NHS Resolution

18 February 2026

REF: SHA/26775

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APPEAL AGAINST SOUTH EAST LONDON ICB DECISION TO REFUSE AN APPLICATION BY TRIBELLE LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT BUENA VISTA, THE HILLSIDE, ORPINGTON, KENT, BR6 7SD 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 TribElle Ltd
Community Pharmacy South East London
PCSE on behalf of South East London ICB

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1 The Application

By application dated 7 July 2025, TribElle Ltd ("the Applicant") applied to South East London ICB ("the Commissioner") for inclusion in the pharmaceutical list at Buena Vista, The Hillside, Orpington, Kent, BR6 7SD under Regulation 25. In support of the application it was stated:

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

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

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

Pharmacy procedures

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

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

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

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

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.

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.

1.5 "TribElle is a fully regulated, remote online pharmacy designed to provide safe, reliable, and uninterrupted essential NHS pharmaceutical services to patients across England. Our systems are cloud-based and supported by robust SOPs that ensure 24/7 platform availability for service requests, with live pharmacist-led oversight during our declared NHS hours.

1.6 All prescriptions are received electronically, and dispensed centrally from a GPhC registered premises. Checks are performed by qualified pharmacists using a standardised procedure that ensures continuity even in cases of staff absence.

1.7 Contingency plans, including secondary pharmacist coverage and mirrored server backup, are in place to avoid downtime or service disruption. We have a robust business continuity plan in place and maintain close working relationships with licensed wholesalers to ensure continuity of medicine supply.

1.8 TribElle's model is built entirely on remote delivery. Patients access services via a secure online platform that allows them to:

1.8.1 Complete an online consultation

1.8.2 Upload identity verification (as required)

1.8.3 Communicate asynchronously with a pharmacist via email/telephone/video

1.8.4 Receive medication by post

1.9 All patient records, communications, and consultation outcomes are securely stored and reviewed in line with NHS IG (Information Governance) standards. Our clinical team uses patient-reported information and established clinical pathways to guide safe prescribing, dispensing, and delivery without the need for face-to-face interaction.

1.10 Pharmacists remain available to patients via email, phone or video to support medication use, conduct MURs (if eligible), and handle urgent safety concerns. As an online-only pharmacy, our registered premises are not open to the public. There are secure gates and an intercom system preventing unauthorised access. See att. doc for additional info. Ref 1"

Ref 1:

1.11 **"TribElle: Additional Information to support the Application Ref 1: Procedure if a patient attends the pharmacy premises requesting essential services:**

1.12 As an online-only pharmacy, our registered premises are not open to the public. There are secure gates and an intercom system preventing unauthorised

access. However, should a patient arrive on-site, clear signage will direct them to use the online portal or telephone service.

1.13 If necessary, staff will support the patient in accessing services remotely or advise them of a local pharmacy better suited to offer in-person care. This process is supported by a documented SOP to ensure regulatory compliance and continuity of care.

1.14 **Provision of advanced services (if undertaken):**

1.15 TribElle may offer certain advanced services such as the New Medicine Service (NMS) remotely, in line with NHS guidance on telephone/video consultations in an area of the pharmacy where calls can be made in private by the Pharmacist. These services will be delivered in a manner that is clearly separate from essential services, using designated staff and systems, and will not compromise or depend upon face-to-face provision. Consent, clinical documentation, and follow-up will be managed digitally or by telephone, as per the service specification."

1.16 [SOPs provided – superseded by SOPs submitted on appeal]

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 The Applicant

2.1.1 "Thank you for your email. We would like to respond to the points raised by [RM], CEO /CPSEL.

2.1.2 We write further to your correspondence and provide the following evidence in support of TribElle's application, with direct reference to the requirements of Regulation 25(2)(a) and (b) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

Regulation 25(2)(a): Uninterrupted Provision of Essential Services

2.1.3 Regulation 25(2)(a) requires that "arrangements are in place to ensure the uninterrupted provision of essential services during the core and supplementary hours for which the pharmacy is to be open."

2.1.4 TribElle confirms that robust arrangements have been established to meet this obligation, including:

2.1.4.1 Workforce continuity: A staffing model comprising employed pharmacists, prescribing pharmacists, and contracted locums, supported by formal agreements to ensure availability at all times.

2.1.4.2 Business continuity planning: Documented procedures addressing contingencies such as staff absence, system outages, or supply chain disruption, ensuring no interruption to service provision.

2.1.4.3 Resilience of infrastructure: Redundant digital platforms compliant with NHS and GPhC requirements, alongside contractual delivery arrangements with secondary providers, guaranteeing safe and timely medicines supply.

2.1.5 On this basis, TribElle submits that the requirement under Regulation 25(2)(a) is fully satisfied.

Regulation 25(2)(b): Safe and Effective Non-Face-to-Face Service Delivery

2.1.6 Regulation 25(2)(b) requires that “arrangements are in place for the safe and effective provision of essential services without face-to-face contact between any person providing those services and the person receiving them.”

2.1.7 TribElle’s operating model is designed specifically to ensure compliance with this requirement, including:

2.1.7.1 Patient identification and security: Secure NHS-accredited systems for patient verification and record-keeping, compliant with GDPR and NHS Digital standards.

2.1.7.2 Clinical governance protocols: Standard operating procedures for prescribing, dispensing, and clinical escalation, ensuring safety and effectiveness in all remote interactions.

2.1.7.3 Safeguarding and accountability: Embedded safeguarding checks, clear consent processes, and auditable clinical records, with regular monitoring and reporting to ensure compliance.

2.1.7.4 Communication accessibility: Provision of telephone, email, and video consultation channels, enabling pharmacist–patient engagement when clinically appropriate, without the need for in person attendance.

2.1.8 Accordingly, TribElle is fully compliant with Regulation 25(2)(b).

Premises and Planning Considerations

2.1.9 Our location is not near Osbon Pharmacy Hub, and we do not share a car park with any other establishment, as demonstrated in the screenshots from Google Maps. The pharmacy is a standalone building

behind a gated barrier, which only allows access for staff via a code or fobs. I hope this clarifies the error made by [RM]. [See Appendix C]

2.1.10 In relation to planning policy and premises use:

2.1.11 TribElle is an online women's health pharmacy, operating under NHS and GPhC regulation, with a clinical model designed around non-face-to-face service provision. Key characteristics of the proposed use include:

2.1.11.1 Low Footfall: Services are delivered remotely; patients do not attend the premises. There will be no public-facing shopfront or collection point.

2.1.11.2 Minimal Impact on Surroundings: Operations are digital and administrative in nature, with medicine dispensing managed in compliance with NHS/GPhC standards. Deliveries are handled via existing postal/courier networks, comparable to ordinary parcel deliveries at a residential address.

2.1.11.3 Small-Scale Operation: Staffing is limited and primarily remote, with only occasional on-site presence of a pharmacist or support staff.

2.1.11.4 No External Alterations: The outbuilding will retain its existing appearance, with no signage, lighting, or structural modifications impacting the residential character.

Planning Considerations

2.1.12 Material Change of Use

2.1.13 The test for material change of use is whether the character of the property is altered. Given the low intensity, digital-first model, there is no significant increase in traffic, noise, or disturbance beyond typical residential activity (e.g., home working). As such, the proposal is unlikely to give rise to material harm.

2.1.14 Residential Character and Amenity

2.1.14.1 No increase in visitor numbers or customer access.

2.1.14.2 Deliveries are equivalent to standard courier activity at a residential property.

2.1.14.3 No signage, lighting, or commercial external features.

2.1.14.4 Noise and disturbance remain negligible.

2.1.15 Accordingly, the residential character of the site and amenity of neighbours is preserved.

2.1.16 Precedent and Enforcement

2.1.17 The proposal is unique in being a regulated healthcare service operating on a distance-selling basis, rather than a retail pharmacy with public access. As such, it does not establish an adverse precedent for incompatible commercial uses within residential areas.

2.1.18 National and Local Policy Compliance

2.1.19 National Planning Policy Framework (NPPF) encourages digital healthcare innovation and supports community access to services where there is no adverse land-use impact.

2.1.20 Local planning policies relating to amenity, character, and sustainable transport are upheld due to the negligible operational footprint of the proposed use.

2.1.21 The use of the premises for the provision of pharmaceutical services is a lawful use and does not constitute a material change of use requiring additional planning permission.

2.1.22 The digital-first nature of the service results in negligible additional footfall, ensuring compatibility with the residential character and amenity of the surrounding area.

2.1.23 The proposal aligns with both local and national planning frameworks and does not give rise to enforcement or precedent-setting concerns.

2.1.24 All activities will be undertaken in compliance with GPhC premises standards and the requirements of planning legislation.

Conclusion

2.1.25 TribElle respectfully submits that the above demonstrates compliance in full with Regulation 25(2)(a) and (b). The proposed service model ensures:

2.1.25.1 uninterrupted provision of essential services (25(2)(a));

2.1.25.2 safe and effective provision of such services without face-to-face contact (25(2)(b)); and

2.1.25.3 adherence to planning and regulatory frameworks governing lawful and safe delivery of pharmaceutical services.

2.1.26 We trust this addresses the matters raised and provides you with the necessary assurances. Should additional information be required, TribElle remains willing to provide the same without delay."

3 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 28 October 2025 states:

3.1 “South East London ICB has considered the above application and I am writing to confirm that it has been refused. Please see the enclosed report for the full reasoning.”

Extract from the London PSRC meeting of 15 October 2025

3.2 “Name of applicant: TribElle Ltd

3.3 Fitness to practise: Cleared for inclusion

3.4 Address of proposed premises: Buena Vista, The Hillside, Orpington, KENT, BR6 7SD

3.5 Status of location: Non-controlled locality.

3.1 Relevant regulations and guidance: Regulations 25 – distance selling premises. Regulation 31 – refusal: same or adjacent premises. DH market entry guidance chapter 11.

Additional Information

3.1 Consider impact of decision on those with protected characteristics under the Equalities Act 2010 and is this in accordance with NHS Public Sector Equality Duty Consider impact of decision on NHS duty on health inequality: None Identified.

Additional Information

3.2 The PSRC have determined that there is enough information to deal with this application without holding an oral hearing

3.3 The comments received from parties is available to the PSRC panel to review.

Community Pharmacy South East London Comments

3.4 Community Pharmacy South East London (CPSEL) acknowledges receipt of the letter from Primary Care Support Services regarding the application under Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (“the Regulations”).

3.5 Under Regulation 25, NHS England (NHSE) must be satisfied that the applicant will be able to provide:

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

3.5.2 (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.

3.6 CPSEL notes that the premises in question are situated within a location that includes a car park currently occupied by Osbon Hub Pharmacy, which offers open access to the general public.

3.7 In light of these circumstances, NHSE must ensure that the applicant provides clear and compelling evidence demonstrating compliance with Regulation 25(2)(a) and (b), specifically:

3.7.1 Uninterrupted Provision of Essential Services: The applicant must explain how they will ensure the continuity of services during all opening hours, especially considering the proximity to existing pharmacy services and potential operational challenges.

3.7.2 Safe and Effective Non-Face-to-Face Service Delivery: The applicant must provide details of the systems, protocols, and safeguards in place to ensure the effective delivery of essential services without requiring face-to-face interaction, in line with Regulation 25(2)(b).

3.7.3 Material Change of Use for Premises:

3.7.3.1 Constitute a material change of use requiring planning permission

3.7.3.2 Be incompatible with residential character and amenity

3.7.3.3 Risk precedent-setting and enforcement issues

3.7.3.4 Likely contravene local and national planning policy The application must demonstrate full adherence to planning policy to support the safe and lawful delivery of pharmaceutical services in line with GPhC standards.

Londonwide LMC Comments

3.8 Londonwide LMCs have approached local GP practices to seek their views on the application and has received no representations. We therefore do not have any comments to make on this occasion, but we would be grateful if you would keep us informed of developments.

3.9 Applicants Further comments – see section 2 above

3.10 With regard to Regulation 31 (Refusal: same or adjacent premises) and to the provisions of Schedule 2 to the Regulations:

Applications seeking the listing of premises that are already, or are in close proximity to, listed chemist premises.

3.11 The proposed pharmacy is not on the same site or adjacent to any other pharmacy, therefore this regulation is not engaged.

3.12 Distance Selling premises applications

3.13 Regulation 25 (1) Section 129(2A) of the 2006 Act(c) (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 also 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) The ICB 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

3.14 The premises in respect of which the application is made 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.

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

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

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

3.15 The applicant provided information via their application, additional information and during the notification process. All of this information has been assessed. There was an issue from the original SOPs with advanced and enhanced services potentially being provided on site, but due to the change in the regulations the applicant has provided clarification on this and the changes to the SOPs.

3.16 We have assessed the elements relating to the NHS contract only, anything outside of this is outside the scope of the regulations.

3.17 Having reviewed the information, we have noted the following:

3.17.1 Paragraph 22B & 22C of Schedule 4 – no information provided.

3.17.2 Paragraph 8(5) of Schedule 4 – no information provided.

3.17.3 PSRC are not satisfied that services would be available to anyone in England that requested them.

3.17.4 PSRC are not satisfied that the applicant has provided sufficient assurance that appropriate procedures will be in place to ensure the

uninterrupted provision of essential services, should the Responsible Pharmacist be absent for any reason.

3.18 It may be concluded that the PSRC is not satisfied that pharmacy procedures for the pharmacy are likely to secure the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.

3.19 It may also be concluded that the applicant is likely to not satisfy the criteria as set out in the Terms of Service of Pharmacists for the safe and effective provision of all essential services without face to face contact.

3.20 Therefore, the PSRC have determined that they are not satisfied that the pharmacy procedures for the pharmacy premises are likely to secure the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

Decision

3.21 Regulation 31.

3.21.1 There are no current pharmacies listed at the proposed premises or adjacent to the proposed premises. Therefore regulation 31 does not apply for this application.

3.22 Regulation 25(2)(1)(a)

3.22.1 The proposed site is not on the same site or in the same building as the premises of a provider of Primary Medical Services with a patient list. Therefore, this regulation does not apply for this application.

3.23 Regulation 25(2)(1)(b)(i)

3.23.1 The PSRC is not satisfied that pharmacy procedures for the pharmacy are likely to secure the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.

3.24 Regulation 25(2)(1)(b)(ii)

3.24.1 The PSRC is not satisfied that the applicant is likely to satisfy the criteria as set out in the Terms of Service of Pharmacists for the provision of all essential services without face to face contact.

3.25 The PSRC is not satisfied that the pharmacy procedures for the pharmacy premises are likely to secure the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff. Therefore, the application has been refused.

3.26 Determination made by London PSRC on behalf of NHS South East London ICB.

Conditions of approval for a Distance Selling Pharmacy

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

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

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

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

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

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

3.27.4.2 the safe and effective provision of pharmaceutical services without face-to face contact at the proposed premises between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff; and

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

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

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

4 The Appeal

In a letter dated 7 November 2025, Rushport Advisory LLP on behalf of the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

4.1 "I act for TriBelle Limited 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's decision report makes reference to a number of factors raised by interested parties that are either incorrect or simply not relevant to the legal test.

4.3 The proposed pharmacy is a standalone building behind a gated barrier, which only allows access for staff via a code or fobs with no access for patients. There is no other pharmacy at either the same or adjacent premises. Matters relating to planning permission are not relevant to the legal test to be applied in this case and are a matter for the local council.

4.4 The Commissioner lists a number of reasons for refusal, namely failure to address Paragraphs 8(5), 22B & 22C of Schedule 4. My client has now updated their SOPs for the provision of NHS pharmaceutical services and these are attached with this appeal. Previous versions of SOPs should now be disregarded.

4.5 Since my client submitted their application they have also prepared a floor plan and for the sake of completeness it is attached along with this appeal.

4.6 Given the clarifications and updated SOPs provided the appeal should be allowed."

5 Summary of Representations

This is a summary of representations received on the appeal.

5.1 THE COMMISSIONER

5.1.1 "I am writing in regard to the above appeal.

5.1.2 Please read this response in conjunction with the decision report that was issued for this application.

5.1.3 The application was refused as there was a number of issues with the information received and our PSRC was not assured that all of the DSP criteria within the regulations was in place.

5.1.4 The applicant has now revised their SOPs and as such all the issues in relation to the SOP have now been resolved. However, there is one thing that remains an issue. Within the comments made through the application process a comment was made about the pharmacy as follows:

5.1.5 TribElle is an online women's health pharmacy, operating under NHS and GPhC regulation, with a clinical model designed around non-face-to-face service provision.

5.1.6 The pharmacy appears to be currently operating as a private pharmacy which is permissible, however on the current website this also states that the pharmacy is a women's health pharmacy and concentrates on women's health. It does not therefore cover men or children and therefore the pharmacy does not appear to be able to provide the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.

5.1.7 Please see attached a screen shot of the website [see Appendix D].

5.1.8 It is unclear how the pharmacy will accommodate Men and Children if they were to granted to provide NHS Services.

5.1.9 As we do not believe that services would be available to anyone in England that requests them, we do believe that this application should be refused."

5.2 COMMUNITY PHARMACY SOUTH EAST LONDON

5.2.1 "Community Pharmacy South East London (CPSEL) Response to Appeal: Application for Inclusion in the Pharmaceutical List (Distance-Selling Premises) to be determined under Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the 2013 Regulations"), which defines the excepted applications route for distance-selling premises (DSP). The Committee must be satisfied that the pharmacy procedures will secure:

5.2.1.1 Reg. 25(2)(a): the uninterrupted provision of essential services during the opening hours of the premises, to persons anywhere in England who request those services; and

5.2.1.2 Reg. 25(2)(b): the safe and effective provision of essential services without face-to-face contact between service users (or representatives) and the applicant or its staff.

5.2.2 We note recent national guidance and market-entry materials confirm both the strict national-footprint requirement for DSPs and the undertaking-based nature of the test, with refusal being appropriate where there is insufficient assurance on uninterrupted, safe, and non-face-to-face provision to anyone in England.

5.2.3 We further note the 2025 regulatory changes: closure of new DSP market entry from 23 June 2025, with transitional provision at Reg. 25A for applications made on or before 22 June 2025, and the tightening of DSP service modality rules from October 2025 (no on-site directed services except limited vaccination transitional arrangements). These underline Parliament's and NHSE's intention that DSPs should be genuinely national "at-distance" providers.

Regulation 25(2)(a): Uninterrupted Provision by Staff at the Registered Premises

5.2.4 The appellant relies on a staffing model comprising employed pharmacists, prescribing pharmacists, and contracted locums supported by formal agreements to ensure availability at all times. However, the evidence on the applicant's own online materials shows named prescribing pharmacists primarily based outside South East London (North of England and North West London). There is no clear assurance that sufficient pharmacist presence and operational staffing will be at the registered premises during all opening hours to deliver uninterrupted essential services (ES) and run the premises systems as required of a DSP. The burden lies with the applicant to demonstrate this; they have not.

5.2.5 Recent NHS Resolution appeal decisions illustrate the Committee's scrutiny where applicants failed to articulate, with specificity, how the premises-based procedures and staffing deliver uninterrupted ES to anyone in England, leading to refusal. The Medtime Pharma Ltd (Bradford) decision (27 March 2025) and Medival (Yorkshire) Ltd (Bradford) (20 April 2023) set out the level of procedural detail expected and the consequences of omissions or inadequacies.

5.2.6 Conclusion on 25(2)(a): The applicant has not evidenced an assured, premises-based staffing and procedural model capable of uninterrupted ES provision to persons anywhere in England throughout opening hours. The requirement is not met.

Regulation 25(2)(b): Safe and Effective Non-Face-to-Face Provision (SOP Adequacy)

5.2.7 CPSEL agrees with the PSRC's earlier assessment that the SOP suite does not secure the safe and effective non-face-to-face delivery of ES. In particular:

5.2.7.1 SOP 3.2 / 8.1 / 16.1 – Safety-netting: There is no robust safety-netting to ensure patients can access care with reasonable promptness commensurate with clinical need. This is fundamental in a DSP model.

5.2.7.2 The GPhC's 2025 guidance for pharmacies providing services at a distance emphasises clear patient pathways, clinical governance, and safe remote processes; the present SOPs do not demonstrate compliance with these standards.

5.2.7.3 The SOPs fail to establish a clear and auditable framework that assures patients that all telephone and video consultations are conducted exclusively from the registered pharmacy premises and under the direct supervision and control of the Responsible Pharmacist, as required by the NHS Regulations 2013 and GPhC premises standards.

5.2.8 The GPhC standards for registered pharmacies require governance, environment, and service-delivery arrangements that safeguard patients, including robust medicines management and continuity; the submitted procedures fall short of that benchmark for a remote model.

5.2.9 Conclusion on 25(2)(b): SOPs lack essential safety-netting and escalation needed for safe, effective, non-face-to-face delivery. The requirement is not met.

Likelihood of Genuine "National" Provision; Local Market Consequences

5.2.10 CPSEL has reviewed Shape Atlas for existing SEL internet/DSP provision and notes the local pattern of operation. This accords with the Company Chemists' Association (CCA) analysis that >70% of DSPs dispense more than 50% of items to patients from a single local postcode area within 10 miles, contrary to the national-footprint intent and creating an uneven playing field which undermines bricks-and-mortar access.

5.2.11 National bodies have acknowledged this problem and, in 2025, moved to close DSP market entry and restrict on-site service delivery by DSPs—confirming the policy concern that many applicants do not operate nationally as envisaged.

5.2.12 Financial fragility is acute. The National Pharmaceutical Association (2025) funding survey and Community Pharmacy England commentaries report over half of owners operating at a loss, underscoring that allowing additional DSP capacity that is unlikely to serve nationally will materially harm local pharmaceutical services sustainability. (Committee may take judicial notice of CPE's 2025 funding statements.)

5.2.13 Conclusion: On the balance of probabilities, this DSP is very unlikely to provide ES outside Orpington/Bromley, failing the national reach implicit in Reg. 25 and risking material detriment to local pharmaceutical services.

Premises, Storage and Planning Compliance

5.2.14 Unregistered storage area: The plan indicates an unregistered storage area outside the GPhC-registered premises. Storage of medicines (including CDs and fridge lines) must comply with the GPhC standards and NHS Approved Particulars – premises; areas used for NHS services must be within the controlled, auditable, and appropriately identified premises. Off-plan storage is non-compliant and raises patient-safety risks (temperature, security, audit trail).

5.2.15 Medicines storage standards: Safe custody and environmental controls (e.g., HBN 14-02, BS 2881; controlled temperature ranges; security for CDs) must be demonstrably met within the registered premises. The appellant has not evidenced how such standards would be achieved, monitored and governed for any off-plan area.

5.2.16 Planning control (material change of use): Operating a regulated pharmacy (including storage of POMs and CDs, enhanced security and deliveries) from a residential address is capable of being a material change of use requiring planning permission. The National Planning

Policy Framework (NPPF) requires decision-makers to protect residential amenity and character; innovation does not displace these safeguards. Authorisation of NHS listing should not proceed where the lawful planning status is unclear; alternatively, it should be conditional upon the grant of any required permission following public consultation.

Governance and Terms of Service Context

5.2.17 From October 2025, DSPs are prohibited from providing directed services face-to-face on site (with limited transitional exceptions). This reinforces that a DSP must truly operate at a distance and maintain robust procedures for national, remote ES delivery—standards this application does not convincingly meet.

5.2.18 PSRC terms of reference emphasise regulatory consistency, robust evidence, and risk management in market-entry determinations; where essential elements are not evidenced, refusal is appropriate to protect service integrity and reduce avoidable appeals.

Overall Assessment and Recommendation

5.2.19 Having reviewed the appeal, prior PSRC analysis, the SOPs and premises plan, and the wider regulatory and policy landscape:

5.2.19.1 Reg. 25(2)(a): Not satisfied—no clear, premises-based staffing and procedural assurance of uninterrupted ES to persons anywhere in England.

5.2.19.2 Reg. 25(2)(b): Not satisfied— SOPs lack adequate safety-netting and escalation for safe and effective non-face-to-face ES provision.

5.2.19.3 National reach & local impact: Evidence (CCA) indicates high risk of localised dispensing inconsistent with DSP obligations, with adverse impact on local pharmaceutical services sustainability.

5.2.19.4 Premises compliance: Presence of an unregistered storage area and lack of assurance on standards-compliant storage; planning status is unresolved and potentially unlawful without permission.

5.2.20 Accordingly, CPSEL respectfully submits that the appeal should be dismissed, and the ICB's refusal upheld. CPSEL further requests to be kept informed of all subsequent correspondence, including any appeals process, and formally requests the opportunity to attend any hearings related to this application."

6 Summary of Observations

This is summary of observations received.

6.1 RUSHPORT ADVISORY LLP ON BEHALF OF THE APPLICANT

6.1.1 “I act for TriBelle Limited and have been instructed by my client to submit this reply to the Commissioner’s / LPC comments on my client’s appeal.

Commissioner

6.1.2 My client notes the Commissioner’s comments on their current website. My client is fully aware that their current website is not appropriate for their future plans to provide NHS services. My client has its own development team that will be producing a completely new website for the NHS pharmacy.

6.1.3 The SOPs provided with my client’s appeal provide additional detail on what will be included in the new website, such as a Health Promotion Zone (page 16), information about pharmacy services (page 14), services being provided to any patient who requests them (page 17), patient registration (page 22), safe storage of medicines (page 81 19.9), returning unwanted medicines (page 97, 24.5), Lifestyle Questionnaires (page 108, 26.8), etc.etc.

6.1.4 My client is also aware that nothing in their publicity material, material published on behalf of my client, or in any communication (written or oral) to any person seeking the provision of pharmaceutical services may either expressly state or imply, that—

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

6.1.4.2 that my client would be likely to refuse, for reasons other than those provided for in their terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients.

LPC

6.1.5 Dealing with the points raised by the LPC in order.

6.1.6 Page 1 of the LPC letter comments on the legal test and we have no comment to make on that.

6.1.7 Regulation 25(2)(a): Uninterrupted Provision by Staff at the Registered Premises

6.1.8 My client’s proposed staffing model is perfectly suitable for the operation of a DSP and provides pharmacist and support staff cover throughout the core opening hours. The LPC has reviewed the current website used by my client to provide private prescribing services. As already discussed this is not relevant to NHS services and is a completely different model.

6.1.9 The LPC then refers to two cases where applications under regulation 25 were refused at appeal. Neither of these cases is relevant as the

evidence provided was different. The Committee will of course consider the evidence in this case rather than a different case.

6.1.10 Regulation 25(2)(b): Safe and Effective Non-Face-to-Face Provision (SOP Adequacy)

6.1.11 In this section the LPC states;

There is no robust safety-netting to ensure patients can access care with reasonable promptness commensurate with clinical need

6.1.12 It is far from clear what the LPC means by this statement. The SOPs set out clearly how services will be provided.

6.1.13 The LPC then refers to GPhC standards which are of course a matter for the GPhC to enforce and not part of the test to be applied in this case.

6.1.14 The LPC then states,

The SOPs fail to establish a clear and auditable framework that assures patients that all telephone and video consultations are conducted exclusively from the registered pharmacy premises and under the direct supervision and control of the Responsible Pharmacist, as required by the NHS Regulations 2013 and GPhC premises standards.

6.1.15 The SOPs clearly set out how all services will be provided from the premises. Notwithstanding this and even though my client will only provide services remotely to patients from their premises, there is no requirement in the "NHS Regulations 2013 and GPhC premises standards." as claimed by the LPC. One example is the provision of the NMS service which may be carried out at premises other than the registered premises by a pharmacist who is an employee of the pharmacy contractor. In fact, due to the number of contractors outsourcing NMS provision to third parties, the Regulations were amended to require the pharmacist to be an employee of the contractor.

Likelihood of Genuine "National" Provision; Local Market Consequences

6.1.16 It is disappointing for the LPC to make remarks about my client without any knowledge and we do not respond further to these comments save to say that my client has been clear that they will provide services to any person in England who requests those services.

Premises, Storage and Planning Compliance

6.1.17 All of the comments in this section of the LPC letter are matters for the GPhC (which has already approved my client's premises as a pharmacy). However, we comment briefly on these points below.

6.1.18 Unregistered storage area – this area is not part of the pharmacy and not used to store pharmacy products. That is why it is referred to as "unregistered".

6.1.19 Medicines storage standards – all relevant standards have already been met and the GPhC has approved the premises.

6.1.20 Planning control (material change of use): Planning is a matter for the local authority."

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 further information provided by the Applicant in comments to the Commissioner which confirmed that the proposed site is not near an existing pharmacy.

7.7 The Commissioner had concluded that "*There are no current pharmacies listed at the proposed premises or adjacent to the proposed premises. Therefore Regulation 31 does not apply for this application*". The Committee noted that this had not been disputed either on appeal or in subsequent representations. Based on the information provided, the Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

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

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

10. *Where, pursuant to this Part, a person is required to provide details, that obligation is only discharged if the information or documentation provided is sufficient to satisfy NHS England in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that NHS England may need to make of the information or documentation when carrying out its functions.*

Regulation 25(1)

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

Regulation 25(2)(a)

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

Regulation 25(2)(b)

7.12 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.

7.13 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.

7.14 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.

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

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

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

7.18 The Committee noted the conclusion of the Commissioner that "*PSRC are not satisfied that the applicant has provided sufficient assurance that appropriate procedures will be in place to ensure the uninterrupted provision of essential services, should the Responsible Pharmacist be absent for any reason*."

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

7.20 SOP 1: "Introduction and Background to SOPs"

7.20.1 "*1.3 Overriding Provisions Applicable to All SOPs*

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

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."

7.21 SOP 33: "The Responsible Pharmacist"

7.21.1 "*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."

7.22 The Committee noted the comments from Community Pharmacy South East London with regard to the uninterrupted provision of services and the "*staffing model comprising employed pharmacists, prescribing pharmacists and contracted locums … the applicant's own online materials show named prescribing pharmacists primarily based outside South East London (North of England and North West London). There is no clear assurance that sufficient pharmacist presence and operational staffing will be at the registered premises during all opening hours to delivery uninterrupted essential services* …" as well as the reference to previous Committee determinations.

7.23 The Committee noted the response from the Applicant's representative and that Community Pharmacy South East London had reviewed the existing website for the Applicant, which is currently being used by the Applicant for promotion of private prescribing services.

7.24 In the Committee's view, how the Applicant currently chooses to run its business and the business model which it operates is not a relevant consideration for the application before it which will be considered against the criteria as set out in the Regulations.

7.25 The Committee was mindful that it considers each application on its own merits based on the information before it. The Committee noted the SOPs, as provided on appeal, and was of the view that there was nothing provided which demonstrated that the Applicant would not be providing essential services without interruption. Based on the information before it the Committee was of the view that the provision of essential services would be without interruption.

7.26 With regard to services being available to persons anywhere in England, the Committee noted the conclusion of the Commissioner that "*PSRC are not satisfied that services would be available to anyone in England that requested them."* The Committee noted the following information in the Applicant's SOPs:

7.27 SOP 1: “Introduction and Background to SOPs”

7.27.1 “*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.”

7.28 SOP 3: “Procedures for NHS Pharmaceutical Services”

7.28.1 “*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.*”

7.29 The Committee noted the comments from Community Pharmacy South East London that “*the applicant has not evidenced an assured, premises based staffing and procedural model capable of uninterrupted ES provision to persons anywhere in England throughout opening hours.”*

7.30 As well as the assertions in the “overriding provisions” in SOP 1, the Committee noted the references throughout the rest of the SOPs with regard to delivery being made by couriers and Royal Mail as well as the Applicant’s own deliver drivers.

7.31 The Committee noted the further comments from Community Pharmacy South East London with regard to the “*likelihood of genuine “national” provision*” and the information provided but was unsure how this demonstrated that the extant application would not comply with the relevant criteria as set out in the Regulations. The Committee was mindful that it is unable to predict what may happen in the future and can only consider the information before it, which demonstrates that the Applicant is proposing to offer essential services to persons anywhere in England.

7.32 The Committee noted the comments from the Commissioner that “*on the current website this also states that the pharmacy is a women’s health pharmacy and concentrates on women’s health. It does not therefore cover men or children and therefore the pharmacy does not appear to be able to provide the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services*.”

7.33 In response, the Applicant’s representative had stated “*My client is fully aware that their current website is not appropriate for their future plans to provide NHS services. My client has its own development team that will be producing a completely new website for the NHS pharmacy*.”

7.34 Whilst the Committee had been provided with a screenshot of the website, it noted that this was from the current website, which the Applicant was using for its existing private business and therefore the Committee took no view on this. The Committee noted the comments from the Applicant with regard to a reconfigured website and references throughout the SOPs and that there was nothing provided which demonstrated that the Applicant would not be providing

services to any patient who requested them and that any services would solely be based on the provision of women's health.

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

7.36 The Committee next considered how the Applicant would provide pharmaceutical services without face to face contact. The Committee noted that in its decision report the Commissioner had concluded *"The PSRC is not satisfied that the applicant is likely to satisfy the criteria as set out in the Terms of Service of Pharmacists for the provision of all essential services without face to face contact".*

7.37 The Committee further noted the comments from Community Pharmacy South East London that it "*agrees with the PSRC's earlier assessment that the SOP suite does not secure the safe and effective non face to face delivery of ES …"* The Committee also noted the references from Community Pharmacy South East London to "safety netting".

7.38 The Committee noted the response from the Applicant's representative to these comments in which they state "*the SOPs set out clearly how services will be provided.*"

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

7.40 SOP 1: "Introduction and Background to SOPs"

7.40.1 "*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."

7.41 SOP 3: "Procedures for NHS Pharmaceutical Services"

7.41.1 "*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.

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."

7.41.2 "*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."

7.42 Whilst the Committee noted the comments from Community Pharmacy South East London, the Committee was of the view, based on the information before it, that there was nothing provided which demonstrated that pharmaceutical services would be provided by face to face contact at the pharmacy premises.

7.43 The Committee was also mindful of the regulatory changes as of 1 October 2025, that distance selling pharmacies can no longer provide Directed services (Advanced, National Enhanced and Enhanced Services, with the exception of Covid-19 and Flu vaccination services) face-to-face with the patient at the pharmacy premises. As a result of this amendment, the Committee noted that the Applicant would not be able to provide any pharmaceutical services at its premises.

7.44 In its application the Applicant stated that it intended to provide "*NMS*" as well as "Medication Review Service". The Committee noted SOP 7 'The New Medicine Service ("NMS")' which states "*The service must be provided remotely by phone or video call.*"

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

7.46 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.

7.47 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

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

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

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

7.50 SOP 6 'Online Order Receipt & Exemption Checking' states:

7.50.1 "*6.2 Scope*

All online services including the following:

…Requests to collect and dispense NHS Prescriptions."

7.50.2 "*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…"

7.51 SOP 19 'Order Delivery' states:

7.51.1 "*19.6 Choice of Delivery Method*

For items <u>other than</u> 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]."

7.52 The Committee was satisfied that the Applicant was proposing to offer the services to all of England, as per the information contained in the SOPs.

7.53 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

7.54 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.

7.55 The Committee noted the information in the Applicant's SOPs under the heading 'Emergency Supply and Urgent Supply' (SOP 16) 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.

7.56 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

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

7.58 The Committee noted SOP 6 'Online Order Receipt & Exemption Checking states:

7.58.1 "*6.8 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."

7.59 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.

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

7.61 The Committee noted SOP 6 'Online Order Receipt & Exemption Checking' states:

7.61.1 "*6.11 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."

7.62 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

7.63 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).

7.64 The Committee noted SOP 19 'Order Delivery' states:

7.64.1 "*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."

7.64.2 "*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."

7.64.3 "*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."

7.64.4 "*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."

7.64.5 "*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."

7.64.6 "*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."

7.64.7 "*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."

7.64.8 "*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."

7.65 SOP 23 ‘Controlled Drugs: Delivery’ states:

7.65.1 “*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.”

7.65.2 “*23.6 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.”

7.65.3 “*23.7 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."

7.65.4 "*23.8 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."

7.65.5 "*23.9 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."

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

7.67 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.

7.68 The Committee noted that the Applicant had left this blank on the application from, however the Committee noted the SOPs as provided with the appeal which set out how the Applicant was proposing to deal with any prescriptions which were presented to it for items that require measing and fitting.

7.69 The Committee noted the Applicant's SOPs state:

7.70 SOP 9 'Pharmaceutical & Legal Assessment':

7.70.1 "*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)"

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

7.71.1 "*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)"

7.72 The Committee was of the view, whilst the Applicant would not be able to provide any appliances, it had been provided with sufficient information to be satisfied that there would be compliance with paragraph 8(4) of Schedule 4.

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

7.74 The Committee noted that SOP 18 'Bagging-Up' states:

7.74.1 "*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 cause freezing in medicines which is damaging to them and such items must not be used." [Applicant's emphasis]

7.75 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

7.76 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.

7.77 The Committee noted SOP 34 'Repeat Dispensing' states:

7.77.1 "*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."

7.77.2 "*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."

7.78 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

7.79 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.

7.80 The Committee noted SOP 34 'Repeat Dispensing' states:

7.80.1 "*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, either in the post or collected from the surgery for the first time, 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.

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."

7.80.2 "*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."

7.81 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

7.82 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.

7.83 The Committee noted SOP 24 'Controlled Drugs: Collection and Disposal of Patient Returns' states:

7.83.1 "*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 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."

7.83.2 "*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."

7.83.3 "*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."

7.84 SOP 25 ‘The Safe and Effective Receipt and Disposal of Medicines’ states:

7.84.1 “*25.6 Process for Patients to Return Medication*

Patient Returned Medication

Patients or their representatives MAY NOT return and 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 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”

7.84.2 "*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."

7.84.3 "*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."

7.84.4 "*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."

7.85 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

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

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

7.87.1 "*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."

7.87.2 "*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."

7.88 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

7.89 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.

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

7.90.1 "*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."

7.90.2 "*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."

7.91 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

7.92 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.

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

7.93.1 "*27.4 Health Campaigns & Community Engagement Exercise*

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."

7.94 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

7.95 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.

7.96 The Committee noted SOP 26 'Support for Self-Care, Signposting and Health Promotion' states:

7.96.1 "*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.*"

7.96.2 "*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."

7.96.3 "*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."

7.97 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

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

7.99 The Committee noted SOP 26 'Support for Self-Care, Signposting and Health Promotion' states:

7.99.1 "*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."

7.99.2 "*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."

7.100 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

7.101 The Committee noted the decision of the Commissioner that the Applicant had not provided any information to demonstrate compliance with paragraph 22B and 22C of Schedule 4 in the original application.

7.102 The Committee reviewed the information provided on appeal and 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.

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

7.104 The Committee noted SOP 28 'Discharge Medicines Service ("DMS")' states:

7.104.1"*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".

7.104.2"*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."

7.104.3"*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."

7.104.4"*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."

7.104.5"*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"

7.104.6"*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 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)."

7.104.7"*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."

7.105 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

7.106 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.

7.107 The Committee noted that SOP 26 'Support for Self-Care, Signposting and Health Promotion' states:

7.107.1"*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."

7.108 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

7.109 The Committee noted the decision of the Commissioner which had concluded that no information had been provided with regard to paragraph 8(5) of Schedule 4.

7.110 Paragraph 8(5) states

"*Providing ordered drugs or appliances*

If the order is for ***[****or a product to be provided in accordance with a SSP is,****]*** *a drug or appliance included in the Drug Tariff, the British National Formulary (including any Appendix published as part of that Formulary), the Dental Practitioner's Formulary, the European Pharmacopoeia or the British Pharmaceutical Codex, the drug or appliance provided must comply with any relevant standard or formula specified therein.*

7.111 The Committee noted that SOP 10 'Interventions and Problem Solving' states:

7.111.1*"10.8 Serious Shortage Protocols*

> *Legislation has been passed that will allow for an emergency measure called the Serious Shortage Protocol (SSP) to be put in place to help manage supply if there is a serious shortage of one or more medicines.*
>
> *The intention is that an SSP will be issued only if a medicine has been judged by the Minister to be in serious short supply. The SSP will set out a clear protocol for community pharmacists to follow if they are unable to source that medicine for patients who have been prescribed it. The protocol will say what other prescription medicines could be dispensed, without the pharmacist needing to go back to the prescriber. …"*

7.112 The Committee was unsure how compliance with paragraph 8(5) was any different in an application for a distance selling pharmacy compared to a standard "bricks and mortar" pharmacy. However, based on the information before it, the Committee was of the view that there would be compliance with paragraph 8(5) of Schedule 4.

7.113 The Committee noted the comments from Community Pharmacy South East London with regard to the "*unregistered storage area*" as shown on the floor plan provided with the appeal. The Committee further noted the comments from the Applicant's representative in response that "*Unregistered storage area – this area is not part of the pharmacy and not used to store pharmacy products. That is why it is referred to as "unregistered"."*

7.114 The Committee further noted the comments from the Applicant's representative that "*all relevant standards have already been met and the GPhC has approved the premises."*

7.115 The Committee noted the floor plan and the area which had been designated as "unregistered storage space". The Committee was of the view that the approval of premises was a matter for the GPhC and that this particular issue was not a relevant criteria under Regulation 25.

7.116 The Committee also noted the comments with regard to planning controls, however it was mindful that this was not a relevant consideration within the context of the Regulations and would be a matter for the local authority and the GPhC if the application was granted.

Summary

7.117 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).

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

7.118.1 confirm the Commissioner's decision;

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

7.118.3 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.

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

7.120 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.

7.121 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.

7.122 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 granted.

Case Manager
Primary Care Appeals