NHS Resolution

5 May 2026

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REF: SHA/ 26846

APPEAL AGAINST SOMERSET ICB DECISION TO REFUSE AN APPLICATION BY KEYNSHAM HEALTHCARE LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 1 COOPERS MILL, TAUNTON, TA2 6NX 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:
Keynsham Healthcare Ltd
PCSE on behalf of Somerset ICB
Healthcare Plus Consulting Ltd on behalf of Vitastock Ltd

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1 The Application

By application dated 10 June 2025, Keynsham Healthcare Ltd ("the Applicant") applied to Somerset ICB ("the Commissioner") for inclusion in the pharmaceutical list at 1 Coopers Mill, Taunton, TA2 6NX under Regulation 25. In support of the application, it was stated:

1.1 In response to "If you are undertaking to provide appliances, specify the appliances that you undertake to provide (or write 'none' if it is intended that the pharmacy will not provide appliances)" the Applicant left this box blank.

1.2 In response to why the application should not be refused pursuant to Regulation 31 the Applicant left this box blank.

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

Pharmacy procedures

1.4 Please explain how the pharmacy procedures used within the premises will secure:

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

1.5 Please describe the procedure that will be followed where a patient attends the premises and asks for one or more of the essential services.

1.6 If you are undertaking to provide advanced services at the premises please describe how you will do so without providing any element of essential services.

1.7 You must ensure that you provide sufficient information within this application form to satisfy NHS England or the relevant delegated integrated care board on the above points. You are not required to submit your standard operating procedures for the premises but if you do they will be circulated to interested parties unless NHS England or the relevant delegated integrated care board is satisfied that the full disclosure principle does not apply.

1.8 “Please see the attached document in support of this application”.

Supporting document

1.9 “Standard Operating Procedures for a Distance Selling Pharmacy (DSP)

1.10 1. Purpose and Overview

1.11 This document serves as a guide and is not the complete Standard Operating Procedure (SOP). It has been prepared to provide an overview of how various aspects of the Distance Selling Pharmacy (DSP) will be operated in line with regulatory expectations.

1.12 This manual outlines the operational standards and procedural guidelines for a Distance Selling Pharmacy (DSP), ensuring consistent, safe, and compliant service delivery without face-to-face interactions with patients. It is designed to meet NHS regulatory requirements and reflect the General Pharmaceutical Council (GPhC) standards.

1.13 The pharmacy will maintain a Governance Framework encompassing clinical governance, information governance, and risk management. This includes a live risk register, performance tracking via Key Performance Indicators (KPIs), and monthly governance meetings. Named Leads will be appointed for Clinical Governance, Information Governance, Safeguarding, and Infection Control to ensure clear accountability across domains.

1.14 2. Governance and Responsibility

1.14.1 Superintendent Pharmacist: Accountable for the SOPs and overall compliance.

1.14.2 Responsible Pharmacist (RP): Oversees daily operations, ensures staff adherence to SOPs, and maintains service quality.

1.14.3 All Staff: Must be trained, competent, and understand all SOPs relevant to their roles.

1.15 All staff must sign a training log confirming they have read, understood, and agreed to abide by the SOPs.

1.16 Patients are informed clearly about the scope and limitations of the services provided, including expected response times for enquiries. Service accessibility and communication responsiveness are audited monthly. An accessibility statement is maintained and made available publicly.

1.17 3. Service Provision Scope

1.17.1 Services are provided exclusively through non-face-to-face methods (e.g., phone, email, online portal, video call). At no point should a patient or their representative be physically present at or near the premises for any NHS service.

1.17.2 This strict separation ensures compliance with the requirements for DSPs, as no in-person interaction is permitted under this model.

1.17.3 Despite the lack of in-person contact, the pharmacy must remain highly accessible and responsive to patient needs. Multiple communication channels (telephone, secure email, live chat, video consultation) are provided to support comprehensive service delivery.

1.17.4 The pharmacy will use platforms like AccuRx to facilitate secure video consultations and text messaging with patients. This platform ensures timely, confidential communication and is integral to maintaining high levels of accessibility and patient engagement.

1.17.5 The pharmacy serves all patients within England.

1.17.6 Essential NHS services must be uninterrupted and available during operational hours.

1.18 4. Patient Registration and Consent

1.18.1 Patients register through an online platform or by submitting a paper form.

1.18.2 Registration includes mandatory consent for communication, storage, and processing of personal and medical data, including for the purpose of dispensing prescriptions.

1.18.3 Patients are provided with a clear explanation of how their data will be used and stored, and must actively acknowledge this before any services are rendered.

1.18.4 Consent also extends to being contacted for service updates, delivery confirmation, and urgent clinical matters.

1.18.5 The importance of obtaining informed consent is vital to uphold patient rights, ensure confidentiality, comply with data protection laws, and maintain transparency.

1.18.6 Automated confirmations ensure registration accuracy and verify contact details. Consent records are maintained securely and reviewed periodically.

1.19 All prescriptions are logged using a digital audit trail system with timestamped entries. Barcoding systems are used to track each item from receipt to dispatch. A second accuracy check is carried out before medicines are dispatched, ensuring error minimisation.

1.20 5. Prescription Handling

1.21 *a. Order Receipt*

1.21.1 Prescriptions may be received via multiple secure channels: electronically through the Electronic Prescription Service (EPS), posted paper prescriptions, or scanned copies sent from verified NHS sources.

1.21.2 Upon receipt, each prescription is logged in the system, capturing patient demographics, prescriber details, medication requested, and delivery instructions.

1.21.3 For paper prescriptions, visual checks are performed to verify legibility and completeness.

1.22 *b. Verification and Validation*

1.22.1 Each prescription is checked to confirm it is valid, in-date, and issued by an authorized prescriber. Prescriptions that are incomplete, expired, or unclear are referred to the RP and may be returned to the prescriber.

1.22.2 The RP or designated team member verifies that the form of the prescription corresponds to legal requirements, including signature, date, and prescriber qualification.

1.22.3 NHS exemptions must be accurately recorded, and where not evident, patients are contacted to supply supporting evidence.

1.22.4 All paid prescriptions are cross-checked to ensure correct fee collection.

1.23 *c. Clinical Assessment*

1.23.1 The pharmacist performs a comprehensive clinical check for potential drug interactions, contraindications, and appropriateness of therapy based on age, gender, and any clinical notes available.

1.23.2 Expiration dates of all medicines must be checked to ensure adequate shelf life throughout the period of use.

1.23.3 If a prescription is unclear or raises concerns (e.g., high-dose, unlicensed indication), the pharmacist will contact the prescriber for clarification and document the intervention.

1.23.4 Any issues identified and resolved must be recorded in the patient's record and reviewed during clinical audits.

1.24 6. Communication Protocols

1.24.1 All communication must be conducted using secure, non-face-to-face methods, maintaining compliance with DSP regulations.

1.24.2 Identity verification is mandatory for all patient interactions, typically using two identifiers such as full name and date of birth.

1.24.3 Communication records should include the method used (e.g., call, text, video), time, date, staff member involved, and key discussion points.

1.24.4 No confidential or clinical information should be left in voicemail or with unauthorized individuals.

1.24.5 AccuRx is used for structured, GDPR-compliant messaging and video consultations. It supports one-way or two-way messaging and enables the sharing of documents, images, and video calls in a secure environment.

1.24.6 All correspondence with other health professionals should occur through NHSmail to ensure encryption and accountability.

1.24.7 Standard operating guidance should be followed for escalating communication to the Responsible Pharmacist when necessary.

1.24.8 Patients must be able to contact the pharmacy during working hours via published communication routes.

1.24.9 Communication must be prompt, professional, and responsive to patient queries or concerns.

1.25 7. NHS Mail and Directories

1.25.1 Maintain and access NHSmail daily.

1.25.2 Keep NHS.uk and NHS Digital Directory profiles up to date quarterly.

1.25.3 Register NHSmail with MHRA for safety alerts.

1.26 In the event of delivery failure, cold chain disruption, or courier delay, contingency protocols include alternative courier engagement and temperature verification checks. Delivery satisfaction surveys are conducted periodically to assess service quality and identify areas for improvement.

1.27 8. Delivery Procedures

1.27.1 All medicines are delivered via tracked courier or Royal Mail, and delivery status is monitored until completion.

1.27.2 Medicines requiring refrigeration (fridge items) are packaged with validated temperature-control systems to maintain cold chain conditions. Delivery must occur within timeframes supported by the cold chain packaging, and upon arrival, patients are advised to refrigerate immediately.

1.27.3 Controlled Drugs (CDs) are packaged securely and must be delivered via a tracked service requiring signature on receipt. Identity of the recipient is verified at the point of delivery, and a signature is captured to confirm safe handover.

1.27.4 A log is maintained for each CD delivery, recording dispatch time, courier details, recipient confirmation, and delivery status.

1.27.5 In the event of failed delivery attempts for fridge items or CDs, immediate follow-up is initiated, and the Responsible Pharmacist must assess whether medicines remain suitable for use or require disposal.

1.27.6 A specialist courier service will be contracted for the delivery of CDs and fridge items to ensure secure handling, temperature control, and full traceability. These couriers are vetted for compliance with MHRA and GPhC standards and must follow chain-of-custody procedures, use tamper-evident packaging, and provide real-time tracking and electronic proof of delivery.

1.27.7 All other non-CD and non-fridge items are delivered using secure, tamper-evident packaging. Patients are informed in advance of delivery, with contact information provided for queries or rescheduling.

1.27.8 Missed deliveries are logged, and efforts are made to reattempt delivery promptly or contact the patient to confirm redelivery preferences.

1.28 9. Controlled Drugs (CDs)

1.28.1 CDs are stored securely in a locked controlled drugs cabinet that meets Misuse of Drugs Regulations 2001 specifications, accessible only to authorized personnel.

1.28.2 A CD register is maintained for each schedule 2 CD, with entries recorded in ink, contemporaneously, and without alteration.

1.28.3 All CD stock is regularly reconciled against the CD register. Discrepancies must be reported immediately to the Responsible Pharmacist and Superintendent Pharmacist for investigation.

1.28.4 Deliveries of CDs require a signature from the named recipient or their authorized representative, with identity verification at the point of handover.

1.28.5 CDs that are refused or undeliverable must be returned to the pharmacy under secure conditions and logged accordingly.

1.28.6 Patient-returned CDs are recorded in a separate destruction register and destroyed in the presence of an authorized witness where required.

1.28.7 Denaturing kits must be used for CD destruction. Waste is then managed through appropriate pharmaceutical waste channels.

1.28.8 All incidents, concerns, or near-misses involving CDs are recorded, reviewed, and investigated under the pharmacy's incident reporting procedure.

1.29 All emergency supplies are documented using a standardised justification form and assessed by the RP. Where repeated emergency requests are identified, GPhC guidance is followed, and the matter is escalated appropriately.

1.30 10. Emergency and Urgent Supply

1.30.1 Emergency and urgent supplies may be provided under the legal frameworks of the Human Medicines Regulations 2012.

1.30.2 Supplies may only be made at the professional discretion of the pharmacist when it is considered clinically necessary, and the patient is unable to obtain a prescription in time.

1.30.3 A thorough consultation must be carried out remotely with the patient, or an authorized representative, to determine the necessity of the supply.

1.30.4 The pharmacist must access and check the patient's Summary Care Record (SCR) to verify medication history and appropriateness.

1.30.5 Records of the emergency supply must include patient details, date, nature of the emergency, medication details (name, strength, quantity), reason for supply, consultation notes, and pharmacist's name.

1.30.6 Supplies must be labelled with the words "Emergency Supply" and must meet all labelling and record-keeping requirements.

1.30.7 Supplies made at the request of a prescriber must still be documented and dispensed only when appropriate.

1.30.8 Controlled Drugs in Schedule 2 and 3 may not be supplied under emergency supply regulations; however, certain Schedule 4 and 5 CDs may be supplied where permitted.

1.30.9 All emergency supplies must be reviewed periodically for patterns or frequency and assessed for appropriateness during clinical audits.

1.31 11. Confidentiality and Data Protection

1.31.1 Full compliance with the UK General Data Protection Regulation (GDPR) and the Data Protection Act 2018 is mandatory across all areas of the pharmacy's operations.

1.31.2 Personal identifiable information (PII) and sensitive health data must be processed lawfully, transparently, and solely for legitimate healthcare purposes.

1.31.3 Data minimisation principles must be followed — only information necessary for the specific healthcare activity is collected and processed.

1.31.4 Secure systems must be in place for storing and transferring patient data, including encrypted software, restricted system access, password protection, and regular system audits.

1.31.5 All staff must complete mandatory data protection and confidentiality training at induction and refresher training annually.

1.31.6 Confidential waste, including printed prescriptions or patient details, must be disposed of using locked bins and a licensed data destruction service.

1.31.7 Any data breaches or near misses must be reported immediately to the Data Protection Officer (DPO) and recorded in the incident log. Significant breaches may need to be reported to the Information Commissioner's Office (ICO) within 72 hours.

1.31.8 Patients have the right to access, rectify, or request deletion of their personal data, in line with GDPR rights.

1.31.9 All data sharing agreements with external parties, such as couriers or IT providers, must include clear confidentiality clauses and adhere to data protection standards.

1.32 12. Patient Support and Adjustments

1.32.1 Offer accessible formats such as large print labels, braille options, and digital communication for those with hearing or visual impairments.

1.32.2 Provide easy-to-open packaging and reminder systems for patients with physical disabilities or cognitive impairment.

1.32.3 Make reasonable adjustments under the Equality Act 2010, including extended consultation time, translation services, and the involvement of carers or advocates when required.

1.32.4 Provide additional counselling or follow-up calls for patients starting new medications or with complex regimens.

1.32.5 Document all patient-specific adjustments and ensure continuity across all staff and communication points.

1.32.6 Multidose dispensing systems (MDS) provided when clinically appropriate, especially for patients with polypharmacy or poor adherence.

1.32.7 Ensure that support services align with patient needs, preferences, and capacity, reviewed periodically.

1.33 Monthly dashboards track key indicators including delivery times, dispensing errors, patient satisfaction, and clinical interventions. An independent external audit is conducted at least every 18 months to ensure objectivity and identify strategic improvements.

1.34 13. Audit and Quality Assurance

1.34.1 Regular internal audits cover staffing, procedures, patient feedback, and complaints.

1.34.2 SOPs are reviewed biannually or after critical incidents.

1.35 14. Handling Complaints and Incidents

1.35.1 All complaints, concerns, and incidents must be logged in the designated complaint management system.

1.35.2 Complaints should be acknowledged within 3 working days and resolved within 20 working days where possible.

1.35.3 All complaints are reviewed by the Responsible Pharmacist and escalated to the Superintendent where necessary.

1.35.4 Root cause analysis must be conducted for significant complaints or incidents.

1.35.5 Outcomes must be communicated clearly and compassionately to the complainant, and learning points implemented across the pharmacy.

1.35.6 A summary of all complaints and actions taken must be reviewed in quarterly governance meetings.

1.36 A risk scoring matrix is maintained, with responses graded (e.g., green, amber, red) to guide escalation. Cross-training ensures staff can step into key roles during absences or emergencies. Cloud-based access is routinely tested for resilience.

1.37 15. Business Continuity

1.38 A risk scoring matrix is maintained, with responses graded (e.g., green, amber, red) to guide escalation. Cross-training ensures staff can step into key roles during absences or emergencies. Cloud-based access is routinely tested for resilience.

1.38.1 A documented Business Continuity Plan (BCP) must be maintained and reviewed annually.

1.38.2 Scenarios covered include IT failures, staffing shortages, courier disruptions, and natural disasters.

1.38.3 Key services must be prioritised in emergencies, including prescription dispensing and urgent patient communication.

1.38.4 Cloud-based and remote-access systems must be tested quarterly to ensure operational resilience.

1.38.5 Staff must be trained on BCP procedures and their specific roles in the event of activation.

1.38.6 Emergency contact details and escalation pathways must be readily accessible.

1.39 All pharmacy professionals must submit an annual CPD portfolio summary. Safeguarding training includes pharmacy-specific case studies and scenarios to reinforce application in DSP settings.

1.40 16. Training and Competency

1.40.1 All staff undergo structured induction training, including health and safety, confidentiality, pharmacy operations, and safeguarding.

1.40.2 Role-specific SOPs must be read and signed off before undertaking duties independently.

1.40.3 Ongoing training is provided through e-learning, in-house sessions, and external CPD.

1.40.4 Staff are assessed for competency regularly through observed practice, quizzes, and one-to-one reviews.

1.40.5 Training records are maintained and audited quarterly.

1.40.6 Underperformance or skills gaps are addressed with personalised development plans.

1.41 17. Review and Amendment of SOPs

1.41.1 SOPs are revised as legislation or practices evolve.

1.41.2 Temporary deviations must be recorded and approved by the Superintendent.

1.42 *This document is intended for internal use to maintain high-quality, compliant operations in a Distance Selling Pharmacy.*

1.43 18. Patient Safety and Clinical Governance

1.44 A proactive patient safety culture is central to the delivery of high-quality services in the Distance Selling Pharmacy.

1.44.1 A designated Patient Safety Officer (PSO) will be appointed to oversee safety reporting, analysis, and learning.

1.44.2 Monthly safety huddles will be conducted where near-misses, adverse events, alerts, and risk trends are reviewed collaboratively by the pharmacy team.

1.44.3 Annual audits will be conducted for clinical areas such as high-risk medications, Controlled Drug reconciliation, and antimicrobial stewardship.

1.44.4 Staff will be encouraged to report concerns via an anonymous whistleblowing system, in line with NHS Freedom to Speak Up guidance.

1.44.5 Lessons learned from safety incidents will be shared internally via newsletters, team meetings, and policy updates.

1.44.6 Implementation of patient safety alerts and MHRA notifications will be tracked for completion and timeliness.

1.45 19. Delivery of Essential Pharmacy Services

1.46 As a Distance Selling Pharmacy (DSP), all essential services must be provided without face-to-face interaction, while ensuring accessibility, safety, and regulatory compliance. Below is a detailed description of how each essential NHS pharmacy service will be delivered:

1.46.1 1. Dispensing of Prescriptions:

1.46.1.1 Prescriptions are received electronically via EPS or by secure post.

1.46.1.2 Clinical checks and accuracy checks are conducted by pharmacists and ACTs.

1.46.1.3 Medicines are dispensed, labelled, and packed with clear usage instructions and delivered using secure, tracked services.

1.46.1.4 Cold chain and CD items are handled as per designated protocols.

1.46.2 2. Repeat Dispensing:

1.46.2.1 Patients or their representatives are enrolled in repeat dispensing through the online portal.

1.46.2.2 Repeatable prescriptions are managed through EPS, and patients are contacted before each issue to confirm ongoing need.

1.46.2.3 Dispensing and delivery follow the standard safe supply procedure.

1.46.3 3. Disposal of Unwanted Medicines:

1.46.3.1 Patients may return unwanted medicines using a prepaid, tracked postal return service arranged through the pharmacy.

1.46.3.2 On receipt, waste is segregated and processed according to pharmaceutical waste regulations.

1.46.3.3 CDs returned are recorded and destroyed using denaturing kits in the presence of an authorized witness.

1.46.4 4. Public Health (Promotion of Healthy Lifestyles):

1.46.4.1 Health promotion campaigns are delivered digitally via email, SMS, and website notifications, aligned with NHS seasonal topics.

1.46.4.2 Posters and digital brochures are included in delivery parcels periodically.

1.46.4.3 Patients may access virtual consultations for lifestyle advice (e.g., smoking cessation, weight loss).

1.46.5 5. Signposting:

1.46.5.1 Pharmacists provide digital signposting via email, SMS, or phone to local NHS services (e.g., GPs, urgent care, community support) based on patient needs.

1.46.5.2 NHS.uk and local service directories are used to ensure accurate referrals.

1.46.5.3 All referrals are recorded in the patient's notes.

1.46.6 6. Support for Self-Care:

1.46.6.1 Pharmacists provide tailored advice on OTC treatments via video consultations or structured messaging.

1.46.6.2 Standardised advice sheets and product leaflets are included with deliveries for minor ailments.

1.46.6.3 Where necessary, the pharmacist advises patients to consult their GP or other appropriate service.

1.46.7 All services are delivered in accordance with the GPhC's Standards for Registered Pharmacies and meet NHS Terms of Service for DSPs. Service performance is monitored monthly and reviewed at quarterly governance meetings to ensure continual improvement.

1.46.8 20. Remote Delivery of Pharmacy First and New Medicine Service (NMS)

1.46.9 As a Distance Selling Pharmacy, we are committed to delivering advanced services such as Pharmacy First and the New Medicine Service (NMS) through secure, remote methods that comply with NHS contractual frameworks and GPhC standards.

1.46.10 Pharmacy First Service:

1.46.10.1 Patients self-refer or are referred by NHS 111, GPs, or other providers via NHS pathways or directly through our online platform.

1.46.10.2 An initial triage is conducted using an online form or structured phone call to confirm service eligibility.

1.46.10.3 A qualified pharmacist conducts the consultation via secure video link (e.g., AccuRx), covering symptoms, history, red flags, and clinical decision-making.

1.46.10.4 Where treatment is appropriate, medication is supplied via tracked courier following the standard dispensing and delivery process.

1.46.10.5 A record of the consultation, clinical notes, and supply details is documented and shared with the patient's GP where applicable.

1.46.10.6 Patients are informed about red flag symptoms and advised to seek further care if symptoms persist or worsen.

1.46.11 New Medicine Service (NMS):

1.46.11.1 Eligible patients are identified during the dispensing of newly prescribed medicines for long-term conditions (e.g., asthma, hypertension, diabetes).

1.46.11.2 The initial NMS invitation is sent via secure SMS or phone call, offering to schedule the first consultation.

1.46.11.3 Stage 1 (Initial Consultation), Stage 2 (Follow-up), and Stage 3 (Final Consultation) are all carried out via video or phone.

1.46.11.4 Pharmacists assess adherence, side effects, and understanding of the new medication, providing tailored advice and reassurance.

1.46.11.5 Summary notes of each stage are recorded and shared with the patient's GP if needed, with consent.

1.46.11.6 The effectiveness of NMS delivery is reviewed quarterly, and patient feedback is used to improve the remote service model.

1.46.12 All interactions are conducted in accordance with clinical governance policies and recorded in the patient medication record (PMR). Our remote model ensures that these services remain accessible, responsive, and of high clinical quality, despite the absence of physical contact.

1.46.1321. Remote Delivery of Other Current and Future Commissioned Pharmacy Services

1.46.14 As part of the evolving role of community pharmacy within the NHS Long Term Plan, the Distance Selling Pharmacy (DSP) model must be capable of delivering both currently commissioned and future advanced services through remote, non-face-to-face methods. This ensures that all patients, regardless of location or mobility, have equitable access to essential and enhanced pharmacy-led care. Services are delivered using secure platforms and in alignment with NHS contractual frameworks, maintaining clinical safety, patient confidentiality, and professional standards."

1.47 [Floor plan provided].

2 Comments to the Commissioner

On reviewing the paperwork provided by PCSE, it was noted that the comments made by the Applicant to the representations on the application, had not been circulated or seen by parties.

In the interests of transparency and fairness, NHS Resolution sought to rely on the discretion afforded in paragraph 7 of Schedule 3 of the Regulations to vary the normal procedures and circulate these comments to parties for them to make observations on them if they so wished.

2.1 The Applicant

2.1.1 “Thank you for the opportunity to respond to the comments received against my above application.

2.1.2 This application is for a Distance Selling Pharmacy (DSP). All NHS services will be provided exclusively by remote means (telephone, email, video, courier). Patients will not attend the premises. This submission responds to each representation in line with Regulations 25 and 64, which govern Distance Selling Pharmacies. Not only have we directly addressed the objections raised by Proheal Pharma and Vitastock, but where necessary, we have clarified our operating model and compliance measures to ensure absolute alignment with Regulations 25 and 64.

2.1.3 Response to Proheal Pharma Objection

2.1.4 We acknowledge the objection submitted by Proheal Pharma regarding our Distance Selling Pharmacy (DSP) application. While we respect their position as a local contractor, the points raised do not identify any regulatory failing under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. We respond to each issue below.

2.1.5 1. Regulation 25 – Scope of Application

2.1.6 The Committee’s test under Regulation 25(2)(b) is whether our procedures are likely to secure safe, uninterrupted, non-face-to-face essential services for all patients in England.

2.1.7 Regulation 25(2)(b) requires NHS England to be satisfied that DSP applicants have procedures in place to secure:

2.1.8 (i) uninterrupted essential services nationwide during opening hours, and

2.1.9 (ii) safe and effective provision of essential services without face-to-face contact.

2.1.10 There is no requirement under the Regulations for a DSP to be a set distance from existing contractors, nor is there a “market need” test for DSPs.

2.1.11 Our premises are not on the same site or adjacent to another pharmacy; therefore, Regulation 31 is not engaged.

2.1.12 Conclusion: Proximity to Proheal Pharma's DSP is not a statutory ground for refusal.

2.1.13 2. Duplication of Services / Market Impact

2.1.14 Proheal Pharma suggests duplication and oversupply. However, DSPs are national contracts, not local ones. Patients across England can choose any DSP.

2.1.15 Unlike Regulation 18 (necessary or unforeseen benefits test), DSP applications are not judged on market need.

2.1.16 Commercial competition is not a ground for refusal under Regulation 25.

2.1.17 Conclusion: Concerns about duplication or business impact are irrelevant to the statutory test.

2.1.18 3. Patient Safety and Operational Risks

2.1.19 The objection raises concerns about prescription confusion, EPS routing errors, and supplier misdeliveries.

2.1.20 EPS Nominations: The EPS system allocates prescriptions using unique pharmacy codes, eliminating "accidental" prescription transfers between DSPs. Patients must expressly nominate a pharmacy.

2.1.21 Supplier Deliveries: Wholesalers and couriers already deliver safely to multiple pharmacies within the same business parks and streets. Our SOPs include reconciliation logs, controlled receipt of medicines, and double-checks to prevent misdeliveries.

2.1.22 Chain-of-Custody: All Controlled Drugs (CDs) and fridge items are handled under documented chain-of-custody procedures, using tamper-proof packaging, ID verification, and courier tracking.

2.1.23 Conclusion: These risks are speculative. Our SOPs contain robust mitigations to ensure patient safety and supply chain integrity.

2.1.24 4. Continuity of Care

2.1.25 Proheal argues that patients may be confused or lose continuity.

2.1.26 Our procedures provide clear communication at the point of nomination, written confirmation of EPS setup, and direct patient contact via phone/email.

2.1.27 Repeat dispensing, medicines reconciliation, and safeguarding processes ensure continuity.

2.1.28 Conclusion: Patient care will not be disrupted. On the contrary, we will provide a transparent, patient-centred approach.

2.1.29 5. Responsible Pharmacist (RP) Cover

2.1.30 The objection questions how uninterrupted services will be maintained.

2.1.31 Our SOP overview confirms:

2.1.31.1 A Responsible Pharmacist (RP) will always be present during published opening hours.

2.1.31.2 To avoid disruption during statutory breaks, the pharmacy will close at lunch hours.

2.1.31.3 Business continuity arrangements are in place for unexpected absences, including a second pharmacist where required. In case of unplanned IT or courier disruption, our business continuity plan activates secondary systems and alternative couriers to ensure uninterrupted supply.

2.1.32 Conclusion: Our arrangements secure uninterrupted provision of essential services.

2.1.33 6.Commercial Impact and Stress on Competitors

2.1.34 Proheal raises concerns about business viability and staff anxiety. While we acknowledge their position, NHS England's statutory duty is not to protect competitors from lawful market entry.

2.1.35 The Regulations provide no grounds to refuse an application based on commercial disadvantage to existing contractors.

2.1.36 7.Objector's Localised Approach

2.1.37 Proheal's objection focuses on local confusion and loss of local business. DSPs must serve patients nationally, not act as local competitors. This emphasis demonstrates commercial motives, not regulatory concerns. DSPs are expressly designed to operate nationally under Regulation 64; local market dynamics are therefore outside the statutory test.

2.1.38 The objection raised by Proheal is based on proximity, duplication, and speculative operational risks, none of which fall within Regulation 25 or 64. Our application ensures uninterrupted, safe, effective, and nationwide provision of essential services without face-to-face contact. Our SOP overview and our submissions fully documents RP cover, delivery integrity, safeguarding, and business continuity plan.

2.1.39 Accordingly, we respectfully submit that the objection from Proheal Pharma should be dismissed.

2.1.40 Response to Vitastock / Healthcare Plus Consulting Objection

2.1.41 We acknowledge the representations submitted on behalf of Vitastock Ltd. While carefully drafted, the objection is based on incorrect assumptions about both the scope of our application and the evidence required under the regulations. We address each point below in detail.

2.1.42 1. Standard Operating Procedures (SOPs)

2.1.43 The objector claims that no SOPs have been provided and that what was submitted is “generic” or “purchased.” The overview submitted was intended to demonstrate procedural compliance, consistent with NHS England’s practice where full internal SOPs remain confidential but available for inspection.

2.1.44 The document filed with the application was a supporting SOP overview, not the full internal SOP pack. This is standard practice.

2.1.45 Regulation 25 does not require applicants to publish or circulate their entire SOP suite to competitors. The legal test is whether NHS England is satisfied that the applicant’s procedures are likely to secure compliance.

2.1.46 Our internal SOPs are complete, operational, and site-specific. They cover the Coopers Mill premises, our governance structure, courier arrangements, cold-chain integrity, safeguarding, and equality adjustments.

2.1.47 2. Uninterrupted Services

2.1.48 The objection suggests we cannot guarantee uninterrupted service.

2.1.49 Our procedures guarantee continuity of service during all published opening hours.

2.1.50 We have opted to close during lunch hours to remove any risk of patients being misled about pharmacist availability during statutory breaks. During all open hours, a Responsible Pharmacist (RP) will be present and accountable.

2.1.51 Our Business Continuity Plan provides resilience for courier disruption, IT downtime, and staff absence.

2.1.52 3. Service delivery

2.1.53 The objection claims certain essential services are not described. This is incorrect.

2.1.54 Our procedures cover all six essential services as required by Schedule 4 of the Regulations:

2.1.54.1 Dispensing & Repeat Dispensing – EPS-enabled dispensing with tracked delivery nationwide.

2.1.54.2 Disposal of Medicines – Prepaid, tracked postal returns, with segregation and lawful disposal (including CDs under denaturing with authorised witness).

2.1.54.3 Healthy Living Pharmacy: Promotion of Healthy Lifestyles & Public Health Campaigns – Remote delivery of campaigns via:

2.1.54.4 leaflets included with prescriptions,

2.1.54.5 SMS/email campaigns, and

2.1.54.6 a Health Promotion Zone on our website updated monthly. Campaign materials are updated monthly and archived for 12 months to evidence compliance.

2.1.54.7 Support for Self-Care – Remote consultations, advice sheets, and safeguarding escalation where needed. SOPs set out referral processes to GPs, NHS 111, and other NHS providers, with records kept in the PMR.

2.1.54.8 Discharge Medicines Service (DMS) – NHSmail/ PharmOutcomes referrals are received, reconciled against the patient record, and followed up by phone or video consultation.

2.1.55 Urgent Supply Service

2.1.56 In line with the NHS England Urgent Medicines Supply Directions, the pharmacy has a protocol for handling urgent requests. Patients may contact us remotely via telephone, email, or website form. The pharmacist will assess the urgency and legal eligibility for supply. Where clinically appropriate and lawful, an emergency supply will be made and dispatched same day by tracked courier. Where supply is not possible, the patient will be immediately signposted to NHS 111, an out-of-hours service, or a suitable community pharmacy. All interventions are recorded in the PMR for audit and safety monitoring.

2.1.57 Service Delivery Model (Patient Journey)

2.1.58 All services are delivered remotely in a fully integrated workflow. Patients contact the pharmacy by phone, email, or secure website form. Prescriptions are received via EPS, clinically checked by the pharmacist, and dispensed in our Coopers Mill premises. Medicines are packaged securely and dispatched by tracked courier with electronic proof of delivery. Patients receive counselling and follow-up advice by telephone or video consultation, and any required documentation is recorded in the PMR. This process applies equally to all essential and advanced services delivered under this contract.

2.1.59 Advanced Services – Remote Provision

2.1.60 Only advanced services capable of remote delivery will be undertaken, including the New Medicine Service (NMS), Discharge Medicines Service (DMS), and permitted remote elements of Pharmacy First

(triage, advice, referral). Services requiring physical examination or measurement (e.g. ear infection, BP checks) will be signposted to appropriate NHS providers. No advanced or enhanced services will be delivered face-to-face at or near the DSP premises.

2.1.61 For completeness, we confirm that our application does not undertake the supply of appliances requiring fitting or measurement, in line with Regulation 25. Any such prescriptions will be referred appropriately with patient consent.

2.1.62 4. Delivery Integrity & Security

2.1.63 The objection suggests delivery procedures lack detail.

2.1.64 Controlled Drugs (CDs) – Supplied using tamper-evident packaging, tracked couriers, electronic proof of delivery, and ID verification. Chain of custody is logged at each handover.

2.1.65 Fridge Lines – Delivered via MHRA-compliant couriers with validated packaging and temperature monitoring. Logs are retained for audit.

2.1.66 National Scope – These safeguards apply equally to all patients across England; there is no limitation by geography.

2.1.67 5. Business Continuity & Safety

2.1.68 RP cover: Continuous during all published hours, supported by lunch closure to prevent statutory break gaps.

2.1.69 Courier resilience: Back-up couriers in case of failure with the preferred contractor.

2.1.70 IT resilience: NHS approved provider will be used as the main dispensing software provider. Pharmacy website will meet the NHS Digital and GPhC website standards, including secure ordering, accessibility and privacy compliance.

2.1.71 Equality & Safeguarding: SOPs include provisions for accessible formats (braille, large print), translation, and use of carers/advocates for patients with barriers. We will make reasonable adjustments under the Equality Act 2010, including large print, braille, translations, and carer/advocate support.

2.1.72 6. On “Generic Documentation”

2.1.73 While the structure of our SOPs reflects industry-standard formats (as is the case across the sector), the substance is tailored to our site and operating model. For example:

2.1.73.1 Cold chain procedures reference specific courier validation requirements,

2.1.73.2 RP cover procedures reflect our decision to close at lunch hours,

2.1.73.3 Equality protocols specify use of multi-format communication and carers/advocates.

2.1.74 These are not generic statements but site-specific operational protocols.

2.1.75 7. Conclusion

2.1.76 The objection misrepresents the nature of the supporting document provided with our application.

2.1.77 Our full SOPs are comprehensive, site-specific, and fully compliant with Regulations 25 and 64.

2.1.78 Essential services, delivery integrity, RP continuity, and equality safeguards are all addressed.

2.1.79 Our procedures guarantee uninterrupted, safe, and effective provision of pharmaceutical services to patients anywhere in England, exclusively by non-face-to-face means.

2.1.80 We respectfully submit that the objection from Vitastock Ltd is unfounded and should be dismissed.

2.1.81 Accordingly, we are confident this application satisfies Regulations 25(2)(b) and 64, and we respectfully request that the application be approved. We look forward to your response."

3 The Decision

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

3.1 "Somerset 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.

3.2 You have a right of appeal to the Secretary of State against Somerset

3.3 ICB's decision. Should you choose to appeal then you should either complete the online form available on the NHS Resolution website or send a concise and reasoned statement of the grounds for your appeal within 30 days of the date of this letter to nhsr.appeals@nhs.net or:

3.4 Primary Care Appeals
NHS Resolution
8th Floor
10 South Colonnade
Canary Wharf
London

E14 4PU".

PSRC Report

3.5 "Case reference - CAS-370504-P2W7Y5

3.6 Name of applicant - Keynsham Healthcare Ltd

3.7 Application type - Application for inclusion in a pharmaceutical list: distance selling premises excepted application

3.8 Address of proposed premises - 1, COOPERS MILL, TAUNTON, TA2 6NX

3.9 **The SW Committee noted:**

3.10 The applicant proposes opening a distance selling pharmacy in premises at 1 Coopers Mill, Taunton.

3.11 There was a Boots Pharmacy operating from the proposed premises. The pharmacy closed in February 2024 under the Market Exit process.

3.12 PRELIMINARY ISSUES

3.13 Nature of the application

3.14 This is application for a 'distance selling pharmacy' and is an excepted application and considered under regulation 25.

3.15 Regulation 31 (same or adjacent premises) [quoted in full]

3.16 There are no other pharmacies at the proposed premises, or adjacent (for either address). The nearest pharmacy is 0.1 miles (Norton Fitzwarren Pharmacy). ***The SW Committee was satisfied it is not required to refuse the application by virtue of Regulation 31.***

3.17 Representations received

3.18 Representation was received from:

3.18.1 Proheal Pharma objects to the application and comment on the physical proximity of premises, existing provision of services, regulatory grounds, duplication and fragmentation risk, no demonstrable need or public benefit, impact on quality and continuity of patient care, confusion among GP's and NHS systems, operational risk and supplier confusion, business harm and commercial threat, impact on staff and management and regulatory exploitation. They ask the ICB to reject the application on grounds of conflict, confusion, operational risk and patient safety and to recognise the regulatory intent of Reg 25 is being comprised and prevent a situation that will cause long term logistical disruption and distress to an existing provider, concluding:

3.18.2 Conclusion

Approving this application would:

Create delivery chaos, customer confusion, and long-term rivalry.

Risk misdelivered medications and associated clinical and reputational harm.

Completely undermine the sustainability of a newly launched NHS service provider (Proheal Pharma).

This is a critical moment to uphold fairness, integrity, and patient safety.

We respectfully request that NHS England reject this application immediately in order to protect the existing distance selling pharmacy located adjacent to the proposed premises. Approving this application would not lead to improved outcomes for the public and would undermine both existing NHS investment and our own investment in pharmaceutical services in the area.

We kindly urge you to protect the trust placed in the NHS and reject this application.

3.19 Community Pharmacy Somerset acknowledges the application but neither supports nor opposes it.

3.20 Healthcare Plus Consulting Ltd, on behalf of Vitastock Ltd, object to the application noting the application must be refused under certain circumstances and submit the application fails to comply with the regulations stating:

3.20.1 Issues with the present application

We note the following issues with the application:

We have not been provided with any Standard Operating Procedures or any way to guarantee that there is any relationship between the information we have been provided and the information that will be provided to the staff. At present we know nothing about the documents which will actually govern the operation of the DSP

We also note that there is no site-specific information, and rather the information provided appears to be a generic statement with no real connection to the present application except that it has been purchased by the applicant.

Even in the heavily summarised information we have been provided we believe that a number of essential services are not even mentioned.

Those essential services which are mentioned lack detail on how they will be delivered and in some cases what the applicant believes the service to be.

In particular, we note that the key section on delivery lacks any details on how integrity and security of items will be preserved.

We are unable to confirm that services will be provide uninterrupted during opening hours while complying with relevant legislation and regulations.

For these reasons we submit that the present application must be refused.

3.20.2 The applicant responded and addressed matters raised by each of the interested party responses, offering explanation on each point raised, submitting the objections should be dismissed. They state they are confident the application satisfies Regulations 25(2)(b) and 64 and respectfully request the application be approved.

3.21 When comments are circulated to the applicant and interest parties the covering letter states:

3.21.1 *Please note that any new information that you submit at this stage will have little or no weight placed upon it unless it can be demonstrated that you are presenting it in response to representations submitted by another party that you believe are not true or are incorrect.*

3.22 REGULATION 25(2) – requirements for distance selling pharmacies

3.23 An application for distance selling premises is, by virtue of regulation 25(1), not subject to the market entry test.

3.24 Regulation 25(2) states: [quoted in full]

3.25 Reg 25(2)(a) – same site as a provider of primary medical services

3.26 There is no provider of primary medical services at the proposed address(es), **so the application does not have to be refused by virtue of Regulation 25(2)(a).**

3.27 Reg 25(2)(b) – the pharmacy procedures

3.28 Information about how the applicant would operate the proposed pharmacy is provided within the supporting information attached to the application.

3.29 The SW Committee must be sure it has sufficient information to determine if it is satisfied that the procedures will secure uninterrupted provision of essential services during opening hours to persons anywhere in England, safely and effectively without face-to-face contact. If not, it must refuse the application.

3.30 *Services available without interruption*

3.31 The applicant has proposed core hours of 9am – 1pm and 2pm – 6pm Monday to Friday. Closed Saturdays and Sundays. No additional supplementary hours are proposed. In response to the interested party response the applicant describes how uninterrupted services will be maintained and notes their SOP overview confirms:

3.31.1 *A Responsible Pharmacist (RP) will always be present during published opening hours. To avoid disruption during statutory breaks, the pharmacy will close at lunch hours. Business continuity arrangements are in place for unexpected absences, including a second pharmacist where required. In case of unplanned IT or courier disruption, our business continuity plan activates secondary systems and alternative couriers to ensure uninterrupted supply.*

3.32 On the basis of the information provided, the SW Committee was satisfied that services will be provided without interruption.

3.33 *Essential services will be provided without face-to-face contact.*

3.34 In the supporting information under Service Provision Scope' the applicant states:

3.34.1 *Services are provided exclusively through non-face-to-face methods (e.g., phone, email, online portal, video call). At no point should a patient or their representative be physically present at or near the premises for any NHS service.*

3.34.2 *This strict separation ensures compliance with the requirements for DSPs, as no in-person interaction is permitted under this model.*

3.34.3 *Despite the lack of in-person contact, the pharmacy must remain highly accessible and responsive to patient needs. Multiple communication channels (telephone, secure email, live chat, video consultation) are provided to support comprehensive service delivery.*

3.34.4 *The pharmacy will use platforms like AccuRx to facilitate secure video consultations and text messaging with patients. This platform ensures timely, confidential communication and is integral to maintaining high levels of accessibility and patient engagement.*

3.34.5 *The pharmacy serves all patients within England.*

3.34.6 *Essential NHS services must be uninterrupted and available during operational hours.*

3.35 Paragraph 5(2) & (3) – how will patients present prescriptions

3.36 In the supporting information under 'Prescription Handling'' the applicant states:

3.36.1 *Order Receipt*

3.36.2 *Prescriptions may be received via multiple secure channels: electronically through the Electronic Prescription Service (EPS), posted paper prescriptions, or scanned copies sent from verified NHS sources.*

3.37 The SW Committee was satisfied the pharmacy will receive prescriptions without face-to-face contact.

3.38 To establish if services will be provided without face-to-face contact it is useful to examine the Terms of Service (Schedule 4 Part 2 essential services) where compliance would ordinarily require face to face contact and assess if the applicant has explained how they will achieve it. The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (legislation.gov.uk)

3.39 Paragraph 6 – Urgent supply without a prescription

3.40 In the supporting information under 'Emergency and Urgent Supply; the applicant states:

3.40.1 *Emergency and urgent supplies may be provided under the legal frameworks of the Human Medicines Regulations 2012.*

3.40.2 *Supplies may only be made at the professional discretion of the pharmacist when it is considered clinically necessary, and the patient is unable to obtain a prescription in time. A thorough consultation must be carried out remotely with the patient, or an authorized representative, to determine the necessity of the supply.*

3.40.3 *The pharmacist must access and check the patient's Summary Care Record (SCR) to verify medication history and appropriateness.*

3.40.4 *Records of the emergency supply must include patient details, date, nature of the emergency, medication details (name, strength, quantity), reason for supply, consultation notes, and pharmacist's name.*

3.40.5 *Supplies must be labelled with the words "Emergency Supply" and must meet all labelling and record-keeping requirements.*

3.40.6 *Supplies made at the request of a prescriber must still be documented and dispensed only when appropriate.*

3.40.7 *Controlled Drugs in Schedule 2 and 3 may not be supplied under emergency supply regulations; however, certain Schedule 4 and 5 CDs may be supplied where permitted. All emergency supplies must be reviewed periodically for patterns or frequency and assessed for appropriateness during clinical audits.*

3.41 The SW Committee noted the applicant refers to the legal position for carrying this out and noted the requirements must be met but does not confirm the procedures to ensure it can be achieved. There was no detail about how urgent requests would be delivered and prioritised.

3.42 The SW Committee was not satisfied the pharmacy has suitable arrangements in place for dealing with urgent requests without a prescription.

3.43 Paragraph 7 – Exemption Checking and payment

3.44 In the supporting information under 'Verification and Validation' the applicant states:

3.44.1 *NHS exemptions must be accurately recorded, and where not evident, patients are contacted to supply supporting evidence.*

3.44.2 *The SW Committee noted the applicant refers to the legal position for carrying this out and noted the requirements must be met but does not confirm the procedures to ensure it can be achieved without face to face contact for patients anywhere in England.*

3.45 The SW Committee was not satisfied the pharmacy has suitable arrangements in place for checking exemptions and collecting payments without face to face contact.

3.46 Paragraph 8 providing ordered drugs or appliances

3.47 In the supporting information under 'Delivery Procedures' the applicant states:

3.47.1 *All medicines are delivered via tracked courier or Royal Mail, and delivery status is monitored until completion.*

3.47.2 *Medicines requiring refrigeration (fridge items) are packaged with validated temperature control systems to maintain cold chain conditions. Delivery must occur within timeframes supported by the cold chain packaging, and upon arrival, patients are advised to refrigerate immediately.*

3.47.3 *Controlled Drugs (CDs) are packaged securely and must be delivered via a tracked service requiring signature on receipt. Identity of the recipient is verified at the point of delivery, and a signature is captured to confirm safe handover.*

3.47.4 *A log is maintained for each CD delivery, recording dispatch time, courier details, recipient confirmation, and delivery status.*

3.47.5 *In the event of failed delivery attempts for fridge items or CDs, immediate follow-up is initiated, and the Responsible Pharmacist must assess whether medicines remain suitable for use or require disposal.*

3.47.6 *A specialist courier service will be contracted for the delivery of CDs and fridge items to ensure secure handling, temperature control, and full traceability. These couriers are vetted for compliance with MHRA and GPhC standards and must follow chain-of-custody procedures, use tamper-evident packaging and provide real-time tracking and electronic proof of delivery.*

3.47.7 *All other non-CD and non-fridge items are delivered using secure, tamper-evident packaging.*

3.47.8 *Patients are informed in advance of delivery, with contact information provided for queries or rescheduling.*

3.47.9 *Missed deliveries are logged, and efforts are made to reattempt delivery promptly or contact the patient to confirm redelivery preferences.*

3.48 The SW Committee was not satisfied that suitable arrangements are in place for the delivery of items including temperature controlled items and CDs. Whilst there is some information regarding temperature controlled items and CDs, there is little about how the integrity of these, and other non-CD or temperature controlled items would be protected to ensure they arrived with the patient in good condition.

3.49 Paragraph 8(4) – Measuring and Fitting - Appliances

3.50 Part 4 of the application form is blank and there is no mention of this in the supporting information.

3.51 As the application was not clear what, if any, appliances would be provided the SW Committee was not satisfied r [sic] suitable arrangements for measuring and fitting will be in place.

3.52 Paragraph 10(1)(c,d) – Repeat Dispensing

3.53 In the supporting information under 'Delivery of Essential Pharmacy Services' the applicant states:

3.53.1 *Repeat Dispensing:*

3.53.2 *Patients or their representatives are enrolled in repeat dispensing through the online portal. Repeatable prescriptions are managed through EPS, and patients are contacted before each issue to confirm ongoing need.*

3.53.3 *Dispensing and delivery follow the standard safe supply procedure.*

3.54 The SW Committee was not satisfied that arrangements are in place for Repeat Dispensing including reminding patients of the importance of only requesting items they need, confirming the medication is being used appropriately, checking for side effects and the patient has not had any changes in health as it is not clear that there is a procedure to ensure all of the relevant checks are caried out

3.55 Paragraph 10(1) - Further activities to be carried out in connection with the provision of dispensing services

3.56 In the supporting information under 'Delivery of Essential Pharmacy Services' the applicant states:

3.56.1 *As a Distance Selling Pharmacy (DSP), all essential services must be provided without face-to-face interaction, while ensuring accessibility, safety, and regulatory compliance.*

3.56.2 *Dispensing of Prescriptions:*

3.56.3 *Prescriptions are received electronically via EPS or by secure post.*

3.56.4 *Clinical checks and accuracy checks are conducted by pharmacists and ACTs. Medicines are dispensed, labelled, and packed with clear usage instructions and delivered using secure, tracked services.*

3.56.5 *Cold chain and CD items are handled as per designated protocols.*

3.57 Also, under Communication protocols it states that all communication must be conducted using secure no-face-to-face methods.

3.58 While the SW Committee noted the information about the use of remote means of communication there was no detail about the provision of appropriate advice or prescription linked interventions (paragraph 17, schedule 4). The SW Committee was NOT satisfied on this point.

3.59 Paragraph 10(1)(da) – benefits of repeat dispensing

3.60 There does not appear to be any information regarding the requirement to promote the benefits of repeat dispensing to suitable patients.

3.61 The SW Committee was not satisfied that suitable arrangements are in place to advise suitable patients of the benefits of repeat dispensing without face to face contact.

3.62 Paragraph 13 – Disposal service in respect of unwanted drugs

3.63 In the supporting information, under 'Delivery of Essential Pharmacy Services' the applicant states:

3.63.1 *Disposal of Unwanted Medicines:*

3.63.2 *Patients may return unwanted medicines using a prepaid, tracked postal return service arranged through the pharmacy.*

3.63.3 *On receipt, waste is segregated and processed according to pharmaceutical waste regulations.*

3.63.4 *CDs returned are recorded and destroyed using denaturing kits in the presence of an authorized witness.*

3.64 The SW Committee was satisfied that suitable arrangements are in place for the disposal of unwanted medicines without face to face contact.

3.65 Paragraph 17 – prescription linked interventions

3.66 There appears to be no mention of this in the application form.

3.67 The SW Committee was not satisfied that suitable arrangements are in place to provide prescription linked interventions and healthy lifestyle advice without face to face contact.

3.68 Paragraph 18 - Public health campaigns

3.69 In the supporting information, under 'Delivery of Essential Pharmacy Services' the applicant states:

3.69.1 *Public Health (Promotion of Healthy Lifestyles):*

3.69.2 *Health promotion campaigns are delivered digitally via email, SMS, and website notifications, aligned with NHS seasonal topics.*

3.69.3 *Posters and digital brochures are included in delivery parcels periodically.*

3.69.4 *Patients may access virtual consultations for lifestyle advice (e.g., smoking cessation, weight loss).*

3.70 The SW Committee was satisfied that suitable arrangements are in place to provide public health campaigns without face to face contact.

3.71 Paragraph 19 and 20 – Signposting

3.72 In the supporting information, under 'Delivery of Essential Pharmacy Services' the applicant states:

3.72.1 *Signposting:*

3.72.2 *Pharmacists provide digital signposting via email, SMS, or phone to local NHS services (e.g., GPs, urgent care, community support) based on patient needs. NHS.uk and local service directories are used to ensure accurate referrals.*

3.72.3 *All referrals are recorded in the patients notes.*

3.73 The SW Committee was satisfied that suitable arrangements are in place to provide signposting services without face to face contact?

3.74 Paragraph 21 and 22 (self-care)

3.75 In the supporting information, under 'Delivery of Essential Pharmacy Services' the applicant states:

3.75.1 *Support for Self-Care:*

3.75.2 *Pharmacists provide tailored advice on OTC treatments via video consultations or structured messaging.*

3.75.3 *Standardised advice sheets and product leaflets are included with deliveries for minor ailments.*

3.75.4 *Where necessary, the pharmacist advises patients to consult their GP or other appropriate service.*

3.76 The SW Committee satisfied that suitable arrangements are in place to provide self-care services without face to face contact? [sic]

3.77 Paragraph 28C requirements in respect of websites and health promotion zones

3.78 There appears to be no mention of this in the application form but in the applicant's response to the IP responses the following is stated:

3.78.1 *a Health Promotion Zone on our website updated monthly. Campaign materials are updated monthly and archived for 12 months to evidence compliance.*

3.79 And

3.79.1 *NHS approved provider will be used as the main dispensing software provider. Pharmacy website will meet the NHS Digital and GPhC website standards, including secure ordering, accessibility and privacy compliance.*

3.80 The SW Committee noted the additional information that mentions a health promotion zone on the website. However, the SW Committee was not clear how the health promotion zone would be promoted to users of the website and so was not satisfied that the applicant has explained how it will ensure that it has a website for use by the public for the purpose of accessing pharmaceutical services from those premises, on which there is an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues.

3.81 Other

3.82 In the supporting information under 'Remote Delivery of Pharmacy First and New Medicine Service (NMS) the applicant has confirmed:

3.82.1 *As a Distance Selling Pharmacy, we are committed to delivering advanced services such as Pharmacy First and the New Medicine Service (NMS) through secure, remote methods that comply with NHS contractual frameworks and GPhC standards.*

3.82.2 *Pharmacy First Service:*

3.82.3 *Patients self-refer or are referred by NHS 111, GPs, or other providers via NHS pathways or directly through our online platform.*

3.82.4 *An initial triage is conducted using an online form or structured phone call to confirm service eligibility.*

3.82.5 *A qualified pharmacist conducts the consultation via secure video link (e.g., AccuRx), covering symptoms, history, red flags, and clinical decision-making.*

3.82.6 *Where treatment is appropriate, medication is supplied via tracked courier following the standard dispensing and delivery process.*

3.82.7 *A record of the consultation, clinical notes, and supply details is documented and shared with the patient's GP where applicable.*

3.82.8 *Patients are informed about red flag symptoms and advised to seek further care if symptoms persist or worsen.*

3.82.9 *New Medicine Service (NMS):*

3.82.10 *Eligible patients are identified during the dispensing of newly prescribed medicines for long-term conditions (e.g., asthma, hypertension, diabetes).*

3.82.11 *The initial NMS invitation is sent via secure SMS or phone call, offering to schedule the first consultation.*

3.82.12 *Stage 1 (Initial Consultation), Stage 2 (Follow-up), and Stage 3 (Final Consultation) are all carried out via video or phone.*

3.82.13 *Pharmacists assess adherence, side effects, and understanding of the new medication, providing tailored advice and reassurance.*

3.82.14 *Summary notes of each stage are recorded and shared with the patient's GP if needed, with consent.*

3.82.15 *The effectiveness of NMS delivery is reviewed quarterly, and patient feedback is used to improve the remote service model.*

3.82.16 *All interactions are conducted in accordance with clinical governance policies and recorded in the patient medication record (PMR). Our remote model ensures that these services remain accessible, responsive, and of high clinical quality, despite the absence of physical contact.*

3.83 **Decision**

3.84 **The SW Committee determined that the application should be refused, Because:**

3.84.1 The SW Committee is satisfied that the proposed premises were not adjacent to or in close proximity to other chemist premises.

3.84.2 The SW Committee is 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.

3.84.3 The SW Committee is satisfied that all essential services were likely to be secured without interruption during the opening hours.

3.84.4 The SW Committee is not satisfied that all essential services were likely to be secured for persons anywhere in England.

3.84.5 The SW Committee is not satisfied that all essential services were likely to be secured without face to face contact

3.84.6 The SW Committee is not satisfied that all essential services were likely to be secured in a safe and effective manner because it had sufficient information to be satisfied that the procedures adopted by the applicant would be likely to secure the safe and effective provision essential services.

3.85 Appeal rights

3.86 The application is refused so the applicant will have appeal rights."

4 The Appeal

In a letter dated 26 December 2025, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

4.1 "This is an appeal against the decision of Somerset Integrated Care Board to refuse the above application for inclusion in the pharmaceutical list in respect of distance selling premises.

4.2 The Appellant respectfully submit that the refusal arises from a misapplication of Regulation 25(2)(b) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations") and a failure to lawfully assess the evidence that was before the Committee.

4.3 The Correct Statutory Test

4.4 Under Regulation 25(2)(b), the decision-maker must determine whether the pharmacy procedures are likely to secure:

4.4.1 the uninterrupted provision of essential services during opening hours to persons anywhere in England; and

4.4.2 the safe and effective provision of essential services without face-to-face contact.

4.5 This is a predictive, likelihood-based test. It is not a requirement to prove operational perfection, nor to submit full internal SOPs, nor to eliminate all theoretical risks.

4.6 Matters Correctly Determined by the Committee

4.7 The Appellant notes and relies upon the Committee's findings that are not in dispute, including that:

4.7.1 Regulation 31 was not engaged (no same or adjacent premises).

4.8 The pharmacy would provide services without interruption during opening hours.

4.9 Prescriptions would be received without face-to-face contact.

4.10 Suitable arrangements existed for:

4.10.1 disposal of unwanted medicines,

4.10.2 public health campaigns,

4.10.3 signposting, and

4.10.4 support for self-care.

4.11 These findings confirm that the Committee accepted the core distance-selling model and that the application was not fundamentally deficient.

4.12 Grounds of Appeal

4.13 Ground 1 – Misapplication of the “likely to secure” test

4.14 The refusal demonstrates that the Committee applied a higher evidential threshold than Regulation 25(2)(b) permits.

4.15 In multiple areas (urgent supply, exemption checking, repeat dispensing, prescription-linked interventions, delivery integrity), the Committee acknowledged that procedures were described, but concluded it was “not satisfied” because it considered the information insufficiently detailed.

4.16 The Regulations do not require exhaustive operational manuals or full SOP disclosure. They require a judgment as to likelihood, based on procedures described.

4.17 By requiring a level of detail more appropriate to inspection or post-listing compliance, the Committee misapplied the statutory test.

4.18 Ground 2 – Failure to properly evaluate evidence provided

4.19 The Appellant had submitted:

4.19.1 a detailed supporting document,

4.19.2 a structured SOP overview,

4.19.3 and a point-by-point response to representations.

4.20 In several instances, the decision report records the existence of this material but does not explain why the procedures described were incapable of securing safe and effective provision.

4.21 A conclusion of “not satisfied” without engagement with the substance of the procedures described amounts to a failure to properly assess relevant evidence, rather than a finding of non-compliance.

4.22 Ground 3 – Internal inconsistency in the decision

4.23 The Committee concluded that:

4.23.1 essential services would be uninterrupted,

4.23.2 several essential services were satisfactorily provided remotely,

4.23.3 yet also concluded that essential services as a whole were not likely to be secured safely and effectively.

4.24 These conclusions cannot logically coexist. If multiple essential services are accepted as compliant, the overall conclusion of failure lacks a coherent evidential basis.

4.25 Ground 4 – Procedural unfairness in expectations placed on the applicant

4.26 The refusal reflects an expectation that applicants must:

4.26.1 submit near-complete SOP content,

4.26.2 describe operational contingencies at inspection-level granularity,

4.26.3 despite Regulation 25 expressly allowing procedural descriptions rather than full SOP disclosure.

4.27 This places DSP applicants at an unfair disadvantage and goes beyond what the Regulations require at application stage.

4.28 The Appellant respectfully requests that the Secretary of State:

4.29 Allows the appeal, and directs that the application be granted; or

4.30 Remits the application for reconsideration, with directions to apply Regulation 25(2)(b) lawfully and on the evidence already provided.

4.31 The application describes a lawful, established distance-selling pharmacy model that the Committee partially accepted as compliant. The refusal does not arise from unsafe procedures, but from an unduly restrictive interpretation of what Regulation 25 requires at application stage.

4.32 For those reasons, the decision cannot stand."

5 Summary of Representations

This is a summary of representations received on the appeal.

5.1 Healthcare Plus Consulting Ltd on behalf of Vitastock Ltd

5.1.1 "Thank you for your letter dated 12th January 2026. We, Healthcare Plus Consulting Ltd, continue to represent Vitastock Limited at appeal. An authorisation letter has previously been provided.

5.1.2 We continue to hold that the DSP regulations have not been met. We note that the applicant does not appear to have added any additional information with the appeal.

5.1.3 Location and Premises

5.1.4 We do not believe that the proposed site is suitable for a DSP. We note that the site, 1 Coopers Mill, Norton Fitzwarren, Taunton, TA2 6NX, was until recently a Boots community pharmacy. As seen below, it is clearly positioned as a community pharmacy and appears to still be fitted as a community pharmacy.

5.1.5 We note that since a community pharmacy was previously located at this site, the public are likely to assume any DSP is also a community pharmacy, thus potentially leading to breaches of the regulations through provision of services face-to-face.

5.1.6 We note that the premises has two small doors suitable only for foot traffic and no access for vehicles such as a loading dock or roller shutter doors.

5.1.7 The area around the proposed site includes a GP, and our client's community pharmacy. It also includes a Co-op, Fish Bar, Café, and the Village Hall. This clearly appears to be an area of high customer foot traffic. Thus, we submit the applicant's location further increases the risk of the public treating the DSP as a community pharmacy and accessing services onsite.

5.1.8 Please see images of the site included below.

5.1.9 *Figure 1: Images from Google Street View of the proposed site.* [provided]

5.1.10 Previous Application

5.1.11 We also express concerns over the intentions of the proposed pharmacy. We note that the applicant's company, Keynsham Healthcare Limited, has two directors and two recorded shareholders – Ms [RS] and Mr [RY] It is notable that these are the same directors and shareholders of Magna Healthcare Limited, who previously applied to open a community pharmacy at this site under Regulation 18, but were rejected in 2024 (see SHA/ 26212).

5.1.12 There is therefore no doubt that the applicant believed that this site was an appropriate venue for a community pharmacy. This seems to us to preclude the site from being an appropriate venue for a DSP.

5.1.13 It is also clear that having failed to have a community pharmacy contract granted under Regulation 18, they have reapplied under Regulation 25. This raises clear doubts as to whether they do intend to operate the pharmacy solely as a DSP.

5.1.14 Essential Services

5.1.15 The provided information continues to fail to address a number of essential services including, but not limited to, the following areas:

5.1.15.1Urgent supply

5.1.15.2Supply in respect of SSPs, PTPs, LPIVs

5.1.15.3Advice surrounding lifestyle and health conditions

5.1.15.4Exemption checking and payments

5.1.15.5Appliances and related advice

5.1.15.6Advice in connection with repeat prescriptions

5.1.16 We also remain of the view that information on the delivery of medications is insufficient. The details on handling dangerous goods, e.g. flammables and oxidisers such as Glycerine Trinitrates, are particularly absent.

5.1.17 In their response to comments, they have stated:

5.1.17.1"Dispensing & Repeat Dispensing – EPS-enabled dispensing with tracked delivery nationwide."

5.1.18 This calls into question whether the DSP will be able to accept non-EPS prescriptions as required by the regulations.

5.1.19 We believe that, given this is our final opportunity to comment on the application, it would not be appropriate for further substantial changes to be made to their application and new information to be added at this stage."

5.2 The Commissioner

5.2.1 "Thank you for your letter, received 14 January 2026, addressed to Mr S at Primary Care Support England (PCSE) enclosing a copy of the above appeal. The South West Pharmaceutical Services Regulations Committee (SW Committee) wishes to make the following comments on the appeal.

5.2.2 The SW Committee noted the applicant submitted information that provided assurance that some of the procedures for service provision would ensure safe and effective delivery. However, as detailed in the decision report, there are a number of services where the procedures described lack sufficient detail on how safe and effective delivery will be achieved. In these cases, the information was insufficient for the SW Committee to be assured the applicant would likely secure the safe and effective provision of essential services to persons anywhere in England, without face to face contact. The SW Committee considered fully the information provided, but as some procedures did not confirm a sufficient level of detail for assurance, the application was refused.

5.2.3 The SW Committee looks forward to receiving the Primary Care Appeals' decision in due course."

6 Summary of Observations

This is summary of observations received.

6.1 Proheal Pharma

6.1.1 “I write to formally submit representations regarding the above application for inclusion in the pharmaceutical list as a Distance Selling Pharmacy (“DSP”) under Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (“the 2013 Regulations”), and to request that the Committee considers these unresolved concerns, which are materially relevant and support refusal of the application.

6.1.2 Introduction

6.1.3 These submissions are made by Proheal Pharma, an existing NHS community pharmacy contractor located within approximately one mile of the proposed premises at 1 Coopers Mill, Taunton, TA2 6NX.

6.1.4 The application is brought pursuant to Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (“the 2013 Regulations”), seeking inclusion in the pharmaceutical list as a Distance Selling Pharmacy (“DSP”).

6.1.4.1 It is submitted that the appeal application must be refused on the basis that:

6.1.4.2 The statutory test under Regulation 25 is not met.

6.1.4.3 The applicant has failed to provide sufficient information to satisfy the decision-maker as required by Regulation 31.

6.1.4.4 The operational model is inconsistent with established DSP jurisprudence.

6.1.4.5 There is evidence suggesting regulatory circumvention following a prior refusal under Regulation 18.

6.1.5 The Statutory Framework

6.1.6 Regulation 25(1) provides that an application in respect of DSP premises is accepted only where:

6.1.6.1 “The means of providing essential services are such that all persons receiving those services do so otherwise than at those premises.”

6.1.7 This requirement is absolute. Statutory wording does not permit occasional, incidental, or discouraged face-to-face provision. It means that all people receiving essential services must do so otherwise than at the premises.

6.1.8 Regulation 31 imposes a mandatory refusal where:

6.1.8.1 The applicant fails to provide sufficient information.

6.1.8.2 The Board cannot be satisfied that regulatory requirements are met.

6.1.8.3 The applicant's undertakings cannot be relied upon.

6.1.9 Authoritative Interpretation in Dsp Appeals

6.1.10 The PCAU has consistently held in DSP determinations that:

6.1.10.1A DSP must be structurally incapable of functioning as a walk-in pharmacy.

6.1.10.2Physical layout and locality are relevant to assessing risk of face-to-face provision.

6.1.10.3The test is one of objective compliance, not subjective assurance.

6.1.11 Appeal decisions in DSP cases have emphasized that:

6.1.11.1In a 2014 DSP appeal involving Pharmacy2U, the Panel refused the application because the applicant failed to show compliance with Regulation 25(2), including safe, uninterrupted nationwide service. Concerns included the delivery model (safe places, controlled drugs, cold chain) and premises features suggesting walk-in operation, confirming that DSPs must demonstrate a purely distance-selling model without structural or procedural ambiguity.

6.1.11.2In a recent DSP appeal involving Pharmacy2U and Lloyds, the Committee again refused the application, finding insufficient evidence that essential services could be provided safely and uninterrupted nationwide, reinforcing that even established DSPs must demonstrate fully compliant distance-selling systems under Regulations 25 and 31.

6.1.11.3The jurisprudential principle arising from these and other DSP decisions is clear: where premises are physically configured and situated so as to invite public attendance, or where delivery and operational arrangements are insufficiently evidenced, the Regulation 25 test is unlikely to be satisfied.

6.1.12 Premises Unsuitability – Structural Non-Compliance

6.1.13 The proposed premises:

6.1.13.1Previously operated as a Boots community pharmacy.

6.1.13.2Remain visibly configured for retail footfall.

6.1.13.3 Are located in a retail parade adjacent to GP services and community amenities.

6.1.13.4 Have standard pedestrian access consistent with high-street pharmacy design.

6.1.13.5 The applicant has not demonstrated any material structural alteration to prevent public access.

6.1.14 The test under Regulation 25 is not whether staff will refuse service, but whether

6.1.15 the means of provision ensure services are delivered otherwise than at the premises. A premises that:

6.1.15.1 Invites footfall.

6.1.15.2 Is adjacent to GP surgery.

6.1.15.3 Appears indistinguishable from a community pharmacy. cannot objectively satisfy that test.

6.1.16 Regulatory Circumvention – Improper Purpose

6.1.17 It is a matter of record that:

6.1.17.1 The same directors previously applied for a Regulation 18 community pharmacy at this site.

6.1.17.2 That application was refused.

6.1.17.3 The present DSP application concerns the identical premises.

6.1.18 This sequence raises legitimate concerns of regulatory circumvention. Regulation 25 is not a fallback mechanism for failed needs-based applications.

6.1.19 The PCAU has previously cautioned that DSP applications must not be used to secure local market presence where Regulation 18 criteria are unmet.

6.1.20 The inference is compelling: the applicant has not altered the premises to create a genuine DSP hub but has instead repurposed a refused community site.

6.1.21 This weighs materially against grant.

6.1.22 Failure to Demonstrate Safe and Lawful Provision of Essential Services

6.1.23 The application provides hookup-level assurances without operational substance.

6.1.24 Non-EPS Prescriptions

6.1.25 The reference to:

6.1.26 “EPS-enabled dispensing with tracked delivery nationwide” fails to demonstrate capacity to process:

6.1.26.1 Paper FP10 prescriptions.

6.1.26.2 Controlled drug prescriptions.

6.1.26.3 Urgent supplies outside EPS.

6.1.26.4 SSP and PTP supplies.

6.1.27 A DSP must accept and dispense all lawful prescriptions. Absence of procedural clarity is fatal.

6.1.28 Urgent Supply Obligations

6.1.29 Schedule 4 essential services include urgent supply under the Human Medicines Regulations 2012.

6.1.30 The applicant has not explained how urgent supply will be provided:

6.1.30.1 Without face-to-face attendance.

6.1.30.2 Without delay inconsistent with clinical need.

6.1.31 Dangerous Goods & Controlled Drugs

6.1.32 No evidence is provided regarding:

6.1.32.1 ADR compliance.

6.1.32.2 Controlled Drug transport security.

6.1.32.3 Cold chain validation.

6.1.32.4 Delivery governance.

6.1.33 Given that DSP provision relies entirely on transport logistics, this omission is substantial and material.

6.1.34 Public Interest and Regulatory Risk

6.1.35 The site is situated in an area of:

6.1.35.1 High pedestrian activity.

6.1.35.2 Immediate proximity to GP services.

6.1.35.3 Residential density.

6.1.36 The likelihood of patients presenting physically is high.

6.1.37 Regulation 25 does not permit a DSP to operate in a manner that relies upon patient compliance with signage or staff refusal. The statutory requirement concerns how services are provided — not how refusals are handled.

6.1.38 If patients attend and are turned away, the model has already failed the Regulation 25 structural test.

6.1.39 Insufficiency of Information – Regulation 31

6.1.40 The applicant bears the burden of satisfying the Board.

6.1.41 The absence of:

6.1.41.1 Detailed SOPs (even redacted).

6.1.41.2 Delivery compliance framework.

6.1.41.3 Non-EPS handling processes.

6.1.41.4 Public access prevention measures.

6.1.42 means the Board cannot properly discharge its statutory function. Regulation 31 requires refusal where satisfaction cannot be reached.

6.1.43 Local Context

6.1.44 Proheal Pharma, located at 27 Frobisher Way, already provides:

6.1.44.1 Full essential services.

6.1.44.2 Advanced services

6.1.44.3 Urgent meds supply.

6.1.44.4 Home deliveries

6.1.45 There is no unmet need locally.

6.1.46 While DSP applications are accepted from routine needs assessment, the Board must ensure statutory compliance.

6.1.47 Conclusion

6.1.48 The application fails for the following reasons:

6.1.48.1 The premises are structurally and geographically inconsistent with Regulation 25.

6.1.48.2 The applicant has not demonstrated that all essential services will be provided otherwise than at the premises.

6.1.48.3 There is credible evidence of regulatory circumvention.

6.1.48.4 Essential service delivery mechanisms are inadequately evidenced.

6.1.48.5 The Board cannot be lawfully satisfied under Regulation 31.

6.1.49 Proheal Pharma respectfully requests that the Committee refuses the application under Regulations 25 and 31 of the 2013 Regulations and records this letter as formal written representations."

6.2 The Applicant

6.2.1 "Thank you for the opportunity to present my observations on the representations received in response to my application. These are confined strictly to matters arising from the decision report of the South West Pharmaceutical Services Regulations Committee ("SW Committee") and the representations submitted by Healthcare Plus Consulting Ltd on behalf of Vitastock Ltd. They should be read consistently with the Grounds of Appeal dated 26 December 2025.

6.2.2 The appeal concerns the application of Regulation 25(2)(b) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and whether the procedures described in the application are likely to secure compliant provision of essential services.

6.2.3 Scope of the Appeal

6.2.4 The SW Committee was satisfied that Regulation 31 was not engaged and that the proposed premises were not on the same site as another contractor. The Committee further accepted that essential services would be uninterrupted during published opening hours, that prescriptions would be received without face-to-face contact, and that arrangements for disposal of unwanted medicines, public health campaigns, signposting and self-care were compliant.

6.2.5 The refusal therefore rests solely upon Regulation 25(2)(b), specifically whether the procedures described were likely to secure provision to persons anywhere in England, without face-to-face contact, and in a safe and effective manner.

6.2.6 The appeal is accordingly focused on whether that statutory threshold was correctly applied.

6.2.7 The Correct Statutory Threshold

6.2.8 Regulation 25(2)(b) requires a predictive assessment of whether the applicant's procedures are likely to secure uninterrupted provision of essential services to persons anywhere in England and safe and effective provision without face-to-face contact.

6.2.9 The Regulation does not require operational perfection, inspection-level exposition of internal workflows, or full disclosure of internal Standard Operating Procedures. The assessment is not whether every conceivable contingency has been exhaustively mapped, but whether

the arrangements described are structurally capable of delivering compliant provision.

6.2.10 The statutory language is directed to likelihood, not to evidential completeness.

6.2.11 Application of the Threshold

6.2.12 A consistent feature of the decision report is the conclusion that the Committee was “not satisfied” because certain matters were insufficiently elaborated. In each of the areas identified — urgent supply, exemption checking, delivery integrity, repeat dispensing and prescription-linked interventions — the Committee acknowledged that procedures had been described but considered them insufficiently detailed.

6.2.13 Where coherent arrangements are described and no structural impediment to compliance is identified, the statutory test is met. A finding that further elaboration might have been desirable is not equivalent to a finding that the procedures are unlikely to secure compliant provision.

6.2.14 It is respectfully submitted that the refusal reflects the application of a heightened “sufficiency of detail” standard rather than the statutory “likely to secure” test required by Regulation 25(2)(b).

6.2.15 Consistency of Statutory Interpretation

6.2.16 Regulation 25(2)(b) has remained materially unchanged in its wording. The statutory question has consistently been whether the applicant’s procedures are likely to secure compliant provision. The Regulation does not require applicants to demonstrate operational perfection or to provide inspection-level documentation at the point of application.

6.2.17 The assessment is predictive in nature and directed to structural capability rather than exhaustive operational exposition. The present application falls squarely within that established statutory framework and should be assessed accordingly.

6.2.18 Provision to Persons Anywhere in England

6.2.19 The application expressly confirms that services will be provided exclusively by non-face-to-face methods, that prescriptions will be received via EPS, post or other secure NHS channels, and that medicines will be dispatched through tracked courier or Royal Mail services. No geographic limitation is placed upon provision within the procedures described.

6.2.20 The decision does not identify any structural impediment to national provision. On the face of the materials submitted, the arrangements described are capable of securing provision to persons anywhere in England.

6.2.21 Specific Areas Identified by the SW Committee Urgent Supply

6.2.22 The procedures describe remote pharmacist consultation, access to the Summary Care Record where appropriate, lawful emergency supply within the scope of the Human Medicines Regulations, documentation and audit, and dispatch through the established delivery workflow. Where supply is not lawful, referral to NHS 111 or other appropriate services is provided.

6.2.23 The Regulations do not require a separate urgent supply infrastructure beyond the DSP model. The arrangements described are structurally capable of compliant urgent supply without face-to-face contact.

6.2.24 Exemption Checking

6.2.25 EPS declarations, remote submission of evidence, and recording within the Patient Medication Record are established DSP mechanisms and inherently non-face-to-face. There is no regulatory requirement for physical interaction in order to verify exemption status.

6.2.26 Delivery Integrity

6.2.27 The procedures describe validated temperature-controlled packaging where required, tracked courier services, electronic proof of delivery, identity verification, chain-of-custody logging, and pharmacist oversight of failed deliveries. No structural deficiency has been identified. The safeguards described are capable of securing safe and effective delivery.

6.2.28 Repeat Dispensing

6.2.29 Patients are contacted prior to each issue and dispensing follows standard safe supply procedures incorporating clinical appropriateness review. The absence of enumerating each conversational step does not undermine the structural adequacy of the process described.

6.2.30 Prescription-Linked Interventions

6.2.31 The application describes pharmacist clinical checks, remote communication channels, documentation within the PMR, and referral where appropriate. These arrangements are capable of delivering compliant pharmaceutical care without face-to-face contact.

6.2.32 Website Health Promotion Zone

6.2.33 The application commits to maintaining an interactive health promotion page compliant with NHS Digital and GPhC standards and updated regularly. At application stage, such a commitment is sufficient to satisfy the requirement.

6.2.34 Internal Consistency of the Decision

6.2.35 The decision records positive findings including that prescriptions would be received without face-to-face contact, that services would be uninterrupted during opening hours, and that several essential services were adequately addressed. It further acknowledges that temperature control and Controlled Drug safeguards were described.

6.2.36 Against those findings, the conclusion that essential services overall were not likely to be secured safely and effectively appears difficult to reconcile. The criticisms relate to perceived insufficiency of elaboration rather than absence of structural arrangements.

6.2.37 Where multiple essential service components were accepted as compliant and no structural impediment to lawful operation was identified, the overall conclusion does not logically follow from the findings recorded.

6.2.38 Response to Healthcare Plus / Vitastock Representations

6.2.39 The representations submitted by Healthcare Plus Consulting Ltd largely reiterate matters already considered by the SW Committee and do not identify structural non-compliance.

6.2.40 It is suggested that the premises are unsuitable because of their previous use as a community pharmacy and their location within an area of foot traffic. Regulation 25 does not prescribe architectural criteria for DSP premises. The statutory question is whether services will be provided without face-to-face contact. The application confirms that no NHS services will be provided face-to-face and that patients will not attend for dispensing or consultation. The physical configuration of the premises does not prevent lawful remote-only operation, and previous use does not alter the regulatory assessment.

6.2.41 Reference is made to a previous Regulation 18 application involving related directors. Each application must be assessed independently under its respective statutory framework. A previous Regulation 18 application neither precludes lawful operation under Regulation 25 nor creates any presumption regarding intended mode of operation.

6.2.42 Concerns are also raised regarding alleged omissions in essential services, including urgent supply, Serious Shortage Protocols, Pandemic Treatment Protocols, lifestyle advice, exemption checking, appliances, repeat prescription advice, delivery of certain medicines, and the acceptance of non-EPS prescriptions. These matters are either addressed directly within the application or operate within the standard dispensing workflow. Mechanisms such as SSPs and PTPs are implemented in accordance with NHS England directions and do not require separate physical infrastructure. Medicines requiring particular handling, including flammable or oxidising products, are supplied in accordance with established pharmaceutical transport standards and courier compliance requirements. The application does not undertake the supply of appliances requiring fitting or measurement and appropriate referral would be made where such prescriptions are

received. Reference to EPS-enabled dispensing does not exclude lawful acceptance of prescriptions in other permitted formats.

6.2.43 Finally, it is suggested that clarification provided at appeal stage constitutes new information. The nature of the application has not changed. Clarification of existing procedures in response to criticisms is inherent in the appeal process and does not amount to a material alteration of the proposal.

6.2.44 Conclusion

6.2.45 Taken as a whole, the procedures described establish a national, remote-only operating model with pharmacist oversight, structured urgent supply and repeat dispensing workflows, secure and traceable delivery safeguards, and appropriate business continuity arrangements.

6.2.46 These arrangements are plainly capable of securing uninterrupted, safe and effective provision of essential services to persons anywhere in England without face-to-face contact.

6.2.47 For the reasons set out in the Grounds of Appeal and elaborated above, the Appellant respectfully invites the Committee to allow the appeal."

7 Further comments

In the interests of transparency and fairness, NHS Resolution used its discretion under Schedule 3, Part 3, paragraph 7 of the Regulations and circulated Proheal Pharma's observations for further comments. Subsequently, NHS Resolution circulated the Applicant's observations and further comments for information purposes only.

7.1 The Applicant

7.1.1 "I write in response to the representations submitted by Proheal Pharma dated 20 February 2026. These observations are confined strictly to rebuttal of the matters raised in that letter and should be read consistently with my previous observations dated 23 February 2026.

7.1.2 Statutory Framework

7.1.3 The objector submits that the application fails to satisfy Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

7.1.4 As explained in my previous observations, Regulation 25 requires a predictive assessment of whether the procedures described are likely to secure compliant provision of essential services without face-to-face contact.

7.1.5 The statutory test concerns the means by which essential services are provided, not the architectural characteristics, location, or historical use of the premises.

7.1.6 The objector's submission appears to introduce an additional requirement that the premises must be "structurally incapable" of operating as a walk-in pharmacy. No such requirement appears within Regulation 25 and it is not reflected in the wording of the Regulations.

7.1.7 Premises Configuration

7.1.8 The objector places reliance on the fact that the premises previously operated as a community pharmacy and are located within a retail environment.

7.1.9 However, Regulation 25 does not prescribe architectural criteria for distance selling pharmacy premises. The statutory question is whether the procedures ensure that essential services are provided otherwise than at the premises.

7.1.10 The application confirms that prescriptions will be received remotely and medicines supplied through delivery mechanisms. No NHS essential services will be provided face-to-face at the premises. The previous use or external appearance of the premises therefore does not alter the regulatory assessment.

7.1.11 It is also relevant to note that patients seeking a traditional walk-in pharmacy service already have access to nearby community pharmacy provision in the locality, including a pharmacy situated closer to the GP surgery referenced by the objector. Patients wishing to access in-person pharmaceutical services are therefore able to do so through existing premises designed and operating for that purpose.

7.1.12 Hypothetical Patient Attendance

7.1.13 The objector places emphasis on the possibility that members of the public may attend the premises due to its location and proximity to healthcare services.

7.1.14 Regulation 25 is directed to the means by which essential services are provided, not to speculative assumptions regarding potential patient behaviour.

7.1.15 The relevant question for the decision-maker is whether the applicant's procedures ensure that essential services are provided otherwise than at the premises. Where an operational model requires prescriptions to be received remotely and medicines supplied through delivery mechanisms, the statutory requirement is satisfied.

7.1.16 The mere possibility that a member of the public may physically attend the premises does not alter that regulatory assessment. The Regulations do not require that distance selling premises be physically inaccessible to the public; rather, they require that essential services are not provided face-to-face.

7.1.17 Reference to a Previous Regulation 18 Application

7.1.18 The objector suggests that the present application represents regulatory circumvention because a previous application under Regulation 18 was refused.

7.1.19 The 2013 Regulations provide two distinct routes for entry onto the pharmaceutical list:

7.1.19.1needs-based applications under Regulation 18; and

7.1.19.2distance selling pharmacy applications under Regulation 25.

7.1.20 Each route is governed by a separate statutory test. The existence of a previous Regulation 18 application does not preclude a lawful application under Regulation 25 and does not affect the assessment required under that provision.

7.1.21 Provision of Essential Services

7.1.22 The objector raises concerns regarding the provision of certain elements of essential services, including the handling of non-EPS prescriptions, urgent supply and delivery arrangements.

7.1.23 These matters were addressed in the application and in my previous observations. The procedures described include remote prescription receipt, pharmacist clinical oversight, secure dispensing workflows and delivery through established courier services.

7.1.24 Regulation 25 requires that the procedures described are likely to secure compliant provision, not that every operational detail be exhaustively documented at the application stage.

7.1.25 The objector does not identify any structural impediment preventing the proposed model from operating lawfully as a distance selling pharmacy.

7.1.26 Delivery Governance and Transport Compliance

7.1.27 The objector refers to matters such as courier governance, controlled drug transport and temperature control.

7.1.28 These issues fall within the wider regulatory framework governing pharmacy practice and medicines distribution and apply to all pharmacy contractors. They do not form part of the statutory entry test under Regulation 25.

7.1.29 The absence of operational-level documentation within an application does not demonstrate that compliant arrangements cannot be implemented.

7.1.30 Local Pharmacy Provision

7.1.31 The objector refers to the services provided by its own pharmacy and to the local pharmacy landscape.

7.1.32 However, distance selling pharmacy applications are expressly exempt from the pharmaceutical needs assessment test. Local service provision therefore does not form part of the statutory criteria for determining an application made under Regulation 25.

7.1.33 Conclusion

7.1.34 The representations submitted by Proheal Pharma do not identify any structural or regulatory impediment preventing the proposed procedures from securing compliant distance-selling provision.

7.1.35 In particular:

7.1.35.1 Regulation 25 concerns the means of service provision, not the previous use or appearance of the premises.

7.1.35.2 A previous Regulation 18 application is not relevant to the statutory assessment under Regulation 25.

7.1.35.3 Speculation regarding possible public attendance does not alter the regulatory test.

7.1.35.4 The objections raised relate largely to matters of operational detail rather than structural compliance.

7.1.36 The statutory task for the decision-maker is to determine whether the procedures described are likely to secure compliant provision of essential services without face-to-face contact. It is not to undertake an inspection-level examination of internal operating procedures or require exhaustive operational exposition at the application stage.

7.1.37 For the reasons set out above, and in my previous observations, I respectfully submit that the statutory requirements of Regulation 25 are satisfied and that the appeal should therefore be allowed."

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.

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") 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).

8.6 Proheal Pharma state that "*The applicant has failed to provide sufficient information to satisfy the decision-maker as required by Regulation 31…*

… Regulation 31 imposes a mandatory refusal where:

1. The applicant fails to provide sufficient information.

2. The Board cannot be satisfied that regulatory requirements are met.

3. The applicant's undertakings cannot be relied upon…

…Insufficiency of Information – Regulation 31

The applicant bears the burden of satisfying the Board.

The absence of:

Detailed SOPs (even redacted).

Delivery compliance framework.

Non-EPS handling processes.

Public access prevention measures.

means the Board cannot properly discharge its statutory function. Regulation 31 requires refusal where satisfaction cannot be reached".

8.7 The Committee considered that Proheal Pharma had misunderstood the provisions of Regulation 31. 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. Furthermore, the Commissioner in its decision report stated that "*There are no other pharmacies at the proposed premises, or adjacent (for either address). The nearest pharmacy is 0.1 miles (Norton Fitzwarren Pharmacy). The SW Committee was satisfied it is not required to refuse the application by virtue of Regulation 31".*

8.8 Based on the information provided, which has not been disputed on appeal, the Committee was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

8.9 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."

8.10 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)

8.11 In relation to Regulation 25(1), the Applicant is applying for inclusion in the relevant pharmaceutical list as 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, and paragraph (1)(b) 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)

8.12 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 "*There is no provider of primary medical services at the proposed address(es), so the application does not have to be refused by virtue of Regulation 25(2)(a).*" The Committee noted this 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)

8.13 As far as Regulation 25(2)(b) is concerned, the Committee considered the information which had been provided by the Applicant in relation to its procedures for the provision of essential services and pharmaceutical services.

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

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

8.16 The Committee noted the Applicant's comments in relation to the Commissioner's decision that there is "*an expectation that applicants must submit near-complete SOP content* [and] *describe operational contingencies at inspection-level granularity, despite Regulation 25 expressly allowing procedural descriptions rather than full SOP disclosure. This places DSP applicants at an unfair disadvantage and goes beyond what the Regulations require at application stage".* The Committee was of the view that there is no requirement for applicants to provide SOPs however the decision makers must be provided with sufficient information and documentation which would address the criteria in Regulation 25(2)(b). On appeal, 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, appeal, representations and observations.

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

8.18 The Commissioner in its decision report stated that "*Part 4 of the application form is blank and there is no mention of this in the supporting information. As the application was not clear what, if any, appliances would be provided the SW Committee was not satisfied r* [sic] *suitable arrangements for measuring and fitting will be in place".*

8.19 The Committee noted that the Applicant had left the box in the application form blank.

8.20 In its representations, Healthcare Plus Consulting Ltd on behalf of Vitastock Ltd state that:

8.20.1 "*Essential Services*

The provided information continues to fail to address a number of essential services including, but not limited to, the following areas:

Appliances and related advice."

8.21 In its observations, the Applicant states that "*The application does not undertake the supply of appliances requiring fitting or measurement and appropriate referral would be made where such prescriptions are received."*

8.22 In the event that the application is granted, the Applicant would not therefore, be able to provide such appliances that require measuring and/or fitting to patients.

8.23 The Committee considered how the Applicant would provide essential services without interruption.

8.24 In the supporting documentation provided with the application, the Applicant states that:

8.24.1 *"Service Provision Scope…*

The pharmacy serves all patients within England…

…15. Business Continuity

A risk scoring matrix is maintained, with responses graded (e.g., green, amber, red) to guide escalation. Cross-training ensures staff can step into key roles during absences or emergencies. Cloud-based access is routinely tested for resilience."

8.25 In its 14 day comments to the Commissioner, the Applicant states that:

8.25.1 "*5. Responsible Pharmacist (RP) Cover*

The objection questions how uninterrupted services will be maintained.

Our SOP overview confirms: A Responsible Pharmacist (RP) will always be present during published opening hours.

To avoid disruption during statutory breaks, the pharmacy will close at lunch hours.

Business continuity arrangements are in place for unexpected absences, including a second pharmacist where required. In case of unplanned IT or courier disruption, our business continuity plan activates secondary systems and alternative couriers to ensure uninterrupted supply.

Conclusion: Our arrangements secure uninterrupted provision of essential services."

8.26 The Committee noted the reference to 'a second pharmacist', and therefore was of the view that from the information essential services would be provided, should they be required, during the absence of the Responsible Pharmacist.

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

8.28 With regard to services being available to persons anywhere in England, the Commissioner found that "*The SW Committee is not satisfied that all essential services were likely to be secured for persons anywhere in England".*

8.29 In the supporting documentation provided with the application, the Applicant states that:

8.29.1 *"Service Provision Scope…*

The pharmacy serves all patients within England."

8.30 In its 14 day comments to the Commissioner, the Applicant states that:

8.30.1 *"2. Duplication of Services / Market Impact*

Proheal Pharma suggests duplication and oversupply. However, DSPs are national contracts, not local ones. Patients across England can choose any DSP.

Unlike Regulation 18 (necessary or unforeseen benefits test), DSP applications are not judged on market need.

Commercial competition is not a ground for refusal under Regulation 25.

Conclusion: Concerns about duplication or business impact are irrelevant to the statutory test…

…4. Delivery Integrity & Security

The objection suggests delivery procedures lack detail…

National Scope – These safeguards apply equally to all patients across England; there is no limitation by geography."

8.31 In its observations, the Applicant states that:

8.31.1 "*Provision to Persons Anywhere in England*

The application expressly confirms that services will be provided exclusively by non-face- to-face methods, that prescriptions will be received via EPS, post or other secure NHS channels, and that medicines will be dispatched through tracked courier or Royal Mail services. No geographic limitation is placed upon provision within the procedures described. The decision does not identify any structural impediment to national provision. On the face of the materials

submitted, the arrangements described are capable of securing provision to persons anywhere in England."

8.32 In its further comments, the Applicant states that "*Local Pharmacy Provision The objector refers to the services provided by its own pharmacy and to the local pharmacy landscape. However, distance selling pharmacy applications are expressly exempt from the pharmaceutical needs assessment test. Local service provision therefore does not form part of the statutory criteria for determining an application made under Regulation 25".*

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

8.34 The Committee considered how the Applicant would provide pharmaceutical services without face to face contact.

8.35 The Commissioner found that "*The SW Committee is not satisfied that all essential services were likely to be secured without face to face contact."*

8.36 In the supporting documentation provided with the application, the Applicant states that:

8.36.1 *"Service Provision Scope*

Services are provided exclusively through non-face-to-face methods (e.g., phone, email, online portal, video call). At no point should a patient or their representative be physically present at or near the premises for any NHS service.

This strict separation ensures compliance with the requirements for DSPs, as no in-person interaction is permitted under this model.

Despite the lack of in-person contact, the pharmacy must remain highly accessible and responsive to patient needs. Multiple communication channels (telephone, secure email, live chat, video consultation) are provided to support comprehensive service delivery.

The pharmacy will use platforms like AccuRx to facilitate secure video consultations and text messaging with patients. This platform ensures timely, confidential communication and is integral to maintaining high levels of accessibility and patient engagement…

… 6. Communication Protocols

All communication must be conducted using secure, non-face-to-face methods, maintaining compliance with DSP regulations.

8.37 Healthcare Plus Consulting Ltd on behalf of Vitastock Ltd state that:

8.37.1 "*Location and Premises*

We do not believe that the proposed site is suitable for a DSP. We note that the site, 1 Coopers Mill, Norton Fitzwarren, Taunton, TA2 6NX, was until recently a Boots community pharmacy. As seen below, it is clearly positioned as a community pharmacy and appears to still be fitted as a community pharmacy.

We note that since a community pharmacy was previously located at this site, the public are likely to assume any DSP is also a community pharmacy, thus potentially leading to breaches of the regulations through provision of services face-to-face.

We note that the premises has two small doors suitable only for foot traffic and no access for vehicles such as a loading dock or roller shutter doors.

The area around the proposed site includes a GP, and our client's community pharmacy. It also includes a Co-op, Fish Bar, Café, and the Village Hall. This clearly appears to be an area of high customer foot traffic. Thus, we submit the applicant's location further increases the risk of the public treating the DSP as a community pharmacy and accessing services onsite."

8.38 In response, in its observations, the Applicant states that "*The representations submitted by Healthcare Plus Consulting Ltd largely reiterate matters already considered by the SW Committee and do not identify structural non-compliance. It is suggested that the premises are unsuitable because of their previous use as a community pharmacy and their location within an area of foot traffic. Regulation 25 does not prescribe architectural criteria for DSP premises. The statutory question is whether services will be provided without face-to-face contact. The application confirms that no NHS services will be provided face-to-face and that patients will not attend for dispensing or consultation. The physical configuration of the premises does not prevent lawful remote-only operation, and previous use does not alter the regulatory assessment".*

8.39 In its observations, Proheal Pharma state that "*The jurisprudential principle arising from these and other DSP decisions is clear:*

where premises are physically configured and situated so as to invite public

attendance, or where delivery and operational arrangements are insufficiently

evidenced, the Regulation 25 test is unlikely to be satisfied.

IV. Premises Unsuitability – Structural Non-Compliance

The proposed premises:

Previously operated as a Boots community pharmacy.

Remain visibly configured for retail footfall.

Are located in a retail parade adjacent to GP services and community amenities.

Have standard pedestrian access consistent with high-street pharmacy design.

The applicant has not demonstrated any material structural alteration to prevent public access.

The test under Regulation 25 is not whether staff will refuse service, but whether the means of provision ensure services are delivered otherwise than at the premises.

A premises that:

Invites footfall.

Is adjacent to GP surgery.

Appears indistinguishable from a community pharmacy.

cannot objectively satisfy that test."

8.40 In response, the Applicant states that:

8.40.1 *"Premises Configuration*

The objector places reliance on the fact that the premises previously operated as a community pharmacy and are located within a retail environment. However, Regulation 25 does not prescribe architectural criteria for distance selling pharmacy premises. The statutory question is whether the procedures ensure that essential services are provided otherwise than at the premises. The application confirms that prescriptions will be received remotely and medicines supplied through delivery mechanisms. No NHS essential services will be provided face-to-face at the premises. The previous use or external appearance of the premises therefore does not alter the regulatory assessment. It is also relevant to note that patients seeking a traditional walk-in pharmacy service already have access to nearby community pharmacy provision in the locality, including a pharmacy situated closer to the GP surgery referenced by the objector. Patients wishing to access in-person pharmaceutical services are therefore able to do so through existing premises designed and operating for that purpose.

Hypothetical Patient Attendance

The objector places emphasis on the possibility that members of the public may attend the premises due to its location and proximity to healthcare services. Regulation 25 is directed to the means by which essential services are provided, not to speculative assumptions regarding potential patient behaviour. The relevant question for the decision-maker is whether the applicant's procedures ensure that essential services are provided otherwise than at the premises. Where

an operational model requires prescriptions to be received remotely and medicines supplied through delivery mechanisms, the statutory requirement is satisfied. The mere possibility that a member of the public may physically attend the premises does not alter that regulatory assessment. The Regulations do not require that distance selling premises be physically inaccessible to the public; rather, they require that essential services are not provided face-to-face."

8.41 The Committee was mindful of the regulatory changes as of 1 October 2025 and 31 March 2026, that distance selling pharmacies can no longer provide Directed services (Advanced, National Enhanced and Enhanced Services) face to face with the patient at the pharmacy premises.

8.42 In its application, which the Committee acknowledged was completed before the regulatory amendments came into force, the Applicant had stated that it intended to provide:

8.42.1 *"New medicine service (NMS)*

NHS Pharmacy First Service

Care Home Service

Home Delivery Service."

8.43 As a result of this amendment, the Committee noted that the Applicant would not be able to provide any pharmaceutical services to patients present at its premises.

8.44 The Committee was aware that if 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.

8.45 The Committee was satisfied that the provision of essential services would be available to persons anywhere in England and without interruption and that pharmaceutical services would be provided without face to face contact. The Committee went on to consider whether the safe and effective provision of pharmaceutical services was likely to be secured.

8.46 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.

8.47 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:

8.47.1 Dispensing of drugs and appliances

8.47.2 Urgent supply without a prescription

8.47.3 Preliminary matters before providing ordered drugs or appliances

8.47.4 Providing ordered drugs or appliances

8.47.5 Refusal to provide drugs or appliances ordered

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

8.47.7 Disposal service in respect of unwanted drugs

8.47.8 Promotion of healthy lifestyles

8.47.9 Prescription linked intervention

8.47.10 Health campaigns

8.47.11 Signposting

8.47.12 Support for self-care

8.47.13 Discharge medicines service

8.47.14 Websites and health promotion zones

8.48 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:

Urgent supply without a prescription

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

8.50 In its decision report, the Commissioner stated "*The SW Committee noted the applicant refers to the legal position for carrying this out and noted the requirements must be met but does not confirm the procedures to ensure it can be achieved. There was no detail about how urgent requests would be delivered and prioritised…was not satisfied the pharmacy has suitable arrangements in place for dealing with urgent requests without a prescription".*

8.51 The Committee noted that in the supporting documentation provided with the application, the Applicant states that:

8.51.1 *"10. Emergency and Urgent Supply*

Emergency and urgent supplies may be provided under the legal frameworks of the Human Medicines Regulations 2012.

Supplies may only be made at the professional discretion of the pharmacist when it is considered clinically necessary, and the patient is unable to obtain a prescription in time.

A thorough consultation must be carried out remotely with the patient, or an authorized representative, to determine the necessity of the supply.

The pharmacist must access and check the patient's Summary Care Record (SCR) to verify medication history and appropriateness.

Records of the emergency supply must include patient details, date, nature of the emergency, medication details (name, strength, quantity), reason for supply, consultation notes, and pharmacist's name.

Supplies must be labelled with the words "Emergency Supply" and must meet all labelling and record-keeping requirements.

Supplies made at the request of a prescriber must still be documented and dispensed only when appropriate.

Controlled Drugs in Schedule 2 and 3 may not be supplied under emergency supply regulations; however, certain Schedule 4 and 5 CDs may be supplied where permitted.

All emergency supplies must be reviewed periodically for patterns or frequency and assessed for appropriateness during clinical audits.

8.52 In its 14 day comments to the Commissioner, the Applicant states that "*In line with the NHS England Urgent Medicines Supply Directions, the pharmacy has a protocol for handling urgent requests. Patients may contact us remotely via telephone, email, or website form. The pharmacist will assess the urgency and legal eligibility for supply. Where clinically appropriate and lawful, an emergency supply will be made and dispatched same day by tracked courier. Where supply is not possible, the patient will be immediately signposted to NHS 111, an out-of-hours service, or a suitable community pharmacy. All interventions are recorded in the PMR for audit and safety monitoring".*

8.53 In its representations, Healthcare Plus Consulting Ltd on behalf of Vitastock Ltd state that:

8.53.1 "*Essential Services*

The provided information continues to fail to address a number of essential services including, but not limited to, the following areas:

- *Urgent supply."*

8.54 In response, in its observations, the Applicant states that "*The procedures describe remote pharmacist consultation, access to the Summary Care Record where appropriate, lawful emergency supply within the scope of the Human Medicines Regulations, documentation and audit, and dispatch through the established delivery workflow. Where supply is not lawful, referral to NHS 111 or other appropriate services is provided. The Regulations do not require a separate urgent supply infrastructure beyond the DSP model. The arrangements described are structurally capable of compliant urgent supply without face-to-face contact".*

8.55 Furthermore, Proheal Pharma in its observations states that:

8.55.1 *"(2) Urgent Supply Obligations*

Schedule 4 essential services include urgent supply under the Human Medicines Regulations 2012.

The applicant has not explained how urgent supply will be provided:

Without face-to-face attendance.

Without delay inconsistent with clinical need."

8.56 Based on the information before it, the Committee was not satisfied that the Applicant had explained how it proposes to safely and effectively receive requests from prescribers for urgent supplies of drugs and appliances. As such, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.

Preliminary matters before providing ordered drugs or appliances

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

8.58 In its decision report, the Commissioner stated "*The SW Committee noted the applicant refers to the legal position for carrying this out and noted the requirements must be met but does not confirm the procedures to ensure it can be achieved without face to face contact for patients anywhere in England. The SW Committee was not satisfied the pharmacy has suitable arrangements in place for checking exemptions…without face to face contact".*

8.59 The Committee noted that in the supporting documentation provided with the application, the Applicant states that:

8.59.1 *"b. Verification and Validation…*

NHS exemptions must be accurately recorded, and where not evident, patients are contacted to supply supporting evidence.

8.60 In its representations, Healthcare Plus Consulting Ltd on behalf of Vitastock Ltd state that:

8.60.1 "*Essential Services*

The provided information continues to fail to address a number of essential services including, but not limited to, the following areas:

Exemption checking and payments."

8.61 In its observations, the Applicant states that "*Exemption Checking…EPS declarations, remote submission of evidence, and recording within the Patient*

Medication Record are established DSP mechanisms and inherently non-face-to-face. There is no regulatory requirement for physical interaction in order to verify exemption status."

8.62 Whilst the Applicant states that "*EPS declarations, remote submission of evidence, and recording within the Patient Medication Record are established DSP mechanisms",* the Committee did not consider that the Applicant had explained if these are the mechanisms it would follow in the context of its own pharmacy nor was there clarity as to the meaning of *'remote submission'*. Therefore, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.

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

8.64 In its decision report, the Commissioner stated "*The SW Committee noted the applicant refers to the legal position for carrying this out and noted the requirements must be met but does not confirm the procedures to ensure it can be achieved without face to face contact for patients anywhere in England. The SW Committee was not satisfied the pharmacy has suitable arrangements in place for…collecting payments without face to face contact".*

8.65 In its representations, Healthcare Plus Consulting Ltd on behalf of Vitastock Ltd state that:

8.65.1 "*Essential Services*

The provided information continues to fail to address a number of essential services including, but not limited to, the following areas:

Exemption checking and payments."

8.66 The Committee noted that the Applicant had not provided any information to explain how charges will be paid.

8.67 The Committee was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(5)(b) of Schedule 4.

Providing ordered drugs or appliances

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

8.69 In its decision report, the Commissioner stated "*The SW Committee was not satisfied that suitable arrangements are in place for the delivery of items including temperature controlled items and CDs. Whilst there is some information regarding temperature controlled items and CDs, there is little about how the integrity of these, and other non-CD or temperature controlled*

items would be protected to ensure they arrived with the patient in good condition".

8.70 The Committee noted that in the supporting documentation provided with the application, the Applicant states that:

8.70.1 *"In the event of delivery failure, cold chain disruption, or courier delay, contingency protocols include alternative courier engagement and temperature verification checks. Delivery satisfaction surveys are conducted periodically to assess service quality and identify areas for improvement.*

8. Delivery Procedures

All medicines are delivered via tracked courier or Royal Mail, and delivery status is monitored until completion.

Medicines requiring refrigeration (fridge items) are packaged with validated temperature-control systems to maintain cold chain conditions. Delivery must occur within timeframes supported by the cold chain packaging, and upon arrival, patients are advised to refrigerate immediately.

Controlled Drugs (CDs) are packaged securely and must be delivered via a tracked service requiring signature on receipt. Identity of the recipient is verified at the point of delivery, and a signature is captured to confirm safe handover.

A log is maintained for each CD delivery, recording dispatch time, courier details, recipient confirmation, and delivery status.

In the event of failed delivery attempts for fridge items or CDs, immediate follow-up is initiated, and the Responsible Pharmacist must assess whether medicines remain suitable for use or require disposal.

A specialist courier service will be contracted for the delivery of CDs and fridge items to ensure secure handling, temperature control, and full traceability. These couriers are vetted for compliance with MHRA and GPhC standards and must follow chain-of-custody procedures, use tamper-evident packaging, and provide real-time tracking and electronic proof of delivery.

All other non-CD and non-fridge items are delivered using secure, tamper-evident packaging. Patients are informed in advance of delivery, with contact information provided for queries or rescheduling.

Missed deliveries are logged, and efforts are made to reattempt delivery promptly or contact the patient to confirm redelivery preferences.

9. Controlled Drugs (CDs)

CDs are stored securely in a locked controlled drugs cabinet that meets Misuse of Drugs Regulations 2001 specifications, accessible only to authorized personnel.

A CD register is maintained for each schedule 2 CD, with entries recorded in ink, contemporaneously, and without alteration.

All CD stock is regularly reconciled against the CD register. Discrepancies must be reported immediately to the Responsible Pharmacist and Superintendent Pharmacist for investigation.

Deliveries of CDs require a signature from the named recipient or their authorized representative, with identity verification at the point of handover.

CDs that are refused or undeliverable must be returned to the pharmacy under secure conditions and logged accordingly.

Patient-returned CDs are recorded in a separate destruction register and destroyed in the presence of an authorized witness where required.

Denaturing kits must be used for CD destruction. Waste is then managed through appropriate pharmaceutical waste channels.

All incidents, concerns, or near-misses involving CDs are recorded, reviewed, and investigated under the pharmacy's incident reporting procedure."

8.71 In its 14 day comments to the Commissioner, the Applicant states that:

8.71.1 "*3. Patient Safety and Operational Risks*

The objection raises concerns about prescription confusion, EPS routing errors, and supplier misdeliveries…

… Chain-of-Custody: All Controlled Drugs (CDs) and fridge items are handled under documented chain-of-custody procedures, using tamper-proof packaging, ID verification, and courier tracking.

Conclusion: These risks are speculative. Our SOPs contain robust mitigations to ensure patient safety and supply chain integrity.

4. Delivery Integrity & Security

The objection suggests delivery procedures lack detail.

Controlled Drugs (CDs) – Supplied using tamper-evident packaging, tracked couriers, electronic proof of delivery, and ID verification. Chain of custody is logged at each handover.

Fridge Lines – Delivered via MHRA-compliant couriers with validated packaging and temperature monitoring. Logs are retained for audit".

8.72 In its observations, Proheal Pharma state that:

8.72.1 "*(3) Dangerous Goods & Controlled Drugs*

No evidence is provided regarding:

ADR compliance.

Controlled Drug transport security.

Cold chain validation.

Delivery governance."

8.73 In response, in its further comments, the Applicant states that "*Delivery Governance and Transport Compliance The objector refers to matters such as courier governance, controlled drug transport and temperature control. These issues fall within the wider regulatory framework governing pharmacy practice and medicines distribution and apply to all pharmacy contractors. They do not form part of the statutory entry test under Regulation 25."*

8.74 The Committee was mindful that it must have regard to whether the safe and effective provision of pharmaceutical services was likely to be secured. By doing so, it would have regard to Schedule 4 of the Regulations ("Terms of Service"). Paragraph 8(1) of Schedule 4 is in relation to "Providing ordered drugs or appliances" as elaborated on at paragraph 8.62 above. Whilst "*courier governance, controlled drug transport and temperature control"* does not form part of Regulation 25, the Committee considered that they are relevant considerations under Paragraph 8(1) of Schedule 4.

8.75 Whilst the Applicant states that "MHRA-compliant couriers" will be used with "validated packaging and temperature monitoring", the Committee noted that no information had been provided to demonstrate how the cold chain would be maintained or monitored in this instance, for example, if there was a breach in the cold chain, how they would become aware of this.

8.76 Further, whilst the Applicant states that "*In the event of delivery failure, cold chain disruption, or courier delay, contingency protocols include alternative courier engagement and temperature verification checks"* and "*In the event of failed delivery attempts for fridge items or CDs, immediate follow-up is initiated, and the Responsible Pharmacist must assess whether medicines remain suitable for use or require disposal*", the Committee noted there was no information on what the process would be for the segregation and return of any medication where the integrity of the cold chain had been breached.

8.77 In relation to cold chain items, 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.

8.78 The Committee considered whether the Applicant had explained what containers will be "suitable" for posted/delivered items.

8.79 The Committee noted that the Commissioner did not make a finding on this point.

8.80 In the supporting documentation provided with the application, the Applicant states that:

8.80.1 *"8. Delivery Procedures…*

Medicines requiring refrigeration (fridge items) are packaged with validated temperature-control systems to maintain cold chain conditions. Delivery must occur within timeframes supported by the cold chain packaging, and upon arrival, patients are advised to refrigerate immediately.

Controlled Drugs (CDs) are packaged securely and must be delivered via a tracked service requiring signature on receipt. Identity of the recipient is verified at the point of delivery, and a signature is captured to confirm safe handover.

These couriers are vetted for compliance with MHRA and GPhC standards and must follow chain-of-custody procedures, use tamper-evident packaging, and provide real-time tracking and electronic proof of delivery.

All other non-CD and non-fridge items are delivered using secure, tamper-evident packaging."

8.81 Whilst the Committee noted the information provided, it was of the view that the Applicant had not provided sufficient information to demonstrate what outer packaging it would be using and how this would be suitable for posted/delivered items to ensure that the integrity of the medication would be maintained.

8.82 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(15) of Schedule 4.

Refusal to provide drugs or appliances ordered

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

8.84 The Committee noted that the Commissioner did not make a finding on this point.

8.85 In the supporting documentation provided with the application, the Applicant states that:

8.85.1 *"2. Repeat Dispensing:*

Patients or their representatives are enrolled in repeat dispensing through the online portal.

Repeatable prescriptions are managed through EPS, and patients are contacted before each issue to confirm ongoing need.

Dispensing and delivery follow the standard safe supply procedure."

8.86 In its representations, Healthcare Plus Consulting Ltd on behalf of Vitastock Ltd state that:

8.86.1 "*Essential Services*

The provided information continues to fail to address a number of essential services including, but not limited to, the following areas:

• *Advice in connection with repeat prescriptions."*

8.87 In its observations, the Applicant states that "*Repeat Dispensing Patients are contacted prior to each issue and dispensing follows standard safe supply procedures incorporating clinical appropriateness review. The absence of enumerating each conversational step does not undermine the structural adequacy of the process described."*

8.88 Whilst the Applicant states that "*Repeat Dispensing Patients are contacted prior to each issue and dispensing follows standard safe supply procedures incorporating clinical appropriateness review"*, the Committee did not consider that, other than specifying a general approach, the Applicant had sufficiently explained how it will be satisfied that when dispensing a repeatable prescription other than on the first occasion, that the patient is still using the medication, is not suffering from any side effects, the medicine regime has not changed in any way and there has been no changes to the patient's health, which may indicate the desirability of review the patients treatment. Therefore, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 9(4) of Schedule 4.

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

8.89 The Committee considered whether the Applicant had explained how appropriate advice about the benefits of repeat dispensing is given to any patient who (i) has long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term), and (ii) requires regular medicine in respect of that medical condition.

8.90 In its decision report, the Commissioner stated that "*Paragraph 10(1)(da) – benefits of repeat dispensing. There does not appear to be any information regarding the requirement to promote the benefits of repeat dispensing to suitable patients. The SW Committee was not satisfied that suitable arrangements are in place to advise suitable patients of the benefits of repeat dispensing without face to face contact."*

8.91 The Committee noted that the Applicant had not provided any information on this point. Therefore, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.

Prescription linked intervention

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

8.93 The Commissioner in its decision report stated that "*There appears to be no mention of this in the application form. The SW Committee was not satisfied that suitable arrangements are in place to provide prescription linked interventions and healthy lifestyle advice without face to face contact".*

8.94 In the supporting documentation provided with the application, the Applicant states that:

8.94.1 *"4. Public Health (Promotion of Healthy Lifestyles):*

Health promotion campaigns are delivered digitally via email, SMS, and website notifications, aligned with NHS seasonal topics.

Posters and digital brochures are included in delivery parcels periodically.

Patients may access virtual consultations for lifestyle advice (e.g., smoking cessation, weight loss)."

8.95 In its 14 day comments to the Commissioner, the Applicant states that "*Service delivery…The objection claims certain essential services are not described. This is incorrect. Our procedures cover all six essential services as required by Schedule 4 of the Regulations…Healthy Living Pharmacy: Promotion of Healthy Lifestyles & Public Health Campaigns – Remote delivery of campaigns via: leaflets included with prescriptions, SMS/email campaigns, and a Health Promotion Zone on our website updated monthly. Campaign materials are updated monthly and archived for 12 months to evidence compliance."*

8.96 In its observations, the Applicant states that "*Prescription-Linked Interventions The application describes pharmacist clinical checks, remote communication channels, documentation within the PMR, and referral where appropriate. These arrangements are capable of delivering compliant pharmaceutical care without face-to- face contact."*

8.97 The Committee noted that the Applicant had not explained how it would specifically assess whether persons require prescription linked intervention advice because they have diabetes, are at risk of coronary heart disease, smoke or are overweight and therefore, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

Discharge medicines service

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

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

8.100 The Committee noted that the Commissioner did not make a finding on this point.

8.101 In its 14 day comments to the Commissioner, the Applicant states that "*Service delivery…The objection claims certain essential services are not described. This is incorrect. Our procedures cover all six essential services as required by Schedule 4 of the Regulations…Discharge Medicines Service (DMS) – NHSmail/ PharmOutcomes referrals are received, reconciled against the patient record, and followed up by phone or video consultation."*

8.102 The Committee noted that the Applicant makes no reference to the procedure that it would follow if a patient who has recently been discharged from hospital is referred to them for advice and support. Further, the Committee noted the limited information provided in relation to the procedures the Applicant has in place for checking referrals for the discharge medicines services.

8.103 The Committee was therefore 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.

Other considerations

8.104 The Committee noted that in its decision report, the Commissioner had made findings and interested parties had made objections in relation to certain aspects of the Terms of Service which it considered important to address.

Dispensing of drugs and appliances

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

8.106 In its representations, Healthcare Plus Consulting Ltd on behalf of Vitastock Ltd state that:

8.106.1 *"In their* [the Applicant's] *response to comments, they have stated:*

"Dispensing & Repeat Dispensing – EPS-enabled dispensing with tracked delivery nationwide."

This calls into question whether the DSP will be able to accept non-EPS prescriptions as required by the regulations."

8.107 Furthermore, Proheal Pharma in its observations states that:

8.107.1"*(1) Non-EPS Prescriptions*

The reference to:

"EPS-enabled dispensing with tracked delivery nationwide"

fails to demonstrate capacity to process:

Paper FP10 prescriptions.

Controlled drug prescriptions.

Urgent supplies outside EPS.

SSP and PTP supplies.

A DSP must accept and dispense all lawful prescriptions.

Absence of procedural clarity is fatal".

8.108 In its observations, the Applicant states that "*Reference to EPS-enabled dispensing does not exclude lawful acceptance of prescriptions in other permitted formats".*

8.109 In its further comments, the Applicant states that "*The objector raises concerns regarding the provision of certain elements of essential services, including the handling of non-EPS prescriptions, urgent supply and delivery arrangements. These matters were addressed in the application and in my previous observations. The procedures described include remote prescription receipt, pharmacist clinical oversight, secure dispensing workflows and delivery through established courier services".*

8.110 The Committee noted that in the supporting documentation provided with the application, the Applicant states that:

8.110.1*"5. Prescription Handling*

a. Order Receipt

Prescriptions may be received via multiple secure channels: electronically through the Electronic Prescription Service (EPS), posted paper prescriptions, or scanned copies sent from verified NHS sources.

Upon receipt, each prescription is logged in the system, capturing patient demographics, prescriber details, medication requested, and delivery instructions.

For paper prescriptions, visual checks are performed to verify legibility and completeness…

… 8. Delivery Procedures

All medicines are delivered via tracked courier or Royal Mail, and delivery status is monitored until completion…

… A specialist courier service will be contracted for the delivery of CDs and fridge items to ensure secure handling, temperature control, and full traceability. These couriers are vetted for compliance with MHRA and GPhC standards and must follow chain-of-custody procedures, use tamper-evident packaging, and provide real-time tracking and electronic proof of delivery."

8.111 Whilst the Committee noted the concerns raised by parties in relation to non-electronic prescriptions, based on the information provided by the Applicant with its application, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 5(2) and 5(3) of Schedule 4.

Providing ordered drugs or appliances

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

8.113 In its decision report, the Commissioner stated "*The SW Committee was not satisfied that suitable arrangements are in place for the delivery of items including temperature controlled items and CDs. Whilst there is some information regarding temperature controlled items and CDs, there is little about how the integrity of these, and other non-CD or temperature controlled items would be protected to ensure they arrived with the patient in good condition".*

8.114 The Committee noted that in the supporting documentation provided with the application, the Applicant states that:

8.114.1 *"In the event of delivery failure, cold chain disruption, or courier delay, contingency protocols include alternative courier engagement and temperature verification checks. Delivery satisfaction surveys are conducted periodically to assess service quality and identify areas for improvement.*

8. Delivery Procedures

All medicines are delivered via tracked courier or Royal Mail, and delivery status is monitored until completion.

Medicines requiring refrigeration (fridge items) are packaged with validated temperature-control systems to maintain cold chain conditions. Delivery must occur within timeframes supported by the cold chain packaging, and upon arrival, patients are advised to refrigerate immediately.

Controlled Drugs (CDs) are packaged securely and must be delivered via a tracked service requiring signature on receipt. Identity of the recipient is verified at the point of delivery, and a signature is captured to confirm safe handover.

A log is maintained for each CD delivery, recording dispatch time, courier details, recipient confirmation, and delivery status.

In the event of failed delivery attempts for fridge items or CDs, immediate follow-up is initiated, and the Responsible Pharmacist must assess whether medicines remain suitable for use or require disposal.

A specialist courier service will be contracted for the delivery of CDs and fridge items to ensure secure handling, temperature control, and full traceability. These couriers are vetted for compliance with MHRA and GPhC standards and must follow chain-of-custody procedures, use tamper-evident packaging, and provide real-time tracking and electronic proof of delivery.

All other non-CD and non-fridge items are delivered using secure, tamper-evident packaging. Patients are informed in advance of delivery, with contact information provided for queries or rescheduling.

Missed deliveries are logged, and efforts are made to reattempt delivery promptly or contact the patient to confirm redelivery preferences.

9. Controlled Drugs (CDs)

CDs are stored securely in a locked controlled drugs cabinet that meets Misuse of Drugs Regulations 2001 specifications, accessible only to authorized personnel.

A CD register is maintained for each schedule 2 CD, with entries recorded in ink, contemporaneously, and without alteration.

All CD stock is regularly reconciled against the CD register. Discrepancies must be reported immediately to the Responsible Pharmacist and Superintendent Pharmacist for investigation.

Deliveries of CDs require a signature from the named recipient or their authorized representative, with identity verification at the point of handover.

CDs that are refused or undeliverable must be returned to the pharmacy under secure conditions and logged accordingly.

Patient-returned CDs are recorded in a separate destruction register and destroyed in the presence of an authorized witness where required.

Denaturing kits must be used for CD destruction. Waste is then managed through appropriate pharmaceutical waste channels.

All incidents, concerns, or near-misses involving CDs are recorded, reviewed, and investigated under the pharmacy's incident reporting procedure."

8.115 In its 14 day comments to the Commissioner, the Applicant states that:

8.115.1"*3. Patient Safety and Operational Risks*

The objection raises concerns about prescription confusion, EPS routing errors, and supplier misdeliveries…

… Chain-of-Custody: All Controlled Drugs (CDs) and fridge items are handled under documented chain-of-custody procedures, using tamper-proof packaging, ID verification, and courier tracking.

Conclusion: These risks are speculative. Our SOPs contain robust mitigations to ensure patient safety and supply chain integrity.

4. Delivery Integrity & Security

The objection suggests delivery procedures lack detail.

Controlled Drugs (CDs) – Supplied using tamper-evident packaging, tracked couriers, electronic proof of delivery, and ID verification. Chain of custody is logged at each handover.

Fridge Lines – Delivered via MHRA-compliant couriers with validated packaging and temperature monitoring. Logs are retained for audit".

8.116 In its observations, Proheal Pharma state that:

8.116.1"*(3) Dangerous Goods & Controlled Drugs*

No evidence is provided regarding:

ADR compliance.

Controlled Drug transport security.

Cold chain validation.

Delivery governance."

8.117 In response, it its further comments, the Applicant states that "*Delivery Governance and Transport Compliance The objector refers to matters such as courier governance, controlled drug transport and temperature control. These issues fall within the wider regulatory framework governing pharmacy practice and medicines distribution and apply to all pharmacy contractors. They do not form part of the statutory entry test under Regulation 25."*

8.118 The Committee was mindful that it must have regard to whether the safe and effective provision of pharmaceutical services was likely to be secured. By doing so, it would have regard to Schedule 4 of the Regulations ("Terms of Service"). Paragraph 8(1) of Schedule 4 is in relation to "Providing ordered drugs or appliances" as elaborated on at paragraph 8.112 above. Whilst "*courier governance, controlled drug transport and temperature control"* does not form part of Regulation 25, the Committee considered that they are relevant considerations under Paragraph 8(1) of Schedule 4.

8.119 In relation to controlled drugs, based on the information before it, the Committee was satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

Websites and health promotion zones

8.120 The Committee considered whether the Applicant had explained how it will ensure that it has a website for use by the public for the purpose of accessing pharmaceutical services from those premises, on which there is an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues.

8.121 In its decision letter, the Commissioner stated that "*the SW Committee was not clear how the health promotion zone would be promoted to users of the website and so was not satisfied that the applicant has explained how it will ensure that it has a website for use by the public for the purpose of accessing pharmaceutical services from those premises, on which there is an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues".*

8.122 In the supporting documentation provided with the application, the Applicant states that:

8.122.1*"4. Public Health (Promotion of Healthy Lifestyles):*

Health promotion campaigns are delivered digitally via email, SMS, and website notifications, aligned with NHS seasonal topics.

Posters and digital brochures are included in delivery parcels periodically.

Patients may access virtual consultations for lifestyle advice (e.g., smoking cessation, weight loss)."

8.123 In its 14 day comments to the Commissioner, the Applicant states that "*Service delivery…The objection claims certain essential services are not described. This is incorrect. Our procedures cover all six essential services as required by Schedule 4 of the Regulations… Healthy Living Pharmacy: Promotion of Healthy Lifestyles & Public Health Campaigns – Remote delivery of campaigns via: leaflets included with prescriptions, SMS/email campaigns, and a Health Promotion Zone on our website updated monthly. Campaign materials are updated monthly and archived for 12 months to evidence compliance…*

…IT resilience: NHS approved provider will be used as the main dispensing software provider. Pharmacy website will meet the NHS Digital and GPhC website standards, including secure ordering, accessibility and privacy compliance."

8.124 In its observations, that Applicant states that "*Website Health Promotion Zone The application commits to maintaining an interactive health promotion page compliant with NHS Digital and GPhC standards and updated regularly. At application stage, such a commitment is sufficient to satisfy the requirement."*

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

8.126 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

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

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

8.128.1 confirm the Commissioner's decision;

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

8.128.3 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.

8.129 Even though the Committee has reached the same decision to that of the Commissioner, it has done so for different reasons. In those circumstances, the Committee determined that the decision of the Commissioner must be quashed.

8.130 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.

8.131 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.

8.132 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 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 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;

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

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

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

9.2.2.5 the Committee was 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