NHS Resolution

26 March 2026

REF: SHA/26830

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APPEAL AGAINST COVENTRY AND WARWICKSHIRE ICB DECISION TO REFUSE AN APPLICATION BY AI SAIDI LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 38 NEWDIGATE ROAD, WEST MIDLANDS, CV6 5ES 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:

Ai Saidi Ltd
PCSE, on behalf of Coventry and Warwickshire ICB

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1 The Application

By application dated 21 June 2025, Ai Saidi Ltd ("the Applicant") applied to Coventry and Warwickshire ICB ("the Commissioner") for inclusion in the pharmaceutical list at 38 Newdigate Road, West Midlands, CV6 5ES under Regulation 25. In support of the application it was stated:

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

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

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

Pharmacy Procedures

1.4 7.1 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.

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

7.3 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 “(a) Uninterrupted Provision of Essential Services Nationwide

1.6 Our DSP is fully equipped to deliver essential services across England throughout our opening hours. Key systems include:

1.6.1 Full staffing with GPhC-registered pharmacists and trained support staff

1.6.2 Cloud-based PMR with EPS integration for real-time processing

1.6.3 Robust IT systems with backup internet, power, and remote access

1.6.4 Tracked home delivery via national couriers

1.6.5 Patient access via phone and website, with 24/7 information available online

1.7 (b) Safe & Effective Provision Without Face-to-Face Contact

1.8 All services are provided remotely. We ensure:

1.8.1 Consultations via phone, video, or secure messaging

1.8.2 No public access to premises; patients contact us online or by phone

1.8.3 Safe, labelled deliveries with PILs and remote pharmacist support

1.8.4 Website offers service access, NHS info, complaints process, and accessibility tools

1.8.5 Strict verification, confidentiality, and data protection procedures

1.9 Procedure for Patients Attending the Premises

1.10 As a DSP, we do not provide in-person services. Clear signage and messaging direct any visitors to contact us remotely by phone or online.

1.11 Provision of Advanced Services Without On-Site Essential Services

1.12 Any advanced services (e.g., NMS) will be provided remotely only. No face-to-face elements will take place, and SOPs will ensure separation from essential services onsite.”

2 **Comments to the Commissioner**

On reviewing the paperwork provided by PCSE, it was noted that the comments made by the Applicant in response to the representations on the application, had not been 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 "I am responding to your letter emailed to me on 16/09/2025.

2.2 I would like to thank Anon Vantage Chemist for their comments regarding my application for a Distance Selling Pharmacy (DSP) contract in Coventry. I respectfully address the points raised as follows:

2.3 **Regulatory Basis for a DSP**

2.4 The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 do not require a DSP applicant to demonstrate a local 'need' or a gap in provision within a specific geographic area. Unlike a standard community pharmacy application, a DSP is not tied to serving only the immediate vicinity. By definition, a DSP must provide essential pharmaceutical services to patients across England, without discrimination based on location. Therefore, local pharmacy density is not a barrier to granting ... [sic]

2.5 **Accessibility and Patient Choice**

2.6 A DSP enhances patient access by offering services remotely, which is particularly valuable to patients who are housebound, elderly, or have limited mobility; patients in rural or underserved areas who may find it difficult to access a physical pharmacy; and patients who prefer remote and digital access to healthcare in line with NHS priorities on digital transformation. Increasing the number of DSPs supports patient choice and convenience, rather than duplicating existing bricks-and-mortar pharmac... [sic]

2.7 **Service Provision (NMS, Pharmacy First, etc.)**

2.8 While it is correct that not all advanced services can currently be provided by a DSP (e.g., certain in-person services), DSPs remain fully compliant in delivering essential NHS pharmaceutical services nationwide, including dispensing, repeat prescriptions, medicines advice, and safe delivery. These services are valuable and widely used by patients. Future service expansion (such as digital-first healthcare initiatives) is also more easily supported through DSPs.

2.9 **Competition Is Not a Criterion**

2.10 The regulations governing DSP contracts do not restrict applications on the basis of existing competitor numbers or perceived market saturation. The role of NHS England is to ensure compliance with DSP requirements, not to restrict applications due to local pharmacy numbers. The fact that there are other DSPs

in Coventry does not preclude another from operating, as patients are free to choose where to access their prescriptions from anywhere in England.

2.11 **Benefit to Patients and NHS Objectives**

2.12 This application aligns with NHS goals around digital healthcare access, allowing patients to order and receive medicines without needing to physically travel; reducing health inequalities, by supporting patients in areas where access to traditional pharmacies is limited; and sustainability, offering modern, efficient dispensing models that reduce unnecessary patient journeys.

2.13 **Conclusion**

2.14 For the reasons above, the objection raised does not invalidate this application. The presence of other pharmacies or DSPs locally is not a legal or regulatory barrier, nor does it diminish the value of patient choice and accessibility that another DSP would bring. This application is fully compliant with the regulatory framework and supports NHS priorities."

3 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 5 December 2025 states:

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

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

Decision report

3.2 "**Decision:**

3.3 **Regulation 31** – refusal: same or adjacent premises

3.4 **Regulation 31 (1)** A routine or excepted application, other than a consolidation application, must be refused where paragraph (2) applies.

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

3.6 As **Regulation 31(2)(a)** does not apply, the Committee is not required to consider Regulation **31(2) (b)**

3.7 Therefore, the Committee concluded that it was not required to refuse the application under the provisions of Regulation 31.

3.8 The Committee then went on to consider Regulation 25.

3.9 **Regulation 25** – Distance Selling Premises Applications

3.10 **Regulation 25(2)(a)** – The NHSCB must refuse an application to which paragraph 1 applies-

3.11 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.

3.12 The Committee was satisfied that the proposed premises are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

3.13 This is confirmed with information available on the NHS.UK website where the nearest general practice is located 0.3 mile away.

3.14 Therefore, the Committee concluded that it is not required to refuse the application under **Regulation 25(2)(a).**

3.15 **Regulation 25(2)(b)(i)** – The uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.

3.16 It was noted that within the application form, the applicant did not confirm their intention to undertake to provide appliances. The Pharmacy Procedures indicate that the service will not be provided as a face-to-face essential service.

3.17 The information submitted by the applicant gives assurance of provision of pharmaceutical services without face to face contact.

3.18 Therefore, **this regulation is deemed to have been met.**

3.19 **Regulation 25(2)(b)(ii)** – The safe and effective provision of pharmaceutical services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

3.20 The information provided by the applicant and confirmed that there is no information as to how medicines requiring cold storage will be delivered nationally and what will happen in the case of a failed delivery.

3.21 In addition there is no information about how CD's will be delivered nationally and what will happen in the case of a failed delivery.

3.22 This regulation is deemed to not have been met.

3.23 Applicant is not undertaking to provide advanced or enhanced services to the patients on the premises.

3.24 Therefore, **this regulation is deemed to not have been met.**

3.25 The Committee **Refused** the application.

3.26 The Committee determined that the applicant has appeal rights."

4 The Appeal

In a letter dated 16 December 2025, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

4.1 "We respectfully submit this appeal against the refusal of our Distance Selling Premises (DSP) application. We acknowledge that the Committee accepted our compliance under Regulations **31**, **25(2)(a)**, and **25(2)(b)(i)**.

4.2 The refusal was solely due to missing information under **Regulation 25(2)(b)(ii)** regarding: - Delivery arrangements for medicines requiring cold storage nationally, and - Delivery arrangements for Controlled Drugs (CDs) nationally, including failed delivery pathways.

4.3 Please see continuation sheet attached onto this document below is our fully revised **DSP Compliance Pack**, including updated Pharmacy Procedures and SOPs for: - Cold-chain delivery - CD delivery (Schedule 2 & 3) - Secure packaging and chain-of-custody - Failed delivery procedures - Audit and governance mechanisms - National delivery systems and patient communication.

4.4 These procedures follow best-practice models used across the UK by established DSPs such as Pharmacy2U, LloydsDirect, Well.co.uk, Boots Online, and PillTime.

4.5 We confirm that all DSP-specific conditions will be met, including: - No face-to-face provision at or near the premises - National availability of essential services to all patients in England - No geographical restriction in practice or communications - Full compliance with Regulation 64(3)

4.6 We respectfully request reconsideration of our application in light of the comprehensive evidence now provided."

4.7 [SOPs 2-7 provided]

5 Summary of Representations

This is a summary of representations received on the appeal.

5.1 The Commissioner

5.1.1 "The Committee considered the appeal received and felt that the additional information provided from the applicant to NHS Resolution in relation to the provision of Essential Services, is new information that was not available to Committee at the time a decision was made. If that information was available, the Committee may have come to a different conclusion."

6 Summary of Observations

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

7 **Consideration**

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

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

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

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

Regulation 31

7.5 The Committee first considered Regulation 31 of the Regulations which states:

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

7.6 The Committee noted that the Applicant had not provided any information in the application form on this point but the Committee noted that the wording of the application form only required the Applicant to include information in the relevant section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee considered it reasonable to determine that the lack of information in the application form on this point when read with the wording of the application form allowed it to be reasonably satisfied that the Applicant considered that the proposed premises were not adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. In its decision report the Commissioner had confirmed "*There is no pharmacy providing pharmaceutical services at the same or adjacent premises.*" Given that there was no dispute on the matter, the Committee was satisfied that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

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

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

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

7.11 As far as Regulation 25(2)(b) is concerned, the Committee considered the information which had been provided by the Applicant in relation to its procedures for the provision of essential services and pharmaceutical services.

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

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

Commissioner may need to make of the information or documentation when carrying out its functions.

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

7.15 In respect of the uninterrupted provision of essential services, the Committee noted that in its application the Applicant states:

7.15.1 "*Uninterrupted Provision of Essential Services Nationwide*

Our DSP is fully equipped to deliver essential services across England throughout our opening hours. Key systems include:

- *Full staffing with GPhC-registered pharmacists and trained support staff*"

7.16 Whilst the Applicant had referred to "Full staffing", the Committee was concerned that no information had been provided to explain what would happen in the event that the Responsible Pharmacist needed to leave the premises, and whether a second pharmacist would be available to ensure uninterrupted provision.

7.17 Based on the lack of information before it, the Committee was therefore unable to be satisfied that the provision of essential services would be without interruption.

7.18 With regard to services being available to persons anywhere in England, the Committee noted the Applicant states that:

7.18.1 "*Uninterrupted Provision of Essential Services Nationwide*

Our DSP is fully equipped to deliver essential services across England throughout our opening hours. Key systems include: …

• Tracked home delivery via national couriers

• Patient access via phone and website, with 24/7 information available online …

• Consultations via phone, video, or secure messaging …

• Website offers service access, NHS info, complaints process, and accessibility tools"

7.19 Based on the information before it, the Committee was therefore satisfied that the provision of essential services would be available to persons anywhere in England.

7.20 The Committee next considered how the Applicant would provide pharmaceutical services without face to face contact. The Committee noted the Applicant states:

7.20.1 "Safe & Effective Provision Without Face-to-Face Contact

All services are provided remotely. We ensure:

• Consultations via phone, video, or secure messaging

• No public access to premises; patients contact us online or by phone

• Safe, labelled deliveries with PILs and remote pharmacist support

• Website offers service access, NHS info, complaints process, and accessibility tools

• Strict verification, confidentiality, and data protection procedures

Procedure for Patients Attending the Premises

As a DSP, we do not provide in-person services. Clear signage and messaging direct any visitors to contact us remotely by phone or online.

Provision of Advanced Services Without On-Site Essential Services

Any advanced services (e.g., NMS) will be provided remotely only. No face-to-face elements will take place, and SOPs will ensure separation from essential services onsite."

7.21 The Committee was 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. The Committee noted that the Applicant did not intend to provide any advanced or enhanced services.

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

7.23 The Committee was not satisfied that the provision of essential services would be without interruption. The Committee was satisfied that the provision of essential services would be available to persons anywhere in England and pharmaceutical services would be without face to face contact. The Committee went on to consider whether safe and effective provision of pharmaceutical services was likely to be secured.

7.24 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.

7.25 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:

7.25.1 Dispensing of drugs and appliances

7.25.2 Urgent supply without a prescription

7.25.3 Preliminary matters before providing ordered drugs or appliances

7.25.4 Providing ordered drugs or appliances

7.25.5 Refusal to provide drugs or appliances ordered

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

7.25.7 Disposal service in respect of unwanted drugs

7.25.8 Promotion of healthy lifestyles

7.25.9 Prescription linked intervention

7.25.10 Health campaigns

7.25.11 Signposting

7.25.12 Support for self-care

7.25.13 Discharge medicines service

7.25.14 Websites and health promotion zones

7.26 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

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

7.28 The Committee noted the application states:

7.28.1 "*Tracked home delivery via national couriers*"; and

7.28.2 "*Safe, labelled deliveries with PILs and remote pharmacist support*"

7.29 Further, the Committee noted that on appeal the Applicant states:

7.29.1 "***7. COURIER SPECIFICATIONS SUMMARY***

Recommended courier features: - GDP-aligned processes - Real-time tracking - ID verification for CDs - Secure return-to-sender protocol - No safe-place deliveries - Next-day guaranteed service - API-enabled tracking notifications

Common couriers used by established DSPs: - Royal Mail Special Delivery (often for CDs) - DPD Medical / DPD Healthcare - UPS Healthcare - Parcelforce Express 24 (with restrictions)"

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

7.31 However, the Committee saw no information to indicate how patients would be able to present non-electronic prescriptions.

7.32 The Committee was therefore 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

7.33 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.

7.34 The Committee noted that the Applicant had made no reference, either in its application form or on appeal as to how it would safely and effectively receive requests from prescribers for urgent supplies of drugs and appliances.

7.35 The Committee was therefore 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 providing ordered drugs or appliances

7.36 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.

7.37 The Committee noted no information had been provided to indicate how the Applicant would obtain evidence from patients regarding their entitlement to exemption.

7.38 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.

7.39 The Committee considered whether the Applicant had explained how charges will be paid and noted that no information had been provided to indicate how

the Applicant would obtain payment from patients or how they would then ascertain that payment had been made.

7.40 The Committee was not 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

7.41 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).

7.42 The Committee noted the application form states:

7.42.1 "*Tracked home delivery via national couriers*"; and

7.42.2 "*Safe, labelled deliveries with PILs and remote pharmacist support*".

7.43 The Committee had regard to the following SOPs provided by the Applicant on appeal:

7.43.1 "***2. SOP: Cold-Chain Delivery (Fridge Items 2–8°C)***

Purpose

To ensure national delivery of refrigerated medicines in compliance with MHRA GDP and DSP regulations.

Scope

All fridge-line prescriptions dispatched from the DSP.

Procedure

Packaging

*Use MHRA-approved insulated packaging validated to maintain **2–8°C for ≥48 hours**.*

Include frozen and chilled gel packs arranged according to manufacturer instructions.

*Place a **single-use temperature indicator** (TimeStrip or equivalent) in each parcel.*

Seal with tamper-evident tape.

Temperature Control

Fridge stock stored between 2–8°C and recorded twice daily.

Parcels packed immediately prior to courier collection.

Courier Requirements

Next-day guaranteed delivery.

Full tracking and delivery notifications.

No "safe place" or neighbour delivery permitted.

Failed Delivery

Parcel returned directly to the pharmacy.

Returned items quarantined in a designated area.

Pharmacist reviews temperature indicator.

If excursion detected → medicine destroyed and re-issued.

Audit

Weekly review of delivery times and exceptions.

Monthly review of packaging performance.

Quarterly temperature validation."

7.43.2 "***3. SOP: Controlled Drug Delivery (Schedule 2 & 3)***

Purpose

To ensure safe and legally compliant delivery of Controlled Drugs nationally.

Procedure

Assembly

Dispense CDs in accordance with CD register requirements.

Apply a unique CD dispatch ID.

*Pack in **tamper-evident packaging** with serial number.*

Courier Handover

Only couriers offering secure hand-to-hand delivery may be used.

Courier must:

*Confirm identity using valid **photo ID**.*

Obtain a signature.

Not leave parcel unattended or with another person.

Failed Delivery

CD must be returned directly to the pharmacy that same day or next business day.

Chain-of-custody logged at every point.

Returned CDs inspected, reconciled, and entered back into the CD register.

Any discrepancies escalated to the Controlled Drugs Accountable Officer.

Audit

Monthly reconciliation of CDs dispatched, delivered, and returned.

Courier performance reviewed quarterly."

7.43.3 "***4. SOP: National Delivery & Patient Communication***

Pre-Dispatch

Patient receives email/SMS confirming: dispatch, tracking link, delivery date.

Patients must confirm availability for fridge or CD deliveries.

Delivery Restrictions

No collection from premises.

No delivery to:

Parcel lockers

Neighbours

Safe places

Commercial PO boxes

Failed Delivery Handling

Automatic return to the pharmacy.

Pharmacist assesses resupply needs."

7.43.4 "***7. COURIER SPECIFICATIONS SUMMARY***

Recommended courier features:

GDP-aligned processes

Real-time tracking

ID verification for CDs

Secure return-to-sender protocol

No safe-place deliveries

Next-day guaranteed service

API-enabled tracking notifications

Common couriers used by established DSPs:

Royal Mail Special Delivery (often for CDs)

DPD Medical / DPD Healthcare

UPS Healthcare

Parcelforce Express 24 (with restrictions)"

7.44 The Committee also noted SOP 6 'Flowcharts' showing flowcharts for the cold chain and controlled drug delivery processes.

7.45 The Committee was of the view that insufficient detail has been provided regarding the Applicant's procedures, including how the Applicant would ensure the integrity of the cold chain throughout the journey, how temperature is monitored and what would happen in the event that the cold chain is breached or an unsuccessful delivery. Further, the Committee was of the view that no detail had been provided regarding the security of controlled drugs when with the courier and throughout its onward journey.

7.46 Given the lack of information, the Committee was not satisfied that there would be compliance with paragraph 8(1) of Schedule 4.

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

7.48 The Committee noted that the whilst the Applicant had referred to the use of "*MHRA-approved insulated packaging*" for cold chain items and "*tamper-evident packaging*" for controlled drugs, no other details had been provided about what containers would be used to package posted/delivered items.

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

Refusal to provide drugs or appliances ordered

7.50 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.

7.51 The Committee noted that no information had been provided either in the application form, or on appeal.

7.52 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

7.53 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.

7.54 The Committee noted that no information had been provided either in the application form, or on appeal.

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

Disposal service in respect of unwanted drugs

7.56 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.

7.57 The Committee noted that no information had been provided either in the application form, or on appeal.

7.58 Therefore, the Committee was not 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

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

7.60 The Committee noted that no information had been provided either in the application form, or on appeal.

7.61 Therefore, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 16-18 of Schedule 4.

Prescription linked intervention

7.62 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.

7.63 The Committee noted that no information had been provided either in the application form, or on appeal.

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

Health campaigns

7.65 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.

7.66 The Committee noted that no information had been provided either in the application form, or on appeal.

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

Signposting

7.68 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.

7.69 The Committee noted that no information had been provided either in the application form, or on appeal.

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

Support for self-care

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

7.72 The Committee noted that no information had been provided either in the application form, or on appeal.

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

Discharge medicines service

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

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

7.76 The Committee noted that no information had been provided either in the application form, or on appeal.

7.77 Therefore, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B & 22C of Schedule 4.

Websites and health promotion zones

7.78 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.

7.79 The Committee noted the application form states:

7.79.1 "Patient access via … website, with 24/7 information available online"; and

7.79.2 "Website offers service access, NHS info, complaints process, and accessibility tools"

7.80 The Committee was of the view that the information provided in this regard was minimal and there was no indication that the content of the website would be interactive and services provided in order to promote healthy lifestyles by addressing a reasonable range of health issues.

7.81 Therefore, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 28C of Schedule 4.

Summary

7.82 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).

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

7.83.1 confirm the Commissioner's decision;

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

7.83.3 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.

7.84 Although the Committee had reached the same decision as the Commissioner, it had done so for more extensive reasons. The Committee therefore determined that the decision of the Commissioner must be quashed.

7.85 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.

7.86 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.

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

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

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

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

8.2.3 The application is refused.

Case Manager
Primary Care Appeals