NHS Resolution

24 March 2026

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

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

REF: SHA/ 26813

APPEAL AGAINST STAFFORDSHIRE AND STOKE-ON-TRENT ICB DECISION TO REFUSE AN APPLICATION BY ASTRA PHARMA STOKE LIMITED FOR INCLUSION IN THE PHARMACEUTICAL LIST AT CENTURION HOUSE, WEST STREET, NEWCASTLE-UNDER-LYME, ST5 1BH 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:
Astra Pharma Stoke Limited
PCSE on behalf of Staffordshire and Stoke-on-Trent

NHS Resolution

REF: SHA/ 26813

APPEAL AGAINST STAFFORDSHIRE AND STOKE-ON-TRENT ICB DECISION TO REFUSE AN APPLICATION BY ASTRA PHARMA STOKE LIMITED FOR INCLUSION IN THE PHARMACEUTICAL LIST AT CENTURION HOUSE, WEST STREET, NEWCASTLE-UNDER-LYME, ST5 1BH UNDER REGULATION 25

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

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

1 The Application

By application dated 18 February 2025, Astra Pharma Stoke Limited ("the Applicant") applied to Staffordshire and Stoke-on-Trent ICB ("the Commissioner") for inclusion in the pharmaceutical list at Centurion House, West Street, Newcastle-Under-Lyme, ST5 1BH under Regulation 25. In support of the application it was stated:

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

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

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

Pharmacy procedures

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

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

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

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

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

1.7 You must ensure that you provide sufficient information within this application form to satisfy NHS England or the relevant delegated integrated care board on the above points. You are not required to submit your standard operating

procedures for the premises but if you do they will be circulated to interested parties unless NHS England or the relevant delegated integrated care board is satisfied that the full disclosure principle does not apply.

1.8 “There will be a Registered Pharmacist and staff members at the premises throughout the opening hours to process any prescriptions they receive via EPS/post/delivery driver. Any advice that the patient/patient representative may need will be provided through the phone or email. There will be a consultation room to provide the staff a space to talk to patients in privacy. Patients will be made aware from start that there will be no face to face contact. This will also be mentioned on our leaflets and the website. Medication will only be delivered to patients with our delivery driver or via post. The doors of the premises will always be closed. Access will only be provided to the pharmacy staff and suppliers delivery drivers. Any patient that does tum up at the premises will be directed to a local community pharmacy. We will have a secure website for the sale of any GSL and P medication through out the country. Advanced services like New Medicine Service and Medication Reviews will happen on the phone.”

1.9 [Floor Plan and SOPs enclosed]

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 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 “I write in response to your letter dated 23rd April 2025. I understand that representations have been made regarding our application for inclusion to the pharmaceutical list. The representations have been noted and this response is to alleviate any and all of those concerns. I have addressed each of the representations from the various interested parties.

2.1.2 Astra Pharma will be operating from Centurion House, West Street, Newcastle, STS 1 BH. The floor plan attached to the application represents the specific area of the premises to use for the pharmacy. The premises consist of a robust building structure with a single, secure entry point designated for pharmacy staff and deliveries. There is no other access to the pharmacy area. Access to the premises will be strictly controlled.

2.1.3 In addition to the physical integrity of the building, we will be implementing a range of security measures to ensure the safety and integrity of pharmacy operations. These measures include having restricted access controls, with barriers and locks to limit access to

authorised personnel only, as well as installing security cameras which will be actively monitored to deter and detect unauthorised access. These measures are part of our commitment to maintaining a secure and compliant pharmacy environment, aligned with regulatory standards and best practices.

2.1.4 Astra Pharma is committed to ensuring the provision of uninterrupted essential pharmacy service during the core hours. To ensure this, the Responsible Pharmacist will be present and signed in at the pharmacy throughout these times, including during lunch breaks, and readily available to address staff, patient, or patient representative's queries. Therefore there will not be any interruptions to providing essential pharmacy services. SOP 3 is intended for unforeseen absences where the Responsible Pharmacist needs to leave, and then a second pharmacist will be arranged to cover the absence.

2.1.5 All communication, including advice or counselling between staff and patients' or a patient's representative will be made by phone, video call, email or via the website. To ensure privacy and confidentiality, there will be a dedicated consultation room so that staff are able to speak to patients without being overheard. SOP 5 (Dispensing Prescription Item) has been amended and attached for your consideration.

2.1.6 Astra Pharma is committed to ensuring that all patients receive equal access to all of our services regardless of their needs and even where they may not have access to the internet.

2.1.7 With respect to patients with sight loss, our website will include features such as screen reader compatibility, ensuring that all content can be accessed using assistive technologies. Adjustable font sizes, contrast options, and audio will be available for patients with varying visual impairments, and alternative text for images and other non-text elements. Our telephone service will be designed to be accessible, with clear audio, and staff will be trained to communicate effectively with patients with varying needs.

2.1.8 With respect to hearing loss, our telephone service will be accessible to patients through the use of text relay services, and we will offer alternative methods of communication, such as by email. Clear written instructions and information will be provided to supplement verbal communication. We will ensure that our communication methods are adaptable to meet a wide range of needs and in addition, staff will receive training on disability awareness and effective communication.

2.1.9 Astra Pharma is committed to ensuring that all of our services are able to be delivered to patients regardless of location. Where it is not possible for the medication to be delivered by our own delivery drivers, we will appoint City Sprint to deliver all our medication, including CD drugs and fridge items. We have already contacted City Sprint to ensure that they are able to do this, and we are also aware that they provide the same service for other pharmacies and hospitals. Our own delivery drivers and City Sprint are aware not to leave medication with anyone

else but the patient or the patient's representative. They are also aware that they need a signature on delivery. If the patient is not there, the driver will bring the medication back to the pharmacy the same day. They are also able to pick up any medicine waste from patients anywhere in the country where requested. Where the medicine waste contains sharps, the driver will signpost them to the local council for collection.

2.1.10 On delivery, the driver will get the patient or patient's representative to tick the exemption and sign the back of the prescription and bring it back to the pharmacy.

2.1.11 SOP 11, 18 and 32 have been amended to reflect the above, and they have been attached for your consideration.

2.1.12 We will be providing emergency supply service for Prescription Only Medicine (POM) without a prescription at the request of a patient or a relevant prescriber. The Pharmacist will interview patients on the phone or video call to obtain all patients information, their medication details, as well as their reason for the emergency supply. The Pharmacist will check the patient medication record, summary care record or get a copy of the repeat prescription from the patient to verify if they have had the medication before. If the emergency supply service conditions are met and at the discretion of the pharmacist, the supply will then be prepared, labelled and delivered promptly by our drivers or City Sprint. The staff will be trained to provide this service. SOP 48 has been attached for your consideration.

2.1.13 According to the Pharmacy First requirements, distance selling pharmacies can only provide 6 of the 7 conditions. As a Distance Selling Pharmacy, we are aware that we can not provide face to face consultations, therefore we will not be offering a consultation for Acute Otitis Media, which is the 7th condition. SOP 49 has been attached for your consideration.

2.1.14 Astra Pharma takes GDPR and data governance very seriously. We will be registering with the Information Commissioner's Office and Data Protection and Information Governance policies have been attached for your consideration. We will be implementing robust procedures to protect patient data. This includes secure data storage and encryption, strict access controls, staff training on data protection and secure communication channels. The consultation room is there so that any conversations by phone/ video call with patients are kept private.

2.1.15 We will have a website where patients can purchase GSL or P medicines. Our registration process will require patients to provide verifiable personal information, including their full name, date of birth, address, contact details, and NHS number. The pharmacist will always exercise their professional judgement and have the authority to request further identification such as a copy of a valid form of photographic identification especially for medications identified as having a higher potential for abuse or refuse a sale if they have any concerns regarding

the identity of the patient. The website will have an assessment form for all P medications which will be checked by the pharmacist for appropriateness before being sent to the patient. Each sale will be saved on our system and monitored. If there are multiple orders for medication with potential for abuse the sale will be declined. We will establish appropriate order limits on the website for such medications. The Pharmacist will contact the patient for advice on the use of medication or to decline the order if deemed necessary to ensure patient safety. All packages will be safely delivered through our well experienced drivers or by City Sprint.

2.1.16 We will have a website with dedicated interactive pages with up-to-date, evidence-based materials on topics like healthy eating, physical activity, mental wellbeing, smoking cessation, and responsible alcohol consumption. This page will be clearly promoted to website users upon access. The website will provide links to reputable external resources, such as the NHS, Public Health England, and local support services. Pharmacists and trained pharmacy staff will offer healthy lifestyle advice via phone, email, or secure messaging, whilst providing other services.

2.1.17 Patients with stable, long-term conditions who regularly order the same medications, will be identified as potentially suitable for the repeat prescription service, with appropriate patient consent obtained and under the pharmacist's oversight. We will then proactively inform them of this option and the benefits it offers, while always ensuring they understand their right to choose. Patients will be able to request repeat prescriptions through the phone, email or through the website. These requests will be reviewed by a pharmacist to ensure that they are clinically appropriate and fall within the agreed repeat dispensing protocol. Patients will be subject to regular reviews by our pharmacists to ensure the ongoing appropriateness and safety of their medication. We will also remind patients of the need for periodic reviews with their GP.

2.1.18 We are confident that the Implementation of these enhanced procedures and policies will address the concerns raised and demonstrate our unwavering commitment to patient safety. We are committed to continuously reviewing and improving our SOPs to reflect best practices and regulatory requirements.

2.1.19 We believe that our commitment to patient safety and the robust procedures in place should allow our application to proceed.

2.1.20 Thank you for your continued consideration, and please do not hesitate to contact me for any further information that you may need."

2.1.21 [Enclosures provided]

3 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 13 November 2025 states:

3.1 “Staffordshire and Stoke on Trent 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 Staffordshire and Stoke on Trent ICB’s decision. Should you choose to appeal then you should either complete the online form available on the NHS Resolution website or send a concise and reasoned statement of the grounds for your appeal within 30 days of the date of this letter to nhsr.appeals@nhs.net or:

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

PSRC report

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

3.4 “**Distance Selling Premises – excepted application**

3.5 **ME3734 CAS-348789-R7V3X7**

3.6 **Astra pharma stoke Limited**

3.7 **CENTURION HOUSE, WEST STREET , NEWCASTLE , ST5 1BH**

3.8 Regulation 31 – refusal: same or adjacent premises Regulation 31 (1) A routine or excepted application, other than a consolidation application, must be refused where paragraph (2) applies.

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

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

3.11 Therefore, the Committee concluded that it was not required to refuse the application under the provisions of Regulation 31. The Committee then went on to consider Regulation 25.

3.12 Regulation 25 – Distance Selling Premises Applications Regulation 25(2)(a) – The NHSCB must refuse an application to which paragraph 1 applies 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.

3.13 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.

3.14 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) – It was noted that within the application form, the applicant did not confirm their intention to undertake to provide appliances. The pharmacy procedures do not meet the standard required to satisfy the regulatory requirements of the provision of essential services.

3.16 The clinical advisor's observation is that the information provided does not give assurance that the applicant will provide the uninterrupted provision of essential services during the opening hours of the premises, to persons anywhere in England.

3.17 There is no assurance provided with regards to the delivery of Sch2&3 Controlled Drugs to persons anywhere in England as little information is provided on the arrangements, and in particular what the process is for failed deliveries and subsequent storage of CDs if they cannot be returned to the pharmacy premises. This is also true of medication that requires refrigeration, as the SOP states that failed deliveries must be returned to the pharmacy, but this would not be possible for deliveries made to areas of England that are several hours drive away from the proposed premises.

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

3.19 Regulation 25(2)(b)(ii) – The pharmacy procedures and detailed SOPs provided appear to not meet the standard required to satisfy the regulatory requirements of the provision of pharmaceutical services without face to face contact. For example SOP 47 NMS services Therefore, this regulation is deemed to have not been met.

3.20 The Committee refused the application. Regulation 25(2)(a) is met. Regulation (2)(b)(i) and (2)(b)(ii) is not met. Regulation 31(2)(a) and (b) does not apply.

3.21 The Committee determined that appeal rights are to the applicant.

3.22 **Specific conditions – Distance Selling Premises**

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

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

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

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

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

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

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

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

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

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

4 The Appeal

In an email received on 10 December 2025, the Applicant appealed against the Commissioner's decision.

Cover email

4.1 "I am writing to formally appeal against the decision of Staffordshire and Stoke-on-Trent Integrated Care Board (ICB), which refused my pharmacy market entry application on the grounds that it did not meet the required access criteria.

4.2 I respectfully request that the matter be reviewed by NHS Resolution's Primary Care Appeals service.

4.3 The ICB's reasoning, as stated in the enclosed report, concludes that our proposed premises do not sufficiently meet certain requirements. We disagree with this assessment and have therefore provided additional and updated documentation to support our position. We kindly request that these new materials be taken into consideration as part of this appeal.

4.4 Please find enclosed copies of:

4.4.1 **The ICB's decision letter.**

4.4.2 **The full ICB report.**

4.4.3 **Signed Appeal Form**

4.4.4 **Essential and Directed Services SOPs**

4.4.5 **Distance Selling Pharmacy Essential Services Compliance Document**

4.4.6 **Pharmacy Business Continuity Plan**

4.4.7 **Pharmacy Floor Plan and Camera points.**

4.5 Thank you for your time and consideration.

4.6 I look forward to your acknowledgement of this appeal and to participating in any further proceedings or requests for clarification as required".

Grounds of appeal contained in NHS Resolution's online appeal form

4.7 "It is submitted that the decision letter and decision report provided by Staffordshire and Stoke on Trent ICB:

4.7.1 Is woefully inadequate in that it contains little information as to why the committee reached the refusal decision AND / OR

4.7.2 Is woefully inadequate in that it contains very little information as to why the application does not meet the requirements of Regulation 25 AND / OR

4.7.3 The decision report appears to have:

4.7.3.1 Failed to take into account the full suite of SOPs provided by the applicant AND / OR

4.7.3.2 Failed to give adequate explanation that the committee have considered all of the SOPs AND/ OR

4.7.3.3 Primarily focused on areas which appear to have been predetermined by the committee namely unsuccessful delivery

and cold chain without an explanation as to why the committee focused on such AND / OR

4.7.3.4 Explain how the committee applied the law to the application that they were tasked with deciding on AND / OR

4.7.3.5 Contained a predetermined decision which was to refuse the application AND / OR

4.7.3.6 Failed to take into account that it is not the committees function to approve or disapprove of the applicants SOPs AND / OR

4.7.3.7 Failed to give any indication whether any further observations, from 3rd parties or the applicant in response to such observations, were taken in to account and what weight they were given

4.7.4 No person, be that the applicant or a member of the public, could be satisfied that the committee reached the correct decision based on the woefully inadequate information provided in the refusal decision and letter.

4.7.5 The decision is therefore:

4.7.5.1 Unsafe as no person, be that the applicant or a member of the public, could be satisfied that the committee reached the correct decision based on the inadequate provided in the refusal decision and letter AND / OR

4.7.5.2 Unlawful as the committee have misdirected themselves on the correct interpretation of the tests laid down in Regulations 25 and 64

4.7.6 The applicant requests that the committee hear the appeal and consider the application afresh. Please also find the following documents attached for your reference.

4.7.6.1 Essential and Directed Services SOPs

4.7.6.2 Distance Selling Pharmacy Essential Services Compliance Document

4.7.6.3 Business Continuity Plan

4.7.6.4 Pharmacy Floor Plan.”

4.7.7 [Enclosures provided]

5 Summary of Representations

This is a summary of representations received on the appeal.

5.1 The Commissioner

5.1.1 "The detailed suite of pharmacy procedures now provided from the applicant to NHS Resolution 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.

7.7 Further, the Commissioner in its decision report stated that "*the Committee concluded that it was not required to refuse the application under the provisions of Regulation 31",* which no party had sought to dispute. Based on the information before it, the Committee determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

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

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

7.11 The Committee noted that the Applicant had not included any information in the relevant section of the application form that deals with this point. The Committee noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Commissioner in its 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*", which no party had sought to dispute. Based on the information available to it, the Committee therefore determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

7.12 As far as Regulation 25(2)(b) is concerned, the Committee considered the information which had been provided by the Applicant in relation to its

procedures for the provision of essential services and pharmaceutical services, including its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.

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

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

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

7.16 It is not for the Committee to 'approve' or 'disapprove' of these SOPs (as they may contain matters not relevant to the Committee's consideration, and there are many ways an applicant can choose to organise itself in order to comply with the various requirements of the Regulations) and the Committee has not sought to do so. The Committee noted that the Applicant has not requested that the SOPs provided with its appeal should supersede those provided with its application instead it states that "*We kindly request that these new materials be taken into consideration as part of this appeal*". The Committee has therefore sought evidence from within both sets of SOPs provided, the application and appeal in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.

7.17 The Committee 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 not indicated that it wished to supply any appliances.

7.18 Further, in the "Providing Uninterrupted Essential Services in Distance Selling Pharmacies" document provided with the appeal, it states that:

7.18.1 *"Dispensing Appliances*

Pharmacy will not be dispensing any appliances. Subject to the consent of the patient, the pharmacist can refer the prescription to another provider electronically for dispensing. If the patient does not consent to the prescription being referred to another provider, the pharmacist must give the patient the contact details of two providers of appliances through telephone, text, email or video call. Pharmacist must ensure

that the patient can consult a person to obtain expert clinical advice about the appliance. If pharmacist is not able to provide remote Appliance Use Review (AUR) service, the patient must be given the contact details of at least two pharmacies or suppliers of appliances who are able to arrange for the service to be provided. The telephone number or the website address of these providers will be listed on the pharmacy website all the time. Advice on how to keep or store medications can be provided through telephone, text, email or video call by trained pharmacy staff.

Appliance measuring and fitting

When the pharmacist is unable to provide an appliance or stoma appliance customisation because such services fall outside the pharmacy's usual scope of operations, the pharmacist must—

(a) with the patient's consent, refer the prescription form or repeatable prescription to another NHS pharmacist or an NHS appliance contractor; and

(b) if the patient does not agree to a referral, provide the patient with contact details for at least two NHS pharmacists or NHS appliance contractors who can supply the required appliance or stoma appliance customisation, provided the pharmacist has this information available.

In relevant cases, the pharmacist will document and maintain a record of any information provided or referrals made for audit purposes and to support follow-up care."

7.19 The Committee noted that on receipt of such requests, the Applicant would contact the patient and signpost them to another provider of the service in their area. In the event that the application is granted, the Applicant would not therefore, be able to provide such appliances that require measuring and/or fitting to patients.

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

7.21 In its decision report, the Commissioner stated that "*the information provided does not give assurance that the applicant will provide the uninterrupted provision of essential services".*

7.22 The "Providing Uninterrupted Essential Services in Distance Selling Pharmacies" document provided with the appeal states that:

7.22.1 "*all essential services to be secured without interruption during the opening hours…*

… A Responsible Pharmacist is present and in charge with pharmacy staff during the core opening hours of the premises to ensure there is uninterrupted provision of essential services to patients…

…If and when required, more staff will be hired to aid the Responsible Pharmacist in his/her role of uninterrupted provision. Uninterrupted NHS Essential Services will be provided by the Pharmacist and qualified, knowledgeable, experienced support staff on duty…

… RP

As a Distance Selling Pharmacy, we must ensure uninterrupted service during opening hours. Unlike in non-Distance Selling Pharmacies, the Responsible Pharmacist (RP) cannot be absent for up to two hours. To maintain continuity, a second pharmacist will be available during all operating hours. If the RP needs to leave or take a break under the Working Time Directive, the second pharmacist must sign in as the RP."

7.23 The "Standard Operating Procedure for Responsible Pharmacist" provided with the appeal states that:

7.23.1 *"5. Ceasing the duties of the RP*

You must cease to be the RP if:

The role of RP is to be assumed immediately by another pharmacist,

It is the close of trading at the end of the day,

You are no longer able to continue your duties (e.g. sickness).

6.Sign off and take down your notice.

Remove or amend the RP notice on display when you cease to act as RP that day. Sign off as responsible pharmacist on PMR, or make an entry in the record book recording the time (using the 24-hour clock) that you ceased to be the RP.

7. Create handover notes if necessary.

Communicate any necessary handover notes, instructions or information via the communications book or in-person if another pharmacist is assuming the role of RP immediately. Leave contact details in the communications book for the next RP in case contact is required to resolve any outstanding issues.

8. Changeover of the RP

The RP taking over from the previous RP needs to follow 'Assuming duties of the RP' as set out above. To maintain continuity, a second pharmacist will be available during all operating hours. If the RP needs to leave or take a break under the Working Time Directive, the second pharmacist must sign in as the RP."

7.24 "SOP 3: Operating in the absence of the RP" provided with the application states that:

7.24.1 *"**Process: Operating in the absence of the responsible pharmacist***

The RP should check the pharmacy record and calculate the maximum amount of time that they may be absent from the pharmacy

Absence is calculated as the total number of hours in a 24-hour period, from midnight to midnight and must not exceed two hours…

…Indicate on the notice that the RP is absent…

…The RP informs the pharmacy staff of the time they expect to return to the pharmacy and how they can be contacted during their absence

The RP must be able to be contacted by the pharmacy staff throughout the absence, and return to the pharmacy reasonably promptly…"

Process: RP absence exceeds two hours and no second pharmacist

Pharmacy staff contacts the RP to obtain additional instructions and an estimated time of return

Pharmacy staff must not engage in the sale or supply of any medicines online or on phone

Process: RP absence exceeds two hours and a second pharmacist is present

The second pharmacist assumes the duties of the RP

Process: RP absence does not exceed two hours

Record the time the RP returned to the pharmacy

RP in charge of the premises and physically present."

7.25 Whilst the documents provided with the appeal suggested to the Committee that the Responsible Pharmacist (RP) must not leave the premises unless another pharmacist is present to assume that role, the wording in SOP 3 outlines what would happen in the event that the RP is absent. As such, there would be period of absences where the RP is not present and no second pharmacist available to ensure non-interruption and assume RP responsibilities, meaning the Applicant would be unable to provide all essential services in line with the Regulations.

7.26 The Committee was therefore not satisfied that the provision of essential services would be without interruption.

7.27 With regard to services being available to persons anywhere in England, the Commissioner in its decision report stated that "*the information provided does not give assurance that the applicant will provide the uninterrupted provision of*

essential services during the opening hours of the premises, to persons anywhere in England".

7.28 The "Providing Uninterrupted Essential Services in Distance Selling Pharmacies" document provided with the appeal states that:

7.28.1 "*all essential services to be secured for persons anywhere in England…*

…Pharmacy has a business continuity plan to ensure that the Applicant delivers essential services safely, effectively, and without interruption to individuals across England who seek these services during the operational hours of the premises…

…this continuity plan is reviewed regularly (minimum annually) to ensure that it is fit for purpose. Patients in England will be able to register receive NHS Essential Services via the website or by contacting the pharmacy via email, telephone, postal services, or social media...

… The pharmacy's practice leaflet, promotional materials, or any communications (written or oral) will not imply or state that:

(i) essential services are limited to specific areas of England…"

7.29 The Committee was therefore satisfied that the provision of essential services would be available to persons anywhere in England.

7.30 The Committee considered how the Applicant would provide pharmaceutical services without face to face contact and noted the Commissioner in its decision report stated that "*The pharmacy procedures and detailed SOPs provided appear to not meet the standard required to satisfy the regulatory requirements of the provision of pharmaceutical services without face to face contact. For example SOP 47 NMS services."*

7.31 The Committee noted SOP 47 NMS Services provided with the application states that:

7.31.1 *"Conducting the NMS*

Patient engagement can be carried out via telephone or video link

The intervention and follow up stage can be carried out via telephone or video link or in the patient's home".

7.32 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.

7.33 The Committee acknowledged that the application and SOP 47 were submitted before the regulatory amendments came into force. The Committee noted the SOP provided on appeal titled "Standard Operating Procedure for Provision of

Essential, Advanced and Enhanced Services without face to face contact" states that:

7.33.1 *"As the regulatory framework has now changed so that no advanced or enhanced services can be delivered to a patient who is physically present at the premises, any SOPs that will be written for advanced and enhanced service delivery will ensure that any service MUST not be delivered face to face within the pharmacy. Any patient who requests any NHS service to be delivered face to face will be informed that this is not possible, under any circumstance. All staff employed by the pharmacy will be informed of this change in the rules".*

7.34 As a result of the amendment, the Committee noted that the Applicant would not be able to provide any pharmaceutical services to patients present at its premises.

7.35 Further, the "Providing Uninterrupted Essential Services in Distance Selling Pharmacies" document provided with the appeal states that:

7.35.1 "*all essential services to be secured without face to face contact…*

… As a Distance Selling Pharmacy, all NHS pharmaceutical services are provided remotely without face-to-face contact. There is no facility for patient attendance, walk-in services, or collection of medication at the premises, and the internal layout contains no retail areas, counters, or features that could imply public services are available. All patient consultations are conducted remotely, and all medicines are delivered to patients via secure, approved delivery services.

Pharmacy premise will operate with an intercom system, a patient will not be able to attend the premises directly. The pharmacy staff will be trained not to provide NHS essential services face to face. In the unlikely event that a patient does attempt to contact the pharmacy via the intercom system to request one or more services, it will be explained that due to our Distance Selling Regulations we are unable to provide face-to-face NHS Directed Services. It will also be explained to the patient that essential services are provided remotely by the pharmacy. Details how to access the essential services remotely will be provided to the patients…

…Provision of NHS Essential and Directed Services without face-to-face contact within premises will be achieved by using:

Telephone, including text messaging where appropriate

Live Video Call

Website inbox (through contact us)

Real-time chat box on website

Email

Electronic Prescription Service (EPS)

Royal Mail postal service

Courier service

Specialised cold chain courier services e.g. DHL COLDCHAIN."

7.36 The "Standard Operating Procedure for Provision of Essential, Advanced and Enhanced Services without face to face contact" states that:

7.36.1 *"All staff must be made aware that face to face contact between patients (or their representatives) is prohibited in respect of any and all Essential, Advanced and Enhanced Services either on or in the vicinity of the premises.*

Where any SOP could be considered to imply that face-to-face contact with a patient or their representative may take place either on or in the vicinity of the premises, then this should be immediately referred to the Responsible Pharmacist (RP) before any further action is taken.

The premises operate exclusively as a distance-selling pharmacy and are not open for public walk-in access, in strict compliance with all relevant NHS and GPhC regulatory requirements.

Access to the pharmacy premises is strictly controlled, only authorised pharmacy personnel are permitted entry, using secure access systems, including locks, key codes, and physical keys. These access controls ensure the security of the premises, the safety of pharmacy stock, and the confidentiality of patient data.

The premises have been fully converted, refurbished, and secured to meet all the regulatory standards required for a registered pharmacy, including appropriate security, storage, environmental controls, and standard operating procedures.

The pharmacy premise is located in a purpose-fitted unit within a quiet residential area. The street-level window is fully blacked out and clear signage indicates that the premises are not open to the public, preventing any misunderstanding or inadvertent entry. The location is in a low-traffic area residential area with minimum passing footfall, which further supports the security, privacy, and integrity of the operation. Access via the rear door is strictly limited to receiving medications and deliveries.

As a Distance Selling Pharmacy, all NHS pharmaceutical services are provided remotely without face-to-face contact. There is intension of no access for the public under any circumstances. There is no facility for patient attendance, walk-in services, or collection of medication at the premises, and the internal layout contains no retail areas, counters, or features that could imply public services are available. All dispensing, clinical checks, and patient consultations are conducted remotely, and

all medicines are delivered to patients via secure, approved delivery services.

Pharmacy premise will operate with an intercom system, a patient will not be able to attend the premises directly. The pharmacy staff will be trained not to provide NHS essential services face to face. In the unlikely event that a patient does attempt to contact the pharmacy via the intercom system to request one or more services, it will be explained that due to our Distance Selling Regulations we are unable to provide face-to-face NHS Directed Services. It will also be explained to the patient that essential services are provided remotely by the pharmacy. Details how to access the essential services remotely will be provided to the patients. The patient will be signposted to other pharmacies who provide NHS services within the area. Staff training will be reviewed once a year or sooner if an incident arise.

It is also noted that the Department of Health & Social Care has confirmed that from October 2025, DSP will not be able to deliver advanced and enhanced services to persons present or in the vicinity of the distance selling premises; such services must be provided remotely in line with the delivery of essential services.

In line with the service specifications, the pharmacy will only offer Advanced and Enhanced services that can be delivered remotely, without requiring patients to attend the premises.

There are various methods to inform general public that pharmacy cannot provide face-to-face essential services within the premises:

Notice on Premises

Notice on Website

Post on Social Media

Pharmacy leaflet and fryers

Alarm system is installed and connected to a monitoring service which would be triggered by unauthorised access attempts, break-ins or fire alarms. Surveillance cameras (24/7 monitoring) are installed at strategic locations both inside and outside the pharmacy to deter potential intruders and in operation at all times. Doors and windows are equipped with secure locks to prevent forced entry. All pharmacy staff are trained on security protocols, emphasising the importance of not sharing access codes or keys or forbes and being vigilant about identifying and reporting suspicious activity. Any incidents involving attempted public access are formally recorded and investigated as part of our clinical governance processes, and routine security audits and risk assessments are undertaken to ensure ongoing improvements in the safety and security of the pharmacy."

7.37 The Committee was satisfied that 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.

7.38 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.

7.39 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:

7.39.1 Dispensing of drugs and appliances

7.39.2 Urgent supply without a prescription

7.39.3 Preliminary matters before providing ordered drugs or appliances

7.39.4 Providing ordered drugs or appliances

7.39.5 Refusal to provide drugs or appliances ordered

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

7.39.7 Disposal service in respect of unwanted drugs

7.39.8 Promotion of healthy lifestyles

7.39.9 Prescription linked intervention

7.39.10 Health campaigns

7.39.11 Signposting

7.39.12 Support for self-care

7.39.13 Discharge medicines service

7.39.14 Websites and health promotion zones

7.40 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.

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 In its decision report, the Commissioner stated that "*There is no assurance provided with regards to the delivery of Sch2&3 Controlled Drugs to persons anywhere in England as little information is provided on the arrangements, and in particular what the process is for failed deliveries and subsequent storage of CDs if they cannot be returned to the pharmacy premises. This is also true of medication that requires refrigeration, as the SOP states that failed deliveries must be returned to the pharmacy, but this would not be possible for deliveries made to areas of England that are several hours drive away from the proposed premises. Therefore, this regulation is deemed to have not been met".*

7.43 The "Standard Operating Procedure for The Delivery of Medicines" provided with the appeal states that:

7.43.1 *"6. Driver arrival.*

Ensure the Responsible Pharmacist (RP) is signed in during all stages where dispensed items are handed over to the delivery driver. Deliveries must not be prepared or dispatched without an RP in charge. When the driver arrives, confirm with patient/representative for their name and address, check the label on the bag against the prescription, branch record sheet and book. File prescriptions. Cold chain medications will be separated from local delivery and to be done via courier. Check and tick against the branch record sheet label when transferring items to the delivery driver. The driver signs and dates the branch record sheet at this stage to confirm the pickup. Ask the patient or representative to sign their details on the delivery sheet…

… Delivery of prescription via Royal Mail (Not for Cold Chain or CDs)

The pharmacist should contact patients before delivery to confirm dispatch and provide any necessary counseling.

Ensure that the RP is available to oversee the handover of all items for delivery.

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

Clearly print a return address on the outer packaging.

Verify the details of all prescriptions to be delivered.

Record all tracking numbers for prescriptions being delivered via Royal Mail on the Delivery Log sheet.

Ensure the Royal Mail driver signs the Delivery Log sheet for all prescriptions accepted for delivery. Retain the Delivery Log sheet for at least 3 months from the dispatch date.

Email patients with dispatch confirmation and their tracking number once the prescriptions have left the premises.

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

Unsuccessful Delivery via Royal Mail

If a delivery attempt is unsuccessful, Royal Mail will leave a 'Sorry We Missed You' card, indicating the date and time of the attempt. The patient can then either choose to collect and sign for their medication at their local post office or reschedule the delivery for a convenient time by phone or email.

Pharmacy Actions following a failed attempt:

Record the failed delivery in the pharmacy Delivery Log, including the date of attempted delivery and tracking number.

Staff should check the online tracking status periodically until the item is delivered or returned to the pharmacy. Any change in status must be logged in the patient's PMR.

Contact the patient within 48 hours if no action has been taken by them, to avoid delays in medication adherence. This is particularly important for essential, high-risk, or time-sensitive medications.

Advise the patient that Royal Mail will hold their parcel for a limited period (normally 18 days). If uncollected, the medication will be returned to the pharmacy.

Undelivered medicines must be reconciled against the delivery record on return to the pharmacy to ensure nothing has been lost, tampered with, or left unattended

Store items appropriately upon return and contact the patient to arrange redelivery

Incident escalation – any failed delivery involving urgent, end-of-life, or critical medicines must be reviewed by the pharmacist the same working day.

Do not reattempt postal delivery until updated consent and delivery instructions have been confirmed with the patient.

7.44 The "Standard Operating Procedure for Cold Chain Delivery" provided with the appeal states that:

7.44.1 *"3. Temperature Record according to "Cold Chain Maintenance SOP"*

All staff will ensure that the temperature of refrigerators used for medication storage is monitored, reset daily, and maintained between 2°–8° C. These temperatures will be recorded daily, and any discrepancies will be addressed according to the SOP.

4. Product dispatch

Ensure any items for cold chain delivery via courier are stored in the fridge and accompanying items are appropriately marked with a fridge line sticker. Accompanying items should include a note to explain that fridge items will be delivered separately to the rest of their items to enable the cold chain to be maintained. Patients will be contacted to inform and arrange for cold chain deliveries. All cold chain deliveries should be booked on courier specific portal. The cold chain medication should be kept in the fridge until the courier arrives to accept the delivery. Verify courier vehicle temperature before transfer. The vehicle must be within 2–8°C at the point of loading. Details of all prescriptions scheduled for delivery will be confirmed with courier driver. The courier must scan a barcode sticker for each item, with the pharmacy retaining a copy of the barcode, which also serves as the tracking number. Ensure the on-duty pharmacist is available to oversee the handover of all items for delivery and match against the delivery log and prescription. Pharmacy staff record all tracking numbers for prescriptions being delivered by the courier on the Delivery Log sheet and confirm the courier signs the Delivery Log sheet for all prescriptions accepted for delivery. Patients will be contacted with dispatch confirmation with their Tracking number when the prescriptions have left the premises. Live tracking with estimated ETA is available via the courier website. All deliveries will require a signature from the patient to confirm receipt of their prescription. Delivery log is stored for a minimum of 3 months from dispatch date.

5. Using courier service

All cold chain deliveries must be done via specialist medical cold chain courier service. Provisions such as DHL COLDCHAIN (or a similar specialist cold chain courier service) maintain the integrity, quality, and effectiveness of temperature-sensitive medications. These services ensure proper packing, transportation, and delivery under fully monitored, temperature-controlled conditions. Real-time monitoring devices are used to track temperature, humidity, and other environmental factors, alongside GPS tracking for precise location updates as well as electronic proof of delivery. Vehicles are equipped with built-in refrigeration systems to maintain the necessary temperature throughout transit. Courier operates under an ISO 9001:2015 certified Quality Management System, ensuring robust processes and quality oversight. In addition, all pharmaceutical warehousing and cold chain distribution used for this service are fully MHRA licensed under Wholesale Distribution Authorisation (WDA(H)) and GDP-compliant, ensuring full regulatory compliance for the storage and distribution of temperature-sensitive medicinal products.

Each cold chain product will be individually bagged, sealed with tamper-evident packaging, and clearly labelled with a "fridge item" sticker to ensure all handlers are aware that it requires cold chain management. The pharmacist will only remove the item from cold storage once the delivery courier is present. The pharmacist or trained staff will oversee

the transfer of the item to the temperature-controlled vehicle, ensuring that the cold chain is maintained throughout the handover process. Delivery drivers are properly trained and would only remove the item from their vehicle upon arrival when the patient has answered the door and verified their identity.

During the transit, temperature alarms must be logged, investigated, and retained as part of GDP documentation. In the event of a cold chain breach, the driver will be immediately notified, and any affected delivery will be cancelled. The pharmacy will be promptly informed of the breach. Medications are stored in temperature-controlled warehouses for interim storage or in cases of failed deliveries.

A list of approved cold chain couriers is maintained by the Pharmacy and will be periodically updated. Each approved courier meets strict criteria to guarantee a fully monitored and dedicated cold chain service.

In case of delay, if the estimated time of arrival changes by more than 4 hours, the courier must notify the pharmacy so the Responsible Pharmacist can assess clinical urgency, contact the patient if required, and document any risk mitigations.

Patient should be advised to immediately refrigerate the medicine, inspect packaging for tamper-evidence, and contact the pharmacy immediately if the product feels warm or frozen at delivery.

6. Unsuccessful cold chain delivery via courier

If a delivery attempt fails, the cold chain courier (e.g., DHL COLDCHAIN) will leave a 'Missed Delivery' card with the date, time, and instructions to reschedule. Medications will not be left unattended if the patient is unavailable to receive the delivery. Patients can rearrange delivery via phone or online. Medications are stored in temperature-controlled warehouses in the interim and maintained for up to 48 hours. Staff should check the online tracking status periodically until the item is delivered or returned to the pharmacy. Any change in status must be logged in the patient's PMR. Contact the patient within 48 hours if no action has been taken by them, to avoid delays in medication adherence. This is particularly important for essential, high-risk, or time-sensitive medications. Advise the patient that cold chain courier (DHL COLDCHAIN) will hold their parcel for a limited period (normally 48 hours). If uncollected, the medication will be returned to the pharmacy. If undelivered within this period, items are returned to the pharmacy with the cold chain maintained throughout the journey, which will contact the patient to arrange a new delivery. The entire journey, from transfer within the warehouse to loading onto the transport vehicle, and throughout transit, is continuously monitored with real-time temperature tracking and alarm systems to ensure the cold chain is consistently maintained. If temperature excursion data cannot be validated, the medicine must be destroyed and recorded in waste logs. Any failed delivery involving urgent, end-of-life, or critical medicines must be reviewed by the Responsible Pharmacist (RP) on the same

working day. The RP will then use their clinical judgment to decide whether it is appropriate to wait for a rescheduled delivery or to release the prescription to the patient's local pharmacy for collection or delivery, with the patient's consent.

7. Breach of Integrity of Cold Chain

DHL vehicles are equipped with built-in refrigeration systems to ensure the required temperature is maintained during road transportation. The system automatically alerts the delivery driver that the cold chain has been breached and affected deliveries will be cancelled. The patient and pharmacy will be promptly informed of the breach, or the patient will receive a 'Missed Delivery' card.

The pharmacy must arrange for an immediate re-delivery of the items via courier and ensure the return of undelivered items to the pharmacy. Items compromised by a cold chain breach are not reused and must be segregated from the pharmacy stock upon their return. If the breach of the cold chain is discovered after the medication has been given to the patient, then the Incident Reporting Policy should be followed. The patient must be referred to the responsible pharmacist for review. Regularly review and audit on courier temperature and tracking data to identify patterns of risk or non-compliance. Conduct stimulated drills or mock scenarios at least once a year to test protocols and response times for breaches or equipment failures."

7.45 "SOP 32: Delivering Pharmacy items" provided with the application states that:

7.45.1 *"Scope*

This SOP sets out the process to be followed when delivering pharmacy items that have been prepared by the pharmacy

This SOP does not cover delivery of Controlled Drugs (CDs) – refer to relevant CD SOPs

Delivery by taxi/courier

Specific verbal or written consent from the patient for the delivery of items by a taxi/courier is required

A comprehensive audit trail would be required– the taxi driver or courier must complete the required information in the delivery driver's record book

Posting medicines

Obtain specific verbal or written consent from the patient for the items to be posted

Confirm that the postal courier can deliver the specific pharmacy items

Take into consideration packaging and storage requirements:

CDs or fridge lines should not be posted

Will the product be stored at the correct temperature during transit?

Items should be packaged in a padded envelope or similar and include a return address for the pharmacy

A clear audit trail must be maintained – only recorded deliveries

Safety considerations in transit

Medicines should be stored securely out of sight in a locked vehicle with the windows shut."

7.46 Further, the Committee noted that the delivery of items flow chart on page 3 of the SOP states that:

7.46.1 *"High risk medicines/fridge items in delivery, or discussion required with patient/representative?…*

…Fridge items must be stored in a cool box during transit."

7.47 The Committee noted that the SOPs provided with the application compared to those provided with the appeal are contradictory. Whilst the Standard Operating Procedure for Cold Chain Delivery (version 9 dated 28 June 2024) provided on appeal states that delivery of cold chain items will be by courier only, SOP 32 (dated 13 January 2025) provided with the application indicates that such items will be delivered by taxi. The Committee noted it had no information to demonstrate how the cold chain would be maintained and monitored throughout delivery by taxi. Further there was no information to explain what would happen in the event of a breach of cold chain or failed/ missed delivery.

7.48 In relation to delivery of cold chain items, based on the information before it, the Committee was not satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

Other considerations

7.49 The Committee noted that in its decision report, the Commissioner had made findings in relation to certain aspects of the Terms of Service which it considered important to address.

Providing ordered drugs or appliances

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

7.51 In its decision report, the Commissioner stated that "*There is no assurance provided with regards to the delivery of Sch2&3 Controlled Drugs to persons anywhere in England as little information is provided on the arrangements, and in particular what the process is for failed deliveries and subsequent storage of CDs if they cannot be returned to the pharmacy premises. Therefore, this regulation is deemed to have not been met".*

7.52 The "Standard Operating Procedure for The Delivery of Medicines" provided with the appeal states that:

7.52.1 *"6. Driver arrival.*

Ensure the Responsible Pharmacist (RP) is signed in during all stages where dispensed items are handed over to the delivery driver. Deliveries must not be prepared or dispatched without an RP in charge. When the driver arrives, confirm with patient/representative for their name and address, check the label on the bag against the prescription, branch record sheet and book. File prescriptions. Cold chain medications will be separated from local delivery and to be done via courier. Check and tick against the branch record sheet label when transferring items to the delivery driver. The driver signs and dates the branch record sheet at this stage to confirm the pickup. Ask the patient or representative to sign their details on the delivery sheet.

7. Controlled drugs delivery.

If a CD is included, phone the patient beforehand to confirm they are in. The driver should sign the blue box on the back of the script and write 'delivery' to complete the audit trail. The driver's name and 'delivery' is written in the CD register as the person collecting the medication. If delivery is unsuccessful, the CD is returned to the pharmacy, booked back into the CD register and signed out again on retry.

8. Driver departure.

Ensure that the driver takes the delivery record book with them. The branch record sheet stays in the pharmacy as a record of which items have been taken by driver. On delivery at the appropriate address, the driver should give the patient every opportunity to answer the door. The delivery driver must not enter the patient or representative's home unless with consent.

IF THE PATIENT IS IN:

1. The driver should state that he is delivering medication from the pharmacy and check the patient's name and address. The number of packages to be delivered should be confirmed against the entry in the delivery record book.

2. The patient must sign the delivery record book on receipt of their medication. The driver should not enter the patient's house if possible.

3. The book must be returned to the pharmacy as proof of delivery before the close of business that day.

4. The driver should not offer medical advice unless qualified to do so. If the patient has a query about their delivered medication, the driver can provide the telephone number of the pharmacy (which is printed on all medication labels) and ask the patient to phone the pharmacy for advice. If the driver is asked to give written advice to a patient in the form of a note or letter from the pharmacy, then the pharmacy should phone the patient after delivery to ensure the note has been received and understood. Medicines should be kept securely in the vehicle, and doors and windows are closed/locked at all times. The medication should be kept out of sight, e.g. in the boot.

IF THE PATIENT IS OUT:

1. In the event of an unsuccessful delivery, the driver will leave a failed delivery card at the delivery address specifying the date and time of the attempted delivery and providing clear instructions and contact details for the patient to contact the pharmacy and reschedule the delivery

2. Undelivered medicines must be reconciled against the delivery record on return to the pharmacy to ensure nothing has been lost, tampered with, or left unattended

3. Redelivery attempts should be documented, including patient contact, revised delivery date/time, and confirmation of patient availability.

4. If multiple delivery attempts fail or the patient remains unreachable, staff should escalate to the pharmacist for clinical review. Pharmacist should assess risk associated with delayed therapy and consider notifying GP or care provider if patient safety is potentially compromised.

DO NOT- Leave the delivery items.

unattended in porches or on doorsteps

with children

neighbours - Unless arrangements have been made by the patient/carer…

… Delivery of prescription via Royal Mail (Not for Cold Chain or CDs)

The pharmacist should contact patients before delivery to confirm dispatch and provide any necessary counseling.

Ensure that the RP is available to oversee the handover of all items for delivery.

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

Clearly print a return address on the outer packaging.

Verify the details of all prescriptions to be delivered.

Record all tracking numbers for prescriptions being delivered via Royal Mail on the Delivery Log sheet.

Ensure the Royal Mail driver signs the Delivery Log sheet for all prescriptions accepted for delivery. Retain the Delivery Log sheet for at least 3 months from the dispatch date.

Email patients with dispatch confirmation and their tracking number once the prescriptions have left the premises.

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

Unsuccessful Delivery via Royal Mail

If a delivery attempt is unsuccessful, Royal Mail will leave a 'Sorry We Missed You' card, indicating the date and time of the attempt. The patient can then either choose to collect and sign for their medication at their local post office or reschedule the delivery for a convenient time by phone or email.

Pharmacy Actions following a failed attempt:

- *Record the failed delivery in the pharmacy Delivery Log, including the date of attempted delivery and tracking number.*
- *Staff should check the online tracking status periodically until the item is delivered or returned to the pharmacy. Any change in status must be logged in the patient's PMR.*
- *Contact the patient within 48 hours if no action has been taken by them, to avoid delays in medication adherence. This is particularly important for essential, high-risk, or time-sensitive medications.*
- *Advise the patient that Royal Mail will hold their parcel for a limited period (normally 18 days). If uncollected, the medication will be returned to the pharmacy.*
- *Undelivered medicines must be reconciled against the delivery record on return to the pharmacy to ensure nothing has been lost, tampered with, or left unattended*
- *Store items appropriately upon return and contact the patient to arrange redelivery*

Incident escalation – any failed delivery involving urgent, end-of-life, or critical medicines must be reviewed by the pharmacist the same working day.

Do not reattempt postal delivery until updated consent and delivery instructions have been confirmed with the patient.

7.53 Further, the "Standard Operating Procedure for Delivering Controlled Drugs" provided with the appeal states that:

7.53.1 *"1. Organise CD deliveries.*

Indicate whether delivery to a specified person other than the patient or carer has been authorised onto the PMR. Where the patient is exempt, record details of the exemption, including the expiry date for any exemption certificate onto the PMR. Where exemption status has expired contact the patient to provide new evidence of exemption status. Where the patient is not exempt, mark 'to pay' on the prescription. For each patient, the pharmacist should clinically assess the prescription.

Controlled drugs should be given extra caution when delivering extra care and record-keeping is required. Figure out which drugs need to be delivered and signed for. Make sure when dispensing CD's the SOP for dispensing controlled drugs is followed.

Controlled Drugs are stored in a compliant CD cabinet fixed to structural walls, meeting all legal security requirements, with access restricted to authorised registrants only. CD items must remain in the CD cabinet until delivery. The prescription should be retained with the item(s) to allow a final check and entry in the CD register. Check that dispensed medicinal products have been bagged and labelled and that the name and address on the bag label corresponds to the prescription. Ensure the bag label has the full address including the postcode. Agree or inform the patient of the expected date and time for delivery if this has not already been done and check that someone will be present to accept the delivery. The prescription should be retained in the pharmacy until the delivery driver returns the appropriate paperwork signed by the patient or representative to confirm successful delivery or the patient signature is confirmed online if delivered by courier.

2. Dispatch the item.

Give the correctly labelled and bagged item to the driver along with the delivery sheet. Make sure that the driver understands that this is not a regular delivery and needs to be signed for. Make sure that the deliverer understands that CDs and any other medicines on that patient's delivery must be stored in the lockable compartment of the delivery van and not out of sight. The delivery van must be kept locked at all times when the driver is not in the vehicle and will not be left unattended. Ensure that the RP is available to oversee the handover of all items for delivery.

3. Driver delivers the item.

The person who is delivering the controlled drug should double-check the address to be delivered to and ask the person who is present for identification if necessary. A signature should be obtained from the patient who receives their item. Where the recipient is not the patient, their full name should be recorded on the delivery record form, along with their signature. If the patient has a carer and is incapable of signing then the delivery driver is effectively the patient's nominated representative authorised to collect the CD on their behalf. As such the driver should sign the 'collected by' section on the reverse of the prescription. The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative (passport, driving licence or government approved photo ID card are acceptable forms of ID). A delivery cannot be left with anyone who is not the patient or their authorised representative.

4. Report back to the pharmacist.

The pharmacist has a legal responsibility to make sure that the patient has received their medication. If the patient/carer is home to accept the delivery, the driver must confirm the patient details and ensure the delivery record form is signed by the recipient. Once delivered, the driver must return the signed delivery note to the pharmacy. File the delivery record form as evidence of successful delivery of the controlled drug. The forms should be stored for a minimum of six months in case the delivery is later queried.

5. Entry into the CD register

This should be exclusively be [sic] performed by the Responsible Person. This is a legal requirement for specific controlled drugs.

6. CD delivery with Courier

Delivery of controlled drugs in local area will be managed by pharmacy delivery driver, otherwise will be handled by DHL, which has pharma-grade specialist facilities meeting specific quality and validation requirements for healthcare products, including Home Office licensed controlled drug stores. DHL holds the following UK licenses and standards:…

… DHL meets all Home Office safe custody and record-keeping requirements. Controlled drugs delivered by DHL Courier Services are all being tracked, with verifiable audit trails. GPS, image & signature data would be checked by the pharmacy team after delivery to ensure that the patient has received the CD delivery.

7. Unsuccessful CD Delivery

If a delivery attempt is unsuccessful, our own delivery driver or DHL (if courier is used) will leave a 'Sorry We Missed You' card, indicating the date and time of the attempt. For local deliveries, the card will provide clear instructions and contact details for the patient to contact the

pharmacy and reschedule the delivery. For courier delivery, the patient can then either choose to collect and sign for their medication at their local post office or reschedule the delivery for a convenient time by phone or email. For local deliveries, if the patient is not home during the agreed delivery slot– the CD must be returned to the pharmacy on the same day by the driver and at the earliest opportunity. Unsuccessful deliveries sent with a courier should be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate. Where the time of attempted delivery means that the return cannot be made on the same day, the courier will store the drugs at their approved warehouse overnight and return the next day.

DO NOT- Leave the delivery items.

unattended in porches or on doorsteps

with children

neighbours - Unless arrangements have been made by the patient/carer

For local unsuccessful deliveries, driver will inform the authorised pharmacy staff upon return to the pharmacy. The CD register entry for failed CD deliveries should be annotated by marginal note or footnote to state that the delivery was not made and the CD entry is not accurate. If the pharmacist is satisfied that the product has been stored correctly and is suitable to be issued to the patient at a later date the item should be re-entered in the supplied section of the CD register.

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

7.54 In relation to delivery of controlled drugs, based on the information before it, the Committee was satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

7.55 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

7.56 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).

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

7.57.1 confirm the Commissioner's decision;

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

7.57.3 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.

7.58 Even though the Committee had reached the same decision as the Commissioner, it had done so for different reasons. In those circumstances, the Committee determined that the decision of the Commissioner must be quashed.

7.59 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.

7.60 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.

7.61 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