

5 September 2025

REF: 26634

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**APPEAL AGAINST NORTHAMPTONSHIRE ICB
DECISION TO GRANT AN APPLICATION BY JRAPHA
CARE LIMITED FOR INCLUSION IN THE
PHARMACEUTICAL LIST AT UNIT 73 ENTERPRISE
CENTRE, MICHAEL WAY, RAUNDS,
WELLINGBOROUGH, NN9 6GR 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:

JRapha Care Ltd (the Applicant)
Rushport Advisory LLP representing Jardines (U.K.) Ltd (the Appellant)
PCSE on behalf of Northamptonshire ICB

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1 The Application

By application dated 29 January 2025, JRapha Care Limited ("the Applicant") applied to Northamptonshire ICB ("the Commissioner") for inclusion in the pharmaceutical list at Unit 73 Enterprise Centre, Michael Way, Raunds, Wellingborough, NN9 6GR under Regulation 25. In support of the application it was stated:

- 1.1 In response to "If you are undertaking to provide appliances, specify the appliances that you undertake to provide (or write 'none' if it is intended that the pharmacy will not provide appliances)" the Applicant stated
- 1.2 [The application form was left blank.]
- 1.3 In response to why the application should not be refused pursuant to Regulation 31 the Applicant stated:
- 1.4 [The application form was left blank.]
- 1.5 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant stated:
- 1.6 [The application form was left blank.]

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

- 1.7 Please find below information to explain how the pharmacy procedures used within the premises will secure:
 - (a) the uninterrupted provision of essential services during the opening hours of the premises, to persons anywhere in England who request those services, and
 - (b) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or someone else's behalf, and the applicant or the applicant's staff.
- 1.8 "Please find in attached document and draft SOPs on essential services. More SOPs can be revealed upon request."
- 1.9 "Uninterrupted Provision of Essential Services in compliance with the Regulatory Requirements for Distance Selling Pharmacies"

- 1.10 Please find below information to explain how the pharmacy procedures used within the premises will secure:
- 1.10.1 (a) all essential services to be secured without face to face contact
 - 1.10.2 (b) all essential services to be secured without interruption during the opening hours
 - 1.10.3 (c) all essential services to be secured for persons anywhere in England
 - 1.10.4 (d) all essential services to be secured in a safe and effective manner
- 1.11 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 non-essential services.
- 1.12 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.
- 1.13 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.
- 1.14 GPhC Guidance
- 1.15 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.
- 1.16 The Applicant will have in place, prior to opening the following;
- 1.17 **1. Risk Assessment**
- 1.18 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:
- 1.18.1 1. Identifying hazards – Determine what could cause harm to patients, staff and others using pharmacy services or within the premises.
 - 1.18.2 2. Evaluating risks - Assess the likelihood and potential impact of identified hazards.
 - 1.18.3 3. Implementing control measures - Develop and apply measures to minimise or eliminate risks.
 - 1.18.4 4. Documentation: Record findings and actions in a Risk Assessment document and risk matrix.
 - 1.18.5 5. Review and Update: Regularly review the Risk Assessment quarterly and update it in response to significant business or operational changes.
- 1.19 Within DSP, risk assessment can be done in the following (but not limited to):

- 1.19.1 Provision of medications and services to high risk and vulnerable patients
- 1.19.2 Errors in dispensing and supplying medications
- 1.19.3 Supply of GSL and P medicines and multiple orders over the internet
- 1.19.4 Delivery of medications
- 1.19.5 Health and safety within premises
- 1.19.6 Data protection
- 1.20 **2. Audit Procedures**
- 1.21 It is important to have audit procedures in place to be compliance 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.
- 1.22 The audit can be done on following (not limited to):
 - 1.22.1 Near miss or incidence logs of medication dispensing
 - 1.22.2 Staff training, competency and SOPs
 - 1.22.3 Records on how medications are stored
 - 1.22.4 Matrix to check medication's expiry
 - 1.22.5 CD balance
 - 1.22.6 Pharmacy services – collect feedback
 - 1.22.7 Concerns or complaints received
 - 1.22.8 Pharmacy equipment and facilities
 - 1.22.9 Communication methods with patients, and between staff and other healthcare providers
 - 1.22.10 Records of decisions to make or refuse a sale
- 1.23 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.
- 1.24 **3. Reactive review**
- 1.25 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.

1.26 **4. Accountability**

1.27 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.

1.28 **5. Training**

1.29 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.

1.30 **6. Record Keeping**

1.31 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.

1.32 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)

1.33 Such records must be:

1.33.1 correctly labelled and archived

1.33.2 records kept of the destruction of the original paper record

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

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

1.35 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.

1.36 **7. Premises**

1.37 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.

1.38 **8. Website**

1.39 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.

1.40 The website will display;

1.40.1 The GPhC pharmacy registration number

1.40.2 The name of the owner of the registered pharmacy

1.40.3 The name of the superintendent pharmacist

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

1.40.5 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)

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

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

1.40.7.1 Return of unwanted medicines

1.40.7.2 Patient Lifestyle Questionnaire

1.40.7.3 How to register exemptions from NHS charges

1.40.7.4 Promotion of Health Lifestyles and details of campaigns being undertaken

1.40.7.5 Procedures for Emergency Supply

1.40.7.6 Explanation of rules on non face to face contact

1.40.7.7 Annual patient survey

1.40.7.8 Patient Information Leaflet

1.40.8 The email address and phone number of the pharmacy

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

- 1.40.10 GPhC internet logo (linked to register entry)
- 1.40.11 Where any medicines are sold online, the pharmacy will be registered with the appropriate agency for online pharmacies.
- 1.40.12 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.
- 1.41 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.
- 1.42 **9. Transparency and Choice**
- 1.43 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.
- 1.44 **10. Managing and Supplying Medicines and Pharmacy Services Safely**
- 1.45 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. 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.
- 1.46 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.
- 1.47 **11. Equipment and Facilities**
- 1.48 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.

- 1.49 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.

1.50 **12. Consent**

- 1.51 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. 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.

1.52 **13. Standard Operating Procedures**

- 1.53 If NHS England requires any further information about any aspect of the operation of the pharmacy then the relevant SOP will be provided upon request.

1.54 **PHARMACY SYSTEMS AND PROCEDURES**

- 1.55 All Essential Services will be delivered in accordance with:

1.55.1 Company Standard Operating Procedures

1.55.2 NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

1.55.3 NHS Act 2006

1.55.4 Human Medicines Regulations 2012

1.55.5 GPhC – Professional Standards and Guidance on Distance Selling Pharmacies

1.55.6 Relevant Data Protection laws

- 1.56 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.

- 1.57 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.
- 1.58 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.
- 1.59 There are various methods to inform general public that pharmacy cannot provide face-to-face essential services within the premises:
- 1.59.1 Notice on Premises
 - 1.59.2 Notice on Website
 - 1.59.3 Post on Social Media
 - 1.59.4 Pharmacy leaflet and flyers [sic]
- 1.60 Provision of NHS Essential Services without face-to-face contact within premises will be achieved by using:
- 1.60.1 Telephone, including text messaging where appropriate Live Video Call
 - 1.60.2 Website inbox (through contact us)
 - 1.60.3 Real-time chat box on website
 - 1.60.4 Email
 - 1.60.5 Electronic Prescription Service (EPS)
 - 1.60.6 Royal Mail postal service
 - 1.60.7 Courier service
 - 1.60.8 Specialised cold chain courier services e.g. DHL COLDCHAIN
- 1.61 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.
- 1.62 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.
- 1.63 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.

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

1.65 **Information Governance**

1.66 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.

1.67 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.

1.68 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.

1.69 **Provision of NHS Essential Services**

1.70 **Dispensing Services**

1.71 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.

1.72 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.

1.73 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.

1.74 Bagging-up NHS prescriptions

- 1.75 For bagging-up prescriptions, use cartons that fit appropriately, making sure the sides are sealed and no medication can come out of the parcel. Make sure the Royal Mail address label is placed on the seal to prevent unauthorised opening 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.

1.76 Choice of packaging

- 1.77 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. If needed plain brown paper can be used to stuff the box to ensure the medicines is protected during transport. 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. Large or any fragile medicines should be packed into cardboard boxes with bubble packaging and filling materials to protect from damage.

1.77.1 Small flat parcels - Small square cartons (Kite Packaging)

1.77.2 Medium and large flat parcels – medium and large Defender boxes

1.77.3 Small parcels - CD1 boxes

1.77.4 Medium parcels – Medium carton (7x5x5) (Kite Packaging)

1.77.5 Large parcels – C1 boxes

1.78 Verification of Declaration of Prescription Exemptions and Paying Prescriptions

- 1.79 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.
- 1.80 The reverse side of the prescription should be fully completed in black ink, except for patients who are age exempt.
- 1.81 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.

- 1.82 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.
- 1.83 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.
- 1.84 **Owings**
- 1.85 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.
- 1.86 **Repeat Dispensing Services**
- 1.87 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.
- 1.88 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.
- 1.89 **Pandemic Treatment Protocol (PTPs)**
- 1.90 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. 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.

- 1.91 A supply of a medicine in accordance with a PTP must be made :
 - 1.91.1 with reasonable promptness and, if asked, an estimate, or, as appropriate, a revised estimate of the time when the medicine will be ready given
 - 1.91.2 generally in the manufacturer's pack where the PTP specifies a pack size of multiple of that is readily available
 - 1.91.3 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
- 1.92 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.
- 1.93 A pharmacy owner may refuse to make a supply in accordance with a PTP where:
 - 1.93.1 the pharmacist considers that the person or representative's request is not genuine;
 - 1.93.2 providing the medicine is contrary to the pharmacist's clinical judgement; or,
 - 1.93.3 where the person or anybody accompanying the person is violent or threatening to pharmacy staff or commits or threatens to commit a criminal offence.
- 1.94 Any refusal to supply must be noted on the patient and / or pharmacy record system.
- 1.95 **Urgent Supply and Emergency Supply**
- 1.96 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.
- 1.97 The request may be received from a Prescriber (Urgent Supply) or from a Patient (Emergency Supply)
- 1.98 The following conditions must apply to the request made by a prescriber:
 - 1.98.1 The Pharmacist must be satisfied that the request is from the appropriate authorised prescriber.
 - 1.98.2 The Pharmacist is satisfied that a prescription cannot be supplied immediately due to an emergency.
 - 1.98.3 The Prescriber agrees to provide a written prescription within 72 hours.
 - 1.98.4 The medication is supplied in accordance with the prescriber's directions.

- 1.98.5 The medication is permitted to be supplied on an Emergency Supply basis.
- 1.98.6 An emergency supply cannot be provided for a Schedule 1, 2 or 3 CD except Phenobarbital for epilepsy by a UK registered prescriber
- 1.98.7 EEA prescribers cannot request an emergency supply of any Schedule 1 - 5 CD.
- 1.99 Full records of the supply will be kept as per the relevant SOP.
- 1.100 The following conditions must apply to the request made by a patient:
- 1.101 **Interview**
- 1.102 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.
- 1.103 **Records**
- 1.104 An entry must be made in the POM register on the day of supply and record all the relevant details.
- 1.105 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.
- 1.106 **Faxed Prescriptions**
- 1.107 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.
- 1.108 The pharmacist should not dispense against faxed prescriptions and instead should use the Emergency Supply procedures.
- 1.109 **Delivery of Urgent Supplies**
- 1.110 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.
- 1.111 **Return and Disposal of Unwanted Medicines**
- 1.112 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:

- 1.112.1 A specialised waste management company will safely and securely dispose of unwanted medicines by collecting them from patients and residential homes.
- 1.112.2 Patients who wish to return unwanted medicines to the pharmacy can do so via courier, with the cost covered by the pharmacy.
- 1.112.3 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.
- 1.113 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.
- 1.114 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.
- 1.115 **Return and Destruction of Controlled Drugs**
- 1.116 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.
- 1.117 **Promotion of Healthy Lifestyles**
- 1.118 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.

- 1.119 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.
- 1.120 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.
- 1.121 **Health Campaigns**
- 1.122 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.
- 1.123 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.
- 1.124 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.
- 1.125 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.
- 1.126 **Signposting**
- 1.127 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.

1.128 Support for Self Care

1.129 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.

1.130 The advice provided encompasses:

1.130.1 (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

1.130.2 (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

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

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

1.131 Dispensing Appliances

1.132 Pharmacy will be dispensing appliances Drug Tariff part IX**EXCEPT items that require measuring or fitting "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. 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). 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.

1.133 Appliance measuring and fitting

- 1.134 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—
- 1.134.1 (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; and
- 1.134.2 (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.
- 1.135 In appropriate cases, the pharmacist will keep and maintain a record of any information given or referral made for auditing and follow-up care.
- 1.136 **Discharge Medicines Services (DMS)**
- 1.137 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.
- 1.138 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.
- 1.139 Stage 1 – Receipt of discharge referral
- 1.140 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.
- 1.141 Stage 2 – Receipt of first prescription following discharge
- 1.142 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.
- 1.143 Stage 3 – Shared decision making discussion with patient
- 1.144 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.

1.145 Delivery

- 1.146 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 from Royal Mail, 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 or doorsteps, with children or with neighbours, unless arrangements have been made by patient/carers. This request would be obtained in writing from the patient/carers 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 re-deliveries/collections from depot can be organised via Royal Mail website for a more appropriate date.

1.147 Cold chain deliveries

- 1.148 All cold chain deliveries must be done via a specialist cold chain courier service. 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. 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 tracking. DHL vehicles have built-in refrigeration systems to maintain the required temperature during road transportation. Any cold chain breach will be reported to the driver, and any impacted delivery will be cancelled, with the pharmacy promptly informed of the breach. Medications are stored in warehouses with temperature-controlled storage facilities for interim or failed delivery storage. A list of approved cold chain couriers is available within the Pharmacy and will be updated from time to time. Each approved courier meets stringent criteria to ensure a fully monitored and dedicated cold chain service.

1.149 Unsuccessful cold chain delivery via courier

- 1.150 If a delivery attempt is unsuccessful, the specialist cold chain courier, DHL COLDCHAIN, will leave a 'Missed Delivery' card. This card will indicate the date and time of the attempted delivery and provide instructions for contacting the courier to arrange a redelivery. Patients can reschedule the delivery at a convenient time via telephone or online.
- 1.151 DHL COLDCHAIN will maintain the cold chain throughout the process, with a maximum 48-hour window for cold chain deliveries. If delivery is not successful within 48 hours,

the items will be returned to the pharmacy. The pharmacy will then contact the patient to arrange a new delivery.

1.152 Breach of Integrity of Cold Chain

1.153 DHL vehicles are equipped with built-in refrigeration systems to ensure the required temperature is maintained during road transportation. The system automatically alerts the delivery driver that the cold chain has been breached and affected deliveries will be cancelled. The patient and pharmacy will be promptly informed of the breach, or the patient will receive a 'Missed Delivery' card.

1.154 The pharmacy must arrange for an immediate re-delivery of the items via courier 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 courier 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.

1.155 Controlled Drugs Delivery

1.156 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:

1.156.1 MHRA Wholesale Dealer License

1.156.2 MHRA Manufacturer's Importer's License

1.156.3 GAMP 4 Systems Validation

1.156.4 MHRA IMP License

1.156.5 MHRA Manufacturer's "Specials" License

1.156.6 ISO 9001:2000 Certification

1.156.7 Clinical trials audited to GMP Annex 13 standards

1.156.8 FDA audited

1.157 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.

1.158 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. 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/carers 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.

- 1.159 The courier provides pharma-grade specialist facilities designed to meet specific quality and validation standards for healthcare products, including Home Office-licensed storage for controlled drugs. Unsuccessful deliveries sent with a courier should be returned to the pharmacy ideally 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. Regularly review and audit on failed deliveries to check for compliance.
- 1.160 **Clinical Governance**
- 1.161 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.
- 1.162 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.
- 1.163 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.
- 1.164 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 expressly 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.
- 1.165 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.

- 1.166 The pharmacy profile will be properly maintained in the NHS Digital Directory of Services.
- 1.167 **Absence of RP**
- 1.168 As a Distance Selling Pharmacy, we are required to provide uninterrupted service during the pharmacy's opening hours. Therefore, the Responsible Pharmacist (RP) is not permitted to leave the premises, unlike in non-Distance Selling Pharmacies where the RP may be absent for up to two hours per day, unless another pharmacist is present.
- 1.169 To ensure continuity, a second pharmacist will be available during the pharmacy's core and any additional operating hours. If the RP needs to leave the premises or take a break in accordance with the Working Time Directive, the second pharmacist must sign in as the RP.
- 1.170 **Support for People with Disabilities**
- 1.171 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.
- 1.172 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.
- 1.173 Compliance aid systems, including blister packs and dosette boxes, will be provided according to service levels 1 and 2, respectively.
- 1.174 **Pharmacy Profile**
- 1.175 The pharmacy profile will be properly maintained in the NHS Digital Directory of Services
- 1.176 **Central Alerting System**
- 1.177 The pharmacy will maintain access to the MHRA Central Alerting System using the premises specific NHS mail email address which will be checked on a daily basis.
- 1.178 **Practice Leaflet**
- 1.179 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—
- 1.179.1 (i) the essential services provided at or from the premises are only available to persons in particular areas of England, or
- 1.179.2 (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)."

2 14 day comments received in response to the 45 day representations from interested parties.

The 14 day comments received by the Commissioner dated 28 March 2025 were not circulated to parties. NHS Resolution therefore circulated along with the appeal.

2.1 THE APPLICANT

2.1.1 “Subject: Response to Objection Raised by Jardines Pharmacy and Community Pharmacy

2.1.2 BLMK and Northants Regarding DSP Pharmacy Application

2.1.3 An objection has been raised regarding the location of the proposed location of the pharmacy within the letter dated 12 March 2025. This has no significance at all to where the pharmacy is to be located nor does the fact that the premises has “shop frontage and car park directly outside the premises with a clear view inside.” We have emphasised many times in our application all essential services will not be provided with face-to-face contact within premises.

2.1.4 The pharmacy is not intended to provide any services that allow customers or patients or carers to come in. The pharmacy operates exclusively on a remote basis which includes all essential, advanced and enhanced services. Pharmacy premise [sic] will operate with 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.

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

2.1.5.1 Notice on Premises

2.1.5.2 Notice on Website

2.1.5.3 Post on Social Media

2.1.5.4 Pharmacy leaflet and flyers [sic]

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

2.1.6.1 *Telephone, including text messaging where appropriate*

2.1.6.2 *Live Video Call*

2.1.6.3 *Website inbox (through contact us)*

2.1.6.4 *Real-time chat box on website*

2.1.6.5 *Email*

2.1.6.6 *Electronic Prescription Service (EPS)*

2.1.6.7 *Royal Mail postal service*

2.1.6.8 *Courier service*

2.1.6.9 *Specialised cold chain courier services e.g. DHL COLDCHAIN™*

- 2.1.7 We contend that the objection has been raised in an attempt to convince the decision making panel that the location for the DSP pharmacy is such that the panel must consider this to be problematic. We further contend that the objection provided by Jardines Pharmacy is such as to try and create confusion and doubt in the panels mind. Providing that the panel are reassured that all essential services will be conducted without face-to face contact, it matters not where the pharmacy is located.
- 2.1.8 It is further noted that within the same objection letter, reference is made to the waiting area. Providing that no essential services are offered to any person who may be within the pharmacy premises and are waiting to, or are, receiving advanced, enhance or private services, then the applicant will be fulfilling their obligation to ensure that no essential services are offered or supplied to that person. There is frequent mention within the applicants bundle as to how a person seeking essential services will be handled if such is requested. There is nothing to suggest that the applicant would not do this apart from a hypothetical scenario as mentioned by Jardines Pharmacy. It is noted that this is based upon the view of a pharmacy contractor who would have a vested financial interest in NOT allowing this application to succeed.
- 2.1.9 The decision-making panel are also reminded that they are tasked with determining the application with reference to essential services only and need not be concerned about advanced, enhanced or private service provision. It is noted that the comments made in the objection letter by Jardines Pharmacy are based upon the view of a pharmacy contractor who would have a vested financial interest in NOT allowing this application to succeed.
- 2.1.10 Staying with the objection letter from Jardines Pharmacy, it is noted that they mention the website that is currently operated. This website is for a pharmacy without an NHS contract and there is nothing to prevent, at this moment in time, the pharmacy advertising in this manner. However, it does not state that we will only provide services locally or that we will not serve individuals nationwide. Once again, our application clearly highlights that we are a pharmacy offering services to anyone within the UK.
- 2.1.11 *'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.'*
- 2.1.12 If an NHS contract were to be awarded and the ICB wishes to do so, it could request screenshots of the website before awarding an ODS code to the applicant if they were successful in their application or an employee of the ICB could check the website. Again, without fear of repetition, it is noted that the comments made in the objection letter by Jardines Pharmacy are based upon the view of a pharmacy contractor who would have a vested financial interest in NOT allowing this application to succeed.
- 2.1.13 Finally, the objection letter mentions matters around disposal of medication and the collection of such. The panel are reminded that essential services must not be delivered face to face on the pharmacy premises – Regulation 25(2)(b).

There is nothing to suggest that the applicant would accept medication for disposal “on the premises.” Without fear of repetition, the applicant has stated, within their contract application bundle:

2.1.14 Return and Disposal of Unwanted Medicines

2.1.15 *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.*

2.1.16 *Patients will be offered various options for disposing of unwanted medicines and out-of-date stock:*

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

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

2.1.16.3 ***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.***
[Emphasis by Applicant]

2.1.17 *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.*

2.1.18 *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.*

2.1.19 *We say that the panel can be satisfied that any collection of medication, by a delivery driver or pharmacy staff, will take place off site. Again, without fear of repetition, it is noted that the comments made in the objection letter by Jardines Pharmacy are based upon the view of a pharmacy contractor who would have a vested financial interest in NOT allowing this application to succeed.*

2.1.20 *The committee should be made aware that [HM] is a director Jardines Ltd and the same person also serves as a committee member in Community Pharmacy BLMK & Northants. With reference to the comments made by Community Pharmacy BLM & Northants, they are not able to point out anything that was missed, we can confidently say that the procedures are robust enough as they stand so as to satisfy the decision making panel that all of the elements in Regulation 25(2) are met.”*

3 The Decision

The Commissioner considered and decided to grant the application. The decision letter dated 4 June 2025 states:

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

- 3.1 "Northamptonshire 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.
- 3.2 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.
- 3.3 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.
- 3.4 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 Northamptonshire 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."

Decision Report:

- 3.5 **"Jrapha Care Ltd, New Distance Selling Premises at Unit 73 Enterprise Centre, Michael Way, Raunds, Wellingborough, NN9 6GR**
- 3.6 **Re: CAS-344410-W7C7Z8**
- 3.7 **Regulation 31 – refusal same or adjacent premises**
- 3.8 The committee noted that there is no person on the pharmaceutical list for the area of North Northampton Health and Wellbeing Board who is providing, or has undertaken to provide, pharmaceutical services from the premises to which the application relates or adjacent premises. It was therefore not required to refuse the application by virtue of this regulation.
- 3.9 **Regulation 25 – Distant Selling Premises Applications**
- 3.10 The committee noted that the application is for distance selling premises and therefore section 129(2A) of the NHS Act 2006 doesn't apply.
- 3.11 **Regulation (25)(2)(a)**
- 3.12 The committee were satisfied that applicant's premises are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. It was therefore satisfied that it is not required to refuse the application under this regulation.
- 3.13 **Regulation 25(2)(b)**

3.14 The committee were satisfied that the pharmacy procedures for the proposed premises are likely to secure:

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

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

3.15 **Regulation 66 – conditions relating to providing directed services**

3.16 The applicant has undertaken to provide the directed services listed in the application if they are commissioned within three years of the date of either the grant of the application or, if later, the listing in relation to the applicant of the premises to which the application relates, to provide those services in accordance with an agreed service specification if they are commissioned, and not to withhold agreement to a service specification unreasonably.

3.17 The PSRC noted that the applicant had undertaken to provide the following advanced services:

3.17.1 new medicine service

3.17.2 community pharmacy seasonal influenza vaccination service

3.17.3 NHS community pharmacy hypertension case-finding service

3.17.4 Pharmacy First.

3.18 It also noted that the Department of Health & Social Care has confirmed that from October 2025, contractors will not be able to deliver advanced and enhanced services to persons present or in the vicinity of their distance selling premises; such services must be provided remotely in line with the delivery of essential services.

3.19 If the application were granted then the applicant would be required to register to provide the above-listed advanced services via the MYS portal within eight weeks of its inclusion in the pharmaceutical list for the area of Leicester City in respect of the premises listed in the application.

3.20 The Committee agreed that if the application were granted it would have no negative impact on those with protected characteristics or on NHS Leicester, Leicestershire and Rutland ICB's duty on health inequality.

3.21 **Decision**

3.22 The committee determined the application is to be approved

3.23 **Third party rights of appeal**

3.24 Jardines UK Ltd and BLMK LPC have been given appeal rights."

4 **The Appeal**

In a letter dated 10 June 2025, Rushport Advisory LLP representing Jardines UK Limited appealed against the Commissioner's decision. The grounds of appeal are:

- 4.1 "I act for Jardines UK Limited and have been instructed by my client to submit this appeal against the attached decision of the Commissioner to refuse the above application.
- 4.2 As the Committee will note, the Commissioner's decision does not deal with the substance of the evidence provided by the Applicant, nor does it address the objections from interested parties. Instead, the Commissioner simply finds (incorrectly) that the Applicant has met the legal test.
- 4.3 As the Committee will be aware, it is not for my client to have to prove anything and the burden of proof is borne by the Applicant to show that they can provide safe and effective services to any person in England who requests those services and do so without face to face contact at the premises.
- 4.4 A previous application from the same Applicant was refused at appeal with case reference SHA/26239. Whilst every case must be considered on its own merits, we highlight the previous decision to show that the Applicant is now well versed in the requirement to provide all relevant information by this stage in the process. The Applicant will likewise be aware that no new information should be submitted from this stage of the process.
- 4.5 In this case the evidence provided does not meet the standard of proof required. Examples of this are below
- 4.6 Dispensing Appliances
- 4.7 The application form requires the Applicant to state if they intend to provide Appliances or not. The Committee will note that the Applicant has simply left this box blank. Whilst the Committee may be tempted to infer that this means that no Appliances will be dispensed, this would not be the correct approach to take. This is because an Applicant is required to state "NONE" if they do not intend to provide Appliances and the Applicant has not stated this.
- 4.8 The Committee should therefore consider the evidence provided by the Applicant and will note that the Applicant has provided an [sic] SOP for "Remote Appliance Fitting and Dispensing Appliances" from page 47 of their supporting information. This confirms that the Applicant intends to dispense Appliances.
- 4.9 The Applicant has simply failed to confirm that they will provide Appliances even though it is clear that they would do so if approved.
- 4.10 Face to Face Contact
- 4.11 Whilst the Applicant claims that services would be provided without face to face contact, their SOPs state otherwise.
- 4.12 Page 126
- 4.13 "Make the patient/representative aware of the importance of the Pharmacist seeing the LRB, **if a patient frequently presents to the Pharmacy without their LRB**, contact prescriber and inform them of the issue and record intervention."
- 4.14 Page 136
- 4.15 5. When labelling and dispensing valproate

- 4.15.1 Proactively setting PMR alerts for relevant patients, reminding team members to discuss risks
- 4.15.2 Flagging up of prescriptions for valproate by having reminder stickers to **counsel patients when handing out medication** [Emphasis by Appellant]
- 4.16 [note: as medicine is being delivered by non-pharmacists this must refer to handing out at the premises]
- 4.17 Pg 25
- 4.18 6. Complete the Checks
- 4.19 *Return bulk packs to the appropriate place to reduce clutter on the dispensary bench. When bagging up the prescription, count the number of items is correct. Prescriptions should be neatly packaged in the appropriate dispensing bag. Check that you have not included any stock containers in the patient's bag. Ensure that 5ml spoons or oral syringes are included if necessary. Seal the bag, attach the prescription and a bag label with the patient's name and address. Attach any owing slips or other notes, e.g. items in fridge or Controlled Drugs cabinet / advice to be given. Check that all relevant records have been made. For CDs, maintain a running balance of stock. **Hand dispensed items to the patient in accordance with your 'Handing out Prescription' SOP** [Emphasis by Appellant] or store neatly in the appropriate **collection area***
- 4.20 The application does not meet the test under regulation 25 and this appeal should be allowed.
- 4.21 We look forward to hearing from you in due course."

5 Summary of Representations

This is a summary of representations received on the appeal.

5.1 THE APPLICANT

- 5.1.1 "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:
- 5.1.2 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 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. Further, we ask that the committee to treat, with extreme caution, the comments made regarding a previous appeal SHA/26239. We submit that SHA/26239 should have no bearing, in part or at all, on the appeal committees decision making process.
- 5.1.3 The original committee stated the following:
- 5.1.4 *Regulation 25 – Distant Selling Premises Applications*
- 5.1.5 *The committee noted that the application is for distance selling premises and therefore section 129(2A) of the NHS Act 2006 doesn't apply.*
- 5.1.6 *Regulation (25)(2)(a)*

- 5.1.7 *The committee were satisfied that applicant's premises are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. It was therefore satisfied that it is not required to refuse the application under this regulation.*
- 5.1.8 *Regulation 25(2)(b)*
- 5.1.9 *The committee were satisfied that the pharmacy procedures for the proposed premises are likely to secure:*
- 5.1.9.1 *The uninterrupted provision of essential services, during the proposed opening hours, to persons anywhere in England who request those services, and*
- 5.1.9.2 *The safe and effective provision of essential services without face-to-face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff.*
- 5.1.10 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.
- 5.1.11 Without fear of repetition, we request that the committee read our original responses to the objections raised by Jardines UK Limited.
- 5.1.12 We note that the appeal written on behalf of the appellant makes an assertion, early on in their letter, that the commissioner "incorrectly" found that Jrapha Care Ltd satisfied the legal test. It is submitted that this comment, early on in the letter, is ill founded and without basis. We ask the committee to ignore this ill placed comment.
- 5.1.13 We request that the committee consider whether the appeal from Jardines UK Limited, through their representative, has been considered 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 Jrapha Care Ltd from their contract application.
- 5.1.14 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.
- 5.1.15 The provision of enhanced and advanced services is out with the provision of Essential Services. When the original application was submitted, advanced and enhanced services could be delivered face to face. It is noted that this position has changed so that no enhanced or advanced NHS service can be provided from a DSP. The legal test has also changed and we direct the committee to the further documentation provided which clearly shows that Jrapha Care Ltd will be able to offer essential, advanced and enhanced services without face-to-face contact. The appeal committee should be satisfied, based on the information before it, that no NHS service will be delivered face to face.
- 5.1.16 Jrapha Care Ltd has provided all documentation which we say satisfies the test under regulation 25.

- 5.1.17 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.
- 5.1.18 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 Jardines UK Limited. 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 Jardine UK Limited's market share of NHS business.
- 5.1.19 If Jardines UK Limited are given an opportunity to respond to these points, we ask the committee to carefully consider their response to ensure that they have not "cherry-picked" certain elements and then attempt to over inflate their true meaning or, in the alternative. We ask the committee to carefully consider any further response by any party to the points raised in this letter and to repeat the question posed in point 8 [paragraph 5.1.17] above to any further response.
- 5.1.20 Taking all of this into account, we urge the appeal committee to dismiss the appeal in its entirety and to allow the contract to be awarded to Jrapha Care Ltd by granting the application."

5.2 NORTHAMPTONSHIRE ICB

- 5.2.1 "Thank you for your letter dated 23rd June 2025; the East Midlands Primary Care Team (EMPCT) on behalf of Northamptonshire ICB would like to make the following representations.
- 5.2.2 Regulation 25(1) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended states that Section 129(2A) of the 2006 Act (regulations as to pharmaceutical services) does not apply to an application—
- 5.2.2.1 for inclusion in a pharmaceutical list by a person not already included;
or
- 5.2.2.2 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,
- 5.2.3 Regulation 25(2) states that in respect of pharmacy premises that are distance selling premises the commissioner must refuse the application to which paragraph (1) applies.
- 5.2.4 (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
- 5.2.5 (b) unless the commissioner is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure—

- 5.2.5.1 (i) the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and
- 5.2.5.2 (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
- 5.2.6 This application by Jrapha Care Limited relates to premises that will operate solely as distance selling premises, as such is an accepted application under regulation 25 of the National Health Services (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended.
- 5.2.7 In respect of Regulation 25(2)(a), the applicant confirms that the premises are not located on the same site or in the same building as any provider of primary medical services with a patient list. The nearest GP practice is situated at a separate location, 3 minutes' drive away, and the proposed pharmacy site is not part of any shared or integrated healthcare facility. Accordingly, there are no grounds for refusal under this section of the Regulation.
- 5.2.8 In relation to Regulation 25(2)(b), the applicant has submitted a detailed set of Standard Operating Procedures (SOPs) and a robust Business Continuity Plan demonstrating that the pharmacy is equipped to meet both requirements: uninterrupted essential services and non-contact delivery.
- 5.2.9 The SOPs clearly describe how the pharmacy will:
 - 5.2.9.1 Provide essential services to persons anywhere in England during all contracted opening hours, using national delivery networks, Electronic Prescription Service (EPS), and secure communication systems including telephone, email, and online messaging.
 - 5.2.9.2 Prevent public access to the premises through the absence of public signage, the use of an intercom system, and procedures which require all in-person inquiries to be redirected to local community pharmacies.
- 5.2.10 The Business Continuity Plan outlines how services will continue in the event of disruption to staff, systems, or logistics. All staff are trained on the specific regulatory requirements governing Distance Selling Pharmacies, including the absolute restriction on face-to-face provision of essential services.
- 5.2.11 In addition, the SOPs make clear that no patient or their representative will be permitted to enter or approach the premises for the purpose of obtaining essential services. All essential services will be delivered remotely, and physical interaction between patients and staff is explicitly prohibited. Communication and clinical support will be provided entirely via remote means including live video link, telephone, email, or website-based messaging platforms.
- 5.2.12 In respect of cold chain handling, the SOPs currently provide for the use of validated cool boxes and specialist couriers. The applicant is committed to refining this SOP to ensure it reflects best practice and NHS England expectations, specifically:
 - 5.2.12.1 That cool boxes will be used only for local deliveries and in accordance with their validated temperature tolerances;

- 5.2.12.2 That such deliveries will include a calibrated thermometer or data logger; and
- 5.2.12.3 That deliveries involving longer distances or multiple recipients will be conducted using an appropriate cold-chain courier service.
- 5.2.13 The applicant also confirms that no biological samples or frozen products will be handled, and any earlier reference to freezer storage in the SOP has been removed or will be amended for clarity.
- 5.2.14 In conclusion, the applicant has demonstrated full compliance with Regulation 25. The proposed premises are not co-located with any GP provider, the procedures submitted evidence a structured, well-managed approach to remote service delivery across England, and essential services will be provided without in-person contact. The application has been made in accordance with all regulatory expectations, and the applicant respectfully submits that it meets the statutory requirements in full.
- 5.2.15 In summary the contractor provided additional information to show compliance with all the elements of regulation 25.
- 5.2.16 The application could not be refused with regards to regulation 31 as there are no persons on the pharmaceutical list (which may or may not be the applicant) is providing or has undertaken to provide pharmaceutical services from
- 5.2.16.1 The premises to which the application relates, or adjacent premises and
- 5.2.16.2 The Integrated Care Board is satisfied that it is reasonable to treat the services that the applicant proposes to provide as part of the service as the existing services (and so the premises to which the application relates, and the existing listed chemist's premises should be treated as the same site)
- 5.2.17 This application by JRapha Care Ltd is for inclusion in the pharmaceutical list in respect of distance selling premises, to be located at Unit 73 Enterprise Centre, Michael Way, Raunds, Wellingborough, NN9 6GR. The application is subject to assessment under Regulation 31 in relation to proximity to existing providers.
- 5.2.18 Following review of local pharmaceutical data and representations, the applicant confirms that no person on the pharmaceutical list is currently providing, or has undertaken to provide, pharmaceutical services from the same premises or from adjacent premises to the proposed site. Two pharmacies were identified in the wider area—both operated by Jardines UK Ltd—but neither are located on or adjacent to the premises. The nearest, The Cottons Medical Centre, is 0.7 miles from the application site. Neither this nor any other known provider is co-located with, or directly adjoining, the proposed pharmacy premises.
- 5.2.19 Moreover, the services proposed by the applicant are distinct in both form and function from any existing services in the area. JRapha Care Ltd is seeking to operate exclusively as a Distance Selling Pharmacy, offering essential services solely through non-face-to-face means and fulfilling prescriptions via national delivery. The service model is not tied to localised footfall or dependent on physical access to the premises, distinguishing it both operationally and practically from any adjacent or local providers.

- 5.2.20 In support of this, the applicant has submitted:
- 5.2.20.1 A full suite of Standard Operating Procedures (SOPs) outlining the remote-only nature of service provision;
 - 5.2.20.2 A Business Continuity Plan ensuring uninterrupted delivery to patients throughout England;
 - 5.2.20.3 Confirmation that no face-to-face essential services will be provided;
 - 5.2.20.4 Website revisions and physical deterrents (e.g. no signage, intercom-based redirection) to reinforce regulatory compliance.
- 5.2.21 Therefore, for the reasons outlined above, the application cannot be refused under Regulation 31.
- 5.2.22 Rushport Advisory asserts that the applicant has “failed to confirm that they will provide appliances even though it is clear that they would do so if approved”. Whilst Rushport Advisory is correct that the appliance declaration box on the application form was left blank, the applicant’s intention to provide appliances is clearly demonstrated through the inclusion of a full Standard Operating Procedure (SOP) titled “Remote Appliance Fitting and Dispensing Appliances.” This SOP details how such items would be dispensed and delivered remotely, in compliance with the regulatory expectations for distance selling pharmacies. The committee believe that the omission on the application form was a clerical oversight, not an attempt to obscure or misrepresent service intentions. The SOP’s presence in the submitted materials provides a clear and unambiguous indication of the applicant’s transparency. In conclusion, While the declaration box was left blank, Regulation 25 does not require the tick-box alone to establish service intentions. The regulatory test concerns the procedures likely to secure service delivery, and those are comprehensively evidenced through the included SOPs. The form omission is administrative and does not detract from the substantive clarity provided in the application.
- 5.2.23 Rushport Advisory references a previously refused application by the same applicant, stating “A previous application from the same Applicant was refused at appeal with case reference SHA/26239. Whilst every case must be considered on its own merits, we highlight the previous decision to show that the Applicant is now well versed in the requirement to provide all relevant information by this stage in the process. The Applicant will likewise be aware that no new information should be submitted from this stage of the process.”
- 5.2.24 This reference appears to imply that the applicant’s prior refusal should influence the current determination or cast doubt on the sufficiency of the evidence provided. However, this is a mischaracterisation of the process and intent of Regulation 25.
- 5.2.25 In this instance, the applicant has made significant improvements and clarifications in response to the earlier refusal:
- 5.2.25.1 The current application includes a more detailed and clearly structured set of Standard Operating Procedures (SOPs) that directly address the requirements under Regulation 25(2)(b), including remote-only provision, public access restrictions, cold-chain delivery protocols, and business continuity planning.

- 5.2.25.2 The applicant has removed or amended any language from SOPs that could suggest face-to-face contact, an issue which appears to have been part of the concern in the previous case.
- 5.2.25.3 The application site is different from the previous submission and has been clearly shown to be compliant with Regulation 25(2)(a) concerning co-location with GP services.
- 5.2.25.4 All required supporting evidence was submitted at the appropriate stage, and the material facts of the case are distinguishable from those considered in SHA/26239.
- 5.2.26 Rushport's assertion that "no new information should be submitted from this stage of the process" is also misapplied. The principle being referred to is that no *substantive new evidence* should be introduced during the appeal that was not made available to the commissioner.
- 5.2.27 However, this does not apply to the original application itself, which was complete at the time of submission and formed the basis of the decision under review. The improvements evident in this application were made *prior to* the initial determination by the commissioner and therefore were appropriately considered in the assessment.
- 5.2.28 In summary, the fact that a previous application was refused is not, in itself, relevant to the outcome of a subsequent, substantively improved application. The applicant has responded constructively to past feedback and has now submitted an application that meets all statutory criteria.
- 5.2.29 I would like to take this opportunity to respond to any further representations provided by Rushport Advisory."

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 affect 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 given the opportunity to provide comments in response.

6.1 THE APPLICANT

- 6.1.1 "Thank you for the email, please find attached the additional information you requested as regards to our DSP Pharmacy.
- 6.1.2 Its indeed sad to know our Competitor Jardines Pharmacy , who is a bigger chain in the community pharmacy continues to legally fight us as adversary, we are an independent new family business desiring to serve our community and UK wide out of necessity, our local community has several new migrant and new estates which Jardines are not currently meeting the demands as well as the pharmacy first services.
- 6.1.3 We will appreciate your support in this continued battle and opposition from the bully pharmacy Jardines, their only interest is to delay or stop us as competitors.
- 6.1.4 Thank you for your understanding and support;

- 6.1.5 Please find attached the documents you requested, please do let me know if any addition is needed.
- 6.1.6 Also, please bear with us as per the initial legal response to Jardines Rushport solicitor appeal, I am currently waiting on my solicitor to provide us with the feedback and response, they promised 13th July, I will send this to the committee as soon as we receive our formal legal response.” [See paragraphs 5.1.1 to 5.1.20 above].
- 6.1.7 “Re: Response from JRapha Care Ltd to the appeal against awarding a DSP contract
- 6.1.8 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.
- 6.1.9 Please find attached updated SOPs and Business Continuity Plan.”
- 6.1.10 [Appendix B for Committee PAGE 3 – 180 – this supersedes Appendix A. Permission sought and given by Applicant for NHS Resolution to circulate]

7 Summary of Observations

This is summary of observations received.

7.1 RUSHPORT ADVISORY LLP REPRESENTING JARDINES UK LTD

- 7.1.1 “I act for Jardines UK Limited and have been instructed by my client to submit these final comments in response to your letter and attachments of 4 August 2025.
- 7.1.2 The Applicant makes a number of comments about my client which are not professional and to which my client does not wish to respond.
- 7.1.3 The Committee will note that the Applicant has made significant changes to their SOPs that go far beyond dealing with the regulatory changes introduced on 23 June 2025. As we show below, the application still does not meet the legal test under regulation 25.
- 7.1.4 **Commissioner Comments**
- 7.1.5 The Commissioner deals with the issue of whether dispensing appliances forms part of the Applicant’s application and states as follows.
- 7.1.6 *Rushport Advisory asserts that the applicant has “failed to confirm that they will provide appliances even though it is clear that they would do so if approved”. Whilst Rushport Advisory is correct that the appliance declaration box on the application form was left blank, the applicant’s intention to provide appliances is clearly demonstrated through the inclusion of a full Standard Operating Procedure (SOP) titled “Remote Appliance Fitting and Dispensing Appliances.” This SOP details how such items would be dispensed and delivered remotely, in compliance with the regulatory expectations for distance selling pharmacies. The committee believe that the omission on the application form was a clerical*

oversight, not an attempt to obscure or misrepresent service intentions. The SOP's presence in the submitted materials provides a clear and unambiguous indication of the applicant's transparency. In conclusion, While the declaration box was left blank, Regulation 25 does not require the tick-box alone to establish service intentions. The regulatory test concerns the procedures likely to secure service delivery, and those are comprehensively evidenced through the included SOPs. The form omission is administrative and does not detract from the substantive clarity provided in the application.

- 7.1.7 We agree with this submission from the Commissioner and it is clear that the application has been determined on the basis that the Applicant intends to provide appliances. This is further evidenced by the Applicant including their SOP for Remote Appliance Fitting (page 41) in their final bundle of SOPs. The Committee will need to determine whether this SOP meets the legal test or not.
- 7.1.8 We further note that the Applicant does not provide SOPs or any evidence in relation to some of the services it proposes to provide. The Applicant simply states that all services will be provided remotely, safely and effectively, but such a comment does not displace the need for evidence to demonstrate that this would in fact be the case.
- 7.1.9 In addition the SOP relating to Supply of Lithium (page 141) states that *"if a patient frequently presents to the Pharmacy without their LRB, contact prescriber and inform them of the issue and record intervention."*
- 7.1.10 The application does not meet the test under regulation 25 and this appeal should be allowed.
- 7.1.11 We look forward to hearing from you in due course."

8 Consideration

- 8.1 The Pharmacy Appeals Committee ("Committee") appointed by NHS Resolution, had before it the papers considered by the Commissioner.
- 8.2 It also had before it the responses to NHS Resolution's own statutory consultations. The Committee noted the Appellant's reference to a previous application from the Applicant which was refused on appeal. The Committee did not have any regard to this determination and considered the instant application on its own merits.
- 8.3 On the basis of this information, the Committee considered it was not necessary to hold an Oral Hearing.
- 8.4 The Committee had regard to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations").

Regulation 31

- 8.5 The Committee first considered Regulation 31 of the Regulations which states:
 - (1) *A routine or excepted application, other than a consolidation application, must be refused where paragraph (2) applies.*
 - (2) *This paragraph applies where -*

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

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

(ii) adjacent premises; and

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

- 8.6 The Committee noted that the Applicant had not provided any information in the application form on this point but the Committee noted that the wording of the application form only required the Applicant to include information in the relevant section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee considered it reasonable to determine that the lack of information in the application form on this point when read with the wording of the application form allowed it to be reasonably satisfied that the Applicant considered that the proposed premises were not adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee noted that the Commissioner had determined that *"there is no person on the pharmaceutical list for the area of North Northampton Health and Wellbeing Board who is providing, or has undertaken to provide, pharmaceutical services from the premises to which the application relates or adjacent premises. It was therefore not required to refuse the application by virtue of this regulation."* No other parties had disputed this information. The Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

- (i) *the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and*
- (ii) *the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff."*

8.8 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)

- 8.9 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)

- 8.10 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 "*applicant's premises are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. It was therefore satisfied that it is not required to refuse the application under this regulation*" which had not been disputed. 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)

- 8.11 As far as Regulation 25(2)(b) is concerned, the Committee considered the information which had been provided by the Applicant in relation to its procedures for the provision of essential services, including its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.
- 8.12 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, across England, and that pharmaceutical services will be provided in a safe and effective way and without face to face contact.
- 8.13 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.
- 8.14 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 updated SOPs which the Applicant has prepared or commissioned.
- 8.15 It is not for the Committee to 'approve' or 'disapprove' of these SOPs (as they may contain matters not relevant to the Committee's consideration, and there are many ways an applicant can choose to organise itself in order to comply with the various requirements of the Regulations) and the Committee has not sought to do so. The Committee has sought evidence within the SOPs and application in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.
- 8.16 The Committee noted the Applicant, in its SOP 'for Provision of Essential Services without face to face contact' stated:
- 8.16.1 *"Purpose*
- 8.16.2 *The uninterrupted provision of essential services, to persons anywhere in England who request those services."*
- 8.17 This is repeated under the heading 'Scope' in the same SOP.
- 8.18 In its SOP 'for Return of Unwanted Controlled Drugs to the Pharmacy' the Applicant stated:
- 8.18.1 *"This service is available to ALL patients living in England."*
- 8.19 Based on the information before it, the Committee was satisfied that the provision of essential services would be available to persons anywhere in England.

- 8.20 With regard to the uninterrupted provision of essential services, the Committee noted the Applicant, in its SOP 'for Operating in the Absence of a Responsible Pharmacist' stated:
- 8.20.1 *"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."*
- 8.20.2 *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.*
- 8.20.3 *1. The Responsible Pharmacist realises that they need to leave the premises.*
- 8.20.4 *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.*
- 8.20.5 *2 The RP leaves the Pharmacy.*
- 8.20.6 *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.*
- 8.20.7 *3 The return of the RP.*
- 8.20.8 *Make sure the RP signs into the pharmacy record noting the duration of absence and reason."*
- 8.21 Based on the information before it, the Committee was therefore satisfied that the provision of essential services would be without interruption.
- 8.22 With regard to the safe and effective provision of pharmaceutical services without face to face contact, the Committee noted the Appellant, in its appeal had disputed the Commissioner's finding in this regard quoting information from the SOPs provided with the application. The Committee was mindful that the Applicant had since provided updated SOPs in response to the amendment to the Regulations on 23 June 2025. The Committee reviewed the updated SOPs and noted the statement at the beginning of the SOPs which stated:
- 8.22.1 ***"THESE ARE SOPs THAT ARE DRAFT IN NATURE NO FACE-TO-FACE CONTACT WITH PATIENTS OR THEIR REPRESENTATIVES IS PERMITTED WHEN DELIVERING ANY NHS SERVICES UNLESS DIRECTED BY THE ICB / LOCAL AREA TEAM."***
- 8.22.2 *While care has been taken to remove any suggestion of face-to-face contact while delivering NHS Pharmacy Services, there may still be references to this. In the Final SOP bundle, all references to face-to-face contact for NHS services will be removed.*
- 8.22.3 *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."

- 8.23 However, the Committee noted the SOP 'for the Supply of Lithium' to which the Appellant had referred to in its appeal. The Applicant stated:

8.23.1 *"Make the patient/representative aware of the importance of the Pharmacist seeing the LRB, if a patient frequently presents to the Pharmacy without their LRB, contact prescriber and inform them of the issue and record intervention."*

- 8.24 The Committee noted the other references to face to face contact which the Appellant had commented upon in its appeal with regard to the SOPs provided with the application which had since been corrected by the Applicant during the appeals process with its updated SOPs, apart from the statement as quoted above at 8.23.1.

- 8.25 The Committee further noted the SOP 'for Provision of Essential Services without face to face contact' stated:

8.25.1 *"Where any SOP could be considered to imply that face-to-face contact with a patient or their representative may take place either on or in the vicinity of the premises, then this should be immediately referred to the Responsible Pharmacist (RP) before any further action is taken."*

- 8.26 Whilst the Committee appreciated that SOPs are subject to being updated, it must have regard to the information before it in order to satisfy itself regarding the distance selling conditions. In this instance the Committee considered that the Applicant's repetition of the statement at 8.22.1, together with the statements in SOP 'for the Supply of Lithium' as noted above, created sufficient doubt that it could not be satisfied that pharmaceutical services would be consistently provided other than on a face-to-face basis at the pharmacy premises.

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

- 8.28 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.

- 8.29 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:

8.29.1 Dispensing of drugs and appliances

8.29.2 Urgent supply without a prescription

8.29.3 Preliminary matters before providing ordered drugs or appliances

8.29.4 Providing ordered drugs or appliances

8.29.5 Refusal to provide drugs or appliances ordered

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

- 8.29.7 Disposal service in respect of unwanted drugs
 - 8.29.8 Promotion of healthy lifestyles
 - 8.29.9 Prescription linked intervention
 - 8.29.10 Health campaigns
 - 8.29.11 Signposting
 - 8.29.12 Support for self-care
 - 8.29.13 Discharge medicines service
 - 8.29.14 Websites and health promotion zones
- 8.30 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

- 8.31 The Committee noted the Appellant states *"The Committee will note that the Applicant has simply left this box blank. Whilst the Committee may be tempted to infer that this means that no Appliances will be dispensed, this would not be the correct approach to take. This is because an Applicant is required to state "NONE" if they do not intend to provide Appliances and the Applicant has not stated this"* and *"the evidence provided by the Applicant and will note that the Applicant has provided an SOP for "Remote Appliance Fitting and Dispensing Appliances"*. The Committee considered whether the Applicant had explained the arrangements which ensure that, for appliances which require measuring / fitting, a registered pharmacist measures / fits them.
- 8.32 The Committee noted that the Applicant had indeed 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 "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 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 it did not propose to provide appliances. However, in its supporting information with the application at paragraph 1.132 above, the Applicant states:
- 8.32.1 *"Pharmacy will be dispensing appliances Drug Tariff part IX**EXCEPT items that require measuring or fitting "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."*
- 8.33 At paragraph 1.133 above, the Applicant states:
- 8.33.1 **"Appliance measuring and fitting**
- 8.33.1.1 *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—*

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

8.33.1.1.2(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.*

8.34 The Applicant has also provided its SOP 'Remote Appliance Fitting and Dispensing Appliance' which states under the heading 'Appliance Fitting':

8.34.1 *"1. Receiving a Repeat Appliance Prescription*

8.34.2 *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.*

8.34.3 *"2. Receiving a New Appliance Prescription*

8.34.4 *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:*

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

8.34.6 *(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."*

8.35 The Committee also noted the Commissioner's comments which states "*the applicant's intention to provide appliances is clearly demonstrated through the inclusion of a full Standard Operating Procedure (SOP) titled "Remote Appliance Fitting and Dispensing Appliances."* This SOP details how such items would be dispensed and delivered remotely, in compliance with the regulatory expectations for distance selling pharmacies. The committee believe that the omission on the application form was a clerical oversight, not an attempt to obscure or misrepresent service intentions. The SOP's presence in the submitted materials provides a clear and unambiguous indication of the applicant's transparency. In conclusion, While the declaration box was left blank, Regulation 25 does not require the tick-box alone to establish service intentions. The regulatory test concerns the procedures likely to secure service delivery, and those are comprehensively evidenced through the included SOPs."

8.36 The Committee is 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 within the application form and the SOPs and what would constitute the "*normal course of business*". Furthermore, it was not explained how the Pharmacist would be satisfied that the appliance size had not changed and if it had, how would that then be measured to ensure it fitted correctly.

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

- 8.38 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

- 8.39 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). Also for the reasons set out at 8.26 above, the Committee concluded that pharmaceutical services would not be delivered by non-face to face means.
- 8.40 Pursuant to paragraph 9(1)(a) of Schedule 3 to the Regulations, the Committee may:
- 8.40.1 confirm the Commissioner’s decision;
 - 8.40.2 quash the Commissioner’s decision and redetermine the application;
 - 8.40.3 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.
- 8.41 The Committee has reached a different conclusion to the Commissioner and it is mindful that Regulation 25 was amended part way through the appeal period. Further, the Applicant, provided new SOPs in response to the amendments to Regulation 25. In those circumstances the Committee determined that the decision of the Commissioner must be quashed.
- 8.42 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.
- 8.43 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.
- 8.44 The Committee concluded that further notification under paragraph 19 of Schedule 2 would not be helpful in this case.

9 Decision

- 9.1 The Committee concluded that it was not required to refuse the application under the provisions of Regulation 31.
- 9.2 Accordingly, the Committee:
- 9.2.1 quashes the decision of the Commissioner; and
 - 9.2.2 redetermines the application as follows -
 - 9.2.2.1 the Committee was satisfied that the proposed premises were not adjacent to or in close proximity to other chemist premises;

9.2.2.2 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;

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

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

9.2.2.5 the Committee was not satisfied that pharmaceutical services were likely to be secured in a safe and effective manner; and

9.2.2.6 the Committee was not satisfied that pharmaceutical services were likely to be secured without face to face contact

9.2.3 The application is refused.

Case Manager
Primary Care Appeals