NHS Resolution

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13 November 2025

REF: SHA/26705

APPEAL AGAINST BUCKINGHAMSHIRE, OXFORDSHIRE AND BERKSHIRE WEST ICB DECISION TO REFUSE AN APPLICATION BY SANBOL LIMITED FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 18/18A MARKET PLACE, FARINGDON, OXFORDSHIRE, SN7 7HP 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:

Sanbol Limited
PCSE on behalf of Buckinghamshire, Oxfordshire and Berkshire West ICB

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1 The Application

By application dated 13 March 2025, Sanbol Limited ("the Applicant") applied to Oxfordshire ICB ("the Commissioner") for inclusion in the pharmaceutical list at 18/18a Market Place, Farringdon, Oxfordshire, SN7 7HP under Regulation 25. In support of the application it was stated:

1.1 In response to "Floor plan showing consultation area" the Applicant stated:

1.1.1 "See enclosed floor plan.

1.1.2 The pharmacy premises will be located on the first floor of 18 Market Place Farringdon. The pharmacy premises can only be accessed via door of 18a Market Place Farringdon. It will not be accessible to member of public for face to face contact.

1.1.3 The door of 18a Market Place will be private and locked.

1.1.4 The ground floor is mainly for private clinics with consulting rooms for various healthcare professionals such as pharmacists, doctors, nurses, phlebotomists to carry out their various clinical services.

1.1.5 It is separate from distance selling pharmacy [sic].

1.1.6 The distance selling pharmacy location in first floor of 18 Market Place building cannot be access through entrance/exit of ground floor. So there is no face to fact contact with patient from the pharmacy in the first floor. [sic]"

1.2 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 "None".

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

1.3.1 “The new distance (online) selling/internet pharmacy will be close proximity to both our Farringdon pharmacy owned by our company at 3 London Street, Farringdon SN7 7AG and Boots Chemist at Market Place.

1.3.2 We would only be carrying out distance selling or internet pharmacy operations in the new location which will not affect the existing pharmaceutical services provided within the vicinity.”

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

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

1.5 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.

1.6 “Firstly we have developed standard operating procedures (SOP) which will be followed for compliance with distance selling pharmacy regulations.

1.7 Our SOPs will be regularly reviewed to ensure we maintain compliance.

1.8 (a) Ensure that the pharmacy is operational and accessible during opening hours. Use automated systems to handle and manage service requests 24/7. Employ adequate staffing levels to meet demand during peak hours.

1.9 (b) Ensure there is sufficient signage in an around the pharmacy to notify patients that they cannot receive face to face essential services.

1.10 7.2: Ensure delivery of essentials being mindful of distance selling pharmacy requirements this include that there are arrangement [sic] in place in our premise which enable a person to perform pharmaceutical services to communicate confidentially with a person accessing pharmaceutical services:

1.10.1 By telephone or another live audio link; and via a live video link.

1.11 As a DSP, it is important to note that we will be providing services to patients in a wider geographical area than most of other pharmacies. [sic] This means as a business we must reflect on the broad health needs of their patients wherever they may live, rather those living in a specific local area maintains a user-friendly website with clear instructions for accessing services. [sic] Ensure all requests are promptly acknowledged and processed within a designated time frame.

1.12 7.2: We would not provide pharmaceutical services to patients who attends premise and ask for one or more essential services [sic]. We would always lock the door to prevent access to premise.

1.13 We will maintain safe and effective provisions without face to face contact. We will ensure that there is a robust internet provision so that the risk of not being able to receive prescriptions electronically through the NHS electronic prescription service (EPS) is minimised. Verify and validate prescription through standard operating procedures. Ensure that there is availability to offer remote consultation services via phone or video call to address patient queries and provide medical advice. Ensure that all consultations are documented and recorded in the patient's record.

1.14 7.3: We are applying to provide essential services. We will be providing Advanced services in later application.

1.15 See our SOP 'enclosed'"

1.16 SOP for Distance Selling Pharmacy to Ensure compliance with NHS Regulations 2013, Section 25 provided with application form. [see Appendix A for Committee].

2 The Decision

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

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

2.1 "Buckinghamshire, Oxfordshire and Berkshire West ICB has considered the above application, and I am writing to confirm that it has been refused. Please see the enclosed report for the full reasoning."

Extract from the Pharmaceutical Services Regulations Committees meeting in common for Buckinghamshire, Oxfordshire and Berkshire West ICB, Hampshire & IOW ICB & Frimley ICB

2.2 "Sanbol Ltd – Distance Selling Premises Application

2.3 CAS no: CAS-357861-K0C0S1

2.4 Address: 18/18a Market Place, Faringdon, Oxfordshire, SN7 7HP

2.5 HWB: Oxfordshire

2.6 ICB: Buckinghamshire, Oxfordshire and Berkshire West

THE APPLICATION

2.7 An application from Sanbol Ltd for a Distance Selling Premises Application was received on 21 March 2025. The Committee was now required to consider the

application in accordance with Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended.

CONSIDERATION

2.8 The Committee considered the following:

2.8.1 The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended.

2.8.2 Department of Health guidance on Distance Selling Premises.

2.8.3 The application form provided by the Applicant.

2.8.4 Representations made by Boots UK Ltd, Community Pharmacy Thames Valley LPC, and Oxfordshire Health and Wellbeing Board.

2.8.5 The Committee decided it was not necessary to hold an oral hearing before determining the application.

2.8.6 A map of the locality showing the nearest community pharmacies and GP Surgeries, in relation to the proposed premises for the Distance Selling pharmacy.

2.8.7 The Committee noted that a site visit had not been undertaken as this application for a distance selling pharmacy is not visited by members of public.

Regulation 31 – Refusal: same or adjacent premises

2.9 The Committee noted that it was required to refuse an excepted application, if the two conditions under paragraph 31(2) applied. These conditions are –

2.9.1 *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 the premises to which the application relates, or adjacent premises; and*

2.9.2 *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).*

2.10 The Committee noted that a pharmacy is providing pharmaceutical services in the adjacent premises, but the applicant and the owner of the adjacent pharmacy are different. The Committee was satisfied that it is not 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 not be treated as the same site).

2.11 The application did not therefore need to be refused in accordance with Regulation 31.

2.12 The Committee noted that the Applicant stated on the application form that it does not intend to provide advanced or enhanced services.

2.13 The Committee noted that the Distance Selling pharmacies are currently able to provide Advanced Services from the pharmacy premises as long as no element of essential services are provided at the same time. The Committee noted that from 1st October 2025 Distance Selling pharmacies will not be able to provide any Advanced or Enhanced services.

2.14 The Committee considered the floor plan provided which detailed a consultation room.

2.15 The Committee noted that the pharmacy intends to open for 40 core hours per week.

2.16 The Committee went on to consider the reasons provided by the Applicant as to why the application should not be refused.

Regulation 25(1)

2.17 The Committee noted that as this was a distance selling application Regulation 25(1) indicates that section 129(2A) of the National Health Service Act 2006 does not apply, provided that Regulation 25(2) does not require the application to be refused.

Regulation 25(2)(a)

2.18 The Committee noted the proposed address and that it is not in the same site or building as a provider of primary medical services with a patient list. The Committee therefore did not have to refuse the application under Regulation 25(2)(a).

Regulation 25(2)(b)

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

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

Regulation 25(2)(b)(i)

2.19 The Committee noted that the Applicant had stated that: all essential services would be delivered in accordance with the relevant regulations, professional

standards and company standard operating procedures and that provision would be uninterrupted to persons anywhere in England who request those services during the opening hours of the premises.

2.20 The Committee noted the applicant had included in their application that there will always be a responsible pharmacist on site during opening hours with accountability set out by the superintendent pharmacist.

2.21 The Committee was satisfied that, based on the information provided, there would be uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services during the stated opening hours.

Regulation 25(2)(b)(ii)

2.22 The Committee went on to consider whether pharmaceutical services would be provided safely and effectively without face-to-face contact at the pharmacy premises between any person receiving the services whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

2.23 The Committee noted that the Applicant does not intend to provide advanced or enhanced.

Schedule 4 Terms of service of NHS pharmacists

2.24 The Committee took the view that where compliance with the Terms of Service would ordinarily require face to face contact, the Applicant must explain how it is going to achieve compliance (and therefore safe and effective provision) without face-to-face contact.

2.25 The Committee went on to consider Schedule 4 to the Regulations having regard to the additional information supplied by the Applicant in support of the application.

2.26 The Committee noted that the applicant had provided very limited information about essential services which did not provide assurance about how it was going to achieve compliance (and therefore safe and effective provision) without face-to-face contact.

2.27 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with the terms of service as set out in Schedule 4.

2.28 The Committee concluded that essential services would not be provided safely and effectively without face-to-face contact between any person receiving the services whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

DECISION

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

2.30 The Committee determined the application as follows –

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

2.30.2 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.

2.30.3 the Committee was satisfied that all essential services were likely to be secured without interruption during the stated opening hours.

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

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

2.30.6 the Committee was not satisfied that all essential services were likely to be secured without face to face contact.

2.31 The Committee determined to refuse the application.

THIRD PARTY RIGHTS OF APPEAL

2.32 The application is refused so the applicant has the right to appeal.

2.33 The Committee decided not to grant third party rights of appeal to the decision to any of the parties that responded during the consultation period because the application had been refused."

3 The Appeal

In a letter dated 31 August 2025, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "I am writing in response to the Pharmaceutical Services Regulations Committee's (PSRC) decision dated 2nd August 2025, which rejected the application of Sanbol Limited for inclusion in a pharmaceutical list at 18/18a Market Place, Faringdon, Oxfordshire , SN7 7HP in respect of distance selling premises.

3.2 I am writing to address the concerns raised by the committee and provide further supporting information to demonstrate compliance with the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

3.3 We fully understand the fundamental requirement needed to comply with DSP regulations for example, no essential service will be provided face to face, all other route of communication such as Telephone, virtual methods.

3.4 Please, I would like the committee to consider how the concerns that have being raised with regards to essential services to be secured in a safe and

effective manner and without face to face contact have been fully addressed under the following points :

3.4.1 Dispensing of drugs and appliances

3.4.2 Urgent supply without a prescription

3.4.3 Preliminary matters before providing ordered drugs or appliances

3.4.4 Providing ordered drugs or appliances

3.4.5 Refusal to provide drugs or appliances ordered

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

3.4.7 Disposal service in respect of unwanted drugs

3.4.8 Promotion of healthy lifestyles

3.4.9 Prescription linked intervention

3.4.10 Public health campaigns

3.4.11 Signposting

3.4.12 Support for self-care

Dispensing of Drugs and appliances

3.5 As outlined in our detailed procedures:

3.6 Handling Non-Electronic Prescriptions: Non-electronic prescriptions will be handled through secure and traceable courier or postal services. These services will utilize tamper-proof packaging to ensure the integrity and confidentiality of the prescription from receipt to return. Upon receiving a non-electronic prescription, our team will immediately log the details into our Patient Medication Record (PMR) system to maintain a traceable and auditable record. Additionally, patients will be provided with clear instructions on how to securely send their prescriptions to the pharmacy using pre-approved couriers.

3.7 We will be using delivery tracking device such as Delivery Mate, where this will date stamp delivery together with proof of delivery. All Controlled drugs medication will be signed for, track and audited.

3.8 Electronic Prescription Service (EPS): As per current prescription trend majority of prescriptions will be received through the Electronic Prescription Service (EPS). This ensures streamlined processing, minimizes delays, and facilitates clinical checks.

3.9 Patients will be informed about the benefits and ease of using EPS during initial communications. Platforms such as Charac, NHS apps will be used to support patient to nominate with ease and give patients options to denominated where

needed. Using such platforms will allow patients to nominate not just locally but also nationally as per DSP contract.

3.10 Non-EPS Prescription: Where prescription are not available as EPS, a pharmacy stamped envelope will be provided for the GP or patients to post prescriptions to us directly. All prescriptions is and will be scrutinised for clinical and legal checks [sic].

3.11 Controlled Drugs Compliance: The handling and dispensing of Controlled Drugs (CDs) will fully adhere to the Misuse of Drugs Act 1971 and its associated regulations.

3.12 Prescriptions for CDs will be processed with heightened scrutiny, ensuring compliance with all legal and professional guidelines. Medications will be delivered via a secure courier or postal service equipped with a tracking mechanism to ensure accountability.

3.13 Tamper-proof packaging will further safeguard the integrity of the medication during transit.

3.14 Standard Operating Procedures (SOPs): Comprehensive SOPs are in place to address every aspect of prescription processing. These include:

3.14.1 Clinical Checks: Each prescription undergoes rigorous clinical and legal review by a qualified pharmacist to identify any potential interactions, errors, or concerns.

3.14.2 Patient Consultations: Consultations will be conducted via secure telephone or live video calls, ensuring patients receive appropriate advice and instructions about their medications. All consultations and actions will be documented and logged in the PMR system. No essential service will be provided face to face under any circumstances.

3.14.3 Resolution of Concerns: Any issues identified during the review process, such as incomplete prescriptions or potential contraindications, will be directly communicated to the prescriber. These communications will be logged for transparency and audit purposes.

Urgent and Emergency Supplies

3.15 2.6 [sic] The position of DSP regarding emergency supply will be clearly presented on the website and the different solution for emergency supply or signposting will be explained. For emergency supplies a comprehensive system and protocols will be in place to ensure these requests are handled promptly and professionally. Staff members will be trained to manage both urgent supply requests from prescribers and emergency supply requests from patients, ensuring compliance with legal and professional requirements.

Urgent Supply Requests (Prescriber-Initiated)

3.16 Urgent supply requests from prescribers are managed under strict conditions to ensure patient safety and regulatory compliance. The following steps are followed:

3.17 Verification of Prescriber: The pharmacist confirms the request is from a legitimate, authorized prescriber, cross-referencing against an approved list to ensure accuracy.

3.18 Emergency Justification: The pharmacist must be satisfied that an emergency prevents the immediate provision of a valid prescription. The urgency of the situation is assessed based on the information provided by the prescriber.

3.19 Written Prescription Commitment: Prescribers are required to confirm that a written prescription will be provided within 72 hours of the request, and a robust tracking system ensures these are received within the stipulated time.

3.20 Authorized Medications Only: Only medications permitted for supply in emergency situations are provided. This excludes Schedule 1, 2, and 3 controlled drugs, except Phenobarbital for epilepsy, as prescribed by a UK-registered practitioner. Prescribers from the EEA are not permitted to request emergency supplies for any controlled drugs.

3.21 Comprehensive Record-Keeping: All supplies are documented in detail in accordance with standard operating procedures, ensuring traceability and regulatory compliance.

Emergency Supply Requests (Patient-Initiated)

3.22 Requests for emergency supplies made directly by patients are carefully assessed to ensure patient need is balanced with regulatory requirements. The following steps are undertaken:

3.23 Remote Consultation: The pharmacist conducts a structured consultation with the patient using non-face-to-face methods, such as telephone or video calls. This ensures accessibility while maintaining a professional standard of care.

3.24 Legal Documentation: An entry is made in the Prescription-Only Medicine (POM) medications include the phrase “Emergency Supply” to comply with legal obligations.

3.25 Use of Faxed or Scanned Prescriptions: Faxed or scanned prescriptions are not considered legally valid. If such documents are presented, the pharmacist does not dispense medication against them but instead uses the emergency supply procedure, ensuring medications are only supplied once all conditions are met.

3.26 Where Emergency supply cannot be fulfilled i.e. for CD prescription, patients will sign posted [sic] to relevant support such as NHS 111 , GP, A&E.

Prioritization of Delivery for Urgent and Emergency Supplies

3.27 Given the critical nature of urgent or emergency requests, delivery processes are designed to prioritize speed and efficiency:

3.28 Deliveries: Drivers are instructed to treat these deliveries with urgency and prioritize them in their schedules. Medications are clearly marked as “URGENT” to ensure rapid handling.

3.29 Courier Services: Couriers are notified of the time-sensitive nature of the items and instructed to use the fastest available delivery methods.

3.30 No Additional Charges: Patients are not charged extra for expedited delivery, even if the pharmacy incurs additional costs to meet the urgency of the request.

Safe Disposal of Unwanted Medicines

3.31 To support environmental responsibility and patient safety, a range of services is available for the safe disposal of unwanted medications:

3.32 Specialist Waste Disposal Services: A licensed waste management company is contracted to collect and dispose of unwanted medications securely, ensuring compliance with environmental and safety regulations.

3.33 Courier Return Options: Patients can return unwanted medications using a pharmacy provided courier service. This service is fully funded by the pharmacy, ensuring accessibility for all patients.

3.34 Local Collection Services: Patients in the surrounding area can arrange for medications to be collected from their home or workplace by contacting the pharmacy through phone or email.

3.35 Pre-Packaged Disposal Kits: Patients are provided with pre-packaged disposal materials, enabling them to securely return medicines. Clear instructions are made available on the pharmacy’s website, along with information about how to arrange.

3.36 Once medicines are returned to the pharmacy, they are carefully sorted and placed in secure disposal units. Regular collections by waste management providers ensure proper handling. This disposal service is promoted through the pharmacy’s website and other informational materials, making it accessible and convenient for patients.

3.37 In no situation as per Essential service would medication be accepted in person; this will be reiterated on the website and clearly signposted so patients can choose the best suitable return method.

Preliminary Matters Before Providing Ordered Drugs or Appliances

3.38 Ensuring the accurate verification of prescription exemption status is a critical part of maintaining compliance with regulatory requirements and delivering a NHS service for patients. To facilitate this, the pharmacy will implement comprehensive systems and protocols as outlined below:

Submission of Exemption Evidence

3.39 Multiple Submission Options: Patients can provide evidence of their exemption through several secure and accessible methods:

3.40 Electronic Upload: Patients can submit scanned or photographed copies of their exemption evidence through a secure online portal or via email. The pharmacy records that the evidence was provided in a digital format for transparency.

3.41 Postal Service: Patients may send original or photocopied exemption evidence by post. To minimize inconvenience, the pharmacy covers postage costs for both sending and returning the evidence.

3.42 Courier Delivery: For local patients using the pharmacy's delivery driver, exemption evidence can be handed over for verification and returned securely after processing.

3.43 Flexibility for Patients:

3.44 Verification and Assessment

3.45 Rigorous Review Process: The pharmacist in charge is responsible for assessing the submitted exemption evidence. They must ensure it meets the regulatory standard of "satisfactory evidence" to confirm the patient's exemption status.

3.46 If the evidence provided is deemed insufficient or invalid, the "Evidence Not Seen" box is marked on the reverse of the prescription, and the patient is informed about the issue promptly.

Detailed Record-Keeping:

3.47 All verified exemptions are recorded in the Patient Medication Record (PMR) system, including:

3.47.1 The type of exemption (e.g., medical condition, maternity exemption, etc.).

3.47.2 The expiration date of the exemption.

3.47.3 The date of verification and the pharmacist's assessment.

3.48 The system also includes functionality to set reminders for follow-up checks, ensuring exemption details remain up to date.

Handling of Prescription Charges

3.49 Efficient Payment Processes: For patients who are not exempt from prescription charges, secure payment systems are in place. Payments can be made online through a secure payment portal linked to the pharmacy's website.

3.50 Once payment is received, the prescription is marked as "paid" in the pharmacy's system, and the dispensing process is initiated without delay. This ensures that all prescriptions are processed promptly while maintaining an accurate audit trail.

Communication with Patients:

3.51 Patients are notified about the status of their prescription, including whether additional information or payments are required, to minimize delays and maintain transparency.

Cost-Free and Secure Processes

3.52 Postal Costs Covered by the Pharmacy: When patients choose to send exemption evidence by post, the pharmacy covers all associated costs, including return postage. This ensures that patients do not face financial barriers to providing the required documentation.

3.53 Evidence is handled securely and returned promptly after verification.

3.54 Patient Privacy and Security: All submissions, whether physical or digital, are processed in line with GDPR and data protection regulations. This ensures patient privacy is maintained at every stage of the process.

System Integration and Ongoing Updates

3.55 PMR System Optimization: The pharmacy's PMR system is designed to integrate seamlessly with exemption verification workflows. This includes real-time updates to records, automated reminders for renewal dates, and clear flags for any outstanding evidence or payments.

3.56 This functionality reduces administrative burdens for staff while ensuring compliance with regulations and continuity of service for patients.

Training and Support:

3.57 Pharmacy staff receive regular training on exemption verification procedures, including recognizing acceptable evidence and handling patient queries effectively.

3.58 A dedicated support team is available to assist patients who have questions about their exemption status or need help submitting their evidence.

Cold Chain and Controlled Drug Compliance

3.59 Provision of Drugs and Appliances

3.60 The pharmacy has implemented robust and detailed procedures to ensure all ordered drugs and appliances are dispensed and delivered safely, efficiently, and in full compliance with applicable regulations.

Receipt and Processing of Prescriptions:

3.61 Prescriptions are received via the Electronic Prescription Service (EPS), post, or courier.

3.62 Upon receipt, prescriptions undergo a thorough clinical and legal assessment by the Responsible Pharmacist (RP). Any clinical concerns, such as potential drug interactions or dosage issues, are escalated to the prescriber for prompt resolution to avoid delays in dispensing.

Standard Operating Procedures (SOPs):

3.63 Comprehensive SOPs are in place to guide staff on every stage of the dispensing process, from receiving prescriptions to the final delivery of medicines.

3.64 SOPs include detailed protocols for handling urgent or emergency requests, managing repeat prescriptions, and maintaining compliance with the Misuse of Drugs Regulations.

Packaging Protocols:

3.65 Medications are packaged securely to protect their integrity during transportation.

3.66 Tamper-evident seals are applied to all packages to ensure security and prevent unauthorized access.

3.67 Fragile items and liquid medicines are cushioned with appropriate materials to withstand transit rigors.

Cold Chain Maintenance

3.68 Maintaining the integrity of cold chain medicines is a top priority. The pharmacy has implemented industry-standard practices to ensure the storage and transportation of thermolabile medications comply with regulatory and safety requirements.

Specialized Packaging:

3.69 Cold chain medicines are packed using insulated containers with temperature-stable cooling elements that maintain the required temperature range during transportation.

3.70 Temperature data loggers are included in each shipment to monitor real-time conditions, ensuring compliance throughout the delivery process.

Dedicated Cold Chain Couriers:

3.71 Deliveries of temperature-sensitive medicines are handled by specialist courier services equipped with temperature-controlled vehicles.

3.72 These couriers are trained in the handling of pharmaceutical products and follow stringent protocols to prevent breaches in the cold chain.

Monitoring and Incident Management:

3.73 Each shipment includes temperature monitoring devices that provide a verifiable record of conditions during transit. If a breach in the cold chain is detected, the courier immediately notifies the pharmacy, and the affected products are returned for safe disposal. Replacement medications are dispatched promptly to avoid any disruption to the patient's treatment.

Routine Audits:

3.74 Cold chain processes are reviewed regularly as part of the pharmacy's audit program.

3.75 These audits assess compliance with protocols, equipment performance, and courier reliability to ensure continuous improvement.

Compliance with the Misuse of Drugs Regulations 2001

3.76 The pharmacy will be fully committed to meeting the requirements of Regulations 14 and 16 of the Misuse of Drugs Regulations 2001, ensuring the secure handling, delivery, and record-keeping of controlled drugs (CDs).

Controlled Drug Storage and Dispensing:

3.77 CDs are stored in a designated, locked cabinet that complies with regulatory requirements for secure storage. Access to this cabinet is restricted to authorized personnel only.

3.78 Dispensing of CDs is conducted by the RP, who ensures all prescriptions meet legal and clinical criteria before the medicines are supplied.

Delivery of Controlled Drugs:

3.79 CDs are transported using specialized courier services equipped to handle controlled substances securely.

3.80 Robust identity verification processes ensure that CDs are delivered only to the intended patient or their authorized representative.

3.81 Patients or representatives are required to provide a signature upon receipt, creating a verifiable audit trail for every delivery.

Record-Keeping:

3.82 All transactions involving CDs are meticulously recorded in the Controlled Drug Register, which is regularly audited to ensure accuracy and compliance. Returns of CDs are logged separately, and unused or expired CDs are destroyed in accordance with regulatory guidelines, witnessed by a trained staff member.

Incident Management:

3.83 Any discrepancies or incidents involving CDs are documented and investigated immediately. The findings are used to refine processes and prevent recurrence.

Additional Safeguards

3.84 Risk Assessments:

3.85 Comprehensive risk assessments are conducted regularly to identify and mitigate potential risks associated with the provision of drugs, including cold chain medicines and CDs.

Training and Accountability:

3.86 All staff undergo regular training to ensure they are fully competent in handling, sensitive drugs and controlled substances.

3.87 Clear lines of accountability are established, with the RP overseeing all dispensing and delivery activities.

Audit and Continuous Improvement:

3.88 The pharmacy conducts regular audits of its processes, including the delivery of cold chain medicines and CDs, to ensure compliance with legal requirements and identify areas for improvement.

Contingency Planning:

3.89 The pharmacy has contingency plans in place to manage potential disruptions, such as courier delays, equipment failures, or medication shortages, ensuring uninterrupted service to patients.

Disposal of Unwanted Drugs

3.90 Disposal of Unwanted Medicines

3.91 The pharmacy will provide a range of convenient and secure options for patients to safely dispose of unwanted medicines, ensuring compliance with environmental regulations and promoting public health. This has been addressed earlier and the following points for the committee to consider:

3.92 Disposal Options for Patients

3.93 Specialist Waste Management Service: The pharmacy partners with a licensed specialist waste management company to ensure the safe and environmentally responsible disposal of unwanted medicines.

3.94 This service extends to residential homes, enabling collection from patients who may have mobility or transportation challenges.

3.95 Courier Return Service: Patients who wish to return unwanted medicines can do so using a dedicated courier service provided by the pharmacy.

3.96 This courier service will be fully funded by the pharmacy, ensuring no additional costs for the patient, and adheres to strict protocols to maintain the safety and security of the returned items.

3.97 Collection Service: The pharmacy will offer a personalized collection home or workplace by contacting the pharmacy via phone or email.

3.98 Pre-Packaged Returns: Patients who prefer to return medicines through courier or local collection will be provided with appropriate packaging materials in advance.

3.99 These packages are designed to ensure the safe handling and secure containment of medicines during transit.

Accessing the Disposal Service

3.100 Online Booking: Comprehensive details about the disposal service, including instructions for booking a collection or courier return, will be available on the pharmacy's website.

3.101 Patients can access step-by-step guidance to ensure a smooth and hassle-free experience.

3.102 Community Awareness: The pharmacy will actively promote its disposal service through multiple channels, including the website, mobile app, and marketing leaflets.

3.103 Information on the importance of safe disposal and the risks of improper handling is also shared to encourage community engagement.

Processing of Returned Medicines

3.104 Sorting and Storage: Once unwanted medicines are received at the pharmacy, they are carefully sorted by trained staff to identify and segregate items for appropriate disposal.

3.105 These medicines are stored securely in designated disposal units to prevent unauthorized access and ensure compliance with regulatory standards.

3.106 Collection by Waste Management Services: The waste management company collects the sorted medicines regularly, ensuring timely and safe disposal in accordance with environmental and pharmaceutical regulations.

3.107 Documentation and Compliance: A detailed log of returned CD medicines will be maintained to track the disposal process and ensure full compliance with regulatory requirements.

3.108 Routine audits will be conducted on return Risk assessment of returns will be established.

Promotion of Healthy Lifestyles

3.109 Comprehensive Strategy for Promoting Healthy Lifestyles

3.110 The pharmacy will be fully committed to promoting healthy lifestyles as part of its essential services, aligning with NHS guidelines and national health objectives. The strategy is designed to provide accessible, engaging, and evidence-based support to patients across England. Below are the key elements of the plan:

3.111 Dedicated Healthy Lifestyle Resources on the Website

3.112 The pharmacy's website will feature a fully developed and dedicated section promoting healthy lifestyles.

3.113 Content and Tools: A wide range of evidence-based resources aligned with NHS guidelines will be provided, covering key health topics such as smoking cessation, alcohol reduction, weight management, mental health, and physical activity.

3.114 Interactive tools, including online lifestyle questionnaires and health assessments, will enable patients to assess their habits and receive tailored advice based on their responses.

3.115 Regular Updates: The content will be reviewed and updated regularly to reflect the latest public health campaigns, seasonal health concerns (e.g., winter flu prevention), and emerging healthcare priorities.

3.116 Patient-Friendly Navigation: The section will be designed for ease of access, ensuring patients of all demographics can locate and utilize resources effectively.

National Health Campaigns

3.117 The pharmacy will actively participate in and support national health campaigns initiated by NHS England, ensuring compliance with Paragraph 17 of Schedule 4.

3.118 Integration with Services: Campaigns will be integrated into essential service delivery by distributing promotional materials, such as leaflets and posters, with medication deliveries.

3.119 Digital materials, including videos and infographics, will be shared via the pharmacy's website, emails and SMS to maximise patient engagement.

3.120 Targeted Outreach: Patients with specific health risks, such as those managing chronic conditions like diabetes or hypertension, will receive tailored messages and resources to address their needs.

3.121 For example, a patient identified as a smoker during a consultation will receive resources on smoking cessation, including links to local cessation services and advice on nicotine replacement therapies.

Proactive Patient Engagement

3.122 The pharmacy will employ proactive methods to engage patients and encourage participation in healthy lifestyle initiatives.

Lifestyle Questionnaires:

3.123 Patients will be invited to complete lifestyle questionnaires provided online or sent with their prescriptions. These questionnaires will assess key health

factors such as diet, exercise, smoking, alcohol consumption, and mental well-being.

3.124 Responses will be analysed to identify at-risk individuals and provide them with tailored advice and resources.

Non-Face-to-Face Consultations:

3.125 Pharmacists and trained staff will engage with patients via phone, video calls, or email to discuss health concerns and provide guidance on improving their lifestyle habits.

3.126 These consultations will be conducted confidentially, with records securely maintained in the Patient Medication Record (PMR) system.

Health Education and Support Materials

3.127 Patients will have access to a broad range of educational materials to support their health journey.

3.128 Example of topics Covered: Resources will address smoking cessation, healthy eating, exercise routines, stress management, and alcohol moderation, among other areas.

3.129 Special focus will be placed on managing chronic conditions such as diabetes, cardiovascular disease, and asthma through lifestyle modifications.

3.130 Modes of Delivery: Information will be presented through multiple channels, including website content, downloadable guides, video tutorials, and links to NHS-endorsed apps and tools.

3.131 Patients will be signposted to local smoking cessation programs, weight management clinics, and mental health support services as appropriate.

3.132 Contact details and guidance for accessing these services will be provided through the website and during consultations.

3.133 The pharmacy will leverage email newsletters and social media platforms to share information about upcoming campaigns, health observances, and resources.

3.134 Feedback will be collected through surveys, questionnaires, and direct patient communication. This information will be used to refine resources and campaigns to better address patient needs.

3.135 Audits will be conducted to assess the impact of healthy lifestyle campaigns and ensure compliance with NHS requirements.

3.136 Metrics such as patient engagement rates, resource utilization, and reported behaviour changes will be analysed.

3.137 Insights from audits and feedback will inform future strategies, ensuring the pharmacy remains effective in promoting healthy lifestyles.

Community Integration

3.138 While operating as a distance-selling pharmacy, the pharmacy will maintain a strong connection to the community by promoting health initiatives and collaborating with local healthcare providers.

Collaboration with Local Services:

3.139 Awareness Campaigns:

3.140 Monitoring and Feedback

3.141 The effectiveness of the pharmacy's healthy lifestyle promotion initiatives will be continually monitored and improved.

3.142 Patient Feedback:

3.143 Clinical Audits:

3.144 Continuous Improvement:

3.145 Compliance with Paragraphs 16–18 of Schedule 4

3.146 The outlined strategy ensures the pharmacy meets the requirements of Paragraphs 16–18 of Schedule 4 by: Providing resources and tools that are accessible to all patients, regardless of location, through a comprehensive online platform (Paragraph 16).

3.147 Actively engaging with patients to address health concerns and encourage positive lifestyle changes through non-face-to-face methods, including consultations and targeted campaigns (Paragraph 17).

3.148 Promoting public health and supporting national health initiatives in alignment with NHS priorities, ensuring that the pharmacy contributes to improving health outcomes across England (Paragraph 18).

3.149 To support public health initiatives:

3.150 The pharmacy's website will host a dedicated section for healthy lifestyle resources, incorporating NHS-approved materials.

3.151 Leaflets and targeted campaigns will accompany prescription deliveries, addressing conditions like diabetes, coronary heart disease, and smoking cessation.

Public Health Campaigns

3.152 The pharmacy is committed to actively supporting and participating in NHS-mandated public health campaigns. These initiatives are designed to raise awareness, educate patients, and promote positive health behaviours across a broad spectrum of health issues. The pharmacy's approach includes a comprehensive, multi-channel strategy to ensure maximum engagement and

impact. This has been discussed earlier, but this is some areas for the committee to consider:

3.153 Distribution of Campaign Materials

3.154 With Prescriptions: Physical campaign materials, such as leaflets and brochures, will be included with medication deliveries to ensure patients receive timely and relevant health information.

3.155 Materials will be tailored to align with national campaigns and specific health conditions, such as smoking cessation, flu vaccination, or diabetes awareness.

3.156 Digital Communication: Campaign information will be shared through electronic means, including emails, SMS alerts, and notifications via the pharmacy's mobile app or website.

3.157 Digital assets, such as downloadable guides, infographics, and links to trusted NHS convenience.

3.158 Proactive Promotion of Campaigns

3.159 Targeted Outreach: The pharmacy will use patient data, such as medication history and lifestyle information, to identify individuals who may benefit most from specific campaigns. Personalized messages and resources will be provided to these patients.

3.160 For example, patients prescribed antihypertensive medications may receive targeted materials on managing cardiovascular health.

3.161 Social Media and Online Platforms:

3.162 Campaigns will be actively promoted through the pharmacy's social media channels, using engaging posts, videos, and infographics to reach a wider audience.

3.163 Blog posts and articles related to the campaign themes will be published on the pharmacy's website, offering in-depth insights and actionable tips.

3.164 Integration with Pharmacy Services

3.165 Routine Consultations: Campaign messages will be integrated into patient interactions, such as medication reviews and consultations, ensuring that public health advice is embedded into routine care.

3.166 Pharmacists will proactively discuss campaign topics relevant to the patient's condition or lifestyle, such as discussing smoking cessation during a prescription consultation for nicotine replacement therapy.

Health Questionnaires:

3.167 Patients will be encouraged to complete health questionnaires related to the campaign themes, helping identify those who may benefit from additional advice or resources.

Signposting

3.168 Commitment to Public Health: Through these activities, the pharmacy demonstrates its commitment to supporting NHS public health objectives and fostering a culture of health awareness and improvement among patients. By leveraging both digital and traditional communication methods, the pharmacy ensures that campaign messages reach patients effectively and make a meaningful impact on their health and well-being.

Active and Passive Patient Assessments

3.169 Active Assessments: Patients who engage with the pharmacy through consultations, lifestyle questionnaires, or health campaigns are actively assessed to identify potential needs for referral to additional services.

3.170 For example, a patient reporting frequent chest infections during a consultation may be referred to a respiratory health specialist or signposted to smoking cessation services if appropriate.

3.171 Passive Assessments: During routine interactions, such as medication reviews or repeat dispensing, the pharmacy team is trained to identify potential unmet needs, even if the patient does not explicitly seek assistance.

3.172 For instance, the prescription history of a patient receiving multiple cardiovascular medications might trigger a conversation about additional services, such as dietary advice or a heart health program.

Provision of Contact Details and Tailored Advice

3.173 Relevant Service Referrals: The pharmacy maintains an up-to-date database of local and national health, social care, and support services. This database includes contact details for organizations such as smoking cessation programs, weight management services, mental health helplines, and social care providers.

3.174 Patients are provided with clear, actionable guidance on how to access these services, including phone numbers, email addresses, and website links.

3.175 Tailored Recommendations: Based on the patient's individual circumstances and health needs, the pharmacy team provides personalized advice and explains the benefits of engaging with the recommended service.

3.176 For example, a patient struggling with anxiety might be directed to both a local counselling service and NHS-approved mental health resources available online.

Non-Face-to-Face Signposting

3.177 Digital Accessibility: Patients can access signposting services remotely via phone, email, or the pharmacy's website. The website features a dedicated section with categorized links need.

3.178 Proactive Outreach: For patients who have been identified as needing additional support, the pharmacy team follows up with tailored information via email or SMS, ensuring continuity of care.

Integration with Essential Services

3.179 Clinical Context: Signposting is seamlessly integrated into essential pharmaceutical services.

3.180 For instance: During medication reviews, pharmacists identify potential unmet needs and offer information on additional support services.

3.181 Patients presenting with minor ailments are signposted to appropriate services, such as walk-in centres or their GP.

3.182 Supporting Chronic Disease Management: Patients managing chronic conditions such as diabetes or COPD are referred to disease-specific support programs, improving health outcomes and reducing the burden on other healthcare providers.

3.183 Monitoring and Feedback

3.184 Patient Follow-Up: Where appropriate, the pharmacy follows up with patients to ensure they have successfully accessed the referred service and received the necessary support.

3.185 Quality Assurance: Regular audits of the signposting process are conducted to ensure the accuracy and effectiveness of referrals. Patient feedback is used to refine and enhance the service over time.

Support for Self-Care

3.186 Via the Website and other social media platforms, the pharmacy is committed to delivering a robust and patient-centred [sic] approach to providing advice and educational resources that empower individuals to manage their health effectively.

3.187 Below is an expanded description of the support and educational services that will be available:

3.188 Personalized Advice and Support: Patients will have access to comprehensive, tailored advice delivered through various secure, non-face-to-face communication channels:

3.189 Telephone Consultations: Patients can speak directly with a qualified pharmacist or trained team member for personalized advice on managing their health concerns, understanding their medications, or addressing any side effects they may experience.

3.190 Calls are conducted in a professional, confidential manner to ensure patient privacy and trust.

3.191 Email Correspondence: For patients who prefer written communication, email provides a convenient option for queries about medications, health concerns, or recommendations for additional services. Responses will be timely and detailed, ensuring patients receive clear, actionable information.

3.192 Video Consultations: Secure video consultations will allow pharmacists to engage with patients in a more interactive and visual manner, particularly useful for discussing lifestyle modifications, medication usage, or assessing specific health concerns.

3.193 Video consultations ensure accessibility for patients who may benefit from visual aids, such as demonstrations or shared screens for educational resources.

Educational Materials for Self-Care

3.194 To encourage informed self-care decisions, the pharmacy will provide an extensive range of educational materials tailored to individual patient needs:

3.195 Digital Resources: Patients will have access to downloadable guides, infographics, and videos on topics such as managing chronic conditions, maintaining a healthy diet, and incorporating exercise into daily routines.

3.196 Resources are designed to be engaging, easy to understand, and aligned with NHS-approved guidelines to ensure accuracy and reliability.

3.197 Condition-Specific Information: For patients managing chronic conditions, targeted educational materials will be provided, covering areas such as blood sugar monitoring for diabetes, inhaler.

3.198 Health Campaign Integration: Educational materials will align with ongoing NHS health campaigns, ensuring patients receive timely and relevant information, such as flu prevention tips during the winter or smoking cessation support during targeted campaigns.

3.199 Promoting Lifestyle Improvements: Resources will address key areas of public health, including smoking cessation, weight management, alcohol moderation, and stress reduction, empowering patients to take proactive steps toward improving their overall well-being.

3.200 Accessibility and Follow-Up Support: The pharmacy's commitment extends beyond the initial interaction to ensure patients feel supported throughout their health journey:

3.201 Accessibility Across Platforms: Educational materials and advice will be accessible through the pharmacy's website, mobile app, or upon request during consultations. Patients can choose their preferred method of communication for convenience.

3.202 Ongoing Follow-Up: For patients requiring additional support, follow-up consultations will be arranged to monitor progress, answer further questions, and provide additional resources as needed.

3.203 Patient-Centred Approach: All advice and educational content will be tailored to individual circumstances, taking into account the patient's medical history, current health concerns, and personal preferences.

Conclusion and Request for Reconsideration

3.204 We believe the additional information provided herein demonstrates our commitment to meeting the regulatory requirements for a distance-selling pharmacy. Our comprehensive SOPs, risk assessments, and operational procedures ensure the safe and effective provision of essential services to all patients across England. We also wish to comply with regulation 66, by informing the Market entry team that we aim to commence services approximately within 12 months of accreditation from the NHS.

3.205 This will give us ample time to retrofit the pharmacy to our needs and no ensure zero compromise in our service delivery.

3.206 We kindly request the committee to reconsider its decision based on this new information. Should you require further clarification or documentation, please do not hesitate to contact us."

4 Summary of Representations

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

5 Consideration

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

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

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

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

Regulation 31

5.5 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") at or 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).

5.6 The Committee noted the comments from the Applicant in respect of Regulation 31 "*The new distance (online) selling/internet pharmacy will be close proximity to both our Farringdon pharmacy owned by our company at 3 London Street, Farringdon SN7 7AG and Boots Chemist at Market Place*."

5.7 The Committee noted the comments from the Commissioner in respect of Regulation 31 "…*a pharmacy is providing pharmaceutical services in the adjacent premises*…"

5.8 The Committee noted that there is no dispute between the parties that there is a pharmacy located in the adjacent premises to the Applicant's proposed site and therefore Regulation 31(2)(a)(ii) is met.

5.9 The Committee went on to consider Regulation 31(2)(b) and noted the comments from the Commissioner that "*the applicant and the owner of the adjacent pharmacy are different*." The Committee further noted the conclusion of the Commissioner that "*The Committee was satisfied that it is not 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 not be treated as the same site)"* and further "*The application did not therefore need to be refused in accordance with Regulation 31*."

5.10 The Committee noted that no party has sought to dispute the conclusion of the Commissioner in respect of Regulation 31.

5.11 The Committee was of the view that although there is a pharmacy adjacent to the proposed site it is not reasonable to treat the services that the Applicant proposes to provide as part of the same services as the existing services. Based on the information provided, the Committee was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

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

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

10. *Where, pursuant to this Part, a person is required to provide details, that obligation is only discharged if the information or documentation provided is sufficient to satisfy 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)

5.14 In relation to Regulation 25(1), the Applicant is applying for inclusion in the relevant pharmaceutical list, as a person not already included in a pharmaceutical list, and paragraph (1)(a) therefore operates to disapply the specified provisions of section 129 of the National Health Service Act 2006, provided that paragraph (2) does not require the application to be refused.

Regulation 25(2)(a)

5.15 As far as Regulation 25(2)(a) is concerned, the Committee noted that the Applicant had not included any information in the relevant section of the application form that deals with this point. The Committee noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

5.16 The Commissioner it is decision report stated that "*proposed address and that it is not in the same site or building as a provider of primary medical services with a patient list. The Committee therefore did not have to refuse the application under Regulation 25(2)(a).*"

5.17 Based on the information available to it, which has not been disputed, 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)

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

5.19 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 without face to face contact.

5.20 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.

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

5.22 The Committee noted that the Applicant had not provided any SOPs to the Commissioner, however as part of the appeal, SOPs had been provided which had been circulated to parties who had the opportunity to comment on them.

5.23 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.

5.24 In relation to the provision of essential services to persons anywhere in England, the Committee noted in the SOPs provided by the Applicant that SOP 1 'Introduction and Background to SOPs' states that the pharmacy must provide:

5.24.1 *"The uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.*

The safe and effective provision of essential services without face-to-face contact between any person receiving the services, whether on their own or on someone else's behalf, and the owner of this pharmacy or any member of staff either on or in the vicinity of the premises."

5.25 Further, SOP 2 'Procedures for NHS Essential Services' states:

5.25.1 "*NHS Essential Services are provided to all patients living in England, this is made clear on the website and in the Practice leaflet*.

All patients in England are able to register to receive NHS Essential Services from The Pharmacy via our website."

5.26 The Committee further noted that the Applicant was proposing to use courier and postal services including a delivery tracking service as well as using its own delivery driver for any local deliveries.

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

5.28 With regard to the uninterrupted provision of essential services, the Committee noted SOP 31 'The Responsible Pharmacist' the Applicant states:

5.28.1 "*As a Distance Selling pharmacy, we must provide uninterrupted service throughout the opening hours of the pharmacy. For this reason, the RP is not allowed to leave the premises in the same way as an RP at a non-Distance Selling Pharmacy is allowed to (for up to 2 hours per day) unless the second pharmacist is present*."

5.29 SOP 31 goes on to state*:*

5.29.1 *"A second pharmacist would be available if for any reason, the RP is required to leave the premises then the second pharmacist must sign in as the RP."*

5.30 The Committee noted that SOP 32 "Preparing for the absence of the RP" states:

5.30.1 *"Preparing for the absence of the RP*

Ensure the 2nd Pharmacist is aware of your leaving and the length of time you will be absent for.

Check the Pharmacy RP Record and calculate the maximum amount of time that the RP can be absent from the pharmacy.

Continue to clearly display your RP notice.

Make an entry into the Pharmacy RP Record to show the date and time your absence started and the reason for your absence.

Inform the pharmacy team what time you expect to return to the pharmacy and how they can contact you in your absence.

The RP should be able to return with reasonable promptness and remain contactable by the pharmacy team during their absence or arrange for another nominated pharmacist to provide advice in their absence.

The pharmacy team must be instructed that in the absence of a RP the second pharmacist is responsible for the operation of the pharmacy and is responsible for:

Sales of GSL and advice about GSL, P and POM medicines.

Sending out dispensed medicines for delivery."

5.31 And further:

5.31.1 *"During the absence of the RP*

All of the pharmacy team must adhere to the pharmacy procedures set down by the RP.

Monitor the time that the RP has been absent.

If the absence exceeds 2 hours:

The second pharmacist must assume the role of RP and the Superintendent Pharmacist should be contacted and informed that there is only one pharmacist on duty.

The pharmacy must contact the RP for additional instructions and the estimated time of return."

5.32 The Committee further noted the table in SOP 32 under the heading "Known Risks" which states:

RP present
RP absent up to 2 hrs. – 2nd pharmacist present
RP absent: more than 2 hrs. – 2nd pharmacist becomes RP

5.33 The Committee noted that a second pharmacist would be present at the pharmacy, therefore based on the information before it, the Committee was satisfied that the provision of essential services would be without interruption.

5.34 With regard to the safe and effective provision of pharmaceutical services without face to face contact, the Committee noted that the Commissioner had concluded that "… *essential services would not be provided safely and effectively without face to face contact* …".

5.35 The Committee went on to consider whether pharmaceutical services would be without face to face contact.

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

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

Face to face contact with patients or their representatives is <u>only</u> allowed in respect of the provision of services other than Essential Services.

These SOPs cover the operating procedures of this Distance Selling Pharmacy. Any reference to 'contact' with or 'contacting' a patient in relation to these SOPs means contact other than face-to-face contact."

5.37 The Committee noted, as per SOP 2 'Procedures for NHS Essential Services', that patients would be able to utilise multiple methods to contact the pharmacy that did not result in face to face communication. The SOP, under the heading 'Communication Channels' point 3.1 states:

5.37.1 "All communication regarding NHS Essential Services should be carried out over the telephone unless the customer has specifically requested to communicate via email.

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

5.38 The Committee was mindful of the references to "essential" services in the SOPs however the Committee noted that the regulations had been amended and now read "*the safe and effective provision of pharmaceutical services without face to face contact at the pharmacy premises, between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff*."

5.39 Whilst the Committee noted the SOPs referred to "essential services" and made no reference to "pharmaceutical services" it also noted that the Applicant was not proposing to offer any advanced or enhanced services at the premises and had confirmed this in the application form stating "*We will be providing Advanced services in later application".* The Committee was of the view that as a result of the amendment to the Regulations, the Applicant would not be able to provide any pharmaceutical services at its premises.

5.40 The Committee considered the information provided in the SOPs was sufficient to provide assurance that the application, if granted, would be offering to provide pharmaceutical services without face to face contact.

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

5.42 The Committee was satisfied that the uninterrupted provision of essential services would be available to persons anywhere in England and pharmaceutical services would be provided without face to face contact..

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

5.44 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.

5.45 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:

5.45.1 Dispensing of drugs and appliances

5.45.2 Urgent supply without a prescription

5.45.3 Preliminary matters before providing ordered drugs or appliances

5.45.4 Providing ordered drugs or appliances

5.45.5 Refusal to provide drugs or appliances ordered

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

5.45.7 Disposal service in respect of unwanted drugs

5.45.8 Promotion of healthy lifestyles

5.45.9 Prescription linked intervention

5.45.10 Health campaigns

5.45.11 Signposting

5.45.12 Support for self-care

5.45.13 Discharge medicines service

5.45.14 Websites and health promotion zones

5.46 The Committee noted that the Applicant had stated on the application form "none" in response to the question as to whether they were undertaking to provide appliances. The Committee was therefore of the view that, if the application was to be granted, the Applicant would not be able to provide any appliances.

5.47 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

5.48 The Committee considered whether the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that (1) the 'cold chain' is maintained, where relevant, and (ii) that the requirements of the Misuse of Drugs Regulations 2001 and, in particular, Regulations 14 and 16, are met).

5.49 The Committee noted SOP 12 "Bagging up" states:

5.49.1 "*Choice of Delivery Method*

For local deliveries (up to 15 miles radius, but may be extended at the discretion of the RP) the delivery driver should deliver medication. Outside this area Royal Mail should be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier should be used (see SOP 18 Delivery of Controlled Drugs), or the items are fridge lines, in which case the cold chain courier should be used (see below).

…

Delivery of a prescription via Royal Mail (Not for Cold Chain or CDs)

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

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

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

Confirm details of all prescriptions to be delivered.

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

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

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

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

…

Cold chain delivery via courier

Explanatory Notes:

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

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

Cold chain management uses its own terminology. Several temperature ranges are specified in the relevant literature, the most common being controlled-room temperature or CRT (often defined from 15oC to 25oC), but also cool (from 8oC to 15oC), cold or refrigerated (from 2oC to 8oC), frozen (around -10oC) and cryogenic (around -150oC). There is, however, no general or universal glossary that is commonly accepted by all regulatory agencies. For courier deliveries the Pharmacy will normally be advising the courier that delivery must be in the "cold or refrigerated" category.

The Cold Shipping Package is designed for customers that require a refrigerated environment of 2-8°C for their shipments and will be the most commonly used in the pharmacy.

The packaging device maintains its exacting "cold ship" temperature requirements and is fully monitored to ensure that any breach is notified to the Pharmacy.

…

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

A delivery should be booked using the couriers specified Cold Chain Services (refer to booking procedure with courier in the "cold chain courier" folder – note this does not form part of the SOP as it will change from courier to courier),

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

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

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

Unsuccessful cold chain delivery via courier

In the event of an unsuccessful delivery, the courier will leave a 'Missed Delivery' card, stating the date and time of the attempted delivery. The patient can then rearrange delivery for a convenient time by telephone or Internet. The courier will keep the cold chain intact until successful delivery.

Breach of Integrity of Cold Chain

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

Where such an event occurs, the courier is instructed to leave a 'Missed Delivery' card and also inform the pharmacy that the delivery was unsuccessful due to a breach of the cold chain. The pharmacy must arrange for immediate re-delivery of the items via courier and the return of the items that have failed to be delivered to the pharmacy by the courier."

5.50 Whilst the Committee noted the information above indicated that cold chain items would be delivered by a specialist courier it also had to regard to SOP 12 under the heading 'Transfer to the Delivery Driver' which states:

5.50.1 *"Ask the delivery driver to check the details on the delivery sheet correspond to the deliveries.*

Ensure the delivery driver completes all the sections on the delivery sheet including their name and the date.

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

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

Ensure deliveries of fridge items are prioritised and items are placed in the refrigerated area of the delivery vehicle.

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

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

5.51 The Committee was of the view that the above extract at 5.50.1 was specific to the Applicant's own local delivery driver as there is a separate section for delivery of cold chain items via courier. This was confirmed by the statement "*Ensure that any deliveries for fridge items and CDs are taken out of storage when appropriate*" which indicated to the Committee that the local delivery driver would be handling and delivering cold chain items.

5.52 As the Committee must be satisfied that the Applicant has explained how drugs/appliances will be provided to the patient (including to ensure that the 'cold chain' is maintained), the Committee considered that the wording creates sufficient ambiguity as to the Applicant's intentions. The Committee noted that apart from the reference to a "*refrigerated area of the delivery vehicle*", the Applicant has not provided any information on the process that would be followed for deliveries of cold chain items by its own driver.

5.53 Therefore, the Committee could not be satisfied, as it was required to be, that during transit, the cold chain would be monitored throughout, or what would happen in the event of a breach of cold chain or failed/ missed delivery by the pharmacy's own driver.

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

Discharge Medicines Service

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

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

5.57 The Committee noted that the Applicant had provided no information either in its initial application, subsequent appeal or SOPs with regard to the Discharge Medicines Service. Therefore the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

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

Summary

5.59 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).

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

5.60.1 confirm the Commissioner's decision;

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

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

5.61 In those circumstances, although the Committee reached the same decision as the Commissioner it did so for different reasons based on additional information which was not available to the Commissioner, the Committee determined that the decision of the Commissioner must be quashed.

5.62 The Committee considered whether there should be a further notification to the parties detailed at paragraph 19 of Schedule 2 of the Regulations to allow them to make representations if they so wished (in which case it would be appropriate to quash the original decision and remit the matter to the

Commissioner) or whether it was preferable for the Committee to reconsider the application.

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

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

6 Decision

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

6.2 The Committee:

6.2.1 quashes the decision of the Commissioner; and redetermines the application as follows -

6.2.1.1 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;

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

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

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

6.2.1.5 the Committee was satisfied that pharmaceutical services were likely to be secured without face to face contact.

6.2.2 The application is refused.

Case Manager
Primary Care Appeals