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REF: SHA/26590

APPEAL AGAINST NORTH WEST LONDON ICB DECISION TO GRANT AN APPLICATION BY QCP1 LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT G116, OXGATE HOUSE, OXGATE LANE, LONDON, NW2 7FS UNDER REGULATION 25

1 **Outcome**

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

1.2 The Committee determined that the application should be refused.

A copy of this decision is being sent to:

QCP1 Ltd
Rushport Advisory LLP on behalf of A.Y.S. Healthcare Ltd t/a Grossman Pharmacy
PCSE on behalf of North West London ICB

NHS Resolution

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1 The Application

By application dated 6 October 2024, QCP1 Ltd ("the Applicant") applied to North West London ICB ("the Commissioner") for inclusion in the pharmaceutical list at G116, Oxgate House, Oxgate Lane, London, NW2 7FS 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 did not complete this part of the application form.

1.2 In response to why the application should not be refused pursuant to Regulation 31 the Applicant did not complete this part of the application form.

1.3 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant did not complete this part of the application form.

Supporting information

1.4 "Uninterrupted Provision of Essential Services in compliance with the Regulatory Requirements for Distance Selling Pharmacies

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

(a) all essential services to be secured without face to face contact

(b) all essential services to be secured without interruption during the opening hours

(c) all essential services to be secured for persons anywhere in England

(d) all essential services to be secured in a safe and effective manner

1.5 NHS England has established premises standards that the pharmacy will adhere to, although not all of these standards apply directly to distance selling premises, except when a patient is accessing nonessential services.

1.6 The pharmacy will be designated as a Healthy Living Pharmacy which premises and facilities are fit for purpose and that the pharmacy engages with the community to deliver consistently high-quality health and wellbeing services.

1.7 The pharmacy will be equipped with different facilities for both phone (or other live audio link) and live video communication with patients, maintaining patient confidentiality.

GPhC Guidance

1.8 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.

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

Risk Assessment

1.10 The pharmacy will implement a comprehensive risk assessment process to identify and manage potential risks. Effective risk management in pharmacy requires a proactive approach, ongoing training, regular assessments, and a commitment to patient safety, regulatory compliance, and business sustainability. This process includes:

1.10.1 Identifying hazards – Determine what could cause harm to patients, staff and others using pharmacy services or within the premises.

1.10.2 Evaluating risks - Assess the likelihood and potential impact of identified hazards.

1.10.3 Implementing control measures - Develop and apply measures to minimise or eliminate risks.

1.10.4 Documentation: Record findings and actions in a Risk Assessment document and risk matrix.

1.10.5 Review and Update: Regularly review the Risk Assessment quarterly and update it in response to significant business or operational changes.

1.11 Within DSP, risk assessment can be done in the following (but not limited to):

1.11.1 Provision of medications and services to high risk and vulnerable patients

1.11.2 Errors in dispensing and supplying medications

1.11.3 Supply of GSL and P medicines and multiple orders over the internet

1.11.4 Delivery of medications

1.11.5 Health and safety within premises

1.11.6 Data protection

Audit Procedures

1.12 It is important to have audit procedures in place to be compliance [sic] with regulations, enhance patient safety, improve the quality of care, and contribute to the efficient and effective management of the pharmacy. Regular audits are essential for maintaining trust, managing risks, and optimal operational performance.

1.13 The audit can be done on following (not limited to):

1.13.1 Near miss or incidence logs of medication dispensing

1.13.2 Staff training, competency and SOPs

1.13.3 Records on how medications are stored

1.13.4 Matrix to check medication's expiry

1.13.5 CD balance

1.13.6 Pharmacy services – collect feedback

1.13.7 Concerns or complaints received

1.13.8 Pharmacy equipment and facilities

1.13.9 Communication methods with patients, and between staff and other healthcare providers

1.13.10 Records of decisions to make or refuse a sale

1.14 If there are any issues identified during our regular audit, we will carry out a reactive review by following our SOPs to ensure our pharmacy services remain safe and improve.

Reactive review

1.15 A reactive review in a pharmacy involves evaluating and addressing issues or incidents when they arise. This approach focuses on carry out root cause analysis, immediate response and problem solving to mitigate risks and improve operations. These triggers include medication errors, adverse drug reactions, regulatory non-compliance, patient complaints, CD stock discrepancies, staff errors or misconduct, IT & data security breaches, equipment failures, unexpected health events, audit findings, and legal issues. Pharmacy owner should also review the effectiveness of the corrective actions and make further adjustments if needed and monitor compliance.

Accountability

1.16 Staffing levels and the skills mix are continually and systemically assessed to align with changing workloads and services provided and suitable strategies are established. Any required adjustments are promptly implemented. Everyone who works within the pharmacy has the responsibility for their actions, decisions and performance in delivering pharmacy services. Staffing levels are regularly reviewed to ascertain they remain appropriate, especially when introducing new services or encountering other alternations within the business. Pharmacy owner has the responsibility to ensure that pharmacy staff adhere to ethical standards, regulatory requirements, and professional guidelines while providing safe, effective, and patient-centered care.

Training

1.17 To ensure that pharmacy staff are all properly trained and competent to provide medicines, advice and other professional pharmacy services safely, a multifaceted approach is necessary with incorporating comprehensive training, continuous learning and assessment, clear communication, and a supportive work environment. Staff will be allocated specific training according to their job role and will be trained in accordance

with GPhC training requirements. All the training need to be completed before delivering the service to members of public. Pharmacy staff should keep up to date with relevant information and training to support them with providing the services. Staff performance is regularly reviewed, offering constructive feedback and promoting continuous learning and improvement.

Record Keeping

1.18 Accurate and timely records are part of robust clinical governance. Records should be managed and maintained properly within pharmacy. Confidentiality should be ensured at every stage of the documentation cycle, including its destruction. Procedures should be in place to cover disposal of any records to ensure compliance with Freedom of Information Legislation.

1.19 Paper records may be scanned provided the correct procedures are followed in committing the record to digital image. Records include but not limited to, patient consent forms, queries, complaints, customer logs, sale refusals, and dispensing).

1.20 Such records must be:

1.20.1 correctly labelled and archived

1.20.2 records kept of the destruction of the original paper record

1.20.3 the scanned copy legally admissible in a court of law if necessary

1.21 Electronic records must back up appropriately; support by audit trails that record details of all additions, changes and deletions.

1.22 Records are retained following NHS England (Records Management Code of Practice for Health and Social Care) as well as the minimum retention periods recommended by the Specialist Pharmacy Service.

Premises

1.23 Premises will be registered with the GPhC prior to entry to the pharmaceutical list and will therefore comply with GPhC requirements for pharmacy premises. Premises is safe, clean, well-maintained, and suitable for the provided pharmacy services, ensuring the privacy, dignity, and confidentiality of patients and the public. The premises are secure and protected against unauthorised access. Risk review and fire alarm check are done every 2 weeks in case there are any tripping hazards, any damage in the pharmacy. A comprehensive cleaning schedule is in place, ensuring that all areas, including shelves, counters, and dispensing areas, are regularly sanitised and maintained in a clean and hygienic condition. Floor spaces are kept clear from obstructions. Consultation rooms are used for confidential conversations, consultations or examinations for non-essential services.

Website

1.24 The website will be secure and follow information security management guidelines and the law on data protection. It will employ secure facilities for gathering, utilising, and safeguarding patient information, as well as a secure connection for processing card payments.

1.25 The website will display;

1.25.1 The GPhC pharmacy registration number

1.25.2 The name of the owner of the registered pharmacy

1.25.3 The name of the superintendent pharmacist

1.25.4 The name and address of the registered pharmacy that supplies the medicines

1.25.5 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)

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

1.25.7 Details of specific services available and how to use them, ie

1.25.7.1 Return of unwanted medicines

1.25.7.2 Patient Lifestyle Questionnaire

1.25.7.3 How to register exemptions from NHS charges

1.25.7.4 Promotion of Health Lifestyles and details of campaigns being undertaken

1.25.7.5 Procedures for Emergency Supply

1.25.7.6 Explanation of rules on non-face to face contact

1.25.7.7 Annual patient survey

1.25.7.8 Patient Information Leaflet

1.25.8 The email address and phone number of the pharmacy

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

1.25.10 GPhC internet logo (linked to register entry)

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

1.25.12 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.

1.26 The pharmacy will offer the public access to pharmaceutical services via website. Upon accessing the website, users will be prominently directed to an interactive page featuring up-to-date materials promoting healthy lifestyles and addressing a variety of health issues. It's important to note under the Regulations exclusively pertains to accessing services via the website and does not extend to in person access to essential pharmaceutical services at the premises.

Transparency and Choice

1.27 A list of pharmacy services would be clearly shown and explained on the pharmacy website and pharmacy leaflets, so people could make an informed decision. People would be given the right to make decisions about their care and medicines, and the services they want to receive and would be signposted to relevant healthcare professionals if they are not eligible. Patients are able to raise queries or withdraw at any time if they do not feel comfortable.

Managing and Supplying Medicines and Pharmacy Services Safely

1.28 Managing and supplying medicines safely in a pharmacy is essential to ensure patient safety and regulatory compliance. All pharmacy operations and services are maintained by SOPs which will be regularly reviewed and updated. Regular audits on pharmacy services are carried out regularly to evaluate their compliance with regulations, quality of care, efficiency and overall effectiveness.

1.29 Certain pharmacy services are provided through PGDs which are signed, reviewed and updated accordingly. All near misses and dispensing errors would be logged and reviewed each month during safety meetings. The owing system is in use when medicines cannot be immediately supplied and patients are informed about the owing items and of the expected date of delivery and if there is any manufacturing issue would be sorted by communicating with prescribers. More detailed clinical checks are carried out when patients are prescribed high risks medications.

1.30 A clear documentation is in place for delivery driver to understand the accountability and responsibility for being a delivery driver, ensuring the medicine will be delivered to patients safely and correctly. Additionally, driver should handle patient information and medications with the utmost confidentiality and privacy, maintaining the security of patient data and prescriptions during transport as well as to ensure that medications and supplies are stored appropriately during transit to maintain their integrity and effectiveness. Any medicines that cannot be delivered must be returned to the pharmacy that day. We have delivery logs and full audit trail for the delivery of medicines which should include a signature on delivery. The pharmacy will utilise third-party tracked delivery and monitor their services, including analysis of patient feedback about deliveries, delivery times and processes.

Equipment and Facilities

1.31 All equipment and facilities are obtained from reputable licensed suppliers. The need to verify the credentials, certifications, and industry reputation of suppliers when necessary. All user guides and reference sources for the equipment would be readily available and be kept appropriately. All equipment would be stored appropriately according to the manufacturer's user guide. All equipment is regularly cleaned, calibrated, tested, and serviced to make sure they are all fit for purpose.

1.32 The IT equipment will adhere to the most current security standards and undergo regular updates, including the utilisation of encrypted networks for both wired and wireless communication. Any system that contains confidential information e.g. PMR is controlled through passwords that are secured and changed frequently. Access to records will be contingent upon an employee's designated level of authority and clearance, as determined by the superintendent pharmacist.

Consent

1.33 Patient consent is a requirement within pharmacy practice to ensure that patients are actively involved in their healthcare decisions and that their rights and autonomy are respected. All pharmacy services provided are subjected to patient consent. Clear policies and procedures outlining when and how patient consent will be obtained for

various pharmacy services, such as medication dispensing, counseling, [sic] and sharing of personal health information. Comprehensive training is provided to all pharmacy staff on the importance of securing consent and the proper procedures for obtaining it.

1.34 Pharmacy staff are required to explain the purpose, nature, potential risks and benefits of the proposed activity or service and make sure patients understand the information provided before proceeding. Consent will be documented in patient's records.

Standard Operating Procedures

1.35 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.

PHARMACY SYSTEMS AND PROCEDURES

1.36 All Essential Services will be delivered in accordance with:

1.36.1 Company Standard Operating Procedures

1.36.2 NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

1.36.3 NHS Act 2006

1.36.4 Human Medicines Regulations 2012

1.36.5 GPhC – Professional Standards and Guidance on Distance Selling Pharmacies

1.36.6 Relevant Data Protection laws

1.37 Pharmacy has a business continuity plan to ensure that the Applicant delivers essential services safely, effectively, and without interruption to individuals across England who seek these services during the operational hours of the premises. These Essential Services outlined in the NHS contractual framework will not be provided face to face within premises between service recipients (whether for themselves or on behalf of others) and the pharmacy staff. This continuity plan is reviewed regularly (minimum annually) to ensure that it is fit for purpose. Patients in England will be able to register receive NHS Essential Services via the website or by contacting the pharmacy via email, telephone, postal services, or social media [sic].

1.38 Pharmacy will not advertise the pharmacy premises on the building, and as there is an intercom system, a patient will not be able to attend the premises directly. If a patient does attempt to contact the pharmacy via the intercom system to request one or more services, it will be explained that due to our Distance Selling Regulations we are unable to provide face-to-face NHS Essential Services. The patient will be signposted to other pharmacies who provide NHS services within the area. If advanced services were to be carried out on the premises, it could only be by appointment, and no essential services could be provided at the same time as any such appointment.

1.39 There are various methods to inform general public that pharmacy cannot provide face-to-face essential services within the premises:

1.39.1 Notice on Premises

1.39.2 Notice on Website

1.39.3 Post on Social Media

1.39.4 Pharmacy leaflet and fryers

1.40 Provision of NHS Essential Services without face-to-face contact within premises will be achieved by using:

1.40.1 Telephone, including text messaging where appropriate

1.40.2 Live Video Call

1.40.3 Website inbox (through contact us)

1.40.4 Real-time chat box on website

1.40.5 Email

1.40.6 Electronic Prescription Service (EPS)

1.40.7 Royal Mail postal service

1.40.8 Courier service

1.40.9 Specialised cold chain courier services e.g. DHL COLDCHAIN

1.41 There will be no interruption to the services which this pharmacy provides. The superintendent reviews the SOP's at least every two years and also continuously keeps policies and procedures of the pharmacy up to date in relation to any new legislation or guidance issued by the GPhC and NHS England.

1.42 A Responsible Pharmacist is present and in charge with pharmacy staff during the core opening hours of the premises to ensure there is uninterrupted provision of essential services to patients who live anywhere in England who require and request the essential services. If and when required, more staff will be hired to aid the Responsible Pharmacist in his/her role of uninterrupted provision.

1.43 Pharmacy 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.

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

Information Governance

1.45 To ensure essential services are delivered safely without face-to-face contact, we comply with UK GDPR and the DPA 2018. 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. Our Data Protection Officer ensures all staff adhere to confidentiality agreements and receive annual training in data protection and cyber security. We use two-step verification passwords for all software containing patient data and maintain an encrypted patient record database, which is automatically backed up

daily with a rolling transaction log for data restoration and recovery. Routine restorations of backups are performed to ensure recovery reliability.

1.46 All computers run the latest version of Windows 10, are equipped with antivirus software, and are kept up to date with the latest updates and patches. Live servers holding patient data are off-site, mitigating internal security vulnerabilities. Each staff member with access to patient data uses a unique 2FA login, with each access request logged. We also have a user access management system to instantly assign and remove access roles. Secure passwords and 2FA authentication are managed through a password management tool. All Wi-Fi access points and routers have unique administration passwords, and no mobile devices hold patient information.

1.47 We demonstrate our compliance with the 10 principles of the National Data Guardian's Data Security Standards by completing the Data Security and Protection Toolkit annually. This shows our adherence to the leadership obligations and ensures that patient data handling complies with NHS standards.

Provision of NHS Essential Services

Dispensing Services

1.48 Prescriptions will be received by EPS, post via the use of pre-paid envelopes, email and fax or where practicable, with the patient's informed consent, collected from a surgery or picked up by the delivery driver. The supply of medicines and appliances ordered on NHS prescriptions, together with information and advice, to enable safe and effective use by patients and carers will not be carried out face to face within premises. Pharmacy staff or pharmacist on duty will provide broader advice to the patient via telephone on the medicine, for example its possible side effects and significant interactions with other substances.

1.49 Prescriptions will be legally, clinically, and accurately checked to determine if they can be dispensed. Patients are provided with a written note for any medicine which is owed, and they are informed when the medicine is expected to be available. A record of items owed is made in the patient's medication record. Any requests to collect and dispense NHS prescriptions from the surgery or patients' household will be done through pharmacy delivery driver, Royal Mail and specialist couriers.

1.50 Orders for NHS medicines and appliances are dispensed to patients on demand, with reasonable promptness. 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.

1.51 For bagging-up prescriptions, use cartons that fit appropriately, making sure the sides are sealed and no medication can come out of the parcel. The packaging should be discreet with no indication on the outside that medicines are being delivered in this parcel. Ensure that all medicines have been supplied with Patient information leaflets and any relevant advice leaflet in relation to health promotion, whether it is general advice to all patients and/or targeted specific advice based on patient's disease state.

Verification of Declaration of Prescription Exemptions and Paying Prescriptions

1.52 For any paid NHS prescriptions, pharmacy team would be checking to confirm how many charges are due, if any fees have been paid and if so, was the correct amount being paid. Pharmacy should use secure, online, payment method to collect payments, i.e. bank transfer or through payment link or for local deliveries via handheld mobile

card machine or over the phone manually using the “customer not present” functionality of our card processing provider.

1.53 The reverse side of the prescription should be fully completed in black ink, except for patients who are age exempt.

1.54 If evidence of exemption is required or provided by the patient, it can be sent to the pharmacy via the delivery driver and then returned to the patient. The type of exemption and its expiry date will be recorded in the Patient Medication Record (PMR). The PMR system should be updated to reflect that the necessary check has been completed, and a note of when the next check is required should be entered into the system. Regulations require patients to produce 'satisfactory evidence' to confirm exemption.

1.55 For deliveries not made by the pharmacy’s delivery driver, the patient may scan or fax copies of the evidence to the pharmacy, or use postal/courier services. The pharmacy can record that the evidence provided was not in the original format. It is the pharmacist in charge who determines if the evidence is satisfactory; if not, they should check the ‘Evidence not Seen’ box.

1.56 Exemptions sent to the pharmacy by post will have postage paid by the pharmacy, and the exemption will be returned to the patient free of charge. If patients are unsure whether they are entitled to free prescriptions, you should advise them to pay for their prescriptions and send them a receipt (FP57), in case they want to claim a refund later.

Owings

1.57 Owings of medicines are dealt with in line with SOP’s. Where manufacturers cannot supply medicines, the patient is contacted and the PMR is updated with information of any owings. An owing note is attached to the delivery to ensure the patient is informed about the owing items and of the expected date of delivery. Where long term supply issues are apparent, after exhausting all possibilities of obtaining a certain medicine, either the patient is informed to enable them to contact their GP or the pharmacy contacts the patient’s GP on their behalf with informed consent from the patient, for an alternative. The option of using another pharmacy, which has the medicine in stock is also presented to the patient, and the prescription is returned to the patient if needed, or in the case of EPS release 2 tokens, the prescription is returned to the spine and the patient is informed of any details they need to obtain their medicines from the pharmacy of choice. Where a prescribed medication is subject to a Serious Shortage Protocol or a request for supply is made in accordance with a Pandemic Treatment Protocol or LPIV, supplies made in accordance with the relevant SSP or PTP/LPIV. Where Serious Shortage Protocols (SSP) has been issued, medicines not available or in short supply by the manufacturer, the SSP is followed to provide an alternative under the protocol. The patient is contacted via telephone to ensure they understand the change and ensure the patient knows how to use their medicine correctly. The patient is also be informed of what to do if they experience any problems with the alternative medicine. Finally, the patients GP is also informed of any adjustments made under the SSP.

Repeat Dispensing Services

1.58 Patients using the service to obtain repeat supplies of NHS prescriptions without the need for their GP practice to issue a prescription each time. This would benefit any patient who has long term but stable medical conditions who require repeat prescriptions. Any advice, dispensing or management on repeat dispensing will be provided to patients without face-to-face contact within the premises.

1.59 Prior to each dispensing episode including those dispensed in dosette boxes as may be required under the Equality Act 2010, the pharmacist will conduct a telephone

consultation to verify that the patient is using the prescribed medicines or appliances correctly and is likely to continue. Pharmacist must ensure that the patient is not suffering any side effects from the treatment otherwise which may suggest the need for a review of treatment. The pharmacist will also assess whether there have been any alterations to the patient's medication regimen or other changes in their health. If the pharmacist approves the request, DSP will dispense in accordance with the directions given on the repeatable prescription.

Pandemic Treatment Protocol (PTPs)

1.60 During a pandemic disease, or in anticipation of a pandemic, POM can be supplied without a prescription, for the prevention or treatment of the disease, in accordance with section 247 of the Human Medicines Regulations 2012 (HMR) under PTPs. Pharmacy receives electronic message via a secure service approved by NHS on an order for the supply of a medicine in accordance with a PTP.

1.61 The arrangements for an assessment of a person's need for the medicine (who assesses and how) will be specified in relation to each PTP and there may be other additional requirements contained in a PTP.

1.62 A supply of a medicine in accordance with a PTP must be made :

1.62.1 with reasonable promptness and, if asked, an estimate, or, as appropriate, a revised estimate of the time when the medicine will be ready given

1.62.2 generally in the manufacturer's pack where the PTP specifies a pack size of multiple of that is readily available

1.62.3 have a dispensing label which must, in addition to the general requirements for dispensing labels, includes information to identify the medicine was dispensed under the specific PTP

1.63 If the PTP does not include the quantity, strength or dosage, the responsible pharmacist, using professional skill, knowledge and care, may provide an appropriate strength and dosage of the medicine and, subject to certain conditions in the terms of service, the quantity of medicine which may not exceed five days.

1.64 A pharmacy owner may refuse to make a supply in accordance with a PTP where:

1.64.1 the pharmacist considers that the person or representative's request is not genuine;

1.64.2 providing the medicine is contrary to the pharmacist's clinical judgement; or,

1.64.3 where the person or anybody accompanying the person is violent or threatening to pharmacy staff or commits or threatens to commit a criminal offence.

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

Urgent Supply and Emergency Supply

1.66 Urgent Supply or Emergency Supply is unlikely to occur as frequently as in a retail pharmacy, all staff will be aware of the procedures to be followed in the event of such a request.

1.67 The request may be received from a Prescriber (Urgent Supply) or from a Patient (Emergency Supply) The following conditions must apply to the request made by a prescriber:

1.67.1 The Pharmacist must be satisfied that the request is from the appropriate authorised prescriber.

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

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

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

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

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

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

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

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

Interview

1.70 The Pharmacist must interview the patient and satisfied there is an immediate need for the POM and that it is not practical for the patient to obtain a prescription without undue delay. Pharmacists must consider the best interests of the patient. The interview may not be by way of face to face contact and must be by other means, e.g. telephone, video call. The POM requested must previously have been used as a treatment and prescribed. Pharmacists need to be vigilant regarding patients misusing emergency supplies and should verify patients' Summary Care Records with their informed consent if necessary to ensure accurate dispensing.

Records

1.71 An entry must be made in the POM register on the day of supply and record all the relevant details. The label for the dispensed medicine must contain the words "Emergency Supply". A record could be made of why request was refused for audit purposes.

Faxed Prescriptions

1.72 A 'faxed prescription' or other forms of scanned prescriptions (e.g. emailed private prescription printed out) 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.

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

Delivery of Urgent Supplies

1.74 Considering the urgency of such requests, the Pharmacy will give priority to delivering the medication to the patient. For local deliveries, the driver will be explicitly notified that the items are "URGENT," and for courier deliveries, the courier will be instructed to deliver the items as soon as possible via the quickest route available. The Pharmacy will not impose additional fees on the patient, even if incurred during the delivery process. Apart from acknowledging the urgent nature of the delivery, standard delivery procedures will be followed.

Return and Disposal of Unwanted Medicines

1.75 Patients or their representatives cannot return any medicines directly to the pharmacy and the team follows the procedures set out in the SOPs to avoid any face-to-face contact. Patients will be offered various options for disposing of unwanted medicines and out-of-date stock:

1.75.1 A specialised waste management company will safely and securely dispose of unwanted medicines by collecting them from patients and residential homes.

1.75.2 Patients who wish to return unwanted medicines to the pharmacy can do so via courier, with the cost covered by the pharmacy.

1.75.3 Patients in the local area can arrange for pharmacy staff or delivery driver to collect unwanted medicines from their home or workplace by contacting the pharmacy via phone or email.

1.76 Patients will receive appropriate packaging in advance, and information about the service and how to schedule a collection will be available on the Pharmacy website. Ensure the patient understands that any sharps and clinical/contaminated waste cannot be returned and they should follow local procedures for disposing of them. Ensure the patient knows that cytotoxic and hazardous waste, as well as CDs, must be separated if possible before returning to the pharmacy.

1.77 Upon return to the pharmacy, unwanted medicines will be sorted and stored accordingly in containers provided by the approved waste disposal contractor, contracted by the local NHS England Team. The waste contractor (PHS) collects the unwanted medicines as per their procedure. Before disposal, any confidential information on packaging will be removed to ensure patient privacy and confidentiality. Information about the disposal service will be advertised on the website/app and in marketing leaflets.

Return and Destruction of Controlled Drugs

1.78 Any returned controlled drugs must not be reused or re-entered into the CD register. The drugs will be denatured and rendered irretrievable as soon as possible to avoid storage issues and increased security risks. Returns will be managed either by collection by pharmacy staff from patients' homes or via DHL pre-paid tracked signed return service. Destruction must be witnessed by another staff member. If not immediately destroyed, returned drugs should be segregated from the main stock, clearly marked "Patient Returns" to minimise the risk of errors and inadvertent supply, and stored separately and securely in a CD cabinet awaiting denaturing. A record of destruction will be maintained in a separate CD Destruction Register designated for this purpose and will be available in the pharmacy for inspection. All patient identifiable information must be removed and destroyed by shredding it out.

Promotion of Healthy Lifestyles

1.79 The provision of healthy lifestyle advice and public health advice to patients receiving prescriptions who appear to have diabetes, be at risk of coronary heart disease, especially those with high blood pressure or who smoke or overweight to be done without face-to-face contact. Identification of patients takes place through three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process. This is through the use of lifestyle questionnaires available via email or sent to the patient and returned by post, during interactions or with consent e.g. medicine sales or the repeat dispensing process which will indicate what conditions a patient suffers from. This advice could be given verbally over phone or video call, or through leaflets to be delivered to patients' home. Where advice is provided it should be recorded on the PMR. The email newsletter and website will also be used to promote a healthy lifestyle. Advice and help is available to patients during opening hours of the pharmacy and patients can access information on the Applicant's website at all times. This ensures the uninterrupted provision of services to patients across England. If it is not appropriate for the pharmacist to give advice then the patient should be signposted to an appropriate health or social care provider. Refer to the SOP on 'Signposting'. An intervention and referral form shall be filled out with information and the referral organisation shall be noted.

1.80 Information about support organisations, the treatment of common illnesses, minor ailments, long term medical conditions and appropriate usage of OTC medications will be available on the website, app and email newsletter. The pharmacist on duty can be contacted by telephone for more advice and drug interactions.

1.81 Pharmacy website will be available for use by the public for the purpose of accessing pharmaceutical services. Website will be an interactive page, provide public access to a range of up to date materials that promote healthy lifestyles by addressing a range of health issues.

Health Campaigns

1.82 The Pharmacy will actively engage in national health campaigns to disseminate health messages to our patients throughout England. This will involve distributing leaflets along with prescriptions during targeted campaign periods and offering additional advice and educational materials through the pharmacy website.

1.83 Patients will receive guidance on accessing these learning resources via email, text messages, and other forms of non-face-to-face communication to ensure awareness of the campaigns.

1.84 Additionally, patients will be evaluated for participation in at least one clinical audit and any other audits specified by the NHSCB. These audits may include clinical audits conducted in accordance with NHSCB data processing arrangements or policy-based audits designed to support the development of NHSCB commissioning policies, all of which will comply with NHSCB data processing protocols.

1.85 All information relating to NHS Essential Services will appear on the website which will be regularly updated to reflect current campaigns. Pharmacy is able to contact patients via email to confer public health campaigns.

Signposting

1.86 When people who require assistance, which cannot be provided by the pharmacy but aware of other appropriate health and social care providers or support organisations who are likely to be able to provide that advice, treatment or support, pharmacy staff will be signposting to other appropriate healthcare professionals through non face-face contact. This can be done through telephone, video calls, website or email. Pharmacy

staff 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. Any help or advice that cannot be accessed on the website and app links will be available by telephoning the pharmacy and asking for advice. The pharmacy's website will contain links to other health care providers and also an A-to-Z healthcare section. Staff should create and keep a record of any information given or referral made and mark an appropriate follow-up date on the PMR system. Where advice cannot be provided should also be recorded as an Intervention on the patient record along with the referral organisation. When signposting patients, use the 'Services Near You' application from NHS Choices to find suitable organisations in the locality of the patient. Please refer to "How to Navigate NHS Choices Website" document for guidance on how to use this application.

Support for Self-Care

1.87 Pharmacy staff offer guidance and assistance to individuals, including caregivers, in managing self-limiting or long-term conditions without requiring in-person interaction. This support is provided through various non-face-to-face methods such as telephone, text messages, video calls, online chat via the website, and email. The goal is to empower individuals with greater understanding of their treatment options and to reduce unnecessary utilisation of health and social care services. Any additional written information can be home delivered or posted to reinforce the message. In appropriate cases, the pharmacist will keep and maintain a record on PMR of any advice given and of any drugs supplied when the advice was given for auditing and follow-up care.

1.88 The advice provided encompasses:

1.88.1 (i) Provision of advice to people, including carers, requesting helping with the treatment of minor illness and long-term conditions, including general information and advice on how to manage illness

1.88.2 (ii) Provision of advice on appropriate use of the wide range of non-prescription medicines which can be used in the self-care of minor illness and long term conditions

1.88.3 (iii) Provision of healthy lifestyle interventions when appropriate for promotion of healthy lifestyle service

1.88.4 (iv) Signpost patients to other health and social care providers when appropriate

Dispensing Appliances

1.89 Pharmacy will be dispensing appliances ''with reasonable promptness" to patients. Patients should be appropriately advised on the importance of only requesting items they actually need to minimise waste without face to face contact. This can be done through telephone, text, email or video call. If pharmacist is unable to provide appliance states on prescription, then subject to the consent of the patient, the pharmacist can refer the prescription to another provider electronically for dispensing.

1.90 If the patient does not consent to the prescription being referred to another provider, the pharmacist must give the patient the contact details of two providers of appliances through telephone, text, email or video call. Home delivery for appliances must be made with reasonable promptness and at a time agreed with the patient. When delivering such appliances, the packaging used for the appliance must not have any markings which could indicate the contents, and the method of delivery must not convey the type of appliance being delivered. Home delivery could be made by the

pharmacy staff, the Royal Mail or another carrier could be used. Pharmacist must provide a reasonable supply of appropriate supplementary items (disposable wipes and disposal bags).

1.91 Pharmacist must ensure that the patient can consult a person to obtain expert clinical advice about the appliance. If pharmacist is not able to provide remote Appliance Use Review (AUR) service, the patient must be given the contact details of at least two pharmacies or suppliers of appliances who are able to arrange for the service to be provided. The telephone number or the website address of these providers will be listed on the pharmacy website all the time. Advice on how to keep or store medications can be provided through telephone, text, email or video call by trained pharmacy staff.

Appliance measuring and fitting

1.92 Where, on presentation of a prescription form or repeatable prescription, pharmacist is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within pharmacy's normal course of business, pharmacist must—

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

1.92.2 (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 pharmacist.

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

Discharge Medicines Services (DMS)

1.94 The DMS SOP's include all the stages & regulations in detail. When patients discharge from hospital is associated with an increased risk of avoidable medication related harm. Pharmacy should make use of DMS to ensure that better communication of changes made to a patient's medications in hospital. Through DMS, pharmacy could help patients to optimise the use of medicines, reduce harm from medicines at transfer of care, improve patients' understanding of their medications and how to take them following discharge from hospital, reduce hospital readmissions and support the development of effective team-working across hospital, community and primary care networks pharmacy teams and general practice teams and provide clarity about respective roles.

1.95 A discharge referral will be received by the pharmacy electronically via PharmOutcomes. A notification email is sent to the pharmacy email address which is accessible by staff and is checked at least 3 times a day. Referrals are actioned within 72 hours of receipt. Consent is taken by the referring trust & patients can withdraw consent in any stage.

1.96 Stage 1 – Receipt of discharge referral

1.97 Patient details and clinical information are checked, medicines on discharge are compared with admission via PMR and SCR. Any concerns are raised with the NHS trust and patient GP. Appropriate notes or any related record are made on PMR. Alerts are set to conduct stage 2 & 3 when the first prescription or contact is received. Any previous prescriptions are returned to spine if not appropriate for supply.

1.98 Stage 2 – Receipt of first prescription following discharge

1.99 Pharmacist compares the discharge referral with the post discharge prescription to ensure no discrepancy. If one is found a referral is made to the GP to resolve any issue and records are made on the PMR. If consent is revoked in either stage 2/3/prescriptions are not received or no contact is made with the patient after a reasonable number of attempts, concerns are relayed to the GP.

1.100 Stage 3 – Shared decision making discussion with patient

1.101 Pharmacist will check patient's understanding of their medicines regimen and provide any relevant advice to support medicines taking by phone, text, email or video calls. Advice can be given to the patient or, where appropriate their carer. 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. The patients PMR is updated and with the patients consent any information of value is shared with the GP/PCN to support the patients on going care. Patient is also offered the return service for any unwanted medicines & also the NMS service if relevant. If patient is uncontactable or withdraws consent during service or switch to another pharmacy, DMS will not be able to complete.

Delivery

1.102 To ensure the safe and appropriate delivery of medicines, local deliveries will be handled by pharmacy own delivery driver. If our delivery driver is unavailable for their shift, we will utilise City Sprint as a backup to ensure uninterrupted delivery services. Nationwide deliveries will be sent via recorded delivery, requiring a signature from the patient, their notified carer, or an authorised representative.

1.103 Patients will receive a tracking number to monitor their delivery status online and will be informed about their delivery through a text messaging system. Medicines will be packed, transported, and delivered to preserve their integrity, quality, and effectiveness. The delivery process will provide a verifiable audit trail from the initial request to final delivery or return to the pharmacy in case of delivery failure. Post delivery items will not be put through letter boxes or left unattended in porches on doorsteps, with children or with neighbours, unless arrangements have been made by patient/carer. This request would be obtained in writing from the patient/carer with a signature authorising delivery to another address. The patient, carer, or authorised representative must always sign and date a receipt to confirm safe receipt of the medicines. If the patient within local area is not at home during the delivery attempt, they will be notified with a non-delivery notice, and an alternative delivery date will be arranged. If patients receiving with postal services are not in or redeliveries/ collections from depot can be organised via Royal Mail website for a more appropriate date.

Choice of packaging

1.104 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. For postal/courier items, at a minimum, use padded envelopes for non-fragile items to protect the manufacturer's packaging. For most items, use bubble wrap and, if necessary, polystyrene filler inside a reinforced cardboard box.

Cold chain deliveries

1.105 Local fridge deliveries will maintain the cold chain by using polystyrene cool box with added ice packs.

1.106 Cool box will contain a wireless thermometer hygrometer (manufactured by ORIA) that connects via Bluetooth for data export and real-time alerts. The temperature sensor will record data every 10 seconds and upload it to the app when connected via Bluetooth. If the temperature or humidity exceeds the pre-set range of 2 to 8 degrees Celsius, the app will display the data in red and send a notification to the pharmacy staff's mobile phone. Daily data can be downloaded for record keeping.

1.107 As with all local deliveries the patient is informed via text/email of the date and time of day the delivery driver will be delivering. Particularly in regard to deliveries involving cold chain items the driver rings the patient to inform/confirm the estimated date and time of delivery before the medication is taken on the route to reduce the chance of delivery failure. In any case if the delivery fails, the driver simply brings the medication back in the temperature controlled cool box and returns the items to the fridge and consequently re-organises delivery for a more convenient date/time with the patient. Temperature within the cool box will be recorded before and after each delivery. If temperature falls outside 2 and 8 degrees, patient will be informed immediately, and re-delivery will be rearranged.

1.108 Provisions such as DHL COLDCHAIN (or a similar specialist cold chain courier service) will ensure the integrity of the cold chain and the maximum stability of temperature-sensitive drugs by packing, transporting, and delivering them in a manner that preserves their integrity, quality, and effectiveness.

1.109 This is a dedicated, fully monitored, and temperature-controlled delivery service. They utilise real time monitoring devices to continuously monitor temperature, humidity and other environmental conditions with GPS tacking. DHL vehicles have built-in refrigeration systems to maintain the required temperature during road transportation. Medications are stored in warehouses with temperature controlled storage facilities for interim or failed delivery storage. In the event of an unsuccessful delivery, DHL COLDCHAIN will leave a 'Missed Delivery' card, stating the date and time of the attempted delivery. The patient can then rearrange delivery for a convenient time by telephone or Internet. DHL COLDCHAIN will keep the cold chain intact until successful delivery. However, in the event of any breach in the integrity of this service the patient is contacted and informed immediately to not use any product that might have been affected. Items subject to a cold chain breach are not re-used and are to be segregated from the pharmacy stock upon arrival at the pharmacy. A list of approved cold chain couriers is available within the Pharmacy and will be updated from time to time.

1.110 Each approved courier meets stringent criteria to ensure a fully monitored and dedicated cold chain service.

Controlled Drugs Delivery

1.111 Delivery of controlled drugs in local area will be managed by pharmacy delivery driver, otherwise will be handled by DHL, which has pharma-grade specialist facilities meeting specific quality and validation requirements for healthcare products, including Home Office licensed controlled drug stores. DHL holds the following UK licenses and standards:

1.111.1 MHRA Wholesale Dealer License

1.111.2 MHRA Manufacturer's Importer's License

1.111.3 GAMP 4 Systems Validation

1.111.4 MHRA IMP License

1.111.5 MHRA Manufacturer's "Specials" License

1.111.6 ISO 9001:2000 Certification

1.111.7 Clinical trials audited to GMP Annex 13 standards

1.111.8 FDA audited

1.112 DHL meets all Home Office safe custody and record-keeping requirements. Controlled drugs delivered by DHL Courier Services are all being tracked, with verifiable audit trails. GPS, image & signature data would be checked by the pharmacy team after delivery to ensure that the patient has received the CD delivery.

1.113 For local area, pharmacy driver is effectively the patient's nominated representative authorised to collect the CD on their behalf. CDs should be in a separate bag to any other medication being delivered and the bags should be attached together. CDs and any other medicines on that patient's delivery must be stored in the lockable compartment of the delivery van and out of sight. The delivery van must be kept locked at all times when the driver is not in the vehicle. As such the driver should sign the 'collected by' section on the reverse of the prescription. It would be good practice to contact the patient prior to the driver leaving to confirm the patient is available to accept the CD delivery. If the patient is not home and therefore the CDs are not delivered, the CD must be returned to the pharmacy on the same day and at the earliest opportunity which would be returned to the CD cabinet.

1.114 Under no circumstances can the controlled drug be left unattended or with anyone other than the patient, their carer, or other person previously authorised by the patient to receive the controlled drug. If the patient/carer is home to accept the delivery, the driver must confirm the patient details and ensure the delivery record form is signed by the recipient and return to pharmacy when delivery is done. Where the recipient is not the patient, their full name should be recorded on the delivery record form, along with their signature.

1.115 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.

Clinical Governance

1.116 Our superintendent and responsible pharmacist will be actively involved in all aspects of clinical governance. This includes compliance with standard operating procedures, reporting patient safety incidents and near misses, providing evidence of continuing professional development (CPD) for pharmacists and pharmacy technicians, conducting clinical audits, and carrying out patient satisfaction surveys. Information on 'How to Make a Complaint or Compliment' will be displayed on the pharmacy website and available for download. Additionally, copies can be requested by phone or mail.

1.117 All staff will be qualified or in the process of completing nationally accredited training, ensuring they are competent to deliver the highest standards of clinical governance. Staff will receive both individual and collective training, development, and education

either in-house or from accredited external providers. They will also participate in annual appraisals, and provide and receive feedback.

1.118 The pharmacy will be registered and compliant with the Data Protection Act, as well as the Access to Health Records Act. It will publish its Freedom of Information Act Publication Scheme on its website, with copies available upon request. All patient data will be kept private and confidential in accordance with NHS standards and legal obligations concerning data security, protection, and confidentiality.

1.119 Practice leaflets are also available on the website which contain information approved by the Department of Health and provide information of the details required. Nothing in the pharmacy's practice leaflet or other material published by the pharmacy represents (either expressively or impliedly) that essential services are only available in particular areas of England or that the pharmacy is likely to refuse to provide prescribed medication by reference to particular categories of patients.

1.120 We will establish direct accounts with pharmacy manufacturers and multiple full-line and shortline pharmaceutical wholesalers to increase stock availability and reduce shortages. A contingency plan will be in place to mitigate the effects of any disruptions to pharmaceutical services, such as medicine shortages, postal strikes, EPS system failures, and more.

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

During the absence of RP

1.122 All of the pharmacy team must adhere to the pharmacy procedures set down by the responsible pharmacist (RP) and monitor the time that the RP has been absent. If the absence exceeds 2 hours, the pharmacy must close temporarily until a pharmacist assumes the duty of RP, the pharmacy must contact the RP for additional instructions and the estimated time of return. If the RP is not contactable, the pharmacy team must contact the nominated advisory pharmacist for additional instructions. Any pre-bagged prescriptions are not allowed handed out for delivery to the delivery driver. 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.

Support for People with Disabilities

1.123 This service will be delivered in compliance with the Equality Act 2010. The Applicant will make reasonable adjustments in pharmaceutical services to ensure that eligible individuals receive appropriate compliance aids.

1.124 An initial assessment will be conducted with the patient, their caregiver, or representative to determine the support needed for improved medication adherence. These assessments will be conducted remotely, eliminating the need for patients to visit the pharmacy in person.

1.125 Compliance aid systems, including blister packs and dosette boxes, will be provided according to service levels 1 and 2, respectively.

Pharmacy Profile

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

1.127 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.

Practice Leaflet

1.128 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—

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

1.128.2 (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).

1.129 List of SOPs

1.130 (DSP) COVID Vaccine Clinic (All providers)

1.130.1 COVID-19 Pharmacy Vaccination Services

1.131 (DSP) Health and Safety (All Providers)

1.131.1 Fire Risk Assessment

1.131.2 Arrangements for dealing with emergencies including resuscitation

1.132 (DSP) Health Improvement Scotland Governance (HIS Care Providers Only)

1.132.1 Referral Criteria Policy

1.132.2 Chaperoning Policy

1.132.3 Safeguarding and protecting people from abuse policy (adult protection/child protection)

1.132.4 Privacy, dignity and respect of service users

1.132.5 Medication policy (dispensing process)

1.132.6 Information management policy

1.132.7 Infection prevention and control

1.132.8 Participation policy

1.132.9 Complaints policy

1.132.10 Duty of Candour policy

1.132.11 Recruitment and induction policy

1.132.12 Staff training and development policy

1.132.13 Bullying and harassment policy

1.132.14 Whistleblowing policy

1.132.15 Equality and Diversity Policy

1.132.16 Clinical governance policy

1.133 (DSP) Staff Handbook (Human Resources)

1.133.1 Staff Handbook

1.134 (DSP) Care Quality Commission Governance (CQC Care Providers only)

1.134.1 Statement of Purpose

1.134.2 Patient Guide

1.134.3 British Code of Advertising

1.134.4 Patient Disclaimer

1.134.5 Disability and the Equality Act 2010

1.134.6 Seeking Clients' Consent

1.134.7 Complaints Procedure

1.134.8 Whistle Blowing Policy

1.134.9 Confidentiality Policy

1.134.10 Clinical Governance

1.134.11 Clinical Audit

1.134.12 Safeguarding Policy

1.134.13 Stress Management

1.134.14 Sickness and Absence Policy

1.134.15 RIDDOR Procedure

1.134.16 Policy on violent or abusive patients

1.134.17 Mental Capacity

1.134.18 Medicine Incident Reporting Policy

1.134.19 Medication Review Policy

1.134.20 Protocol for the Identification of Patients with Learning Disabilities

1.134.21 Electronic Transfer of Patient Data Policy

1.134.22 Medicines Safety Alerts Policy

1.134.23 Disciplinary Policy

1.134.24 Disclosure and Barring Policy

1.134.25 Computer Misuse Policy

1.134.26 Computer and Data Security Procedure

1.134.27 Caldicott Protocol

1.134.28 Business Continuity Plan

1.134.29 Repeat Prescription Rationalisation (â€˜Tidy-Upâ€™) [sic] by Medicines Management Team in Primary Care [sic]

1.134.30 Pre-Agreed Practice Specific Medication Switches to the Health Board Preferred Generic, Brand or Branded Generic by Medicines Management Team in Primary Care

1.134.31 Updating Repeat Medication from Community Pharmacy Medication Use Review by Medicines Management Team in Primary Care

1.134.32 Adding the Medication of a Newly Registered Patient onto the Repeat Prescription by Medicines Management Team in Primary Care

1.134.33 Medicines Reconciliation from Hospital Outpatient Documentation by Medicines Management Team in Primary Care

1.134.34 Medicines Reconciliation from a Hospital Discharge Notification by Medicines Management Team in Primary Care

1.134.35 Domiciliary Medication Adherence Assessment by Medicines Management Team in Primary Care

1.134.36 Level 2 Medication Review (including repeat medication reauthorisation) by Medicines Management Team in Primary care

1.134.37 Level 3 Medication Review (including repeat medication reauthorisation) by Medicines Management Team in Primary Care

1.134.38 Memorandum of Understanding with the Medicines Management Team

1.135 (DSP) Wholesale Dealers License (MHRA License Holders only)

1.135.1 Wholesale Dealers Licence Overidding Single Pharmacy [sic]

1.136 (DSP) Supplying Specific Products (GPhC Registration Holders only)

1.136.1 Specials

1.136.2 Supply of Insulin

1.136.3 Supply of Lithium

1.136.4 Supply of Methotrexate

1.136.5 Supply of Oral Anticoagulant Medication

1.136.6 Supply of Paraffin Based Skin Products

1.136.7 Sale and Supply of Veterinary Medicines

1.136.8 Supplying of Oral Anti-Cancer Medicines

1.136.9 False Medicine Directive (FMD)

1.136.10 Supply of Valproate/ Valproic acid

1.137 (DSP) Information Governance (All Healthcare Providers)

1.137.1 Summary Care Records Privacy Officer

1.137.2 Staff Confidentiality Agreement

1.137.3 IG Policy

1.137.4 Code of Conduct for Employees in Respect of Confidentiality

1.137.5 Data Handling Procedures

1.137.6 Mobile Computing Guidelines

1.137.7 Information Security Incident Management

1.137.8 Access Control and Password Management Procedure

1.137.9 Ensuring Staff Compliance with RA01 Terms Template SOP

1.137.10 GDPR Privacy notice for employees workers and contractors UK

1.137.11 Privacy Statement for GDPR

1.138 (DSP) Staff Induction (All Healthcare Providers)

1.138.1 Locum Induction

1.138.2 Staff Induction

1.139 (DSP) Private Services (GPhC Registration Holders only)

1.139.1 Salbutamol Supply to Schools

1.139.2 Blood Diagnostics via Finger Prick

1.139.3 Dispensing Private Prescriptions

1.139.4 (DSP) Operational (All Healthcare Providers)

1.139.5 Cleaning

1.139.6 Cold Chain Maintenance

1.139.7 Equipment Maintenance

1.139.8 Health and Safety - Risk Assessment

1.140 (DSP) Internet Pharmacy & Essential Services (GPhC Distance Selling Registration Holders only)

1.140.1 Dispatching an Internet Order

1.140.2 Final Checking an Internet Order

1.140.3 Providing Services via an Internet Pharmacy

1.140.4 Overarching Internet Pharmacy

1.140.5 Preparing an Internet Order

1.140.6 Receiving and Internet Order

1.140.7 Setting up an internet pharmacy in the UK

1.140.8 Pharmacy Social Media

1.140.9 Cold Chain Delivery

1.140.10 Selling OTC or P Medicines Online

1.140.11 Pharmacy Cybersecurity

1.140.12 Checking NHS Exemptions (GPhC + NHS License Holders only)

1.140.13 Taking an NHS Prescription Charge (GPhC + NHS License Holders only)

1.140.14 Remote Appliance Fitting and Dispensing Appliances

1.140.15 Remote Patient Assessment of Repeat Dispensing Need (GPhC + NHS License Holders only)

1.140.16 Remote Promotion of Healthy Lifestyle and Public Health Campaigns (GPhC + NHS License Holders only)

1.140.17 Remote Signposting (GPhC + NHS License Holders only)

1.140.18 Disposal of Unwanted Medicines Returned to the Pharmacy

1.140.19 Remote Support for Self-Care (GPhC + NHS License Holders only)

1.140.20 Remote Discharge Medicine Service

1.140.21 Provision of Essential Services without face to face contact

1.140.22 Repeat Dispensing

1.141 (DSP) Pharmacy Practice and Management (GPhC Registration Holders only)

1.141.1 Accuracy Check by an Acccredited Checking Technician [sic]

1.141.2 Accuracy Checking

1.141.3 Assembling and labelling prescriptions

1.141.4 Chaperoning

1.141.5 Date Checking

1.141.6 Delivery of Medicines

1.141.7 Dispensing Medicines with a Compliance Aid

1.141.8 Dispensing of Prescriptions

1.141.9 Electronic Prescription Service Release 2

1.141.10 Emergency Supply

1.141.11 NHS End of Month Procedures

1.141.12 Owing Medication Supply

1.141.13 Receiving Stock into the Pharmacy

1.141.14 Roles and Responsibilities of Pharmacy Staff

1.141.15 Support For People With Disabilities (Disability Act 2010)

1.141.16 Responsible Pharmacist

1.141.17 EPS Nominations

1.141.18 Drug Recalls And Drug-Device Alerts

1.142 (DSP) Errors, Interventions and Complaints (All Healthcare Providers)

1.142.1 Complaints, Concerns, Enquiries and Compliments Procedure

1.142.2 Dealing with Dispensing Errors

1.142.3 Interventions and Problem Solving

1.142.4 Near Miss Audit

1.142.5 Pharmacy Patient Safety Incident Report and Follow Up

1.142.6 Preventing errors and recording near misses

1.142.7 Dealing with Serious Shortage Protocols (SSPs)

1.142.8 (DSP) Enhanced Services (GPhC Registration Holders only) Blood

1.142.9 Glucose Monitoring

1.142.10 Monitoring Blood Pressure

1.142.11 Cardiovascular Screening

1.142.12 Chlamydia Testing

1.142.13 Cholesterol, Glucose, Hemoglobin Point of Care Testing [sic]

1.142.14 Emergency Hormonal Contraception

1.142.15 Minor Ailments Scheme

1.142.16 Monitored Dose Systems

1.142.17 Needle and Exchange Service Scheme

1.142.18 Palliative Care Enhanced Service

1.142.19 Pharmacy Urgent Repeat Medicine Service

1.142.20 Smoking Cessation

1.143 (DSP) Controlled Drugs (GPhC Registration Holders only)

1.143.1 Balance Check and Record Keeping

1.143.2 Delivering Controlled Drugs

1.143.3 Destruction of Controlled Drugs

1.143.4 Dispensing of Controlled Drugs

1.143.5 Recording Concerns over CD management

1.143.6 Security and Storage of Controlled Drugs

1.143.7 Supply of Sativex

1.143.8 Return of Unwanted Controlled Drugs To The Pharmacy

1.144 (DSP) Business Continuity (All Healthcare Providers)

1.144.1 Operating in the Absence of a Responsible Pharmacist

1.144.2 Pandemic Protocol

1.144.3 Business Continuity Plan

1.144.4 COVID Social Distancing and Infection Control Risk Assessment Tool for Non-Essential Services (inc PSNC guidance)

1.145 (DSP) Advanced Services (GPhC Registration Holders only)

1.145.1 Appliance Use Reviews

1.145.2 Medicine Use Reviews

1.145.3 New Medicine Service

1.145.4 Stoma Appliance Customisation Service

1.145.5 DMIRs

1.145.6 Pharmacy First Service

1.145.7 Hypertension Case-Finding Service

1.146 (DSP) Seasonal Vaccines (GPhC Registration Holders only)

1.146.1 Infection Control

1.146.2 Influenza Vaccination

1.146.3 Needlestick Injuries and Contamination"

1.147 The SOPs as provided with the application form are enclosed at Appendix A.

2 **The Decision**

The Commissioner considered and decided to grant the application. The decision letter dated 2 April 2025 states:

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

2.1 "North West London 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 North West London 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."

Extract from the minutes of the London Pharmaceutical Services Regulations Committee of 26 March 2025

2.5 "Part 2, London Area agenda item number 5A – decision report on an application for inclusion in a pharmaceutical list: distance selling premises excepted application

2.6 Brent HWBB

2.7 Additional information

2.8 The London region PSRC have determined that there is enough information to deal with this application without holding an oral hearing.

2.9 The comments received from parties is available to the PSRC panel to review.

Boots Comments

2.10 Boots UK Ltd would like to respectfully request that members of the deciding committee are satisfied that this application fully meets the criteria set out in Regulation 25 and the conditions set out in Regulation 64 when determining this application. We note that the applicant has made reference to offering the flu vaccination service as well as Pharmacy First. We remind the committee that no face to face NHS services can be offered by a pharmacy operating by means of a distance selling contract.

Grossman Pharmacy Comments

2.11 The application falls to be considered under regulation 25 of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. As the ICB will be aware, regulation 25 states;

(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.

2.12 It is the responsibility of the Applicant to demonstrate that the legal test will be met in full and the Applicant has failed to provide sufficient supporting information that would enable the ICB to be satisfied that any part of the legal test set out above is met.

2.13 We note that a considerable amount of the information provided at the start of the Applicant's supporting information has been copied, in many cases word for word, from information that Rushport has previously produced for clients. This is an unlawful breach of our copyright and a matter that we will address directly with the Applicant.

2.14 The Applicant provides a list of its SOPs and these include SOPs for services such as Blood Pressure Monitoring, Chlamydia Testing, Needle Exchange etc. These are listed as "Enhanced Services" (page 30 of the SOP document) but no such request to provide these services has been made on the main application form. If the Applicant intends to provide these services they will need to demonstrate how the services will be provided without providing any element of essential services to patients attending the premises.

We note the Applicant also lists SOPs for Advanced Services that have not been commissioned for some time, eg MURs. It would appear that the Applicant is not clear about which services will be provided or how they will be provided.

2.15 There are various other areas in which the Applicant does not demonstrate that safe and effective services will be provided. The Applicant proposes using a cool box for local deliveries of fridge lines with a thermometer that requires a Bluetooth connection to work as the Applicant describes it.

2.16 In relation to providing services which are safe and effective, the Applicant has provided insufficient detail to enable NHSE to be satisfied that all essential service provision would be provided in a manner that is both safe and effective.

2.17 We further note that the GPhC shows 2 pharmacies registered at Oxgate House, namely Medcann Pharma Ltd at Unit G114 and QCP1 Ltd at Unit G116. In the event that the ICB receives an application under regulation 25 from Medcann Pharma Ltd then regulation 31 may also be relevant in this case.

2.18 With regard to Regulation 31

2.19 (Refusal: same or adjacent premises) and to the provisions of Schedule 2 to the Regulations:

"Applications seeking the listing of premises that are already, or are in close proximity to, listed chemist premises."

2.20 The proposed pharmacy is not on the same site or adjacent to any other pharmacy, therefore this regulation is not engaged.

Distance Selling premises applications

2.21 Regulation 25 (1) Section 129(2A) of the 2006 Act(c) (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 also 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 ICB 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*

2.22 (a) The premises in respect of which the application is made 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.

(b) unless the ICB 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."

2.23 (b) The applicant provided information via their application.

2.24 We will assess the application on the information provided, we note the comment from [CD] but this is outside our scope and we will leave this for him to deal with. The information provided has been assessed and we note that the applicant is offering some advanced services potentially on a face to face basis, which is acceptable as long as no essential services are provided at the same time. The regulations does not prevent these being provided.

2.25 It may be concluded that the London region PSRC are satisfied that pharmacy procedures for the pharmacy 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.

2.26 It may also be concluded that the applicant is likely to satisfy the criteria as set out in the Terms of Service of Pharmacists for the safe and effective provision of all essential services without face to face contact.

2.27 Therefore, the London region PSRC are satisfied that the pharmacy procedures for the pharmacy premises are likely to secure 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.

Decision

2.28 Regulation 31.

2.28.1 There are no current pharmacies listed at the proposed premises or adjacent to the proposed premises. Therefore regulation 31 does not apply for this application.

2.29 Regulation 25(2)(1)(a)

2.29.1 The proposed site 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. Therefore, this regulation does not apply for this application.

2.30 Regulation 25(2)(1)(b)(i)

2.30.1 The London region PSRC are satisfied that pharmacy procedures for the pharmacy 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.

2.31 Regulation 25(2)(1)(b)(ii)

2.31.1 The London region PSRC are satisfied that the applicant is likely to satisfy the criteria as set out in the Terms of Service of Pharmacists for the provision of all essential services without face to face contact.

2.32 The London region PSRC are satisfied that the pharmacy procedures for the pharmacy premises are likely to secure 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. Therefore, the application has been granted.

2.33 Determination made by London PSRC on behalf of NHS North West London ICB

Conditions of approval for a Distance Selling Pharmacy

2.34 As this application is in respect of distance selling premises, regulation 64(3) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 applies and the inclusion in the pharmaceutical list in respect of these premises is subject to the following conditions:

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

2.34.2 the means by which you provide pharmaceutical services must be such that any person receiving those services does so otherwise than at the proposed premises;

2.34.3 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;

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

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

2.34.4.2 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 you or your staff; and

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

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

2.34.5.2 you are likely to refuse, for reasons other than those provided for in your 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 you is limited to other categories of patients)."

3 The Appeal

In a letter dated 12 April 2025, Rushport Advisory LLP on behalf of A.Y.S. Healthcare Ltd t/a Grossman Pharmacy ("the Appellant") appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "I act for A.Y.S. Healthcare Ltd t/a Grossman Pharmacy at 6 Oxgate Court Parade, NW2 7ET. I have been instructed by my client to submit the following appeal against the decision of the Commissioner to approve the above application made under regulation 25 by QCP1 Limited.

3.2 The application will be considered against regulation 25 of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

3.3 As the ICB will be aware, regulation 25 states; [quoted in full]

3.4 It is the responsibility of the Applicant to demonstrate that the legal test will be met in full and the Applicant has failed to provide sufficient supporting information that would enable the decision maker to be satisfied that any part of the legal test set out above is met.

3.5 We note that a considerable amount of the information provided at the start of the Applicant's supporting information has been copied, in many cases word for word, from information that Rushport has previously produced for clients. This is an unlawful breach of our copyright and a matter that we will address directly with the Applicant.

3.6 The Applicant provides a list of its SOPs and these include SOPs for services such as Blood Pressure Monitoring, Chlamydia Testing, Needle Exchange etc. These are listed as "Enhanced Services" (page 30 of the SOP document) but no such request to provide these services has been made on the main application form. If the Applicant intends to provide these services they will need to demonstrate how the services will be provided without providing any element of essential services to patients attending the premises. We note the Applicant also lists SOPs for Advanced Services that have not been commissioned for some time, eg MURs. It would appear that the Applicant is not clear about which services are currently commissioned, will be provided, or how they will be provided.

3.7 There are various other areas in which the Applicant does not demonstrate that safe and effective services will be provided. The Applicant proposes using a cool box for local deliveries of fridge lines with a thermometer that requires a Bluetooth connection. The Applicant provides no evidence that using ice packs would keep the contents of the cool box within a set temperature range.

3.8 The Applicant has provided a large amount of information including information on how they will dispense appliances (page 17 and 18 of supporting information) but they do not state on their application that they intend to provide appliances. The Applicant should confirm if they intend to provide Appliances or not, but from the supporting evidence it seems clear that the Applicant does intend to dispense Appliances.

3.9 The Applicant provides information on deliveries of cold chain items at page 20 of their supporting information including details of local deliveries (cool box with ice packs) and the use of couriers, which is presumably for non-local deliveries. It is unclear how unsuccessful deliveries would be dealt with by the pharmacy.

3.10 Page 23 of the Applicant's supporting information deals with matters such as the procedure to follow during the absence of the RP, supporting people with disabilities and other more minor points.

3.11 The Applicant then provides a long list of SOPs, many of which have nothing to do with the operation of a DSP and it is unclear if these SOPs are to be used within the pharmacy or not.

3.12 As the Applicant has failed to provide sufficient information to demonstrate that the legal test will be met, the application should be refused and the appeal allowed.

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

4 Summary of Representations

This is a summary of representations received on the appeal.

4.1 THE APPLICANT

4.1.1 "After reading the appeal letter and original responses to the application from the parties who did respond to the circulation of the application, we respond as follows:

4.1.2 1. The appeal committee will be aware that the application must be heard afresh. However, this does not prevent the appeal committee considering the original decision in the which the [sic] DSP contract was successfully awarded. We respectfully ask the committee to consider this document carefully and to take into account the matters which the original committee commented upon.

4.1.3 2. The original committee stated the following:

It may be concluded that the London region PSRC are satisfied that pharmacy procedures for the pharmacy 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.

It may also be concluded that the applicant is likely to satisfy the criteria as set out in the Terms of Service of Pharmacists for the safe and effective provision of all essential services without face to face contact.

4.1.4 We urge the appeal committee to pay particular attention to these comments as the original application has already been scrutinised by a competent committee who are well versed in making these decisions.

4.1.5 3. We note that the original responses to the application, drafted by Rushport Advisory appear to be very similar in construction. It appears to be a standard template that has been used for the response. The appeal committee may need to ask itself if the response has taken into account the full details of the QCP1 Ltd application or whether this is a knee jerk reaction response.

4.1.6 4. We note that the appeal letter as drafted by Rushport is very similar to the original letter which they submitted on behalf of their client. This begs the question as to whether Rushport and their client have considered their appeal in full or whether there are other factors at play which have caused them to lodge the appeal i.e. to cause doubt and disruption to the application in a futile attempt to dissuade QCP1 from their contract application

4.1.7 5. We note that the original responses by Rushport to the application, paying regard to the future correspondence sentence in both letters, are incomplete. This further begs the question as to whether these letters have been prepared

in full knowledge of the QCP1 Ltd original application or have they been rushed as outlined in our response in paragraph 3.

4.1.8 6. In relation to the response from AYS, through Rushport Advisory, the letter writer states, at page 2:

We note that a considerable amount of the information provided at the start of the Applicant's supporting information has been copied, in many cases word for word, from information that Rushport has previously produced for clients. This is an unlawful breach of our copyright and a matter that we will address directly with the Applicant.

4.1.9 The information was taken from a publicly available document. Furthermore, this bears no relation to the decision that the ICB will need to make when deciding the QCP1 Ltd application. It is a matter for Rushport Advisory to address with QCP1 Ltd outside of this process. The same information appears within the appeal letter and we repeat our comments.

4.1.10 7. In the appeal letter Rushport Advisory, on behalf of their client, make numerous comments on the Draft SOP bundle provided with the original application. This SOP bundle was submitted in its entirety and included the Draft SOPs for the running of the pharmacy and other matters out with the provision of Essential Services.

4.1.11 The provision of enhanced and advanced services is out with the provision of Essential Services. The committee will only be dealing with, and have consideration of, the delivery of essential services for this application. Providing that those seeking enhanced and advanced services are informed that any service provided which is consequential to, and flows from, the enhanced and advanced service provided is a private service, then no essential service will have been provided face to face. It is also noted that there are upcoming changes to the provision of enhanced and advanced services from a DSP so that no enhanced or advanced NHS service can be provided from a DSP. The appeal committee should be satisfied, based on the information before it, that no NHS service will be delivered face to face

4.1.12 8. QCP1 Ltd has provided all documentation which we say satisfies the test under regulation 25.

4.1.13 9. With reference to the cold chain comments outlined by Rushport Advisory on behalf of their clients, we ask the committee to consider the following amendment to our application:

Delivery of Refrigerated Medicinal Products - For cold chain products, delivery times will always be pre-arranged with the patient to minimise the risk of failed delivery. The patient's contact number will be given to the delivery driver so they can again call the patient approximately 15-30 minutes prior to so they can check that somebody will be at the address to receive the medication. Cold chain products will be packed in such a way as to ensure that the required temperatures are maintained throughout the journey and the medicines are transported in accordance with their labelling requirements to maintain product integrity.

For delivery of medication with short journey times of less than 3 hours, validated medical cool boxes will be used as recommended by the MHRA. For extended journeys, gels/ ice packs will be added to the packaging to maintain appropriate temperatures throughout. Extra caution will be taken with regards

[sic] to the positioning of these packs within the consignments as this would be deemed extremely important as they must not be allowed to come into direct contact with the medicines being delivered. Temperatures will be strictly controlled and monitored with calibrated temperature probes to provide temperature data for the entire journey. This will be done by the driver. Temperatures will be recorded at the beginning of the journey and again at the point of delivery to ensure it stays between 2-8°C. If the temperature is outside of the required range, then the product will be deemed unsafe to deliver, marked as waste and returned to the pharmacy for destruction. Thermometer(s) will be calibrated annually against a certified standard to ensure safe and effective use. When used to deliver medication, the delivery driver must only remove the item from cold storage once the patient has answered the door and verified their identity. In the event of failed delivery, the cold storage item must be returned to the pharmacy as soon as possible, with the maximum and minimum temperatures again being recorded at the point of return. Once again, if temperature monitoring suggests that the medication may have been transported outside of the required range, then the product will be destroyed by the pharmacy and then item will be re-dispensed by the pharmacy. Once again, a new delivery will be agreed with the patient prior to redelivery.

4.1.14 There are 2 pharmacies within the building in which QCP1 Ltd seeks to provide NHS services. Medcann Pharma Ltd is a private pharmacy and does not provide NHS services. Medcann Pharma Ltd provides medicinal cannabis. At this moment in time Dar Tejara Limited is a private pharmacy and does not provide NHS services. Dar Tejara Limited provides skin care products. The committee are drawn to Regulation 31(2)(b) and we say that this is not engaged in that:

4.1.14.1 QCP1 Ltd will NOT be providing the same services as Medcann Pharma Ltd or Dar Tejara Limited if the DSP application is successful.

4.1.15 As both 31(2)(a) and (b) need to be met for Regulation 31 to be engaged, the test under Regulation 31 must fail as 31(2)(b) is NOT met.

4.1.16 The appeal committee must also ask itself the real reason why the objections have been placed. Is it out of genuine need to prevent an unnecessary provision of services or is it out of the other parties' fear of financial detriment and reduced market share of the NHS prescription business. We also make the same comment about the appeal letter.

4.1.17 The appeal committee will note that the substance of the appeal letter from Rushport, on behalf of their clients, is very similar in construction to the original representations that were made in the first instance. We ask the appeal committee to consider the real underpinning reasons for this appeal. We say that the appeal was lodged not out of a genuine need to prevent unnecessary provision but as a further attempt to undermine and block the DSP application through fear of financial detriment to AYS Healthcare Ltd. We say they have attempted to muddy the waters and that the appeal letter from Rushport, on behalf of their clients, is a last ditch attempt to be able to retain AYS Healthcare Ltd's market share of NHS business.

4.1.18 12. Taking all of this into account, we urge the appeal committee to dismiss the appeal in its entirety and to allow the contract to QCP1 Ltd to proceed by granting the application."

5 Summary of Observations

This is summary of observations received.

5.1 RUSHPORT ADVISORY LLP ON BEHALF OF THE APPELLANT

5.1.1 "I act for A.Y.S. Healthcare Ltd t/a Grossman Pharmacy at 6 Oxgate Court Parade, NW2 7ET. I have been instructed by my client to submit these final comments to the Applicant's letter dated 26 May 2025.

5.1.2 Points 1 to 6 of the Applicant's letter do not require further comment, but for the sake of completeness, the points raised are denied.

5.1.3 Point 7 of the Applicant's letter states that;

Providing that those seeking enhanced and advanced services are informed that any service provided which is consequential to, and flows from, the enhanced and advanced service provided is a private service, then no essential service will have been provided face to face.

5.1.4 As the Committee will be aware, enhanced and advanced services are not "private" services as claimed by the Applicant.

5.1.5 Point 8 does not require further comments save to say that the Applicant's claim is false.

5.1.6 Point 9 – the Applicant seeks to further change their SOP for cold chain deliveries. The Applicant refers to an MHRA recommendation to use validated medical cool boxes for deliveries taking less than 3 hours. The MHRA makes no such recommendation for pharmacy deliveries and the guidance referred to is only applicable to "small volumes of low risk products" and applies to the wholesaling of pharmaceutical products. The Applicant refers to "probes" and then to "thermometers" and claims that temperatures will be "strictly controlled" – which of course cannot be done with ice packs.

5.1.7 The remaining point of the Applicant's letter do not require further comment, but for the sake of completeness, the comments made are denied.

5.1.8 We further note that the Applicant has simply failed to deal with the specific points raised in our letter of appeal, specifically;

5.1.9 The Applicant provides a list of its SOPs and these include SOPs for services such as Blood Pressure Monitoring, Chlamydia Testing, Needle Exchange etc. These are listed as "Enhanced Services" (page 30 of the SOP document) but no such request to provide these services has been made on the main application form. If the Applicant intends to provide these services they will need to demonstrate how the services will be provided without providing any element of essential services to patients attending the premises. We note the Applicant also lists SOPs for Advanced Services that have not been commissioned for some time, eg MURs. It would appear that the Applicant is not clear about which services are currently commissioned, will be provided, or how they will be provided.

5.1.10 There are various other areas in which the Applicant does not demonstrate that safe and effective services will be provided. The Applicant proposes using a cool box for local deliveries of fridge lines with a thermometer that requires a Bluetooth connection [note the Applicant does not appear to continue to claim that they will use such thermometers however it is unclear if this is correct].

The Applicant provides no evidence that using ice packs would keep the contents of the cool box within a set temperature range.

5.1.11 The Applicant has provided a large amount of information including information on how they will dispense appliances (page 17 and 18 of supporting information) but they do not state on their application that they intend to provide appliances. The Applicant should confirm if they intend to provide Appliances or not, but from the supporting evidence it seems clear that the Applicant does intend to dispense Appliances.

5.1.12 Page 23 of the Applicant's supporting information deals with matters such as the procedure to follow during the absence of the RP, supporting people with disabilities and other more minor points.

5.1.13 As the Applicant has failed to provide sufficient information to demonstrate that the legal test will be met, the application should be refused and the appeal allowed.

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

6 Amendments to Regulation 25

On 23 June 2025, amendments to Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 came into force, which affected this application. Given the amendments represent a new test the Applicant was given the opportunity to make comments in support of its application and parties were given the opportunity to provide comments in response.

6.1 THE APPLICANT

6.1.1 "Response from QCP1 Ltd to the appeal against awarding a DSP contract

6.1.2 As the regulatory framework has now changed so that no advanced or enhanced services can be delivered to a patient who is physically present at the premises, any SOPs that will be written for advanced and enhanced service delivery will ensure that any service MUST not be delivered face to face within the pharmacy. Any patient who requests any NHS service to be delivered face to face will be informed that this is not possible, under any circumstance. All staff employed by the pharmacy will be informed of this change in the rules.

6.1.3 Please find attached updated SOPs and Business Continuity Plan. [Copy provided]"

7 Unsolicited comments

7.1 PHARMACEUTICAL DEFENCE ON BEHALF OF THE APPLICANT

7.1.1 "I have been instructed by the above in relation to this matter and in particular, to the points raised by Rushport Advisory in their letter dated 5 June 2025.

7.1.2 The first point to raise is that it seems extremely injudicious to allow Rushport Advisory to make further comments on QCP1 Ltd's comments in relation to this appeal. It is contended that it would offend the principles of fairness and natural justice if QCP1 Ltd were not allowed to make final comments on any new material that Rushport Advisory had requested that the committee take into account when hearing the appeal.

7.1.3 The second point to raise is in relation to the 3rd paragraph of the further letter from Rushport Advisory. Rushport have misdirected themselves on the construction of QCP1 Ltd's original submission. QCP1 Ltd is fully aware that enhanced and advanced services are part of the NHS Pharmacy Contract and are not "private services" as such. If the committee follow the misdirected comment from Rushport, the committee will be in danger of misdirecting themselves on this point. Further, as the legislative framework has now changed so that no NHS services are allowed to be face-to-face, this point is now rather moot.

7.1.4 With reference to the rest of the comments made by Rushport Advisory within their letter dated 5 June 2025, QCP1 Ltd stands by their responses to the appeal.

7.1.5 I would be grateful if you could take this information into account."

8 **Parties comments in response**

8.1 RUSHPORT ADVISORY LLP ON BEHALF OF THE APPELLANT

8.1.1 "I act for A.Y.S. Healthcare Ltd t/a Grossman Pharmacy at 6 Oxgate Court Parade, NW2 7ET. I have been instructed by my client to submit these final comments in reply to the Applicant's updated SOPs.

8.1.2 We note that the Applicant has attempted to deal with some of the points raised in my letter of 6 June 2025. Despite this the application is still deficient in many areas.

8.1.3 Points 1 to 6 of the Applicant's letter do not require further comment, but for the sake of completeness, the points raised are denied.

8.1.4 The Applicant seeks to further change their SOP for cold chain deliveries and has presented what is now their fourth attempt at a cold chain deliver SOP. The Applicant refers to an MHRA recommendation to use validated medical cool boxes for deliveries taking less than 3 hours. The MHRA makes no such recommendation for pharmacy deliveries and the guidance referred to is only applicable to "small volumes of low risk products" and applies to the wholesaling of pharmaceutical products. The Applicant refers to "probes" and then to "thermometers" and claims that temperatures will be "strictly controlled" – which of course cannot be done with ice packs.

8.1.5 The Applicant states (page 37) that,

"Temperatures will be strictly controlled and monitored with calibrated temperature probes to provide temperature data for the entire journey. This will be done by the driver."

8.1.6 The Applicant has now removed their previous references to this process being somehow monitored using Bluetooth and simply asks the Committee to believe that a temperature can be "controlled" by a driver using a probe.

8.1.7 In the very next sentence the Applicant states,

"*Temperatures will be recorded at the beginning of the journey and again at the point of delivery to ensure it stays between 2-8°C."*

8.1.8 This would be a different process from that described in the previous sentence.

8.1.9 We note that the Applicant has now deleted many of the SOPs that it had previously provided and that the SOPs provided do not cover the services the Applicant proposes to provide. Page 42 of the new SOPs contains the procedure for "Remote Appliance Fitting".

8.1.10 The Committee is asked to note that despite multiple requests to clarify their position with respect to dispensing Appliances, the Applicant has failed to address this question. The Committee cannot simply say that because the Applicant failed to include Appliances on its application form that it will not be able to dispense them. The application form specifically states that an Applicant should write "NONE" if they do not intend to dispense appliances and the Applicant has not done so. The Committee should therefore look at the content of the entire application and SOPs and in this case the Applicant has retained its SOP for Appliances despite deleting many others from its final SOP bundle. As the Applicant has provided the Committee with this SOP it is clear that they intend to dispense Appliances and their application should be assessed against those requirements.

8.1.11 As the Applicant has failed to provide sufficient information to demonstrate that the legal test will be met, the application should be refused and the appeal allowed.

8.1.1 We 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 noted the comments from the Appellant's representative that "*a considerable amount of the information provided at the start of the Applicant's supporting information has been copied, in many cases word for word, from information that Rushport has previously produced for clients. This is an unlawful breach of our copyright and a matter that we will address directly with the Applicant*". The Committee took no view on this matter.. The Committee was mindful that it considers each application on its own merits based on the information which it has before it.

9.5 The Committee had regard to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations").

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

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

9.8 The Committee noted the conclusion of the Commissioner that "*there are no current pharmacies listed at the proposed premises or adjacent to the proposed premises. Therefore regulation 31 does not apply for this application.*" Whilst the Commissioner's decision of Regulation 31 had not been disputed, the Committee noted the comments from the Applicant in subsequent representations regarding Regulation 31. The Committee noted that there are other pharmacies located within the proposed premises, however from the information before it the Committee noted that neither of these pharmacies provide NHS services and are therefore not on the pharmaceutical list. The Committee noted that this had not been disputed by parties in subsequent representations.

9.9 Based on the information before it, the Committee determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

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

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

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

Regulation 25(1)

9.12 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)

9.13 The Committee noted that the Applicant had not included any information in the relevant section of the application form that deals with this point. The Committee noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Commissioner in its decision report stated that "*the premises in respect of which the application is made are not on the same site or in the same building as the premises of a provider of medical services with a patient list*". The Committee noted that this had not been disputed either on appeal

or in subsequent correspondence. Based on the information available to it, the Committee therefore determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

9.14 As far as Regulation 25(2)(b) is concerned, the Committee considered the information which had been provided by the Applicant in relation to its procedures for the provision of essential services and pharmaceutical services, including its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.

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

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

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

9.18 The Committee noted the comments from the Appellant's representative to the extensive list of SOPs which had been provided initially with the application form. The Committee further noted that, following the change of wording in the Regulations, the Applicant had submitted a further set of SOPs. The Committee was mindful that it is not for it '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.

9.19 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.

9.20 The Committee noted the references from the Applicant to prescriptions being received electronically as well as by post, using pre-paid envelops, and further that it had gone on to confirm that as well as local delivery drivers they would also be using Royal Mail and couriers which would ensure that the provision of services was to all of England.

9.21 The Committee was satisfied, based on the information before it, that the provision of essential services would be available to persons anywhere in England.

9.22 The Committee noted the SOP "Procedure for Responsible Pharmacist" as well as the SOP "Procedure for operating in the absence of a Responsible Pharmacist" which states:

9.22.1 *"As a Distance Selling pharmacy, we are required to offer continuous service during our operating hours. Therefore, the Responsible Pharmacist (RP) must remain on the premises at all times during working hours.*

The Pharmacy will have a second pharmacist available during both core and additional operating hours. If the RP needs to leave the premises or take a break on an ad-hoc basis or planned, the second pharmacist must sign in as the RP.

The Responsible Pharmacist realises that they need to leave the premises.

Make sure that the RP tells staff well in advance that they are going to leave the premises. Make sure that the RP has already signed the Pharmacy Record. Make sure all staff understand what the legislation means. Ensure the second pharmacist is aware of your leaving and the length of time RP will be absent for and take over to become RP straight away.

The RP leaves the Pharmacy.

The Responsible Pharmacist should ensure that he/ she remain contactable e.g. leaving their phone number. Monitor the time that the RP has been absent. The second pharmacist must assume the role of RP and the Superintendent Pharmacist should be contacted and informed that there is only one pharmacist on duty.

The return of the RP.

Make sure the RP signs into the pharmacy record noting the duration of absence and reason (GP). The Pharmacy Record should be kept for a minimum of 5 years."

9.23 Based on the information before it, the Committee was satisfied that the provision of essential services would be without interruption.

9.24 The Committee noted the references through the application form, SOPs and supporting information which sets out how the Applicant intends to provide pharmaceutical services without face to face contact by using permissible methods of communication which includes email, telephone and video calls. The Committee further noted the SOP "Provision of Essential Services without face to face contact" states:

9.24.1 *"Purpose*

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 services 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.

…

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, Advanced and Enhanced Services either on or in the vicinity of the premises."

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

9.26 The Committee was satisfied that the provision of pharmaceutical services would be without face to face contact.

9.27 The Committee went on to consider whether safe and effective provision of pharmaceutical services was likely to be secured.

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

9.29 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:

9.29.1 Dispensing of drugs and appliances

9.29.2 Urgent supply without a prescription

9.29.3 Preliminary matters before providing ordered drugs or appliances

9.29.4 Providing ordered drugs or appliances

9.29.5 Refusal to provide drugs or appliances ordered

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

9.29.7 Disposal service in respect of unwanted drugs

9.29.8 Promotion of healthy lifestyles

9.29.9 Prescription linked intervention

9.29.10 Health campaigns

9.29.11 Signposting

9.29.12 Support for self-care

9.29.13 Discharge medicines service

9.29.14 Websites and health promotion zones

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

Providing ordered drugs or appliances

9.31 The Committee noted that the Applicant, at Part 4 of the application form “Pharmaceutical services to be provided at these premises” 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 had left this blank. The Committee noted that the Applicant, in subsequent correspondence and in direct response to this being raised by the Appellant had not confirmed if they were or were not going to be undertaking to provide appliances.

9.32 The Committee noted that within the SOPs provided was a SOP entitled "Remote Appliance Fitting and Dispensing Appliances". The Committee therefore went on to consider whether the Applicant had explained the arrangements that it will have in place to ensure that for appliances which require measing/fitting, a registered pharmacies measures/fits them.

9.33 The SOP states:

9.33.1 *"Purpose*

To inform staff working within a pharmacy how to go about remotely fitting and dispensing an appliance for patients in need.

Scope

This SOP covers all appliances which may need to be fitted as per the NHS contract.

Appliance Fitting

1. Receiving a Repeat Appliance Prescription

In the event that a prescription for an appliance which needs fitting is received from a patient, before ordering the medicine, pharmacy staff will check the patient's PMR history as to whether they have had the appliance before and as such confirm with the patient that there is no change to the size that is needed.

2. Receiving a New Appliance Prescription

If a new prescription for an appliance requires fitting, and the pharmacy cannot provide or customise the appliance or stoma appliance because it is outside the pharmacy's regular services, the pharmacist will:

(a) With the patient's consent, refer the prescription to another NHS pharmacist or NHS appliance contractor; and

(b) If the patient does not consent to a referral, give the patient contact details of at least two NHS pharmacists or NHS appliance contractors who can provide the required appliance or customisation, if the pharmacist knows these details.

The pharmacist will also keep and maintain a record of any information given or referrals made to ensure proper auditing and follow-up care when appropriate.

Dispensing Appliances

Pharmacy will be dispensing appliances ''with reasonable promptness" to patients. Patients should be appropriately advised on the importance of only requesting items they actually need to minimise waste without face to face contact. This can be done through telephone, text, email or video call. Home delivery for appliances must be made with reasonable promptness and at a time agreed with the patient. When delivering such appliances, the packaging

used for the appliance must not have any markings which could indicate the contents, and the method of delivery must not convey the type of appliance being delivered. Home delivery could be made by the pharmacy staff, the Royal Mail or another carrier could be used. Pharmacist must provide a reasonable supply of appropriate supplementary items (disposable wipes and disposal bags). Pharmacist must ensure that the patient can consult a person to obtain expert clinical advice about the appliance. If pharmacist is not able to provide remote Appliance Use Review (AUR) service, the patient must be given the contact details of at least two pharmacies or suppliers of appliances who are able to arrange for the service to be provided. The telephone number or the website address of these providers will be listed on the pharmacy website all the time. Advice on how to keep or store medications can be provided through telephone, text, email or video call by trained pharmacy staff."

9.34 The Committee was of the view that it was ambiguous as to whether or not the Applicant would or would not be providing appliances which require measuring and/or fitting, given the conflicting information contained within the application form and SOPs. In this regard, *Receiving a Repeat Appliance Prescription* suggests that the Applicant would be supplying repeat appliances and requests the patient to confirm no change. However, the term of service requires all necessary arrangements must be made for a registered pharmacist to measure the person named on the prescription form or repeatable prescription for the appliance and to fit the appliance. The Applicant had not explained which appliances were within its 'normal course of business'.

9.35 If it was the Applicant's intention to provide appliances that require measuring and fitting, then there was no information provided to explain how a registered pharmacist would measure or fit an appliance which needed to be measured/fitted.

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

Other considerations

9.37 The Committee noted the further comments from the Appellant on appeal.

9.38 The Committee, taking into account the additional information provided by the Applicant in subsequent representations, considered these areas of the Terms of Service in more detail.

Providing ordered drugs or appliances

9.39 The Committee noted the comments from the Appellant with regard to the information on delivery of cold chain items and in particular *"it is unclear how unsuccessful deliveries would be dealt with by the pharmacy*".

9.40 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).

9.41 The Committee noted the various SOPs which referred to the delivery of medication and the procedures to follow in the event of unsuccessful deliveries which included:

9.41.1 *"The Delivery of Medicines*

9.41.2 *Scope*

This SOP encompasses all medicines which are delivered from a pharmacy, however for Controlled Drugs (CDs), please consult the CD Delivery SOP.

…

6. Controlled drugs delivery.

If a CD is included, phone the patient beforehand to confirm they are in. The driver should sign the blue box on the back of the script and write 'delivery' to complete the audit trail. The driver's name and 'delivery' is written in the CD register as the person collecting the medication. If delivery is unsuccessful, the CD is returned to the pharmacy, booked back into the CD register and signed out again on retry.

IF THE PATIENT IS OUT:

1. In the event of an unsuccessful delivery, the driver will leave a failed delivery card at the delivery address specifying the date and time of the attempted delivery and providing clear instructions and contact details for the patient to contact the pharmacy and reschedule the delivery

2. The driver returns to the pharmacy with any undelivered medication and the delivery record book.

DO NOT- Leave the delivery items.

• unattended in porches or on doorsteps

• with children

• neighbours - Unless arrangements have been made by the patient/carer

To ensure the safe and appropriate delivery of medicines, local deliveries (apart from cold chain deliveries) will be handled by pharmacy own delivery driver. Nationwide deliveries will be sent via recorded delivery, requiring a signature from the patient, their notified carer, or an authorised representative. Patients will receive a tracking number to monitor their delivery status online and will be informed about their delivery through a text messaging system. Medicines will be packed, transported, and delivered to preserve their integrity, quality, and effectiveness. The delivery process will provide a verifiable audit trail from the initial request to final delivery or return to the pharmacy in case of delivery failure. Post delivery items will not be put through letter boxes or left unattended in porches on doorsteps, with children or with neighbours, unless arrangements have been made by patient/carer. This request would be obtained in writing from the patient/carer with a signature authorising delivery to another address. A signature is always required from the recipient to indicate safe receipt. For postal/courier items, at a minimum, use padded envelopes for non-fragile items to protect the manufacturer's packaging. For most items, use bubble wrap and, if necessary, polystyrene filler inside a reinforced cardboard box. The patient, carer, or authorised representative must always sign and date a receipt to confirm safe receipt of the medicines. If the patient is not at home during the delivery attempt, they will be notified with a non-delivery notice, and an alternative delivery date will be arranged."

9.41.3 *"Delivery Controlled Drugs*

…

6. Failure to Deliver

If the patient is not home during the agreed delivery slot– the CD must be returned to the pharmacy on the same day and at the earliest opportunity. Do NOT push the medicines through the letterbox. Do NOT leave the medicines outside the door. Inform the authorised pharmacy staff upon return to the pharmacy. The CD register entry for failed CD deliveries should be annotated by marginal note or footnote to state that the delivery was not made and the CD entry is not accurate. If the pharmacist is satisfied that the product has been stored correctly and is suitable to be issued to the patient at a later date the item should be re-entered in the supplied section of the CD register.

7. Following delivery or attempted delivery

Check the Driver's delivery schedule against the detached prescriptions. Prescriptions for packages which been successfully delivered may be treated as completed and filed. Prescriptions for packages which have not been delivered should be reattached to the package. Contact the patient to confirm the next details for the next delivery. Return the prescription and package to the delivery storage area or the fridge if applicable.

8. CD delivery with 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 and return the next day.

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."

9.41.4 *"Cold Chain Delivery*

Purpose

To ensure that cold chain is maintained between storage within the pharmacy and delivery to the patient. This process has been deemed the responsibility as a medicine distributor/transporter.

Scope

Cold chain maintenance within the remit of the organisation's responsibility. This Standard Operating Procedure (SOP) covers all staff involved in cold chain maintenance during delivery to the patient. It is important for all staff to understand if they are involved in this process that inadequate temperature control during storage and transport of vaccines or fridge line pharmaceuticals can reduce the efficacy of the product and be at the detriment of the patient's health.

…

4. Product dispatch

For cold chain products, delivery times will always be pre-arranged with the patient to minimise the risk of failed delivery. The patient's contact number will be given to the delivery driver so they can again call the patient approximately 15-30 minutes prior to so they can check that somebody will be at the address to receive the medication. Cold chain products will be packed in such a way as to ensure that the required temperatures are maintained throughout the journey and the medicines are transported in accordance with their labelling requirements to maintain product integrity.

For delivery of medication with short journey times of less than 3 hours, validated medical cool boxes will be used as recommended by the MHRA. For extended journeys, gels/ ice packs will be added to the packaging to maintain appropriate temperatures throughout. Extra caution will be taken with regards to the positioning of these packs within the consignments as this would be deemed extremely important as they must not be allowed to come into direct contact with the medicines being delivered. Temperatures will be strictly controlled and monitored with calibrated temperature probes to provide temperature data for the entire journey. This will be done by the driver. Temperatures will be recorded at the beginning of the journey and again at the point of delivery to ensure it stays between 2-8°C. If the temperature is outside of the required range, then the product will be deemed unsafe to deliver, marked as waste and returned to the pharmacy for destruction. Upon successfully delivery, driver will require a signature from the patient, their notified carer, or an authorised representative to confirm the receipt. Thermometer(s) will be calibrated annually against a certified standard to ensure safe and effective use. When used to deliver medication, the delivery driver must only remove the item from cold storage once the patient has answered the door and verified their identity. In the event of failed delivery, the cold storage item must be returned to the pharmacy as soon as possible, with the maximum and minimum temperatures again being recorded at the point of return. Once again, if temperature monitoring suggests that the medication may have been transported outside of the required range, then the product will be destroyed by the pharmacy and then item will be re-dispensed by the pharmacy. Once again, a new delivery will be agreed with the patient prior to redelivery.

6. Unsuccessful cold chain delivery

If a delivery attempt fails, the delivery driver will leave a 'Missed Delivery' card with the date, time, and instructions to reschedule. Medications will not be left unattended if the patient is unavailable to receive the delivery. Patients can rearrange delivery via phone or online. Items are returned to the pharmacy within the same day with the cold chain maintained throughout the journey with the maximum and minimum temperatures again being recorded at the point of return.

7. Breach of Integrity of Cold Chain

The deliver driver able to check maximum and minimum temperature for the whole journey, if the cold chain has been breached or the delivery has been cancelled due to extreme weather or road shut. The patient and pharmacy will be promptly informed of the breach, or the patient will receive a Missed Delivery card.

The pharmacy must arrange for an immediate re-delivery of the items and ensure the return of undelivered items to the pharmacy. Items compromised by a cold chain breach are not reused and must be segregated from the

pharmacy stock upon their return. If the breach of the cold chain is discovered after the medication has been given to the patient, then the Incident Reporting Policy should be followed. The patient must be referred to the responsible pharmacist for review. Regularly review and audit on delivery temperature and tracking data to identify patterns of risk or non-compliance. Conduct stimulated drills or mock scenarios at least once a year to test protocols and response times for breaches or equipment failures."

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

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

Summary

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

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

9.45.1 confirm the Commissioner's decision;

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

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

9.46 As the Committee has reached a different conclusion to the Commissioner for the reasons set out above, the Committee determined that the decision of the Commissioner must be quashed.

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

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

9.49 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 the Commissioner; 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 not satisfied that pharmaceutical services were likely to be secured in a safe and effective manner, and

10.2.2.6 the Committee was satisfied that pharmaceutical services were likely to be secured without face to face contact at the pharmacy premises.

10.2.3 The application is refused.

Case Manager
Primary Care Appeals