

17 July 2026

REF: SHA/26932

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

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

**APPEAL AGAINST SOUTH YORKSHIRE ICB
DECISION TO REFUSE AN APPLICATION BY SRG
SERVICES (YORKSHIRE) LTD FOR INCLUSION IN
THE PHARMACEUTICAL LIST AT 20 ASLINE
ROAD, HIGHFIELD, SHEFFIELD, S2 4UJ UNDER
REGULATION 25**

1 Outcome

- 1.1 The Pharmacy Appeals Committee (“Committee”), appointed by NHS Resolution, quashes the decision of the Commissioner and redetermines the application.
- 1.2 The Committee determined that the application should be refused.

A copy of this decision is being sent to:

PCSE on behalf of South Yorkshire ICB
SRG Services (Yorkshire) Ltd

REF: SHA/26932

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

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

**APPEAL AGAINST SOUTH YORKSHIRE ICB
DECISION TO REFUSE AN APPLICATION BY SRG
SERVICES (YORKSHIRE) LTD FOR INCLUSION IN
THE PHARMACEUTICAL LIST AT 20 ASLINE
ROAD, HIGHFIELD, SHEFFIELD, S2 4UJ UNDER
REGULATION 25**

1 The Application

By application dated 21 June 2025, SRG Services (Yorkshire) Ltd, (“the Applicant”) applied to South Yorkshire ICB (“the Commissioner”) for inclusion in the pharmaceutical list at 20 Asline Road, Highfield, Sheffield, S2 4UJ under Regulation 25. In support of the application it was stated:

- 1.1 In response to “If you are undertaking to provide appliances, specify the appliances that you undertake to provide (or write ‘none’ if it is intended that the pharmacy will not provide appliances)” the Applicant stated:
- 1.2 “none.”
- 1.3 In response to why the application should not be refused pursuant to Regulation 31 the Applicant stated:
- 1.4 “While this application is for a **Distance Selling Pharmacy (DSP)**, which by nature does not provide walk-in services, we believe it is important to contextualise the history and ongoing needs of the local area. These premises were previously occupied by **Boots Pharmacy**, which served the **4,500 registered patients of Mathews Practice**. Since Boots closed its branch at this location, patients have experienced considerable disruption, and the GP practice has received a high number of complaints regarding the lack of accessible, reliable pharmacy services.
- 1.5 In response, **Dr. G.S. Chetty**, the sole partner of Mathews Practice, has consistently advocated for the reintroduction of a pharmacy service in the vicinity. We understand he remains supportive of this DSP application and is willing to confirm his endorsement if contacted.
- 1.6 This DSP application seeks to **restore confidence in local pharmaceutical services**, especially by offering a **dependable, culturally competent, and community-focused service** that understands and caters to the specific needs of the local population, including areas of deprivation and ethnic diversity.
- 1.7 While the DSP will operate under the required national terms and not offer walk-in services, we are committed to:

- 1.8 Providing **rapid dispensing and delivery** services to meet the demands of patients who previously relied on Boots.
- 1.9 **Supporting the Mathews Practice's Out-of-Hours Hub**, which operates three evenings a week (6:30–9:00 PM), as part of a city-wide collaborative group of 15 GP surgeries offering extended hours care. Our DSP will operate **in alignment with these extended access hours**, ensuring timely response to acute prescription needs during evenings.
- 1.10 This proposal does not replicate the traditional walk-in pharmacy model but provides a **highly responsive and structured pharmaceutical service**, tailored to both local and broader NHS service access models. We believe this application addresses a genuine gap in service and re-establishes a trusted link between patients and local health provision.”
- 1.11 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant stated:
- 1.12 **“Dedicated, Independent Entrance:** The proposed premises, although physically attached to the GP practice, have been designed with a completely separate and independent entrance. This clear physical demarcation ensures that the pharmacy’s operational area is accessed exclusively through its own entryway, thereby preventing any inadvertent mixing of patient streams between the GP practice and the pharmacy.
- 1.13 **Absence of Internal Connectivity:** There is no internal linkage—such as corridors, doorways, or shared reception areas—between the pharmacy premises and the GP practice. This deliberate design feature guarantees that the pharmacy functions as an autonomous entity, reinforcing the required separation and ensuring that all transactions and essential services are delivered remotely without any face-to-face interactions at the registered premises.”

Pharmacy procedures

- 1.14 Please explain how the pharmacy procedures used within the premises will secure:
- (a) the uninterrupted provision of essential services during the opening hours of the premises, to persons anywhere in England who request those services, and
 - (b) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or someone else's behalf, and the applicant or the applicant's staff.
- 1.15 Please describe the procedure that will be followed where a patient attends the premises and asks for one or more of the essential services.
- 1.16 If you are undertaking to provide advanced services at the premises please describe how you will do so without providing any element of essential services.

- 1.17 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.
- 1.18 “(a) Uninterrupted Provision During Opening Hours
- 1.19 **Robust IT and Communication Infrastructure:** The premises will be equipped with dedicated, high-reliability telephone lines, secure video conferencing systems, and an online patient portal. These tools are continuously monitored and supported by IT services to ensure that any patient request—no matter where in England they are based—is immediately received and acted upon. Our systems include redundancy measures (such as backup power supplies and alternative communication routes) to guarantee continuous service throughout our stated opening hours.
- 1.20 **Clear, Documented Operating Procedures:** Detailed Standard Operating Procedures (SOPs) have been established to manage incoming requests for essential services. These include:
- 1.21 A centralised call logging system that records the time and nature of each request.
- 1.22 Pre-allocated staffing schedules ensuring that at least one qualified pharmacist is always available to intervene.
- 1.23 Emergency response protocols that trigger when any delay or technical issue is detected, thereby redirecting calls to alternative contact points.
- 1.24 **Regular Testing and Audits:** The system and procedures are subject to regular internal audits and risk assessments. Testing of communication channels and remote consultation processes is carried out routinely, with documented reviews ensuring that any potential disruption is identified and remedied before patients are affected.
- 1.25 (b) Safe and Effective Provision Without Face-to-Face Contact
- 1.26 **Strict Remote Service Delivery Protocols:** All patient interactions, from the initial contact through to consultation and subsequent follow-up, occur via designated remote channels only (telephone or secure video link). The physical layout of the premises has been designed so that the area used for processing essential service requests is strictly segregated from any face-to-face consultation areas. Though the pharmacy may be part of a larger complex, our procedures and the designated remote consultation zones ensure that the staff handling NHS essential services never engage directly with patients on the premises.
- 1.27 **Training and Staff Awareness:** All pharmacy staff are rigorously trained in the regulatory requirements governing distance selling pharmacies. They understand that under this regime, no element of the NHS essential service should result in any face-to-face contact. Staff undergo periodic reviews and

simulated drills to ensure compliance, reinforcing the practice of deferring any unavoidable physical presence to a secure, remote method.

- 1.28 **Physical and Procedural Segregation:** Signage and clear physical demarcations are in place to guide patients. The designated entrance and reception procedures ensure that any patient arriving at the premises is directed immediately, via pre-set scripts, to the remote consultation process. This communication is reinforced by barrier installations and logical routing within the premises that physically separate the door designated for remote service operations from any portion where direct contact might occur.
- 1.29 Procedure When a Patient Attends the Premises Requesting Essential Services
- 1.30 **Initial Reception and Redirection:** typical the door would be sealed, entrance via telcom [sic]. If a patient arrives in person and requests one or more essential services, the following steps will be immediately implemented:
- 1.31 **Greeting and Identification:** The patient is courteously greeted by a member of the reception staff who confirms their details and notes the nature of their request.
- 1.32 **Explanation of Remote-Only Policy:** The staff member explains that, in compliance with regulatory requirements, essential services are provided exclusively by remote means (for example, via telephone or secure video call). Clear written and verbal guidance is provided, reiterating that this measure is in place to ensure patient safety and service integrity.
- 1.33 **Assistance in Initiating Remote Contact:** The patient is then assisted to access a dedicated tele-consultation booth or is provided with a direct phone number or a tablet kiosk located in a specially designated area. If necessary, the patient is shown how to use the online registration tool or given details to schedule a remote consultation immediately.
- 1.34 **Documentation:** The incident is logged with the patient's details, the time of arrival, and the manner in which the redirection was communicated. This record forms part of our ongoing audit process, ensuring transparency and enabling continuous improvement.
- 1.35 **Visible Signage and Pre-Warnings:** In addition to the above face-to-face protocol, clear signage at the entrance and digital displays reinforce the message that essential services are only available remotely. This proactive measure minimizes the likelihood of unintentional in-person requests.
- 1.36 Provision of Advanced Services Without Incorporating Essential Services
- 1.37 **Separate Operational Pathways:** Where advanced services (for example, the New Medicines Service or remote medication reviews) are provided at the premises, they are managed via entirely separate operational procedures and patient flow systems. This means:
- 1.38 Advance bookings for advanced service consultations are made through a distinct digital platform.

- 1.39 Dedicated spaces or remote consultation rooms (if any physical space is required for support activities) are used strictly for these advanced services while ensuring they do not overlap with the channels for essential services.
- 1.40 **Clear Segregation in Documentation and Communication:** The SOPs and training materials emphasise that the provision of advanced services must not involve any element of the essential services. This is achieved by:
 - 1.41 Utilising separate patient identifiers and booking systems so that advanced services are recorded and administered independently.
 - 1.42 Reinforcing the distinction in staff training so that actions involving essential service procedures (for example, discreet handling of repeat dispensing or prescription verification) remain solely remote, while advanced services are carefully monitored through the appointed channels.
- 1.43 **Compliance and Continuous Monitoring:** Regular audits will ensure that no element of a face-to-face encounter—whether intentional or inadvertent—takes place for essential services. Any advanced service conducted on-site will adhere strictly to its designated protocol, with contingency steps to switch immediately to a remote mode if any risk of direct contact is identified. Developments or changes in regulatory guidance are tracked, with corresponding updates to the SOPs occurring without delay.
- 1.44 **Enhanced Staff Training and Validator Systems:** The advanced services team will undergo additional training to reaffirm the boundaries between advanced service delivery and the essential service framework. A validator or internal quality assurance process ensures that every advanced service appointment is reviewed, confirming that it contains no element of the essential service provision.
- 1.45 These detailed procedures illustrate our comprehensive strategy to secure uninterrupted, safe, and regulation-compliant remote delivery of essential services while managing any physical presence appropriately and ensuring a clear separation from advanced service operations. This framework not only meets the requirements set by NHS England and the relevant integrated care boards but also establishes a robust system of risk management, continuous improvement, and patient safety assurance.”

2 Comments to the Commissioner

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

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

2.1 The Applicant

- 2.1.1 “Thank you for providing the representations submitted in relation to our distance selling pharmacy
- 2.1.2 (DSP) application.
- 2.1.3 We welcome the opportunity to respond and address the points raised.
- 2.1.4 This response deals comprehensively with:
- 2.1.5 1. Representations from Community Pharmacy South Yorkshire (CPSY)
- 2.1.6 2. Representations from Lo’s Pharmacy Group
- 2.1.7 The response relies solely on information already contained within the original application and the subsequent addendum submitted on 30 September 2025, in accordance with your instruction not to introduce new standalone information unless directly addressing another party’s inaccuracies.
- 2.1.8 1. Response to CPSY / LPC Representations
- 2.1.9 1.1 Compliance with Regulations 25(2)(a) and 25(2)(b)
- 2.1.10 CPSY notes that NHS England must be satisfied that Regulations 25(2)(a) and 25(2)(b) do not apply.
- 2.1.11 We confirm:
 - 2.1.11.1The application demonstrates full compliance with both subsections.
 - 2.1.11.2Section 7 of the application provides a detailed explanation of procedures ensuring:
 - 2.1.11.2.1Uninterrupted provision of essential services remotely to persons anywhere in England.
 - 2.1.11.2.2No face-to-face contact for any pharmaceutical services at, or in the vicinity of, the premises.
- 2.1.12 The addendum further clarifies that only Pharmacy First and New Medicine Service (NMS) are proposed and delivered exclusively remotely.
- 2.1.13 No element of either service involves on-site interaction.
- 2.1.14 1.2 Concern: Avoiding prescription collection and preventing perception as a walk-in pharmacy
- 2.1.15 CPSY raises the risk that patients may believe the premises function as a traditional walk-in pharmacy.

- 2.1.16 This is fully addressed in section 7.2 of the application:
- 2.1.16.1 No public access to the premises is permitted; the entrance is locked and access-controlled.
 - 2.1.16.2 Clear external signage states that no NHS services, including prescription collection, are available on-site.
 - 2.1.16.3 Any person attending is immediately redirected to remote channels; this redirection is logged for compliance audits.
 - 2.1.16.4 No medicines will be handed to patients at or near the premises, in line with Regulation 25(2)(b).
- 2.1.17 These measures ensure that the premises cannot operate—or be perceived—as a walk-in pharmacy.
- 2.1.18 1.3 Comment regarding “gap in service” and the PNA
- 2.1.19 CPSY suggests the application “tries to demonstrate a need”.
- 2.1.20 For clarity:
- 2.1.20.1 The DSP application does not rely on any PNA-identified need, nor does it claim such a need.
 - 2.1.20.2 Any contextual information provided regarding the former Boots closure and patient experience merely reflects factual background (as permitted).
- 2.1.21 The application explicitly acknowledges its status as an excepted application under
- 2.1.22 Regulation 25, where PNA considerations do not apply.
- 2.1.23 This corrects any misunderstanding that the application seeks to demonstrate localised need.
- 2.1.24 1.4 Advanced services provided on the premises CPSY notes that advanced services may no longer be provided on the premises.
- 2.1.25 This concern is already addressed in our addendum :
- 2.1.25.1 Flu vaccination and Hypertension Case-Finding have been withdrawn.
 - 2.1.25.2 Only Pharmacy First and NMS remain.
 - 2.1.25.3 Both are delivered fully remotely, with no on-site provision of any service whatsoever.
- 2.1.26 This aligns precisely with the June 2025 regulatory amendments.

- 2.1.27 1.5 Comment regarding Out-of-Hours (OOH) support
- 2.1.28 The LPC states that the DSP may only interact with the OOH service by supplying at the doorway, which is prohibited.
- 2.1.29 We confirm:
- 2.1.29.1 Our application does not propose supplying medicines at the doorway.
 - 2.1.29.2 No patients are invited to attend the premises for OOH support.
 - 2.1.29.3 Any references to responsiveness to local prescribing patterns were purely contextual and do not indicate any on-site interaction.
- 2.1.30 Furthermore, our stated opening hours (09:00–20:00) are not presented as aligning directly with the OOH session end time; they simply reflect the pharmacy’s operational choice, consistent with DSP regulations.
- 2.1.31 1.6 Concern that patients may complain due to lack of physical access DSP contractors, by definition, must not offer physical access.
- 2.1.32 Our application ensures:
- 2.1.32.1 Clear communication materials
 - 2.1.32.2 Prominent signage
 - 2.1.32.3 Locked premises
 - 2.1.32.4 Mandatory redirection protocols
- 2.1.33 These eliminate any reasonable uncertainty about the nature of service provision.
- 2.1.34 2. Response to Lo’s Pharmacy Group Representations
- 2.1.35 (Email dated 04/09/2025)
- 2.1.36 2.1 Statement about the premises being “co-located” with the GP practice and therefore inviting face-to-face services
- 2.1.37 The representation suggests that proximity to Mathews Practice may lead patients to assume walk-in services are available.
- 2.1.38 However:
- 2.1.38.1 The premises have a completely separate, independent entrance, as stated in section 6.1 of the application.
 - 2.1.38.2 There is no internal connectivity with the GP practice (no shared corridor, reception, or access).

- 2.1.38.3 External signage explicitly prohibits face-to-face provision.
- 2.1.38.4 The door remains sealed and controlled, preventing unintended access.
- 2.1.39 These safeguards directly satisfy Regulation 25(2)(a).
- 2.1.40 2.2 Misinterpretation of references to face-to-face services by the previous pharmacy operator
- 2.1.41 The representation states that our application “refers to offering face-to-face Advanced and Enhanced Services”.
- 2.1.42 This is incorrect.
- 2.1.42.1 The only references to face-to-face services relate to historical services previously available under Boots—not services we propose.
- 2.1.42.2 The addendum explicitly removes any services that would require face-to-face interaction.
- 2.1.42.3 Only Pharmacy First and NMS remain, and both are delivered 100% remotely.
- 2.1.43 Thus, the allegation that we intend to offer face-to-face elements is factually incorrect.
- 2.1.44 2.3 Concern regarding Out-of-Hours support being “face-to-face”
- 2.1.45 Lo’s Pharmacy asserts that responding to OOH needs would require face-to-face delivery, which is prohibited.
- 2.1.46 We clarify:
- 2.1.46.1 Our application never proposes face-to-face OOH support.
- 2.1.46.2 Any mention of responsiveness relates to remote dispensing and delivery, not collection or on-site presence.
- 2.1.47 This ensures compliance with Regulation 25(2)(b), which prohibits services “in the vicinity” of the premises.
- 2.1.48 2.4 Allegation that the DSP would operate as a “pseudo-DSP” serving only the immediate neighbourhood
- 2.1.49 This is incorrect.
- 2.1.49.1 Section 7.1(a) of the application confirms that essential services will be provided to persons anywhere in England via telephone, website, and secure video channels.

2.1.49.2 Remote infrastructure includes national telephone access, courier arrangements, and online contact portals.

2.1.49.3 No part of the application restricts service to the immediate neighbourhood.

2.1.50 The suggestion that the intention is to operate hyper-locally is not supported by any part of the application.

2.1.51 3. Conclusion

2.1.52 Both representations contain several assumptions that do not reflect the content of the application or addendum.

2.1.53 To summarise:

2.1.53.1 No face-to-face services of any kind will be provided at or near the premises.

2.1.53.2 The premises are separate and physically independent from the GP practice.

2.1.53.3 Prescription collection is impossible due to locked-door, signage, and redirection protocols.

2.1.53.4 Only remote-only advanced services (Pharmacy First and NMS) are proposed.

2.1.53.5 All essential services are provided remotely to England as a whole, not just the local area.

2.1.53.6 No element of the application seeks to demonstrate or rely upon PNA need.

2.1.54 We therefore maintain that the application fully complies with Regulation 25 and respectfully request that NHS England proceed accordingly.”

3 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 4 February 2026 states:

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

3.2 You have a right of appeal to the Secretary of State against South Yorkshire ICB’s decision. Should you choose to appeal then you should either complete the online form available on the NHS Resolution website or send a concise and reasoned statement of the grounds for your appeal within 30 days of the date of this letter to nhsr.appeals@nhs.net or: Primary Care Appeals, NHS Resolution, 8th Floor, 10 South Colonnade, Canary Wharf, London, E14 4PU.”

Decision report

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

- 3.3 **“Re: Application for inclusion in a pharmaceutical list at 20 Asline Road, Highfield, Sheffield, S2 4UJ in respect of distance selling premises by SRG Services (Yorkshire) Ltd**
- 3.4 The Committee first considered Regulation 31 and determined that it did not apply. There is no pharmacy at the same or adjacent premises to the proposed site, nor is there any suggestion that any of the nearby pharmacies are in any way connected with this application. Thus, the Committee concluded that it was not required to refuse the application under the provisions of Regulation 31.
- 3.5 The Committee then proceeded to consider Regulation 25. Having regard to Regulation 25(2)(a), the Committee was satisfied that 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, namely the Mathews Practice – Belgrave Medical Centre.
- 3.6 Regarding Regulation 25(2)(b), the Committee considered the information provided by the applicant in relation to its procedures for the provision of pharmaceutical services. Based on the information provided, the Committee was not satisfied that the pharmacy procedures for the pharmacy premises are likely to secure—
- 3.7 (i)the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and
- 3.8 (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.
- 3.9 For example, the applicant has not explained:
- 3.10 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.
- 3.10.1 what containers will be “suitable” for posted/delivered items (Paragraph 8(15) of Schedule 4).
- 3.10.2 how evidence will be sought and provided about the patients' entitlement to exemption or remissions from NHS Charges (Paragraph 7(3) of Schedule 4).
- 3.10.3 how appropriate advice about the benefits of repeat dispensing will be given to any patient who (i) has a long term, stable medical condition,

and (ii) requires regular medicine in respect of that medical condition (paragraph 10(1) of Schedule 4).

3.10.4 how the pharmacy will safely and effectively accept and dispose of unwanted drugs presented for disposal (Paragraphs 13, 14 & 15 of Schedule 4).

3.10.5 what procedures are in place for the Discharge Medicines Service (paragraphs 22B and 22C of Schedule 4).

3.11 Having considered all the information provided and assessed it against the requirements of the Regulations, the Committee refused this application.

3.12 Rights of appeal: SRG Services (Yorkshire) Ltd.”

4 The Appeal

Using the online appeal form dated 1 March 2026, the Applicant appealed against the Commissioner’s decision. The grounds of appeal are:

4.1 “I write on behalf of SRG Services (Yorkshire) Ltd (“the Appellant”) to formally lodge an appeal against the decision of South Yorkshire Integrated Care Board dated 4th February 2026 refusing the Appellant’s application for inclusion in the pharmaceutical list in respect of distance selling premises at the above address.

4.2 This appeal is submitted pursuant to the statutory right of appeal outlined within the decision letter issued by NHS England’s Pharmacy Market Administration Services.

4.3 1. Nature of the Appeal

4.4 The Appellant notes that the Committee:

4.4.1 determined that Regulation 31 did not apply, and

4.4.2 did not refuse the application on grounds of location incompatibility, policy prohibition, or connection with existing pharmacies.

4.5 The refusal instead arose solely from the Committee’s conclusion that it was not satisfied under Regulation 25(2)(b) that the pharmacy procedures described were sufficient to secure uninterrupted provision of essential services and safe remote provision without face-to-face contact.

4.6 Accordingly, this appeal concerns the legal standard applied by the Committee when assessing the Appellant’s procedures, rather than any inherent incompatibility of the proposed distance selling pharmacy model.

4.7 The Appellant respectfully submits that, applying Regulation 25 afresh and on the material before NHS Resolution, the statutory test is met.

4.8 2. Summary of Grounds of Appeal

- 4.9 The Appellant respectfully submits that the decision should be set aside for the following principal reasons.
- 4.10 2.1 Misapplication of Regulation 25(2)(b)
- 4.11 The Committee imposed an unduly elevated evidential threshold when assessing the Appellant's pharmacy procedures.
- 4.12 Regulation 25 requires the decision-maker to be satisfied that procedures are likely to secure compliant service provision. It does not require applicants to provide comprehensive operational manuals or SOP-level detail addressing every element of Schedule 4 at application stage.
- 4.13 The Decision Report demonstrates that refusal was based upon the absence of granular operational descriptions relating to matters such as cold-chain handling, controlled drug delivery processes, packaging specifications, exemption verification, disposal arrangements, and Discharge Medicines Service workflows.
- 4.14 These matters represent routine operational components of any compliant distance selling pharmacy and do not, individually or collectively, demonstrate that the proposed procedures were incapable of satisfying Regulation 25.
- 4.15 The Committee therefore substituted a requirement for exhaustive operational documentation in place of the statutory test of likelihood and adequacy.
- 4.16 2.2 Failure Properly to Consider Information Provided
- 4.17 The application and subsequent addendum clearly described:
- 4.17.1 a remote-only service model,
 - 4.17.2 controlled premises access,
 - 4.17.3 prohibition of face-to-face services,
 - 4.17.4 national access via remote consultation channels, and
 - 4.17.5 delivery-based supply arrangements.
- 4.18 The addendum further removed services requiring in-person interaction and confirmed that remaining services would be delivered exclusively remotely.
- 4.19 The Decision Report does not adequately explain why these safeguards were insufficient to satisfy Regulation 25(2)(b), nor does it demonstrate balanced engagement with the information provided.
- 4.20 The refusal therefore reflects insufficient consideration of relevant material.
- 4.21 2.3 Inadequate Reasons
- 4.22 The Decision Report lists examples of matters said to be insufficiently explained but does not:

- 4.22.1 identify what aspects of the application were accepted as adequate,
- 4.22.2 explain why the procedures described failed to meet the statutory test,
- 4.22.3 clarify what level of detail would have been sufficient, or
- 4.22.4 demonstrate why clarification could not reasonably resolve the Committee's concerns.
- 4.23 The absence of clear reasoning prevents meaningful understanding of how the statutory test was applied and frustrates effective appellate review.
- 4.24 2.4 Error of Fact: Regulation 25(2)(a)
- 4.25 The Premises are Distinct. The Committee erred in fact by concluding that the proposed premises are "on the same site" as the Mathews Practice (Belgrave Medical Centre).
- 4.26 The Appellant submits that the pharmacy premises are legally, operationally, and physically distinct:
 - 4.26.1 Distinct Postal Addresses: The pharmacy is located at 20 Asline Road, whereas the Medical Centre is located at 22 Asline Road. These are separate postal delivery points.
 - 4.26.2 Legal Separation: The pharmacy premises are held under a separate lease agreement distinct from the Medical Centre. The pharmacy is a completely separate legal entity with no financial or administrative link to the GP practice.
 - 4.26.3 Physical Separation: There is no internal connectivity between the buildings. A patient cannot move from the surgery to the pharmacy without leaving the surgery building entirely.
- 4.27 Therefore, the Appellant submits that Regulation 25(2)(a) does not apply.
- 4.28 3. Procedural Clarification Documents
- 4.29 Without introducing new operational proposals, the Appellant provides supporting procedural documents as appendices solely to illustrate the practical implementation of procedures already described within the application.
- 4.30 These materials demonstrate that the examples cited by the Committee represent standard operational arrangements inherent within a compliant DSP model and confirm that the Committee's concerns arose from a demand for excessive operational granularity rather than any substantive deficiency.
- 4.31 4. Outcome Sought
- 4.32 The Appellant respectfully requests that the Secretary of State (through NHS Resolution):

- 4.33 1. Allow the appeal and direct that the application be granted; or
- 4.34 2. Alternatively remit the application for reconsideration with directions that Regulation 25 be applied using the correct legal threshold and with adequate reasoning.
- 4.35 5. Documents Enclosed
- 4.36 Grounds of Appeal
- 4.37 Decision Letter dated 4 February 2026
- 4.38 Decision Report
- 4.39 Appendix A: Cold Chain SOP (addressing maintenance of cold chain during transit).
- 4.40 Appendix B: Delivery Service SOP (specifically addressing Regulations 14 & 16 of the Misuse of Drugs Regulations 2001).
- 4.41 Appendix C: CD6 Delivery of CDs SOP
- 4.42 Appendix E: Waste Management & Disposal SOP.”

5 **Summary of Representations**

This is a summary of representations received on the appeal.

5.1 The Commissioner

- 5.1.1 “Thank you for your letter dated 16 March 2026 regarding the above appeal. When considering this application, NHS South Yorkshire Integrated Care Board (ICB) was satisfied that 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, namely the Mathews Practice – Belgrave Medical Centre. Therefore, the ICB determined that Regulation 25(2)(a) applies.
- 5.1.2 The applicant submits that Regulation 25(2)(a) does not apply and that the ICB Pharmaceutical Services Regulations Committee erred in fact. However, the examples provided by the applicant do not demonstrate that the proposed pharmacy premises are in a different building from the Medical Centre. The applicant notes that the proposed pharmacy premises are located at 20 Asline Road, whereas the Medical Centre is located at 22 Asline Road. However, a single building can have multiple postal addresses. Indeed, some buildings have multiple postcodes. Regulation 25(2)(a) does not state that there is an exemption on the grounds of having no internal connectivity or a separate lease agreement. The ICB has previously provided a map, with satellite imagery, which illustrates that the proposed pharmacy premises and the Medical Centre share the same roof and external walls. A copy is attached. The land on which the building stands is bounded by Asline

Road, Belgrave Square and Colver Road. There are a perimeter fence and hedge, and a single car park.”

6 Summary of Observations

This is summary of observations received.

6.1 The Applicant

- 6.1.1 “I write with respect to our application for licence to practice as a distance selling, non face to face pharmacy service being declined.
- 6.1.2 Historically, the present premises was run by Boots pharmacy, providing a service to > 6000 of our patients. That dissipated following Boots closure of the premises.
- 6.1.3 You refer to Regulation 25(2)(a) as the basis for refusing to grant the licence. I disagree with the decision based on a few points.
- 6.1.4 Regulation 25(2)(a) of the Pharmaceutical Services Committee pertains to the conditions under which an application to relocate to different premises for pharmaceutical services must be refused. Specifically, it states that an application will not be accepted if the premises are on the same site or in the same building as those of a provider of primary medical services with a patient list, ***unless certain conditions are met, such as ensuring uninterrupted provision of essential services without face-to-face contact.***
- 6.1.5 In so exercising the regulation to justify your refusal, you assume that the offices being in the same building of Mathews practice, there’s risk of interruption of pharmacy services by the Public. I respectfully challenge that on the basis that it is grossly misunderstood.
- 6.1.6 The premises has been a service provider for almost 18 months. As the GP partner working next door, I can assure you it is a separate service. It will NOT be open to the public. It has the benefit of being in a location which makes immediate and emergency service deliveries feasible to the patients home. Example, if an urgent script is needed, the medication will be delivered the same day. Distance selling pharmacies do not provide that continuity, care closer to home approach. As a GP I know of quite a few incidents, based on my patients discontent over the recent years. My patients often resort to changing their pharmacies to one closer to home when it comes to urgent on the day scripts. We can manage that WITHOUT opening our doors because we are LOCAL. We know the area, the population too.
- 6.1.7 I’m also of the opinion that in holding steadfast to regulations and not exercising judgement based on the future of the NHS, you are ruling against the NHS 10 year plan. I draw specific attention to the Neighbourhood model (attached) which strongly encourages working in partnership with local services.

- 6.1.8 We do not see ourselves as a business. We see ourselves as a service provider. No other Pharmacy in the locality, and I know as a GP here for 20 years, has ever invested their energy into the needs of the local community or Primary care network.
- 6.1.9 We do. We have a model of service provision, to suit the Primary Care Network and Neighbourhood model, and I know for sure the other local services do not. The big corporates work as a business. We are local and that's what matters to the local community. Many online pharmacies are not local nor do they know the population they serve.
- 6.1.10 Think managing the local care homes under the Network GP practices with a patient population ranging from 10 to 80 dependent on which care home we are talking.
- 6.1.11 At present they are managed by Corporate pharmacies who are not local.
- 6.1.12 Think our 2 expert pharmacists, who are prescribers, taking on the complex patients, and managing polypharmacy and de-prescribing. Using the neighbourhood model, working with Network pharmacists to reconcile meds management in those most vulnerable.
- 6.1.13 The local pharmacies DO NOT provide these services.
- 6.1.14 In conclusion, I would respectfully ask that a committee please invite us to hear oral representation, as I believe the decision as it stands, is not in full appraisal of the wider picture of the future of NHS and Pharmacy services but most importantly what we would bring to the local community and GP practices."

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 relevant section of the application form had been completed and included supporting information relating to the application. Although the Applicant had not provided specific information in relation to Regulation 31, the Committee noted that the wording of the application form only required such information where the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. In those circumstances, the Committee considered it reasonable to conclude that the absence of information on this point indicated that the Applicant did not consider the proposed premises to be adjacent to, or in close proximity to, such premises.

7.7 The Committee noted the conclusion of the Commissioner that "*There is no pharmacy at the same or adjacent premises to the proposed site*" and 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 In relation to Regulation 25(2)(a), the Committee had regard to the application form, in which the Applicant stated:

7.11.1 ***“Dedicated, Independent Entrance:*** *The proposed premises, although physically attached to the GP practice, have been designed with a completely separate and independent entrance. This clear physical demarcation ensures that the pharmacy’s operational area is accessed exclusively through its own entryway, thereby preventing any inadvertent mixing of patient streams between the GP practice and the pharmacy.*

Absence of Internal Connectivity: *There is no internal linkage—such as corridors, doorways, or shared reception areas—between the pharmacy premises and the GP practice. This deliberate design feature guarantees that the pharmacy functions as an autonomous entity, reinforcing the required separation and ensuring that all transactions and essential services are delivered remotely without any face-to-face interactions at the registered premises.”*

- 7.12 The Committee also noted the Commissioner’s comments that:

7.12.1 ***“Having regard to Regulation 25(2)(a), the Committee was satisfied that 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, namely the Mathews Practice – Belgrave Medical Centre.”***

- 7.13 In the appeal, the Applicant responded as follows:

7.13.1 ***“The Appellant submits that the pharmacy premises are legally, operationally, and physically distinct:***

Distinct Postal Addresses: *The pharmacy is located at 20 Asline Road, whereas the Medical Centre is located at 22 Asline Road. These are separate postal delivery points.*

Legal Separation: *The pharmacy premises are held under a separate lease agreement distinct from the Medical Centre. The pharmacy is a completely separate legal entity with no financial or administrative link to the GP practice.*

Physical Separation: *There is no internal connectivity between the buildings. A patient cannot move from the surgery to the pharmacy without leaving the surgery building entirely.*

Therefore, the Appellant submits that Regulation 25(2)(a) does not apply.”

- 7.14 The Committee further had regard to the Commissioner’s representations that:

7.14.1 *“The applicant submits that Regulation 25(2)(a) does not apply and that the ICB Pharmaceutical Services Regulations Committee erred in fact. However, the examples provided by the applicant do not demonstrate that the proposed pharmacy premises are in a different building from the Medical Centre. The applicant notes that the proposed pharmacy premises are located at 20 Asline Road, whereas the Medical Centre is located at 22 Asline Road. However, a single building can have multiple postal addresses. Indeed, some buildings have multiple postcodes. Regulation 25(2)(a) does not state that there is an exemption on the grounds of having no internal connectivity or a separate lease agreement. The ICB has previously provided a map, with satellite imagery, which illustrates that the proposed pharmacy premises and the Medical Centre share the same roof and external walls. A copy is attached. The land on which the building stands is bounded by Asline Road, Belgrave Square and Colver Road. There are a perimeter fence and hedge, and a single car park.”*

- 7.15 Having considered the evidence provided by the Commissioner which showed an aerial view of the site, and by the Applicant, including the Applicant's own statement that the proposed premises were physically attached to the GP practice, the Committee determined that the proposed premises were located in the same building, albeit with different postal addresses, as the GP practice and that Regulation 25(2)(a) therefore applied.

Regulation 25(2)(b)

- 7.16 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.
- 7.17 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.
- 7.18 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.
- 7.19 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, appeal and the SOPs which the Applicant has prepared or commissioned and provided as part of the appeal process.

- 7.20 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 application, appeal and SOPs in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.
- 7.21 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. The Committee noted that on the application form the Applicant had indicated that it would not supply any appliances which required measuring / fitting. Therefore, in the event that the application is granted, the Applicant would not be able to supply appliances which require measuring and fitting.
- 7.22 The Committee noted the comments from the Applicant that *"the refusal... arose solely from the Committee's conclusion that it was not satisfied under Regulation 25(2)(b) that the pharmacy procedures described were sufficient to secure uninterrupted provision of essential services and safe remote provision without face-to-face contact"* and that *"Regulation 25 requires the decision-maker to be satisfied that procedures are **likely** to secure compliant service provision. It does not require applicants to provide comprehensive operational manuals or SOP-level detail addressing every element of Schedule 4 at application stage."* The Committee considered that it is a matter for the Applicant to provide the relevant information required, either in the first instance to the Commissioner or on appeal, to demonstrate that there would be compliance with Regulation 25. The Committee is of the view that this does not have to be in the form of SOPs (as they may contain matters not relevant to the Committee's consideration) as there are many ways an applicant can choose to organise itself in order to comply with the various requirements of the Regulations.
- 7.23 The Committee first considered how the Applicant would provide essential services without interruption and noted the comments from the Commissioner that they were *"not 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."*
- 7.24 The Committee noted that there was no information provided by the Applicant with regard to staffing in general, the responsibilities of the Responsible Pharmacist and how they would ensure that essential services would be available without disruption, for example during any absence of the Responsible Pharmacist.
- 7.25 Based on the lack of information before it, the Committee was not satisfied that the provision of services would be without interruption.
- 7.26 The Committee noted the statement from the Applicant that the pharmacy will operate under *"a remote-only service model"* with *"national access via remote consultation channels, and delivery-based supply arrangements."*

- 7.27 The Committee noted that no information had been provided by the Applicant as to how nationwide deliveries would take place. The SOP dedicated to the delivery of medicines referred to the delivery of medicines using the pharmacy's own delivery driver and there was no mention of how patients living outside of the local vicinity would receive medication. In addition, the Applicant had focused on arguments which suggested that service provision would be localised, for example *"We are local and that's what matters to the local community"*. The Committee was therefore not satisfied that the provision of essential services would be available to persons anywhere in England.
- 7.28 The Committee was mindful of the regulatory changes as of 1 October 2025 and 31 March 2026, that distance selling pharmacies can no longer provide Directed services (Advanced, National Enhanced and Enhanced Services) face to face with the patient at the pharmacy premises. As a result of this amendment, the Committee noted that if the application was granted, the Applicant would not be able to provide any pharmaceutical services to patients present at its premises.
- 7.29 In terms of providing pharmaceutical services without face to face contact, the Committee noted the Applicant's submissions in the appeal that the proposed pharmacy would operate through:
- 7.29.1 *"a remote-only service model, controlled premises access, prohibition of face-to-face services, national access via remote consultation channels, and delivery-based supply arrangements."*
- 7.30 However, the Committee also noted that the SOP entitled 'Disposal of Unwanted Medicines' states:
- 7.30.1 *"Pharmacy staff should use the 'Returning your unwanted medicines card' (See Appendix 3) to question people returning medicines to ensure there are no items in the returns which the pharmacy cannot accept for disposal, for example sharps or chemicals."*
- When a patient or their representative is returning unwanted medicines - ask them to wait until you have 'safely' checked the contents of the bag."*
- 7.31 The Committee considered that this wording indicates that patients would attend the pharmacy in person to return unwanted medicines for disposal, as the SOP envisages patients being asked to wait while the contents of the returned items are checked.
- 7.32 Furthermore, the Committee noted that the SOP entitled 'Delivery Service' states:
- 7.32.1 *"Greet patient/carer requesting a delivery service. Request can be face-to-face, via telephone, e-mail, freepost reply-paid cards."*
- 7.32.2 ...
- 7.32.3 *"Any unsuccessful deliveries should be returned to the pharmacy and contact made with the patient to discuss redelivery or collection."*

- 7.33 The Committee considered that this wording also indicates that patients or carers would be able to access the pharmacy premises to request a delivery service in person. Further, the wording indicates that patients can collect any unsuccessful deliveries from the pharmacy.
- 7.34 The Committee noted the Pharmacy Procedures states:
- 7.34.1 ***“Physical and Procedural Segregation: Signage and clear physical demarcations are in place to guide patients. The designated entrance and reception procedures ensure that any patient arriving at the premises is directed immediately, via pre-set scripts, to the remote consultation process. This communication is reinforced by barrier installations and logical routing within the premises that physically separate the door designated for remote service operations from any portion where direct contact might occur.”***
- 7.35 The wording used above suggests that patients would be able to physically access the pharmacy premises as patients would be “*arriving at the premises*”. Accordingly, the Committee was of the view, on the basis of the information before it, that the proposed provision of pharmaceutical services would not be without face to face contact.
- 7.36 The Committee was not 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.
- 7.37 The Committee considered pharmaceutical services including each essential service in paragraphs 3 to 22 of schedule 4 of the Regulations ("Terms of Service") in turn.
- 7.38 The Committee paid particular attention to the following aspects of the essential services, which it considered were more difficult to provide safely and effectively in a distance selling context:
- 7.38.1 Dispensing of drugs and appliances
 - 7.38.2 Urgent supply without a prescription
 - 7.38.3 Preliminary matters before providing ordered drugs or appliances
 - 7.38.4 Providing ordered drugs or appliances
 - 7.38.5 Refusal to provide drugs or appliances ordered
 - 7.38.6 Further activities to be carried out in connection with the provision of dispensing services
 - 7.38.7 Disposal service in respect of unwanted drugs
 - 7.38.8 Promotion of healthy lifestyles

7.38.9 Prescription linked intervention

7.38.10 Health campaigns

7.38.11 Signposting

7.38.12 Support for self-care

7.38.13 Discharge medicines service

7.38.14 Websites and health promotion zones

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

Dispensing of drugs and appliances

- 7.40 The Committee considered whether the Applicant had explained how non-electronic prescriptions will be presented by the patient and how products will be provided.
- 7.41 The Committee was of the view that no information had been provided by the Applicant as to how non-electronic prescriptions would be presented at the pharmacy. Therefore, the Committee was not 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

- 7.42 The Committee considered whether the Applicant had explained how it proposes safely and effectively to receive requests from prescribers for urgent supplies of drugs and appliances.
- 7.43 The Committee noted the Applicant's comment in their observations that due to the location of the pharmacy, it "*makes immediate and emergency service deliveries feasible to the patients home. Example, if an urgent script is needed, the medication will be delivered the same day.*"
- 7.44 The Committee noted, however, that the Applicant had made no reference, either in its original application form or on appeal or subsequent correspondence as to how it would safely and effectively receive requests from prescribers for urgent supplies of drugs and appliances.
- 7.45 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.

Preliminary matters before ordering drugs or appliances

- 7.46 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.

- 7.47 The Committee found no specific reference to how evidence will be sought and provided about the patients' entitlement to exemption or remissions from NHS Charges.
- 7.48 The Committee was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.
- 7.49 The Committee considered whether the Applicant had explained how charges will be paid.
- 7.50 The Committee noted that the Applicant had not made any reference to the arrangements for payment of charges. In the absence of such information, the Committee was not satisfied that it had been provided with sufficient evidence to demonstrate compliance with paragraph 7(5)(b) of Schedule 4.

Providing ordered drugs or appliances

- 7.51 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).
- 7.52 The Committee noted the SOP entitled 'Cold-Chain Medicines (Medicines Requiring Storage at 2oc to 8oc)' states:

7.52.1 *"Delivery routes should be planned so as to ensure fridge lines are delivered as soon as possible and the cold-chain is maintained. If possible, a cool box or insulated padded bags should be used to maintain low temperatures during transit"*

The recipient should be reminded to follow the manufacturer's instructions on domestic storage of the medicine

If a fridge line cannot be successfully delivered for any reason then it must be returned to the pharmacy as soon as reasonably possible. The pharmacist must be satisfied that the cold chain has been maintained before deciding to issue the medication to the patient."

- 7.53 And further, the SOP entitled 'Delivery Service' states:

7.53.1 *"Fridge line deliveries- contact the patient before leaving the pharmacy to confirm the patient is able to accept the delivery"*

Ensure the Responsible Pharmacist (RP) is on duty before handing medication for delivery to the delivery driver.

Confirm the RP will be on duty when the delivery is handed to the patient / carer

DELIVERY - PROMPT & SAFE

Hand over the medicine to the patient/carer, after having confirmed that the name and address of the patient is correct. Obtain a signature from the patient/carer indicating safe delivery of the medicine

Take care with medicines with special storage requirements i.e.

Fridge & CD items.

For fridge items – Maintain the cold chain and use specially provided padded bags.

For CD items – the delivery driver should sign the back of the prescription as the patient's representative. The prescription should be retained in the pharmacy. (See SOP for Delivery of Schedule 2 Controlled Drugs).

DO NOT: Post delivery items through letter boxes or leave the delivery items unattended in porches or on doorsteps with children with neighbours - Unless arrangements have been made by the patient/carer. Obtain this request in writing from the patient/ carer with a signature authorising delivery to another address (see Appendix 1)

ALWAYS-Obtain a signature from the recipient to indicate safe receipt."

- 7.54 The Committee noted that whilst the Applicant had mentioned in its SOP how it intended to deliver cold chain items to local patients, there was no mention of how it intended to deliver fridge-line items to patients living outside the local area, for example through the use of a courier service.
- 7.55 Furthermore, there was nothing provided to demonstrate the monitoring of the cold chain and how the Applicant would be assured that this had not been compromised during transit. There was nothing provided as to how the pharmacist on duty would be aware of a breach of cold chain once the medication left the premises and was in the custody of the delivery driver beyond the items being placed in a "cool box".
- 7.56 As the Committee must be satisfied that the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that the 'cold chain' is maintained), the Committee considered that the wording and processes provided a lack of assurance as to the Applicant's procedures.
- 7.57 Therefore, the Committee could not be satisfied, as it was required to be, that during transit, the cold chain would be monitored throughout, or what would happen in the event of a breach in cold chain delivery. Further, the Committee was not satisfied that sufficient information had been provided to explain how the security of Controlled Drugs would be maintained while they were in transit with the delivery driver.
- 7.58 Based on the information before it, the Committee was not satisfied that there would be compliance with paragraph 8(1) of Schedule 4.

- 7.59 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.
- 7.60 The Committee considered whether the Applicant had explained what containers will be “suitable” for posted/delivered items.
- 7.61 The Committee noted that in the SOP entitled ‘Cold-chain Medicines’, it states that fridge line items will be delivered in “*a cool box or insulated padded bags should be used to maintain low temperatures during transit*”. The Committee was of the view that the Applicant had not provided sufficient information to demonstrate what outer packaging it would be using for all delivered medicines and how this would be suitable for posted/delivered items to ensure that the integrity of the medication would be maintained.
- 7.62 Based on the information before it, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(15) of Schedule 4.

Refusal to provide drugs or appliances ordered

- 7.63 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.
- 7.64 The Committee noted that the Applicant had not provided information on this point in their application or appeal. Therefore, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 9(4) of Schedule 4.

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

- 7.65 The Committee considered whether the Applicant had explained how appropriate advice about the benefits of repeat dispensing is given to any patient who (i) has a long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term), and (ii) requires regular medicine in respect of that medical condition.
- 7.66 The Committee noted that there was no mention in the application form or on appeal with regard to how the Applicant would provide appropriate advice about the benefits of repeat dispensing.
- 7.67 The Committee was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.

Promotion of healthy lifestyles

- 7.68 The Committee considered whether the Applicant had explained how it will safely and effectively promote healthy lifestyles.
- 7.69 The Committee noted that no information had been provided by the Applicant as to how it would safely and effectively promote healthy lifestyles therefore the Committee was not 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

- 7.70 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.
- 7.71 The Committee noted that no information had been provided in this regard. The Committee was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

Health campaigns

- 7.72 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.
- 7.73 The Committee did not consider there to be any clear information provided as to how the Applicant would safely and effectively participate in public health campaigns.
- 7.74 The Committee was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 16 - 18 of Schedule 4.

Signposting

- 7.75 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.
- 7.76 The Committee noted that no information had been provided in this regard. The Committee was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 19 – 20 of Schedule 4.

Support for self-care

- 7.77 The Committee considered whether the Applicant had explained or otherwise demonstrated how it will provide advice and support for people caring for their families.

- 7.78 The Committee noted that no information had been provided in this regard. It was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 19 – 20 of Schedule 4.

Discharge medicines service

- 7.79 The Committee considered whether the Applicant had explained how it will provide advice, assistance and support to and in respect of a health service patient – (a) recently discharged from hospital who is referred to P for advice, assistance and support in respect of the patient's medication regimen by the staff of the hospital in which the patient stayed; or (b) who is otherwise referred to P for advice, assistance and support in respect of the patient's medication regimen by the staff of an NHS trust and NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.
- 7.80 Further, the Committee considered whether the Applicant had explained what procedures it has in place for checking referrals for the discharge medicines service.
- 7.81 The Committee noted that no information had been provided in this regard. It was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

Websites and health promotion zones

- 7.82 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.
- 7.83 The Committee noted that no information had been provided in this regard. 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.
- 7.84 In relation to all other essential services, the Committee was, on balance, satisfied that procedures adopted by the pharmacy (and general adherence to the Terms of Service) would be "likely to secure" safe and effective provision.

Summary

- 7.85 On the information before it, the Committee could not be satisfied that there are procedures likely to secure the safe and effective provision of pharmaceutical services as required by Regulation 25(2)(b).
- 7.86 Pursuant to paragraph 9(1)(a) of Schedule 3 to the Regulations, the Committee may:
- 7.86.1 confirm the Commissioner's decision;

- 7.86.2 quash the Commissioner's decision and redetermine the application;
- 7.86.3 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.
- 7.87 Although the Committee reached the same conclusion as the Commissioner, it did so for different reasons therefore the Committee determined that the decision of the Commissioner must be quashed.
- 7.88 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.
- 7.89 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.
- 7.90 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 not 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 not satisfied that all essential services were likely to be secured without interruption during the opening hours;
 - 8.2.2.3 the Committee was not satisfied that all essential services were likely to be secured for persons anywhere in England;
 - 8.2.2.4 the Committee was not satisfied that pharmaceutical services were likely to be secured in a safe and effective manner; and

8.2.2.5 the Committee was not satisfied that pharmaceutical services were likely to be secured without face to face contact.

8.2.3 The application is refused.

Case Manager
Primary Care Appeals