to 9.78 above.

9.80 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 13 – 15 of Schedule 4.

Promotion of healthy lifestyles

9.81 The Committee considered whether the Applicant had explained how it will safely and effectively promote healthy lifestyles.

9.82 The Committee noted that SOP 25 'Promotion of Healthy Living, Lifestyles & Health Campaigns' under the heading 'Health Campaigns and Community Engagement Exercise' states at point 25.4:

> *"…. The Pharmacy will take part in national health campaigns to promote public health messages to 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 on the health promotion zone. ….*
>
> *We will also offer help and support on our website and direct patients to appropriate links for the health campaigns. This will ensure that patients across the UK are able to easily access information about health campaigns at all times."*

9.83 Further, in SOP 25, under the heading 'Identification of patients for promotion of healthy lifestyles' states at point 25.3):

> *"…. 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. The website, app and email newsletters will also be used to promote healthy lifestyles via the health promotion zone."*

9.84 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 16 – 18 of Schedule 4.

Prescription linked intervention

9.85 The Committee considered whether the Applicant had explained how it will assess whether persons require prescription linked intervention advice because they have diabetes, are at risk of coronary heart disease, smoke or are overweight.

9.86 The Committee noted SOP 25 'Promotion of Healthy Living, Lifestyle & Health Campaigns' at point 25.3 under the heading 'Identification of patients for promotion of Healthy Lifestyles' states:

> *"…. 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. The website, app and email newsletters will also be used to promote healthy lifestyles via the health promotion zone." …..*
>
> *"Identification can take three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process.*
>
> *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. 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.*
>
> *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 / diabetes etc.*
>
> *As part of repeat dispensing process (or during any other interaction with a patient) staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from promotion of healthy lifestyles they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided.*
>
> *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. The website, app and email newsletters will also be used to promote healthy lifestyles via the health promotion zone."*

9.87 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

Health Campaigns

9.88 The Committee considered whether the Applicant had explained how it will safely and effectively participate in health campaigns, if and to the extent required by NHS England.

9.89 The Committee noted that in SOP 25 'Promotion of Healthy Living, Lifestyle & Health Campaigns' under the heading 'Health Campaigns and Community Engagement Exercise', at point 25.4 states:

> *"…. The Pharmacy will take part in national health campaigns to promote public health messages to 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 on the health promotion zone. …..*
>
> *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. …..*
>
> *We will also offer help and support on our website and direct patients to appropriate links for the health campaigns. This will ensure that patients across the UK are able to easily access information about health campaigns at all times.*
>
> *The Pharmacy will use the opportunity when dispensing prescriptions for patients who have conditions such as diabetes, heart disease, obesity and high blood pressure, to offer health advice over the phone or provide them with leaflets about their conditions. Patients will also be able to speak to the pharmacist regarding information about the campaigns. Advice and help will be available to patients during opening hours of the pharmacy and patients can access information on our pharmacy website at all times. This ensures the uninterrupted provision of the service to patients across England."*

9.90 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 18 of Schedule 4.

Signposting

9.91 The Committee considered whether the Applicant had explained how it will provide information to users of the pharmacy about other health and social care providers and support organisations.

9.92 The Committee noted that in SOP 24 'Support for Self-Care, Signposting and Health Promotion' under the heading 'Patient Identification' at point 24.13, states:

> *"Identification can take place during any interaction that the patient has with the pharmacy staff. In particular, staff should consider the results from the identification of patients for the promotion of healthy lifestyles and those who have filled in the Lifestyle Questionnaire on the website.*
>
> *Staff should always consider that in order to minimise inappropriate use of health and social care services and of support services and person who:*
>
> > *requires advice, treatment or support that we cannot provide; but*
> >
> > *we are aware of another provider of health services who is likely to be able to provide that advice, treatment or support.*
>
> *We must provide the patient with contact details of that provider and, where appropriate, refer the person to the provider. At least two providers should be identified if this is possible."*

9.93 The Committee noted that in SOP 24 under the heading 'Other Provider Organisations and Support Details' at point 24.10 states:

"Details of local health and social care providers to whom patients can be referred as well as contact details for local patient and support groups can should [sic] be provided to patients via written mailshots, flyers, sent with prescription deliveries, our website and by telephone or email."

9.94 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 19 – 20 of Schedule 4.

Support for Self-Care

9.95 The Committee considered whether the Applicant had explained how it will provide advice and support to people caring for their families.

9.96 The Committee noted SOP 24 'Support for Self-care, Signposting and Health Promotion' under the heading 'Service Outline' at point 24.9 states:

"Upon receipt of a request for help with the Support for Self-Care, including treatment of minor illness and long-term conditions, pharmacy staff should consider available resources and provide general information and advice on how to manage illness.

If appropriate, access the patient's Summary Care Record to see if it assists in delivery of the service."

9.97 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 21 – 22 of Schedule 4.

Discharge medicines service

9.98 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.

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

9.100 The Committee noted SOP 26 'Discharge Medicines Service ("DMS")' states:

"*Process*

Every day the RP must check the pharmacy's NHS mail system, PharmOutcomes and Refer to Pharmacy for referrals to the DMS. Pharmacy contractors must consider any communication in the following form and manner as constituting a referral: "Any written patient information received by a community pharmacy via secure electronic message from an NHS trust or other provider of NHS services concerning a patient's discharge to usual primary care services and their medicines regimen". …

DMS Stages

It is expected that all patients referred to the pharmacy will receive all three stages of the service. Note that stages 1, 2 and 3 of the service may occur in parallel and first contact with the patient (as defined in the NHS Discharge Medicines Service toolkit) could happen at any stage in the process. …..

Additional advice, assistance and support

When the pharmacy either receives a prescription (in whatever form) or has been made aware via a referral to the DMS that a prescription is the first prescription for a medicine that has been made following the patient's discharge from hospital, or where the patient's care has been transferred from another NHS service provider, the following steps must be followed:

Summary Care Record ….. - If appropriate, access the patient's Summary Care Record ….. to see if it assists in providing the service

Arrange a live video call or audio call with the patient (or where appropriate and bearing in mind the duty of confidentiality their carer to;

Assess the patient / carer understanding of the medicines that the patient should be taking

The patient should have received a copy of the prescribed medication from the hospital which lists the medication you are taking. This must match the discharge prescription when written.

If changes have been made to the patient's medication regimen, clearly explain the changes.

Offer such advice, assistance and support as is appropriate in your clinical judgement in respect of the medicines being taken and the medication regimen overall.

Think about high risk medicines or those where the treatment is more complex and where extra advice and support should be provided – e.g. anticoagulants

Discuss common or expected side effects

Discuss the use of medication apps which can be downloaded and may help the patient stick to their treatment plan.

If injectables have been prescribed and the patient is considered to be able to self-administer these, then have they received appropriate training from their GP practice nurse or hospital?

Inform the patient / carer about

The disposal service offered in respect of unwanted drugs (see separate SOP). This is particularly relevant to medicines which may still be in the patient's home but may no longer be prescribed.

Any other pharmaceutical services that the patient or their carer may benefit from following their stay in hospital and / or the transfer of care from another NHS pharmacy

Follow up

Where you identify any areas of concern then to the extent it is appropriate to do so in your clinical judgement, contact the patient's GP to discuss the concerns and consider any appropriate action plan to deal with the concerns.

In every case it is important to keep and maintain records of the above discussions, concerns and actions taken as part of providing this service and these will also assist in service evaluation processes."

9.101 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

Website and health promotion zones

9.102 The Committee considered whether the Applicant had explained how it will ensure that it has a website for use by the public for the purpose of accessing pharmaceutical services from those premises, 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.

9.103 The Committee noted SOP 24 'Support for Self-care, signposting and health promotion' states under the heading 'Health Promotion Zone on our website' at point 24.11:

"The website allows patients to access pharmaceutical services via our interactive page.

Explaining the Interactive Page to Patients

The interactive page is promoted on the website so that when a patient first visits the website they are signposted to a range of up to date materials that promote healthy lifestyles.

The Superintendent Pharmacist is responsible for ensuring that a reasonable range of materials are accessible via the interactive page and that they address a reasonable range of health issues.

The health promotion zone may also includes details of current health campaigns and other information to promote healthy lifestyle choices as well as providing access to the Lifestyle Questionnaire that is used to target health information to patients."

9.104 The Committee also noted further mention of health promotion zones is made in SOP 25 'Promotion of Healthy Living, Lifestyle & Health Campaigns' under the heading 'Identification of patients for promotion of healthy lifestyles' at point 25.3 which states:

"The website, app and email newsletters will also be used to promote healthy lifestyles via the health promotion zone."

9.105 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 28C of Schedule 4.

Summary

9.106 On the information before it, the Committee could be satisfied that there are procedures likely to secure safe and effective provision of essential services as required by Regulation 25(2)(b).

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

9.107.1 confirm the ICB's decision;

9.107.2 quash the ICB's decision and redetermine the application;

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

9.108 As South Yorkshire ICB did not provide any reasons to explain why it was satisfied that the pharmacy procedures for the premises are likely to secure the safe and effective provision of all essential services, the Committee determined that the decision must be quashed.

9.109 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 South Yorkshire ICB) or whether it was preferable for the Committee to reconsider the application.

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

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

10 Decision

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

10.2 Accordingly, the Committee:

10.2.1 quashes the decision of South Yorkshire ICB; and

10.2.2 redetermines the application as follows -

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

10.2.2.2 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,

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

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

10.2.2.5 the Committee was satisfied that all essential services were likely to be secured in a safe and effective manner, and

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

10.2.3 The application is granted.

Case Manager
Primary Care Appeals