10 February 2025

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REF: SHA/ 26343

APPEAL AGAINST NHS BEDFORDSHIRE, LUTON AND MILTON KEYNES ICB DECISION TO REFUSE AN APPLICATION BY EMWHY PHARMA LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT UNIT A2 IVINGHOE ESTATE, HOUGHTON REGIS, BEDFORDSHIRE, LU5 5BQ 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:
Emwhy Pharma Ltd
PCSE on behalf of NHS Bedfordshire, Luton and Milton Keynes ICB

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1 The Application

By application dated 7 March 2024, Emwhy Pharma Ltd ("the Applicant") applied to Bedfordshire, Luton and Milton Keynes ICB ("the Commissioner") for inclusion in the pharmaceutical list at Unit A2 Ivinghoe Estate, Houghton Regis, Bedfordshire, LU5 5BQ 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.

Further Information in Relation to Provision of Essential Services in Accordance With the Regulatory Requirements for Distance Selling Pharmacies

1.4 Please find below information to 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 "a) Pharmacist present on site during opening hours of the pharmacy.

1.8 Phone lines open during these hours.

1.9 Booking system available to request video calls.

1.10 No entry is granted to the pharmacy premises except to pharmacy staff, except with prior booking for Advanced or Enhanced Services.

1.11 All pharmacy staff including delivery drivers will be highly trained to ensure services can be provided.

1.12 b) Patients attending requesting essential services will be politely explained that we are not licensed to provide face to face services.

1.13 We will direct them to the appropriate methods to receive essential services from our business:

1.14 HLP- Articles on website promoting healthy living. Updated on a monthly basis. Advice hotline by phone.

1.15 Booking system on encrypted video calls

1.16 Dispensing medicines- Pick up service for paper prescriptions from patients location (usually home) by courier or mail. Electronic prescriptions sent directly from prescriber Medicines delivered to patient by courier.

1.17 Advice provided by phone, or video call Repeat Dispensing.

1.18 Trained Delivery drivers and pharmacy staff will arrange repeat dispensing medication using phone, email or via our website.

1.19 Unwanted medicines collected from patients home by trained employed drivers to ensure safe transfer to the pharmacy.

1.20 OMS Referrals are electronic and come directly to the pharmacy with phone/email communication only.

1.21 Public Health- Healthy Living Campaigns will take place on our website.

1.22 We will promote 6 campaigns per year as a minimum and these will be available on our home page, and healthy living pages.

1.23 Phone/video Interventions will take place for target groups by sending questionnaires and maintaining a patient profile for the purpose of promoting healthy living only.

1.24 Opportunistic advice will also be given to patients at the time of dispensing their prescriptions.

1.25 Advanced/Enhanced services will be provided and patients requesting essential services will be directed to our procedures."

2 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 12 September 2024 states:

2.1 "Bedfordshire, Luton & Milton Keynes 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.

2.2 You have a right of appeal to the Secretary of State against Bedfordshire, Luton & Milton Keynes 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:

2.3 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]

2.4 "New Inclusion Pending Distance Selling: Emwhy Pharma Ltd, Unit A2 Ivinghoe Estate, Houghton Regis, Bedfordshire, LU5 5BQ.

2.5 The Committee considered the application in respect of distance selling premises, which was determined under the following regulations:

2.6 **Regulation 31**: [Regulation 31(1) and (2) quoted in full].

2.7 The Committee noted the nearest pharmacies located within 1-mile to the proposed premises.

2.8 The Committee noted that no pharmacy existed or was said to exist at or adjacent to the proposed location. In addition, there was no person on the pharmaceutical list providing or undertaking to provide pharmaceutical services from or adjacent to the premises.

2.9 The recommendation was, the Committee should be satisfied that the application meets the tests of Regulation 31.

2.10 **Regulation 25**: [Regulation 25(1) and (2) quoted in full].

2.11 **Regulation 25(2)(a)**

2.12 The Committee noted the nearest GP Practice is Houghton Regis Medical Centre, Peel Street, Houghton Regis, Dunstable, LU5 5EZ which is situated 0.9 miles from the proposed location which is 4 mins by car and a 20-minute walk (source Google maps).

2.13 The Committee noted that the premises in respect of which the application was made, is not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

2.14 The recommendation was, the Committee should be satisfied that the application meets the tests of Regulation 25(2)(a).

2.15 **Regulation 25(2)(b)**

2.16 The Committee considered the information provided by the Applicant. The Committee noted that in relation to its procedures for the provision of essential services, no

Standard Operating Procedures (SOPs) that it intended to use at the proposed pharmacy premises had been provided.

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

2.18 The Committee noted that the core opening hours declared on the application form must and did total 40 core hours per week, and were listed as:

2.18.1 Monday to Friday 09:00 – 17.00.

2.19 There were no supplementary hours declared and therefore the total number of hours of opening were 40.

2.20 The Committee noted the document provided by the applicant, namely: "distant selling application". In support of their application the applicant stated: [1.7 – 1.25 above].

2.21 **Representations**

2.22 The Committee noted the following representations/comments received:

2.23 Community Pharmacy BLMK & Northants dated 18th June: *"Having regard for the information provided by the applicant we observe that the applicant has implied that its procedures will comply with the requirements, however, it has not provided sufficiently detailed explanations in support of its application. Consequently, NHSE cannot be satisfied that this requirement will be met, and the applicant should, we suggest be refused in pursuant to Regulation 25(2)."*

2.24 Jhoots Pharmacy dated 14th June: *"The application suggest that patients will be able to access the premises as it states" patients attending requesting pharmaceutical services will be politely explained that not licensed to provide face to face services". The applicant however states that the patient will be directed how to access such services. No details are provided with regards to deliveries as to what procedures and processes will be in place as to how cold chain lines will be secured. I submit that Regulation 25 and associated conditions have not been met and the application should be refused on this basis."*

2.25 Boots Support Office dated 8th May: *Boots UK Ltd would like to respectfully request that members of the deciding committee are satisfied that this application fully meets the criteria set out in Regulation 25 and the conditions set out in Regulation 64 when determining this application. In particular those around the procedures the applicant has in place when carrying out Advanced Services.*

2.26 The Committee noted that in response to the representations received the applicant responded as detailed below, dated 1st July:

2.26.1 *"I understand that Jhoots have objected on the basis that they believe we have not met Regulation 25 in explaining how we will ensure no essential services will be made face to face. We provided information on how we would conduct each essential service without face to face contact with the patient., in our application.*

2.26.2 *We may provide Advanced and Enhanced services however patients requesting Essential services will always be directed to the correct method of receiving these services.*

2.26.3 *They have also mentioned their objection to the supply of cold chain medications. As a pharmacist and healthcare professional, our responsibility is to ensure that medication reaches our patients safely and adheres to the manufacturer's storage instructions. All of our medications will be delivered to patients using our own drivers or third party couriers which are authorised to carry medications. For cold chain medications, we will use specialised cold chain couriers such as Polar Speed, or refrigerated transport using our own couriers.*

2.26.4 *We will ensure that the transport is safe by initially and regularly testing with temperature probes to notify of any temperature spikes.*

2.26.5 *We will deliver nationwide using the aforementioned methods and will not refuse any medication based on distance nor treatment type. I believe this addresses Boots concerns on our ability to fulfil Regulation 64.*

2.26.6 *As previously mentioned, all medications will be delivered therefore this should alleviate any concerns about the supply of medications on premises during any services. We intend to always provide or offer a follow up by phone to provide any further support which may fall under essential services. to any patient presenting themselves at the premises.*

2.26.7 *I hope this has addressed the concerns presented by the two companies, however, will be happy to clarify further".*

2.27 The Committee considered each Essential Service in Paragraphs 3 to 22 of Schedule 4 of the Regulations ("Terms of Service").

2.28 The Committee paid particular attention to the following aspects of the essential services, which were considered more difficult to provide safely and effectively in a distance selling context:

2.28.1 Dispensing of drugs and appliances.

2.28.2 Urgent supply without a prescription.

2.28.3 Preliminary matters before providing ordered drugs or appliances.

2.28.4 Providing ordered drugs or appliances.

2.28.5 Refusal to provide drugs or appliances ordered.

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

2.28.7 Disposal service in respect of unwanted drugs.

2.28.8 Promotion of healthy lifestyles.

2.28.9 Prescription linked intervention.

2.28.10 Public health campaigns.

2.28.11 Signposting.

2.28.12 Support for self-care.

2.29 **Dispensing of drugs and appliances**

2.30 The Committee considered whether the applicant explained how non-electronic prescriptions would be presented by the patient and how products would be provided.

2.31 The Committee noted the information provided within the application states:

2.31.1 *"Pick up service for paper prescriptions from patients' location (usually home) by courier or mail. Electronic prescriptions sent directly from prescriber. Medicines delivered to patient by courier*".

2.32 The Committee were not satisfied that it was provided with sufficient information to provide assurance that there would be compliance with Paragraph 5(2)(3) of Schedule 4.

2.33 **Urgent supply without a prescription**

2.34 The Committee considered whether the applicant explained how it would propose safely and effectively to receive requests from prescribers for urgent supplies of drugs and appliances.

2.35 Based on the information before it, the Committee must be satisfied that it had been provided with information sufficient to show that there would be compliance with Paragraph 6 of Schedule 4

2.36 **Preliminary matters before providing ordered drugs or appliances.**

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

2.38 The Committee noted that the applicant did not provide detail relating to preliminary matters before providing ordered drugs or appliances and their process for

2.39 'Verification of Declarations of Prescription Exemptions'.

2.40 Based on the information before it, the Committee must be satisfied that it was provided with information sufficient to show that there would be compliance with Paragraph 7(3) of Schedule 4.

2.41 **Providing ordered drugs or appliances**

2.42 The Committee considered whether the applicant explained how drugs/appliances would 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).

2.43 The Committee noted that this was not included within the application. The applicant however did provide some details when responded to the representations that were made, as detailed below:

2.43.1 *"For cold chain medications, we will use specialised cold chain couriers such as Polar Speed, or refrigerated transport using our own couriers".*

2.44 Based on the information before it, the Committee must be satisfied that it was provided with information sufficient to show that there would be compliance to this regard.

2.45 **Refusal to provide drugs or appliances ordered.**

2.46 The Committee needed to ask itself how the applicant would 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 might indicate the desirability of review the patients treatment.

2.47 The Committee noted that the applicant stated within their application:

2.47.1 *"Trained delivery drivers and pharmacy staff will arrange repeat dispensing medication using phone, email or via our website".*

2.48 Based on the information before it, the Committee must be satisfied that it was provided with information sufficient to show that there would be compliance with paragraph 9(4) of Schedule 4.

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

2.50 The Committee considered whether the applicant 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.

2.51 The Committee noted that the applicant didn't provide any supporting information relating to further activities carried out in connection with the provision of dispensing services.

2.52 Based on the information before it, the Committee must be satisfied that it was provided with information sufficient to show that there would be compliance with 10(1) of Schedule 4.

2.53 **Disposal service in respect of unwanted drugs**

2.54 The Committee considered whether the applicant explained how it would safely and effectively accept and dispose of unwanted drugs presented to it for disposal.

2.55 The Committee noted that the applicant states: "unwanted medicines collected from patients home by trained employed drivers to ensure safe transfer to the pharmacy".

2.56 Based on the information before it, the Committee must be satisfied that it was provided with information sufficient to show that there would be compliance with Paragraphs 13 - 15 of Schedule 4.

2.57 **Promotion of healthy lifestyles**

2.58 The Committee considered whether the applicant explained how it would safely and effectively promote healthy lifestyles.

2.59 The Committee noted that in support of the promotion of healthy lifestyles they stated within their application:

2.59.1 *"Articles on website promoting health living. Updated on a monthly basis. Advice hotline by phone. Booking system on encrypted video calls".*

2.60 Based on the information before it, the Committee might be satisfied that it was provided with information sufficient to show that there would be compliance with Paragraph 16 – 18 of Schedule 4.

2.61 **Prescription linked intervention**

2.62 The Committee considered whether the applicant explained how it would assess whether persons require prescription linked intervention advice because they have diabetes, are at risk of coronary heart disease, smoke or are overweight.

2.63 The Committee noted the applicant didn't provide information relating to prescription linked interventions.

2.64 Based on the information before it, the Committee must be satisfied that it was provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

2.65 **Public health campaigns**

2.66 The Committee considered whether the applicant explained how it would safely and effectively participate in public health campaigns, if and to the extent required by the NHSCB.

2.67 The Committee noted that the applicant provided the following information within their application:

2.67.1 *"Public Health – Healthy Living Campaigns will take place on our website. We will promote 6 campaigns a year as a minimum and these will be available on our home page and healthy living pages. Phone/video interventions will take place for target groups by sending out questionnaires and maintaining a patient profile for the purpose of promoting healthy living only. Opportunistic advice will also be given to patients at the time of dispensing their prescriptions".*

2.68 Based on the information before it, the Committee must be satisfied that it was provided with information sufficient to show that there would be compliance with Paragraph 18 of Schedule 4.

2.69 **Signposting**

2.70 The Committee considered whether the applicant explained how it would provide information to users of the pharmacy about other health and social care providers and support organizations.

2.71 The Committee noted that the applicant didn't provide information on Signposting patients within their application.

2.72 Based on the information before it, the Committee must be satisfied that it was provided with information sufficient to show that there would be compliance with Paragraphs 19 – 20 of Schedule 4.

2.73 **Support for self-care**

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

2.75 The Committee noted that the applicant didn't provide information on support for self-care within their application.

2.76 Based on the information before it, the Committee must be satisfied that it was provided with information sufficient to show that there would be compliance with Paragraphs 21 – 22 of Schedule 4.

2.77 **Decision:**

2.78 The Committee agreed to refuse the application as the requirements set out in Regulation 25 were not met.

2.79 The contractor has a right of appeal."

3 The Appeal

In a letter dated 12 October 2024, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "I am appealing the decision on the following grounds:

3.1.1 Representation from BLMK: I did not receive any representation from BLMK, which was dated 18th June. As a result, I was unable to respond appropriately to this representation. However, I did receive and respond to representations from the other two parties, to which I provided further supporting information to strengthen my application.

3.1.2 Character Limit on the Application Form: The webform section requesting details on how essential services will be provided in compliance with Regulation 25 was subject to a 2000-character limit. This character limit applied only to this section, while other sections did not impose such a restriction. Due to this limit, I provided concise responses under the assumption that this was expected.

3.1.3 Guidance on SOPs: The application form explicitly indicated that Standard Operating Procedures (SOPs) were not required. This further reinforced my understanding that concise, rather than comprehensive, information was appropriate. Had I known that comprehensive details were required, I would have included more elaborate information and uploaded the relevant SOPs, which were prepared and readily available at the time of application.

3.1.4 Vagueness of the Decision Letter: The language in the decision letter was unclear, with phrases such as "might be satisfied," "must be satisfied," and "should be satisfied" used in different sections without clear correlation. This inconsistency creates confusion regarding which points the Committee is satisfied with and which require further clarification.

3.1.5 Compliance with Regulation 25: I believe that the proposed distance-selling pharmacy will fully comply with Regulation 25. However, I do not feel that the initial application allowed for a proper representation of our compliance. An appeal would give me the opportunity to submit more comprehensive information, including the prepared SOPs, to demonstrate our compliance and satisfy all of the Committee's requirements."

3.2 In conclusion, I believe the decision should not have been based on the limited details provided due to a misunderstanding of the application process. I would like to appeal

to present the comprehensive and supporting information, which was readily available but not requested or allowed by the application form. Below is information about our website, and an explanation to outline how we will provide Essential Services without face to face contact.

3.3 I have also attached SOPs as a separate document [appendix A] which will be used internally to thoroughly outline how each service is carried out. The SOPs should satisfy the committee that Regulation 25 will be met by providing an uninterrupted provision of essential services to any person in England.

Dispensing of drugs and appliances

3.3.1 Pharmacist Supervision: During core hours, a pharmacist is always on-site to supervise dispensing activities, and available to speak with patients on the phone or other non-face to face methods such as video-call and email, ensuring that patient needs are met promptly. The pharmacist conducts initial assessments, reviews any concerns, and monitors staff to maintain high service standards.

3.3.2 Patient Registration Process: New patients register through our secure website, completing a consent form to acknowledge the pharmacy's distance-selling service. The registration process includes a comprehensive questionnaire covering medical history, allergies, current medications, and preferences for receiving medication delivery. This information is securely stored both electronically and in hard copy, and the pharmacist reviews it to understand the patient's needs before the first prescription is dispensed.

3.3.3 The initial consent form will also include a consent form to nominate out pharmacy for EPS prescriptions

3.3.4 Paper Prescription Handling: For patients who provide paper prescriptions, we offer prepaid envelopes and postage labels. Prescriptions can also be collected from patients using our delivery driver. Paper Prescriptions from prescribers are collected by our delivery driver.

3.4 Patient Medication Record (PMR) Maintenance:

3.4.1 Comprehensive Data Logging: Each patient's PMR is manually updated to reflect new prescriptions, allergies, conditions, and any changes in their medication regimen. This record includes contact details, authorised representatives, and delivery preferences. Any patient requesting or recognised as potentially eligible for compliance aids, such as MDS, is assessed remotely through a phone or video consultation to confirm suitability.

3.4.2 Medication History Tracking: The PMR also records interactions with the patients, or medicine interactions, and any special instructions from the prescriber or patient. We record repeat prescriptions and set delivery due dates to ensure that medications are dispensed on time. In cases of out-of-stock medications, the pharmacist updates the PMR with patient preferences for partially dispensed or alternative options such as signposting to other pharmacists, or prescription changes.

3.5 Dispensing and Clinical Checks:

3.5.1 Clinical Review: Every prescription undergoes a clinical check, where the pharmacist evaluates potential interactions, proper dosage, and

appropriateness based on the patient's medical history. If a discrepancy arises, the pharmacist contacts the prescriber immediately to clarify or adjust the prescription as needed.

3.5.2 Legal and Accuracy Checks: The pharmacist checks the prescription for legality and a second check for accuracy prior to despatch to the patient.

3.5.3 Patient Counselling: For each new prescription, the pharmacist provides counselling on correct medication usage, storage requirements, and potential side effects. Counselling is provided over the phone, via secure video call, and through written instructions included in the package if necessary. For certain medications, such as cold chain items, additional guidance on storage (e.g., refrigeration) is given, with reminders included in the package. The outer packaging is clearly marked with a label, such as 'fridge item' or 'cold chain' to recognise that it is a fridge item.

3.6 Preparation for Delivery:

3.6.1 Packaging and Tamper-Proofing: Once the prescription is checked, the medication is packed using tamper-evident seals. Fragile items are cushioned with bubble wrap or polystyrene filler, and cold chain items are placed in insulated boxes such as polystyrene lined to maintain the appropriate temperature. The pharmacist ensures that each package includes proper labelling and handling instructions.

3.6.2 Items are packed in pharmacy bags for local deliveries and double walled cardboard boxes with all sides sealed for courier deliveries. The pharmacy will use sift-proof or leak proof boxes where appropriate.

3.6.3 Special Instructions: The pharmacist attaches specific instructions for the delivery driver, such as details on handling controlled drugs separately or keeping cold chain items refrigerated. The pharmacist verifies that all packages are sealed securely and accurately labelled to prevent tampering.

3.6.4 Tracking and Confirmation: Each delivery is logged in the pharmacy's system, with tracking numbers assigned for courier deliveries. The pharmacist oversees the entire preparation process and confirms that all documentation, including delivery receipts and special handling forms, is completed.

3.7 Delivery Execution and Security:

3.7.1 Local Deliveries: Our Enhanced DBS-checked driver is trained to follow a secure delivery protocol. This includes ID verification, obtaining a signature, and transporting medications in a locked and/or temperature-controlled vehicle when necessary. For controlled drugs, the driver completes a Controlled Drugs Delivery Sheet and verifies the identity of the person accepting the delivery.

3.7.2 Courier Deliveries: For deliveries beyond the local area, we use approved couriers such as Royal Mail, DHL Medical Express or Polarspeed for cold chain items. Couriers follow strict protocols, such as temperature monitoring and secure handling for controlled drugs. They are required to notify the pharmacy immediately in the event of a failed delivery attempt, and medications are returned to a licensed storage facility if not delivered.

3.7.3 Cold Chain Integrity: Cold chain medications are monitored continuously during transit. Couriers equipped with temperature-controlled vehicles handle

items at 2-8°C, with alerts set up to notify both the driver and the pharmacy if a temperature breach occurs. In such cases, medications are returned immediately, and patients are contacted for redelivery.

3.8 Handling Unsuccessful Deliveries:

3.8.1 Failed Delivery Process: In the event of a missed delivery, the courier leaves a 'Missed Delivery' card for the patient with instructions for rescheduling. If cold chain items are involved, the courier's temperature-controlled facilities maintain product integrity until redelivery. The pharmacist logs all failed delivery attempts in the PMR, records the reasons, and updates the patient on new delivery options.

3.8.2 Controlled Drugs: If a controlled drug delivery fails, the driver returns it to the pharmacy the same day for secure storage. The patient is informed of the failed delivery and offered the next available delivery slot.

3.9 Cold Chain and Controlled Drugs Protocols:

3.9.1 Cold Chain Packaging and Monitoring: Cold chain items are packaged using validated materials such as insulated cool boxes and "FRIDGE LINE" labels. If a temperature excursion is detected, the courier notifies the pharmacy, and the medication is returned for safe disposal. Cold chain breaches are documented, and a new delivery is arranged immediately to prevent patient delays.

3.9.2 Our employed driver will carry a digital monitor that logs temperature during transit. Third party couriers are expected to have a full audit trail of temperature logs during transit and this will be requested.

3.9.3 Controlled Drugs Compliance: The pharmacy maintains a separate Controlled Drugs Delivery Sheet for each CD transaction. The driver verifies the recipient's identity and signs a declaration upon delivery. All CDs are recorded in the pharmacy's controlled drugs register, including entries for unsuccessful deliveries, ensuring a robust audit trail.

3.10 Counselling and Follow-Up:

3.10.1 Patient Notifications: Patients receive dispatch confirmation, tracking details, and estimated delivery times. Prior to delivery, the pharmacist contacts the patient to provide additional counselling on specific medications if required. For example, cold chain items are discussed to confirm that the patient understands proper storage conditions.

3.10.2 Ongoing Feedback and Improvement: Patients are encouraged to participate in feedback surveys accessible on the website or via email. Feedback is reviewed regularly, and the pharmacy will update its SOPs to address any recurring issues or improve service delivery based on patient experiences.

Emergency Supply

3.11 Emergency Requests from Prescribers:

3.11.1 Upon receiving an urgent request from a prescriber, through email, phone, or video call, we will assess the clinical need for an emergency supply and verify that the request meets legal requirements for dispensing.

3.11.2 Once approved, we will promptly inform the patient via their preferred communication method that an emergency supply will be provided.

3.12 Emergency Requests from Patients:

3.12.1 Patients are encouraged to call the pharmacy directly to avoid delays. During the call, or via video call if needed, we will assess whether an emergency supply can be clinically and legally provided.

3.12.2 If approved, we will arrange a same-day delivery time for the medication.

3.13 Delivery of Emergency Medications:

3.13.1 For patients within the local area, our delivery driver will ensure safe, same-day delivery of the medication.

3.13.2 For patients outside the local area, we will use CitySprint or DHL Medical Express to facilitate a same-day delivery.

3.13.3 All delivery costs for the emergency supply will be covered by the pharmacy, and the patient will not be charged for this service.

3.13.4 Our cut off time to supply an Urgent Delivery will be at the end of our core hours (5pm) to ensure that we can fully adhere to providing this essential service.

Preliminary matters before providing ordered drugs or appliances. Procedure for Verifying Exemption and Collecting Payment.

3.14 Verification of Exemption Status:

3.14.1 When patients request drugs or appliances, pharmacy staff will verify whether they qualify for an exemption from prescription charges.

3.14.2 For patients aged 16 and under or 60 and over, no exemption evidence is required.

3.14.3 For other patients, satisfactory evidence of exemption will be confirmed through Real-Time Exemption Checking (RTEC) or by reviewing valid exemption certificates. These may include plastic, paper, or digital certificates, as long as they are in date and cover the required period.

3.14.4 Patients can send evidence of exemption to the pharmacy via delivery drivers, email, fax, or mail. If using mail, patients will be provided with a prepaid method of delivery, with postage costs covered by the pharmacy.

3.14.5 Upon receipt, the evidence will be documented in the Patient Medication Record (PMR), noting the exemption type, start date, and expiry date. For income-based exemptions, evidence will need to be reviewed at each dispensing to confirm ongoing eligibility.

3.15 Documentation and System Update:

3.15.1 Pharmacy staff will update the PMR system to record that exemption checks have been completed and note the next required check date.

3.15.2 If a copy of the exemption certificate is provided instead of the original, the system will reflect this, and the responsible pharmacist will determine if it meets the standards for 'satisfactory evidence.' If not, the “Evidence not Seen” box on the prescription will be marked accordingly.

3.15.3 If a valid certificate is in place and noted on the PMR, additional evidence will not be required within the certificate’s validity period, except for income-based exemptions.

3.16 Handling Patients without Evidence:

3.16.1 If patients cannot provide evidence or if there is any doubt about the authenticity of their exemption, the pharmacy staff will mark the “Evidence not Seen” box on the prescription.

3.16.2 Regardless, pharmacy staff will continue to dispense necessary items and will not refuse to provide prescriptions due to a lack of exemption evidence.

3.17 Payment Collection:

3.17.1 For patients who do not qualify for exemption, the pharmacy staff will determine the charges due and inform the patient of the total via their preferred communication method—phone, text, or email.

3.17.2 Patients will be directed to arrange payment using the pharmacy's secure remote payment system via our website. We will also have a method for taking payment over the phone through the back end of our online payment system.

3.17.3 If any discrepancies exist between the fees recorded and fees due, staff will notify the patient and direct them to complete payment through the secure payment portal.

3.18 Guidance on Prepayment Certificates:

3.18.1 Pharmacy staff will provide patients with information on prepayment certificates (PPC) or HRT prepayment certificates if they qualify and could benefit from this option. This guidance will include steps for obtaining a PPC if the patient is expected to need ongoing prescriptions.

3.19 Use of Delivery and Return Services:

3.19.1 Patients using postal services to submit exemption evidence will be provided with a secure prepaid method. The pharmacy will cover postal costs for these submissions and return any original documents securely using the same method.

Repeat Dispensing

3.20 Pharmaceutical & Legal Assessment

3.21 Pre-Dispensing Patient Contact:

3.21.1 Before issuing each repeat prescription, the pharmacist will contact the patient via telephone or secure and encrypted video call to:

3.21.1.1 Confirm that the patient is actively using the medication as prescribed and is likely to continue its proper use.

3.21.1.2 Assess whether the patient is experiencing any side effects that might indicate a need for a review or change in their medication.

3.21.1.3 Verify that there have been no recent changes in the patient's health status that could affect the safety or effectiveness of the prescribed medication.

3.21.1.4 Confirm that there have been no changes to the medication regimen since the prescriber last authorised the repeat.

3.21.1.5 Advise the patient to only order items they currently need to help reduce medication waste.

3.22 Surplus Medication Check:

3.22.1 During this discussion, the pharmacist will ask if the patient has any surplus stock at home. If so, the pharmacist will adjust the dispense and delivery date to match the patient's needs, ensuring responsible stock management and minimising wastage.

3.23 Documenting Clinically Significant Interventions:

3.23.1 Any interventions, referrals to the GP, or decisions to withhold medications that are deemed clinically significant are meticulously documented on an Intervention and Referral Form. This form is shared with the patient's GP to maintain continuity of care and a comprehensive clinical audit trail.

3.23.2 Documentation includes the clinical issues identified, actions taken, and any follow-up required, creating a clear record for future reference.

3.24 Encouragement of Repeat Dispensing Benefits

3.25 Patient Education on Repeat Dispensing:

3.25.1 The pharmacist will explain the benefits of repeat dispensing, particularly for patients with long-term, stable conditions. These benefits include:

3.25.1.1 Reducing the need for frequent GP visits to request prescriptions, simplifying the patient's healthcare routine.

3.25.1.2 Helping to manage medication supply efficiently to minimise waste.

3.25.1.3 Encouraging patients with stable conditions to discuss their medication needs with their GP regularly.

3.26 Written and Verbal Information:

3.26.1 Patients will receive written information about repeat dispensing, either in their delivery package or via email. This document outlines how the service works, their role in the process, and the importance of regular consultation with their prescriber.

3.27 Prescription Reception and Patient Consent

3.28 Initial Registration and Consent:

3.28.1 For patients new to the NHS repeat dispensing service, the pharmacist will contact them by phone to provide a detailed explanation, covering aspects such as:

3.28.1.1 The convenience of repeat dispensing and its benefits, including reduced GP contact and minimise wastage.

3.28.1.2 An invitation to complete a consent form online. If the patient does not have internet access, a consent form and prepaid return envelope are mailed to them.

3.29 Patient Control of Repeat Dispensing Forms:

3.29.1 Patients may choose to retain their Repeat Dispensing (RD) forms or allow the pharmacy to hold them. If the patient keeps the forms, the pharmacy retains the Repeat Authorisation (RA) form and provides prepaid envelopes for the patient to send in RD forms as needed. This flexibility empowers patients to manage their own repeat dispensing needs effectively.

3.30 Review of Dispensing Interval and Medication Suitability

3.31 Dispensing Interval Verification:

3.31.1 Before dispensing, the pharmacist checks the RA form for a specified dispensing interval. If none is specified, the pharmacist uses professional judgement to determine the appropriate timing for the next supply.

3.32 Medication Usage and Need Assessment:

3.32.1 The pharmacist evaluates the patient's need for each medication on the repeat prescription. If any surplus exists at home, the pharmacist adjusts the dispensed quantity accordingly, helping manage stock responsibly.

3.33 Suitability and Safety Checks:

3.33.1 With each dispensing cycle, the pharmacist reviews the medication's suitability for the patient. This includes verifying its appropriateness based on the patient's age, health conditions, and recent changes documented in their Patient Medication Record (PMR).

3.34 Cold Chain and Controlled Drugs Protocols

3.35 Cold Chain Medication Handling:

3.35.1 Medications requiring refrigeration are managed under strict cold chain protocols. These items are packaged in temperature-controlled containers (2-8°C).

3.36 Cold Chain Breach Protocol:

3.36.1 If a temperature breach occurs, the delivery is immediately returned to the pharmacy, and a replacement is arranged. The patient is notified promptly, and any breached medication is disposed of safely in accordance with regulatory standards.

3.37 Controlled Drugs Delivery:

3.37.1 The pharmacy adheres to stringent protocols for controlled drugs. These drugs are recorded on a Controlled Drugs Delivery Sheet, with each delivery requiring recipient confirmation through signature.

3.37.2 If the recipient is not the patient, the delivery driver verifies authorisation for another person to accept the medication.

3.37.3 Unsuccessful deliveries of controlled drugs are returned to the pharmacy or held in a secure facility when same-day return is not feasible. Every step is logged in the CD register.

3.38 Failed Delivery Management and Follow-Up

3.39 Failed Delivery Process:

3.39.1 For unsuccessful deliveries, the courier leaves a "Missed Delivery" card with instructions for rescheduling. Cold chain items are maintained within their temperature range, and any temperature breach results in the medication's immediate return to the pharmacy.

3.40 Controlled Drug Returns:

3.40.1 If a controlled drug cannot be delivered, it is returned to secure storage at the pharmacy on the same day. In cases where same-day return isn't feasible, the drug is stored in the courier's secure, temperature-controlled facility, ensuring regulatory compliance.

3.41 Patient Notification:

3.42 After a failed delivery, the pharmacy contacts the patient to arrange redelivery. Delivery status, attempts, and outcomes are recorded in the patient's PMR, ensuring thorough tracking and accountability.

3.43 Record-Keeping, Documentation, and Audit

3.44 Comprehensive Patient Medication Records (PMR):

3.44.1 All patient interactions, including side effects, medication changes, and clinical interventions, are meticulously logged in the PMR. This record supports ongoing patient monitoring and serves as a resource for pharmacists and prescribers during treatment reviews.

3.45 Use of a CD Register for Controlled Drugs:

3.45.1 The pharmacy maintains a CD register specifically for controlled drugs, documenting all dispensed items, returns, and storage details. Each entry is cross-referenced with the patient's prescription and the Controlled Drugs Delivery Sheet.

3.46 Audit Trail for Deliveries:

3.46.1 Delivery tracking information, along with patient signatures confirming receipt, is documented to maintain a complete audit trail. Records are stored for

regulatory inspections, supporting accountability in the case of delivery discrepancies.

3.47 Patient Education, Safety, and Feedback

3.48 Regular Patient Education:

3.48.1 Patients receive ongoing education on the correct usage, storage, and disposal of medications. Those with long-term stable conditions are reminded to consult their GP periodically regarding the continued appropriateness of their repeat prescriptions.

3.49 Encouragement for Proper Disposal of Unused Medications:

3.49.1 Patients are informed about the importance of returning unused medications to the pharmacy for safe disposal, supporting environmental responsibility.

3.50 Feedback Mechanism:

3.50.1 Patients are encouraged to provide feedback on the repeat dispensing service through online surveys or by contacting the pharmacy directly. This feedback is reviewed regularly to enhance service quality and address patient needs.

3.51 Annual Review for Long-Term Repeat Prescriptions

3.52 Comprehensive Annual Assessment:

3.52.1 For patients on long-term repeat prescriptions, the pharmacy conducts an annual assessment to evaluate medication efficacy, side effects, and overall condition stability. This review is conducted in collaboration with the GP as needed.

3.53 Prescription Renewal Verification:

3.53.1 The pharmacist regularly ensures that each long-term repeat prescription aligns with the patient's current health status and documents any modifications or updates in the PMR.

Disposal service in respect of unwanted drugs

3.54 Patient Returns and Disposal Procedures:

3.54.1 Patients or their representatives are not permitted to return unwanted medications directly to the pharmacy. To arrange the return of unwanted medicines, including controlled drugs, the patient or their representative must call the pharmacy and speak to a member of the dispensary team. If controlled drugs are being returned, the pharmacist on duty will handle the call.

3.54.2 Information on returning unwanted medications is made available on the pharmacy's website, providing patients with guidance on how to proceed.

3.54.3 Patients may return medications via:

3.54.3.1 The pharmacy's delivery driver, who will collect the items at an appointed time.

3.54.3.2A courier service arranged by the pharmacy, such as Royal Mail or a specialist medical waste contractor if applicable such as hazardous waste, at the pharmacy's expense.

3.54.4 If the patient prefers, they are signposted to nearby local pharmacies for in-person disposal.

3.55 Controlled Drugs Disposal:

3.55.1 Controlled drugs returned by patients are handled following strict guidelines. When received at the pharmacy, the controlled drugs are securely placed in a designated area in the CD cabinet, away from pharmacy stock, until they are denatured.

3.55.2 A CD denaturing kit is used following the directions specified, and the details are documented in the Patient Returned Controlled Drugs Register, with records retained for two years.

3.55.3 In cases where controlled drugs are returned via courier, they are labelled "Patient-returned CDs for destruction" and stored securely in a separate area until the destruction process.

3.56 Collection and Documentation Protocols:

3.56.1 The pharmacy driver and staff members handling returns are equipped with the appropriate protective equipment, such as gloves and materials for spillages, to safely handle returned items. Staff are also trained on the risks and procedures for handling waste medicines.

3.56.2 The driver confirms the collection booking before accepting any returns, ensuring that each item is appropriately packed and segregated. The driver will assess for controlled drugs, cytotoxic items, flammable waste, and sharps. Hazardous items are separated, labelled, and stored according to regulatory guidelines.

3.56.3 The driver keeps a "Patients Return Sheet," logging the details of the return, which is also recorded in the patient's PMR. All returned items are stored in a designated quarantine area within the vehicle during transit to ensure security.

3.57 Safe Storage and Disposal:

3.57.1 Upon arrival at the pharmacy, unwanted medicines are stored in containers provided by NHS England or an approved waste contractor. The pharmacy complies with requirements to sort solid drugs, ampoules, liquids, and aerosols into appropriate containers. Hazardous and flammable items are separated and stored until they can be collected by a specialised waste management company.

3.57.2 The pharmacy has a dedicated disposal system, partnering with a waste management company that regularly collects and disposes of returned drugs according to NHS guidelines. Disposal units are provided for the safe and compliant disposal of returned medicines.

3.57.3 Patients returning large quantities of a specific medication are flagged to the pharmacist, indicating a possible compliance issue requiring further investigation.

3.58 Informing and Assisting Patients:

3.58.1 Patients are advised not to hoard out-of-date or unwanted medicines and are reminded of this via an information label attached to their deliveries. The label includes contact details for returning items through the pharmacy's designated methods.

3.58.2 For items unsuitable for return, such as sharps, patients are directed to local disposal services, ensuring safe and compliant handling of all forms of medical waste.

3.59 Online Guidance:

3.59.1 A dedicated “Returning Unwanted Medication” page on the pharmacy’s website outlines the return process, acceptable items, and restrictions for patient guidance. This helps patients understand the proper method for returning unused medication and provides clear instructions on returning hazardous materials.

Promotion of healthy lifestyles

3.60 National and Local Health Campaign Participation:

3.60.1 The pharmacy will proactively participate in national and local health campaigns as requested by NHS England, taking part in up to six campaigns per financial year. These campaigns aim to promote public health messages covering various health issues such as diabetes, coronary heart disease, smoking cessation, and weight management.

3.60.2 To reach a broader audience, campaign materials, such as leaflets, will be included with prescription deliveries during designated campaign periods. The pharmacy’s website will host a dedicated health promotion zone, featuring up-to-date information and interactive resources on ongoing campaigns.

3.60.3 Additionally, the pharmacy will leverage email, text messages, and prescription delivery to inform patients about campaign details and encourage them to engage with health resources on the website.

Prescription-Linked Interventions:

3.60.4 When the pharmacy receives a prescription, whether electronic or non-electronic, the pharmacist will assess whether the patient has a condition or risk factor that aligns with specific health issues, such as diabetes, high blood pressure, or smoking. If appropriate, the pharmacist will provide tailored advice to increase the patient's understanding of these health issues and the importance of lifestyle modifications.

3.60.5 This advice will be supplemented with written materials, such as informational leaflets, and the patient may be referred to additional resources, such as local health services or support groups, to further support their health and wellbeing.

3.60.6 To ensure continuity of care, the pharmacist will document all relevant interactions in the Patient Medication Record (PMR), enabling follow-up care and auditing. These records will allow the pharmacy to monitor the effectiveness of interventions and maintain compliance with regulatory requirements.

3.61 Identification and Targeting of Patients for Health Promotion:

3.61.1 The pharmacy will identify patients who may benefit from targeted health promotion efforts based on their medical conditions or risk factors, including those with COPD, asthma, high blood pressure, or those who are overweight or smoke. These patients will receive additional resources tailored to their specific health needs, with a focus on preventative care and lifestyle improvements.

3.61.2 Promotional materials tailored to these conditions will accompany prescription deliveries, and patients will be directed to specific online resources for further information and guidance. This targeted approach allows the pharmacy to address high-risk groups effectively, contributing to the overall promotion of healthier lifestyles.

3.62 Documentation and Record-Keeping:

3.62.1 For each health campaign, the pharmacy will record the number of patients who received campaign materials or engaged with the pharmacy's resources. Where required by NHS England, this information will be submitted electronically, ensuring that the data is anonymised to maintain patient confidentiality.

3.62.2 Detailed records of advice given and any materials provided during prescription-linked interventions will be maintained, allowing the pharmacy to evaluate the impact of these campaigns on patient outcomes. This documentation will support the auditing process and facilitate the pharmacy's compliance with NHS England's reporting requirements.

3.63 Patient Education and Digital Resources:

3.63.1 The pharmacy's website will serve as a central hub for health promotion, offering patients access to a range of educational materials and tools. Resources will cover topics such as diabetes management, heart disease prevention, blood pressure control, and smoking cessation, with the content regularly updated to align with ongoing health campaigns.

3.63.2 In addition to the website, the pharmacy will engage patients through email newsletters and app-based notifications, which will include tips for maintaining a healthy lifestyle and updates on upcoming health campaigns. This multi-channel approach ensures that patients are consistently reminded of the importance of healthy living.

3.64 Clinical Audits and Health-Related Interventions:

3.64.1 As part of its commitment to promoting public health, the pharmacy will conduct at least one clinical audit annually. This may include evaluating the effectiveness of health campaigns or identifying opportunities for improvement in patient care. The audits will be conducted via telephone consultation or web-based questionnaires.

3.64.2 For patients involved in prescription-linked interventions, the pharmacy will track their engagement with recommended resources and assess their progress in managing conditions such as diabetes, high blood pressure, and smoking cessation. This will enable the pharmacy to refine its approach to

health promotion and contribute to the continuous improvement of NHS England's public health initiatives.

Prescription-Linked Intervention

3.65 Patient Identification for Intervention:

3.65.1 Active Identification: Patients are identified through the use of a Lifestyle Questionnaire available on the pharmacy's website or via postal return. Patients can voluntarily complete this questionnaire, which gathers information on medical conditions, lifestyle habits, and risk factors.

3.65.2 Passive Identification: Dispensary staff may identify patients who appear to have risk factors such as diabetes, high blood pressure, smoking habits, or being overweight during interactions such as prescription dispensing or repeat prescriptions.

3.65.3 Prescription Review: During each dispensing process, pharmacists and staff review the patient's prescription history and any available PMR (Patient Medication Record) notes to determine if the patient falls into one of the risk categories.

3.66 Providing Tailored Advice:

3.66.1 For patients identified as having diabetes, high blood pressure, coronary heart disease risk, smoking habits, or overweight issues, pharmacists provide lifestyle advice aimed at increasing their understanding of health-related issues.

3.66.2 Advice is delivered through multiple channels:

3.66.2.1 Verbal Communication: Advice can be provided via telephone or video consultations, tailored to each patient's circumstances.

3.66.2.2 Written Materials: Leaflets and other educational resources are included with prescription deliveries to reinforce verbal advice and provide additional guidance.

3.66.2.3 Digital Resources: Patients are directed to the pharmacy's website, which features a Health Promotion Zone with targeted information on managing conditions such as diabetes, heart disease, and smoking cessation.

3.67 Documentation and Follow-Up:

3.67.1 Each interaction involving health advice is recorded in the patient's PMR to ensure continuity of care and provide an audit trail for quality assurance.

3.67.2 The recorded information facilitates follow-up interactions, ensuring that the pharmacist can provide ongoing support tailored to the patient's health needs.

3.67.3 For patients requiring further assistance, the pharmacist may provide referrals to external healthcare providers or support organisations, with these referrals also documented in the PMR.

3.68 Audit and Reporting:

3.68.1 The pharmacy maintains records of interventions for auditing purposes, allowing for periodic review to evaluate the effectiveness of health advice provided.

3.68.2 These records also support any required reporting to NHS England regarding the number of patients advised and the types of advice provided, ensuring compliance with NHS public health campaign goals.

Public Health Campaigns

3.69 As part of the NHS Terms of Service, the pharmacy will participate in up to six public health campaigns per financial year, as requested by NHS England, to promote health messages to our patients and the broader community. These campaigns will be conducted in a manner that ensures accessibility to all patients, utilising both digital and non-digital methods for maximum reach.

3.70 Campaign Participation

3.70.1 The pharmacy will proactively participate in both national and local health campaigns. Campaign materials, including leaflets and brochures, will be sent out with patient prescriptions during targeted periods. Additionally, information will be accessible on the pharmacy's website, where a dedicated section for health promotion will be regularly updated.

3.70.2 The website will feature HTML5 banners promoting current health campaigns, linking directly to relevant content. This ensures that campaign information is easily accessible to all patients, regardless of their location.

3.70.3 Campaign messages will be further disseminated through emails and text messages, directing patients to the pharmacy's website and other credible health resources. This non-face-to-face method of communication enables broad outreach, ensuring continuous access to information.

3.71 Recording and Reporting

3.71.1 During each campaign, dispensary staff will maintain records of the number of patients who receive health promotion materials. This will include a count of leaflets distributed with prescriptions and any advice given during telephone or video consultations.

3.71.2 In cases where a patient's interaction involves campaign-specific advice, a note will be made on their Patient Medication Record (PMR) to facilitate future audits and potential follow-up care.

3.71.3 Where requested by NHS England, the pharmacy will submit anonymised data on the number of patients reached and any additional requested information to assist in evaluating the campaign's effectiveness and to support policy development. Data will be submitted via electronic communication as specified by NHS England.

3.72 Patient Interaction and Advice

3.72.1 Dispensary staff will use prescription interactions to provide campaign-related health advice to patients with specific conditions such as diabetes, coronary heart disease, obesity, or high blood pressure. Advice will be tailored to each

patient’s individual health needs and will aim to improve their understanding of the campaign's health messages.

3.72.2 Advice may include lifestyle recommendations, such as smoking cessation support, weight management tips, or dietary guidance, based on the campaign focus. Patients requiring further assistance will be signposted to appropriate healthcare providers or support organisations as necessary.

3.73 Non-Face-to-Face Campaign Support

3.73.1 The pharmacy will utilise non-face-to-face methods to support public health campaigns. Patients will be encouraged to access additional resources on the pharmacy website and in digital newsletters.

3.73.2 Campaign-specific pages on the website will include outbound links to recognized health organisations, providing patients with reliable information on topics relevant to the campaigns.

3.73.3 For patients who prefer physical materials, campaign leaflets will be included with their prescription deliveries, ensuring they have access to information in a format that best suits their needs.

3.74 Community Engagement and Feedback

3.74.1 The pharmacy will also conduct at least one community engagement exercise annually to promote healthy living. Feedback from patients will be collected through online surveys or direct communication, allowing the pharmacy to assess the impact of the campaigns and identify areas for improvement.

3.74.2 Campaign effectiveness and patient reach will be reviewed periodically, with the results used to enhance future health promotion efforts. This ensures that the pharmacy not only meets NHS requirements but also continuously strives to improve the quality of service for its patients.

Signposting

3.75 Identification During Interactions:

3.75.1 Pharmacy staff will assess each patient interaction (over the phone or through the website) for signs that a patient may require services beyond the scope of the pharmacy.

3.75.2 Patients who have completed a Lifestyle Questionnaire on the website, or those identified through health promotion activities, will also be assessed for additional service needs.

3.76 Referral Process:

3.76.1 If it is determined that a patient requires advice, treatment, or support that the pharmacy cannot provide, staff will:

3.76.1.1Provide contact details for suitable health or social care providers.

3.76.1.2Where possible, offer at least two providers for the patient to consider.

3.76.1.3 Record the information given to the patient in the Patient Medication Record (PMR) to facilitate follow-up care and ensure continuity.

3.77 Use of Resources for Effective Signposting:

3.77.1 Staff will utilise resources such as NHS Choices, Health and Wellbeing Boards, and Local Area Teams to identify and provide accurate contact information for healthcare providers.

3.77.2 The pharmacy's website will have a dedicated section for signposting, listing national and local health resources, emergency contact information, and a directory of support services.

3.78 Prescription Linked Signposting:

3.78.1 If the pharmacy is unable to provide a specific appliance or treatment, the following steps will be taken:

3.78.2 With patient consent, refer the prescription to another NHS pharmacy or appliance contractor.

3.78.3 If consent is not given, the pharmacy will provide contact details for at least two other providers who can fulfil the prescription.

3.78.4 Document the referral or information provided in the PMR to ensure thorough record-keeping and allow for auditing.

3.79 Recording and Maintaining Signposting Information:

3.79.1 All signposting interactions, including contact details provided and referrals made, will be documented in a manner that supports auditing and facilitates follow-up care.

3.79.2 In situations where advice or signposting information is provided over the phone, via email, or through video consultations, records will be kept to support ongoing patient management and compliance with regulatory standards.

3.80 Staff Training and Competency:

3.80.1 All pharmacists and staff will undergo Continuous Professional Development (CPD) training focused on effective signposting.

3.80.2 Training will cover the use of NHS resources, such as the "Services Near You" application on NHS Choices, to find suitable providers and support networks for patients.

3.80.3 The Responsible Pharmacist will ensure that staff are aware of available resources and are able to make appropriate referrals based on the patient's needs and location.

3.81 Additional Protocols for Out-of-Hours Support:

3.81.1 During non-operational hours, the pharmacy's website will direct patients to alternative resources such as the NHS 111 service or emergency contacts.

3.81.2 For non-urgent inquiries, patients can leave messages to be followed up during the next available working hours.

Support for self care

3.82 Patient Identification and Needs Assessment:

3.82.1 Pharmacy staff will identify patients needing self-care support during interactions and assess whether their needs can be met by self-care advice or require referral to another provider.

3.82.2 Staff will utilise a checklist during patient interactions to determine if the patient's symptoms, condition, or medication needs could be met with non-prescription treatment or lifestyle adjustments.

3.83 Provision of Advice on Treatment Options:

3.83.1 Patients and carers will receive guidance on appropriate non-prescription medicines, with specific recommendations tailored to the condition (e.g., analgesics for pain management or antihistamines for allergies).

3.83.2 Each OTC treatment recommended will include clear usage instructions, precautions, and potential side effects to promote safe and effective use.

3.83.3 If necessary, patients will be educated on appropriate lifestyle changes to help manage or alleviate symptoms. For example, advice on diet and exercise will be provided to help manage chronic conditions like hypertension, diabetes, or obesity.

3.84 Encouragement of Lifestyle Modifications:

3.84.1 Pharmacy staff will offer advice on healthy lifestyle changes based on the patient's specific medical condition, including guidance on physical activity, dietary modifications, smoking cessation, and other relevant health behaviours.

3.84.2 Where appropriate, patients will receive printed leaflets or access to online resources through the pharmacy's website, ensuring that advice can be reinforced beyond the consultation.

3.85 Signposting and Referral to Other Providers:

3.85.1 When the pharmacy cannot meet the patient's needs directly, staff will refer the patient to appropriate healthcare or social service providers. This includes situations requiring specialist services or facilities for services like stoma appliance customization.

3.85.2 Staff will provide contact details for at least two providers, when available, and ensure the patient is fully informed of their options.

3.86 Record-Keeping and Follow-Up:

3.86.1 All advice given, including specific recommendations for non-prescription treatments and lifestyle adjustments, will be recorded in the Patient Medication Record (PMR).

3.86.2 The PMR entry will facilitate follow-up care, allowing pharmacy staff to review previous advice and track the patient's progress.

3.86.3 When follow-up is necessary, the pharmacist may arrange a callback or email follow-up, ensuring that patients have ongoing support for their self-care practices.

3.87 Staff Training and Competency:

3.87.1 Staff will undergo regular training on supporting self-care effectively and providing tailored recommendations for OTC medications and lifestyle advice.

3.87.2 Training will also cover documentation practices to ensure records are comprehensive, support auditing, and facilitate continuity of care.

Discharge Medicine Service

3.88 Secure Referral Management

3.88.1 Referral Systems: The pharmacy uses secure electronic systems such as NHSmail, PharmOutcomes, and Refer to Pharmacy to receive DMS referrals. These systems are checked at 9 am, 12 pm, and 4 pm on days the pharmacy is open to promptly act on referrals.

3.88.2 Handling Referrals in Error: If a referral is received in error, the pharmacy will promptly notify the referring NHS Trust and assist in redirecting the referral to the correct pharmacy, ensuring that patient care is not delayed.

3.89 Patient Consent and Data Sharing

3.89.1 Consent Protocol: Consent from the patient is obtained by the referring trust and reconfirmed at the beginning of the DMS service. Patients are informed that they can withdraw consent at any time, which would impact subsequent stages. Consent is explicitly documented in the patient's record.

3.89.2 Data Sharing with Healthcare Providers: Where clinically appropriate and with the patient's consent, any relevant information will be shared with the patient's GP or Primary Care Network (PCN) pharmacy team to support ongoing care, utilising secure NHSmail for data transmission.

3.90 Access to Summary Care Record (SCR)

3.90.1 SCR Verification: The pharmacist will access the Summary Care Record (SCR) with patient consent to verify medication details or clarify the patient's medication history. This additional check helps ensure that medication information is accurate and up-to-date.

3.91 Patient Follow-Up and Support Tools

3.91.1 Adherence Support through Digital Tools: The pharmacy provides patients with recommendations for digital tools, such as medication reminder apps, to help them adhere to their new medication regimen post-discharge.

3.91.2 High-Risk Medication Counselling: For patients prescribed high-risk medications, such as anticoagulants, the pharmacist will provide additional

counselling on potential side effects, adherence importance, and any specific administration guidelines.

3.92 Record-Keeping for Audit and Follow-Up

3.92.1 Comprehensive Documentation: Each stage of the DMS will be thoroughly documented on the patient's PMR, including all actions, interactions, and any concerns raised. This documentation is critical for audit purposes and supports follow-up care.

3.92.2 Monthly Reporting: The pharmacy submits data on DMS cases through the MYS portal at the end of each month, ensuring an accurate record of service delivery. Reports will include details of each stage completed, allowing for service evaluation and payment processing.

3.93 Fallback and Escalation Procedures

3.93.1 Protocol for Uncontactable Patients: If a patient cannot be contacted for stages 2 or 3, the pharmacy will make reasonable attempts to reach them. Should contact not be possible, the patient's GP will be notified, and the case will be documented accordingly.

3.93.2 Escalation for Unresolved Issues: If issues arise that cannot be directly resolved with the patient's GP, the pharmacy will escalate to a PCN pharmacist or specialist, as appropriate, ensuring that patient care remains comprehensive and uninterrupted.

3.94 Service Delivery and Confidentiality

3.94.1 Confidential Consultations: All DMS consultations are conducted via secure phone or video call, ensuring patient confidentiality. A dedicated consultation room is used for these discussions to maintain privacy.

3.94.2 Commitment to Confidentiality: All patient information is handled following NHS confidentiality guidelines. Patient records, electronic communications, and verbal consultations are conducted with the highest regard for privacy.

3.95 Post-Discharge Education and Patient Engagement

3.95.1 Provision of Educational Materials: Patients are provided with digital resources or emailed educational materials on medication adherence, lifestyle changes, and self-care following discharge.

3.95.2 Encouraging Patient Questions: The pharmacy actively encourages patients to ask questions regarding their medication. This ensures that patients understand their treatment plan and feel supported, reducing the risk of medication errors or non-adherence.

3.96 Discharge Medicines Service Stages

3.96.1 Stage 1 - Receipt of Discharge Referral:

3.96.1.1 The referral is reviewed within 72 hours, with any issues raised to the referring hospital or the patient's GP.

3.96.1.2 The pharmacist compares pre- and post-discharge medication lists, checking any previous prescriptions for relevance and safety.

3.96.1.3 Notes are added to the patient's PMR, with alerts set for subsequent stages to ensure continuity of care.

3.96.2 Stage 2 - First Prescription Post-Discharge:

3.96.2.1 The first prescription following discharge is reviewed against the referral and PMR. Any discrepancies are discussed with the patient's GP, and necessary adjustments are recorded.

3.96.2.2 If contact is not possible with the patient or if the patient withdraws consent, the GP will be notified, and the PMR updated accordingly.

3.96.3 Stage 3 - Patient Engagement:

3.96.3.1 The pharmacist contacts the patient (or their carer) for a confidential discussion on their medication regimen, addressing any questions and promoting a shared decision-making approach.

3.96.3.2 If needed, the patient is offered disposal services for unneeded medication and additional services, such as the New Medicines Service (NMS), where eligible.

3.96.3.3 Details of the discussion are recorded on the PMR, with relevant information shared with the patient's GP to support ongoing care.

Website & Health Promotion Zone

3.97 Website Purpose and Accessibility

3.97.1 The website will be designed for public use, enabling users to easily access pharmaceutical services remotely. Upon initial access, users will encounter a prominently displayed interactive page.

3.97.2 This interactive page will serve as the entry point to a health promotion zone, where users can access a variety of up-to-date resources aimed at promoting healthy lifestyles. This zone will address a wide range of health issues, such as diabetes, heart disease, hypertension, smoking cessation, and obesity.

3.98 Content and Material Management

3.98.1 The Superintendent Pharmacist will oversee the maintenance of this section, ensuring the materials are current and cover a reasonable range of health topics. This will include articles, leaflets, and multimedia content on lifestyle changes, dietary advice, exercise tips, and general health maintenance.

3.98.2 The health promotion zone will also include specific information related to national and local health campaigns as directed by NHS England. All materials will be reviewed and updated regularly to reflect ongoing and seasonal health campaigns, such as flu vaccination drives or mental health awareness initiatives.

3.99 Interactive Features

3.99.1 Users will be prompted to engage with tools such as health assessment quizzes, interactive lifestyle questionnaires, and links to external resources for further information.

3.99.2 The website will include sections for self-assessment questionnaires and forms that users can complete to receive personalised recommendations and feedback based on their responses. For example, if a user indicates a risk of heart disease, the site will display relevant resources on heart health.

3.100 Promotion of Health Campaigns

3.100.1 The health promotion zone will actively highlight current health campaigns through banners on the homepage, pop-ups, and targeted email notifications for registered users. Users can subscribe to receive email or SMS updates on new campaigns, ensuring that they remain informed of upcoming or ongoing health initiatives.

3.100.2 The website will also provide links to reputable external health sources, such as NHS Choices, to further support users in accessing information on common conditions and preventive care.

3.101 User Engagement and Feedback

3.101.1 An on-site feedback form will be available for users to share their thoughts on the resources provided. The pharmacy team will review this feedback regularly to make improvements to the materials offered.

3.101.2 To facilitate accessibility, the website will be compatible with assistive technologies, and content will be provided in a range of formats (e.g., downloadable PDFs, video, and text) to cater to different user needs and preferences.

3.102 Tracking and Record-Keeping

3.102.1 A system will be in place to record user interactions with the health promotion zone. This data will assist in auditing website traffic related to health campaigns and user engagement. While this data will be anonymized, the pharmacy will maintain records of these interactions for evaluation and to improve the range of services offered.

3.102.2 The health promotion materials on the website will be reviewed monthly, with records kept of updates to ensure compliance with NHS England requirements and to support the ongoing development of the website's health resources.

Website Details:

3.103 Compliance and Security:

3.103.1 The pharmacy will be registered with the GPhC as a distance-selling pharmacy, ensuring full compliance with GPhC regulations.

3.103.2 The website will adhere to information security management standards and data protection laws. Secure and encrypted methods will be used for collecting, storing, and using patient information, as well as for processing card payments.

3.103.3 All information on the website will be clear, accurate, and regularly updated to meet current standards and patient needs.

3.104 Prominent Website Information:

3.104.1 The website will prominently display the following details:

3.104.2 The GPhC pharmacy registration number (once acquired)

3.104.3 The name of the pharmacy owner

3.104.4 The name of the superintendent pharmacist

3.104.5 The name, address, phone number, and email of the registered pharmacy supplying medicines

3.104.6 A link to the GPhC website to verify the registration status of the pharmacy and the superintendent pharmacist

3.105 Details When Listed on the NHS Pharmaceutical List:

3.105.1 Information on specific services available, along with clear guidance on how to use each service.

3.105.2 An explanation of the rules around face-to-face contact near or in the pharmacy and the reasons that services cannot be provided in these instances.

3.106 Details on the return process for unwanted medicines.

3.106.1 Access to a Patient Lifestyle Questionnaire to support patient engagement and health awareness.

3.106.2 Information on how patients can register for exemptions from NHS charges.

3.106.3 Promotion of healthy lifestyles, including information on health campaigns currently being undertaken.

3.106.4 Procedures for emergency supplies.

3.106.5 Regular patient surveys conducted at least annually to gather feedback and improve services.

3.106.6 Contact information, including the pharmacy's phone number and email address.

3.106.7 A downloadable Patient Information Leaflet that highlights all services provided by the pharmacy, and the manner in which they will be provided

3.106.8 A dedicated section for patients to give feedback, raise concerns, and access the pharmacy's complaints procedure.

3.107 Enhanced Patient Accessibility and Engagement:

3.107.1 Accessibility: The website will be designed to meet Web Content Accessibility Guidelines (WCAG) standards, ensuring that it is usable by people with disabilities, including screen reader compatibility and adjustable text sizes.

3.107.2 FAQ Section: A comprehensive FAQ section will be included to address common patient questions about pharmacy services, exemptions, delivery procedures

3.107.3 User Experience (UX): A user-friendly navigation menu will make it easy for patients to locate information on services, NHS charge exemptions, and contact details.

3.107.4 Live Chat Support: The website will offer live chat support or an AI-driven chatbot, allowing patients to receive immediate assistance and answers to their questions in real-time, improving patient engagement and satisfaction. The chatbot will be used as a tool for customer service and will not be used to provide medical advice

3.107.5 Privacy Policy and Terms of Use: Clearly accessible links to the website's privacy policy and terms of use will be provided, ensuring transparency regarding how patient data is handled and used.

3.107.6 Service Updates and News: A section or blog will be dedicated to pharmacy updates, health tips, and news on ongoing campaigns. This will help patients stay informed about any changes in services, as well as important health information and promotions.

3.108 Security and Data Protection:

3.108.1 Secure Communication: All forms of communication on the website, including patient registration and feedback forms, will use encrypted channels to protect patient data.

3.108.2 Card Payment Processing: Secure payment gateways will be used to ensure safe and compliant processing of patient payments, adhering to PCI-DSS standards for data security."

4 Summary of Representations

After reviewing the appeal and the paperwork provided by the Commissioner, NHS Resolution applied its discretion under Schedule 3, Part 3, paragraph 7 and allowed the Applicant, to make comments on Community Pharmacy BLMK & Northants' [late] representations. This is a summary of representations received on the appeal.

4.1 The Applicant

4.1.1 "I believe that the contents of my grounds for appeal should cover any representation I want to make against BLMKs representation, since I received it as part of the decision letter.

4.1.2 I would prefer to avoid any further delay and do not wish to submit anything further at this stage. My grounds for appeal can be used as my response to BLMKs representation."

4.2 The Commissioner

4.2.1 "Please note that from the 1 April 2023, community pharmacy contracting and commissioning has been delegated to Integrated Care Boards (ICBs). Hertfordshire and West Essex (HWE) ICB are hosting the function on behalf of

the six East of England ICBs. The six ICBs have formed one Pharmaceutical Services Regulation Committee (PSRC) which is also hosted by HWE ICB.

4.2.2 Please find below information we wish to be considered in relation to EMWHY PHARMA LTD.

4.2.3 EMWHY PHARMA LTD are appealing against the decision to refuse their application for inclusion in the pharmaceutical list to provide pharmaceutical services as a distance selling pharmacy under Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the Regulations).

4.2.4 The appellant sets out 5 grounds for their appeal. For ease of reference, each point is detailed below with our response and observations underneath:

4.2.5 Representation from BLMK: I did not receive any representation from BLMK, which was dated 18th June.

4.2.5.1 It is noted the BLMK representations were received outside the 45-day period. It is acknowledged that these should have been circulated, giving parties the opportunity to respond. We note the appellant has now had the opportunity to respond and has provided additional information as part of the appeal.

4.2.6 Character Limit on the Application Form

4.2.6.1 We note the comment by the appellant in regard to the character limit on the Application Form accessed via Primary Care Support England (PCSE). PCSE is commissioned on behalf of NHS England and although there is a character limit, there is the opportunity to attach documents as part of an application. No additional documents were attached or submitted.

4.2.7 Guidance on SOPs: The application form explicitly indicated that Standard Operating Procedures (SOPs) were not required.

4.2.7.1 SOPs are not required however the applicant does need to demonstrate that the requirements of the Regulations are met. The PSRC was required to make a decision based on the information available to it at the time. When the PSRC made the determination, it did not have the information now supplied on appeal by the appellant (the additional 170 pages). It is recognised that had this information been available to PSRC, a different determination may have been made.

4.2.8 Vagueness of the Decision Letter: The language in the decision letter was unclear, with phrases such as "might be satisfied," "must be satisfied," and "should be satisfied" used in different sections without clear correlation.

4.2.8.1 On reflection it is noted the decision wording could be clearer.

4.2.8.2 The decision was made following an assessment of each regulatory requirement against the information and evidence provided. There was very limited evidence provided to satisfy each of the essential services in paragraphs 3 to 22 of Schedule 4 of the Regulations.

4.2.9 Compliance with Regulation 25: I believe that the proposed distance-selling pharmacy will fully comply with Regulation 25. However, I do not feel that the initial application allowed for a proper representation of our compliance. An appeal would give me the opportunity to submit more comprehensive information, including the prepared SOPs, to demonstrate our compliance and satisfy all of the Committee's requirements.

4.2.9.1 As acknowledged by the appellant, the appeal has provided the opportunity to submit more comprehensive information to demonstrate compliance with the Regulations. If this information had been made available to the PSRC, demonstrating that all requirements were met, the decision may have been different.

4.2.10 We note that NHS Resolution will have regard to all information provided to date including the revised and additional information submitted by the appellant as part of this appeal."

5 Summary of Observations

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

6 Consideration

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

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

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

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

Regulation 31

6.5 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") 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).

6.6 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.

6.7 In the decision letter, the Commissioner stated that *"The Committee noted that no pharmacy existed or was said to exist at or adjacent to the proposed location. In addition, there was no person on the pharmaceutical list providing or undertaking to provide pharmaceutical services from or adjacent to the premises"*. The Committee noted this had not been disputed by any party.

6.8 The Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

6.9 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 essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff."

6.10 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)

6.11 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)

6.12 As far as Regulation 25(2)(a) is concerned, 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 noted that the premises in respect of which the application was made, is not on the same site or in the same building as the premises of a provider of primary medical services with a patient list."*

6.13 Based on the information available to it, which had not been disputed by any party, 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)

6.14 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, including its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.

6.15 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, in a safe and effective way, across England, and without face to face contact.

6.16 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.

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

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

6.19 The Committee considered how the Applicant would provide essential services without interruption and noted the Applicant's SOPs under the following headings:

6.20 End of Shift Procedures

6.20.1 *"The RP no longer feels able to undertake RP duties, in which case the Pharmacy Superintendent must be contacted immediately."*

6.21 Absence of the RP

6.21.1 *"As a Distance Selling pharmacy, an uninterrupted service must be maintained throughout operating hours.*

The rules differ to non-Distance Selling pharmacy where the RP can be absent, for up to 2 hours per day, therefore the RP cannot be absent unless another pharmacist is present to continue the provision of these services

A second pharmacist should be available during core and additional hours. If the RP needs to leave the premises or take a break, the second pharmacist must sign in as the RP."

6.22 Preparing for the Absence of the RP

6.22.1 *"Notify the second pharmacist of the departure time and expected duration of absence.*

Check the Pharmacy RP Record to ensure that the RP absence complies with permitted time limits.

Continue to display the RP notice.

Make an entry in the Pharmacy RP Record indicating the start time and reason for the absence.

Inform the pharmacy team of the expected return time and contact details in the RP's absence.

The RP must remain contactable during the absence or designate another pharmacist for support. The pharmacy team must be informed that the second pharmacist will be responsible during the RP's absence."

6.23 During the Absence of the RP

6.23.1 *"All pharmacy team members must adhere to the SOPs established by the RP.*

Monitor the duration of the RP's absence.

If the absence exceeds 2 hours: The second pharmacist must assume the RP role, and the Superintendent Pharmacist should be informed that only one pharmacist is on duty.

The pharmacy must contact the RP for additional instructions and an estimated return time.

The pharmacy must contact the RP for additional instructions and the estimated time of return."

6.24 With regard to services being available to persons anywhere in England, the Committee noted in the Applicant's SOPs under the following headings:

6.25 Overriding Provisions Applicable to All SOPs

6.25.1 *"All pharmacy staff must note that this pharmacy operates in accordance with specific approval under the Regulations and these premises are 'Distance Selling Premises'. In order to comply with our terms of service, this pharmacy will provide;*

The uninterrupted provision of essential services…to persons anywhere in England who request those services."

6.26 Communication Channels

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

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

6.27 The Committee considered how the Applicant would provide essential services without face to face contact and noted the following in the application form:

6.27.1 *"No entry is granted to the pharmacy premises except to pharmacy staff, except with prior booking for Advanced or Enhanced Services."*

6.28 The Committee also noted the following in the Applicant's SOPs under several headings.

6.29 Introduction and Background to SOPs

6.29.1 *"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 Services either on or in the vicinity of the premises.*

Face to face contact with patients or their representatives either on or in the vicinity of the premises is only allowed in respect of the provision of services other than Essential Services.

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

6.30 Communication Channels

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

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

6.31 The Committee was satisfied that the provision of services would be without interruption, would be without face to face contact and would be available to persons anywhere in England. The Committee went on to consider whether safe and effective provision of essential services was likely to be secured.

6.32 The Committee considered each essential service in paragraphs 3 to 22 of schedule 4 of the Regulations ("Terms of Service") in turn.

6.33 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:

6.33.1 Dispensing of drugs and appliances

6.33.2 Urgent supply without a prescription

6.33.3 Preliminary matters before providing ordered drugs or appliances

6.33.4 Providing ordered drugs or appliances

6.33.5 Refusal to provide drugs or appliances ordered

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

6.33.7 Disposal service in respect of unwanted drugs

6.33.8 Promotion of healthy lifestyles

6.33.9 Prescription linked intervention

6.33.10 Health campaigns

6.33.11 Signposting

6.33.12 Support for self-care

6.33.13 Discharge medicines service

6.33.14 Websites and health promotion zones

6.34 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

6.35 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). The Committee noted the Commissioner's findings on this point and was mindful that it had been provided with SOPs on appeal, which the Commissioner had not been provided with when it considered the application.

6.36 In relation to cold chain deliveries, the Committee noted the information in the Applicant's SOPs under the following headings:

6.37 Order Delivery

6.37.1 *"Transfer to the Delivery Driver*

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

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

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

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

Ensure that any deliveries for fridge items and CDs are taken out of storage when appropriate.

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

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

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

6.37.2 *"Cold chain delivery via courier*

All cold chain deliveries must be carried out by couriers with verified and approved cold chain procedures. A list of approved cold chain couriers is available within the Pharmacy and will be updated from time to time.

Each approved courier meets stringent criteria to ensure a fully monitored and dedicated cold chain service.

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

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

…Ensure any items for cold chain delivery via courier are stored in the fridge and accompanying items are appropriately marked with a fridge line sticker. Accompanying items 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.

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

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

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

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

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

Confirm details of all prescriptions to be delivered.
The courier must scan a barcode sticker for each item. The pharmacy retains a copy of the barcode which is also the tracking number."

6.37.3 *"Unsuccessful cold chain delivery via courier*

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

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

6.37.4 *"Breach of Integrity of Cold Chain*

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

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

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

6.38 The Committee also noted the information in the appeal under the following headings:

6.39 Preparation for Delivery:

"…cold chain items are placed in insulated boxes such as polystyrene lined to maintain the appropriate temperature. The pharmacist ensures that each package includes proper labelling and handling instructions.

Special Instructions: The pharmacist attaches specific instructions for the delivery driver… for keeping cold chain items refrigerated…"

6.40 Delivery Execution and Security:

"Local Deliveries: Our Enhanced DBS-checked driver is trained to follow a secure delivery protocol. This includes ID verification, obtaining a signature, and transporting medications in a locked and/or temperature-controlled vehicle when necessary.

…Courier Deliveries: For deliveries beyond the local area, we use approved couriers such as Royal Mail, DHL Medical Express or Polarspeed for cold chain items. Couriers follow strict protocols, such as temperature monitoring and secure handling for controlled drugs. They are required to notify the pharmacy immediately in the event of a failed delivery attempt, and medications are returned to a licensed storage facility if not delivered…

Cold Chain Integrity: Cold chain medications are monitored continuously during transit."

6.41 Cold Chain and Controlled Drugs Protocols

"…Our employed driver will carry a digital monitor that logs temperature during transit. Third party couriers are expected to have a full audit trail of temperature logs during transit and this will be requested."

…Cold Chain Medication Handling: Medications requiring refrigeration are managed under strict cold chain protocols. These items are packaged in temperature-controlled containers (2-8°C).

Cold Chain Breach Protocol: If a temperature breach occurs, the delivery is immediately returned to the pharmacy, and a replacement is arranged. The patient is notified promptly, and any breached medication is disposed of safely in accordance with regulatory standards."

6.42 Failed Delivery Management and Follow-Up

"For unsuccessful deliveries, the courier leaves a "Missed Delivery" card with instructions for rescheduling. Cold chain items are maintained within their temperature range, and any temperature breach results in the medication's immediate return to the pharmacy."

6.43 Whilst the Committee noted the information in the Applicant's SOPs indicated that cold chain items would be delivered by a specialist courier, it noted the appeal letter indicated that the Applicant was also proposing to use their own delivery driver. With regard to local deliveries, the Committee noted that no information was provided to outline the procedure that would be followed in the event of a failed/missed delivery. It noted that the relevant sections in the appeal and Applicant's SOPs only referred to the process that would be followed by the courier. Therefore the Committee could not be satisfied that the cold chain would be maintained in the event of a failed/missed delivery by the pharmacy's own driver.

6.44 Based on the information before it, the Committee was therefore not satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

6.45 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.

Other considerations

6.46 The Committee noted that the Commissioner had refused the application on the basis that "*the requirements set out in Regulation 25 were not met*". The Committee noted the unclear findings from the Commissioner in relation to certain aspects of the Terms of Service. Taking into account the additional information provided by the Applicant on appeal, the Committee considered these areas of the Terms of Service in more detail.

Dispensing of drugs and appliances

6.47 The Committee considered whether the Applicant had explained how non-electronic prescriptions will be presented by the patient and how products will be provided. The Committee noted the Commissioner was not satisfied that it had but the Committee was mindful that it had been provided with SOPs on appeal which the Commissioner had not been provided with when it considered the application.

6.48 The Committee noted the information in the application which was also highlighted by the Commissioner in its decision letter:

6.48.1 *"Dispensing medicines - Pick up service for paper prescriptions from patients location (usually home) by courier or mail. Electronic prescriptions sent directly from prescriber Medicines delivered to patient by courier."*

6.49 The Committee further noted the information in the Applicant's SOPs under the following headings:

6.50 EPS Dispensing Process

6.50.1 *"Patients must have nominated the community pharmacy for their electronic prescriptions to be automatically retrieved or manually pulled down by that pharmacy using the Electronic Prescription Service."*

6.51 Online Order Receipt & Exemption Checking

6.51.1 *"Scope…All online services including the following:*

Requests to collect and dispense NHS Prescriptions.

Requests to dispense a prescription received in the post.

Any requests from the "contact us" section of the website".

6.52 Prescription Order Processing

6.52.1 *"Administration Checks*

Check all prescriptions received in the post against printed and written prescription reception forms.

Check the corresponding prescription has been received in the post and match with the received and printed order by confirming the unique voucher number, patient name, address and DOB.

The cost of sending non-electronic prescriptions will be covered by the pharmacy"

6.53 Order Delivery

6.53.1 *"Choice of Delivery Method*

For items other than cold chain / "fridge line" items, local deliveries (up to 35 miles radius, but may be extended at the discretion of the RP) the delivery driver should deliver medication. Outside this area Royal Mail should be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier should be used (see SOP for Delivery of Controlled Drugs), or the items are fridge lines, in which case the cold chain courier should be used (see below)."

6.54 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, and was of the view that the Applicant would not be just serving the immediate locality using a local delivery driver. The Committee was satisfied that the Applicant's SOPs had explained how patients could post their paper prescriptions free of charge.

6.55 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 5(2)(3) of Schedule 4.

Urgent supply without a prescription

6.56 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. The finding of the Commissioner in its decision letter is unclear on this aspect. The Committee was mindful that it had been provided with SOPs on appeal which the Commissioner had not been provided with when it considered the application.

6.57 The Committee noted the information in the Applicant's SOPs under the heading "Emergency Supply and Urgent Supply" which describes how the Applicant will process such a request. The Committee noted that the SOPs refer to Essential Services being delivered by several means of non-face-to-face communication including telephone and email, and considered that it was reasonable to infer that these methods would be used to receive requests from prescribers for the urgent supply of drugs.

6.58 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.

Preliminary matters before providing ordered drugs or appliances

6.59 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. The finding of the Commissioner in its decision letter is unclear on this aspect. The Committee was mindful that it had been provided with SOPs on appeal which the Commissioner had not been provided with when it considered the application.

6.60 The Committee further noted the information in the Applicant's SOPs under the following heading:

6.61 Prescription Order Processing

6.61.1 *"Exempt NHS Prescriptions*

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

…Where a patient uses the postal system to provide evidence of exempt status then the patient should be advised to use Special Delivery Postal Services or our own courier service. The pharmacy should cover the cost of any postal / courier for the patient and return documents the same way."

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

6.63 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 the Commissioner had not considered this term of service in their decision and was mindful that it had been provided with SOPs on appeal, which the Commissioner had not been provided with when it considered the application.

6.64 The Committee noted that in response to the question in the application form "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 did not complete this section of the form and left it blank. As with its finding on Regulation 25(2)(a) above, 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 it did not intend to provide appliances, including those which require measuring or fitting.

6.65 The Committee also noted the information in the Applicant's SOPs under the following headings:

6.66 Pharmaceutical & Legal Assessment

6.66.1 *"Items Requiring Measuring and Fitting*

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

6.67 Signposting

6.67.1 *"Items Requiring Measuring and Fitting*

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

6.68 In the event that the application is granted, the Applicant would not, therefore, be able to provide those appliances as listed in the application form to patients.

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

6.70 The Committee considered whether the Applicant had explained what containers will be "suitable" for posted/delivered items. The finding of the Commissioner in its decision letter is unclear on this aspect. The Committee was mindful that it had been provided with SOPs on appeal which the Commissioner had not been provided with when it considered the application.

6.71 The Committee noted the information in the Applicant's SOPs under the following heading:

6.72 Bagging-Up

6.72.1 *"Choice of Packaging*

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

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

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

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

For postal items, either:

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

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

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

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

6.73 Based on the information before it, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(15) of Schedule 4.

Refusal to provide drugs or appliances ordered

6.74 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. The finding of the Commissioner in its decision letter is unclear on this aspect. The Committee was mindful that it had been provided with SOPs on appeal which the Commissioner had not been provided with when it considered the application.

6.75 The Committee also noted the information in the Applicant's SOPs under the following heading:

6.76 Repeat Dispensing

6.76.1 *"Pharmaceutical & Legal Assessment*

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

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

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

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

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

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

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

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

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

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

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

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

6.78 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. The finding of the Commissioner in its decision letter is unclear on this aspect. The Committee was mindful that it had been provided with SOPs on appeal which the Commissioner had not been provided with when it considered the application.

6.79 The Committee also noted the information in the Applicant's SOPs under the following heading:

6.80 Repeat Dispensing

6.80.1 *"Process*

Prescription Reception

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

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

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

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

On receipt of a repeatable prescription from the patient, either in the post or collected from the surgery for the first time, the pharmacy staff should ensure that the patient fully understands the Repeat Dispensing Process and is provided with a patient information leaflet that outlines the benefits of the service.

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

6.80.2 *"Pharmaceutical & Legal Assessment*

The pharmacist should telephone and speak with the patient before issuing a repeat and ensure… Provide advice and encourage patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber."

6.81 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.

Disposal service in respect of unwanted drugs

6.82 The Committee considered whether the Applicant had explained how it will safely and effectively accept and dispose of unwanted drugs presented to it for disposal. The finding of the Commissioner in its decision letter is unclear on this aspect. The Committee was mindful that it had been provided with SOPs on appeal which the Commissioner had not been provided with when it considered the application.

6.83 The Committee also noted the information in the Applicant's SOPs under the following headings:

6.84 The Safe and Effective Receipt and Disposal of Medicines

6.84.1 *"Process for Patients to Return Medication*

Patient Returned Medication

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

This service is available to all patients living in England.

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

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

Patients may

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

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

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

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

Explaining the Process to Patients

Check which patient or patients the medication belonged to.
Check the relevant PMR to identify any hazardous / dangers drugs or items that have been dispensed and could potentially form part of the return.

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

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

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

6.84.2 *"Process for accepting patient returns by the Driver*

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

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

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

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

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

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

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

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

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

Store returned medicines in the quarantine area of the van for transport.
The returnable items can be taken back to the pharmacy for destruction.
Ensure medicines are not visible in the vehicle at all times."

6.84.3 *"Return by Royal Mail or other courier*

The pharmacist must

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

Assess the items for suitability for return by courier.

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

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

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

Contact the patient to ensure the packaging to the patient along with the instructions for appropriate packing of e that the packaging has been received.

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

6.84.4 *"Disposal of returned medicines*

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

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

6.85 Controlled Drugs: Collection and Disposal of Patient Returns

6.85.1 *"Process*

Return by courier

The pharmacist must

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

Assess the items for suitability for return by courier.

If items are suitable for return by courier then make a note on the PMR and arrange to send the appropriate packaging to the patient for safe return (refer to bagging up SOP for appropriate packaging).
If items are not suitable for return by courier (e.g. clinical or contaminated waste) then provide the patient with details of their local procedures for disposal.

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

Contact the patient to ensure that the packaging has been received
Provide signposting to other pharmacies where the patient prefers to dispose of unwanted medicines locally."

6.85.2 *"Handling Patient-Returned CDs from Delivery Driver*

Drivers need to:

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

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

Pharmacy staff need to:

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

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

6.86 Based on all of the information before it, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 13 - 15 of Schedule 4.

Promotion of healthy lifestyles

6.87 The Committee considered whether the Applicant had explained how it will safely and effectively promote healthy lifestyles. The Committee noted the Commissioner's findings on this point were unclear, and was mindful that it had been provided with SOPs on appeal which the Commissioner had not been provided with when it considered the application.

6.88 The Committee also noted the information in the Applicant's SOPs under the following heading:

6.89 Promotion of Healthy Living, Lifestyle & Health Campaigns

6.89.1 *"Aims and intended service outcomes*
Identification of patients for promotion of Healthy Lifestyles

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

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

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

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

Leaflets will be delivered to patients with their medication…the website, app and email newsletters will also be used to promote healthy lifestyles via the health promotion zone."

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

Prescription linked intervention

6.91 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. The finding of the Commissioner in its decision letter is unclear on this aspect. The Committee was mindful that it had been provided with SOPs on appeal which the Commissioner had not been provided with when it considered the application.

6.92 The Committee further noted the information in the Applicant's SOPs under the following heading:

6.93 Promotion of Healthy Living, Lifestyle & Health Campaigns

6.93.1 *"Health Campaigns & Community Engagement Exercise*

Long Term Conditions

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

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

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

6.93.2 *"Aims and intended service outcomes*

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

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

Health campaigns

6.95 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. The finding of the Commissioner in its decision letter is unclear on this aspect. The Committee was mindful that it had been provided with SOPs on appeal which the Commissioner had not been provided with when it considered the application.

6.96 The Committee further noted the information in the Applicant's SOPs under the following heading:

6.97 Promotion of Healthy Living, Lifestyle & Health Campaigns

6.97.1 *"Health Campaigns & Community Engagement Exercise*

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

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

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

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

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

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

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

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

Signposting

6.99 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. The finding of the Commissioner in its decision letter is unclear on this aspect. The Committee was mindful that it had been provided with SOPs on appeal which the Commissioner had not been provided with when it considered the application.

6.100 The Committee further noted the information in the Applicant's SOPs under the following headings:

6.101 Signposting

6.101.1 *"Service Description*

To minimise inappropriate use of health and social care services and support services, patients who require further support, advice or treatment which cannot be provided by the pharmacy, on other health and social care providers

or support organisations who may be able to assist the person must be given sufficient information to enable them to access those services. Where appropriate, this may take the form of a referral…

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

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

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

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

6.102 Support for Self Care

6.102.1 *"Other Provider Organisations and Support Details*

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

6.103 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 19 – 20 of Schedule 4.

Support for self-care

6.104 The Committee considered whether the Applicant had explained how it will provide advice and support to people caring for their families. The finding of the Commissioner in its decision letter is unclear on this aspect. The Committee was mindful that it had been provided with SOPs on appeal which the Commissioner had not been provided with when it considered the application.

6.105 The Committee further noted the information in the Applicant's SOPs under the following heading:

6.106 Support for Self Care

6.106.1 *"Service outline*

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

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

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

6.106.2 *"Patient Identification*

As part of the repeat dispensing process / medicine sale or during any other interaction with a patient, staff should record the information provided by patients on the PMR system.

Where a patient provides information that indicates that they would benefit from support for self-care they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided and should include:

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

and on changes to the patient's lifestyle."

6.107 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 21 – 22 of Schedule 4.

Summary

6.108 On the information before it, the Committee could not be satisfied that there are procedures likely to secure safe and effective provision of essential services as required by Regulation 25(2)(b).

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

6.109.1 confirm the Commissioner's decision;

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

6.109.3 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.

6.110 In those circumstances, even though the Committee has reached the same overall decision as the Commissioner, as the Committee found different reasoning for its decision, the Committee determined that the decision of the Commissioner must be quashed.

6.111 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.

6.112 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.

6.113 The Committee concluded that further notification under paragraph 19 of Schedule 2 would not be helpful in this case.

7 Decision

7.1 The Committee concluded that it was not required to refuse the application under the provisions of Regulation 31.

7.2 Accordingly, the Committee:

7.2.1 quashes the decision of the Commissioner; and

7.2.2 redetermines the application as follows -

7.2.2.1 the Committee was satisfied that the proposed premises were not adjacent to or in close proximity to other chemist premises,

7.2.2.2 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,

7.2.2.3 the Committee was satisfied that all essential services were likely to be secured without interruption during the opening hours,

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

7.2.2.5 the Committee was not satisfied that all essential services were likely to be secured in a safe and effective manner,

7.2.2.6 the Committee was satisfied that all essential services were likely to be secured without face to face contact;

7.2.3 The application is refused.

Case Manager
Primary Care Appeals