NHS Resolution

5 June 2026

REF: SHA/26875

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APPEAL AGAINST DERBY AND DERBYSHIRE ICB DECISION TO REFUSE AN APPLICATION BY ANTHUS PHARMA LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 12 TOTON CLOSE, UNIT E2, NOTTINGHAM, DERBYSHIRE, NG10 3TP 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 granted.

A copy of this decision is being sent to:
Rushport Advisory LLP, on behalf of Anthus Pharma Ltd
PCSE, on behalf of Derby and Derbyshire ICB
Jaysons Pharmacy
Community Pharmacy Derbyshire
Community Pharmacy Nottinghamshire

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1 The Application

By application dated 17 June 2025, Anthus Pharma Ltd ("the Applicant") applied to Derby and Derbyshire ICB ("the Commissioner") for inclusion in the pharmaceutical list at 12 Toton Close, Unit E2, Nottingham, Derbyshire, NG10 3TP under Regulation 25. In support of the application it was stated:

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

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

1.3 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant left the section 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 "There will be a Registered Pharmacist and staff members at the premises throughout the opening hours to process any prescriptions they receive via EPS/post/delivery driver. Any advice that the patient/patient representative may need will be provided through the phone or email. There will be a consultation room to provide the staff a space to talk to patients in privacy. Patients will be made aware from start that there will be no face to face contact. This will also be mentioned on our leaflets and the website. Medication will only be delivered to patients with our delivery driver and far areas we use City Sprint delivery or via post. The doors of the premises will always be closed. Access will only be provided to the pharmacy staff and suppliers delivery drivers. Any patient that does tum up at the premises will be directed to a local community pharmacy. We will have a secure website for the sale of any GSL and P medication throughout the country. Advanced services like New Medicine Service and Medication Reviews will happen on the phone.

1.9 In addition to the physical integrity of the building, we will be implementing a range of security measures to ensure the safety and integrity of pharmacy operations. These measures include having restricted access controls, with barriers and locks to limit access to authorised personnel only, as well as installing security cameras which will be actively monitored to deter and detect unauthorised access. Anthus Pharma is committed to ensuring the provision of uninterrupted essential pharmacy service during the core hours. To ensure this, the Responsible Pharmacist will be present and signed in at the pharmacy throughout these times, including during lunch breaks and readily available to address staff, patient, or patient representative's queries. With respect to patients with sight loss, our website will include features such as screen reader compatibility, ensuring that all content can be accessed."

1.10 [SOPs provided]

2 Comments to the Commissioner

On reviewing the paperwork provided by PCSE, it was noted that the comments made by the Applicant and interested parties 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 Rushport Advisory LLP, on behalf of the Applicant

2.1.1 "Thank you for your letter of 24 November 2025. I act for Anthus Pharma Ltd in the above application and have been instructed by my client to submit the following reply to consultation comments received.

2.1.2 On review of the application form we have noted that clarification is required on both the provision of Advanced services and also the provision of Appliances as listed in the Drug Tariff.

2.1.3 My client has asked me to notify the ICB that, as a result of changes to the relevant Regulations which prohibit services being provided face to face at the proposed premises, it will no longer seek to provide the services listed on the application form. In addition, my client listed a number of services that are not in fact commissioned and wishes to clarify the services that will be provided.

2.1.4 The Advanced / Enhanced services that would be provided are as listed below.

Service	**Accredited to provide (Y/N/NA)**	**Premises accredited (Y/N/NA)**	**Consultation area (Y/N/NA)**
NMS (remotely with consent where required)	Y	N	Y
PHARMACY FIRST (remotely only)	Y	N	Y

2.1.5 Part 4 of the application forms requires an Applicant to confirm which Appliances they will provide or to state "NONE" if no Appliances will be provided. This section of the application form is currently blank.

2.1.6 My client confirms that Appliances as listed in Part IX of the Drug Tariff will be provided except for those that require measuring or fitting. [Rushport's emphasis]

2.1.7 This notification is made in accordance with the undertaking provided by my client to notify the Commissioner within 7 days of any material changes to the information provided in the application that occur before the application is decided (Schedule 2, Part 1, para 9 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.)

2.1.8 My client has no further comments to make at this stage and we look forward to hearing from you in due course.

2.1.9 We look forward to hearing from you in due course."

2.2 Community Pharmacy Nottinghamshire

2.2.1 "Thank you for sending through the comments received for the above distance selling pharmacy application. Community Pharmacy Nottinghamshire would like to make the following comments:

2.2.2 We stand by our original response and we support the comments received from other respondents, as the application does not meet Regulation 25 criteria we believe this application should not be granted.

2.2.3 We would like the opportunity if it arises to be able to comment further and attend any hearings, as well as be kept informed of progress. Thank you."

2.3 Community Pharmacy Derbyshire

2.3.1 "Thank you for sending through the comments received for the above distance selling pharmacy application.

2.3.2 Community Pharmacy Derbyshire stand by our original response and we also support the comments received from other respondents.

2.3.3 Community Pharmacy believe the application does not meet Regulation 25 criteria and therefore should not be granted.

2.3.4 Community Pharmacy Derbyshire would like the opportunity if it arises, to be able to comment further and attend any hearings, as well as be kept informed of progress. Thank you."

3 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 26 January 2026 states:

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

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

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

3.3 Primary Care Appeals, NHS Resolution, 8th Floor, 10 South Colonnade, Canary Wharf, London, E14 4PU"

Decision report

3.4 "**Regulation 25 (1)**

3.5 The application is for distance selling premises and therefore section 129(2A) of the NHS Act 2006 doesn't apply.

3.6 **Regulation (25)(2)(a)**

3.7 The applicant's premises are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. There are therefore no grounds to refuse the application by virtue of this regulation.

3.8 **Regulation 25(2)(b)(i) - Is the applicant seeking to restrict the provision of essential services in any way?**

3.9 The applicant has provided supporting information and has confirmed within part 4 of the application form that they will provide all Essential services set out in paragraphs 3 to 22, Schedule 4 of the National Health Services (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended.

3.10 **Regulation 25(2)(b)(ii) - Does any element of essential service provision involve face to face contact with the applicant or their staff?**

3.11 The documentation provides assurance in relation to most aspects of how the pharmacy will safely and effectively deliver pharmaceutical services without face-to-face contact.

3.12 However, areas not explicitly addressed within the documentation is:

3.12.1 Cold-chain integrity: No documented assurance of maintaining temperature-sensitive products during delivery, nor contingency measures for delays.

3.12.2 Checks on patient safety: No detailed description of phone-based review to ensure patients still require medications or are not experiencing adverse effects.

3.12.3 Health campaigns: No information on how the DSP will safely and effectively participate in health campaigns remotely.

3.12.4 Discharge Medicines Service: No SOP describing how recently discharged patients will be supported or advised regarding medications.

3.12.5 Website and digital services: No information on public access to essential services, healthy lifestyle materials, or health promotion content.

3.12.6 Responsible Pharmacist absence: SOP allows short absences (up to 2 hours) where the RP remains contactable; however, for absences over 2 hours, only prescription receipt and assembly is permitted. This does not ensure continuity of all essential services

3.12.7 Prescription-linked interventions: Guidance exists for staff referral to the RP for diabetes, CHD risk, smoking, or weight management advice, but does not demonstrate how this will be consistently delivered to patients as part of essential services.

3.13 The applicant has not fully demonstrated that the proposed arrangements are likely to secure the safe, effective and uninterrupted provision of all essential services, without face-to-face contact, as required by Regulation 25 of the NHS

(Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (as amended).

3.14 **Regulation 25**

3.15 The Committee have noted that the applicant will intend to provide advanced services from the premises, these service will be – New Medicines Service (NMY) and Pharmacy First.

3.16 **Regulation 31**

3.17 Regulation 31 does not apply as the proposed pharmacy will not be adjacent or in close proximity to an existing pharmacy premises.

3.18 There are no existing pharmacies operating from the proposed best estimate location and therefore, under this provision, Regulation 31 would not cause the application to be refused by virtue of this regulation.

3.19 **Regulation 66**

3.20 Regulation 66 applies where DSPs propose to provide directed services (e.g. supervised consumption, vaccination). The commissioner must ensure compliance with specific conditions before approval. The applicant is proposing to provide the following directed services remotely; New Medicines Services and Pharmacy First.

3.21 There are no grounds for refusal under Regulation 66.

3.22 **Decision**

3.23 The Committee acknowledged that representations were received from Jaysons Pharmacy, Boots Pharmacy, Derbyshire County Council and Community Pharmacy Derbyshire regarding full compliance of Regulation 25 which has not been met.

3.24 The Committee agreed that the approval of the application will have no impact on those with protected characteristics or on NHS England's duty on health inequality.

3.25 The Committee was not satisfied that the applicant meets all of the criteria for opening a wholly, internet/mail order-based distance selling premises and therefore determined to **refuse** this application

3.26 **Appeal Rights**

3.26.1 Applicant”

4 The Appeal

In a letter dated 26 January 2026, the Applicant, through its representative Rushport Advisory LLP, appealed against the Commissioner’s decision. The grounds of appeal are:

4.1 “I act for ANTHUS PHARMA LTD and have been instructed by my client to submit this appeal against the attached decision of the Commissioner to refuse the above application.

4.2 As the Committee will note, the Commissioner refused my client’s application as they did not evidence that they had proper procedures in place to cover:

4.2.1 Cold-chain integrity: No documented assurance of maintaining temperature-sensitive products during delivery, nor contingency measures for delays.

4.2.2 Checks on patient safety: No detailed description of phone-based review to ensure patients still require medications or are not experiencing adverse effects.

4.2.3 Health campaigns: No information on how the DSP will safely and effectively participate in health campaigns remotely.

4.2.4 Discharge Medicines Service: No SOP describing how recently discharged patients will be supported or advised regarding medications.

4.2.5 Website and digital services: No information on public access to essential services, healthy lifestyle materials, or health promotion content.

4.2.6 Responsible Pharmacist absence: SOP allows short absences (up to 2 hours) where the RP remains contactable; however, for absences over 2 hours, only prescription receipt and assembly is permitted. This does not ensure continuity of all essential services.

4.2.7 Prescription-linked interventions: Guidance exists for staff referral to the RP for diabetes, CHD risk, smoking, or weight management advice, but does not demonstrate how this will be consistently delivered to patients as part of essential services.

4.3 My client has instructed me to provide the attached updated SOPs to support their appeal and these SOPs address all the issues raised by the Commissioner. The SOPs have been approved by my client’s superintendent pharmacist. My client’s premises will not be open to the public and all services will be provided remotely.

4.4 The Committee is asked to note that on the original application form my client included Care Home Service, Home Delivery Service, Medication Review Service and Emergency Supply Service. Of these, Emergency Supply is an (essential) service and none of the others are commissioned services and are not relevant for the purposes of this application. Procedures for NMS and Pharmacy First (which are commissioned) are included in the updated SOPs.

4.5 My client has prepared an updated floor plan and for the sake of completeness this is attached along with this appeal.

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

4.7 [Updated SOPs and floor plan provided]

5 Summary of Representations

This is a summary of representations received on the appeal.

5.1 Jaysons Pharmacy

5.1.1 “We write in response to the appeal lodged by Anthus Pharma Ltd against the Commissioner’s refusal of its application for inclusion in the pharmaceutical list in respect of the above distance selling premises.

5.1.2 The Commissioner refused the application pursuant to Regulation 25(2)(b) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (as amended), on the basis that the applicant failed to demonstrate that its procedures were likely to secure:

5.1.2.1 The uninterrupted provision of essential services to persons anywhere in England; and

5.1.2.2 The safe and effective provision of pharmaceutical services without face-to-face contact.

5.1.3 Those deficiencies are clearly identified in the Commissioner’s Decision Report dated 26 January 2026 (Ref: CAS-370147-M0X7G9) and form the subject of the Appeal Submission dated 26 January 2026 (Ref: CAS-370147-M0X7G9).

5.1.4 Even taking the updated material submitted on appeal at its highest, the statutory test remains unsatisfied.

5.1.5 This appeal should be dismissed on the papers.

5.1.6 A. THE LEGAL TEST

5.1.7 Regulation 25(2)(b) imposes a strict statutory safeguard. The applicant must demonstrate procedures that are likely to secure:

5.1.7.1 Uninterrupted essential services; and

5.1.7.2 Safe and effective delivery without face-to-face contact.

5.1.8 This is a forward-looking, structural assessment. It is not satisfied by:

5.1.8.1 Statements of intent;

5.1.8.2 Additional narrative explanation;

5.1.8.3 Post-refusal elaboration.

5.1.9 It requires demonstrable procedural certainty and operational resilience.

5.1.10 B. THE THREE DETERMINATIVE FAILURES

5.1.11 The appeal fails on three decisive and independently sufficient grounds.

5.1.12 **1. FAILURE TO DEMONSTRATE NATIONAL, UNINTERRUPTED PROVISION**

5.1.13 (Regulation 25(2)(b)(i))

5.1.14 The applicant's operating model comprises:

5.1.14.1 In-house drivers for local deliveries;

5.1.14.2 Third-party courier providers for national deliveries.

5.1.15 This inherently introduces:

5.1.15.1 Non-uniform reliability;

5.1.15.2 Dependence on third-party logistics;

5.1.15.3 Delay risk beyond applicant control.

5.1.16 Particular concern arises in relation to the proposed national delivery of Schedule 2 and 3 Controlled Drugs using third-party couriers. The materials do not demonstrate secure custody protocols, defined chain-of-possession governance, or safe storage contingencies in the event of failed delivery attempts. Where essential services include lawful CD supply, a delivery model reliant upon external couriers without demonstrable national secure infrastructure does not demonstrate the level of controlled custody and national contingency required to satisfy the "likely to secure uninterrupted provision" test under Regulation 25.

5.1.17 What also remains absent is evidence of:

5.1.17.1 Enforceable national service-level guarantees;

5.1.17.2 Validated cold-chain performance data;

5.1.17.3 Defined temperature breach response thresholds;

5.1.17.4 Contractual remedies for courier failure;

5.1.17.5 Demonstrable contingency resilience nationally;

5.1.17.6 Emergency supply protection for patients outside local geography.

5.1.18 Regulation 25 requires procedures likely to secure uninterrupted provision.

5.1.19 A model dependent upon external courier performance, without evidenced control and enforcement mechanisms, does not satisfy that statutory certainty threshold.

5.1.20 This deficiency is, of itself, sufficient to justify dismissal of the appeal.

5.1.21 **2. FAILURE TO DEMONSTRATE CONTINUOUS RESPONSIBLE PHARMACIST COVERAGE**

5.1.22 The Commissioner correctly identified concerns regarding RP absence procedures in the formal refusal letter dated 26 January 2026 (Ref: CAS-370147-M0X7G9).

5.1.23 The statutory requirement is uninterrupted essential services during all opening hours.

5.1.24 The materials continue to demonstrate:

5.1.24.1 Permission for RP absences exceeding two hours;

5.1.24.2 Restricted operational capability during such absences;

5.1.24.3 No evidenced rota-based secondary RP system;

5.1.24.4 No formal remote supervision governance framework;

5.1.24.5 No defined procedural safeguards ensuring essential services are not functionally impaired.

5.1.25 Partial operational continuity is not uninterrupted provision.

5.1.26 If pharmacist supervision cannot be guaranteed continuously during opening hours in a manner that secures all essential services, the statutory test is not met.

5.1.27 This is independently determinative.

5.1.28 **3. FAILURE TO DEMONSTRATE SYSTEMISED REMOTE CLINICAL GOVERNANCE**

5.1.29 (Regulation 25(2)(b)(ii))

5.1.30 It is insufficient to assert that services will be delivered remotely.

5.1.31 The applicant must demonstrate that such delivery is structurally safe and effective.

5.1.32 The original refusal identified deficiencies including:

5.1.32.1 Cold-chain assurance;

5.1.32.2 Prescription-linked intervention structure;

5.1.32.3 Health campaign delivery;

5.1.32.4 Discharge Medicines Service workflow;

5.1.32.5 RP absence safeguards.

5.1.33 Those deficiencies are set out in the Commissioner's Decision Report dated 26 January 2026 (Ref: CAS-370147-M0X7G9). The appeal submission asserts that updated SOPs address these matters.

5.1.34 However:

5.1.34.1 Descriptive SOP text is not equivalent to enforceable safeguards;

5.1.34.2 Discretion-based referral language is not equivalent to mandatory intervention triggers;

5.1.34.3 Communication availability is not equivalent to structured consultation governance;

5.1.34.4 Policy wording does not demonstrate audit-backed compliance certainty.

5.1.35 Regulation 25 requires likelihood of secure delivery, not theoretical alignment.

5.1.36 The applicant's material continues to lack demonstrable procedural compulsion and audit certainty necessary to meet that threshold.

5.1.37 C. NO REQUIREMENT FOR ORAL HEARING

5.1.38 There is no material factual dispute.

5.1.39 This appeal turns solely upon:

5.1.39.1 The adequacy of written procedures against the statutory test.

5.1.40 There are:

5.1.40.1 No contested premises facts;

5.1.40.2 No factual contradictions requiring witness evidence;

5.1.40.3 No complex evidential disputes;

5.1.40.4 No credibility determinations required.

5.1.41 The issue is purely regulatory sufficiency.

5.1.42 The matter is therefore suitable for determination on the papers in accordance with the NHS Resolution circular letter dated 10 February 2026 (Ref: SHA/26875).

5.1.43 An oral hearing would not materially assist.

5.1.44 D. CONCLUSION

5.1.45 Even taking the appeal material at its highest:

5.1.45.1 National uninterrupted provision is not demonstrably secured;

5.1.45.2 Continuous RP governance is not structurally guaranteed;

5.1.45.3 Remote clinical governance is not procedurally systemised to the statutory threshold.

5.1.46 Any one of these failures is sufficient to dismiss the appeal.

5.1.47 Collectively, they confirm that the Commissioner's refusal was correct and proportionate.

5.1.48 NHS Resolution is respectfully invited to:

5.1.48.1 Determine this appeal on the papers; and

5.1.48.2 Dismiss the appeal and uphold the refusal.

5.1.49 Regulation 25 operates as a statutory safeguard in circumstances where Parliament has removed the traditional market-need test for distance selling premises. The requirement to demonstrate procedures "likely to secure" uninterrupted national provision and safe governance without face-to-face contact is deliberately exacting. Approval in the absence of demonstrable structural certainty would undermine that safeguard. NHS Resolution is therefore respectfully invited to apply the statutory test strictly and uphold the Commissioner's refusal.

5.1.50 **ANNEX A**

5.1.51 STATUTORY MISMATCH ANALYSIS

5.1.52 1. Regulation 25(2)(b)(i)

5.1.53 Requirement: Likely to secure the uninterrupted provision of essential services to persons anywhere in England.

5.1.54 Applicant Position:

5.1.55 Reliance on internal local drivers and third-party couriers for wider England; general cold-chain SOP references.

5.1.56 Mismatch:

5.1.57 No demonstrated:

5.1.57.1 Nationally enforceable service continuity guarantees;

5.1.57.2 Evidence of contractual performance standards;

5.1.57.3 Defined national contingency infrastructure;

5.1.57.4 Validated temperature monitoring data with enforcement accountability.

5.1.58 The procedure described is operationally aspirational, not structurally secured.

5.1.59 2. Regulation 25(2)(b)(i)

5.1.60 Requirement: Uninterrupted provision during opening hours.

5.1.61 Applicant Position:

5.1.62 RP absence procedures allow limited activity during extended absences.

5.1.63 Mismatch:

5.1.64 Essential services require pharmacist governance — not administrative continuity alone.

5.1.65 Absence allowances without demonstrated supervisory framework undermine continuity.

5.1.66 3. Regulation 25(2)(b)(ii)

5.1.67 Requirement: Safe and effective provision without face-to-face contact.

5.1.68 Applicant Position:

5.1.69 Remote communication mechanisms and updated SOP narratives.

5.1.70 Mismatch:

5.1.71 No evidence of:

5.1.71.1 Mandatory intervention triggers;

5.1.71.2 Structured, system-enforced consultation pathways;

5.1.71.3 Defined safeguarding escalation audits;

5.1.71.4 Measurable compliance assurance processes.

5.1.72 The materials describe processes; they do not demonstrate enforceable governance certainty.”

5.2 The Commissioner

5.2.1 “The Commissioner maintains that the decision to refuse this application under Regulation 25 was lawful, proportionate, and correctly reasoned.

5.2.2 This appeal concerns whether the Applicant has demonstrated that its pharmacy procedures are likely to secure:

5.2.2.1 The uninterrupted provision of essential services during opening hours to persons anywhere in England; and

5.2.2.2 The safe and effective provision of pharmaceutical services without face-to-face contact.

5.2.3 The burden rests on the Applicant.

5.2.4 **1. The Position at Determination**

5.2.5 At the time of determination, the Applicant had not provided sufficient evidence to satisfy Regulation 25(2)(b). The deficiencies identified were substantive and went directly to operational safety and service continuity.

5.2.6 The decision was not based on the absence of paperwork alone, but on the failure to demonstrate operational readiness and robustness.

5.2.7 **2. Post-Refusal Documentation**

5.2.8 The Appellant has now submitted revised SOPs.

5.2.9 However:

5.2.9.1 Regulation 25 requires the decision-maker to be satisfied that procedures are likely to secure compliance.

5.2.9.2 The test is qualitative and prospective.

5.2.9.3 The mere existence of expanded documentation does not equate to operational assurance.

5.2.10 The revised SOP bundle contains generic and template-based provisions, including sections marked for completion prior to opening. This raises concern as to whether the arrangements are fully implemented or aspirational.

5.2.11 The Commissioner remains unsatisfied that the documentation demonstrates an embedded, auditable and operationally mature framework capable of securing uninterrupted and safe service delivery.

5.2.12 **3. Continuing Concerns**

5.2.13 Without repeating the full decision notice, the Commissioner maintains concerns in the following areas:

5.2.13.1 **Cold-chain governance:** Absence of validated, auditable assurance mechanisms evidencing temperature integrity throughout delivery and contingency management.

5.2.13.2 **Responsible Pharmacist absence:** Arrangements that may restrict the continuity of essential service provision during extended absence.

5.2.13.3 **Health promotion and campaign delivery:** Insufficient evidence of structured, commissioned-compliant participation beyond generic website statements.

5.2.13.4 **Operational maturity:** The documentation does not demonstrate established systems, oversight mechanisms, or tested delivery pathways sufficient to meet the statutory threshold.

5.2.14 The Regulation requires confidence that procedures are likely to secure safe and uninterrupted provision. The Commissioner was not so satisfied at determination and remains not so satisfied on reconsideration.

5.2.15 **4. Regulatory Integrity**

5.2.16 To permit wholesale reconstruction of an application post-refusal would undermine the Regulation 25 framework and dilute the evidential threshold required of distance selling premises at the point of determination.

5.2.17 The statutory burden lies with the Applicant to demonstrate compliance.

5.2.18 That burden has not been discharged.

5.2.19 **Conclusion**

5.2.20 For the reasons above, the Commissioner respectfully submits that the appeal should be dismissed."

5.3 Community Pharmacy Derbyshire

5.3.1 "Thank you for sending the appeal documents for the above distance selling pharmacy application. Community Pharmacy Derbyshire committee reviewed the appeal information and wish to make the following comment

5.3.1.1 Whilst the applicant has clarified a number of points their delivery process still details a disparity in service to patients depending on where they live and provides discretion for the Responsible Pharmacist that suggests a focus on local delivery rather than, as the regulations require, a pharmaceutical service to the whole of England.

5.3.2 Community Pharmacy Derbyshire would like the opportunity if it arises, to be able to comment further and attend any hearings, as well as be kept informed of progress."

5.4 Community Pharmacy Nottinghamshire

5.4.1 "Thank you for sending Community Pharmacy Nottinghamshire the appeal documents for the above application with regards to a distance selling pharmacy application. Community Pharmacy Nottinghamshire would like to make the following comments

5.4.1.1 Although the applicant has clarified several points, their delivery process still results in unequal service for patients depending on their location. It also gives the Responsible Pharmacist discretion that appears to prioritise local delivery rather than providing a pharmaceutical service across the whole of England, as required by the regulations

5.4.2 Please keep Community Pharmacy Nottinghamshire (LPC) informed of progress. Community Pharmacy Nottinghamshire may like to comment further should the opportunity arise including attending and commenting at any oral hearing."

6 Summary of Observations

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

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 that the Applicant had not provided any information in the application form on this point but the Committee noted that the wording of the application form only required the Applicant to include information in the relevant section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee considered it reasonable to determine that the lack of information in the application form on this point when read with the wording of the application form allowed it to be reasonably satisfied that the Applicant considered that the proposed premises were not adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee noted the Commissioner in its decision report had stated that "*Regulation 31 does not apply as the proposed pharmacy will not be adjacent or in close proximity to an existing pharmacy premises.*" The Committee therefore determined that it 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 The Committee noted that the Applicant had not included any information in the relevant section of the application form that deals with this point. The

Committee noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Commissioner in its decision report stated that "*The applicant's premises are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. There are therefore no grounds to refuse the application by virtue of this regulation.*" Based on the information available to it, which had not been disputed, the Committee therefore determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

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 updated SOPs provided on appeal.

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 updated SOPs 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 and noted the concerns raised by the Commissioner and Jaysons Pharmacy regarding the Applicant's intention to permit the absence of the Responsible Pharmacist.

7.17 The Committee considered the following information in the Applicant's updated SOPs which were provided on appeal:

7.18 SOP 1: 'Introduction and Background to SOPs'

7.18.1 "*1.3 Overriding Provisions Applicable to All SOPs*

… In order to comply with our terms of service, this pharmacy will provide;

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

7.19 SOP 33: 'The Responsible Pharmacist'

7.19.1 "*33.9 Absence of the RP*

As a Distance Selling pharmacy, we must provide uninterrupted service throughout the opening hours of the pharmacy. Whilst the GPhC permits the absence of the RP from the pharmacy in particular situations, the NHS Terms of Service still require a pharmacist to be present so that services are not interrupted. [Applicant's emphasis]

If, for any reason, the RP wishes to leave the premises or wishes to take a break then the second pharmacist must sign in as the RP and arrangements must be made for this prior to one RP leaving the premises and another RP signing in."

7.20 The Committee noted Rushport Advisory's comment on appeal that "*The SOPs have been approved by my client's superintendent pharmacist.*" Based on the updated SOPs which were before it, the Committee was satisfied that the provision of essential services would be without interruption.

7.21 With regard to essential services being available to persons anywhere in England, the Committee noted both Community Pharmacy Derbyshire and Community Pharmacy Nottinghamshire had concerns around the delivery process and there being an "unequal" service for patients depending on their location, with the Applicant appearing to prioritise local delivery. The Committee noted the following information in the Applicant's updated SOPs:

7.22 SOP 1: 'Introduction and Background to SOPs'

7.22.1 "*1.3 Overriding Provisions Applicable to All SOPs*

In order to comply with our terms of service, this pharmacy will provide… to persons anywhere in England who request those services."

7.23 SOP 3: 'Procedures for NHS Pharmaceutical Services'

7.23.1 "*NHS Pharmaceutical Services will be provided to any patient living in England who requests such services, this is made clear on the website and in the Practice leaflet.*"

7.24 The Committee next considered how the Applicant would provide pharmaceutical services without face to face contact. The Committee noted the following information in the Applicant's updated SOPs:

7.25 SOP 1: 'Introduction and Background to SOPs'

7.25.1 "*1.3 Overriding Provisions Applicable to All SOPs*

… In order to comply with our terms of service, this pharmacy will provide; …

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 owner of this pharmacy or any member of staff either on or in the vicinity of the premises.

… All staff must be made aware that face to face contact between patients (or their representatives) is prohibited in respect of any and all NHS services either on or in the vicinity of the premises.

Any reference to 'contact' with or 'contacting' a patient in relation to these SOPs means contact other than face-to-face contact either on or in the vicinity of the premises."

7.26 SOP 3: 'Procedures for NHS Pharmaceutical Services'

7.26.1 "*3.1 Communication Channels*

All communication regarding NHS Pharmaceutical Services should be carried out using the most suitable non face to face method for the patient and the service being provided with particular consideration to maintaining confidentiality. This may be telephone, email, video-conferencing or other types of non face to face communications such as text messages using the pharmacy's secure system.

The pharmacy has provision for both live audio and live video communication with patients and this must always be carried out in the specified confidential area of the pharmacy premises."

7.26.2 "*3.2 Request for face-to-face service provision*

OUR PHARMACY OPERATES FROM SELF-CONTAINED PREMISES THAT USE A CONTROLLED ACCESS SYSTEM. MEMBERS OF THE PUBLIC ARE NOT ABLE TO ATTEND THE PREMISES TO RECEIVE ANY NHS SERVICES [Applicant's emphasis]

If any member of staff receives a query from any member of the public, or patient or their carers that requests the provision of any pharmaceutical service face to face on or in the vicinity of the premises then they must;

Inform the person that, we cannot provide any face to face NHS services

Refer the person to the Responsible Pharmacist if they require any further explanation."

7.27 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.

7.28 In its application the Applicant states that it intends to provide the New Medicine Service (NMS), Pharmacy First Service, Care Home Service, Home Delivery Service, Medication Review Service and Emergency Supply Service. The Committee noted that on appeal the Applicant had acknowledged that Emergency Supply is an essential service and of the others, only NMS and Pharmacy First are commissioned services.

7.29 The Committee noted SOP 3 'Procedures for NHS Pharmaceutical Services' states:

7.29.1 "*3.3 Provision of Advanced or Enhanced Services*

The Pharmacy does not provide advanced or enhanced services to patients on the premises. NMS will be conducted remotely with no patients accessing the service at the premises (see NMS SOP).

Pharmacy First will be provided remotely if the pharmacy has been approved to provide the service (see Pharmacy First SOP)."

7.30 The Committee noted SOP 7 'The New Medicine Service ("NMS")' which states "*The service must be provided remotely by phone or video call*" and also SOP 8 'The Pharmacy First Service' which states "*Patients may not attend the premises to receive the service and the service must be provided remotely*".

7.31 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.

7.32 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.

7.33 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.

Dispensing of drugs and appliances

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

7.35 The Committee had regard to the updated SOPs and noted SOP 3 'Procedures for NHS Pharmaceutical Services' states:

7.35.1 "*…Patients who wish to send paper prescriptions to the pharmacy by post should be sent stamped addressed envelopes to enable them to do so.*"

7.36 SOP 6 'Prescription Receipt & Exemption Checking' states:

7.36.1 "*6.2 Scope*

All online services including the following:

… NHS Prescriptions."

7.36.2 "*6.7 Administration Checks*

Check all prescriptions received in the post against printed and written prescription reception forms. Check the corresponding prescription has been received in the post…"

7.37 SOP 19 'Order Delivery' states:

7.37.1 "*19.6 Choice of Delivery Method*

*For items **other than** cold chain / "fridge line" items, local deliveries (up to 30 miles radius, but may be extended at the discretion of the RP) the delivery driver should deliver medication. Outside this area Royal Mail should be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier must be used (see SOP for Delivery of Controlled Drugs), or the items are fridge lines, in which case the cold chain courier must be used (see below).*" [Applicant's emphasis]

7.38 On the basis of the information supplied in the updated SOPs, the Committee was satisfied that the Applicant was proposing to offer the service to all of England, as per the information contained in the SOPs.

7.39 The Committee was therefore 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.

Urgent supply without a prescription

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

7.41 The Committee noted Jaysons Pharmacy's comment that "*What also remains absent is evidence of: …Emergency supply protection for patients outside local geography.*"

7.42 The Committee had regard to the updated SOPs and noted SOP 16 'Emergency Supply and Urgent Supply' which describes how the Applicant will 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.

7.43 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.

Preliminary matters before providing ordered drugs or appliances

7.44 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.

7.45 The Committee had regard to the updated SOPs and noted SOP 6 'Prescription Receipt & Exemption Checking' states:

7.45.1 *"6.9 Exempt NHS Prescriptions*

Where evidence of exemption is required or provided by the patient it can be sent to the pharmacy for verification via the delivery driver and then returned to the patient. The PMR system should be updated to reflect that necessary check has been carried out and a note of when the next check is required should be entered onto the system. The Regulations require a patient to produce 'satisfactory evidence' to confirm exemption. Where appropriate (i.e., for deliveries made other than by the pharmacy's delivery driver), the patient may scan or fax copies of the evidence to the pharmacy (or use the postal / courier service, but see NOTE below) and the pharmacy can note that the evidence provided was not in original format. It is for the pharmacist in charge to determine if the evidence is satisfactory or not and, if not, then cross the 'Evidence not Seen' box."

7.46 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.

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

7.48 The Committee considered the updated SOPs and noted SOP 6 'Prescription Receipt & Exemption Checking' states:

7.48.1 "*6.12 Paid NHS Prescription*

Check the prescription to confirm how many charges are due.

Check to see if any fees have been paid and if so, was the correct amount paid?

Contact the patient to arrange payment using the secure payments system using the "customer not present" option.

If no fees have been paid or there is a discrepancy between fees paid and those due, the patient should be contacted and directed to pay the appropriate fees via the online payment system."

7.49 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

7.50 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).

7.51 The Committee noted the Commissioner had stated in its decision that there was "*No documented assurance of maintaining temperature-sensitive products during delivery, nor contingency measures for delays.*"

7.52 In response to the appeal, the Commissioner further stated "*Without repeating the full decision notice, the Commissioner maintains concerns in the following areas: Cold-chain governance: Absence of validated, auditable assurance mechanisms evidencing temperature integrity throughout delivery and contingency management…"*.

7.53 The Committee also noted Jaysons Pharmacy's comment that "*Particular concern arises in relation to the proposed national delivery of Schedule 2 and 3 Controlled Drugs using third-party couriers. The materials do not demonstrate secure custody protocols, defined chain-of-possession governance, or safe storage contingencies in the event of failed delivery attempts.*"

7.54 The Committee had regard to the updated SOPs and noted SOP 19 'Order Delivery' states:

7.54.1 "*19.10 Transfer to the Delivery Driver*

Ensure that the pharmacist on duty is available to supervise the handing over of all items for delivery.

Ensure that any special instructions for the delivery are included with the packaging.

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

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

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

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

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

7.54.2 "*19.11 Delivery of prescription to patient or representative address*

…Ask the patient/representative for their name and address.

Check the patient name and address against the prescription and the bag label. Patient confidentiality should be maintained at all times, especially if delivering to a representative.

Where appropriate ask the patient or representative to complete the reverse of the prescription.

Hand the medication to the patient or representative.

Ask the patient or representative to sign their details on the delivery sheet. If they are unable to sign the delivery sheet the delivery driver should sign on their behalf with their consent and write a note explaining the reason the patient or representative could not sign.

If necessary, collect any medication returns. Always use the Patient Returned Medication Tray that is available in the delivery vehicle. Refer to the Patient Returned Medicines SOP for further guidance."

7.54.3 "*19.12 Successful delivery*

Once the deliveries are completed, return the delivery sheets to the pharmacy on the same day. The delivery sheets must be scanned into the pharmacy IT system and kept for a minimum period of 7 years."

7.54.4 "*19.13 Unsuccessful Delivery*

If the patient or representative is not able to receive the delivery of their medication, complete the 'attempted delivery' form and post it through the letterbox. The form will have details for arranging re-delivery.

The prescription and medication must be returned to the pharmacy on the same day and the pharmacist informed of the unsuccessful delivery.

The pharmacy must follow up the unsuccessful delivery by contacting the patient to arrange a second delivery time.

DO NOT:

Post the medication through the letter/post box.

Leave the medication in the porch or any other out building.

Leave the medication at an unauthorised address."

7.54.5 "*19.14 Delivery of a prescription via Royal Mail (Not for Cold Chain or CDs)*

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

Ensure that the pharmacist on duty is available to supervise the handing over of all items for delivery.

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

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

Confirm details of all prescriptions to be delivered.

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

Ensure Royal Mail driver signs Delivery Log sheet for all prescriptions being accepted for delivery. The delivery sheets must be scanned into the pharmacy IT system and kept for a minimum period of 7 years.

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

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

7.54.6 "*19.15 Unsuccessful Delivery via Royal Mail*

In the event of an unsuccessful delivery, Royal Mail will leave a 'Sorry We Missed You' card, stating the date and time of the attempted delivery. The patient can then either choose to collect and sign for their medicines at their local post office, or rearrange delivery for a convenient time by telephone or email."

7.54.7 "*19.16 Cold chain delivery via courier*

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

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

Any breach of cold chain conditions will be notified to the driver and any affected delivery will be cancelled with the pharmacy informed of the cold chain breach.

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

Ensure that the pharmacist on duty is available to supervise the handing over of all items for delivery.

A delivery must be booked using the couriers specified Cold Chain Services (refer to booking procedure with courier in the "cold chain courier" folder),

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

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

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

Confirm details of all prescriptions to be delivered.

The courier must scan a barcode sticker for each item. The pharmacy retains a copy of the barcode which is also the tracking number."

7.54.8 "*19.17 Unsuccessful cold chain delivery via courier*

In the event of an unsuccessful delivery, the courier will leave a 'Missed Delivery' card, stating the date and time of the attempted delivery along with details of how to contact the courier to arrange the redelivery. The patient can then rearrange delivery for a convenient time by telephone or Internet.

We operate to a 48 hour maximum window for cold chain deliveries and the courier will keep the cold chain intact until successful delivery for up to 48 hours. After 48 hours the items will be returned to the pharmacy and the pharmacy will contact the patient to rearrange delivery."

7.54.9 "*19.18 Breach of Integrity of Cold Chain*

The courier ensures temperature integrity throughout the supply chain, from point of collection & goods-in to pharmaceutical storage to final delivery.

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

Where such an event occurs, the courier is instructed to leave a 'Missed Delivery' card and also inform the pharmacy that the delivery was unsuccessful due to a breach of the cold chain. The pharmacy must arrange for immediate re-delivery of the items via courier and the return of the items that have failed to be delivered to the pharmacy by the courier. items subject to a cold chain breach may not be re-used and must be segregated from the pharmacy stock."

7.55 SOP 23 'Controlled Drugs: Delivery' states:

7.55.1 "*23.5 Delivery of Schedule 2 & 3 CDs*

A robust audit trail is essential when controlled drugs are involved. The delivery can be made to a person who is not the patient (the patient must have given authorisation for a representative to take receipt of CDs on their behalf). A Controlled Drugs Delivery Sheet must also be filled in for CD deliveries in addition to the Delivery Log sheet.

CDs must be in a separate bag to any other medication being delivered and the bags should be attached together.

CDs and any other medicines on that patient's delivery must be stored in the lockable compartment of the delivery van and out of sight.

The delivery van must be kept locked at all times when the driver is not in the vehicle.

The delivery driver/courier must sign the back of the prescription as the representative when accepting the CD for delivery.

The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative (passport, driving licence or government approved photo ID card are acceptable forms of ID). A delivery cannot be left with anyone who is not the patient or their authorised representative.

All entries in the CD register must be made when the medication leaves the pharmacy premises. The delivery driver/courier must be entered as the 'person collecting'.

The prescription must be retained in the pharmacy until the delivery driver returns the appropriate paperwork signed by the patient or representative to confirm successful delivery or the patient signature is confirmed online if delivered by courier."

7.55.2 "*23.7 Successful Schedule 2 & 3 Delivery*

The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative. A delivery cannot be left with anyone who is not the patient or their authorised representative.

For all successful deliveries the Controlled Drug delivery sheet signed by the patient or online courier delivery record should be cross-referenced with the prescription and CD register prior to the prescription being processed as part of the end of day procedure."

7.55.3 "*23.8 Unsuccessful Schedule 2 & 3 Delivery via pharmacy driver*

Unsuccessful deliveries sent with a pharmacy driver must be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate."

7.55.4 "*23.9 Unsuccessful Schedule 2 & 3 Delivery via courier*

Unsuccessful deliveries sent with a courier must be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate. Where the time of attempted delivery means that the return cannot be made on the same day, the courier will store the drugs at their approved warehouse overnight.

When a failed delivery occurs, the tracking service will notify the pharmacy and the patient of the failed delivery so that delivery can be re-arranged for the patient at the next convenient time or returned to the pharmacy."

7.55.5 "*23.10 Note re Use of Couriers for Controlled Drugs Deliveries*

The courier has pharma grade specialist facilities to meet specific quality and validation requirements for healthcare products. This includes Home Office licensed controlled drug stores."

7.56 Based on the information provided within the updated SOPs, the Committee was satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

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

7.58 The Committee noted that in the application form, in response to the question as to whether they were undertaking to provide appliances, the Applicant had left the section blank. In its comments to the Commissioner, at paragraph 2.1.6 above, the Applicant's representative stated that *"Appliances as listed in Part IX of the Drug Tariff will be provided <u>except</u> for those that require measuring or fitting."*

7.59 The Committee noted the Applicant's updated SOPs state:

7.60 SOP 9 'Pharmaceutical & Legal Assessment':

7.60.1 "*9.9 Items Requiring Measuring and Fitting*

Where a prescription is received for an item that requires measuring or fitting the patient should be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients should be signposted to at least two other providers of the service in their area. (see signposting SOP)"

7.61 SOP 26 'Support for Self-Care, Signposting and Health Promotion':

7.61.1 "*26.14 Items Requiring Measuring and Fitting*

Where a prescription is received for an appliance or stoma appliance customisation or any item that requires measuring or fitting the patient must be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients must be signposted to at least two other providers of the service in their area. (see signposting SOP)"

7.62 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 8(4) of Schedule 4.

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

7.64 The Committee had regard to the updated SOPs and noted that SOP 18 'Bagging-Up' states:

7.64.1 "*18.7 Choice of Packaging*

Choice of packaging will depend on the nature of the items being delivered and the appropriate level of protection must be used to ensure that the item can withstand the normal rigours of the delivery process.

All packaging must have the tamper proof seals provided in the pharmacy attached to the packaging so that any tampering with the packaging will be evident.

Medicine for local delivery which is not fragile and to be delivered by the delivery driver can be packaged in the using the pharmacy bags supplied for standard prescription items.

DO NOT use normal cardboard boxes. When cardboard boxes are required ALWAYS use the re-enforced boxes that are purchased for delivery purposes.

For postal items, either:

At the very least - padded envelopes even for non-fragile items as this will help to ensure the integrity of the manufacturers packaging.

*For most items - bubble wrap and where necessary, polystyrene filler, placed within a cardboard box. **use the re-enforced cardboard boxes***

Large or any fragile medicines should be packed into the re-enforced cardboard boxes with bubble packaging and filling material to protect from damage.

Coldchain items should be bubble wrapped and placed in Styrofoam filled re-enforced cardboard boxes and kept in the DELIVERIES FRIDGE (rather than the storage fridge) with the "FRAGILE" and "FRIDGE LINE" stickers attached. The courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box ("cold ship" packaging) and are fully monitored – typically at 2 to 8 degrees Celsius range- (see delivery SOP). Pharmacy staff should be aware that some thermolabile products can be damaged by excessive cold as well as heat. Items such as ice packs can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in medicines which is damaging to them and such items must not be used." [Applicant's emphasis]

7.65 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 8(15) of Schedule 4.

Refusal to provide drugs or appliances ordered

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

7.67 The Committee noted the Commissioner in its decision had stated "*Checks on patient safety: No detailed description of phone-based review to ensure patients still require medications or are not experiencing adverse effects.*"

7.68 The Committee had regard to the updated SOPs and noted SOP 34 'Repeat Dispensing' states:

7.68.1 "*34.10 Prescription Reception*

…The pharmacy record card must be completed and attached to a RA and an entry made on each occasion a dispensing takes place.

Any amendments to the RD, e.g. items not issued or change to expected interval must be recorded in the comment section of the pharmacy copy of the card."

7.68.2 "*34.11 Pharmaceutical & Legal Assessment*

Terms of Service states that a pharmacy must, when providing drugs in accordance with a repeatable prescription the importance of only requesting those items which they need. Patients should be so advised either by phone or through the inclusion of written information with delivered medication.

The pharmacist should telephone and speak with the patient before issuing a repeat and ensure:

They are taking or using, and likely to continue to take or use the medicine or appliances appropriately

Advise the patient that they should only order items that they need

Check that the patient is not suffering any side effects which may suggest they need a review of their medication

Check that the patient's regimen has not been changed since the prescriber authorised the repeatable medication.

Check that there has not been any change to the patient's health since prescription was authorised

Provide advice and encourage patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber.

Any interventions, referrals (to the patient's GP or otherwise) or refusal to supply decisions which are deemed to be clinically significant should be recorded on the Intervention and Referral Form which must be shared with the patient's GP.

The prescriber must have signed the RA. The RDs will not be signed but will be numbered as appropriate. The RA will detail the specific number of issues and, if appropriate, the dispensing interval."

7.69 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 9(4) of Schedule 4.

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

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

7.71 The Committee had regard to the updated SOPs and noted SOP 34 'Repeat Dispensing' states:

7.71.1 "*34.10 Prescription Reception*

Appropriate advice about the benefits of repeat dispensing must be given to any patient who:

has a long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term); and,

requires regular medicine in respect of that medical condition, including, where appropriate, advice that encourages the patient to discuss repeat dispensing of that medicine with a prescriber at the provider of primary medical services whose patient list the patient is on.

Such advice will be provided by the Pharmacy using its permissible methods of non face-to-face contact with patients.

On receipt of a repeatable prescription from the patient, the pharmacy staff should ensure that the patient fully understands the Repeat Dispensing Process and is provided with a patient information leaflet that outlines the benefits of the service. Contact the patient to discuss the service and confirm if they wish to access the information leaflet online, by email or by post.

Check to confirm if the patient has a long term, stable medical condition that requires regular medicine in the short to medium term and ensure relevant patients have the scheme explained to them."

7.71.2 "*34.11 Pharmaceutical & Legal Assessment*

The pharmacist should telephone and speak with the patient before issuing a repeat and ensure:

… Provide advice and encourage patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber."

7.72 The Committee was 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

7.73 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.

7.74 The Committee had regard to the updated SOPs and noted SOP 24 'Controlled Drugs: Collection and Disposal of Patient Returns' states:

7.74.1 "*24.5 Patient Returned Medication*

This service is available to <u>all</u> patients living in England.

Patients or their representatives <u>may not</u> return and [sic] *medicines directly to the pharmacy and must follow the procedures set out in this SOP.* [Applicant's emphasis]

Patients should be referred to the 'Returning unwanted medication' page on the website for information.

To arrange the return of unwanted medicines to the Pharmacy the patient must telephone and speak to a member of the dispensary team. For controlled drugs this must always be the pharmacist on duty.

The process for returning medication must be explained to the patient.

Each return will be made by booking an appointment for the pharmacy's driver to visit the patient's home to collect the returned medication or by sending the appropriate packaging to the patient to arrange for return by Royal Mail – Note the Royal Mail website refers to a prohibition on carrying "controlled drugs" but this refers only to illicit controlled drugs and not those supplied under the direction of a physician."

7.74.2 "*24.7 Return by Royal Mail*

The pharmacist must

Speak to the patient about the return and clarify the items being returned.

Assess the items for suitability for return by Royal Mail

If items are suitable for return by Royal Mail then make a note on the PMR and arrange to send the appropriate packaging to

the patient for safe return (refer to bagging up SOP for appropriate packaging)

If items are not suitable for return by Royal Mail (eg clinical or contaminated waste) then provide the patient with details of their local procedures for disposal.

Send the packaging to the patient along with the instructions for appropriate packing of the goods

Contact the patient to ensure that the packaging has been received

Provide signposting via phone or email to other pharmacies where the patient prefers to dispose of unwanted medicines locally."

7.74.3 "*24.8 Handling Patient-Returned CDs from Delivery Driver*

Drivers need to:

Be aware that they cannot accept patient returns from patients without prior arrangement. The driver must notify the patient to follow the "returning unwanted medication" process as set out on the website.

Ensure that appropriate packaging is within the van prior to starting the journey as the patient may not have requested the correct type or there may be a requirement for additional packaging.

Pharmacy staff need to:

If CDs have been identified, immediately on receipt from the driver, secure them in a bag, clearly marking on 'Patient-returned CDs for destruction' and include the date of return; place the bag in the CD cabinet away from pharmacy stock until they can be destroyed.

As soon as possible, Refer to the 'Returned medicines form' to make the entry in the 'Patient returned CD register', to record the CD that require destruction at a later date"

7.75 SOP 25 'The Safe and Effective Receipt and Disposal of Medicines' states:

7.75.1 "*25.6 Process for Patients to Return Medication*

Patient Returned Medication

Patients or their representatives MAY NOT return and [sic] *medicines directly to the pharmacy and must follow the procedures set out in this SOP.*

This service is available to all patients living in England.

Patients can be referred to the 'Returning unwanted medication' page on the website for information.

To arrange sending medication back to the Pharmacy the patient must telephone and speak to a member of the dispensary team.

Patients may

Arrange collection by the Pharmacy driver at an appointed time, or

Send unwanted medication back to the Pharmacy via courier (at the pharmacy's cost), or Royal Mail (subject to risk assessment of contents by the RP in advance) or,

The Pharmacy can arrange for medication to be collected by our specialist waste management contractor.

Advise patient of their other options to dispose of unwanted or expired medication if none of these options is suitable for them (signposting to local pharmacies).

Explaining the Process to Patients

Check which patient or patients the medication belonged to.

Check the relevant PMR to identify any hazardous / dangers [sic] *drugs or items that have been dispensed and could potentially form part of the return.*

Ask the patient to identify the type of medication being returned.

If there is any item considered dangerous, such as a cytotoxic, inform the patient that we will collect items using the specialist waste management contractor and arrange for that collection to take place at a convenient time.

Go through the "unwanted medicines card" (available from the CPE website) over the phone with the patient"

7.75.2 "*25.7 Process for accepting patient returns by the Driver*

Confirm that a collection of unwanted medication for disposal has been booked. Returns without a booking should only happen in exceptional circumstances as this increases the chance that the proper process for segregation of medicine has not been followed.

Ensure you are fully equipped with the utensils in your vehicle to accept unwanted medication as patients may have placed unwanted medication into incorrect bags.

Wear appropriate protective clothing where there is a requirement to handle any returned waste.

Identify any controlled drugs (check with the pharmacist if necessary); segregate these and place in a labelled clear bag for the pharmacist for denaturing and disposal. For further guidance read SOP Controlled Drugs: Disposal of Patient returned medication'.

Identify any sharps and ask the customer to take these back if it safe to do so, signposting to the most appropriate route of disposal.

Identify any cytotoxic or other hazardous waste (check with the pharmacist where necessary).

Identify any flammable waste and store separately until this can be removed by the waste contractor.

Where large quantities of the same medicine are being returned, then report this to the pharmacist as this could indicate a compliance issue requiring intervention.

Complete the 'Patients Returns Sheet' detailing the patients name and address, also if relevant their representatives name.

Store returned medicines in the quarantine area of the van for transport.

The returnable items can be taken back to the pharmacy for destruction.

Ensure medicines are not visible in the vehicle at all times."

7.75.3 "*25.9 Return by Royal Mail*

The pharmacist must

Speak to the patient about the return and clarify the items being returned.

Assess the items for suitability for return by Royal Mail

If items are suitable for return by Royal Mail then make a note on the PMR and arrange to send the appropriate packaging to the patient for safe return (refer to bagging up SOP for appropriate packaging)

If items are not suitable for return by Royal Mail (eg clinical or contaminated waste) then provide the patient with details of their local procedures for disposal.

Send the packaging to the patient along with the instructions for appropriate packing of the goods

Contact the patient to ensure that the packaging has been received

Provide signposting via phone or email to other pharmacies where the patient prefers to dispose of unwanted medicines locally."

7.75.4 "*25.10 Disposal of returned medicines*

Use the specialist waste management company to provide safe and secure disposal of unwanted medicines by collection of unwanted medicines from patients and residential homes.

Unwanted medicines collected by the driver must be sorted and placed in disposal units / containers provided by the NHSCB or a waste contractor retained by the NHSCB ready for waste management services to collect."

7.76 Based on all of 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 13 - 15 of Schedule 4.

Promotion of healthy lifestyles

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

7.78 The Committee noted the Commissioner's concern raised in its representations: "*Health promotion and campaign delivery: Insufficient evidence of structured, commissioned-compliant participation beyond generic website statements.*"

7.79 The Committee had regard to the updated SOPs and noted SOP 27 'Promotion of Healthy Living, Lifestyle & Health Campaigns' states:

7.79.1 "*27.3 Identification of patients for promotion of Healthy Lifestyles*

Identification can take three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process.

Active patients will be those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further information should be sent, or who should be called to follow up on the results and offer additional support and information. All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight and also lifestyle questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.

Passive patients are those where the identification happens as part of another interaction with the patient, but where the patient does not appear to be actively seeking additional assistance. For example, the dispensing of a prescription which identifies the patient as having high blood pressure / diabetes etc.

As part of repeat dispensing process (or during any other interaction with a patient) staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from promotion of healthy lifestyles they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided.

Leaflets will be delivered to patients with their medication. Those identified as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns. The website, app and email newsletters will also be used to promote healthy lifestyles via the health promotion zone."

7.79.2 "*27.4 Health Campaigns & Community Engagement Exercise*

Terms of Service require participation in a maximum of 2 campaigns per financial year, but you should agree to take part in all campaigns where practicable.

The Pharmacy will take part in national health campaigns to promote public health messages to patients across England. This will be achieved by sending out leaflets with prescriptions during specific targeted campaign periods and providing additional advice and learning resources via the website on the health promotion zone.

… We will also offer help and support on our website and direct patients to appropriate links for the health campaigns. This will ensure that patients across the UK are able to easily access information about health campaigns at all times."

7.80 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 16 – 18 of Schedule 4.

Prescription linked intervention

7.81 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.

7.82 The Committee noted the Commissioner in its decision had stated "*Prescription-linked interventions: Guidance exists for staff referral to the RP for diabetes, CHD risk, smoking, or weight management advice, but does not demonstrate how this will be consistently delivered to patients as part of essential services.*"

7.83 The Committee had regard to the updated SOPs and noted SOP 27 'Promotion of Healthy Living, Lifestyle & Health Campaigns' states:

7.83.1 "*27.6 Long Term Conditions*

If it is appropriate to provide advice the pharmacist should provide any advice necessary and within their area of competency. Where advice is provided it should be recorded on an Intervention & Referral form. Any advice given should always aim to include counselling on healthy lifestyle as well as management of the long-term condition.

If it is not appropriate to provide advice the patient should be referred to the appropriate health or social care provider or support organisation (see Signposting SOP). Where advice cannot be provided it should be recorded on an Intervention & Referral form along with the referral organisation.

For specific groups of patients (those with diabetes, at risk of coronary heart disease, especially those with high blood pressure, and patients who smoke or who are overweight) the pharmacists must provide advice without face-to face interaction (eg telephone, Live video, via the website). Such advice should be backed up, as appropriate, by the provision of written material such as leaflets."

7.83.2 "*27.7 Identification of patients for Support with Long Term Conditions*

Identification can take three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process.

Active patients will be those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further information should be sent, or who should be called to follow up on the results and offer additional support and information. All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight and also lifestyle questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.

Passive patients are those where the identification happens as part of another interaction with the patient, but where the patient does not appear to be actively seeking additional assistance. For example, the dispensing of a prescription which identifies the patient as having high blood pressure / diabetes etc.

As part of repeat dispensing process (or during any other interaction with a patient) staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from promotion of healthy lifestyles they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided.

Leaflets will be delivered to patients with their medication. Those identified as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other

conditions will also receive targeted campaigns. The website, app and email newsletters will also be used to promote healthy lifestyles."

7.84 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

Health campaigns

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

7.86 The Committee noted the Commissioner in its decision had stated "*Health campaigns: No information on how the DSP will safely and effectively participate in health campaigns remotely.*"

7.87 The Committee considered the Applicant's updated SOPs.

7.88 The Committee noted SOP 27 'Promotion of Healthy Living, Lifestyle & Health Campaigns' states:

7.88.1 "*27.4 Health Campaigns & Community Engagement Exercise*

Terms of Service require participation in a maximum of 2 campaigns per financial year, but you should agree to take part in all campaigns where practicable.

The Pharmacy will take part in national health campaigns to promote public health messages to patients across England. This will be achieved by sending out leaflets with prescriptions during specific targeted campaign periods and providing additional advice and learning resources via the website on the health promotion zone.

The pharmacy will also take part in at least one approved community engagement exercise in relation to the promotion of health living each financial year.

Patients will be directed to the learning resources via email, text and other non face-to-face communication so that they are aware of the campaign.

Patients should also be assessed for participation in at least one clinical audit and whichever of the following that the NHSCB specifies—

(i) a clinical audit carried out in a manner which is compatible with the NHSCB's arrangements for the receiving and processing of data from the audit, or

(ii) a policy based audit (to support the development of the commissioning policies of the NHSCB) carried out in a manner which is compatible with the NHSCB's arrangements for the receiving and processing of data from the audit.

We will also offer help and support on our website and direct patients to appropriate links for the health campaigns. This will ensure that patients across the UK are able to easily access information about health campaigns at all times.

The Pharmacy will use the opportunity when dispensing prescriptions for patients who have conditions such as diabetes, heart disease, obesity and high blood pressure, to offer health advice over the phone or provide them with leaflets about their conditions. Patients will also be able to speak to the pharmacist regarding information about the campaigns. Advice and help will be available to patients during opening hours of the pharmacy and patients can access information on our pharmacy website at all times. This ensures the uninterrupted provision of the service to patients across England."

7.89 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 18 of Schedule 4.

Signposting

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

7.91 The Committee had regard to the updated SOPs and noted SOP 26 'Support for Self-Care, Signposting and Health Promotion' states:

7.91.1 "*26.10 Other Provider Organisations and Support Details*

Details of local health and social care providers to whom patients can be referred as well as contact details for local patient and support groups can should [sic] *be provided to patients via written mailshots, flyers sent with prescription deliveries, our website and by telephone or email.*"

7.91.2 "*26.12 Signposting*

Service Description

To minimise inappropriate use of health and social care services and support services, patients who require further support, advice or treatment which cannot be provided by the pharmacy, on other health and social care providers or support organisations who may be able to assist the person must be given sufficient information to enable them to access those services. Where appropriate, this may take the form of a referral."

7.91.3 "*26.13 Patient Identification*

Identification can take place during any interaction that the patient has with the pharmacy staff. In particular, staff should consider the results

from the identification of patients for the promotion of healthy lifestyles and those who have filled in the Lifestyle Questionnaire on the website.

Staff should always consider that in order to minimise inappropriate use of health and social care services and of support services and person who:

requires advice, treatment or support that we cannot provide; but

we are aware of another provider of health services who is likely to be able to provide that advice, treatment or support.

We must provide the patient with contact details of that provider and, where appropriate, refer the person to the provider. At least two providers should be identified if this is possible."

7.92 The Committee was 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

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

7.94 The Committee had regard to the updated SOPs and noted SOP 26 'Support for Self-Care, Signposting and Health Promotion' states:

7.94.1 "*26.8 Patient identification*

As part of repeat dispensing process / medicine sale or during any other interaction with a patient staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from support for self-care they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided and should include:

treatment options, including advice on the selection and use of appropriate drugs which are not prescription only medicines; and

on changes to the patient's lifestyle."

7.94.2 "*26.9 Service outline*

Upon receipt of a request for help with the Support for Self-Care, including treatment of minor illness and long-term conditions, pharmacy staff should consider available resources and provide general information and advice on how to manage illness.

If appropriate, access the patient's Summary Care Record / National Care Records Service to see if it assists in delivery of the service.

…The pharmacist should provide advice on the appropriate use of non-prescription medicines which can be used in the self-care of the relevant minor illness and / or long-term conditions."

7.95 The Committee was 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

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

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

7.98 The Committee noted the Commissioner in its decision had stated "*Discharge Medicines Service: No SOP describing how recently discharged patients will be supported or advised regarding medications.*"

7.99 The Committee had regard to the updated SOPs and noted SOP 28 'Discharge Medicines Service ("DMS")' states:

7.99.1 "*28.3 Process*

Every day the RP must check the pharmacy's NHS.net Connect system, PharmOutcomes and Refer to Pharmacy for referrals to the DMS. Pharmacy contractors must consider any communication in the following form and manner as constituting a referral: "Any written patient information received by a community pharmacy via secure electronic message from an NHS trust or other provider of NHS services concerning a patient's discharge to usual primary care services and their medicines regimen"."

7.99.2 "*28.4 Consent*

Obtain and record the informed consent from the patient prior to provision of the service using the consent form. As part of obtaining consent discuss the requirements for data sharing. Inform the patient that any information discussed as part of the service may be shared with their GP."

7.99.1 "*28.5 DMS Stages*

It is expected that all patients referred to the pharmacy will receive all three stages of the service. Note that stages 1, 2 and 3 of the service may occur in parallel and first contact with the patient (as defined in the NHS Discharge Medicines Service toolkit) could happen at any stage in the process."

7.99.2 "*28.6* ***DMS Stage 1 (within 72 hours of referral excluding times when the pharmacy is not open)***

The community pharmacy receives a discharge referral. A clinical review is undertaken by a community pharmacist following receipt of a patient referral. The community pharmacy team may contact the referring NHS trust contact or the PCN pharmacy team to discuss any concerns (eg an important medicine the patient usually takes is omitted on the discharge referral) and to seek clarification about the discharge referral."

7.99.3 "*28.7 Considering the appropriateness of any medication changes prior to discharge*

DMS requests will not necessarily all be in the same form.

Summary Care Record / National Care Records Service Access - If appropriate, access the patient's Summary Care Record / National Care Records Service to see if it assists in providing the service

The pharmacist must review the actions requested in the DMS and consider whether the actions requested are, in the pharmacists clinical judgement, appropriate.

For actions that are considered appropriate the pharmacist must;

Use the information in the referral, to compare (as far as possible) the patient's medicines at discharge to those they were taking before admission to hospital.

Check any prescriptions issued to be dispensed to assess whether any changes are appropriate and identify any areas of concern.

Where necessary, discuss changes that may be appropriate or raise any issues of concern identified, to the extent that in accordance with the pharmacist's clinical judgement, it appropriate to do so with—

(i) the staff of the hospital or other provider of NHS services that made the referral, and

(ii) any provider of primary medical services on whose patient list the patient is; and

keep and maintain records of the DMS referrals received and of any actions taken, as appropriate (in particular, to support delivery of stages 2 and 3 of the service).

REQUIRED ACTIONS AS PER NHS GUIDANCE"

7.99.4 "*28.8 DMS Stage 2*

The community pharmacy receives the first prescription following discharge. The pharmacist or pharmacy technician will ensure medicines prescribed post-discharge take account of the appropriate changes made during the hospital admission. If there are discrepancies, the pharmacy team will try to resolve them with the general practice, utilising existing communication channels. Alternatively, the community pharmacist may refer the patient to the PCN pharmacy team for a Structured Medication Review or other intervention.

If the pharmacy receives either a written or electronic prescription (or repeatable prescription) or EPS token and the pharmacy as received a request for Stage 2 of the DMS service either from Stage 1 or

Even without a referral to Stage 2, the pharmacy receives such a prescription as described above and the pharmacy is aware as a result of an earlier referral to Stage 2 or Stage 3 that this is the first prescription for a medicinal product following the patient's discharge from hospital, or a transfer of the patient's care from another NHS service provider, AND

The pharmacy is aware that either the patient, or their carer wishes the pharmacy to provide Stage 2 of the DMS service then the pharmacy must provide the following service as part of Stage 2

Then the pharmacist must:

Review / perform a further review of any prescription

Summary Care Record / National Care Records Service Access - If appropriate, access the patient's Summary Care Record / National Care Records Service to see if it assists in providing the service.

Specifically consider if in your clinical judgement appropriate account has been taken to any changes in the medication regimen during the patient's stay in hospital or prior to the transfer of the DMS from another pharmacy.

Where you see areas of concern, raise those issues as appropriate with the patient's GP

Keep and maintain records of the DMS referrals received and of any actions taken, as appropriate (in particular, to support delivery of stage 3 of the service)."

7.99.5 "*28.9 DMS Stage 3*

The NHS Discharge Medicines Service should also be used as an opportunity to engage with patients about their medicines on a shared decision-making basis. Whether the patient or their carer makes contact themselves for advice, a referral is received from an NHS trust on discharge or a prescription is received following prescribing changes, the pharmacist or pharmacy technician should take the opportunity to establish the patient's understanding of their condition(s), their associated medications and how each medicine can be best administered to get optimum benefit and reduce unwanted side effects.

The community pharmacy checks the patient's understanding of their medicines regimen. The pharmacist or pharmacy technician will hold a discussion, adopting a shared decision-making approach, with the patient (or the carer if appropriate) to check their understanding of their post-discharge medicines' regimen. The pharmacist or pharmacy technician will identify any adherence, clinical issues, outstanding questions or needs the patient may have regarding their medicines."

7.100 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

Websites and health promotion zones

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

7.102 The Committee noted that the Commissioner in its decision had stated "*Website and digital services: No information on public access to essential services, healthy lifestyle materials, or health promotion content.*"

7.103 The Committee had regard to the updated SOPs and noted that SOP 26 'Support for Self-Care, Signposting and Health Promotion' states:

7.103.1"*26.11 Health promotion zone on our website*

The website allows patients to access pharmaceutical services via our interactive page.

Explaining the Interactive Page to Patients

The interactive page is promoted on the website so that when a patient first visits the website they are signposted to a range of up to date materials that promote healthy lifestyles.

The Superintendent Pharmacist is responsible for ensuring that a reasonable range of materials are accessible via the interactive page and that they address a reasonable range of health issues.

The health promotion zone may also includes [sic] *details of current health campaigns and other information to promote healthy lifestyle choices as well as providing access to the Lifestyle Questionnaire that is used to target health information to patients.*"

7.104 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.

Other considerations

7.105 The Committee noted the Commissioner's comment in its representations that "*To permit wholesale reconstruction of an application post-refusal would undermine the Regulation 25 framework and dilute the evidential threshold required of distance selling premises at the point of determination.*" The Committee was mindful that the appeal is a reconsideration of the application and whilst it must have regard to the information originally provided to the Commissioner in support of the application, it may also take into account any further information provided by the Applicant. The Committee has done so on the basis of the updated SOPs.

Summary

7.106 On the information before it, the Committee could be satisfied that there are procedures likely to secure the safe and effective provision of pharmaceutical services as required by Regulation 25(2)(b).

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

7.107.1 confirm the Commissioner's decision;

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

7.107.3 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.

7.108 Given the Committee had reached a different decision, albeit based on information that was not available to the Commissioner at the time that it considered the application, the Committee determined that the decision of the Commissioner must be quashed.

7.109 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.

7.110 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.

7.111 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 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 granted.

Case Manager
Primary Care Appeals