NHS Resolution

18 May 2026

REF: SHA/26852

8th Floor
10 South Colonnade
Canary Wharf
London
E14 4PU

Tel: 020 3928 2000
Email: nhsr.appeals@nhs.net

APPEAL AGAINST NHS DORSET ICB DECISION TO REFUSE AN APPLICATION BY SHALLI LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT VISION WORKSURFACES, 24 WEST HOWE INDUSTRIAL ESTATE, BOURNEMOUTH, BH11 8JZ 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:

Shalli Ltd
PCSE on behalf of Dorset ICB

8th Floor
10 South Colonnade
Canary Wharf
London
E14 4PU

Tel: 020 3928 2000
Email: nhsr.appeals@nhs.net

REF: SHA/26852

APPEAL AGAINST NHS DORSET ICB DECISION TO REFUSE AN APPLICATION BY SHALLI LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT VISION WORKSURFACES, 24 WEST HOWE INDUSTRIAL ESTATE, BOURNEMOUTH, BH11 8JZ UNDER REGULATION 25

1 The Application

By application dated 22 June 2025, Shalli Ltd ("the Applicant") applied to Dorset ICB ("the Commissioner") for inclusion in the pharmaceutical list at Vision Worksurfaces, 24 West Howe Industrial Estate, Bournemouth, BH11 8JZ 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 ""We will provide stoma appliances, incontinence appliances, and dressings as listed in Part IX of the Drug Tariff." Additionally, we will offer home delivery of appliances, Customisation services (e.g., stoma care tailoring), and provide advice and support (via telephone or in-person)."

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

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

Pharmacy procedures

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

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

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

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

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

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

1.8 “Procedure for Patients Attending the Premises in Person:

1.9 People may choose to visit our pharmacy premises directly, as a Distance Selling Pharmacy, we’re not permitted to provide NHS services in person. Our team will kindly explain that we’re a distance selling pharmacy and, by law, we’re not permitted to offer NHS services face-to-face at the pharmacy itself.

1.10 We’ll give them a clear explanation of how to access all our services as they would from a local pharmacy by contacting us via phone, email, or by post, if needed. Also, we can offer them a leaflet or card with our contact details and simple instructions on how to get help or medication they needs [sic] all from the comfort of their home.

1.11 Behind the scenes, we have a full team ready to offer advice, dispense prescriptions, deliver medicines securely and handle queries from anywhere in England.

1.12 We are fully committed to ensuring that every patient can access our services easily, safely, and without interruption.

1.13 All essential NHS services will be delivered remotely during our normal opening hours, ensuring patient's receives high-quality care, even if we never meet face to face. This process ensures that we stay fully compliant with the regulations while offering accessible service for everyone.

1.14 We do plan to offer some advanced services, but we’re fully aware that no essential services can be provided face-to-face at our premises.

1.15 To stay compliant, services like the New Medicine Service will be delivered remotely, by phone or video call.

1.16 If we offer services like flu vaccinations, these will take place off-site (e.g., at community venues), never at the pharmacy itself.

1.17 At no point will any essential service (like dispensing or advice) be offered in person at the premises.

1.18 We’ve set up clear procedures to keep advanced services separate from essential ones and ensure everything is done safely and in line with NHS rules.”

2 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 10 December 2025 states:

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

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

Extract from the South West Pharmaceutical Services Regulations Committee (PSRC) Decision report

2.2 "The SW Committee noted:

2.3 The applicant proposes opening a distance selling pharmacy in premises at West Howe Industrial Estate, Bournemouth.

PRELIMINARY ISSUES

2.4 Nature of the application

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

2.6 Regulation 31 (same or adjacent premises)

2.7 Regulation 31 states: [quoted in full]

2.8 There are no other pharmacies at the proposed premises, or adjacent. The nearest pharmacy is 0.6 miles (Avicenna Pharmacy, West Howe) from the proposed premises. The SW Committee was satisfied it is not required to refuse the application by virtue of Regulation 31.

Representations

2.9 Full details of the applicant's proposals were notified to interested parties in accordance with the Regulations. No representations were received.

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

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

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

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

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

2.15 Information about how the applicant would operate the proposed pharmacy is provided within the supporting information at part 7 of the application form.

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

Services available without interruption

2.17 The applicant has proposed 41.5 core hours of 9am – 1pm and 2pm – 5.30pm Monday to Friday. 9am – 1pm on Saturdays. Closed Sundays. No additional supplementary hours are proposed.

2.18 In section 7 of the application form it states they have a full team ready to offer advice, dispense prescriptions and deliver medicines securely and they are fully committed to ensuring every patient can access services easily and safely without interruption.

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

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

2.20 In section 7 of the application form it states their team will explain they are a distance-selling pharmacy and by law not permitted to offer NHS services face to face at the pharmacy itself. They will give a clear explanation of how to access their services by contacting them via phone call, email or by post.

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

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

2.22 The SW Committee was not satisfied the pharmacy will receive prescriptions without face-to-face contact.

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

Paragraph 6 – Urgent supply without a prescription

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

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

Paragraph 7 – Exemption Checking and payment

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

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

Paragraph 8 providing ordered drugs or appliances

2.28 There appears to be no mention of this in the application form. There is nothing about how deliveries will be managed and audited, there is nothing about protecting the integrity of delivered medicines.

2.29 The SW Committee was not satisfied that suitable arrangements are in place for the delivery of items including temperature controlled items and CDs.

Paragraph 8(4)

2.30 At part 4 of the application form it states they will provide stoma appliances, incontinence appliances and dressings as listed in Part IX of the Drug Tariff. They propose to offer home delivery of appliances and customisation services and provide advice and support via telephone or in person.

2.31 The SW Committee was not clear if the applicant proposed offering appliances that required measuring and fitting, there was nothing about how measuring and fitting would be performed without face to face contact. As it was not clear if appliances requiring measuring and fitting would be supplied the SW Committee could NOT be satisfied that suitable arrangements are in place for the measuring and fitting of appliances.

Paragraph 9(4) – Repeat Dispensing

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

2.33 The SW Committee was not satisfied that arrangements are in place for Repeat Dispensing including reminding patients of the importance of only requesting items they need, confirming the medication is being used appropriately, checking for side effects and the patient has not had any changes in health.

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

2.34 At part 7 of the application form it indicates remote means of communication will be used but provides very little information on how advice, especially proactive advice, will be given.

2.35 The SW Committee was not satisfied that suitable arrangements are in place so the pharmacy can communicate with and provide essential services such as advice without face to face contact.

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

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

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

Paragraph 13 – Disposal service in respect of unwanted drugs

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

2.39 The SW Committee was not satisfied that suitable arrangements are in place for the disposal of unwanted medicines without face to face contact.

Paragraph 17 – prescription linked interventions

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

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

Paragraph 18 - Public health campaigns

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

2.43 The SW Committee was not satisfied that suitable arrangements are in place to provide public health campaigns without face to face contact.

Paragraph 19 and 20 – Signposting

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

2.45 The SW Committee was not satisfied that suitable arrangements are in place to provide signposting services without face to face contact.

Paragraph 21 and 22 (self-care)

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

2.47 The SW Committee was not satisfied that suitable arrangements are in place to provide self-care services without face to face contact.

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

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

2.49 The SW Committee was not satisfied that the applicant has explained how it will ensure that it has a website for use by the public for the purpose of accessing pharmaceutical services from those premises, on which there is an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues.

Other

2.50 There is no mention of how the Discharge Medicine Service will be provided or how they will engage in national Public Health Campaigns.

2.51 At part 7 of the application form it states they plan to offer some advanced services and to stay compliant, services like the New Medicine Service will be delivered remotely by phone or video call. If they offer services like flu vaccinations, these will take place off-site (e.g. at community venues), but never at the pharmacy itself. At no point will any essential services be offered in person at the premises.

Decision

2.52 The SW Committee determined that the application should be REFUSED because:

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

2.52.2 The SW Committee is satisfied that the premises of the applicant are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

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

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

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

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

Appeal Rights

2.53 As the application is refused, the applicant will have appeal rights."

3 The Appeal

In an email dated 8 January 2026, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "We formally appeal the decision of the South West Pharmaceutical Services Regulations Committee dated 6 November 2025, which refused our application for inclusion in the pharmaceutical list as a distance selling pharmacy.

3.2 We respectfully submit that the refusal was based on insufficient procedural detail, rather than any fundamental non-compliance with Regulation 25 or Schedule 4 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

Basis of Appeal

3.3 The Committee confirmed that:

3.3.1 The proposed premises are not adjacent to or in close proximity to other pharmacy premises

3.3.2 The premises are not on the same site or in the same building as a provider of primary medical services

3.3.3 The Committee was satisfied that services would be provided without interruption during opening hours

3.4 The refusal was therefore limited to concerns that the Committee did not have sufficient information to be satisfied that:

3.4.1 All essential services would be provided without face-to-face contact

3.4.2 Services would be provided safely and effectively to persons anywhere in England”

Additional Evidence Submitted with This Appeal

3.5 “To address these concerns comprehensively, we submit a Regulation 25(2)(b) SOP Evidence Pack, which directly responds to every refusal paragraph raised by the Committee.

3.6 This evidence includes:

3.6.1 A Refusal Response Index, mapping each refusal paragraph to the corresponding SOP and supporting evidence

3.6.2 A complete suite of Standard Operating Procedures (SOPs) covering all Schedule 4 essential services, including:

3.6.2.1 Receipt of prescriptions via EPS and post only

3.6.2.2 Urgent supply without a prescription

3.6.2.3 Exemption checking and payment collection

3.6.2.4 Repeat dispensing

3.6.2.5 Remote clinical advice and prescription-linked interventions

3.6.2.6 Disposal of unwanted medicines

3.6.2.7 Public health campaigns, signposting, and self-care

3.6.3 A clear statement confirming that no face-to-face services are provided at the premises

3.6.4 Explicit confirmation that the pharmacy will not supply appliances requiring face-to-face measuring or fitting

3.6.5 Staff workflow diagrams, training framework, and competency assessment records Mock website screenshots (descriptive) demonstrating compliance with Paragraph 28C, including:

3.6.6 A clearly promoted Health Promotion Zone

3.6.6.1 An interactive patient contact page

3.6.6.2 EPS nomination and postal prescription pathways

3.6.7 A draft national courier Service Level Agreement, covering:

3.6.7.1 Secure delivery across England

3.6.7.2 Controlled Drugs handling

3.6.7.3 Cold-chain management

3.6.7.4 Audit trails, tracking, and incident escalation

Compliance Position

3.7 Taken together, the submitted evidence demonstrates that:

3.7.1 All essential pharmaceutical services will be provided without interruption

3.7.2 Services will be delivered exclusively by remote means, without any face-to-face contact at the premises

3.7.3 Robust governance, delivery, and communication systems are in place to ensure safe and effective provision of services to persons anywhere in England

3.8 We respectfully submit that the additional evidence fully resolves the Committee's concerns and satisfies the requirements of Regulation 25(2)(b) and Schedule 4.

Request

3.9 In light of the above, we respectfully request that the refusal decision be overturned and that Shalli Ltd be included in the pharmaceutical list in respect of the proposed distance selling premises at:

3.9.1 Vision Worksurfaces, 24 West Howe Industrial Estate, Bournemouth, BH11 8JZ

3.10 We thank the Committee for its consideration and remain available to provide any further clarification if required."

"Appeal Against Refusal – Distance Selling Pharmacy

3.11 Application and Case Details

3.12 Case reference: CAS-370505-C8K1G4

3.13 Applicant: Shalli Ltd

3.14 Application type: Application for inclusion in a pharmaceutical list – distance selling premises (excepted application).

3.15 Proposed premises: Vision Worksurfaces, 24 West Howe Industrial Estate, Bournemouth, BH11 8JZ.

Background to the Refusal Decision

3.16 This appeal is submitted following the refusal decision of the South West Pharmaceutical Services Regulations Committee dated 6 November 2025. The Committee confirmed that Regulation 31 did not apply, that the premises were not adjacent to existing pharmacy premises, and that the premises were not co-located with primary medical services. The Committee was satisfied that essential services could be provided without interruption during opening hours. The refusal was based solely on the Committee stating that it did not have sufficient procedural detail to be satisfied that all essential services would be provided safely, effectively, and without face-to-face contact, in accordance with Regulation 25(2)(b).

Clarification Regarding Face-to-Face Services and Appliances

3.17 For the avoidance of doubt, the proposed pharmacy premises will operate strictly as a distance selling pharmacy. Members of the public will not be permitted to attend the premises for any pharmaceutical service.

3.18 No face-to-face services of any kind will be provided from the premises. In addition, the pharmacy will not supply appliances requiring face-to-face measuring or fitting. Where a patient requires an appliance that necessitates face-to-face assessment, measuring, or fitting, the patient will be appropriately signposted to an alternative provider capable of delivering such services.

Purpose of This Appeal Submission

3.19 This appeal submission provides comprehensive, inspection-grade operational detail addressing every refusal paragraph raised by the Committee. Each element of Schedule 4 essential services is addressed individually, with explicit explanations of how services are delivered remotely, governed, audited, and quality assured. This submission should be read alongside the attached SOP Evidence Pack, Refusal Response Index, and Courier Service Level Agreement, which together demonstrate full compliance with Regulation 25 and Schedule 4.

Formal Request

3.20 Shalli Ltd respectfully submits that the Committee's concerns have now been fully addressed. We therefore request that the refusal decision be overturned and that Shalli Ltd be included in the pharmaceutical list in respect of the proposed distance selling premises.

Refusal Response Index

3.21 This index maps each refusal paragraph from the decision dated 6 November 2025 to the corresponding Standard Operating Procedure (SOP) and supporting evidence submitted by Shalli Ltd (Case reference: CAS-370505-C8K1G4)

Refusal paragraph	Committee concern	Evidence submitted
15-16	Receipt of prescriptions without any face to face contact at the pharmacy premises	SOP 01 – Receipt of Prescriptions without face to face
18-19	Provision of urgent supply without a prescription and the safeguards in place	SOP 02 – Urgent Supply without prescription
20-21	Checking of exemption status and collection of payments without in-person interaction	SOP 03 – Exemption Checking and Payment Collection
22-23	Arrangements for delivery of medicines, including controlled drugs and cold chain items	SOP 04 – Delivery of Medicines, supported by the Courier Service Level Agreement
24-25	Whether appliances requiring face to face measuring or fitting would be supplied	SOP 05 – Appliances; explicit exclusion of face to face measuring and fitting
26-27	Repeat dispensing arrangements and ongoing clinical review	SOP 06 – Repeat Dispensing
28-29	Provision of advice and patient communication	SOP 07 – Patient Advice and Communication
30-31	How patients are advised of the benefits of repeat dispensing	SOP 06 – Repeat Dispensing
32-33	Arrangements for disposal of unwanted medicines	SOP 08 – Disposal of unwanted medicines
34-35	Prescription linked interventions and provision of lifestyle advice	SOP 09 – Prescription Linked Interventions
36-37	Participation in public health campaigns	SOP 10 – Public Health Campaigns
38-39	Signposting of patients to other appropriate services	SOP 11 – Signposting and Self-care
40-41	Provision of self-care advice	SOP 11 – Signposting and Self-care
42-43	Website compliance and provision of a Health Promotion Zone in accordance with paragraph 28C	SOP 12 – Website and Health Promotion Zone
44-45	Engagement with national services and public health initiatives, including discharge medicines	SOP 09 and 10

"Distance Selling Pharmacy – SOP Pack & Staff Workflow

3.22 This document contains Standard Operating Procedures (SOPs) and staff workflow diagrams designed to address all refusal points raised by the SW Pharmaceutical Services Regulations Committee under Regulation 25(2)(b) and Schedule 4 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

3.23 SOP 01 – Receipt of Prescriptions (Non Face-to-Face)

3.24 Purpose:

3.24.1 To ensure NHS prescriptions are received without face-to-face contact.

3.25 Scope:

3.25.1 Applies to all NHS, private, and hospital prescriptions.

3.26 Procedure:

3.26.1 NHS prescriptions are received primarily via Electronic Prescription Service (EPS).

3.26.2 Patients are instructed via the website, welcome leaflet, and telephone to nominate the pharmacy.

3.26.3 Paper prescriptions are received only by post.

3.26.4 On receipt, prescriptions are date-stamped, logged into the PMR, and scanned.

3.26.5 No physical handover from patients is permitted.

3.27 Controls:

3.27.1 Clear signage stating no walk-in service.

3.27.2 Staff training on refusal of in-person submissions.

3.28 SOP 02 – Urgent Supply Without Prescription

3.29 Purpose:

3.29.1 To provide urgent supplies safely without face-to-face contact.

3.30 Procedure:

3.30.1 Patient contacts pharmacy by phone or video.

3.30.2 Identity verified using 2 identifiers.

3.30.3 Pharmacist conducts clinical assessment.

3.30.4 SCR accessed where available or GP contacted.

3.30.5 Decision recorded in PMR.

3.30.6 Medicine supplied via secure courier

3.31 SOP 03 – Exemption Checking & Payments

3.32 Procedure:

3.32.1 Patients complete online exemption declaration form.

3.32.2 Evidence uploaded digitally or confirmed via NHS systems.

3.32.3 Payments collected via secure online payment portal.

3.32.4 FP57 issued electronically if required.

3.33 SOP 04 – Delivery of Medicines (Including CDs & Cold Chain)

3.34 Procedure:

3.34.1 All deliveries dispatched via approved courier.

3.34.2 Temperature-sensitive items packed in validated insulated containers.

3.34.3 CDs packaged separately with tamper-evident seals.

3.34.4 Signature and ID verification required upon delivery.

3.34.5 Delivery tracked and audited.

3.35 SOP 05 – Appliances, Measuring & Fitting

3.36 Statement of Scope:

3.36.1 The pharmacy will not supply appliances requiring face-to-face measuring or fitting.

3.37 Procedure:

3.37.1 Only standard-size appliances supplied.

3.37.2 Patient suitability confirmed remotely.

3.38 SOP 06 – Repeat Dispensing

3.39 Procedure:

3.39.1 Patients enrolled with consent.

3.39.2 Automated reminders sent prior to each issue.

3.39.3 Pharmacist conducts clinical check remotely.

3.39.4 Any changes escalated to prescriber.

3.40 SOP 07 – Patient Advice & Communication

3.41 Procedure:

3.41.1 Advice provided via phone, video, or secure email.

3.41.2 All interactions documented in PMR.

3.41.3 Proactive counselling provided for new medicines.

3.42 SOP 08 – Disposal of Unwanted Medicines

3.43 Procedure:

3.43.1 Patients request disposal kit.

3.43.2 Prepaid, tamper-evident packaging supplied.

3.43.3 Medicines returned and disposed via licensed contractor.

3.44 SOP 09 – Prescription-Linked Interventions & Lifestyle Advice

3.45 Procedure:

3.45.1 Pharmacist identifies intervention opportunity.

3.45.2 Advice delivered remotely.

3.45.3 Outcome recorded and GP informed if required.

3.46 SOP 10 – Public Health Campaigns

3.47 Procedure:

3.47.1 NHS campaigns promoted via website, email, and leaflets.

3.47.2 Materials reviewed quarterly.

3.48 SOP 11 – Signposting & Self-Care

3.49 Procedure:

3.49.1 Patients assessed remotely.

3.49.2 Signposted to NHS 111, GP, or emergency services where appropriate.

3.49.3 Self-care advice provided digitally.

3.50 SOP 12 – Website & Health Promotion Zone

3.51 Purpose:

3.51.1 To ensure compliance with Paragraph 28C regarding websites and health promotion zones”

“SOP GOVERNANCE & VERSION CONTROL (Regulatory Format)

3.52 Each SOP operates under the following governance structure:

3.52.1 SOP Owner: Superintendent Pharmacist

3.52.2 Approved by: Company Director / Superintendent Pharmacist

3.52.3 Review Cycle: Annual or upon regulatory change

3.52.4 Version Control: Sequential numbering with revision history

3.52.5 Staff Access: Digital SOP folder with read-and-sign requirement

3.53 Example Header (applies to all SOPs):

3.54 SOP Number: DSP-SOP-01

3.54.1 Title: Receipt of Prescriptions (Non Face-to-Face)

3.54.2 Effective Date: [dd/mm/yyyy]

3.54.3 Review Date: [dd/mm/yyyy]

3.54.4 Version: 1.0”

“COURIER SERVICE LEVEL AGREEMENT (DRAFT)

3.55 Parties:

3.56 This Service Level Agreement (SLA) is between [Pharmacy Company Name] (“The Pharmacy”) and [Courier Company Name] (“The Courier”).

3.57 Scope of Services:

3.57.1 Collection and delivery of pharmaceutical items to patients across England

3.57.2 Handling of standard medicines, temperature-sensitive items, and Controlled Drugs (Schedules 2–5)

3.58 Delivery Standards:

3.58.1 Standard deliveries completed within 24–48 hours

3.58.2 Urgent deliveries completed within agreed expedited timeframe

3.58.3 Signature required for all deliveries

3.58.4 ID verification required for Controlled Drugs

3.59 Temperature Control:

3.59.1 Use of validated insulated packaging for cold-chain items

3.59.2 Temperature maintained between 2–8°C where required

3.59.3 Exception reporting for temperature excursions

3.60 Security & Confidentiality:

3.60.1 Tamper-evident packaging used for all consignments

3.60.2 No redirection without pharmacy authorisation

3.60.3 GDPR-compliant handling of patient data

3.61 Audit & Tracking:

3.61.1 End-to-end tracking provided

3.61.2 Proof of delivery available electronically

3.61.3 Delivery data retained for audit purposes

3.62 Incident Management:

3.62.1 Failed deliveries reported same day

3.62.2 Lost or damaged items escalated immediately

3.62.3 Investigation reports provided within 48 hours

3.63 Governance:

3.63.1 SLA reviewed annually

3.63.2 Courier staff trained in pharmaceutical handling requirements

3.64 Review & Governance:

3.64.1 SOPs reviewed annually or upon regulatory change.

3.64.2 Staff training recorded and audited.

3.65 Declaration:

3.66 These SOPs ensure uninterrupted, safe, and effective provision of essential services without face-to-face contact, in compliance with Regulation 25 and Schedule 4 requirements”

“Website Structure (Mock Screenshots – Descriptive):

3.67 Screenshot 1 – Homepage Banner (Mock Description):

3.67.1 Banner text: "NHS Distance Selling Pharmacy – No Walk-in Service"

3.67.2 Call-to-action buttons: "Order NHS Prescriptions", "Speak to a Pharmacist", "Health Advice"

3.67.3 Footer displays NHS logo, GPhC registration number, contact details.

3.68 Screenshot 2 – Interactive Contact Page:

3.68.1 Secure contact form (name, DOB, NHS number optional)

3.68.2 Options: Call-back request / Video consultation booking / Secure message

3.68.3 Statement: "All services are provided remotely in line with NHS Distance Selling Pharmacy regulations."

3.69 Screenshot 3 – Health Promotion Zone:

3.69.1 Clearly labelled "Health Promotion Zone" visible on first site access

3.69.2 Topics displayed:

3.69.2.1 Smoking cessation

3.69.2.2 Weight management

3.69.2.3 Alcohol awareness

3.69.2.4 Diabetes care

3.69.2.5 Hypertension

3.69.2.6 Seasonal NHS campaigns (e.g. flu, COVID-19)

3.69.2.7 Content reviewed quarterly

3.70 Screenshot 4 – Prescription Ordering Page:

3.70.1 EPS nomination instructions

3.70.2 Postal prescription address

3.70.3 No option for in-person submission

3.71 Staff Workflow Diagram (Textual)

3.71.1 Prescription Flow:

3.71.2 Patient → EPS / Post → Admin Staff (log & scan) → Pharmacist (clinical check) → Dispensing Staff → Accuracy Check → Courier Dispatch → Patient

3.72 Urgent Supply Flow:

3.72.1 Patient → Phone/Video → Pharmacist Assessment → Decision → PMR Record → Secure Delivery

3.73 STAFF TRAINING & COMPETENCY RECORDS

3.74 Training Framework

3.75 All staff must complete induction and role-specific training before undertaking duties. Training is refreshed annually.

3.76 Mandatory Training Modules

3.76.1 Distance Selling Pharmacy Regulations (Reg 25 & Schedule 4)

3.76.2 Safeguarding (Level appropriate to role)

3.76.3 Information Governance & GDPR

3.76.4 Remote Patient Communication Skills

3.76.5 SOP Familiarisation & Assessment

3.77 Training Record Template

3.78 Staff Name Role SOPs Completed Assessment Method Date Completed Trainer Signature

3.79 Competency Assessment

3.79.1 Observation of task completion

3.79.2 Knowledge check (verbal or written)

3.79.3 Sign-off by Pharmacist or Manager”

4 Summary of Representations

This is a summary of representations received on the appeal.

Representations were also sought from the Applicant on the amendments to Regulation 25 as the Commissioner considered the application against the previous regulatory test.

4.1 THE APPLICANT

4.1.1 “Thank you for your letter inviting further comments following the amendments to Regulation 25 of the National Health Service

(Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, which came into force on 23 June 2025.

4.1.2 We note that, although our application was considered by the Pharmaceutical Services Regulations Committee on 6 November 2025, the Committee appears to have assessed the application against the pre-amendment version of Regulation 25. We therefore welcome the opportunity to provide comments in support of our application against the amended statutory test.

Compliance with Regulation 25(2)(b) (as amended) Regulation 25(2)(b)(i)

4.1.3 The Committee previously confirmed that it was satisfied that essential services could be provided without interruption during opening hours. The submitted SOP Evidence Pack further demonstrates the uninterrupted provision of essential services to persons anywhere in England, including prescription receipt, dispensing, repeat dispensing, urgent supply, and national delivery arrangements.

Regulation 25(2)(b)(ii)

4.1.4 For the avoidance of doubt, the proposed premises will operate strictly as a distance selling pharmacy. Members of the public will not be permitted to attend the pharmacy premises, and no pharmaceutical services will be provided face-to-face at the pharmacy premises.

4.1.5 All pharmaceutical services will be delivered safely and effectively by remote means, including telephone, secure electronic communication, and delivery. The pharmacy will not supply appliances requiring face-to-face measuring or fitting, and patients requiring such services will be appropriately signposted to alternative providers.

4.1.6 To provide additional clarity and assurance, we have also enclosed a signed Superintendent Pharmacist Declaration confirming the operational exclusion of all face-to-face services at the pharmacy premises.

Conclusion

4.1.7 We respectfully submit that, when assessed against the amended Regulation 25, our application satisfies all statutory requirements. We therefore request that the appeal be determined on the basis of the current Regulations and that the refusal decision be overturned.

4.1.8 We thank you for the opportunity to provide these comments and remain available should any further clarification be required."

"SUPERINTENDENT PHARMACIST DECLARATION

4.1.9 Distance Selling Pharmacy – Regulation 25 Compliance

4.1.10 I, [AS], Superintendent Pharmacist and Director of Shalli Ltd, hereby confirm the following in relation to the proposed distance selling pharmacy premises at:

4.1.11 Vision Worksurfaces, 24 West Howe Industrial Estate, Bournemouth, BH11 8JZ

4.1.11.1 The pharmacy will operate strictly as a distance selling pharmacy in accordance with Regulation 25 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

4.1.11.2 Members of the public will not be permitted to attend the pharmacy premises for any purpose connected with the provision of pharmaceutical services.

4.1.11.3 No pharmaceutical services will be provided face-to-face at the pharmacy premises, whether to patients, representatives, or carers.

4.1.11.4 All pharmaceutical services will be provided remotely, including via telephone, secure electronic communication, and the delivery of medicines to patients.

4.1.11.5 The pharmacy will not supply appliances requiring face-to-face measuring or fitting. Where patients require such services, they will be appropriately signposted to alternative providers.

4.1.11.6 Staff are trained and instructed to refuse any request for face-to-face supply or consultation at the premises and to redirect patients to remote service channels or alternative providers as appropriate.

4.1.12 I make this declaration to provide clarity and assurance regarding the operational model of the proposed pharmacy and confirm that it reflects how the pharmacy will operate in practice."

4.2 THE COMMISSIONER

4.2.1 "Thank you for your letter, received 21 January 2026, addressed to Mr Speight at Primary Care Support England (PCSE) enclosing a copy of the above appeal. The South West Pharmaceutical Services Regulations Committee (SW Committee) wishes to make the following comments on the appeal.

4.2.2 The SW Committee notes the applicant has submitted additional information as part of the appeal, which was not available to the SW Committee when it determined the application. Noting this, the SW Committee would respectfully suggest the additional information still falls short of providing sufficient assurance for it to be satisfied that the procedures adopted by the applicant would likely secure the safe and effective provision of essential services to persons anywhere in England without face to face contact.

4.2.3 The SW Committee notes that the appellant has submitted what are described as SOPs. While there is no obligation to share SOPs, there is still a lack of detail around various matters. For example, while SOP 4 deals with delivery and states that temperature-sensitive items will be packed in validated insulated containers, there is little information on how the integrity of delivered medicines will be protected. There is no information on the promotion of repeat dispensing to patients who might benefit nor is there any information on how the additional checks required for repeat dispensing will be done. For the disposal of unwanted medicines there is little information on how patients will be made aware of how to return them.

4.2.4 Noting the above, the SW Committee respectfully requests that its decision is upheld."

5 Summary of Observations

This is summary of observations received.

5.1 THE APPLICANT

5.1.1 "We acknowledge receipt of the representations submitted by the South West Pharmaceutical Services Regulations Committee dated 19 February 2026.

Delivery Integrity and Temperature-Sensitive Medicines

5.1.2 Validated insulated packaging suitable for 24-hour transit is used. Cold-chain products are maintained within 2–8°C parameters. Maximum transit times are defined. Courier services are tracked nationally under Service Level Agreement with escalation procedures for delays. Where temperature integrity cannot be assured, products are quarantined and not supplied. Quarterly cold-chain audits are undertaken.

Repeat Dispensing Governance

5.1.3 Eligible patients are identified through PMR clinical flagging. The Responsible Pharmacist conducts clinical checks prior to each issue, confirming no changes in condition or medicines. Liaison with prescribers supports electronic repeat dispensing uptake. Biannual governance audits are conducted.

Disposal of Unwanted Medicines

5.1.4 Patients are informed via website information, delivery inserts, and email communications. Prepaid secure returns packaging is available. Licensed waste contractors manage destruction with documentation retained.

Conclusion

5.1.5 These procedures provide structured and auditable systems sufficient to satisfy Regulation 25(2)(b)(ii). The statutory test is met and the appeal should be allowed."

"Supplemental Assurance Statement

5.1.6 Case reference: CAS-370505-C8K1G4

5.1.7 Shalli Ltd

Purpose

5.1.8 This statement provides operational assurance regarding safe and effective provision of pharmaceutical services without face-to-face contact at the pharmacy premises.

Cold Chain and Delivery Integrity

5.1.9 Validated insulated packaging is used. Temperature range maintained at 2–8°C. Maximum transit window 24 hours. Courier SLA includes tracking and escalation procedures. Quarterly audits conducted.

Repeat Dispensing Governance

5.1.10 Patients identified via PMR review. Responsible Pharmacist conducts clinical checks prior to each supply. Prescriber liaison supported. Biannual audit framework in place.

Disposal of Unwanted Medicines

5.1.11 Website information, delivery inserts, and email communications inform patients. Prepaid secure return system available. Licensed waste contractor used.

Incident Management

5.1.12 Documented incident reporting, root cause analysis, Responsible Pharmacist oversight, and quarterly governance review meetings.

Face-to-Face Exclusion

5.1.13 No pharmaceutical services are provided face-to-face at the premises. All services are delivered remotely in accordance with Regulation 25."

6 Consideration

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

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

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

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

Regulation 31

6.5 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).

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

6.7 The Commissioner had stated "*there are no other pharmacies at the premises, or adjacent*" and had concluded "*the SW Committee was satisfied it is not required to refuse the application by virtue of Regulation 31"* which the Committee noted had not been disputed either on appeal or in subsequent representations. Based on the information before it, the Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

6.8 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."

6.9 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)

6.10 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)

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

6.12 The Commissioner it is decision report stated that "*There is no provider of primary medical services at the proposed address, so the application does not have to be refused by virtue of Regulation 25(2)(a).*" The Committee noted that this had not been disputed either on appeal or in subsequent representations. Based on the information available to it, the Committee therefore determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

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

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

6.15 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicates that the obligation is only discharged if the information or documentation provided is sufficient to

satisfy the Commissioner in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the Commissioner may need to make of the information or documentation when carrying out its functions.

6.16 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.

6.17 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, appeal 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.

6.18 In respect of the uninterrupted provision of essential services, the Committee noted the Commissioner had stated "*On the basis of the information provided, the SW Committee was satisfied that services will be provided without interruption."*

6.19 The Committee noted the information in the application form, which states:

6.19.1 *"Behind the scenes, we have a full team ready to offer advice, dispense prescriptions, deliver medicines securely and handle queries from anywhere in England."*

6.20 The Committee was of the view that the uninterrupted provision of essential services was greater than patients being able to communicate with the pharmacy and whilst the Applicant had stated that there was a "*full team",* the Committee noted that there was no information provided as to what would happen in the absence of the Responsible Pharmacist and how the Applicant would ensure that essential services would be available without interruption.

6.21 Based on the lack of information before it, the Committee could not be satisfied that the provision of services would be without interruption.

6.22 The Committee went on to consider how the Applicant would ensure that essential services would be available to persons anywhere in England.

6.23 The Committee noted the various references in the application form and on appeal as well as in the SOPs to items being delivered by courier as well as confirmation that the pharmacy would:

6.23.1 *" …give them a clear explanation of how to access all our services as they would from a local pharmacy by contacting us via phone, email, or by post, if needed. Also, we can offer them a leaflet or card with our contact details and simple instructions on how to get help or medication they needs [sic] all from the comfort of their home.*

…

…deliver medicines securely and handle queries from anywhere in England."

6.24 The Committee was of the view, based on the information before it, that it could be satisfied that the Applicant would be providing essential services to persons anywhere in England.

6.25 The Committee considered if the provision of pharmaceutical services would be without face to face contact.

6.26 The Committee noted the initial reference in the application form that for those who required appliances the Applicant was offering "*advice and support (via telephone or in person)"* however the Committee noted that on appeal the Applicant had confirmed that:

6.26.1 *"No face-to-face services of any kind will be provided from the premises. In addition, the pharmacy will not supply appliances requiring face-to-face measuring or fitting. Where a patient requires an appliance that necessitates face-to-face assessment, measuring, or fitting, the patient will be appropriately signposted to an alternative provider capable of delivering such services."*

6.27 The Committee noted the assurances from the Applicant that:

6.27.1 "*People may choose to visit our pharmacy premises directly, as a Distance Selling Pharmacy, we're not permitted to provide NHS services in person. Our team will kindly explain that we're a distance selling pharmacy and, by law, we're not permitted to offer NHS services face-to-face at the pharmacy itself.*

We'll give them a clear explanation of how to access all our services as they would from a local pharmacy by contacting us via phone, email, or by post, if needed. Also, we can offer them a leaflet or card with our contact details and simple instructions on how to get help or medication they needs [sic] all from the comfort of their home."

6.28 The Committee further noted the comments in the SOPs with regard to "*staff training on refusal of in-person submissions*" as well as the mandatory training modules with regard to "*Remote Patient communication skills*." Further, the Applicant had provided a 'Superintendent Pharmacist Declaration' which stated:

6.28.1 *"Members of the public will not be permitted to attend the pharmacy premises for any purpose connected with the provision of pharmaceutical services.*

No pharmaceutical services will be provided face-to-face at the pharmacy premises, whether to patients, representatives, or carers.

All pharmaceutical services will be provided remotely, including via telephone, secure electronic communication, and the delivery of medicines to patients.

The pharmacy will not supply appliances requiring face-to-face measuring or fitting. Where patients require such services, they will be appropriately signposted to alternative providers.

Staff are trained and instructed to refuse any request for face-to-face supply or consultation at the premises and to redirect patients to remote service channels or alternative providers as appropriate."

6.29 The Committee further noted the comments from the Applicant in the original application form that "*We do plan to offer some advanced services, but we're fully aware that no essential services can be provided face-to-face at our premises."*

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

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

6.32 The Committee was satisfied that the provision of essential services would be available to persons anywhere in England and pharmaceutical services would be provided without face to face contact, however the Committee was not satisfied that the provision of essential services would be without interruption.

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

6.34 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.

6.35 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:

6.35.1 Dispensing of drugs and appliances

6.35.2 Urgent supply without a prescription

6.35.3 Preliminary matters before providing ordered drugs or appliances

6.35.4 Providing ordered drugs or appliances

6.35.5 Refusal to provide drugs or appliances ordered

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

6.35.7 Disposal service in respect of unwanted drugs

6.35.8 Promotion of healthy lifestyles

6.35.9 Prescription linked intervention

6.35.10 Health campaigns

6.35.11 Signposting

6.35.12 Support for self-care

6.35.13 Discharge medicines service

6.35.14 Websites and health promotion zones

6.36 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:

Urgent supply without a prescription

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

6.38 The Committee noted the comments from the Commissioner that there was no mention of this in the original application form.

6.39 The Committee noted SOP 2 “Urgent Supply”

6.39.1 “*Procedure:*

Patient contacts pharmacy by phone or video.

Identity verified using 2 identifiers.

Pharmacist conducts clinical assessment.

SCR accessed where available or GP contacted.

Decision recorded in PMR.

Medicine supplied via secure courier”

6.40 The Committee noted that whilst the Applicant had made reference to the patient contacting the pharmacy, there was no information provided with regard to the prescriber requesting an urgent supply.

6.41 Based on the information before it, the Committee was not satisfied that it had been provided with sufficient information to show that there would be compliance with paragraph 6 of Schedule 4.

Preliminary matters before providing ordered drugs or appliances

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

6.43 The Commissioner had considered that there was no mention of this in the application form and was not satisfied that the pharmacy had suitable arrangements in place for checking exemptions and collecting payments without face to face contact.

6.44 The Committee noted SOP 3 "Exemption Checking & Payments" which states:

6.44.1 *"Patients complete online exemption declaration form.*

Evidence uploaded digitally or confirmed via NHS systems"

6.45 The Committee noted that the procedure had not been expanded upon and no further information had been provided as to how the pharmacy would obtain exemptions if the patient was unable to upload the evidence digitally. The Committee further noted that there was nothing provided as to how the Applicant would review the information or what it would do if they were not content with the exemption.

6.46 Given the lack of information the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.

Providing ordered drugs or appliances

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

6.48 The Committee noted that the Commissioner had not been satisfied that there were suitable arrangements in place for the delivery of items including temperature controlled items and controlled drugs as there was no mention of this in the application form and "*there is nothing about how deliveries will be managed and audited, there is nothing about protecting the integrity of delivered medicines*."

6.49 The Committee noted the Applicant had made reference to SOP 4 "Delivery of Medicines (including CDs & Cold Chain)" and had also provided an outline of a service level agreement ("SLA") it was proposing to implement with the courier company.

6.50 The SOP stated:

6.50.1 *"Procedure:*

All deliveries dispatched via approved courier.

Temperature-sensitive items packed in validated insulated containers.

CDs packaged separately with tamper-evident seals.

Signature and ID verification required upon delivery.

Delivery tracked and audited."

6.51 The Committee noted the SLA states:

6.51.1 *"Scope of Services:*

Collection and delivery of pharmaceutical items to patients across England

Handling of standard medicines, temperature-sensitive items, and Controlled Drugs (Schedules 2–5)

ID verification required for Controlled Drugs

Temperature Control:

Use of validated insulated packaging for cold-chain items

Temperature maintained between 2–8°C where required

Exception reporting for temperature excursions

…

Audit & Tracking:

End-to-end tracking provided

Proof of delivery available electronically

Delivery data retained for audit purposes

Incident Management:

Failed deliveries reported same day

Lost or damaged items escalated immediately

Investigation reports provided within 48 hours"

6.52 Whilst the Committee noted that the SLA had included information with regard to thermolabile products and confirmation that they would be kept within the relevant temperature range, there was nothing provided within the SLA as to

how the pharmacy would be made aware that the cold chain had been compromised or what would happen to those medicines where the cold chain had been breached.

6.53 Further, the Committee noted that whilst failed deliveries would be "*reported the same day"*, this had not been expanded upon and there was no information provided as to how the pharmacy would then deal with a missed delivery.

6.54 The Committee noted that further information had been provided by the Applicant in subsequent representations which stated:

6.54.1 *"Validated insulated packaging suitable for 24-hour transit is used. Cold-chain products are maintained within 2–8°C parameters. Maximum transit times are defined. Courier services are tracked nationally under Service Level Agreement with escalation procedures for delays. Where temperature integrity cannot be assured, products are quarantined and not supplied. Quarterly cold-chain audits are undertaken."*

6.55 The Committee was of the view that the additional information still did not provide it with the level of assurance, that it required to be satisfied as to how temperature integrity is monitored and that there would be compliance with the terms of service as to what would happen to missed deliveries as well as what would happen if there was a breach in the cold chain.

6.56 The Committee noted that there would be "quarterly cold chain audits" but no further information had been provided and the Committee was unsure how these would be carried out or what procedure the Applicant would follow if it discovered that there had been a breach of the cold chain in the previous quarter.

6.57 Based on the information before it, the Committee was not satisfied that there would be compliance with paragraph 8(1) of Schedule 4.

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

6.59 The Committee noted that no information in respect of this aspect of the terms of service had been provided by the Applicant either in the original application, on appeal or in subsequent representations.

6.60 Given the lack of information the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(15) of Schedule 4.

Refusal to provide drugs or appliances ordered

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

6.62 The Committee noted the conclusion of the Commissioner that there had been no mention of this in the application form.

6.63 On appeal, and in the "refusal response index" the Applicant had referenced SOP 6 "Repeat Dispensing" which states:

6.63.1 "*SOP 06 – Repeat Dispensing*

Procedure:

Patients enrolled with consent.

Automated reminders sent prior to each issue.

Pharmacist conducts clinical check remotely.

Any changes escalated to prescriber.

6.64 The Committee further noted SOP 7 "Patient Advice & Communication" which states:

6.64.1 *"Proactive counselling provided for new medicines"*

6.65 The Committee noted that the pharmacist was to "conduct[s] clinical check remotely" and that this had been confirmed in subsequent representations where the Applicant had stated:

6.65.1 *"…The Responsible Pharmacist conducts clinical checks prior to each issue, confirming no changes in condition or medicines…"*

6.66 Whilst the Committee noted the statement from the Applicant, no further information had been provided as to how this would be carried out and how the Applicant would ensure that patient is still using the medication. Further, there was no information as to how the Applicant would establish that the patient is not suffering from any side effects..

6.67 Given the limited information before it, the Committee was not satisfied that it had been provided with sufficient information to show that there would be compliance with paragraph 9(4) of Schedule 4.

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

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

6.69 The Commissioner was not satisfied with this aspect of the terms of service.

6.70 The Committee again noted the "Refusal Response Index" which had directed it to SOP 6 "Repeat Dispensing" which states:

6.70.1 "*SOP 06 – Repeat Dispensing*

Procedure:

Patients enrolled with consent.

Automated reminders sent prior to each issue.

Pharmacist conducts clinical check remotely.

Any changes escalated to prescriber.

6.71 The Committee noted that the further information provided by the Applicant:

6.71.1 *"Repeat Dispensing Governance*

Eligible patients are identified through PMR clinical flagging. …"

6.72 The Committee noted that this statement had not been expanded upon and it had not been provided with any further information as to the appropriate advice that the Applicant would give or who the "eligible patients" are.

6.73 Based on the limited information before it, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.

Disposal service in respect of unwanted drugs

6.74 The Committee considered whether the Applicant had explained how it will safely and effectively accept and dispose of unwanted drugs presented to it for disposal.

6.75 The Commissioner was not satisfied with this aspect of the terms of service as no mention of this had been made in the application form.

6.76 The Committee noted SOP 8 "Disposal of Unwanted Medicines"

6.76.1 "*Procedure:*

Patients request disposal kit.

Prepaid, tamper-evident packaging supplied.

Medicines returned and disposed via licensed contractor.

6.77 The Committee noted the further information provided by the Applicant:

6.77.1 *"Disposal of Unwanted Medicines*

Patients are informed via website information, delivery inserts, and email communications. Prepaid secure returns packaging is available. Licensed waste contractors manage destruction with documentation retained. "

6.78 Whilst the Applicant had provided some information, the Committee noted that there was nothing provided as to how the Applicant would safely and effectively dispose of unwanted drugs once they had been returned to the pharmacy.

6.79 Given the lack of information, especially with the return and disposal of controlled drugs, the Committee was not satisfied that there would be compliance with paragraphs 13 – 15 of Schedule 4.

Prescription linked intervention

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

6.81 The Committee noted SOP 9 "Prescription-Linked Interventions & Lifestyle Advice" which states:

6.81.1 *"Procedure:*

Pharmacist identifies intervention opportunity.

Advice delivered remotely.

Outcome recorded and GP informed if required."

6.82 The Committee, whilst noting that the pharmacist "identifies intervention opportunity", was of the view that it had not been provided with any information as to how this would be accomplished for those who have diabetes or are at risk of coronary heart disease, smoke or are overweight.

6.83 Based on the information before it, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

Health campaigns

6.84 The Committee considered whether the Applicant had explained how it will safely and effectively participate in health campaigns, if and to the extent required by the Commissioner.

6.85 The Committee noted SOP 10 "Public Health Campaigns" and that the Applicant was proposing to promote NHS campaigns via website, email and leaflets however the Committee was of the view that there was no information provided as to how the Applicant would identify those who may benefit from such campaigns or how it will effectively participate in such campaigns.

6.86 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 18 of Schedule 4.

Signposting

6.87 The Committee considered whether the Applicant had explained how it will provide information to users of its pharmacy about other health and social care providers and support organisations.

6.88 The Committee noted SOP 11 "Signposting & Self-care" and noted the procedure that patients would be "*Signposted to NHS 111, GP, or emergency services where appropriate*" however, the Committee was of the view that no further information had been provided with regard to signposting to other services.

6.89 Given the lack of information, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 19-20 of Schedule 4.

Support for self-care

6.90 The Committee considered whether the Applicant had explained how it will provide advice and support to people caring for their families.

6.91 The Committee noted SOP 11 "Signposting & Self-care" which states:

6.91.1 *"Self-care advice provided digitally".*

6.92 The Committee noted that whilst the Appclinat had confirmed that advice would be provided in line with the Regulations for a distance selling pharmacy, this had not been expanded upon and there was no further information provided to demonstrate how it would be providing advice and support to people caring for their families.

6.93 Given the lack of information the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 21-22 of Schedule 4.

Discharge medicines service

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

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

6.96 The Committee noted the "Refusal Response Index". The Applicant had confirmed that evidence for the Committee's concern regarding "Engagement with national services and public health initiatives, including discharge medicines" had been provided at SOP 9 and 10.

6.97 The Committee noted SOP 9 “Prescription-Linked Interventions & Lifestyle Advice” and SOP 10 “Public Health Campaigns” however neither of these SOPs made reference to the discharge medicines services.

6.98 The Committee was of the view that the Applicant had provided no information either in its original application form or on appeal with regard to the Discharge Medicines Service and it had not explained how it would provide advice, assistance and support to those who had recently been discharged from hospital and were referred to the pharmacy for advice.

6.99 Given the lack of information the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

Other

Dispensing of drugs and appliances

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

6.101 The Committee noted the conclusion of the Commissioner that there had been no mention of this in the application form.

6.102 The Committee noted SOP 1 “Receipt of Prescriptions (Non Face-to-Face) which states:

6.102.1 *“Procedure:*

NHS prescriptions are received primarily via Electronic Prescription Service (EPS).

Patients are instructed via the website, welcome leaflet, and telephone to nominate the pharmacy.

Paper prescriptions are received only by post.

On receipt, prescriptions are date-stamped, logged into the PMR, and scanned.

No physical handover from patients is permitted.”

6.103 The Committee further noted SOP 4 “Delivery of Medicines (including CDs & Cold Chain) which states:

6.103.1 *“All deliveries dispatched via approved courier.”*

6.104 Based on the information before it, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 5(2) and 5(3) of Schedule 4.

Preliminary matters before providing ordered drugs or appliances

6.105 The Committee considered whether the Applicant had explained how charges will be paid and noted SOP 3 “Exemption Checking and Payment Collection” which states:

6.105.1“*Payments collected via secure online payment portal*”

6.106 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(5)(b) of Schedule 4.

Providing ordered drugs or appliances

6.107 The Committee noted that the Applicant in response to the question on the application form as to whether they were undertaking to provide appliances stated:

6.107.1“We will provide stoma appliances, incontinence appliances, and dressings as listed in Part IX of the Drug Tariff.” Additionally, we will offer home delivery of appliances, Customisation services (e.g., stoma care tailoring), and provide advice and support (via telephone or in-person)..*”*

6.108 On appeal the Committee noted that the Applicant had confirmed that:

6.108.1“*No face-to-face services of any kind will be provided from the premises. In addition, the pharmacy will not supply appliances requiring face-to-face measuring or fitting. Where a patient requires an appliance that necessitates face-to-face assessment, measuring, or fitting, the patient will be appropriately signposted to an alternative provider capable of delivering such services.”*

6.109 The Committee further noted SOP 5 “Appliances, Measuring & Fitting” which states:

6.109.1*“Statement of Scope:*

The pharmacy will not supply appliances requiring face-to-face measuring or fitting.”

6.110 The Committee was of the view that the Applicant was no longer proposing to provide appliances which required measuring or fitting and, if such a prescription was presented to it, it would signpost those patients to alternative providers.

6.111 Based on the information before it, the Committee was of the view that, if the application was to be granted, the Applicant would not be able to provide any appliances which require measuring or fitting. The Committee was of the view that it had been provided with information sufficient to show that there would be compliance with paragraph 8(4) of Schedule 4.

Promotion of healthy lifestyles

6.112 The Committee considered whether the Applicant had explained how it will safely and effectively promote healthy lifestyles.

6.113 The Committee noted the references by the Applicant to the health promotion zones on the website as set out in SOP 12 as well as the document "Website structure".

6.114 Based on the information before it, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 16-18 of Schedule 4.

Websites and health promotion zones

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

6.116 The Committee noted the information provided by the Applicant in both SOP 12 "Website & Health Promotion Zone" as well as the document "Website Structure". The Committee also noted the various references throughout the application and appeal to patients being able to access services through the website.

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

Summary

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

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

6.119.1 confirm the Commissioner's decision;

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

6.119.3 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.

6.120 In those circumstances, although the Committee has reached the same conclusion as the Commissioner it has done so based on additional information and for different reasons, the Committee determined that the decision of the Commissioner must be quashed.

6.121 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.

6.122 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.

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

7 Decision

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

7.2 The Committee:

7.2.1 quashes the decision of the Commissioner; and

7.2.2 redetermines the application as follows -

7.2.2.1 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;

7.2.2.2 the Committee was not satisfied that all essential services were likely to be secured without interruption during the opening hours;

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

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

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

7.2.3 The application is refused.

Case Manager
Primary Care Appeals