NHS Resolution

11 March 2026

REF: SHA/26803

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APPEAL AGAINST COVENTRY AND WARWICKSHIRE ICB DECISION TO GRANT AN APPLICATION BY MEDICARE CONNECT LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 52 COVENTRY STREET, SOUTHAM, WARWICKSHIRE, CV47 0EP 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:

MediCare Connect Ltd
Rushport Advisory LLP on behalf of Southam Pharmacy
PCSE on behalf of Coventry and Warwickshire ICB

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1 The Application

By application dated 20 November 2024, MediCare Connect Ltd ("the Applicant") applied to Coventry and Warwickshire ICB ("the Commissioner") for inclusion in the pharmaceutical list at 52 Coventry Street, Southam, Warwickshire, CV47 0EP under Regulation 25. In support of the application it was stated:

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

1.1.1 "Drug Tariff Part IX"

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

1.3 "As the premises for our distance selling pharmacy are located in close proximity to another brick and mortar pharmacy, we would like to clarify the following key points to ensure there is no overlap in service provision and to demonstrate how we will operate distinctly from the neighbouring pharmacy:

Nature of Operations

1.4 **Distance Selling Model**: Unlike the nearby pharmacy, our pharmacy operates exclusively as a distance-selling pharmacy. This means that **we do not provide face-to-face services on the premises**. All interactions with our customers will occur remotely, either online, over the phone, or via other non-face-to-face communication methods.

1.5 **No Walk-In Services**: We do not allow customers to walk in and collect medications or seek consultations at our physical location. This ensures that our services do not compete with or replicate those offered by the nearby pharmacy.

Target Audience

1.6 Our pharmacy primarily serves patients who prefer or require remote access to pharmaceutical services. This may include:

1.6.1 Patients living in remote or rural areas across England where access to physical pharmacies may be limited.

1.6.2 Individuals who are housebound, unable to travel, or prefer the convenience of home delivery for their medications.

1.6.3 Those who seek privacy and prefer to receive medication or consultations without visiting a pharmacy in person.

1.6.4 As a distance selling pharmacy, we cater to patients who are not able to, or do not wish to, access the local brick-and-mortar pharmacy down the road.

Service Differentiation

1.7 While the local pharmacy provides traditional face-to-face services, including prescription dispensing and in-person consultations, we focus entirely on the **non face- to-face provision** of essential pharmacy services.

1.8 Our services include:

1.8.1 **Prescription dispensing and home delivery** through secure courier networks.

1.8.2 **Remote consultations** via telephone or video calls.

1.8.3 Access to **advice on medications and health concerns** via our website or through our customer service helpline.

1.8.4 Additionally, our pharmacy will utilize the **Electronic Prescription Service (EPS)** to securely process prescriptions for patients all over England, further distinguishing our service model from the traditional pharmacy setting.

Collaboration, Not Competition

1.9 We do not intend to compete with the local pharmacy for walk-in customers.

1.10 Instead, we complement their services by offering an alternative, remote-based service model.

1.11 Our pharmacy will work within the established framework to meet the needs of patients who cannot, or prefer not to, visit physical pharmacies.

1.12 If appropriate, we are open to collaborating with local healthcare providers, including the nearby pharmacy, to ensure that patient needs are met, particularly in scenarios where urgent local assistance is required.

Compliance with Distance Selling Requirements

1.13 As a distance selling pharmacy, we are committed to complying with NHS and regulatory guidelines for this model of pharmacy. This includes:

1.13.1 Offering the **full range of essential services** without requiring patients to physically visit the premises.

1.13.2 Ensuring that all services provided are accessible remotely, and that patient safety and privacy are maintained throughout.

1.13.3 Distinctly separating our operations from the traditional pharmacy model in terms of service delivery.

1.14 By adhering to the principles of a distance selling pharmacy and maintaining a clear distinction from the nearby pharmacy, we believe our premises and services will meet the needs of patients without causing any disruption or overlap with the services provided by the neighbouring pharmacy."

1.15 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant stated "N/a".

Pharmacy procedures

1.16 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.

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

1.18 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.

1.19 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.

"7.1 Securing Uninterrupted and Safe Provision of Essential Services Uninterrupted Provision of Essential Services to Persons Anywhere in England

1.20 To ensure the uninterrupted provision of essential services, the following procedures will be implemented:

Online Accessibility:

1.21 Our pharmacy will operate an online platform that is accessible 24/7, allowing patients across England to request services, order medications, and access health advice at any time. While our official opening hours are Mon – Fri 09:00 – 17:00, the platform will remain accessible around the clock for prescription submissions and inquiries.

1.22 All essential services will be available remotely, including prescription dispensing, medication advice, repeat prescriptions, and health consultations. Patients can submit their prescription requests online, and our staff will process them during our operational hours.

Staff Scheduling and Availability:

1.23 We will ensure that qualified staff, including a pharmacist, are available during all opening hours to process prescriptions, offer consultations, and respond to any requests or emergencies.

1.24 Staff shift patterns will be managed to ensure there is no gap in service provision, and contingency plans are in place to cover for absences or emergencies.

Secure Prescription Handling:

1.25 We will utilize the **Electronic Prescription Service (EPS)** to receive and process prescriptions in a timely manner. This enables us to dispense and dispatch medications without interruption, regardless of the patient's location.

1.26 Paper prescriptions, if received by post, will be processed promptly and securely, with the same level of diligence and care as electronic ones

Home Delivery and Courier Services:

1.27 Medications will be delivered to patients' homes using a reliable courier service that ensures secure, trackable, and timely delivery across England. We will maintain partnerships with reputable courier services that guarantee consistent delivery times, even during high demand or peak periods.

1.28 For urgent or emergency prescriptions, we will offer expedited delivery options to ensure patients receive their medications without delay.

Safe and Effective Provision of Services Without Face-to-Face Contact

1.29 To ensure the safe and effective provision of essential services without the need for face-to-face contact, we will implement the following:

Remote Consultations:

1.30 All consultations, including those related to medication advice, will be conducted remotely through secure video calls, telephone calls, or via encrypted messaging on our website. This ensures that patients can access the advice they need without visiting the premises.

1.31 Pharmacists will be available to provide remote consultations during operating hours, ensuring that patients receive personalized care and attention.

GDPR-Compliant Systems:

1.32 We will use secure systems that comply with **GDPR** regulations to handle patient data and communication. Patients' personal and health information will be protected with encryption and other data security measures.

1.33 Patients will have access to their prescription and consultation records through a secure portal.

Contactless Prescription Ordering and Delivery:

1.34 All aspects of prescription handling, from submission to delivery, will be contactless.

1.35 Patients can upload or send their prescriptions electronically, and medications will be dispatched to their homes with no physical interaction between patients and pharmacy staff.

1.36 For repeat prescriptions, patients will be able to manage their orders online, further minimizing the need for any contact.

Emergency Support:

1.37 In the event of an emergency or if a patient needs urgent advice, we will have a dedicated phone line and email system to offer immediate assistance, ensuring that patients can reach us and receive the care they need without visiting the pharmacy.

7.2 Procedure When a Patient Attends the Premises to Request Essential Services

1.38 As a distance selling pharmacy, we do not offer any face-to-face for essential services on the premises. However, should a patient mistakenly attend the premises, the following procedure will be followed:

Informing the Patient:

1.39 The patient will be courteously informed by a member of staff that we are a distance selling pharmacy and that all essential services are provided remotely. We will explain that, in accordance with our operating model and regulatory requirements, we cannot dispense medications or offer consultations on the premises.

Offering Remote Assistance:

1.40 The staff member will guide the patient on how to access our services remotely.

1.41 This may include:

1.41.1 Providing them with information on how to submit their prescription via our website or EPS.

1.41.2 Directing them to our online platform or providing the contact details for our customer service line, where they can receive remote assistance.

1.41.3 Explaining the process for home delivery of their medication.

Emergency or Urgent Situations:

1.42 If the patient is in urgent need of medication or health advice, the staff will assist by directing them to the nearest appropriate pharmacy or healthcare provider that offers face-to-face services.

1.43 If necessary, we will contact the patient's GP or other relevant healthcare professionals to ensure they receive timely assistance.

7.3 Provision of Advanced Services Without Providing Any Element of Essential Services

1.44 We undertake to provide advanced services at the premises, such as Pharmacy First, New Medicine Service (NMS) and Flu Vaccinations, we will ensure that these services are offered distinctly from essential services by following these guidelines:

Remote Advanced Services:

1.45 Nearly all advanced services such as Pharmacy First or NMS will be provided remotely through video consultations, telephone consultations, or secure messaging platforms. This ensures that the patient does not need to attend the premises for any element of the service, and we remain compliant with our distance selling model.

1.46 However, for advance services such as flu vaccinations we will need the patient to attend the premises and explain the reasoning behind this. Hence the consultation room is separate to the dispensing area so that patients do not get confused, and this can easily be explained.

Distinct Appointment System for Advanced Services:

1.47 We will use a separate, appointment-based system for advanced services. Patients will be able to book a time slot for their remote consultation, and this will be handled separately from any essential services such as medication dispensing or health advice.

1.48 The pharmacist offering advanced services will have dedicated time to focus solely on these services, ensuring no overlap with the provision of essential services.

Remote Monitoring and Follow-Up:

1.49 Where advanced services require follow-up, such as monitoring the patient's adherence to a new medication, this will also be handled remotely. Patients will

be able to communicate with the pharmacist via phone or video call to report their progress and receive ongoing advice.

Records and Documentation:

1.50 Records of advanced services provided will be kept separately from essential service records, ensuring that the two service types remain distinct. This helps ensure that we meet the requirements for providing advanced services without inadvertently offering essential services through the same processes.

1.51 By structuring our operations this way, we can provide both essential and advanced services effectively within the constraints of a distance selling pharmacy model, ensuring that all services are delivered remotely, and that patient safety and service continuity are maintained."

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 your correspondence dated 23 September 2025, in relation to our abovementioned application.

2.1.2 We note that there have been representations made by Community Pharmacy Arden in their correspondence dated 06 August 2025 and by Southam Pharmacy in their correspondence dated 11 September, respectively, opposing our application on various grounds. Upon review of these representations, we respond as follows:

Community Pharmacy Arden – Letter dated 06 August 2025;

2.1.3 Firstly, turning to the correspondence by Community Pharmacy Arden (CPA), who alleged in their correspondence that our proposed services are in contravention of regulation 25 (2) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, particularly in relation to the following subclauses:

"*25 (2) The NHSCB must refuse an application to which paragraph (1) applies— (a) if the premises in respect of which the application is made are on the same site or in the same building as the premises of a provider of primary medical services with a patient list; and*

(b) unless the NHSCB is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure:

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

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

Regulation 25(2)(a)

2.1.1 We can confirm Regulation 25(2)(a) is not relevant in these particular circumstances, as our business does not fall within a premises noted in this subsection.

2.1.2 We submit that, the provision is **not applicable** to this application, as the pharmacy premises are not situated on the same site, nor in the same building, as the premises of a provider of primary medical services with a patient list.

2.1.3 We can confirm that the premises are **wholly separate from any provider of primary medical services with a patient list**, designed exclusively for the operation of a Distance Selling Pharmacy (DSP), and not co-located with or within any GP surgery or other provider of primary medical services.

2.1.4 We therefore submit that Regulation 25(2)(a) does not apply, and the application should be considered solely under Regulation 25(2)(b).

Regulation 25(2)(b)

2.1.5 Turning to Clauses 25 (2) (b) (i) and (ii) respectively, which confirm that our services must adhere to these subsections in order for the NHSCB to satisfy themselves that our services have merit and our application should indeed be accepted. These allegations are also very similar to the concerns raised by Southam Pharmacy in their correspondence dated 11 September and therefore, in an effort to avoid duplication, please see below our responses in relation to these particular allegations.

Southam Pharmacy- Letter dated 11 September 2025

2.1.6 Southam Pharmacy, have confirmed we must satisfy NHSE that all the regulatory requirements have or will be met and the application must be refused unless the NHS England Committee is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure, and citing Regulation 25(2)(b) –

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

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

2.1.7 We shall respond to each concern in turn, referencing the particular Standard Operating Procedures (SOPs) we have in place and thus ensuring that the legal test is satisfied, and our service practices are in line with the highest standards in accordance with the NHSE requirements.

Regulation 25(2)(b)(i): Uninterrupted Provision of Essential Services

2.1.8 As such, turning firstly to Regulation 25(2)(b)(i) where we note the objection raised here is that we have not demonstrated that essential services can be provided **uninterrupted, nationwide, without face-to-face contact**. Please note, we set out in detail below how this requirement is indeed fully satisfied, by embedding the pharmacy's Standard Operating Procedures (SOPs).

Dispensing of Prescriptions – EPS & Nominations **(SOP 8, 9 & 30)**

2.1.9 These SOP's explicitly states the following:

"Prescriptions cannot be handed directly to patients on pharmacy premises. All NHS prescriptions are obtained electronically via the Electronic Prescription Service (EPS) through patient nomination. Patients nominate Medicare Chemist as their chosen pharmacy remotely (via the NHS app, GP practice, or directly with the pharmacy) without the need for face-to-face contact. Once prescriptions are received electronically, they are processed within the Patient Medication Record (PMR) system in accordance with EPS2 standards."

"Patients are contacted by telephone, email, or secure message for counselling, clinical queries, or to confirm delivery arrangements. At no stage are patients required to attend the pharmacy premises."

2.1.10 This, therefore, demonstrates compliance with DSP regulations by ensuring prescriptions are only accessed **electronically** and without in-person interaction. Further, having these measures in place also satisfies the requirement under the statute to ensure that our procedures are in line with the relevant legal requirements of practice.

Urgent Supply - (SOP 13)

2.1.11 Moreover, the Emergency and Urgent Supply of Prescription Only Medicines (POM) SOP sets out clear, robust procedures which will be in place to ensure that no face – to- face contact is carried out in the following ways:

"Urgent supplies are handled through direct patient requests received by phone, website form, or email. Identity is verified before processing.

Where an EPS prescription can be arranged with the prescriber, this is dispensed immediately and dispatched using either same-day courier (local delivery) or Royal Mail Special Delivery (nationwide). Where appropriate under the Human Medicines Regulations, an emergency supply may be made at the pharmacist's discretion, following completion of the structured remote questionnaire and professional clinical judgement."

*"**No face-to-face interaction occurs**. Patients are counselled remotely, and medicines are delivered using validated couriers ensuring secure, uninterrupted supply."*

2.1.12 This directly addresses concerns that the respondents may have in relation to our practices, particularly regarding urgent supplies, ensuring timeliness and compliance with legal requirements.

Controlled Drugs Delivery - (SOP 19)

2.1.13 We also believe that the Controlled Drugs Delivery SOP, is also relevant in addressing the respondent's concerns. Please note, this SOP states in full the following:

"If a Controlled Drug (CD) is included, phone the patient beforehand to confirm they are in. The driver should sign the delivery sheet with the script to complete the audit trail. The driver's name and 'delivery' is written in the CD register as the person collecting the medication. If delivery is unsuccessful, the CD is returned to the pharmacy, booked back into the CD register and signed out again on retry. CDs are always packaged separately from other medication and a CD sticker attached to the bag. The items are placed in a coded locked safe box within the vehicle to keep them secure. Additionally, all vehicles are locked each time the driver leaves. The type of vehicle used is always a van with no rear windows, minimising any potential break-in risk."

"CD deliveries carried out via Royal Mail use the Tracked 24 service, providing flexibility for patients to monitor delivery. Patients are notified by telephone before dispatch and receive a tracking link. Daily online checks are carried out to confirm delivery signatures and statuses. Any failed deliveries are returned immediately to the pharmacy for re-entry into the CD register."

2.1.14 This ensures CDs are handled safely, securely, and lawfully, maintaining an auditable trail.

2.1.15 Again, demonstrating that we have robust practices in place to ensure that the service we are providing is effective, efficient and serves patients without the need to provide face-to-face services.

Cold Chain Medicines Packaging & Delivery - (SOP 14 & 15)

2.1.16 Further, The Bagging Up and Delivery Order SOP's provides detailed controls in relation to the packaging and the service maintenance of our offerings, for example:

"Refrigerated medicines (fridge lines) are packaged using validated insulated containers with corrugated liners, thermal barriers, and ice packs, maintaining a temperature range of 2–8°C for the full duration of transit. Couriers used are audited to ensure compliance with pharmaceutical cold chain standards."

"Packages are labelled 'Store in refrigerator 2–8°C' and tracked electronically. If delivery is unsuccessful, the courier leaves a missed delivery card and medicines remain in the cold chain until redelivery. If any breach of the 2–8°C temperature range occurs, the courier alerts the pharmacy immediately. Medicines exposed to excursions are quarantined and destroyed in accordance with the Waste Medicines SOP."

"Cold chain items remain in the pharmacy refrigerator until just before handover to courier or driver, minimising time out of refrigeration. Patients are provided with information leaflets on home storage requirements."

2.1.17 Therefore, demonstrating that our robust systems ensure cold chain integrity and patient safety, which will always be at the forefront of our offering, and offering both legal and regulatory compliance.

Regulation 25(2)(b)(ii): Safe and Effective Provision Without Face-to-Face Contact

2.1.18 Moving on to address the concerns in relation to the Responders objections, namely that we have not demonstrated how safe and effective services are provided without face-to-face contact. This is not accepted, and we confirm that this is explicitly addressed in multiple SOPs, each of which embeds DSP regulatory requirements.

2.1.19 To address these concerns, we shall discuss the relevant SOP's in place to ensure strict compliance with regulatory requirements at all times, ensuring our services are not compromised and patients still receive the best level of care and assistance required to meet their needs.

2.1.20 **Patient Consultation & Identity Verification - (SOP 3)**

2.1.21 To ensure effective onboarding, and the ensure we are providing the correct level of patient service, the **Procedures for NHS Essential Services & Advanced and Enhances Services and Contacting Patients by Phone or Email SOP** is in place and which states:

"All consultations, whether for essential, advanced, or enhanced services, are carried out remotely via encrypted telephone or secure video call. Identity verification is mandatory before the consultation begins, using at least two identifiers (e.g., name, date of birth, address, or NHS number). Patients are informed that no consultations are carried out on the DSP premises and that all interactions take place remotely."

"Clinical pathways requiring visual assessment are conducted by secure video link, using a link sent via the patient's preferred contact method. For minor illnesses that do not require visual examination, telephone consultation is used. The system ensures confidentiality, auditability, and compliance with NHS DSP guidance."

2.1.22 This ensures patients are properly identified and that care is delivered **without face-to-face interaction**, satisfying the required DSP regulations.

Structured Remote Questionnaires - (SOP 5 and 9)

2.1.23 The **Online Ordering & Exemption Checking and EPS2 Nomination and Information SOP** further confirms:

"Patients complete structured digital questionnaires via the website or app before consultations. These questionnaires capture medical history, current medicines, allergies, safeguarding information, and lifestyle factors (e.g., smoking, alcohol, exercise). The system prevents incomplete submissions and flags high-risk responses to the pharmacist for followup."

"These replace the traditional WWHAM questions and provide a consistent, auditable, and legally compliant data capture process that can be reviewed within the PMR system."

2.1.24 This clearly demonstrates that we have safe and effective assessments in place and these are possible without the need for face-to-face interactions.

2.1.25 **Remote Counselling and Advice - (SOP 3, 8 & 21)**

2.1.26 These **SOPs** provides:

"Following clinical and accuracy check, patients are contacted by telephone or secure video link for counselling. Information provided includes dose, frequency, administration, side effects, interactions, and safe storage requirements. Where counselling is declined, a record is made in the PMR."

"For fridge lines and CDs, additional advice is given on secure storage and safe disposal. Patients are also provided with written information leaflets sent electronically or included with delivery."

2.1.27 This ensures continuity of care and safeguards equivalent to, or stronger than, traditional face-to-face counselling, thus confirming that our offerings go above and beyond the requirements and we are committed to ensure our offerings do not fall below the legal tests in place to ensure patient safety is not compromised.

Discharge Medicine Service- "DMS" (SOP 33)

2.1.28 The DMS SOP ensures safe transfer of care from hospital to home, entirely remotely:

"Referrals are received via NHSmail, PharmOutcomes, or other approved NHS referral platforms. Patients or carers are contacted by telephone to confirm identity and explain the service. No walk-in or face-to-face referrals are accepted in compliance with DSP requirements."

"Counselling is delivered via secure telephone or video consultation. Content includes: indication, dose, frequency, administration; side effects, interactions, missed doses; changes compared to pre-admission regimen; storage and disposal requirements. Written information leaflets are provided electronically or sent with deliveries."

2.1.29 This prevents any interruption in medicines supply post-discharge, with remote support fully embedded, to ensure patient care is not compromised.

Advanced & Enhanced Services - (SOP 3)

2.1.30 The Respondents also raised a concern that we have not explained how advanced or enhanced services are provided, nor provided sufficient clarity on how Advanced and Enhanced services will be provided **without face-to-face contact**. We can confirm this is directly addressed in the SOPs, which explicitly incorporate DSP regulations.

2.1.31 We trust the below extracts from our SOP's will further demonstrate how each service is safely and effectively provided in line with DSP regulations and NHS England service specifications, as well as not compromising the legal tests in place under the relevant subsection 25(2)(b) respectively.

Pharmacy First - (SOP 3)

2.1.32 From the **SOP, you will note that this SOP confirms**:

"Consultations are provided remotely via secure video call as arranged with the patient (no face to- face at DSP premises). Consultations may be conducted via video or telephone, depending on clinical need and pharmacist discretion, e.g., clinical pathways and minor illnesses. Other pathways must be provided via video call. Video calls are generally conducted via a secure link sent to the patient."

"Where clinically appropriate, an EPS token is generated for the correct medication/treatment. Medicines are supplied via national courier service or local delivery. Patients unsuitable for remote management are signposted to appropriate NHS services."

"Patients contact the pharmacy via phone, website, or email. Identity verification is conducted before any consultation."

"Consultations are conducted remotely via secure video call or, where clinically appropriate, telephone. Clinical pathways requiring video consultation are followed precisely."

"Where treatment is indicated, electronic prescriptions are issued and medicines dispatched via national courier. Where face-to-face assessment is needed, patients are referred to NHS 111, GP, or urgent care services."

2.1.33 This demonstrates Pharmacy First can be fully delivered remotely, in compliance with DSP rules ensuring **timely, safe, and regulation-compliant care** under the NHS Pharmacy First Service Specification (2025) for all patients accessing our services.

2.1.34 **New Medicines Service (NMS) - (SOP 3)**

2.1.35 From the **SOP**:

"Eligible patients are identified via EPS nomination or GP referral. Initial consultation is provided remotely via encrypted telephone or video call. Follow-up consultations are arranged and documented, with no requirement for patients to attend DSP premises. Outcomes are recorded in the PMR and reported via the MYS portal."

"Eligible patients are identified via EPS nomination or GP referral. Pharmacists confirm eligibility remotely by cross-checking prescription data and verifying patient identity by telephone or video consultation."

"The initial consultation is provided via encrypted telephone or video call. The pharmacist records all details in the PMR, including clinical checks, advice given, and patient understanding. A follow-up call is arranged, documented, and undertaken within agreed timelines."

"Patients unsuitable for remote management are referred back to their GP or a community pharmacy providing face-to-face services."

2.1.36 This shows NMS can be delivered securely and effectively without face-to-face contact, ensuring patients receive structured support **without face-to-face contact**, with outcomes reported via the MYS portal, satisfying NHS requirements.

2.1.37 **Contraception Service - (SOP 3)**

2.1.38 Please note the below extract from the **SOP,** which confirms:

"Remote eligibility and safeguarding checks are carried out via secure video call. Counselling and clinical assessment are conducted remotely, with prescriptions issued electronically and medicines supplied via national courier. If physical measurements (e.g., blood pressure, BMI) are required, patients are referred to a local provider."

"Identity verification is mandatory before supply. Safeguarding concerns are escalated in line with NHS guidance."

"All eligibility and safeguarding checks are conducted via secure video call, using structured clinical assessment forms embedded in the PMR."

"Where a physical measurement (e.g., blood pressure, weight, BMI) is required, patients are signposted to an appropriate healthcare professional. Supplies are only issued once full eligibility criteria are satisfied."

"Prescriptions are issued electronically, and medicines are supplied via national courier in accordance with the Delivery SOP."

2.1.39 This ensures the service is compliant, safe, and accessible nationwide, guaranteeing **compliance with DSP restrictions**, while still providing a safe and accessible national service, which is fundamental for the services we provide patients.

Flu Vaccination - (SOP 3)

2.1.40 The **SOP,** confirms:

"Until 31 March 2026, flu vaccinations may be administered on DSP premises under NHS transitional rules. After this date, patients will be signposted to other service providers. Eligibility and consent checks are carried out remotely, and cold chain procedures are strictly maintained."

"Until 31 March 2026, flu vaccinations may be administered on DSP premises under NHS transitional rules. After this date, all patients are referred to external face-to-face providers."

"Eligibility and consent are checked remotely, and vaccination data is recorded in the PMR and reported via MYS."

"Cold chain vaccines are managed in line with the Cold Chain SOP, ensuring compliance with MHRA requirements."

2.1.41 This confirms compliance with **current transitional rules** while future-proofing the service in line with DSP regulations. This ensures compliance with transitional rules and DSP restrictions.

Smoking Cessation - (SOP 3)

2.1.42 From the **SOP**:

"Electronic referral is received from secondary care. Behavioural support is provided remotely by trained pharmacists via telephone or video. Nicotine replacement therapy is supplied via national courier. Where CO monitoring is required, patients are signposted to local providers."

"Patients are referred electronically from secondary care into the pharmacy's secure system."

"Behavioural support is delivered via scheduled telephone or video consultations, with records of each session entered into the PMR."

"Nicotine replacement therapy (NRT) is supplied via tracked delivery. If Carbon Monoxide (CO) monitoring is required, patients are referred to local face-to-face providers."

2.1.43 This demonstrates the service can be safely and effectively delivered without face-to-face interaction, and further, demonstrate **safe and effective delivery** without on-site patient attendance.

Essential Services - (SOP 3)

2.1.44 The Respondents have raised concerns that we have not explained in sufficient detail how essential services will be delivered safely, effectively, and without face-to-face contact. Below we set out each essential service, embedding detail from the SOPs, and demonstrating compliance with **Regulation 25(2)(b)(i)–(ii)** and **DSP regulations,** which we trust is satisfactory for your purposes.

Dispensing of Medicines and Repeat Dispensing - (SOP 8 & 9)

2.1.45 The **SOPs** makes clear that:

"Patients cannot attend the DSP premises to present paper prescriptions or collect medicines. All prescriptions are received electronically via EPS nomination, GP referral, or secure transfer from prescribing systems. This ensures prescriptions are obtained without face-to-face contact, in full compliance with DSP regulations."

"EPS nominations are managed remotely. Patients are supported via telephone or secure online channels to complete nomination requests. Once confirmed, prescriptions are downloaded electronically by the pharmacy without any physical attendance by the patient."

"Before dispensing, prescriptions undergo clinical screening by the pharmacist, accuracy checking by an ACT, and packaging in line with the Delivery SOP. Patients are then contacted by telephone or secure video for counselling."

2.1.46 This ensures medicines can be dispensed nationally without patient visits to the DSP premises, ensuring that we do not fall foul of our responsibilities both towards patients as well as our regulatory requirements.

Urgent Supply - (SOP 13)

2.1.47 The **SOP** provides:

"Where an urgent supply is requested, the pharmacist conducts a structured remote consultation using the online questionnaire or secure telephone call. The consultation records: patient identity, reason for urgency, medical history, and suitability of supply."

"If supply is clinically appropriate, an EPS prescription is generated (where authorised) and medicines are dispatched via same-day courier (local) or national tracked courier with temperature control as required. Patients are informed of delivery timelines, and counselling is provided by telephone prior to dispatch."

"If urgent supply cannot be safely made, patients are referred to an appropriate NHS service such as NHS 111, GP out-of-hours, or urgent care centre. This ensures uninterrupted access to care without face-to-face pharmacy attendance."

2.1.48 This satisfies DSP requirements that urgent supply is provided promptly and safely, and therefore adheres to the processes and requirement.

Disposal of Unwanted Medicines - (SOP 21)

2.1.49 The **SOP** states:

"Patients request medicine returns via telephone, website, or app. A secure container is delivered to the patient for collection of unwanted medicines, which is then retrieved by courier or local driver."

"Controlled drugs returned by patients are recorded in the CD Register, quarantined, and destroyed in the presence of an authorised person, in line with CD disposal regulations."

2.1.50 This ensures disposal is offered nationally, in compliance with essential services, and without face-to-face pharmacy contact.

Healthy Lifestyle Promotion and Public Health Campaigns - (SOP 23)

2.1.51 The **Healthy Lifestyle & Public Health Campaigns SOP** provides:

2.1.52 *"The pharmacy participates in all required NHS England public health campaigns. Information is delivered via prescription leaflets, website content, app notifications, and email newsletters."*

"Campaign resources are included with deliveries (e.g., smoking cessation leaflets with NRT, diabetes management leaflets with metformin). Additional advice is offered remotely by telephone or secure video consultation."

"Service users across England are targeted by reviewing PMR records to identify at-risk groups (e.g., smokers, overweight patients, those with diabetes or hypertension). These patients are contacted proactively to provide tailored advice."

2.1.53 This ensures campaigns are fully delivered across England without face-to-face contact, without compromising NHS Terms of Service.

Signposting - (SOP 22)

2.1.54 The **SOP** provides:

"Where a patient's needs fall outside the scope of pharmacy services, patients are remotely signposted to NHS 111, GP practices, sexual health clinics, or other relevant services. Records of signposting are logged in the PMR system."

2.1.55 This SOP is in place, to ensure continuity of care without physical attendance at DSP premises thus not compromising the service provided to patients, and again, adhering to regulatory requirements.

Support for Self-Care - (SOP 22)

"Self-care support is provided remotely via structured questionnaires, telephone advice, or video consultations. Where OTC medicines are appropriate, they are supplied in accordance with the Sales of GSL and P Medicines SOP, which requires pharmacist approval for all nonroutine supplies. Where supply is inappropriate, the patient is advised and referred accordingly."

2.1.56 Again, this further ensures compliance with essential service requirements, ensuring we adhere to the best practices in line with NHS requirements.

Controlled Drugs & Cold Chain Medicines - (SOP 15 & 19)

2.1.57 For the purposes of confirming our compliance with Regulation 25(2)(b)(ii), we note that the Responders expressed concern that no detail was provided on controlled drugs (CDs) or cold chain deliveries. These are explicitly covered in the SOPs, and we will address these further below in line with the above.

Controlled Drugs - (SOP 19)

2.1.58 The **SOP** provides:

"All CD deliveries must comply with legal requirements, be clearly marked, and remain under the pharmacist's and Responsible Pharmacist's control until handover to the driver or courier."

"The delivery record must include 'CD' and a note that delivery must occur within 28 days of the prescription date. Safe custody is maintained at all times, including locked storage during transport."

"The recipient must provide proof of identity (passport, driving licence, or NHS-standard digital verification). The patient, or authorised representative, must sign for receipt. If delivery is unsuccessful, CDs are returned to the pharmacy immediately and stored in the CD cabinet."

2.1.59 This confirms that the CDs are delivered legally, securely, and safely nationwide, ensuring both compliance and patient care.

Cold Chain Medicines - (SOP 15)

2.1.60 The **SOP** provides:

"Refrigerated medicines are packaged using validated insulated systems (e.g., Puffin or equivalent) with corrugated liners, ice packs, and thermal barriers to maintain 2–8°C for the full transit period. Each system is validated to ensure stability during transport times."

"Cold chain items are stored in the pharmacy refrigerator until immediately before dispatch. Couriers are required to scan packages on collection, and patients receive live tracking details."

"If delivery is unsuccessful, cold chain items remain within the validated insulated system and are returned to the pharmacy the same day. If a breach of the 2–8°C range occurs, medicines are quarantined, not reused, and destroyed in line with waste SOPs."

"Patients are counselled remotely on correct storage on receipt (2–8°C) and advised not to use medicines that have been exposed to inappropriate temperatures."

2.1.61 This ensures cold chain compliance, safeguarding patient safety and alignment with national standards, again, demonstrating compliance..

Delivery Systems and Nationwide Coverage - (SOP 14 & 15)

2.1.62 The **SOP** specially states:

"Medicines are dispatched via Royal Mail Tracked 24 service or equivalent national courier, ensuring delivery to all addresses in England. All items are dispatched with live tracking links sent to patients. For high-risk or urgent deliveries, same-day courier services are used where available."

"If delivery is unsuccessful, items are returned to the pharmacy the same day. Controlled Drugs are re-entered into the CD register, while cold chain items are quarantined pending review. A second delivery attempt is arranged at patient convenience. This ensures patients never lose access to medicines due to a failed delivery."

2.1.63 This guarantees **uninterrupted provision** by combining reliable national courier infrastructure with internal audit trails, confirming that we have systems in place to ensure the security of our courier services to ensure products are delivered to patients in a timely manner, as well as ensuring products are not compromised in the delivery of our services.

Business Continuity and Service Resilience - (SOP 32)

2.1.64 Further, our **Business Continuity SOP** provides the following:

"Essential services are maintained during staff absences, IT outages, or supply chain disruptions. Cloud-based PMR systems ensure remote access for pharmacists to process EPS prescriptions. A backup pharmacy premises agreement is in place to cover emergencies."

"Deliveries are routed via multiple national couriers to avoid disruption if one provider fails. Daily monitoring of courier status ensures early detection of delays."

2.1.65 This demonstrates that we have acknowledged limitations and put in place processes which will enable services to continue, with minimal interruption, satisfying **Regulation 25(2)(b)(i)**.

Patient Communication - (SOP 4)

2.1.66 Our SOP's also address communication channels with patients, to ensure a streamlined service, this includes:

"Patients are contacted via telephone, SMS, or secure email to confirm prescription receipt, expected delivery date, and counselling as required. Counselling is repeated if a patient cannot be contacted initially. A record of contact is logged in the PMR."

2.1.67 This proactive communication ensures no patient is left without information or support, even if deliveries are delayed.

Delivery Audit Trail - (SOP 15 &19)

2.1.68 We have in place a **SOP**, which requires:

"Every dispatched package is recorded in the Delivery Log, linked to the patient's PMR entry. This includes prescription details, packaging used, courier reference, tracking number, and name of staff member dispatching."

"For Controlled Drugs, the driver signs the delivery sheet and their name is recorded in the CD register as the collecting party. On delivery, the patient (or authorised representative) signs electronically. If undelivered, the CD is immediately returned, logged back into the register, and signed out again for re-delivery."

2.1.69 By having this in place, this ensures a full audit trail for all medicines, minimising risk of diversion or loss of our supplies.

Cold Chain Monitoring - (SOP 15)

2.1.70 We have also put in place the **SOP,** which confirms the following:

"Each insulated system contains an integrated data logger which records the internal temperature during transit. On delivery, patients are advised to check the temperature monitor to confirm compliance with 2–8°C storage. If readings show deviation, the medicine is not used and is destroyed."

2.1.71 This affords safety and transparency in temperature-controlled deliveries. Further reinforcing our robust systems, ensuring patient care and our safety compliance are adhered to.

Patient Safety and Governance - (SOP 24)

2.1.72 We have also implemented the **Near Miss & Error SOP,** which provides that:

"All near misses and dispensing errors are logged and reviewed weekly. Monthly reviews are conducted with the Superintendent Pharmacist to identify trends and implement corrective actions."

"Training records confirm staff have read, understood, and agreed to follow SOPs. Refresher training is delivered annually and after any critical incident."

2.1.73 By implementing this SOP, this guarantees a culture of continuous safety improvement. Further strengthening our commitment to ensuring patient safety and compliance.

2.1.74 In conclusion, having reviewed the Responders reservations, and considered their allegations at length, we have demonstrated our commitment to offer patients a dedicated, robust and confirmations of our reasonings and confirmed that our internal SOP's confirm that we uphold systems and have put in place practices, which are in line with and adhere to both patient care and our regulatory responsibilities towards our obligations under the legal framework.

2.1.75 Therefore, we are of the view that our application satisfies the legal test, namely that our intended processes do indeed secure (i) the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and (ii) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff. Therefore, adhering to both relevant limbs of the legal test. The SOPs confirm out dedication and commitment to providing patients with a streamlined service, in a DSP capacity, and will ensure ongoing commitment towards compliance. Attached are copies of the relevant SOP's for your perusal. As such, we are of the view that our application should be approved by NHSE.

2.1.76 We trust the above is sufficient for your purposes and look forward to your confirmation that our application has now been approved."

2.2 Enclosed with the letter were SOPs dated "Version 1 – July 2025". [These have been superseded by the SOPs as provided with representations.]

3 The Decision

The Commissioner considered and decided to grant the application. The decision letter dated 20 November 2025 states:

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

3.1 "Coventry and Warwickshire ICB has considered the above application and I am writing to confirm that it has been granted. Please see the enclosed report for the full reasoning.

3.1 The report details the conditions that will be placed upon your inclusion in the relevant pharmaceutical list should a valid notice of commencement be received. Enclosed is a form confirming acceptance of these conditions. It should be completed by an authorised person and returned to me with your notice of commencement."

Extract from the PSRC Meeting of 5th November 2025

3.2 "Distance Selling Premises – excepted application

3.3 CAS-340125-M4X9S1

3.4 Medicare Connect Ltd - 52 Coventry Street, Southam, Warwickshire, CV47 0EP

Decision:

3.5 The committee decided that the application is granted. Regulation 25 and all subsections of this regulation are met as per the report. Regulation 31 does not apply. Regulations 31(i),31(ii) does not apply.

3.6 Regulation 25(2)(a) – The proposed premises are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

3.7 The applicant did not provide details within the application form, however the proposed premises are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

3.8 This is confirmed with information available on the NHS.UK website where the nearest general practice is located 0.2 miles away.

3.9 This regulation is deemed to have been met.

3.10 Regulation 25(2)(b)(i) – The Pharmacy Procedures indicate that the service will be provided as uninterrupted provision of pharmaceutical services, during the opening hours of the premises, to persons anywhere in England who request those services.

3.11 This regulation is deemed to have been met.

3.12 Regulation 25(2)(b)(ii) – The pharmacy procedures and detailed SOPs provided appear to meet the standard required to satisfy the regulatory requirements of the provision of pharmaceutical services without face to face contact.

3.13 This regulation is deemed to have been met.

3.14 Regulation 31 – refusal: same or adjacent premises [quoted in full]

3.15 Regulation 31(1) The application is a for Distance Selling premises, therefore Regulation 31(2) needs to be considered.

3.16 Regulation 31(2)(a)(i)(ii) There is no pharmacy providing pharmaceutical services at the same or adjacent premises.

3.17 This regulation therefore does not apply.

3.18 As Regulation 31(2)(a) does not apply, the committee is not required to consider Regulation 31(2) (b)

3.19 Therefore, the committee is not required to refuse the application under the provisions of Regulation 31.

3.20 Who has right of appeal: Southam Pharmacy, please see below."

"Specific conditions – Distance Selling Premises

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

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

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

3.21.3 The proposed premises must not be on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

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

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

3.21.4.2 the safe and effective provision of pharmaceutical services without face-to-face contact at the proposed 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; and

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

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

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

4 The Appeal

In a letter dated 28 November 2025, Rushport Advisory LLP on behalf of Southam Pharmacy ("the Appellant") appealed against the Commissioner's decision. The grounds of appeal are:

4.1 "I act for Southam Pharmacy which operates a pharmacy at 4 Market Hill, Southam and have been instructed by my client to submit this appeal against the decision of the Commissioner to approve the above listed application made by Medicare Connect Ltd.

4.2 The application falls to be considered under regulation 25 of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

4.3 It is for the Applicant to satisfy the decision maker that all regulatory test has or will be met and the application must be refused unless the Committee is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure –

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

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

4.4 The Commissioner's Decision Report provides no intelligible reasons for approving the application. Instead, the report simply states that the various aspects of the legal test have been met without any discussion of how the Applicant has met the test. It is possible that the Applicant has submitted additional information that neither I nor my clients have had sight of and this appeal can only focus on the information that we have seen.

4.5 The Applicant has indicated that they provide enhanced or advanced services but has not been clear how these will be provided without face to face contact.

4.6 Whilst the Applicant has provided some commentary on their processes and procedures, they are silent on a significant number of parts of the relevant legal test such as Urgent Supply, or the provision of live video consultations.

4.7 In relation to providing services which are safe and effective, the Applicant has likewise provided insufficient detail to enable the Committee to be satisfied that all pharmaceutical services provided would be both safe and effective. No information is provided in relation to matters such as the delivery of controlled drugs.

4.8 In this case, we submit that the Committee cannot be satisfied that the legal test is met and the application should therefore be refused."

5 Summary of Representations

This is a summary of representations received on the appeal.

5.1 THE APPLICANT

5.1.1 "Thank you for your correspondence dated 22 December 2025, where you have confirmed the decision to approve our application has been disputed by Southam Pharmacy.

5.1.2 Firstly, referring to Regulation 31 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the "Regulations"), which states that:

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

(2) This paragraph applies where—

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

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

(ii)adjacent premises; and

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

5.1.3 We can confirm this Regulation does not apply in this instance, as our pharmacy is a Distance Selling Pharmacy ("DSP") and further, there is no other pharmacy located in the same or adjacent premises. Therefore Regulation 31 (1) does not apply, and on this basis Regulation 31 (2) is

also not applicable. As such, the Committee is directed to take this into account for the purposes of this appeal.

5.1.1 Further, for the avoidance of doubt, referring to your point in your correspondence, where you have mentioned Section 129 (2A- 2B) of the National Health Service Act 2006 Act (NHSA 2006), it is our view that these subsections also do not apply in this instance, as we are applying to be added to the list, and our pharmacy is a DSP applying for a new contract as new applicants. As such, this application must be assessed solely by reference to the criteria applicable to distance-selling pharmacies under the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, and not by reference to local pharmaceutical need, proximity, or impact on existing providers.

5.1.2 Now turning to, the further representations made by Southam Pharmacy, represented by Rushport Advisory, in their correspondence dated 28 November 2025, opposing the success of our application on various grounds. Upon review of these representations, we respond as follows:

5.1.3 It is alleged that our application does not meet the legal test as set out in Regulation 25 of the Regulations. Namely, that in order for an application to be approved, we must prove the grounds as set out in Regulation 25 (2) (b) of the Regulations, have been met, thus satisfying the legal test.

5.1.4 Regulation 25 (2) *(b)* confirms:

"… unless the NHSCB is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure:

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

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

5.1.5 The respondent alleges that the Commissioner's Decision Report provides no intelligible reasons for approving the application, on the following basis:

5.1.5.1 The report simply states that the various aspects of the legal test have been met without any discussion of how the Applicant has met the test;

5.1.5.2 The Applicant has indicated that they provide enhanced or advanced services but has not been clear how these will be provided without face to face contact;

5.1.5.3 Whilst the Applicant has provided some commentary on their processes and procedures, they are silent on a significant number of parts of the relevant legal test such as Urgent Supply, or the provision of live video consultations;

5.1.5.4 In relation to providing services which are safe and effective, the Applicant has likewise provided insufficient detail to enable the Committee to be satisfied that all pharmaceutical services provided would be both safe and effective. No information is provided in relation to matters such as the delivery of controlled drugs.

5.1.6 For the avoidance of doubt, Regulation 25 (2) (a) does not apply to our application, as the DSP is not on the same site or in the same building as a premises of a provider of primary medical services with a patient list.

5.1.7 Turning to the above further concerns raised by the respondent we note that the respondent generally queries whether all of our procedures and practices will be both safe and effective. We are of the view that our Standard Operating Procedures (SOPs), as supplied previously, adequately deal with and address these concerns. These SOP's have been put in place to ensure that our procures and practices allow for the safe, suitable and effective supply of pharmaceutical services to patients without compromising on the quality and care we will provide.

5.1.8 The respondent alleges that they have not had sight of the information relating to why our application successfully meets the legal test. We shall address each concern, again, referencing the particular SOPs we have in place and which affirm the legal test has indeed been satisfied, and our service practices are in line with the highest standards in accordance with the NHSE requirements, and therefore, the decision to approve our application should be upheld. We trust this will also provide the respondent with the assurance that our pharmacy will have robust provisions in place to ensure we do not compromise on the level of care and service required to ensure patients are given the best level of service at all times.

Regulation 25(2)(b)(i): Uninterrupted Provision of Essential Services

5.1.9 As such, turning again to Regulation 25(2)(b)(i) where we note the objection raised here is that we have not demonstrated that essential services can be provided uninterrupted, nationwide, without face-to-face contact. Please note, we set out in detail below, once more, how this requirement is indeed fully satisfied, by embedding the pharmacy's SOPs. A full copy of our SOPs are also provided again, with this correspondence [see Appendix A].

Dispensing of Prescriptions – EPS & Nominations (SOP 8, 9 & 30)

5.1.10 Firstly, our Dispensing of Prescriptions SOP's explicitly states the following:

"Prescriptions cannot be handed directly to patients on pharmacy premises. All NHS prescriptions are obtained electronically via the Electronic Prescription Service (EPS) through patient nomination. Patients nominate Medicare Chemist as their chosen pharmacy remotely (via the NHS app, GP practice, or directly with the pharmacy) without the need for face-to-face contact. Once prescriptions are received electronically, they are processed within the Patient Medication Record (PMR) system in accordance with EPS2 standards."

"Patients are contacted by telephone, email, or secure message for counselling, clinical queries, or to confirm delivery arrangements. At no stage are patients required to attend the pharmacy premises."

5.1.11 This, therefore, clearly demonstrates compliance with the relevant DSP regulations by ensuring prescriptions are only accessed **electronically** and without in-person interaction. Further, having these measures in place also satisfies the requirement under the statute to ensure that our procedures are in line with the relevant legal requirements of practice, and we are not falling foul of our requirements to provide a good, effective and safe standard of service, even though face-to-face interactions will not be taking place.

Urgent Supply - (SOP 13)

5.1.12 Moreover, the respondent has raised their concerns in relation to our processes and procedures, relating to urgent supply. We confirm that the Emergency and Urgent Supply of Prescription Only Medicines (POM) SOP sets out clear, robust procedures which will be in place to ensure that no face – to- face contact is carried out in the following ways:

5.1.13 *"Urgent supplies are handled through direct patient requests received by phone, website form, or email. Identity is verified before processing. Where an EPS prescription can be arranged with the prescriber, this is dispensed immediately and dispatched using either same-day courier (local delivery) or Royal Mail Special Delivery (nationwide). Where appropriate under the Human Medicines Regulations, an emergency supply may be made at the pharmacist's discretion, following completion of the structured remote questionnaire and professional clinical judgement."*

"No face-to-face interaction occurs. Patients are counselled remotely, and medicines are delivered using validated couriers ensuring secure, uninterrupted supply."

5.1.14 Therefore, this directly addresses concerns that the respondent may have in relation to our practices, particularly regarding urgent supplies, ensuring timeliness and compliance with legal requirements at all times, whilst also ensuring the safety and effectiveness of our services is not compromised.

Cold Chain Medicines Packaging & Delivery - (SOP 14 & 15)

5.1.15 Further, The Bagging Up and Delivery Order SOP's provides detailed controls in relation to the packaging and the service maintenance of our offerings, for example:

5.1.16 *"Refrigerated medicines (fridge lines) are packaged using validated insulated containers with corrugated liners, thermal barriers, and ice packs, maintaining a temperature range of 2–8°C for the full duration of transit. Couriers used are audited to ensure compliance with pharmaceutical cold chain standards."*

"Packages are labelled 'Store in refrigerator 2–8°C' and tracked electronically. If delivery is unsuccessful, the courier leaves a missed delivery card and medicines remain in the cold chain until redelivery. If any breach of the 2–8°C temperature range occurs, the courier alerts the pharmacy immediately. Medicines exposed to excursions are quarantined and destroyed in accordance with the Waste Medicines SOP."

"Cold chain items remain in the pharmacy refrigerator until just before handover to courier or driver, minimising time out of refrigeration. Patients are provided with information leaflets on home storage requirements."

5.1.17 Accordingly, this demonstrates that our robust systems ensure cold chain integrity and patient safety, which will always be at the forefront of our offering, and offering both legal and regulatory compliance.

Controlled Drugs Delivery – (SOP 19)

5.1.18 The respondent did raise a concern in relation to the delivery of controlled drugs. We would therefore, like to refer the respondent to the Controlled Drugs Delivery SOP, which is also relevant in addressing the respondent's concerns. Please note, this SOP states in full the following:

"If a Controlled Drug (CD) is included, phone the patient beforehand to confirm they are in. The driver should sign the delivery sheet with the script to complete the audit trail. The driver's name and 'delivery' is written in the CD register as the person collecting the medication. If delivery is unsuccessful, the CD is returned to the pharmacy, booked back into the CD register and signed out again on retry. CDs are always packaged separately from other medication and a CD sticker attached to the bag. The items are placed in a coded locked safe box within the vehicle to keep them secure. Additionally, all vehicles are locked each time the driver leaves. The type of vehicle used is always a van with no rear windows, minimising any potential break-in risk."

"CD deliveries carried out via Royal Mail use the Tracked 24 service, providing flexibility for patients to monitor delivery. Patients are notified by telephone before dispatch and receive a tracking link. Daily online checks are carried out to confirm delivery signatures and statuses. Any failed deliveries are returned immediately to the pharmacy for re-entry into the CD register."

5.1.19 As such, and as previously confirmed, this ensures CDs are handled safely, securely, and lawfully, maintaining an auditable trail. Again, demonstrating that we have robust practices in place to ensure that the service we are providing is effective, efficient and serves patients without the need to provide face-to-face services and without interruption.

Regulation 25(2)(b)(ii): Safe and Effective Provision Without Face-to-Face Contact

5.1.20 Moving on to address the respondents' further objections, namely that we have not demonstrated how safe and effective services are provided without face-to-face contact. This is not accepted, and we confirm that this is explicitly addressed in multiple SOPs, each of which embeds DSP regulatory requirements.

5.1.21 To address these concerns, we shall discuss the relevant SOP's in place to ensure strict compliance with regulatory requirements at all times, ensuring our services are not compromised and patients still receive the best level of care and assistance required to meet their needs.

Patient Consultation & Identity Verification - (SOP 3)

5.1.22 To ensure effective onboarding, and to ensure we are providing the correct level of patient service, the **Procedures for NHS Essential Services & Advanced and Enhances Services and Contacting Patients by Phone or Email SOP** is in place and states:

"All consultations, whether for essential, advanced, or enhanced services, are carried out remotely via encrypted telephone or secure video call. Identity verification is mandatory before the consultation begins, using at least two identifiers (e.g., name, date of birth, address, or NHS number). Patients are informed that no consultations are carried out on the DSP premises and that all interactions take place remotely."

"Clinical pathways requiring visual assessment are conducted by secure video link, using a link sent via the patient's preferred contact method. For minor illnesses that do not require visual examination, telephone consultation is used. The system ensures confidentiality, auditability, and compliance with NHS DSP guidance."

5.1.23 This ensures patients are properly identified and that care is delivered **without face-to-face interaction**, satisfying the required DSP regulations.

Structured Remote Questionnaires - (SOP 5 and 9)

5.1.24 The **Online Ordering & Exemption Checking and EPS2 Nomination and Information SOP** further confirms:

"Patients complete structured digital questionnaires via the website or app before consultations. These questionnaires capture medical

history, current medicines, allergies, safeguarding information, and lifestyle factors (e.g., smoking, alcohol, exercise). The system prevents incomplete submissions and flags high-risk responses to the pharmacist for follow-up."

"These replace the traditional WWHAM questions and provide a consistent, auditable, and legally compliant data capture process that can be reviewed within the PMR system."

5.1.25 This clearly demonstrates that we have safe and effective assessments in place and these are possible without the need for face-to-face interactions, which continues to ensure that the service we offer is indeed safe, effective and robust.

Remote Counselling and Advice - (SOP 3, 8 & 21)

5.1.26 These SOPs provide:

"Following clinical and accuracy check, patients are contacted by telephone or secure video link for counselling. Information provided includes dose, frequency, administration, side effects, interactions, and safe storage requirements. Where counselling is declined, a record is made in the PMR."

"For fridge lines and CDs, additional advice is given on secure storage and safe disposal. Patients are also provided with written information leaflets sent electronically or included with delivery."

5.1.27 These SOPs are in place to ensure continuity of care and safeguards equivalent to, or stronger than, traditional face-to-face counselling, thus confirming that our offerings go above and beyond the requirements and we are committed to ensure our offerings do not fall below the legal tests in place to ensure patient safety is not compromised.

Discharge Medicine Service- "DMS" (SOP 33)

5.1.28 The DMS SOP ensures safe transfer of care from hospital to home, entirely remotely:

"Referrals are received via NHSmail, PharmOutcomes, or other approved NHS referral platforms. Patients or carers are contacted by telephone to confirm identity and explain the service. No walk-in or face-to-face referrals are accepted in compliance with DSP requirements."

"Counselling is delivered via secure telephone or video consultation. Content includes: indication, dose, frequency, administration; side effects, interactions, missed doses; changes compared to pre-admission regimen; storage and disposal requirements. Written information leaflets are provided electronically or sent with deliveries."

5.1.29 This prevents any interruption in medicines supply post-discharge, with remote support fully embedded, to ensure patient care is not

compromised, and again the safety and care for patients remains uninterrupted.

Advanced & Enhanced Services - (SOP 3)

5.1.30 The respondent also raised a concern that we have not explained how advanced or enhanced services are provided, nor provided sufficient clarity on how advanced and enhanced services will be provided **without face-to-face contact**. We can confirm this is directly addressed in the SOPs, which explicitly incorporate DSP regulations.

5.1.31 We trust the below extracts from our SOP's will further demonstrate how each service is safely and effectively provided in line with DSP regulations and NHS England service specifications, as well as not compromising the legal tests in place under the relevant subsection 25(2)(b) respectively. Again, we trust you will agree these processes and procedures in place confirm that we are committed to ensure that our offering does not fall below the legal and regulatory requirements and our commitment to ensure patient safety is always at the forefront.

Pharmacy First - (SOP 3)

5.1.32 From the **SOP, you will note that this SOP confirms**:

"Consultations are provided remotely via secure video call as arranged with the patient (no face-to-face at DSP premises). Consultations may be conducted via video or telephone, depending on clinical need and pharmacist discretion, e.g., clinical pathways and minor illnesses. Other pathways must be provided via video call. Video calls are generally conducted via a secure link sent to the patient."

"Where clinically appropriate, an EPS token is generated for the correct medication/treatment. Medicines are supplied via national courier service or local delivery. Patients unsuitable for remote management are signposted to appropriate NHS services."

"Patients contact the pharmacy via phone, website, or email. Identity verification is conducted before any consultation."

"Consultations are conducted remotely via secure video call or, where clinically appropriate, telephone. Clinical pathways requiring video consultation are followed precisely."

"Where treatment is indicated, electronic prescriptions are issued and medicines dispatched via national courier. Where face-to-face assessment is needed, patients are referred to NHS 111, GP, or urgent care services."

5.1.33 This demonstrates Pharmacy First can be fully delivered remotely, in compliance with DSP rules ensuring **timely, safe, and regulation-compliant care** under the NHS Pharmacy First Service Specification (2025) for all patients accessing our services.

New Medicines Service (NMS) - (SOP 3)

5.1.34 From the **SOP**:

"Eligible patients are identified via EPS nomination or GP referral. Initial consultation is provided remotely via encrypted telephone or video call. Follow-up consultations are arranged and documented, with no requirement for patients to attend DSP premises. Outcomes are recorded in the PMR and reported via the MYS portal."

"Eligible patients are identified via EPS nomination or GP referral. Pharmacists confirm eligibility remotely by cross-checking prescription data and verifying patient identity by telephone or video consultation."

"The initial consultation is provided via encrypted telephone or video call. The pharmacist records all details in the PMR, including clinical checks, advice given, and patient understanding. A follow-up call is arranged, documented, and undertaken within agreed timelines."

"Patients unsuitable for remote management are referred back to their GP or a community pharmacy providing face-to-face services."

5.1.35 This shows NMS can be delivered securely and effectively without face-to-face contact, ensuring patients receive structured support **without face-to-face contact**, with outcomes reported via the MYS portal, satisfying NHS requirements and ensuring a safe and effective level of service to patients.

Contraception Service - (SOP 3)

5.1.36 Please note the below extract from the **SOP,** which confirms:

5.1.37 *"Remote eligibility and safeguarding checks are carried out via secure video call. Counselling and clinical assessment are conducted remotely, with prescriptions issued electronically and medicines supplied via national courier. If physical measurements (e.g., blood pressure, BMI) are required, patients are referred to a local provider."*

"Identity verification is mandatory before supply. Safeguarding concerns are escalated in line with NHS guidance."

"All eligibility and safeguarding checks are conducted via secure video call, using structured clinical assessment forms embedded in the PMR."

"Where a physical measurement (e.g., blood pressure, weight, BMI) is required, patients are signposted to an appropriate healthcare professional. Supplies are only issued once full eligibility criteria are satisfied."

"Prescriptions are issued electronically, and medicines are supplied via national courier in accordance with the Delivery SOP."

5.1.38 This ensures the service is compliant, safe, and accessible nationwide, guaranteeing **compliance with DSP restrictions**, while still providing a safe and accessible national service, which is fundamental for the services we provide patients.

Flu Vaccination - (SOP 3)

5.1.39 The **SOP,** confirms*:*

"Until 31 March 2026, flu vaccinations may be administered on DSP premises under NHS transitional rules. After this date, patients will be signposted to other service providers. Eligibility and consent checks are carried out remotely, and cold chain procedures are strictly maintained."

"Until 31 March 2026, flu vaccinations may be administered on DSP premises under NHS transitional rules. After this date, all patients are referred to external face-to-face providers."

"Eligibility and consent are checked remotely, and vaccination data is recorded in the PMR and reported via MYS."

"Cold chain vaccines are managed in line with the Cold Chain SOP, ensuring compliance with MHRA requirements."

5.1.40 This confirms compliance with **current transitional rules** while future-proofing the service in line with DSP regulations. This ensures compliance with transitional rules and DSP restrictions, noting that DSPs will no longer be able to provide this service as of 31 March 2026.

Smoking Cessation - (SOP 3)

5.1.41 From the **SOP**:

"Electronic referral is received from secondary care. Behavioural support is provided remotely by trained pharmacists via telephone or video. Nicotine replacement therapy is supplied via national courier. Where CO monitoring is required, patients are signposted to local providers."

"Patients are referred electronically from secondary care into the pharmacy's secure system."

"Behavioural support is delivered via scheduled telephone or video consultations, with records of each session entered into the PMR."

"Nicotine replacement therapy (NRT) is supplied via tracked delivery. If Carbon Monoxide (CO) monitoring is required, patients are referred to local face-to-face providers."

5.1.42 This demonstrates the service can be safely and effectively delivered without face-to-face interaction, and further, demonstrate **safe and effective delivery** without on-site patient attendance. Which we understand is essential for DSP practices.

Essential Services - (SOP 3)

5.1.43 The respondent has raised concerns that we have not explained in sufficient detail how essential services will be delivered safely, effectively, and without face-to-face contact. Below we set out each essential service, embedding detail from the SOPs, and demonstrating compliance with Regulation 25(2)(b)(i)–(ii) and DSP regulations, which we trust is satisfactory for your purposes.

Dispensing of Medicines and Repeat Dispensing - (SOP 8 & 9)

5.1.44 The SOPs makes clear that:

"*Patients cannot attend the DSP premises to present paper prescriptions or collect medicines. All prescriptions are received electronically via EPS nomination, GP referral, or secure transfer from prescribing systems. This ensures prescriptions are obtained without face-to-face contact, in full compliance with DSP regulations."*

"EPS nominations are managed remotely. Patients are supported via telephone or secure online channels to complete nomination requests. Once confirmed, prescriptions are downloaded electronically by the pharmacy without any physical attendance by the patient."

"Before dispensing, prescriptions undergo clinical screening by the pharmacist, accuracy checking by an ACT, and packaging in line with the Delivery SOP. Patients are then contacted by telephone or secure video for counselling."

5.1.45 This ensures medicines can be dispensed nationally without patient visits to the DSP premises, ensuring that we do not fall foul of our responsibilities both towards patients as well as our regulatory requirements.

Urgent Supply - (SOP 13)

5.1.46 The **SOP** provides:

"Where an urgent supply is requested, the pharmacist conducts a structured remote consultation using the online questionnaire or secure telephone call. The consultation records: patient identity, reason for urgency, medical history, and suitability of supply."

"If supply is clinically appropriate, an EPS prescription is generated (where authorised) and medicines are dispatched via same-day courier (local) or national tracked courier with temperature control as required. Patients are informed of delivery timelines, and counselling is provided by telephone prior to dispatch."

"If urgent supply cannot be safely made, patients are referred to an appropriate NHS service such as NHS 111, GP out-of-hours, or urgent care centre. This ensures uninterrupted access to care without face-to-face pharmacy attendance."

5.1.47 This satisfies DSP requirements that urgent supply is provided promptly and safely, and therefore adheres to the processes and requirements.

Disposal of Unwanted Medicines - (SOP 21)

5.1.48 The **SOP** states:

"Patients request medicine returns via telephone, website, or app. A secure container is delivered to the patient for collection of unwanted medicines, which is then retrieved by courier or local driver."

"Controlled drugs returned by patients are recorded in the CD Register, quarantined, and destroyed in the presence of an authorised person, in line with CD disposal regulations."

5.1.49 This ensures disposal is offered nationally, in compliance with essential services, and without face-to-face pharmacy contact.

Healthy Lifestyle Promotion and Public Health Campaigns - (SOP 23)

5.1.50 The **Healthy Lifestyle & Public Health Campaigns SOP** provides:

"The pharmacy participates in all required NHS England public health campaigns. Information is delivered via prescription leaflets, website content, app notifications, and email newsletters."

"Campaign resources are included with deliveries (e.g., smoking cessation leaflets with NRT, diabetes management leaflets with metformin). Additional advice is offered remotely by telephone or secure video consultation." "Service users across England are targeted by reviewing PMR records to identify at-risk groups (e.g., smokers, overweight patients, those with diabetes or hypertension). These patients are contacted proactively to provide tailored advice."

5.1.51 This ensures campaigns are fully delivered across England without face-to-face contact, without compromising NHS Terms of Service.

Signposting - (SOP 22)

5.1.52 The **SOP** provides:

"Where a patient's needs fall outside the scope of pharmacy services, patients are remotely signposted to NHS 111, GP practices, sexual health clinics, or other relevant services. Records of signposting are logged in the PMR system."

5.1.53 This SOP is in place, to ensure continuity of care without physical attendance at DSP premises thus not compromising the service provided to patients, and again, adhering to regulatory requirements.

Support for Self-Care - (SOP 22)

5.1.54 The **SOP** provides:

"Self-care support is provided remotely via structured questionnaires, telephone advice, or video consultations. Where OTC medicines are appropriate, they are supplied in accordance with the Sales of GSL and P Medicines SOP, which requires pharmacist approval for all non-routine supplies. Where supply is inappropriate, the patient is advised and referred accordingly."

5.1.55 Again, this further ensures compliance with essential service requirements, ensuring we adhere to the best practices in line with NHS requirements.

Controlled Drugs & Cold Chain Medicines - (SOP 15 & 19)

5.1.56 For the purposes of confirming our compliance with Regulation 25(2)(b)(ii), we note that the Responders expressed concern that no detail was provided on controlled drugs (CDs) or cold chain deliveries. These are explicitly covered in the SOPs, and we will address these further below in line with the above.

Controlled Drugs - (SOP 19)

5.1.57 The **SOP** provides:

"All CD deliveries must comply with legal requirements, be clearly marked, and remain under the pharmacist's and Responsible Pharmacist's control until handover to the driver or courier."

"The delivery record must include 'CD' and a note that delivery must occur within 28 days of the prescription date. Safe custody is maintained at all times, including locked storage during transport."

"The recipient must provide proof of identity (passport, driving licence, or NHS-standard digital verification). The patient, or authorised representative, must sign for receipt. If delivery is unsuccessful, CDs are returned to the pharmacy immediately and stored in the CD cabinet."

5.1.58 This confirms that the CDs are delivered legally, securely, and safely nationwide, ensuring both compliance and patient care.

Cold Chain Medicines - (SOP 15)

5.1.59 The **SOP** provides:

"Refrigerated medicines are packaged using validated insulated systems (e.g., Puffin or equivalent) with corrugated liners, ice packs, and thermal barriers to maintain 2–8°C for the full transit period. Each system is validated to ensure stability during transport times."

"Cold chain items are stored in the pharmacy refrigerator until immediately before dispatch. Couriers are required to scan packages on collection, and patients receive live tracking details."

"If delivery is unsuccessful, cold chain items remain within the validated insulated system and are returned to the pharmacy the same day. If a breach of the 2–8°C range occurs, medicines are quarantined, not reused, and destroyed in line with waste SOPs."

"Patients are counselled remotely on correct storage on receipt (2–8°C) and advised not to use medicines that have been exposed to inappropriate temperatures."

5.1.60 This ensures cold chain compliance, safeguarding patient safety and alignment with national standards, again, demonstrating compliance.

Delivery Systems and Nationwide Coverage - (SOP 14 & 15)

5.1.61 The **SOP** specially states:

"Medicines are dispatched via Royal Mail Tracked 24 service or equivalent national courier, ensuring delivery to all addresses in England. All items are dispatched with live tracking links sent to patients. For high-risk or urgent deliveries, same-day courier services are used where available."

"If delivery is unsuccessful, items are returned to the pharmacy the same day. Controlled Drugs are re-entered into the CD register, while cold chain items are quarantined pending review. A second delivery attempt is arranged at patient convenience. This ensures patients never lose access to medicines due to a failed delivery."

5.1.62 This guarantees **uninterrupted provision** by combining reliable national courier infrastructure with internal audit trails, confirming that we have systems in place to ensure the security of our courier services to ensure products are delivered to patients in a timely manner, as well as ensuring products are not compromised in the delivery of our services.

Business Continuity and Service Resilience - (SOP 32)

5.1.63 Further, our **Business Continuity SOP** provides the following:

"Essential services are maintained during staff absences, IT outages, or supply chain disruptions. Cloud-based PMR systems ensure remote access for pharmacists to process EPS prescriptions. A backup pharmacy premises agreement is in place to cover emergencies."

"Deliveries are routed via multiple national couriers to avoid disruption if one provider fails. Daily monitoring of courier status ensures early detection of delays."

5.1.64 This demonstrates that we have acknowledged limitations and put in place processes which will enable services to continue, with minimal interruption, satisfying **Regulation 25(2)(b)(i)**.

Patient Communication - (SOP 4)

5.1.65 Our SOP's also address communication channels with patients, to ensure a streamlined service, this includes:

"Patients are contacted via telephone, SMS, or secure email to confirm prescription receipt, expected delivery date, and counselling as required. Counselling is repeated if a patient cannot be contacted initially. A record of contact is logged in the PMR."

5.1.66 This proactive communication ensures no patient is left without information or support, even if deliveries are delayed.

Delivery Audit Trail - (SOP 15 &19)

5.1.67 We have in place the following **SOP**, which requires:

"Every dispatched package is recorded in the Delivery Log, linked to the patient's PMR entry. This includes prescription details, packaging used, courier reference, tracking number, and name of staff member dispatching."

"For Controlled Drugs, the driver signs the delivery sheet and their name is recorded in the CD register as the collecting party. On delivery, the patient (or authorised representative) signs electronically. If undelivered, the CD is immediately returned, logged back into the register, and signed out again for re-delivery."

5.1.68 By having this in place, we ensure a full audit trail for all medicines takes place, minimising risk of diversion or loss of our supplies. This means we are able to closely monitor and observe supplies, to ensure the effective delivery of our services to patients.

Cold Chain Monitoring - (SOP 15)

5.1.69 We have also put in place the following **SOP,** which confirms:

"Each insulated system contains an integrated data logger which records the internal temperature during transit. On delivery, patients are advised to check the temperature monitor to confirm compliance with 2–8°C storage. If readings show deviation, the medicine is not used and is destroyed."

5.1.70 This affords safety and transparency in temperature-controlled deliveries. Further reinforcing our robust systems, ensuring patient care and our safety compliance are adhered to at all times.

Patient Safety and Governance - (SOP 24)

5.1.71 Furthermore, we have also implemented the **Near Miss & Error SOP,** which provides that:

"All near misses and dispensing errors are logged and reviewed weekly. Monthly reviews are conducted with the Superintendent Pharmacist to identify trends and implement corrective actions."

"Training records confirm staff have read, understood, and agreed to follow SOPs. Refresher training is delivered annually and after any critical incident."

5.1.72 By implementing this SOP, this guarantees a culture of continuous safety improvement. Ensuring that our commitment to ensuring patient safety and compliance is not compromised.

5.1.73 To conclude, having considered the respondents objections at length, we have demonstrated that our practices and procedures do indeed satisfy the legal and regulatory test as set out in Regulation 25 (2) (b) confidently ensuring that the legal test is satisfied by ensuring (i) the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and (ii) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff. Therefore, adhering to and satisfying both relevant limbs of the legal test. Our SOPs, a complete list which we attach herewith once more, confirm our dedication and commitment to providing patients with a streamlined service, in a DSP capacity, and will ensure ongoing commitment towards compliance.

5.1.74 Accordingly, we believe the Committee should be assured that its decision to approve our application, is indeed the correct decision and this should indeed be upheld.

5.1.1 We trust the above is sufficient for your purposes and look forward to your confirmation that our application has now been approved."

5.2 RUSHPORT ADVISORY LLP ON BEHALF OF THE APPELLANT

5.2.1 "I act for Southam Pharmacy which operates a pharmacy at 4 Market Hill, Southam and have been instructed by my client to submit this reply to your letter and attachments of 22 December 2025.

5.2.2 We have now had sight of the new information that was provided by the Applicant in support of their application. This new information still falls well short of the standard required to meet the legal test under regulation 25.

5.2.3 Examples of this include (using page numbering from the combined letter and SOP document dated 30 September 2025)

5.2.4 Page 3 the Applicant states;

"CD deliveries carried out via Royal Mail use the Tracked 24 service, providing flexibility for patients to monitor delivery. Patients are notified by telephone before dispatch and receive a tracking link. Daily online checks are carried out to confirm delivery signatures and statuses. Any failed deliveries are returned immediately to the pharmacy for re-entry into the CD register"

5.2.5 Royal Mail Tracked 24 service does not support ID checks, making it entirely inappropriate for deliveries of controlled drugs. In addition, Royal Mail Tracked 24 service does not support delivery immediately back to the pharmacy in the event of a failed delivery.

5.2.6 Page 4 the Applicant states.

"Refrigerated medicines (fridge lines) are packaged using validated insulated containers with corrugated liners, thermal barriers, and ice packs, maintaining a temperature range of 2–8°C for the full duration of transit. Couriers used are audited to ensure compliance with pharmaceutical cold chain standards."

5.2.7 What this means is that the Applicant is relying on corrugated liners, thermal barriers, and ice packs that they position in some manner within boxes in order to maintain the cold chain. The courier is simply used to deliver the parcel but cannot maintain the cold chain independently or advise of a breach.

5.2.8 Page 81 – Bagging up SOP, confirms that cold chain items would use "Puffin or equivalent validated system" with no further details provided.

5.2.9 Page 86 states "*If a temperature excursion occurs, the courier alerts the pharmacy immediately. Medicines exposed to conditions outside 2–8°C must not be reused. They are quarantined, logged, and destroyed under the Waste SOP*.". This is contradictory as the SOPs elsewhere claim that the "Puffin or equivalent validated system" is used to maintain the cold chain.

5.2.10 Page 21 SOP 3 – Procedures for NHS Essential Services & Advanced and Enhanced Services

5.2.11 This SOP is deficient in several areas. The entire process for Pharmacy First is deficient. The process fails to explain how consultations will be carried out, what consultations may be accepted for, how deliveries of different types of medicines will be handled, or even how a consultation will be carried out to ensure privacy.

5.2.12 The procedure for provision of NMS, contraception service, smoking cessation and flu vaccinations is similarly brief and vague.

5.2.13 Page 85 contains a procedure for Local Delivery for all medicine types.

5.2.14 Page 100 states that "*Drivers and couriers are responsible for secure transport, identity verification of the recipient, and maintaining the audit trail*.".

5.2.15 Page 101 reverts to claiming that Royal Mail Tracked 24 would be used for controlled drugs. As previously stated Royal Mail Tracked 24 does not include ID verification. An option (at additional cost) for a photograph of delivery is available, but this is simply a photo of a parcel at delivery. Similarly, it is not possible to rearrange delivery of a controlled drug using this system as the Royal Mail cannot store controlled drugs for a pharmacy.

5.2.16 This contradicts earlier claim that Royal Mail would delivery [sic] controlled drugs (unless they are viewed as the courier) and shows a lack of awareness of the responsibilities that the pharmacy has. It is the pharmacy and not any courier that is responsible for secure transport, identity verification and maintaining the audit trail.

5.2.17 In this case, we submit that the Committee cannot be satisfied that the legal test is met and the application should therefore be refused."

6 Summary of Observations

This is summary of observations received.

6.1 THE APPLICANT

6.1.1 "By way of a reminder, the appeal falls to be determined in accordance with Regulation 25 (2) (b) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the "Regulations"). This sets out a clear legal test, which confirms that the Committee is required, when considering the application, to be satisfied that the arrangements in place are likely to secure:

6.1.1.1 the uninterrupted provision of essential services to persons anywhere in England who request those services; and

6.1.1.2 the safe and effective provision of pharmaceutical services without face-to-face contact between the patient and the pharmacy.

6.1.2 Upon consideration of the Respondent's representations, it is clear, that whist they have suggested that our SOPs and practices fall short of meeting the requirements of the legal test, they have failed to adequately address how we have failed to meet the requirements, as set out in the relevant limbs of the legal test for distance selling pharmacies ("DSPs"). From review of their representations, we note they have made various generic representations, by way of cherry picking at the SOPs we have produced, and misconstruing both the context in which they are drafted and their intended meaning, by largely disregarding the SOP as a whole. This is therefore misleading and does not adequately address, how, we are allegedly falling short of meeting the legal test. We will of course, address each representation at length and in turn below.

6.1.3 Turning to the Respondent's first representation, in relation to delivery methods. We submit that when our procedures are considered as a

whole, they successfully demonstrate a coherent and pharmacy-led governance framework that is fully aligned with NHS England and General Pharmaceutical Council (GPhC) expectations for DSPs. The further representations do not identify any absence of arrangements. Rather, they seek to impose requirements which are not prescribed by the regulatory framework and importantly, which do not form part of the statutory test under Regulation 25, of which our application falls.

6.1.4 NHS England and the GPhC both recognise that DSPs operate under a different service delivery model to that of traditional community pharmacies. This model is expressly permitted, provided that appropriate safeguards exist to ensure patient safety, continuity of care, and professional accountability. The Respondent fails to recognise this distinction, in making their representations.

6.1.5 Central to both NHS England guidance and the GPhC Standards for Registered Pharmacies is the principle that responsibility remains with the pharmacy and the Responsible Pharmacist at all times. Governance is therefore assessed by reference to systems, procedures, auditability, and professional oversight, rather than by prescriptive requirements relating to delivery mechanics. Our SOPs are designed on this basis; they reflect and are in alignment with established DSP practice across England.

6.1.6 The Respondent places significant emphasis on the delivery mechanism used for controlled drugs, and the absence of identity checks undertaken by delivery providers. It is our submission, that this approach misconstrues the regulatory framework. Controlled drug legislation, supported by Home Office guidance and NHS controlled drugs governance arrangements, places responsibility for safe custody, lawful supply, record-keeping, and audit squarely upon the pharmacy contractor and the Responsible Pharmacist. The framework does not prescribe specific delivery mechanisms, nor does it require third-party carriers to undertake identity verification. We confirm, in accordance with this framework, responsibility for controlled drugs within our pharmacy remains pharmacy-led at all times. That said, delivery tracking and proof-of-delivery are used as monitoring tools within an auditable system, rather than as substitutes for professional oversight. All identity verification, authorisation of supply, and clinical assessments are undertaken prior to dispatch as part of our dispensing process and in line with the regulatory frameworks.

6.1.7 Further, where in the event that a delivery is unsuccessful or delayed - escalation, reconciliation of supply, and maintenance of controlled drug records remain strictly under the control of the pharmacy, which is regularly monitored by our staff to ensure continuity of custody and accountability. The Respondent's focus on courier functionality therefore does not demonstrate an absence of appropriate safeguards, and we submit that our arrangements are consistent with NHS England and Home Office expectations for controlled drug governance. Thus, we do not agree that our processes fall short of meeting the legal test, as set out further above.

6.1.8 The Respondents second limb of their first representation refers to an extract of our SOP 19, which was referred to in our letter dated 30 September 2025. This noted that “any failed deliveries are returned immediately to the pharmacy” in the context of controlled drugs. This describes the initiation of the return process following a failed delivery, rather than an assertion of instantaneous physical return. Noting also, the Respondent was provided a copy of our complete SOP for their consideration, when making representations. To be clear, where delivery is unsuccessful, the pharmacy monitors the status of the item, escalates appropriately, and reconciles the supply within controlled drug records in accordance with governance requirements. At no point does the pharmacy relinquish accountability for controlled drugs, nor does the use of a tracked delivery service transfer responsibility to the carrier. When considered in the round, these arrangements demonstrate that controlled drugs are supplied under active pharmacy control, with monitoring, escalation, and reconciliation processes in place. Importantly, the absence of courier-performed ID checks or instantaneous return capability does not indicate a failure to meet the requirements of Regulation 25, which is the purpose of this appeal.

6.1.9 Next, referring to the Respondent’s second representation, where they allege that we have failed to demonstrate how cold chain medicines are maintained safely during transit. Upon consideration, we are of the view that this position arises from a misunderstanding of how temperature control is achieved within a DSP model.

6.1.10 NHS England and GPhC guidance clearly recognise that cold chain integrity in DSPs is ordinarily achieved through validated insulated packaging systems, rather than through refrigerated vehicles. These systems are designed to maintain medicines within the required 2–8°C range for the anticipated delivery period and are widely used across DSP contractors nationally. Thus, our arrangements reflect this recognised approach. Further, cold chain governance remains pharmacy-led and includes defined procedures for packaging, monitoring delivery outcomes, professional assessment of suitability for supply, and management of potential temperature excursions through quarantine, review, manufacturer consultation where appropriate, and disposal in instances where integrity cannot be assured. The Respondent quotes an aspect of our SOP, again an extract of which was noted in our correspondence to you dated 30 September 2025, and states that we are “relying on corrugated liners, thermal barriers, and ice packs that they position in some manner within boxes in order to maintain the cold chain. The courier is simply used to deliver the parcel but cannot maintain the cold chain independently or advise of a breach.” This insinuates a lack of know-how on our part and undermines the integrity of the systems we are using, which are indeed manufactured, and designed specifically for pharmaceutical cold chain distribution. We are therefore at a loss, as to what the Respondent expects us to utilise, given that arrangements in place, are not merely positioned ‘in some manner within boxes’ but are robust validated systems designed specifically for use as cold chain distributions.

6.1.11 As such, these safeguards are in place to operate as part of a structured risk-management framework and do not contradict the use of validated packaging systems. Rather, they demonstrate professional oversight consistent with GPhC expectations that pharmacies manage risk proactively and in the interests of patient safety.

6.1.12 Moving on, the Respondent in their further representation, notes that the Bagging Up SOP refers to the use of a “Puffin or equivalent validated system” and suggests that no further detail is provided. This, again purports to overlook the purpose and content of the Bagging Up SOP as a whole. The Respondent, again, chooses to cherry pick the SOP, which results in misconstruing the intended meaning of the SOP. The SOP is constructed to work in unison as oppose [sic] to standalone, and had the Respondent read the SOP in full, they would have been aware that the SOP does not merely name the use of validated insulated packaging; it also sets out the practical steps for assembling and preparing cold chain consignments, including the placement of medicines within insulated containers and the use of cooling elements in accordance with manufacturer guidance.

6.1.13 To add, the SOP is intended to guide staff in the operational preparation of refrigerated medicines for dispatch, rather than to reproduce technical validation reports or temperature-mapping data within the application documentation. The reference to a “Puffin or equivalent validated system” confirms that only packaging systems validated to maintain 2–8°C are used, while the Bagging Up SOP provides the procedural framework for their correct use in practice.

6.1.14 Therefore, taken together, these arrangements demonstrate that cold chain items are prepared using validated systems, assembled in a controlled and consistent manner, and subject to professional oversight. This satisfies the requirement under Regulation 25 to demonstrate arrangements capable of maintaining medicine integrity - safely and effectively within a DSP model and therefore successfully meets the legal test required.

6.1.15 Moving on to the Respondents next representation, still referencing the puffin or equivalent validated systems, goes on to state that we have contradicted ourselves, in the SOP extract they refer to, as being “If a temperature excursion occurs, the courier alerts the pharmacy immediately. Medicines exposed to conditions outside 2–8°C must not be reused. They are quarantined, logged, and destroyed under the Waste SOP.” Which is an extract from our SOP 15. They essentially question, that if our systems are as robust as we make out, then why are we referencing a potential breach. To this, we respond that, it is reasonable and sensible given our professional responsibility, both in the practice that we undertake and under the Regulations, to implement contingencies, where required. The inclusion of procedures for managing potential temperature excursions does not contradict the use of validated packaging. Rather, it reflects standard risk management practice, whereby contingency safeguards are in place should the integrity of the cold chain be uncertain for any reason, including delay,

damage, or unforeseen deviation from expected conditions, which is outside our control.

6.1.16 Couriers may notify the pharmacy of delivery incidents such as delay, damage, failed delivery, or return-to-sender events via tracking or exception reporting. That said, the Pharmacy ensures that the medication is tracked at all times, to enable us to deal diligently and efficiently, in instances where the unlikely event of if a breach does indeed occur. Where such an event, does occur and may reasonably give rise to concern regarding cold chain integrity, the pharmacy undertakes a professional assessment, drawing off years of experience. If cold chain integrity cannot be confidently assured following that assessment, medicines are quarantined and managed in accordance with documented procedures, including logging and disposal where appropriate. Responsibility for assessment, decision-making, and governance remains pharmacy-led at all times.

6.1.17 The Respondent's observation, that the courier does not independently maintain the cold chain does not indicate a deficiency in arrangements. Rather, it reflects a packaging-controlled, risk-based cold chain model, supported by professional oversight, which is consistent with NHS England commissioning expectations and the GPhC's standards for DSPs and is most importantly, capable of maintaining medicine integrity safely and effectively in accordance with Regulation 25.

6.1.18 Further, the Respondent also contends that insufficient detail has been provided regarding the provision of NHS essential services, advanced and enhanced services and alleges these SOPs are 'deficient' and 'vague'. This criticism misunderstands the role of the Committee and the nature of the Regulation 25 assessment. NHS England service specifications and GPhC guidance permit the delivery of a range of pharmaceutical services remotely, provided that patient identity is verified, confidentiality is maintained, clinical judgement is exercised appropriately, and referral pathways exist where face-to-face care is required.

6.1.19 Our SOPs demonstrate a layered approach, that advanced and enhanced services are delivered through:

6.1.19.1 secure remote consultations, ensuring the integrity of our offering is not compromised;

6.1.19.2 mandatory identity verification prior to engagement, ensuring regulatory compliance is adhered to at all crucial times;

6.1.19.3 documented clinical decision-making within the PMR;

6.1.19.4 safeguarding processes, to ensure that patients are kept well informed and access our offering in a safe and coherent manner;

6.1.19.5 structured referral and signposting to local NHS services where remote management is not clinically appropriate,

demonstrating our professional know-how, sound professional judgement and maintaining high levels of patient care and integrity.

6.1.20 These arrangements are aligned with NHS England service specifications and reflect the safeguards expected of DSP contractors.

6.1.21 The Respondent alleges that our SOPs are deficient in many areas, referring specially to our SOP 3 in relation to “Procedures for NHS Essential Services & Advanced and Enhanced Services.” They submit that, the entire process for Pharmacy First is deficient, and allege that our process “fails to explain how consultations will be carried out, what consultations may be accepted for, how deliveries of different types of medicines will be handled, or even how a consultation will be carried out to ensure privacy.” This is disputed, the Respondent’s observations that SOP 3 is ‘brief and vague’ is incorrect and appears to arise from a failure to read the SOP in full, or to recognise how NHS service specifications are implemented within a DSP model. From review of SOP 3, it is evident that it provides clear, structured and service specific procedures for the delivery of NHS Essential, Advanced and Enhanced services fully aligned with NHS England’s service specifications and DSP regulatory requirements.

6.1.22 Contrary to the Respondent’s claims, SOP 3 clearly explains how consultations are carried out, which consultations may be accepted, how medicines are supplied, and how patient privacy is ensured. Specifically, the SOP states, how patients access our services, namely, via telephone, website, or email, with mandatory identity verification prior to consultation. The SOP confirms that all consultations are conducted remotely, using telephone or secure, encrypted video calls, consistent with DSP regulations and thus not compromising on the privacy of patients. It also clearly sets out that Pharmacists assess patients against NHS England Pharmacy First clinical pathways, using professional judgement to determine suitability for telephone or video consultation. Medicines are supplied via tracked national courier or approved local delivery drivers, with unsuitable cases referred to NHS 111, GPs, or urgent care. Further, the SOP confirms where face-to-face assessment is required, patients are signposted to appropriate local NHS providers using NHS.uk. These processes are explicitly set out in SOP 3 and reflect the Pharmacy First Service Specification (2025), adapted appropriately for a DSP environment, and therefore adhere to the requirements under Regulation 25. Further, please note, SOP 3 does not seek to replicate or paraphrase the entirety of each NHS service specification; to do so, I am sure you will agree, would be inappropriate and unnecessary. Instead, it functions as an implementation and governance document, translating nationally mandated service requirements into a structured, auditable process suitable for delivery within a DSP capacity, while remaining fully subordinate to the NHS service specifications themselves. Service delivery is therefore governed primarily by NHS England specifications, supported by SOP 3, and overseen by the Responsible Pharmacist and Superintendent Pharmacist in line with their statutory and contractual

responsibilities. This layered approach to governance reflects established NHS pharmacy practices and ensures that services are delivered safely, lawfully, and consistently.

6.1.23 Therefore, when SOP 3 is read as it is intended, which is alongside the NHS England service specifications and wider professional standards; it clearly provides a comprehensive, compliant, and regulator-robust framework for NHS service delivery. The Respondent's characterisation of the SOP as vague or deficient fails to acknowledge this regulatory structure and does not reflect the contractual reality under which NHS pharmacy services are commissioned and delivered.

6.1.24 Respectfully, the purpose of the SOPs at application stage is to demonstrate governance and capability, not to reproduce the full operational detail contained within nationally published service specifications. When considered collectively, our procedures show that services can be delivered safely, effectively, and without face-to-face contact, which meets the legal test as stipulated in Regulation 25 (2) (b).

6.1.25 Finally, the Respondent sets out various processes in relation to our SOPs, in particular references page 85 (SOP 15, referencing only local delivery) and pages 100 and 101 (SOP 19 – Controlled Drugs SOP). With regard to the Respondent's reference to page 85, the respondent refers to page 85 as containing a procedure for "local delivery for all medicine types." We note that this wording is not a quotation from the SOP. As confirmed, the section referenced forms part of SOP 15, which sets out the general operational steps for local delivery. It does not purport to define regulatory responsibility, nor does it override or replace the specific controlled drug and cold chain governance procedures set out elsewhere within the SOP framework.

6.1.26 Further, in regard to the Respondent's references to page 100, we note that the respondent places weight on the wording at page 100 which states that "drivers and couriers are responsible for secure transport, identity verification of the recipient, and maintaining the audit trail."

6.1.27 From consideration of the Respondent's comments, we note that the Respondent has misconstrued the meaning of "identity verification" when used in this context. When read in the operational context of the delivery process, it is intended to refer to confirmation that delivery has been made to the intended recipient or address, rather than to clinical or legal identity verification for the purposes of authorising supply. For clarity, clinical identity verification and authorisation of supply are undertaken by the pharmacy prior to dispatch and remain pharmacy-led at all times, as mentioned in SOP 19 as part of the Pharmacist's responsibility. Delivery providers do not undertake clinical identity checks. Further, confirmation of delivery is supported by mechanisms such as delivery signatures, photographic proof of delivery where available, and tracked delivery status updates. These elements form part of the audit trail reviewed by the pharmacy to confirm receipt and to identify and escalate any exceptions. Again, when the SOPs are read

as a whole, they demonstrate a clear distinction between pharmacy-led identity verification prior to supply and courier-supported confirmation of receipt, with accountability remaining with the pharmacy and Responsible Pharmacist throughout.

6.1.28 With regard to the Respondents comments in relation to page 101, the Respondent suggests that delivery cannot be rearranged because Royal Mail cannot store controlled drugs for a pharmacy. Respectfully, we submit that this conflates temporary handling within the postal network during transit with controlled drug storage. To be clear, Royal Mail does not act as a controlled drug storage provider; however, items may be held temporarily as part of the delivery or return process, with accountability remaining with the pharmacy throughout. Further, under Royal Mail's standard Tracked 24 service, proof of delivery is provided through tracked status updates and confirmation of delivery, which may include a delivery signature or, where a signature is not obtained, a photographic record of delivery is provided. Contrary to the Responder's interpretation, the photographic record service, is not a paid add-on service, selected by the sender, but forms part of the service's standard delivery confirmation processes, and therefore, does not come at an additional cost. As such, the Respondent's characterisation of photographic proof of delivery as an optional additional feature is incorrect and the processes in place, do not undermine the existence of a delivery audit trail within our arrangements.

6.1.29 Moreover, please note that the temporary custody of sealed parcels within the postal network, including during failed delivery, redirection, or return-to-sender processes, forms part of the transport function and does not constitute controlled drug storage within the meaning of the Misuse of Drugs Regulations 2001. Legal accountability for the controlled drug remains with the supplying pharmacy throughout transit - until lawful receipt by the patient or return to the pharmacy. This distinction between storage and transport is well established within NHS pharmacy practice and controlled drug governance, and therefore the Respondents claim has no basis and is irrelevant in regard to the application at hand.

6.1.30 To conclude, the Respondent alleges that the Committee cannot be satisfied that the legal test as set out in Regulation 25 (2) (b) of the Regulations has been met. This is not agreed. The Respondent's submissions include a number of operational assertions that do not accurately reflect how the services described operate in practice. By way of example, the respondent characterises photographic proof of delivery under Royal Mail Tracked services as an optional paid feature, when, as we have mentioned above, in fact such photographic records form part of standard delivery confirmation where a signature is not obtained. We note, the Respondent also conflates licensed controlled-drug storage with temporary handling and redelivery processes within a postal network. In light of these inaccuracies, we invite the Committee to place limited weight on the Respondent's operational conclusions

and instead to assess the application against the statutory test under Regulation 25, for which this application falls to be considered.

6.1.31 In their submissions, the Respondent's approach relies heavily on extracting individual phrases from discrete SOPs and reading them in isolation. However, when the SOP framework is considered as a whole, it demonstrates clearly, a coherent governance structure with pharmacy-led accountability, defined escalation pathways, and professional oversight throughout dispensing, delivery, and post-delivery reconciliation. Aspects, which the Respondent has generally raised concerns in respect of. It is to be noted, that the Respondent's misinterpretations do not equate to an absence of appropriate arrangements, particularly where the underlying governance model and allocation of responsibility are clear and consistent. For the avoidance of doubt, we do not rely on delivery providers to undertake clinical identity verification, controlled drug authorisation, temperature monitoring, or regulatory decision-making. These functions remain pharmacy-led and under the control of the Responsible Pharmacist at all times.

6.1.32 Ironically, whilst the Respondent states that our delivery process in respect of the controlled drugs element "shows a lack of awareness of the responsibilities that the pharmacy has" it is actually their inability to properly construe the intended purpose and meaning of the relevant SOP as a collective, which shows a considerable lack of awareness on their part.

6.1.33 As confirmed above, our application must demonstrate and the Committee must be satisfied that the relevant limb of the legal test as set out in Regulation 25 (2) (b) of the Regulations has been met. The Respondents representations merely seek to impose requirements which are not prescribed by the regulatory framework. We have demonstrated above, how, in contrary to the Respondents allegations, our application has in fact, when considered as a collective in unison with our supporting documentation, the NHS England service specifications and wider professional standards - successfully demonstrates that the statutory test applicable to DSPs has indeed been fully satisfied. Therefore, in accordance with the relevant and applicable limb of the legal test, as set out in Regulation 25(2)(b) of the Regulations, our procedures 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 between any person receiving the services and the pharmacy or its staff.

6.1.34 Our arrangements demonstrate a pharmacy-led governance framework, supported by appropriate systems, professional oversight, and audit processes, and are aligned with NHS England commissioning

guidance and the GPhC's standards for registered pharmacies operating as distance selling contractors.

6.1.35 The representations submitted do not identify any failure to meet the requirements of Regulation 25, nor do they demonstrate that our procedures are incapable of safe and effective implementation within a DSP model.

6.1.36 Accordingly, we respectfully submit that the Committee may properly be satisfied that the legal test applicable to DSP applications has indeed been met, and that the Commissioner's original decision to approve the application was indeed correct and should be upheld.

6.1.37 We look forward to hearing from you with your confirmation that our application has been successful and thank you for your time and commitment in considering our application."

6.2 RUSHPORT ADVISORY LLP ON BEHALF OF THE APPELLANT

6.2.1 "I act for Southam Pharmacy which operates a pharmacy at 4 Market Hill, Southam and have been instructed by my client to submit these final comments in response to the new SOPs provided by the Applicant as part of this appeal.

6.2.2 SOP 19 the Applicant states;

"Deliveries may be carried out by our own staff (drivers) or through authorised specialist couriers such as Royal Mail. Both methods are designed to maintain safe custody of CDs, provide patients with flexibility, and ensure traceable, verifiable audit trails. All patients in England are entitled to access this service when prescribed CDs."

6.2.3 Royal Mail Tracked 24 service (listed in the Applicant's previous version of their SOP whereas simply "Royal Mail" is listed now) does not support ID checks, making it entirely inappropriate for deliveries of controlled drugs. In addition, Royal Mail Tracked 24 service does not support delivery immediately back to the pharmacy in the event of a failed delivery.

6.2.4 For successful deliveries the SOP has no requirement to check a patient, or their representatives, ID, meaning it is not safe.

6.2.5 SOP 15 Order Delivery states that for local deliveries the pharmacy's driver can deliver medication. It then states,

"*Refrigerated medicines must be packaged using validated cold chain systems (e.g., Puffin or equivalent) designed to maintain 2–8°C for a defined period (up to 50–54 hours).*

Packaging includes insulated liners, phase-change ice packs, and thermal barriers. Each pack type is tested and validated to withstand variable external conditions (summer/winter).

Cold chain integrity is maintained by:

o Keeping medicines in the pharmacy refrigerator until just prior to dispatch.

o Pre-conditioning ice packs to correct temperatures before packing.

o Using tamper-evident seals to prevent unauthorised opening.

o Limiting time between pharmacy release and courier collection.

Each courier is contracted to meet Good Distribution Practice (GDP) standards for pharmaceuticals and must provide tracking and confirmation of temperature-controlled handling.

Barcoded tracking ensures full visibility. Records are retained for at least 3 months.

Live tracking links are shared with patients upon dispatch so they can anticipate receipt.

In case of a failed delivery, couriers must ensure the parcel remains within the validated cold chain container and attempt redelivery.

If a temperature excursion occurs, the courier alerts the pharmacy immediately. Medicines exposed to conditions outside 2–8°C must not be reused. They are quarantined, logged, and destroyed under the Waste SOP.

Rationale for packaging choice: Validated insulated containers and phase-change cooling systems are used because they are proven to maintain stability within 2–8°C during transport, even under external stress (heat or cold). This protects medicine efficacy, patient safety, and ensures compliance with MHRA expectations for DSPs handling fridge lines."

6.2.6 In response we note;

6.2.7 No details have been provided or what "puffin or equivalent" means or what standards are adhered to.

6.2.8 A courier cannot track the temperature of the contents of a package if the pharmacy has also added "phase change cooling systems" (which are not even explained).

6.2.9 SOP 14 Bagging up – contradicts previously referred to processes for cold chain items. Now the SOP, confirms that cold chain items would use "Puffin or equivalent validated system" and now also adds things like ice packs, thermal blockers and fleece liners will be placed in parcels.

6.2.10 SOP 14 now, for the first time, refers to a "alarmed temperature data logger", which may be placed inside the cooling bag to verify stability

during transit. Products of this nature are not intended for use within packages for deliveries. Alarmed versions require either or both wi-fi or a power source. If such an item were included within multiple parcels it is unclear how a driver would hear an audible alarm as these are not linked to the vehicle system. It is also unclear what a patient would be supposed to do when presented with one of these loggers or if they would be advised to check for themselves if the logger noted any deviation in temperatures.

6.2.11 SOP 33 – DMS

6.2.12 This is the first time the Applicant has included a DMS SOP. The SOP is deficient and unsafe. The DMS process involves multiple stages from 1 to 3. Each stage requires specific processes. Referrals must be checked for regularly each day. All the Applicant has done is provide a basic (and incorrect) overview of DMS.

6.2.13 SOP 3 – Procedures for NHS Essential Services & Advanced and Enhanced Services

6.2.14 This SOP is deficient in several areas. The entire process for Pharmacy First is deficient. The process fails to explain how consultations will be carried out, what consultations may be accepted for, how deliveries of different types of medicines will be handled, or even how a consultation will be carried out to ensure privacy.

6.2.15 The procedure for provision of NMS, contraception service, smoking cessation and flu vaccinations is similarly brief and vague.

6.2.16 In each case the Applicant has simply provided a vague description of what each service is (often incorrectly) and a few words about how the pharmacy might carry out the service. The flu vaccination SOP does not even go through the basic questions that a pharmacist must ask a patient. The Pharmacy First SOP does not mention which pathways can or cannot be provided, does not even explain the purpose of the service, fails to note that patients must be advised on data sharing with the NHS, provides incorrect information about how a patient may access the service (does not even mention referring organisations), makes no mention of the need to have access to the SCR, etc, etc.

6.2.17 Finally, and whilst Committee may not read Business Continuity Plans in much detail, the SOP for Business Continuity and Contingency Planning has almost zero information about Business Continuity or Contingency Planning and instead simply suggests that emergencies will not happen at this pharmacy.

6.2.18 In this case, we submit that the Committee cannot be satisfied that the legal test is met and the application should therefore be refused. SOPs provided are contradictory and confused or do not in fact contain “procedures” for how a service would be provided.

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

7 Consideration

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

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

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

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

Regulation 31

7.5 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).

7.6 The Committee noted the comprehensive response from the Applicant as to why the application should not be refused pursuant to Regulation 31. The Commissioner had concluded that "*There is no pharmacy providing pharmaceutical services at the same or adjacent premises. This regulation therefore does not apply."* The Committee noted that this had not been disputed either on appeal or in subsequent representations. Based on the information provided, the Committee was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

(ii) the safe and effective provision of 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."

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

10. *Where, pursuant to this Part, a person is required to provide details, that obligation is only discharged if the information or documentation provided is sufficient to satisfy NHS England in receipt of it, with good*

cause, that no relevant information or documentation is missing, having regard to the uses that NHS England may need to make of the information or documentation when carrying out its functions.

Regulation 25(1)

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

Regulation 25(2)(a)

7.10 As far as Regulation 25(2)(a) is concerned, the Committee had regard to the application form in which the Applicant states "n/a". The Commissioner, in its decision report, had stated that "*the proposed premises are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list"* and further *"this is confirmed with information available on the NHS.uk website where the nearest general practice is 0.2 miles away."* The Committee noted that this had not been disputed and that it had not been provided with any information to persuade it otherwise. The Committee was therefore satisfied that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

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

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

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

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

7.15 It is not for the Committee to 'approve' or 'disapprove' of these SOPs (as they may contain matters not relevant to the Committee's consideration, and there are many ways an applicant can choose to organise itself in order to comply with the various requirements of the Regulations) and the Committee has not sought to do so. The Committee has sought evidence within the SOPs and application in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.

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

7.17 The Committee noted the following information in the Applicant's SOPs:

7.17.1 *"SOP 1 - Overriding Provisions & Obligations*

Essential Services Obligation

We must provide essential services continuously during our published opening hours to individuals anywhere in England who request them.

These services must be delivered without face-to-face contact at or near the premises i.e. patients (or their representatives) must not meet pharmacy staff in person at or around the premises for essential services."

7.18 SOP 28 – The Responsible Pharmacist

7.18.1 *"RP Absence*

Because Medicare Chemist is a distance-selling pharmacy, continuous cover must be maintained throughout all opening hours.

An RP cannot leave the premises unless another pharmacist is present and signs into the RP Record.

A second pharmacist is always rostered during core and extended hours to ensure uninterrupted supervision.

Before absence, the RP must: Inform the second pharmacist of the reason and expected duration.

Record the absence start time and reason in the RP Record.

Remain contactable and able to return promptly if required.

Instruct the team that the second pharmacist assumes RP responsibilities during the absence.

If an absence exceeds 2 hours:

The second pharmacist must formally assume the RP role.

The Superintendent Pharmacist must be notified."

7.19 Whilst the Committee noted the slightly contradictory information regarding the absence of the Responsible Pharmacist, if the absence exceeds 2 hours, the Committee noted that the Applicant was proposing to have a second pharmacist present at the premises who would be able to sign in as the Responsible Pharmacist during any absence.

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

7.21 With regard to services being available to persons anywhere in England, the Committee noted the following information in the Applicant's SOPs:

7.22 SOP 3 – Procedures for NHS Essential Services & Advanced and Enhanced Services

7.22.1 "*Procedures for NHS Essential Services*

NHS Essential Services are available to any patient in England who requests them. This commitment is communicated through the pharmacy website and the patient information leaflet."

7.23 The Committee also noted the references throughout the SOPs to the use of Royal Mail and couriers as well as the pharmacy's own delivery driver.

7.24 The Committee was of the view, based on all of the information before it, that the services would be provided to persons anywhere in England, who requested those services.

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

7.26 The Committee noted the following information in the Applicant's SOPs:

7.27 SOP 1 – Introduction and Background of SOPs

7.27.1 "*No Face-to-face Contact*

All staff must receive training, including induction, covering the specific terms of service for distance selling pharmacies.

No essential services may involve physical, in-person interaction either on or in the vicinity of the premises.

Any reference in the SOPs to "contact" with a patient should be understood as non–face-to-face (e.g. by phone, email, video call, post).

If any SOP wording suggests that face-to-face contact might occur, staff must immediately refer that to the RP before proceeding."

7.28 SOP 3 - Procedures for NHS Essential Services & Advanced and Enhanced Services

7.28.1 *Communication Channels*

All communication relating to NHS Essential Services will normally be carried out by telephone. Patients may, however, request to communicate by email, text message, secure messaging applications (e.g., WhatsApp on a work mobile), or video call. These methods are acceptable provided patient identifiers have been verified to ensure safe and confidential communication.

7.29 The Committee was of the view that there was nothing provided in the information submitted by the Applicant which demonstrated that pharmaceutical services would be provided by face to face contact at, or in the vicinity of, the pharmacy premises.

7.30 The Committee was also mindful of the regulatory changes as of 1 October 2025, that distance selling pharmacies can no longer provide Directed services (Advanced, National Enhance and Enhanced Services, with the exception of Covid-19 and Flu vaccination services) face to face with the patient at the pharmacy premises. 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.

7.31 In its application, the Applicant stated that it intended to provide Pharmacy First, NMS, Contraception Service, Flu vaccination, Smoking cessation and Hypertension Case Finding. The Committee noted SOP 3 - Procedures for NHS Essential Services & Advanced and Enhanced Services which detailed "The Advanced and Enhanced Services provided by Medicare Chemist" and set out that all services to be provided would be provided on a nationwide basis and would be compliant with "*full alignment with DSP restrictions* …"

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

7.33 The Committee was satisfied that the provision of essential services would be without interruption, would be available to persons anywhere in England and 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.

7.34 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.

7.35 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:

7.35.1 Dispensing of drugs and appliances

7.35.2 Urgent supply without a prescription

7.35.3 Preliminary matters before providing ordered drugs or appliances

7.35.4 Providing ordered drugs or appliances

7.35.5 Refusal to provide drugs or appliances ordered

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

7.35.7 Disposal service in respect of unwanted drugs

7.35.8 Promotion of healthy lifestyles

7.35.9 Prescription linked intervention

7.35.10 Health campaigns

7.35.11 Signposting

7.35.12 Support for self-care

7.35.13 Discharge medicines service

7.35.14 Websites and health promotion zones

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

Providing ordered drugs or appliances

7.37 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 Misue of Drugs Regulations 2001 and, in particular, Regulations 14 and 16, are met).

7.38 The Committee noted that this had also been challenged on appeal by the Appellant's representative who were of the view that "*no information is provided in relation to matters such as the delivery of controlled drugs."*

7.39 The Applicant, in its representations had provided a full suite of SOPs which included SOPs regarding the receipt, dispensing and delivery of controlled drugs as well as the collection and disposal of patient returns.

7.40 The Committee noted SOP 19 – Controlled Drugs: Delivery

7.40.1 *"**Purpose***

This procedure ensures that the delivery of controlled drugs (CDs), including Schedule 2 and 3 medicines, is carried out securely, legally, and in a manner that protects both patients and staff. In line with distant selling pharmacy (DSP) requirements, this SOP integrates secure audit trails, patient communication, identity verification, and packaging standards, ensuring that CDs reach the intended recipient safely while complying with Home Office, NHS, and GPhC guidance.

Scope of Service

Deliveries may be carried out by our own staff (drivers) or through authorised specialist couriers such as Royal Mail. Both methods are designed to maintain safe custody of CDs, provide patients with flexibility, and ensure traceable, verifiable audit trails. All patients in England are entitled to access this service when prescribed CDs.

…

Delivery Procedures for Schedule 2 and 3 CDs *Because CDs present a higher risk of misuse and diversion, the following safeguards apply:*

Pre-delivery checks: *Where a CD is included in the delivery, the pharmacy must telephone the patient in advance to confirm they will be available to accept the medicine. Patients must also be notified when CDs are dispatched by courier, and provided with tracking information.*

Prescription and register entries: *Before leaving the premises, the driver signs the delivery sheet and prescription to complete the audit trail. In the CD register, the driver's name and the word delivery are recorded as the person collecting the medicine.*

Packaging: *CDs are always packed separately in a tamper-evident bag, with a CD alert sticker attached. Where the patient has additional medicines, the CD bag is attached securely to the remainder of the delivery. Packaging must not disclose the contents to maintain confidentiality.*

Vehicle security: *Pharmacy deliveries are transported only in coded, locked safe boxes inside vehicles. Vans used for CD deliveries have no rear windows, reducing the risk of break-in. All vehicles must remain locked at all times when unattended.*

Courier arrangements: *Royal Mail Tracked 24 is used for CD deliveries, offering patients greater flexibility to monitor deliveries, reschedule, or arrange alternative delivery addresses or safe places (where permitted by the patient). Each CD dispatch is preceded by a telephone notification, and delivery signatures and statuses are checked daily online.*

Audit trail: *A Controlled Drugs Delivery Sheet is completed in addition to the standard delivery log. On receipt, patients or their authorised representatives must sign either the pharmacy delivery sheet (driver deliveries) or the Royal Mail/courier tracking system.*

Successful Deliveries

On successful delivery, the patient or their authorised representative must sign to confirm receipt. These signatures, whether on paper or electronically via courier systems, must be cross-referenced against the prescription and CD register before the end-of-day reconciliation.

Unsuccessful Deliveries

By pharmacy driver*: If the delivery is unsuccessful, the CD must be returned to the pharmacy on the same day, re-entered into the CD register with an explanation, and stored securely in the CD cabinet until redelivery. On retry, the item is signed out again.*

By Royal Mail/courier: *Failed deliveries are reported to both the pharmacy and the patient via the tracking system. If CDs cannot be returned the same day, the courier stores them securely in a Home Office-licensed facility overnight. The pharmacy conducts daily checks on all courier-delivered CDs to verify delivery status and patient signatures."*

7.41 Under "Roles and Responsibilities" the Committee noted that "*Drivers and couriers are responsible for secure transport, identity verification of the recipient and maintaining the audit trail*." The Committee noted the use of the Royal Mail tracked service and that they would also be used for "identity verification". The Committee noted that no further information was provided by the Applicant as to how the identity would be verified, which had been questioned by the Appellant on several occasions.

7.42 The Committee noted the SOPs with regard to the delivery of cold chain medicines.

7.43 SOP 14 – Bagging up

7.43.1 *"Cold Chain Packaging (Temperature – Sensitive Medicines)*

For medicines requiring refrigeration (2–8°C), additional validated packaging processes must be followed:

Corrugated Insulated Liners: Flat-packed liners are folded and fitted to reinforce the inside of delivery boxes, creating full thermal protection. These liners provide insulation against external temperature changes.

Thermal Blockers and Fleece Liners: Placed between ice packs and medicines to prevent direct contact and avoid freezing damage. This protects thermolabile products from cold as well as heat.

Ice Packs and Data Logging: Ice packs are added around the liners, and an alarmed temperature data logger may be placed inside the cooling bag to verify stability during transit.

Reinforced Outer Packaging: All cold chain packages are placed inside reinforced cardboard boxes, tamper-proof sealed, and labelled with "FRIDGE LINE" and "FRAGILE" stickers.

Validation: The packaging solution used (e.g., Puffin or equivalent validated system) is designed to maintain medicines at 2–8°C for up to 50–54 hours, exceeding the maximum required stability period for both local driver deliveries and national courier shipments.

This validated process ensures end-to-end integrity of temperature-sensitive medicines until dispatch, supporting DSP obligations to deliver medicines safely without in-person handover."

7.44 SOP 15 – Delivery Order

7.44.1 *"Purpose*

…

Patients received their medicines intact, including those requiring controlled handling or refrigeration.

…

Delivery Process

Preparation for Delivery

Ensure all prescriptions are clinically and accuracy checked, bagged securely, and appropriately labelled.

For each item, complete the Delivery Log (electronic or paper) with: Patient name and address (with alternative delivery address if authorised).

Any relevant notes for the patient.

Confirmation of written authorisation if delivery is to a third party.

Securely package items using validated materials: Ambient medicines in reinforced bags or padded packaging with tamper seals.

Refrigerated medicines (fridge lines) in validated insulated packaging with corrugated liners, thermal barriers, and ice packs, ensuring temperature stability of 2–8°C for the duration of transit.

All packages labelled discreetly as "Private & Confidential" and, where applicable, marked with storage requirements (e.g., "Store in refrigerator 2–8°C").

Send confirmation to the patient (SMS, email, or app notification) once items are ready, including estimated delivery time.

Supervised Handover to Driver / Courier

The pharmacist on duty must supervise the transfer of all items for delivery.

The delivery driver must check that items correspond to the Delivery Log and sign the record before leaving.

Deliveries must be stored securely in the locked vehicle, out of sight, and removed only when making the delivery.

Cold chain and controlled drug items should remain in the pharmacy refrigerator or CD cabinet until just before handover.

Local Delivery (Pharmacy Driver)

The driver must confirm the patient's or representative's full name and address before handing over the package.

Medicines must not be left unattended, posted through letterboxes, or left with unauthorised individuals.

The recipient must sign the Delivery Log. If unable, the driver may sign on their behalf with consent, noting the reason.

Returns must be collected in the designated Patient Returned Medication container and processed as per the Returns SOP.

Postal Delivery (Royal Mail)

Used for non-CD, non-fridge items outside the local delivery radius.

All packages sent via Royal Mail Tracked or Signed For with proof of delivery.

Tracking numbers must be logged against each patient's delivery and stored for at least 3 months.

Patients receive confirmation with their tracking number once dispatched.

If unsuccessful, Royal Mail will leave a "Sorry We Missed You" card, and the patient must rearrange delivery or collect from their local post office.

Cold Chain Medicines (Courier Delivery)

Refrigerated medicines must be packaged using validated cold chain systems (e.g., Puffin or equivalent) designed to maintain 2–8°C for a defined period (up to 50–54 hours).

Packaging includes insulated liners, phase-change ice packs, and thermal barriers. Each pack type is tested and validated to withstand variable external conditions (summer/winter).

Cold chain integrity is maintained by:

- *Keeping medicines in the pharmacy refrigerator until just prior to dispatch.*

Pre-conditioning ice packs to correct temperatures before packing.

Using tamper-evident seals to prevent unauthorised opening.

Limiting time between pharmacy release and courier collection.

Each courier is contracted to meet Good Distribution Practice (GDP) standards for pharmaceuticals and must provide tracking and confirmation of temperature-controlled handling.

Barcoded tracking ensures full visibility. Records are retained for at least 3 months.

Live tracking links are shared with patients upon dispatch so they can anticipate receipt.

In case of a failed delivery, couriers must ensure the parcel remains within the validated cold chain container and attempt redelivery.

If a temperature excursion occurs, the courier alerts the pharmacy immediately. Medicines exposed to conditions outside 2–8°C must not be reused. They are quarantined, logged, and destroyed under the Waste SOP.

Rationale for packaging choice: Validated insulated containers and phase-change cooling systems are used because they are proven to maintain stability within 2–8°C during transport, even under external stress (heat or cold). This protects medicine efficacy, patient safety, and ensures compliance with MHRA expectations for DSPs handling fridge lines."

7.45 The Committee noted the use of "ice packs" for cold chain delivery and whilst the Applicant had stated that these would not be placed next to the medication, there was no information provided as to how these would ensure that a consistent temperature was maintained which would not compromise the integrity of the medication. The Committee noted that there was reference to the fridge lines, once packaged with the ice packs, being able to maintain the temperature for 50 to 54 hours but this was with regard to using a courier, presumably for long haul journeys.

7.46 The Committee was mindful that the "live tracking links" referred to in the SOP were with regard to tracing the location of the items being delivered rather than a system which tracked the temperature of the fridge lines. The Committee further noted the use of the word "*may*" with regard to the use of an "*alarmed data logger*" in SOP 14, which was not referenced in SOP 15, which suggested it would not be used for every local cold chain delivery, and was therefore unsure under which circumstances this would be used to ensure the integrity of every cold chain or if this was at the discretion of the pharmacist. Where the data logger was used, there was no reference to the Applicant's own delivery driver actively checking the log prior to handing over medicines to patients.

7.47 Whilst the Committee noted the comments with regard to a *"temperature excursion"* occurring, the Committee noted that there was very little information provided as to how the courier would ensure that the cold chain was maintained or, if there was a breach in the cold chain, how they would become aware of this and what the process was for the return of any medication where the integrity of the cold chain had been breached.

7.48 The Committee noted that SOP 15 under "Scope and responsibility" states "*Delivery Drivers/Couriers: Transport and deliver medicines safely, maintaining confidentiality and any required conditions (eg cold chain)."* The Committee read this to mean there could be two separate means of delivering cold chain items. The Committee considered that if there was a deviation in temperature outside of the recommended limits there was nothing provided as to how either the pharmacist at the pharmacy or the delivery driver would know that this had occurred and ensure that compromised medicines were not delivered.

7.49 Taking all of the information before it into account, the Committee was of the view that the Applicant had not provided sufficient information for it to be satisfied that there would be compliance with paragraph 8(1) of Schedule 4.

7.50 The Committee noted that, in the application form, in response to "*If you are undertaking to provide appliances, specify the appliances that you undertake to provide (or write 'none' if it is intended that the pharmacy will not provide appliances)*" the Applicant had stated "Drug Tariff Part IX".

7.51 The Committee noted that the Applicant had not expanded upon this in further representations but noted reference in the SOPs to appliances and in particular:

7.52 SOP 6 – Pharmaceutical and Legal Assessment;

7.52.1 *"Items Requiring Measuring and Fitting*

Where a prescription is received for an item that requires measuring or fitting, the following steps apply:

Contact the patient promptly to explain that the pharmacy does not provide a measuring and fitting service.

Advise the patient that these items cannot be supplied by this pharmacy.

Signpost the patient to at least two alternative providers in their local area who can supply and fit the item appropriately.

Record the advice given, including the details of providers signposted, in the patient's record.

Refer to the pharmacy's Signposting SOP for further guidance on identifying alternative providers."

7.53 SOP 9 – EPS2 Nomination and Information stated:

7.53.1 "*Distance Selling Pharmacy Considerations*

…

This pharmacy does not provide appliances that require measuring or fitting. Patients must be referred to at least two local providers for these services (see Signposting SOP)."

7.54 SOP 10 – EPS2 Release Dispensing Process

7.54.1 *"Constraints & Guidance*

…

Appliances requiring measuring/fitting are not supplied. If the prescription includes such items, they must be refused and the patient signposted to at least two other providers."

7.55 SOP 22 – Support for Self-Care, Signposting and Health Promotion

7.55.1 "*Items Requiring Measuring and Fitting*

For appliances, stoma customisation, or any item requiring fitting, patients must be informed that Medicare Chemist cannot provide this service.

Patients must be signposted to at least two alternative providers in their area.

The Signposting SOP should be followed in all such cases.

7.56 Whilst the Committee noted the consistency within the SOPs that the Applicant was not going to be providing appliances, it was mindful that this was not what the Applicant had applied for in the original application form which was "Drug Tariff Part IX" with no exemptions or exceptions.

7.57 The Committee was of the view that this led to ambiguity as to whether or not the Applicant would be providing all appliances as set out in the Drug Tariff Part IX or only those that did not require measuring or fitting, given the conflicting information contained within the application form and the SOPs.

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

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

Other considerations

7.60 The Committee noted the Appellant's representative's comments regarding "*the provision of live video consultations."* The Committee noted the various references throughout the SOPs to "video call" as well as the use of other non-face to face methods of communication. The Committee was of the view that there was sufficient information for it to be satisfied that, if required, the Applicant would be able to provide services to patients via live video consultations.

7.61 The Committee noted the Appellant's representative had stated, on appeal, that the Applicant had been *"silent on a significant number of parts of the relevant legal test such as Urgent Supply."* The Committee noted that the Applicant had provided, in representations SOPs which included "SOP 13 – Emergency and Urgent Supply of Prescription Only Medicines (POM)" which stated:

7.61.1 *"Purpose*

This SOP sets out the procedures for handling requests for emergency supply and urgent supply of Prescription Only Medicines (POMs) in a Distance Selling Pharmacy (DSP). Although the remote nature of the service means that such requests occur less frequently than in traditional community pharmacies, staff must be prepared to respond appropriately in line with legal and professional requirements.

The objective of this SOP is to ensure:

Patients have safe and timely access to medicines in emergency situations.

Pharmacists act within the provisions of the Medicines Act 1968 and Human Medicines Regulations 2012.

All requests are assessed, verified, recorded, and supplied only where lawful and clinically appropriate.

Distance selling limitations (no face-to-face services) are respected, with communication carried out through telephone, video call, email, or other secure digital means.

Delivery processes prioritise urgent cases without imposing additional costs on patients.

…

Scope

This SOP applies to all NHS and private prescriptions handled by the pharmacy, covering both:

Urgent supply at the request of a prescriber.

Emergency supply at the request of a patient."

7.62 The Committee noted the information contained within SOP 13 which went on to describe how the Applicant would process such a request. The Committee noted that the SOPs refer to pharmaceutical services being delivered by several means of non-face to face communication including telephone and email and considered that it was reasonable to infer that these methods would be used to receive requests from prescribers for the urgent supply of drugs.

7.63 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.

7.64 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" the safe and effective provision.

Summary

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

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

7.66.1 confirm the Commissioner's decision;

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

7.66.3 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.

7.67 In those circumstances, given that the Committee has reached a different conclusion to the Commissioner, the Committee determined that the decision of the Commissioner must be quashed.

7.68 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.

7.69 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.

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

8 Decision

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

8.2 The Committee:

8.2.1 quashes the decision of the Commissioner; and

8.2.2 redetermines the application as follows -

8.2.2.1 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;

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

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

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

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

8.2.3 The application is refused.

Case Manager
Primary Care Appeals