

9 July 2026

REF: SHA/26948

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

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

**APPEAL AGAINST HERTFORDSHIRE AND WEST
ESSEX ICB DECISION TO REFUSE AN
APPLICATION BY FIRSTLINE PHARMA LTD FOR
INCLUSION IN THE PHARMACEUTICAL LIST AT
PHARMACY UNIT, RAVALCO HOUSE,
CLEVELAND WAY, HEMEL HEMPSTEAD,
HERTFORDSHIRE, HP27DL UNDER REGULATION
25**

1 Outcome

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

A copy of this decision is being sent to:

Rushport Advisory LLP on behalf of Firstline Pharma Ltd
Community Pharmacy Hertfordshire
PCSE on behalf of Hertfordshire and West Essex ICB

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1 The Application

By application dated 5 June 2025, Firstline Pharma Ltd (“the Applicant”) applied to Hertfordshire and West Essex ICB (“the Commissioner”) for inclusion in the pharmaceutical list at Pharmacy Unit, Ravalco House, Cleveland Way, Hemel Hempstead, Hertfordshire, HP2 7DL under Regulation 25. In support of the application it was stated:

- 1.1 In response to “If you are undertaking to provide appliances, specify the appliances that you undertake to provide (or write ‘none’ if it is intended that the pharmacy will not provide appliances)” the Applicant stated:
 - 1.1.1 “Drug Tariff part IX*
 - 1.1.2 *Except items that require measuring or fitting.”
- 1.2 In response to why the application should not be refused pursuant to Regulation 31 the Applicant stated:
 - 1.2.1 “Not applicable as no other pharmacy in same or adjacent premises.”
- 1.3 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant stated:
 - 1.3.1 “Application 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.”

Pharmacy procedures

- 1.4 Please explain how the pharmacy procedures used within the premises will secure:
 - (a) the uninterrupted provision of essential services during the opening hours of the premises, to persons anywhere in England who request those services, and

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

- 1.5 Please describe the procedure that will be followed where a patient attends the premises and asks for one or more of the essential services.
- 1.6 If you are undertaking to provide advanced services at the premises please describe how you will do so without providing any element of essential services.
- 1.7 You must ensure that you provide sufficient information within this application form to satisfy NHS England or the relevant delegated integrated care board on the above points. You are not required to submit your standard operating procedures for the premises but if you do they will be circulated to interested parties unless NHS England or the relevant delegated integrated care board is satisfied that the full disclosure principle does not apply.
- 1.8 "The pharmacy unit will be entirely self-contained with no access to the public."
- 1.9 "In addition see attached information."
- 1.10 [SOPs were provided with the application from however these have now been superseded by the SOPs provided on appeal.]

2 **Comments to the Commissioner**

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

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

2.1 RUSHPORT ADVISORY LLP ON BEHALF OF THE APPLICANT

- 2.1.1 "Thank you for your letter of 18 August 2025. I act for Firstline Pharma Ltd in the above application and have been instructed by my client to submit the following reply to the consultation comments received.
- 2.1.2 The LPC asks the ICB applies the correct legal test when determining the application and to be satisfied that proper procedures are in place.
- 2.1.3 As the ICB will be aware, the relevant Regulations were amended on 23 June 2025 and the amendment requires my client to demonstrate that all pharmaceutical services that they propose to provide will be provided without face to face contact at the premises and in a safe and effective way. Previously the requirement only extended to essential services. As my client is also applying to provide NMS I have added this additional SOP for the ICB's attention. [SOP provided however this has now been superseded by the SOPs as provided on appeal.]

- 2.1.1 The information already provided demonstrates how the legal test will be met in full and the application should therefore be approved.”

3 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 20 February 2026 states:

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

- 3.1 “Hertfordshire and West Essex ICB has considered the above application and I am writing to confirm that it has been refused. Please see the enclosed report for the full reasoning.”

Extract from the “Decision Wording - CAS-369941-B5D5H7”

- 3.2 “Application in respect of distance selling premises: Firstline Pharma Ltd, Pharmacy Unit, Ravalco House, Cleveland Way, Hemel Hempstead, Hertfordshire, HP2 7DL.
- 3.3 The Pharmaceutical Services Regulations Committee (hereafter referred to as “the Committee”) considers all pharmaceutical services applications for the 6 Integrated Care Boards (ICB) within the East of England footprint. NHS Hertfordshire & West Essex ICB (HWE ICB) hosts the meeting on behalf of the 6 ICBs, in accordance with the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended (hereafter referred to as “the Regulations”).
- 3.4 The Committee considered this excepted application in respect of a DSP, which is determined under the following Regulations:
- 3.5 The Committee noted that the application has been submitted by Rushport Advisory LLP on behalf of the applicant.

Regulation 31: Refusal: same or adjacent premises.

- 3.6 The Committee noted that there is no person on the pharmaceutical list providing or undertaking to provide pharmaceutical services from or adjacent to the premises.
- 3.7 The Committee agreed it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25A: Transitional provision: distance selling premises applications for new inclusions made before 23rd June 2025

- 3.8 The Committee noted that the application was made before 23rd June 2025.

Regulation 25: Distance selling premises applications.

- 3.9 Regulation 25(2)(a)

- 3.10 The Committee noted that where the application asks at section 6.1, “In my/our view this application should not be refused pursuant to Regulation 25(2)(a) for the following reasons:”, the applicant stated:

3.10.1 *“Application 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.”*

- 3.11 The Committee noted that the premises in respect of which the application is 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.
- 3.12 The Committee agreed it is not required to refuse the application under the provisions of Regulation 25(2)(a).

Regulation 25(2)(b)

- 3.13 The Committee considered the information which has been provided by the applicant in relation to its procedures for the provision of essential services, including any Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.
- 3.14 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.
- 3.15 As of June 2025, the Regulations were amended and therefore would also require the Committee to be satisfied that the pharmacy procedures are likely to secure the safe and effective provision of all pharmaceutical services (not just essential services) without face-to-face contact at the pharmacy premises.
- 3.16 The Committee considered the documents provided by the applicant, namely:

3.16.1 Annex 1 - Application Form

3.16.2 SOPs - Hussain Healthcare Group Ltd

3.16.3 NMS SOP Only

Representations

- 3.17 The Committee noted the full representations/comments made and the summaries below:
- 3.18 **Boots UK Limited** – who 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.
- 3.19 **Community Pharmacy Hertfordshire (CPH)** – who requests that NHS England ensures the application meets all requirements under Regulation 25 of the Regulations. Key assurances sought also includes:

- 3.19.1 **Nationwide Service Provision:** Essential services must be available to anyone in England, delivered safely and effectively without face-to-face contact.
- 3.19.2 **Compliance in Publicity:** Materials must not imply services are limited to a local area, and directed services should not appear to extend to walk-in patients.
- 3.19.3 **Operational Safeguards:** Monitoring of opening hours and SOPs that support national service delivery rather than local focus.
- 3.19.4 **Commissioning Caveats:** Many proposed services depend on commissioner agreement; some are not commissioned in Hertfordshire.
- 3.19.5 **Premises Layout:** No floor plan was provided; NHS England should confirm that the final layout supports non-face-to-face service delivery.

Response to Representations

- 3.20 The Committee noted that Rushport Advisory LLP responded on behalf of the applicant to the representations made.
- 3.21 The Committee considered the full document, and noted the summary below:
- 3.22 **Key Points:**
 - 3.22.1 **Legal Compliance:** The applicant emphasises that the ICB must apply the correct legal test under the amended Regulations (effective 23 June 2025). The amendment requires all proposed pharmaceutical services—not just essential services—to be delivered without face-to-face contact and in a safe, effective manner.
 - 3.22.2 **Evidence Provided:** The applicant asserts that the information submitted already demonstrates full compliance with the legal requirements and supports approval of the application.
 - 3.22.3 **Additional SOP:** As the applicant intends to provide the New Medicine Service (NMS), an additional Standard Operating Procedure has been included for the ICB's consideration.
 - 3.22.4 **Conclusion:** The applicant expresses confidence that the application meets all regulatory requirements and requests approval.
- 3.23 The Committee considered each essential service in paragraphs 3 to 28C of Schedule 4 of the Regulations as this is the approach of NHS Resolution (NHSR).
- 3.24 The Committee paid particular attention to the following aspects of the essential services, which are considered more difficult to provide safely and effectively in a distance selling context:
 - 3.24.1 Dispensing of drugs and appliances

- 3.24.2 Urgent supply without a prescription
- 3.24.3 Preliminary matters before providing ordered drugs or appliances
- 3.24.4 Providing ordered drugs or appliances
- 3.24.5 Refusal to provide drugs or appliances ordered
- 3.24.6 Further activities to be carried out in connection with the provision of dispensing services
- 3.24.7 Disposal service in respect of unwanted drugs
- 3.24.8 Promotion of healthy lifestyles
- 3.24.9 Prescription linked intervention
- 3.24.10 Health Campaigns
- 3.24.11 Signposting
- 3.24.12 Support for self-care
- 3.24.13 Discharge Medicine Service
- 3.24.14 Websites and health promotion zones

Dispensing of drugs and appliances

- 3.25 The Committee considered whether the applicant has explained how non-electronic prescriptions will be presented by the patient and how products will be provided.
- 3.26 The Committee noted the SOP sets out the process for handling prescriptions received by post and ensuring safe provision of medicines. Key points:
 - 3.26.1 Presentation of Non-Electronic Prescriptions:
 - 3.26.2 Patients who wish to send paper prescriptions by post are supported:
 - 3.26.3 *“Patients who wish to send paper prescriptions to the pharmacy by post should be sent stamped addressed envelopes to enable them to do so.”* (Page 18).
 - 3.26.4 On receipt:
 - 3.26.5 *“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.”* (Page 27)

- 3.27 Prescriptions should arrive within 5 working days; if not, the patient is contacted and may need to request a new prescription from their GP.
- 3.28 Verification and Legal Checks:
- 3.28.1 *“Check the patient’s details on the prescription. They must include: Full name, Address including postcode, Date of birth.”* (Page 27)
- 3.28.2 *“Check the prescriber has signed the prescription and it is in date.”* (Page 27).
- 3.29 Provision of Products:
- 3.30 Once validated, items are processed and dispatched:
- 3.30.1 *“Patients would receive a delivery note with their despatched order, advising that the pharmacist can be consulted by contacting them by telephone or e-mail.”* (Page 26)
- 3.31 Delivery follows the Order Delivery SOP ensuring secure packaging and audit trail (Page 64-68).
- 3.32 The Committee was satisfied that it has been provided with information sufficient to show that there would be compliance with paragraph 5 of Schedule 4.

Urgent supply without a prescription

- 3.33 The Committee considered whether the applicant has explained how it proposes safely and effectively to receive requests from prescribers for urgent supplies of drugs and appliances.
- 3.34 The SOP provides a process for urgent supply at the request of a prescriber, ensuring safety and compliance:
- 3.35 Conditions for Urgent Supply:
- 3.35.1 *“The following conditions must apply to the request made by a prescriber:*
- 3.35.2 *Prescriber – The Pharmacist must be satisfied that the request is from the appropriate authorised prescriber... The RP should still carry out appropriate checks on professional registers in order to satisfy themselves that the request is a legitimate one.”* (Page 57)
- 3.35.3 *“Emergency – The Pharmacist is satisfied that a prescription cannot be supplied immediately due to an emergency.”* (Page 57)
- 3.35.4 *“Prescription – The Prescriber agrees to provide a written prescription within 72 hours.”* (Page 57)
- 3.35.5 *“Directions – The medication is supplied in accordance with the prescriber’s directions.”* (Page 57)

3.35.6 *“Controlled Drugs – An emergency supply cannot be provided for a Schedule 1, 2 or 3 CD except Phenobarbital for epilepsy by a UK registered prescriber.” (Page 57)*

3.36 Record-Keeping Requirements:

3.36.1 “An entry must be made in the POM register on the day of supply with the following details:

3.36.1.1 *The date the supply was made.*

3.36.1.2 *The name, quantity, strength and form of the medicine.*

3.36.1.3 *The name and address of the prescriber requesting the emergency supply.*

3.36.1.4 *The name and address of the patient for whom the medication is supplied.*

3.36.1.5 *The date on the prescription.*

3.36.1.6 *The date on which the prescription is received in the Pharmacy.*

3.36.1.7 *The amount charged to the patient, if required.*

3.36.1.8 *The nature of the emergency (i.e. the reason for request).”*
(Page 57)

3.37 Additional Safeguards:

3.37.1 The SOP requires checks against professional registers, confirmation of prescriber legitimacy, and adherence to legal restrictions on controlled drugs.

Summary

3.38 The applicant has explained a structured process for urgent supply requests from prescribers, including verification of prescriber identity, confirmation of emergency circumstances, requirement for a written prescription within 72 hours, compliance with legal restrictions, and detailed record-keeping.

3.39 Based on the information before it, the Committee was satisfied that it has 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

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

- 3.41 The SOP sets out a structured approach to verifying and recording exemption status:
- 3.41.1 Objective and Evidence Collection:
 - 3.41.2 *“Prescription charge exemption is verified with scanned/posted evidence and records maintained.”* (Page 25)
 - 3.41.3 Patients may send evidence by post or electronically (e.g., scanned copies). The pharmacy maintains records of this evidence for audit and compliance.
 - 3.41.4 Recording Exemption Status:
 - 3.41.5 *“If the prescription charge exemption status is known then this should be entered accurately at the time of dispensing.”* (Page 48)
 - 3.41.6 The exemption status is recorded in the PMR system during dispensing, ensuring accurate claims and compliance with NHS requirements.
 - 3.41.7 Process for Missing or Doubtful Evidence:
 - 3.41.8 If evidence is missing or unclear, the SOP requires contacting the patient to request the missing information. Where evidence cannot be confirmed, the “Evidence not seen” box on the prescription is marked (as per NHS guidance referenced elsewhere in the SOP).
 - 3.41.9 Risk Management:
 - 3.41.10 *“Known Risks – Exemption details are not accurate.”* (Page 25)
 - 3.41.11 The SOP identifies inaccurate exemption details as a risk and mitigates this through verification and record-keeping.

Summary

- 3.42 The applicant has explained that exemption evidence will be sought via scanned or posted documents, verified by pharmacy staff, and recorded in the PMR system. If evidence is missing or doubtful, the SOP outlines steps to contact the patient and mark prescriptions appropriately.
- 3.43 Based on the information before it, the Committee was satisfied that it has been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.

Providing ordered drugs or appliances

- 3.44 The Committee considered whether the applicant has 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).

- 3.44.1 Cold Chain Maintenance
- 3.44.2 The SOP specifies that all cold chain deliveries must use approved couriers with validated procedures:
- 3.44.3 *"All cold chain deliveries must be carried out by couriers with verified and approved cold chain procedures... Each approved courier meets stringent criteria to ensure a fully monitored and dedicated cold chain service."* (Page 67)
- 3.44.4 Packaging and temperature control requirements:
- 3.44.5 *"Specialist cold chain courier service will ensure the integrity of the cold chain and the maximum stability of thermo-labile drugs by packing, transporting and delivering in such a way that their integrity, quality and effectiveness are always preserved."* (Page 67)
- 3.44.6 Breach protocol:
- 3.44.7 *"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."* (Page 68)
- 3.44.8 Compliance with Misuse of Drugs Regulations (Regulations 14 and 16)
- 3.44.9 Controlled Drugs handling is detailed under a separate section for receipt, storage, dispensing, and delivery:
- 3.44.10 Receipt and Storage:
- 3.44.11 *"Items subject to Safe Custody Regulations must be stored in the CD cabinet immediately — this includes ALL Schedule 2 CDs and certain Schedule 3 CDs."* (Page 73)
- 3.44.12 Dispensing:
- 3.44.13 *"Confirm the prescription is legally correct and on the correct type of prescription form... Make an entry in the CD register as soon as possible when issuing to a delivery driver."* (Pages 76-78)
- 3.44.14 Delivery:
- 3.44.15 *"A robust audit trail is essential when controlled drugs are involved... The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative."* (Page 79)
- 3.45 The SOP also addresses record-keeping and security:
 - 3.45.1 *"All entries in the CD register must be made when the medication leaves the pharmacy premises. The delivery driver/courier must be entered as the 'person collecting'."* (Page 79)

Summary

- 3.46 The applicant has explained procedures for:
- 3.46.1 Maintaining cold chain integrity through specialist couriers, monitored temperature control, and breach protocols.
 - 3.46.2 Meeting Misuse of Drugs Regulations requirements via secure storage, legal checks, CD register entries, and strict delivery verification processes.
- 3.47 Based on the information before it, the Committee was satisfied that it has been provided with information sufficient to show that there would be compliance to this regard.

Refusal to provide drugs or appliances ordered

- 3.48 The Committee considered how the applicant has satisfied the test 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 reviewing the patients treatment.
- 3.49 The SOP sets out checks and actions the pharmacist must take before issuing a repeat supply:
- 3.49.1 Verification Steps Before Dispensing:
 - 3.49.2 *"The pharmacist should telephone and speak with the patient before issuing a repeat and ensure: • They are taking or using, and likely to continue to take or use the medicine or appliances appropriately • Advise the patient that they should only order items that they need • Check that the patient is not suffering any side effects which may suggest they need a review of their medication • Check that the patient's regimen has not been changed since the prescriber authorised the repeatable medication. • Check that there has not been any change to the patient's health since prescription was authorised • Provide advice and encourage patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber."* (Pages 127 - 128)
 - 3.49.3 Clinical Judgment and Record-Keeping:
 - 3.49.4 *"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."* (Page 128)
 - 3.49.5 Professional Oversight:
 - 3.49.6 The SOP emphasises that, "The pharmacist must be satisfied that the supply of medicines is clinically appropriate." (Page 128)

Summary

- 3.50 The applicant has explained the process for ensuring that, before dispensing a repeatable prescription after the first occasion, the pharmacist will confirm continued use, check for side effects, verify no changes in regimen or health status, and record any interventions or referrals.
- 3.51 Based on the information before it, the Committee was satisfied that it has 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

- 3.52 The Committee considered whether the applicant has explained how appropriate advice about the benefits of repeat dispensing is given to any patient who (i) has a long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term), and (ii) requires regular medicine in respect of that medical condition.
- 3.53 The SOP sets out requirements for advising patients:
 - 3.53.1 Advice Obligation:
 - 3.53.2 *“Appropriate advice about the benefits of repeat dispensing must be given to any patient who:*
 - 3.53.2.1 *has a long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term); and,*
 - 3.53.2.2 *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.”* (Page 127)
 - 3.53.3 Method of Providing Advice:
 - 3.53.4 *“Such advice will be provided by the Pharmacy using its permissible methods of non face-to-face contact with patients.”* (Page 127)
 - 3.53.5 Supporting Information:
 - 3.53.6 *“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.”* (Page 127)
 - 3.53.7 Additional Checks and Records:

- 3.53.8 The SOP requires confirming the patient's condition, explaining the scheme, and recording details on the pharmacy record card for audit and continuity.

Summary

- 3.54 The applicant has explained that advice about repeat dispensing will be given to eligible patients using non-face-to-face methods (e.g., phone, written information). Patients will receive a leaflet outlining benefits, and staff will confirm suitability and record relevant details.
- 3.55 Based on the information before it, the Committee was satisfied that it has been provided with information sufficient to show that there would be compliance with 10(1) of Schedule 4.

Disposal service in respect of unwanted drugs

- 3.56 The Committee considered whether the applicant has explained how it will safely and effectively accept and dispose of unwanted drugs presented to it for disposal.

3.56.1 Patient Returns – Acceptance Process

3.56.2 *“Patients or their representatives may not return medicines directly to the pharmacy and must follow the procedures set out in this SOP.”*

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

3.56.4 Options for return:

3.56.5 *“Patients may:*

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

3.56.7 *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*

3.56.8 *The Pharmacy can arrange for medication to be collected by our specialist waste management contractor.”* (Page 85)

3.56.9 Safety Measures

3.56.10 *“Advise patient of their other options to dispose of unwanted or expired medication if none of these options is suitable for them (signposting to local pharmacies).”* (Page 83)

3.56.11 *“Check which patient or patients the medication belonged to. Check the relevant PMR to identify any hazardous/dangerous drugs or items that have been dispensed and could potentially form part of the return.”* (Page 84)

3.56.12 *"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."* (Page 86)

3.56.13 Disposal Process

3.56.14 *"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."* (Page 88)

3.56.15 *"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."* (Page 86)

3.56.16 Hazardous and controlled drugs:

3.56.17 *"Hazardous medicines ... must be handled with care and separated for disposal"*)

3.56.18 *"Refer to SOP Controlled Drugs: Disposal of Patient Returns."* (Page 88)

Summary

3.57 The applicant has explained a comprehensive process for accepting and disposing of unwanted medicines, including:

3.57.1 Controlled access (no direct returns to premises).

3.57.2 Pre-arranged collection or postal return with risk assessment.

3.57.3 Specialist handling for hazardous items and controlled drugs.

3.57.4 Use of licensed waste management contractors and compliance with NHS England's requirements.

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

Promotion of healthy lifestyles

3.59 The Committee considered whether the applicant has explained how it will safely and effectively promote healthy lifestyles.

3.59.1 Objectives and Scope

3.59.2 *"Implementing this SOP will ensure:*

3.59.3 *Ensure Services are provided without face to face contact between pharmacy staff and the patient or their representative.*

- 3.59.4 *Increased patient and public knowledge and understanding of key healthy lifestyle and public health messages.*
- 3.59.5 *Opportunistic provision of health promotion advice to encourage patients to take action to improve their health.” (Page 91)*
- 3.59.6 Methods of Delivery
- 3.59.7 *“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.” (Page 96)*
- 3.59.8 *“The website, app and email newsletters will also be used to promote healthy lifestyles via the health promotion zone.” (Page 96)*
- 3.59.9 *“Health promotion zone on our website... signposted to a range of up-to-date materials that promote healthy lifestyles... includes details of current health campaigns and other information to promote healthy lifestyle choices.” (Page 93)*
- 3.59.10 Patient Identification
- 3.59.11 *“Identification can take three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process.” (Pages 92)*
- 3.59.12 *“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.” (Pages 97)*
- 3.59.13 Community Engagement
- 3.59.14 *“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.” (Page 96)*

Summary

- 3.60 The applicant has explained a multi-channel approach to promoting healthy lifestyles, including:
- 3.60.1 Opportunistic advice during interactions.
- 3.60.2 Targeted campaigns via leaflets, website, app, and email.
- 3.60.3 Use of lifestyle questionnaires to identify patients needing support.
- 3.60.4 Participation in national/local health campaigns and community engagement exercises.

- 3.60.5 Delivery of services without face-to-face contact, ensuring compliance with distance selling requirements.
- 3.61 Based on the information before it, the Committee was satisfied that it has been provided with information sufficient to show that there would be compliance with paragraph 16 – 18 of Schedule 4.

Prescription linked intervention

- 3.62 The Committee considered whether the applicant has 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.

3.62.1 Specific Patient Groups for Intervention:

- 3.62.2 *“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.” (Page 98)*

3.62.3 Identification Methods:

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

3.62.5 Active patients:

- 3.62.6 *“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.”*

3.62.7 Passive patients:

- 3.62.8 *“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.” (Page 98)*

3.62.9 Recording and Follow-Up:

- 3.62.10 *“As part of repeat dispensing process (or during any other interaction with a patient) staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from promotion of healthy lifestyles they should be recorded as a ‘target patient’ and the appropriate information that is relevant to them should be provided.” (Page 98)*

3.62.11 Supporting Materials and Campaigns:

3.62.12 *“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.”* (Page 98)

Summary

- 3.63 The applicant has explained a structured approach to identifying patients who may need prescription-linked intervention advice through active (questionnaires), passive (prescription review), and repeat dispensing processes. Advice will be provided remotely (phone, video, website) and supported by written materials and targeted campaigns. Records of interventions will be maintained in the PMR system for continuity and audit.
- 3.64 Based on the information before it, the Committee was satisfied that it has been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

Public health campaigns

- 3.65 The Committee considered whether the applicant has explained how it will safely and effectively participate in public health campaigns, if and to the extent required by NHS England.

3.65.1 Commitment to Campaigns:

3.65.2 *“Terms of Service require participation in up to 6 campaigns per financial year, but you should agree to take part in all campaigns where practicable.”* (Page 96)

3.65.3 Method of Participation:

3.65.4 *“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.”* (Page 96)

3.65.5 Community Engagement:

3.65.6 *“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.”* (Page 96)

3.65.7 Safe Delivery and Confidentiality:

3.65.8 *“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.”* (Page 96)

3.65.9 Integration with Dispensing:

3.65.10 *“Leaflets will be delivered to patients with their medication... The website, app and email newsletters will also be used to promote healthy lifestyles.”* (Page 98)

Summary

3.66 The applicant has explained that it will participate in NHS England-required public health campaigns by:

3.66.1 Distributing campaign materials with prescription deliveries.

3.66.2 Using digital channels (website, email, text) for safe, non-face-to-face communication.

3.66.3 Maintaining confidentiality and compliance with distance selling requirements.

3.66.4 Engaging in at least one community health promotion exercise annually.

3.67 Based on the information before it, the Committee was satisfied that it has been provided with information sufficient to show that there would be compliance with paragraph 18 of Schedule 4.

Signposting

3.68 The Committee considered whether the applicant has explained how it will provide information to users of the pharmacy about other health and social care providers and support organisations.

3.68.1 Purpose of Signposting:

3.68.2 *“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.”* (Page 93)

3.68.3 Aims and intended service outcomes:

3.68.4 *“To inform or advise people who require assistance, which cannot be provided by the pharmacy, of other appropriate health and social care providers or support organisations. To enable people to contact and/or access further care and support appropriate to their needs.”* (Page 93)

3.68.5 Identification and Referral Process:

3.68.6 *“Staff should always consider that in order to minimise inappropriate use of health and social care services and of support services any*

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.” (Page 94)

3.68.7 Special Cases:

3.68.8 *“Where a prescription is received for an appliance or stoma appliance customisation or any item that requires measuring or fitting the patient must be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients must be signposted to at least two other providers of the service in their area.” (Page 94)*

Summary

3.69 The applicant has explained that signposting will be carried out by:

3.69.1 Identifying patients who need services the pharmacy cannot provide.

3.69.2 Giving sufficient information and contact details for at least two alternative providers.

3.69.3 Making referrals where appropriate.

3.69.4 Ensuring this process is documented and delivered via non-face-to-face methods, in line with distance selling requirements.

3.70 Based on the information before it, the Committee was satisfied that it has been provided with information sufficient to show that there would be compliance with paragraphs 19 – 20 of Schedule 4.

Support for self-care

3.71 The Committee considered whether the applicant has explained how it will provide advice and support to people caring for their families.

3.71.1 Commitment to Supporting Carers:

3.71.2 *“The service allows and requires the pharmacy to help not only the patient directly, but also (within the bounds of confidentiality) their carers and also provide them with assistance and support.” (Discharge Medicines Service context – Page 99)*

3.71.3 Scope of Self-Care Support (Page 91-93):

3.71.4 The SOP includes guidance for providing advice to patients and carers to enable them to manage minor illnesses and long-term conditions safely at home. This includes:

3.71.4.1 Offering advice on medicine use.

3.71.4.2 Providing written materials (leaflets) and directing carers to online resources.

3.71.4.3 Using non-face-to-face methods (telephone, video, email) to maintain confidentiality and comply with distance selling requirements.

3.71.5 Practical Support for Carers:

3.71.6 The SOP highlights that carers may need help interpreting medication instructions and understanding treatment plans. Pharmacy staff are instructed to:

3.71.7 Confirm consent before sharing information.

3.71.7.1 Offer tailored advice based on the patient's needs.

3.71.7.2 Signpost carers to other health and social care providers when additional support is required.

Summary

3.72 The applicant has explained that advice and support for self-care will be provided remotely and safely, including to carers, through:

3.72.1 Confidential communication channels.

3.72.2 Written and digital resources.

3.72.3 Active engagement in medication reviews and health promotion.

3.72.4 Signposting to other providers where necessary.

3.73 Based on the information before it, the Committee was satisfied that it has been provided with information sufficient to show that there would be compliance with paragraphs 21 – 22 of Schedule 4.

Discharge Medicine Service (DMS)

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

3.75 Further the Committee considered whether the applicant has explained what procedures it has in place for checking referrals for the discharge medicines service.

3.75.1 Provision of Advice, Assistance and Support

3.75.2 *“Under the DMS the pharmacy must provide assistance and support to, and in respect of, an NHS patient*

(a) recently discharged from hospital who is referred to the pharmacy for advice, assistance and support in respect of the patient’s medication regimen by the staff of the hospital in which the patient stayed; or

(b) who is otherwise referred to the pharmacy for advice, assistance and support in respect of the patient’s medication regimen by the staff of an NHS trust or NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.” (Page 99).

3.75.3 The SOP confirms that the service covers patients and their carers, with advice provided remotely (phone or video) to maintain confidentiality and compliance with distance selling requirements.

3.75.4 *“Arrange a live video call or audio call with the patient (or where appropriate and bearing in mind the duty of confidentiality their carer) to:*

3.75.5 *Assess the patient/carer understanding of the medicines that the patient should be taking*

3.75.6 *If changes have been made to the patient’s medication regimen, clearly explain the changes.*

3.75.7 *Offer such advice, assistance and support as is appropriate in your clinical judgement in respect of the medicines being taken and the medication regimen overall.”* (Pages 101-102).

3.75.8 Procedures for Checking Referrals

3.75.9 *“Every day the RP must check the pharmacy’s NHS mail system, PharmOutcomes and Refer to Pharmacy for referrals to the DMS. Pharmacy contractors must consider any communication in the following form and manner as constituting a referral: ‘Any written patient information received by a community pharmacy via secure electronic message from an NHS trust or other provider of NHS services concerning a patient’s discharge to usual primary care services and their medicines regimen’.”* (Page 99).

3.75.10 The SOP also details:

3.75.11 Verification of referral details against the patient’s Summary Care Record.

3.75.12 Recording actions and maintaining an audit trail for all stages of the service.

3.75.13 Structured process across three stages:

3.75.14 Stage 1: Clinical review of discharge referral.

3.75.15 Stage 2: Review of first prescription post-discharge.

3.75.16 Stage 3: Patient/carer engagement to confirm understanding and adherence.

Summary

3.76 The applicant has explained a comprehensive process for delivering the DMS, including:

3.76.1 Daily checks for referrals via secure NHS systems.

3.76.2 Verification against Summary Care Records.

3.76.3 Remote consultations with patients/carers to provide advice and support.

3.76.4 Detailed guidance for explaining medication changes, managing high-risk medicines, and ensuring continuity of care.

3.77 The Committee was satisfied that it has been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

Websites and health promotion zones

3.78 The Committee considered whether the applicant has explained how it will ensure that it has a website for use by the public for the purpose of accessing pharmaceutical services from those premises, on which there is an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues.

3.79 The SOP confirms that the pharmacy will operate a Health Promotion Zone on its website:

3.79.1 *"The website, app and email newsletters will also be used to promote healthy lifestyles."* (Page 98)

3.79.2 *"The interactive page is promoted on the website so that when a patient first visits the website they are signposted to a range of up to date materials that promote healthy lifestyles."* (Page 93)

3.80 The SOP also states that the website will:

3.80.1 Include targeted campaigns for patients with conditions such as diabetes, coronary heart disease, COPD, asthma, high blood pressure, and lifestyle risks (e.g., smoking, obesity).

3.80.2 Clearly promote the interactive health promotion page when users first access the site.

3.80.3 Use digital channels (website, app, email newsletters) to ensure safe, non-face-to-face delivery of health information.

Summary

- 3.81 The applicant has explained that its website will feature an interactive health promotion zone, prominently signposted to users, offering a wide range of current materials on healthy lifestyles and public health issues. This will be supported by targeted campaigns and digital engagement tools to ensure accessibility and compliance with NHS requirements.
- 3.82 The Committee was satisfied that it has been provided with information sufficient to show that there would be compliance with paragraph 28C of Schedule 4.

Advanced and Enhanced Services

- 3.83 The Committee considered any advanced or enhanced services proposed to being undertaken. These are:

3.83.1 New Medicine Service

- 3.84 The Committee paid particular attention to the following aspects taken from the service specification, which are considered more difficult to provide without face-to-face contact in a distance selling context.

5.2 How will the applicant gain the patient's informed verbal consent prior to providing the service?

- 3.84.1 *"Prior to provision of the service, informed verbal consent (phone call or video call) must be sought from the patient and recorded in the pharmacy's clinical record for the service."* (Page 3).

5.2 How will the applicant advise the patient of the following information sharing that may take place?

- 3.84.2 The sharing of information between the pharmacy and the patient's general practice will be provided, if needed, to enable the provision of appropriate care; and
- 3.84.3 The sharing of information about the service with NHS England as part of service monitoring; and
- 3.84.4 The sharing of information about the service with NHS England and the NHSBSA as part of post-payment verification.
- 3.85 The Committee noted the applicant has provided the same wording as above within the NMS SOP.

5.3 Where consent cannot be given by the person themselves, how will the applicant gain informed verbal consent from that person's carer or parent/guardian?

3.86 In the first section of the NMS SOP, under “Objective”, the applicant states:

3.86.1 *“help patients and carers manage newly prescribed medicines for an LTC, supporting patients to make shared decisions about their LTC”*

3.87 The Committee noted that even though the SOP does not explicitly detail how the applicant will obtain informed verbal consent from the patient’s carer or guardians, carers are mentioned in the objective of the SOP as shown above. The structure may imply that consent would be obtained from an authorised representative and would be through phone or video call.

5.4 If the patient is not registered with a GP practice, how will the applicant recommend registration and advise how to do this?

3.88 The Committee noted, the SOP does not explicitly cover this scenario.

5.5 How will the applicant gain the patient’s consent to check the national care record and/or locally available clinical records?

3.88.1 *“Reconfirm patient consent to information sharing and to the NMS service.” (Page 4)*

3.89 The Committee noted that while the Summary Care Record (SCR) access is implied as part of clinical checks on page 3, explicit mention of SCR consent is not detailed in the SOP.

5.6 How will the applicant provide opportunistic advice on healthy living/public health topics and signpost further support?

3.89.1 *“At this stage the pharmacist should also, if appropriate, offer the patient opportunistic advice on healthy living / public health topics in line with the promotion of healthy lifestyles essential service.” (Page 5)*

3.89.2 *“At this stage the pharmacist should also, if appropriate, offer the patient opportunistic advice on healthy living / public health topics in line with the promotion of healthy lifestyles essential service.” (Page 6).*

5.10 How will the applicant agree the method and date of each consultation with the patient?

3.89.3 *“The pharmacy and patient will agree a method (phone or video call) and time for the service, typically between seven and fourteen days after patient engagement and dispensing of the new medicine.” (Page 4).*

5.12 How will patients be recruited to the service?

3.89.4 *“Patients may be referred to the pharmacy for this service by*

3.89.4.1 *a prescriber (primary / secondary care)*

3.89.4.2 *If prescriptions are received by post the patient may be identified as suitable for the service*

3.89.4.3 *If prescriptions are received by EPS the patient may be identified as suitable for the service.” (Page 2).*

5.16 How will patients be given information on the service at the engagement stage?

3.89.5 *“Provide the patient with information on the service (for example, this could be verbally over the phone, via a leaflet emailed to the patient or directing the patient to a web link where the patient can access information online).” (Page 3).*

5.17 How will the consultations be held?

3.89.6 *“All stages of the NMS consultation must be undertaken by telephone or video consultation.” (Page 3).*

- 3.90 In conclusion, the Committee agreed that the applicant has not satisfied Regulation 25(2)(b)(ii) around securing –

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

Regulation 66 - Conditions relating to providing directed services

- 3.91 The Committee noted that Regulation 66 is to be considered if the application is granted.
- 3.92 The applicant has listed the following service within the application form.

3.92.1 New Medicines Service (NMS)

- 3.93 The Committee noted that Regulation 66(4) applied and the inclusion of the applicant and the pharmacy premises on the pharmaceutical list for the area of Luton Health and Wellbeing Board would be subject to the condition set out in Regulation 66(5).
- 3.94 The Committee noted that the service listed is an advanced service. The Committee considered whether or not to specify a date by which the condition to provide this service is to take effect if the application is granted.

Consider impact of decision on those with protected characteristics under the Equalities Act 2010 and is this in accordance with NHS England/the ICB's Public Sector Equality Duty. Consider impact of decision on NHS England/the ICB's duty on health inequality.

- 3.95 The Committee agreed this would not be affected if granting this application.

Decision

- 3.96 The Committee refused the application from Firstline Pharma Ltd as not all the requirements set out in Regulation 25 had been met:

- 3.96.1 The Committee was not required to refuse the application under the provisions of Regulation 31 as the proposed premises are not adjacent to or in close proximity to other chemist premises.
 - 3.96.2 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.
 - 3.96.3 The Committee was satisfied that all essential services are likely to be secured without interruption during the opening hours.
 - 3.96.4 The Committee was satisfied that all essential services are likely to be secured for persons anywhere in England
 - 3.96.5 The Committee was not satisfied that all pharmaceutical services are likely to be secured in a safe and effective manner as the NMS service specification at section 5.4 has not been covered.
 - 3.96.6 The Committee was satisfied that all pharmaceutical services are likely to be secured without face-to-face contact.
- 3.97 The Committee agreed that Firstline Pharma Ltd, Pharmacy Unit, Ravalco House, Cleveland Way, Hemel Hempstead, HP2 7DL has the right of appeal.”

4 **The Appeal**

In a letter dated 9 March 2026, Rushport Advisory LLP on behalf of the Applicant appealed against the Commissioner’s decision. The grounds of appeal are:

- 4.1 “I act for Firstline Pharma Ltd and have been instructed by my client to submit this appeal against the attached decision of the Commissioner to refuse the above application.
- 4.2 The Commissioner refused my client’s application on what we respectfully suggest were very minor grounds that did not justify refusal. For example, not having a process to tell patients who wanted to access the New Medicines Service but did not have an NHS prescription that they should register with an NHS GP and not having specific requirements to access the SCR (which was dealt with in SOP 3).
- 4.3 Despite this my client is always happy to improve SOPs in any way to avoid confusion and has therefore instructed me to submit the attached updated version of their SOPs which replace any previous version. [see Appendix A for Committee]. The SOPs deal with all points identified by the Commissioner for refusing the application and incorporate a number of other best practice changes.
- 4.4 Since my client submitted its application, it has prepared a floor plan and for the sake of completeness this is attached along with this appeal. [see Appendix B for Committee].

- 4.5 We submit that the information provided with this appeal satisfies the legal test in full and the appeal should be allowed and we look forward to hearing from you in due course.”

5 Summary of Representations

This is a summary of representations received on the appeal.

5.1 THE COMMISSIONER

- 5.1.1 “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.
- 5.1.2 Thank you for your letter advising that Firstline Pharma Ltd (the Appellant) has submitted an appeal 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).
- 5.1.3 We note that on appeal, the Appellant has provided additional information to demonstrate compliance with the Regulations. This information was not available to the ICB when the original decision was made. The PSRC notes that had this information been provided by the Appellant as part of the application process, the decision made by PSRC may have been different.
- 5.1.4 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.”

5.2 COMMUNITY PHARMACY HERTFORDSHIRE

- 5.2.1 “Community Pharmacy Hertfordshire (CPH) acknowledges the appeal made by Firstline Pharma, dated 9 March 2026, and has reviewed the supplementary information provided.
- 5.2.2 CPH’s position remains as stated in our original representation dated 13 August 2025 (enclosed). We note that in response to concerns raised during the initial application and the subsequent refusal by the ICB, the applicant has now provided a revised suite of Standard Operating Procedures (SOPs). These include processes for directing non-NHS patients to GP registration for the New Medicines Service (NMS), clarifying requirements for Summary Care Record (SCR) access, and the provision of a floor plan.
- 5.2.3 Following a review of this information, CPH submits the following observations:

5.2.3.1 Regulation 25(2) Compliance: Under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, a Distance Selling Pharmacy (DSP) must demonstrate that all pharmaceutical services are provided without face-to-face contact. The Committee must determine whether the updated SOPs (March 2026) sufficiently ensure that this requirement is maintained for any person in England requesting such services, particularly regarding the clinical elements of the NMS.

5.2.3.2 Premises and Access: CPH notes the applicant's assertion that the premises are self-contained with a controlled access system. It remains a matter of fact for the Committee to ensure that the physical layout and operational procedures strictly prevent any face-to-face contact and that the premises always remain closed to the public.

5.2.3.3 Operational Requirements: The Committee should assess whether the newly provided floor plan and revised procedures align with the restricted access requirements for DSPs, ensuring that no essential or advanced services are facilitated on a face-to-face basis at or in the vicinity of the premises.

5.2.4 CPH trusts that these points, along with our original representation, will be fully considered in the final decision. We look forward to being kept informed of the progress of this appeal."

In a letter dated 13 August to the Commissioner, Community Pharmacy Hertfordshire stated:

5.2.5 "Thank you for your letter dated 1 July 2025 notifying Community Pharmacy Hertfordshire (CPH) of this application which is made under Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

5.2.6 CPH would respectfully ask that when considering the application, NHS England is satisfied that the pharmacy procedures for the pharmacy premises will ensure:

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

5.2.6.2 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.

5.2.7 NHS England should additionally be satisfied that:

5.2.7.1 the applicant's practice leaflet and publicity material does not suggest that essential services are only available to patients living in a particular area;

5.2.7.2 should the applicant commence offering directed services, the applicant does not appear to offer pharmaceutical services other than directed services, to patients who are present at, or in the vicinity of, the proposed premises;

5.2.7.3 there will be arrangements in place to monitor the opening hours offered in the application.

5.2.8 NHS England should be assured that the evidence put forward in the form of Standard Operating Procedures (SOPs), do not focus on local provision and compromise the proposed pharmacy in providing services to anyone in England requesting or receiving their services.

5.2.9 CPH would ask that NHS England, when considering the application, decide if the procedures set out in the application supported by the SOPs can deliver the safe and effective provision of essential services as required by Regulation 25(2).

5.2.10 CPH notes that the ability to provide most of the commissioned services offered would depend on whether commissioners agreed to commission them from this pharmacy and the commissioning of proposed services from this pharmacy could not be guaranteed. It should also be noted that a few of the commissioned services listed are not commissioned within Hertfordshire.

5.2.11 CPH has noted no floor plan layout was provided by the applicant. CPH would request that NHS England is satisfied that when the proposed floor plan is submitted it does not compromise that essential services are made without face-to-face contact and are available to anyone in England.”

6 **Summary of Observations**

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

7 **Consideration**

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

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

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

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

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

- 7.6 The Committee noted that the Applicant had stated *"Not applicable as no other pharmacy in same or adjacent premises"* in response to the question of Regulation 31. The Commissioner had noted *"there is no person on the pharmaceutical list providing or undertaking to provide pharmaceutical services from or adjacent to the premises"* and had concluded that *"it was not required to refuse the application under the provisions of Regulation 31"*. The Committee noted that this had not been disputed either on appeal or in subsequent representations. Based on the information provided, the Committee was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

- (b) *unless NHS England is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure—*
 - (i) *the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and*
 - (ii) *the safe and effective provision of pharmaceutical services without face to face contact at the pharmacy premises between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff."*

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

Additional information to be included with excepted applications

- 8. *If the applicant (A) is making an excepted application, A must include in that application details that explain—*
 - (a) *A's belief that the application satisfies the criteria included in one of the regulations in Part 4 which need to be satisfied if section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) are not to apply in relation to that application; and*
 - (b) *if the regulation includes reasons for which the application must be refused, why the application should not be refused for those reasons.*

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

- 7.10 As far as Regulation 25(2)(a) is concerned, the Committee had regard to the application form in which the Applicant states "*Application 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.” The Commissioner also noted *“the premises 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”* and *“agreed it is not required to refuse the application under the provisions of Regulation 25(2)(a).”* The Committee noted that this had not been disputed and that it had not been provided with any information to persuade it otherwise. The Committee was therefore satisfied that the proposed premises were not on the same site as, or in the same building as, the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

- 7.11 As far as Regulation 25(2)(b) is concerned, the Committee considered the information which had been provided by the Applicant in relation to its procedures for the provision of essential services and pharmaceutical services, including its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.
- 7.12 The Regulations require the Committee to be satisfied as to a number of matters, including that essential services will be provided on an uninterrupted basis, across England, and that pharmaceutical services will be provided in a safe and effective way without face to face contact.
- 7.13 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicates that the obligation is only discharged if the information or documentation provided is sufficient to satisfy the Commissioner in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the Commissioner may need to make of the information or documentation when carrying out its functions.
- 7.14 The Committee has asked itself whether it has sufficient information and documentation which would address the criteria in Regulation 25(2)(b). If the Committee is to be satisfied of the matters in that paragraph, the Committee must be provided with evidence to demonstrate these matters. In this case, that evidence put forward has taken the form of the revised SOPs, as provided on appeal, which the Applicant has prepared or commissioned.
- 7.15 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 revised SOPs in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.
- 7.16 The Committee first considered how the Applicant would provide essential services without interruption.
- 7.17 The Committee noted the following information in the Applicant's SOPs:
- 7.18 SOP 1: “Introduction and Background to SOPs”

7.18.1 “1.3 Overriding Provisions Applicable to All SOPs

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

7.19 SOP 33: “The Responsible Pharmacist”

7.19.1 “33.9 Absence of the RP

As a Distance Selling pharmacy, we must provide uninterrupted service throughout the opening hours of the pharmacy. Whilst the GPhC permits the absence of the RP from the pharmacy in particular situations, the NHS Terms of Service still require a pharmacist to be present so that services are not interrupted. [Applicant’s emphasis]

If, for any reason, the RP wishes to leave the premises or wishes to take a break then the second pharmacist must sign in as the RP and arrangements must be made for this prior to one RP leaving the premises and another RP signing in.”

7.20 Based on the information before it, the Committee was of the view that the provision of essential services would be without interruption.

7.21 With regard to services being available to persons anywhere in England, the Committee noted the following information in the Applicant’s SOPs:

7.22 SOP 1: “Introduction and Background to SOPs”

7.22.1 “1.3 Overriding Provisions Applicable to All SOPs

In order to comply with our terms of service, this pharmacy will provide... to persons anywhere in England who request those services.”

7.23 SOP 3: “Procedures for NHS Pharmaceutical Services”

7.23.1 “*NHS Pharmaceutical Services will be provided to any patient living in England who requests such services, this is made clear on the website and in the Practice leaflet.*”

7.24 As well as the assurance in the “overriding provisions” in SOP 1, as set out above with regard to pharmaceutical services being available to patients anywhere in England, the Committee noted references throughout the rest of the SOPs to delivery being made by couriers and Royal Mail as well as the Applicant’s own delivery driver.

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

7.26 The Committee next considered how the Applicant would provide pharmaceutical services without face to face contact.

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

7.28 SOP 1: "Introduction and Background to SOPs"

7.28.1 "1.3 Overriding Provisions Applicable to All SOPs"

In order to comply with our terms of service, this pharmacy will provide;

...

The safe and effective provision of pharmaceutical services without face-to-face contact between any person receiving the services, whether on their own or on someone else's behalf, and the owner of this pharmacy or any member of staff either on or in the vicinity of the premises.

... All staff must be made aware that face to face contact between patients (or their representatives) is prohibited in respect of any and all NHS services either on or in the vicinity of the premises.

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

7.29 SOP 3: "Procedures for NHS Pharmaceutical Services"

7.29.1 "3.1 Communication Channels"

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

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

7.29.2 "3.2 Request for face-to-face service provision"

OUR PHARMACY OPERATES FROM SELF-CONTAINED PREMISES THAT USE A CONTROLLED ACCESS SYSTEM. MEMBERS OF THE PUBLIC ARE NOT ABLE TO ATTEND THE PREMISES TO RECEIVE ANY NHS SERVICES [Applicant's emphasis]

If any member of staff receives a query from any member of the public, or patient or their carers that requests the provision of any pharmaceutical service face to face on or in the vicinity of the premises then they must;

Inform the person that, we cannot provide any face to face NHS services

Refer the person to the Responsible Pharmacist if they require any further explanation.”

- 7.30 The Committee noted the comments from Community Pharmacy Hertfordshire with regard to the absence of a floorplan in the original application form. The Committee noted that, on appeal, the Applicant had provided a floor plan. The Committee was of the view that there was nothing provided in the information submitted by the Applicant which demonstrated that pharmaceutical services would be provided by face to face contact at, or in the vicinity of, the pharmacy premises.
- 7.31 The Committee was mindful of the regulatory changes as of 1 October 2025 and 31 March 2026, that distance selling pharmacies can no longer provide Directed services (Advanced, National Enhanced and Enhanced Services) face to face with the patient at the pharmacy premises. As a result of this amendment, the Committee noted that the Applicant would not be able to provide any pharmaceutical services to patients present at its premises.
- 7.32 In its application the Applicant stated that it intended to provide “NMS (*remotely with consent where required*)”.
- 7.33 The Commissioner, in its decision report stated:
- 7.33.1 *“The Committee was not satisfied that all pharmaceutical services are likely to be secured in a safe and effective manner as the NMS service specification at section 5.4 has not been covered.”*
- 7.34 Section 5.4 of the NMS Service specification states:
- 7.34.1 *“If the patient is not registered with a GP practice, how will the applicant recommend registration and advise how to do this?”*
- 7.35 The Committee had regard to the SOPs and noted SOP 3 ‘Procedures for NHS Pharmaceutical Services’ states:
- 7.35.1 *“3.3 Provision of Advanced or Enhanced Services*
- The Pharmacy does not provide advanced or enhanced services to patients on the premises. NMS will be conducted remotely with no patients accessing the service at the premises (see NMS SOP).*
- Pharmacy First will be provided remotely if the pharmacy has been approved to provide the service (see Pharmacy First SOP).”*
- 7.36 The Committee noted the updated SOP 7 ‘The New Medicine Service (“NMS”)
- which states “*The service must be provided remotely by phone or video call.*”
- 7.37 SOP 7 goes on to state:
- 7.37.1 *“7.6 Process*

1. Patients may be referred to the pharmacy for this service by ...

If the prescription / referral is from a non-NHS source then advise the patients that they must register with an NHS GP to access the service and explain how to do so (via video/ telephone call)

...

7.38 In its decision report, the Commissioner went on to state:

7.38.1 *"The Committee noted that while the Summary Care Record (SCR) access is implied as part of clinical checks on page 3, explicit mention of SCR consent is not detailed in the SOP."*

7.39 The Committee noted SOP 7 "New Medicine Service (NMS)" states:

7.39.1 *"Patient Engagement: Day 1*

All stages of the NMS consultation must be undertaken by telephone or video consultation

...

Prior to provision of the service, informed verbal consent (phone call or video call) must be sought from the patient or their carer and recorded in the pharmacy's clinical record for the service. This consent covers the provision of the service, and the patient should also be advised of the following information sharing that may take place:

...

the pharmacy may access the patients Summary Care Record."

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

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

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

Dispensing of drugs and appliances

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

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

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

7.45 SOP 6 'Prescription Receipt & Exemption Checking' states:

7.45.1 "6.2 Scope

All online services including the following:

... NHS Prescriptions."

7.45.2 "6.7 Administration Checks

Check all prescriptions received in the post against printed and written prescription reception forms. Check the corresponding prescription has been received in the post..."

7.46 SOP 19 'Order Delivery' states:

7.46.1 "19.6 Choice of Delivery Method

For items other than cold chain / "fridge line" items, local deliveries (up to 30 miles radius, but may be extended at the discretion of the RP) the delivery driver should deliver medication. Outside this area Royal Mail should be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier must be used (see SOP for Delivery of Controlled Drugs), or the items are fridge lines, in which case the cold chain courier must be used (see below). [Applicant's emphasis]."

7.47 The Committee was satisfied as to how patients throughout England would present their prescriptions and that the Applicant was proposing to offer products and services to all of England, as per the information contained in the SOPs.

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

Urgent supply without a prescription

7.49 The Committee considered whether the Applicant had explained how it proposes to safely and effectively receive requests from prescribers for urgent supplies of drugs and appliances.

7.50 The Committee noted the information in the Applicant's SOPs under the heading 'Emergency Supply and Urgent Supply' (SOP 16) which describes how the Applicant will process such a request. The Committee noted that the SOPs refer to pharmaceutical services being delivered by several means of non-face

to face communication including telephone and email, and considered that it was reasonable to infer that these methods would be used to receive requests from prescribers for the urgent supply of drugs.

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

Preliminary matters before providing ordered drugs or appliances

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

- 7.53 The Committee noted SOP 6 'Prescription Receipt & Exemption Checking' states:

7.53.1 "6.9 Exempt NHS Prescriptions

...

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

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

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

- 7.56 The Committee noted SOP 6 'Prescription Receipt & Exemption Checking' states:

7.56.1 "6.12 Paid NHS Prescription

Check the prescription to confirm how many charges are due.

Check to see if any fees have been paid and if so, was the correct amount paid?

Contact the patient to arrange payment using the secure payments system using the “customer not present” option.

If no fees have been paid or there is a discrepancy between fees paid and those due, the patient should be contacted and directed to pay the appropriate fees via the online payment system.”

- 7.57 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(5)(b) of Schedule 4.

Providing ordered drugs or appliances

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

- 7.59 The Committee noted SOP 19 ‘Order Delivery’ states:

7.59.1 “19.10 Transfer to the Delivery Driver

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

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

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

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

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

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

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

7.59.2 “19.11 Delivery of prescription to patient or representative address

Ask the patient/representative for their name and address.

Check the patient name and address against the prescription and the bag label. Patient confidentiality should be maintained at all times, especially if delivering to a representative.

Where appropriate ask the patient or representative to complete the reverse of the prescription.

Hand the medication to the patient or representative.

Ask the patient or representative to sign their details on the delivery sheet. If they are unable to sign the delivery sheet the delivery driver should sign on their behalf with their consent and write a note explaining the reason the patient or representative could not sign.

If necessary, collect any medication returns. Always use the Patient Returned Medication Tray that is available in the delivery vehicle. Refer to the Patient Returned Medicines SOP for further guidance."

7.59.3 "19.12 Successful delivery

Once the deliveries are completed, return the delivery sheets to the pharmacy on the same day. The delivery sheets must be scanned into the pharmacy IT system and kept for a minimum period of 7 years."

7.59.4 "19.13 Unsuccessful Delivery

If the patient or representative is not able to receive the delivery of their medication, complete the 'attempted delivery' form and post it through the letterbox. The form will have details for arranging re-delivery.

The prescription and medication must be returned to the pharmacy on the same day and the pharmacist informed of the unsuccessful delivery.

The pharmacy must follow up the unsuccessful delivery by contacting the patient to arrange a second delivery time.

DO NOT:

Post the medication through the letter/post box.

Leave the medication in the porch or any other out building.

Leave the medication at an unauthorised address."

7.59.5 "19.14 Delivery of a prescription via Royal Mail (Not for Cold Chain or CDs)

Follow preparation for delivery process. The pharmacist must contact any patients for whom there are relevant messages or counselling required.

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

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

Ensure a return address is printed clearly on the outer packaging.

Confirm details of all prescriptions to be delivered.

Make a note of all Tracking numbers for prescriptions being delivered by Royal Mail on Delivery Log sheet.

Ensure Royal Mail driver signs Delivery Log sheet for all prescriptions being accepted for delivery. The delivery sheets must be scanned into the pharmacy IT system and kept for a minimum period of 7 years.

Email patients dispatch confirmation with their Tracking number when the prescriptions have left the premises.

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

7.59.6 "19.15 Unsuccessful Delivery via Royal Mail

In the event of an unsuccessful delivery, Royal Mail will leave a 'Sorry We Missed You' card, stating the date and time of the attempted delivery. The patient can then either choose to collect and sign for their medicines at their local post office, or rearrange delivery for a convenient time by telephone or email."

7.59.7 "19.16 Cold chain delivery via courier

All cold chain deliveries must be carried out by couriers with verified and approved cold chain procedures. A list of approved cold chain couriers is available within the Pharmacy and will be updated from time to time. Each approved courier meets stringent criteria to ensure a fully monitored and dedicated cold chain service.

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

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

...Ensure any items for cold chain delivery via courier are stored in the fridge and accompanying items are appropriately marked with a fridge line sticker. Accompanying items must include a note to explain that fridge items will be delivered separately to the rest of their items to enable the cold chain to be maintained.

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

A delivery must be booked using the couriers specified Cold Chain Services (refer to booking procedure with courier in the “cold chain courier” folder),

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

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

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

Confirm details of all prescriptions to be delivered.

The courier must scan a barcode sticker for each item. The pharmacy retains a copy of the barcode which is also the tracking number.”

7.59.8 “19.17 Unsuccessful cold chain delivery via courier

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

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

7.59.9 “19.18 Breach of Integrity of Cold Chain

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

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

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

7.60 SOP 23 ‘Controlled Drugs: Delivery’ states:

7.60.1 “23.5 Delivery of Schedule 2 & 3 CDs

A robust audit trail is essential when controlled drugs are involved. The delivery can be made to a person who is not the patient (the patient must have given authorisation for a representative to take receipt of CDs on their behalf). A Controlled Drugs Delivery Sheet must also be filled in for CD deliveries in addition to the Delivery Log sheet.

CDs must be in a separate bag to any other medication being delivered and the bags should be attached together.

CDs and any other medicines on that patient's delivery must be stored in the lockable compartment of the delivery van and out of sight.

The delivery van must be kept locked at all times when the driver is not in the vehicle.

The delivery driver/courier must sign the back of the prescription as the representative when accepting the CD for delivery.

The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative (passport, driving licence or government approved photo ID card are acceptable forms of ID). A delivery cannot be left with anyone who is not the patient or their authorised representative.

All entries in the CD register must be made when the medication leaves the pharmacy premises. The delivery driver/courier must be entered as the 'person collecting'.

The prescription must be retained in the pharmacy until the delivery driver returns the appropriate paperwork signed by the patient or representative to confirm successful delivery or the patient signature is confirmed online if delivered by courier."

7.60.2 "23.7 Successful Schedule 2 & 3 Delivery

The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative. A delivery cannot be left with anyone who is not the patient or their authorised representative.

For all successful deliveries the Controlled Drug delivery sheet signed by the patient or online courier delivery record should be cross-referenced with the prescription and CD register prior to the prescription being processed as part of the end of day procedure."

7.60.3 "23.8 Unsuccessful Schedule 2 & 3 Delivery via pharmacy driver

Unsuccessful deliveries sent with a pharmacy driver must be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate."

7.60.4 "23.9 Unsuccessful Schedule 2 & 3 Delivery via courier

Unsuccessful deliveries sent with a courier must be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate. Where the time of attempted delivery means that the return cannot be made on the same day, the courier will store the drugs at their approved warehouse overnight.

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

7.60.5 "23.10 Note re Use of Couriers for Controlled Drugs Deliveries

The courier has pharma grade specialist facilities to meet specific quality and validation requirements for healthcare products. This includes Home Office licensed controlled drug stores."

- 7.61 Based on the information before it, the Committee was satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.
- 7.62 The Committee considered whether the Applicant had explained the arrangements which ensure that, for appliances which require fitting/measuring, a registered pharmacist measures/fits them.
- 7.63 The Committee noted that in the application form, in response to the question as to whether they were undertaking to provide appliances, the Applicant had stated "*Drug Tariff Part IX* (*Except items that require measuring or fitting)*".
- 7.64 The Committee noted the Applicant's SOPs state:
- 7.65 SOP 9 'Pharmaceutical & Legal Assessment':

7.65.1 "9.9 Items Requiring Measuring and Fitting

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

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

7.66.1 "26.14 Items Requiring Measuring and Fitting

Where a prescription is received for an appliance or stoma appliance customisation or any item that requires measuring or fitting the patient must be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service.

Patients must be signposted to at least two other providers of the service in their area. (see signposting SOP)”

- 7.67 The Committee was of the view that it had been provided with information sufficient to show that there would be compliance with paragraph 8(4) of Schedule 4.
- 7.68 The Committee considered whether the Applicant had explained what containers will be “suitable” for posted/delivered items.
- 7.69 The Committee noted that SOP 18 ‘Bagging-Up’ states:

7.69.1 “18.7 Choice of Packaging

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

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

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

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

For postal items, either:

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

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

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

Coldchain items should be bubble wrapped and placed in Styrofoam filled re-enforced cardboard boxes and kept in the DELIVERIES FRIDGE (rather than the storage fridge) with the “FRAGILE” and “FRIDGE LINE” stickers attached. The courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box (“cold ship” packaging) and are fully monitored – typically at 2 to 8 degrees Celsius range - (see delivery SOP). Pharmacy staff should be aware that some thermolabile products can be damaged by excessive cold as well as heat. Items such as ice packs can cause

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

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

Refusal to provide drugs or appliances ordered

- 7.71 The Committee asked itself how the Applicant will be satisfied that when dispensing a repeatable prescription other than on the first occasion, that the patient is still using the medication, is not suffering from any side effects, the medicine regime has not changed in any way and there has been no changes to the patient's health, which may indicate the desirability of review the patients treatment.

- 7.72 The Committee noted SOP 34 'Repeat Dispensing' states:

7.72.1 "34.10 Prescription reception

...

The pharmacy record card must be completed and attached to a RA and an entry made on each occasion a dispensing takes place.

Any amendments to the RD, e.g. items not issued or change to expected interval must be recorded in the comment section of the pharmacy copy of the card."

7.72.2 "34.11 Pharmaceutical & Legal Assessment

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

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

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

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

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

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

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

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

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

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

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

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

- 7.74 The Committee considered whether the Applicant had explained how appropriate advice about the benefits of repeat dispensing is given to any patient who (i) has long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term), and (ii) requires regular medicine in respect of that medical condition.

- 7.75 The Committee noted SOP 34 'Repeat Dispensing' states:

7.75.1 "34.10 Prescription Reception

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

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

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

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

On receipt of a repeatable prescription from the patient, either in the post or collected from the surgery for the first time, the pharmacy staff should ensure that the patient fully understands the Repeat Dispensing

Process and is provided with a patient information leaflet that outlines the benefits of the service.

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

7.75.2 “34.11 Pharmaceutical & Legal Assessment

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

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

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

Disposal service in respect of unwanted drugs

- 7.77 The Committee considered whether the Applicant had explained how it will safely and effectively accept and dispose of unwanted drugs presented to it for disposal.

- 7.78 The Committee noted SOP 24 ‘Controlled Drugs: Collection and Disposal of Patient Returns’ states:

7.78.1 “24.5 Patient Returned Medication

This service is available to all patients living in England.

Patients or their representatives may not return and medicines directly to the pharmacy and must follow the procedures set out in this SOP. [Applicant’s emphasis]

Patients should be referred to the ‘Returning unwanted medication’ page on the website for information.

To arrange the return of unwanted medicines to the Pharmacy the patient must telephone and speak to a member of the dispensary team. For controlled drugs this must always be the pharmacist on duty.

The process for returning medication must be explained to the patient.

Each return will be made by booking an appointment for the pharmacy’s driver to visit the patient’s home to collect the returned medication or by sending the appropriate packaging to the patient to arrange for return by Royal Mail – Note the Royal Mail website refers to a prohibition on carrying “controlled drugs” but this refers only to illicit controlled drugs and not those supplied under the direction of a physician.”

7.78.2 “24.7 Return by Royal Mail

The pharmacist must

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

Assess the items for suitability for return by Royal Mail

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

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

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

Contact the patient to ensure that the packaging has been received

Provide signposting via phone or email to other pharmacies where the patient prefers to dispose of unwanted medicines locally.”

7.78.3 “24.8 Handling Patient-Returned CDs from Delivery Driver

Drivers need to:

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

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

Pharmacy staff need to:

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

As soon as possible, Refer to the ‘Returned medicines form’ to make the entry in the ‘Patient returned CD register’, to record the CD that require destruction at a later date.”

7.79 SOP 25 'The Safe and Effective Receipt and Disposal of Medicines' states:

7.79.1 "25.6 Process for Patients to Return Medication

Patient Returned Medication

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

This service is available to all patients living in England.

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

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

Patients may

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

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

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

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

Explaining the Process to Patients

Check which patient or patients the medication belonged to.

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

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

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

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

7.79.2 “25.7 Process for accepting patient returns by the Driver

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

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

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

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

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

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

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

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

Complete the ‘Patients Returns Sheet’ detailing the patients name and address, also if relevant their representatives name.

Store returned medicines in the quarantine area of the van for transport.

The returnable items can be taken back to the pharmacy for destruction.

Ensure medicines are not visible in the vehicle at all times.”

7.79.3 “25.9 Return by Royal Mail

The pharmacist must

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

Assess the items for suitability for return by Royal Mail

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

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

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

Contact the patient to ensure that the packaging has been received

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

7.79.4 "25.10 Disposal of returned medicines

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

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

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

Promotion of healthy lifestyles

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

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

7.82.1 "27.3 Identification of patients for promotion of Healthy Lifestyles

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

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

Passive patients are those where the identification happens as part of another interaction with the patient, but where the patient does not

appear to be actively seeking additional assistance. For example, the dispensing of a prescription which identifies the patient as having high blood pressure / diabetes etc.

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

Leaflets will be delivered to patients with their medication. Those identified as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns. The website, app and email newsletters will also be used to promote healthy lifestyles via the health promotion zone."

7.82.2 "27.4 Health Campaigns & Community Engagement Exercise

Terms of Service require participation in a maximum of 2 campaigns per financial year, but you should agree to take part in all campaigns where practicable.

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

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

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

Prescription linked intervention

- 7.84 The Committee considered whether the Applicant had explained how it will assess whether persons require prescription linked intervention advice because they have diabetes, are at risk of coronary heart disease, smoke or are overweight.

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

7.85.1 "27.6 Long Term Conditions

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

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

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

7.85.2 “27.7 Identification of patients for Support with Long Term Conditions

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

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

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

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

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

conditions will also receive targeted campaigns. The website, app and email newsletters will also be used to promote healthy lifestyles.”

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

Health campaigns

- 7.87 The Committee considered whether the Applicant had explained how it will safely and effectively participate in public health campaigns, if and to the extent required by the Commissioner.

- 7.88 The Committee noted SOP 27 ‘Promotion of Healthy Living, Lifestyle & Health Campaigns’ states:

7.88.1 “27.4 Health Campaigns & Community Engagement Exercise

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

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

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

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

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

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

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

The Pharmacy will use the opportunity when dispensing prescriptions for patients who have conditions such as diabetes, heart disease, obesity and high blood pressure, to offer health advice over the phone or provide them with leaflets about their conditions. Patients will also be

able to speak to the pharmacist regarding information about the campaigns. Advice and help will be available to patients during opening hours of the pharmacy and patients can access information on our pharmacy website at all times. This ensures the uninterrupted provision of the service to patients across England."

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

Signposting

- 7.90 The Committee considered whether the Applicant had explained how it will provide information to users of the pharmacy about other health and social care providers and support organisations.
- 7.91 The Committee noted SOP 26 'Support for Self-Care, Signposting and Health Promotion' states:

7.91.1 "26.10 Other Provider Organisations and Support Details

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

7.91.2 "26.12 Signposting

Service Description

To minimise inappropriate use of health and social care services and support services, patients who require further support, advice or treatment which cannot be provided by the pharmacy, on other health and social care providers or support organisations who may be able to assist the person must be given sufficient information to enable them to access those services. Where appropriate, this may take the form of a referral."

7.91.3 "26.13 Patient Identification

Identification can take place during any interaction that the patient has with the pharmacy staff. In particular, staff should consider the results from the identification of patients for the promotion of healthy lifestyles and those who have filled in the Lifestyle Questionnaire on the website.

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

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

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

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

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

Support for self-care

- 7.93 The Committee considered whether the Applicant had explained how it will provide advice and support to people caring for their families.
- 7.94 The Committee noted SOP 26 'Support for Self-Care, Signposting and Health Promotion' states:

7.94.1 "26.8 Patient Identification

As part of repeat dispensing process / medicine sale or during any other interaction with a patient staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from support for self-care they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided and should include:

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

on changes to the patient's lifestyle."

7.94.2 "26.9 Service outline

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

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

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

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

Discharge medicines service

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

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

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

7.98.1 "28.3 Process

Every day the RP must check the pharmacy's NHS.net Connect system, PharmOutcomes and Refer to Pharmacy for referrals to the DMS. Pharmacy contractors must consider any communication in the following form and manner as constituting a referral: "Any written patient information received by a community pharmacy via secure electronic message from an NHS trust or other provider of NHS services concerning a patient's discharge to usual primary care services and their medicines regimen".

7.98.2 "28.4 Consent

Obtain and record the informed consent from the patient prior to provision of the service using the consent form. As part of obtaining consent discuss the requirements for data sharing. Inform the patient that any information discussed as part of the service may be shared with their GP."

7.98.3 "28.5 DMS Stages

It is expected that all patients referred to the pharmacy will receive all three stages of the service. Note that stages 1, 2 and 3 of the service may occur in parallel and first contact with the patient (as defined in the NHS Discharge Medicines Service toolkit) could happen at any stage in the process."

7.98.4 "28.6 DMS Stage 1 (within 72 hours of referral excluding times when the pharmacy is not open)

The community pharmacy receives a discharge referral. A clinical review is undertaken by a community pharmacist following receipt of a patient referral. The community pharmacy team may contact the referring NHS trust contact or the PCN pharmacy team to discuss any concerns (eg an important medicine the patient usually takes is omitted on the discharge referral) and to seek clarification about the discharge referral."

7.98.5 “28.7 Considering the appropriateness of any medication changes prior to discharge

DMS requests will not necessarily all be in the same form.

Summary Care Record / National Care Records Service Access - If appropriate, access the patient's Summary Care Record / National Care Records Service to see if it assists in providing the service

The pharmacist must review the actions requested in the DMS and consider whether the actions requested are, in the pharmacists clinical judgement, appropriate.

For actions that are considered appropriate the pharmacist must;

Use the information in the referral, to compare (as far as possible) the patient's medicines at discharge to those they were taking before admission to hospital.

Check any prescriptions issued to be dispensed to assess whether any changes are appropriate and identify any areas of concern.

Where necessary, discuss changes that may be appropriate or raise any issues of concern identified, to the extent that in accordance with the pharmacist's clinical judgement, it appropriate to do so with—

(i) the staff of the hospital or other provider of NHS services that made the referral, and

(ii) any provider of primary medical services on whose patient list the patient is; and

keep and maintain records of the DMS referrals received and of any actions taken, as appropriate (in particular, to support delivery of stages 2 and 3 of the service).

REQUIRED ACTIONS AS PER NHS GUIDANCE”

7.98.6 “28.8 DMS Stage 2

The community pharmacy receives the first prescription following discharge. The pharmacist or pharmacy technician will ensure medicines prescribed post-discharge take account of the appropriate changes made during the hospital admission. If there are discrepancies, the pharmacy team will try to resolve them with the general practice, utilising existing communication channels. Alternatively, the community pharmacist may refer the patient to the PCN pharmacy team for a Structured Medication Review or other intervention.

If the pharmacy receives either a written or electronic prescription (or repeatable prescription) or EPS token and the pharmacy has received a request for Stage 2 of the DMS service either from Stage 1 or

Even without a referral to Stage 2, the pharmacy receives such a prescription as described above and the pharmacy is aware as a result of an earlier referral to Stage 2 or Stage 3 this is the first prescription for a medicinal product following the patient's discharge from hospital, or a transfer of the patient's care from another NHS service provider, AND

The pharmacy is aware that either the patient, or their carer wishes the pharmacy to provide Stage 2 of the DMS service then the pharmacy must provide the following service as part of Stage 2

Then the pharmacist must:

Review / perform a further review of any prescription

*Summary Care Record / National Care Records Service Access
- If appropriate, access the patient's Summary Care Record / National Care Records Service to see if it assists in providing the service.*

Specifically consider if in your clinical judgement appropriate account has been taken to any changes in the medication regimen during the patient's stay in hospital or prior to the transfer of the DMS from another pharmacy.

Where you see areas of concern, raise those issues as appropriate with the patient's GP

Keep and maintain records of the DMS referrals received and of any actions taken, as appropriate (in particular, to support delivery of stage 3 of the service)."

7.98.7 "28.9 DMS Stage 3

The NHS Discharge Medicines Service should also be used as an opportunity to engage with patients about their medicines on a shared decision-making basis. Whether the patient or their carer makes contact themselves for advice, a referral is received from an NHS trust on discharge or a prescription is received following prescribing changes, the pharmacist or pharmacy technician should take the opportunity to establish the patient's understanding of their condition(s), their associated medications and how each medicine can be best administered to get optimum benefit and reduce unwanted side effects.

The community pharmacy checks the patient's understanding of their medicines regimen. The pharmacist or pharmacy technician will hold a discussion, adopting a shared decision-making approach, with the patient (or the carer if appropriate) to check their understanding of their

post-discharge medicines' regimen. The pharmacist or pharmacy technician will identify any adherence, clinical issues, outstanding questions or needs the patient may have regarding their medicines."

- 7.99 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

Websites and health promotion zones

- 7.100 The Committee considered whether the Applicant had explained how it will ensure that it has a website for use by the public for the purpose of accessing pharmaceutical services from those premises, on which there is an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues.

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

7.101.1 *"26.11 Health promotion zone on our website*

The website allows patients to access pharmaceutical services via our interactive page.

Explaining the Interactive Page to Patients

The interactive page is promoted on the website so that when a patient first visits the website they are signposted to a range of up to date materials that promote healthy lifestyles.

The Superintendent Pharmacist is responsible for ensuring that a reasonable range of materials are accessible via the interactive page and that they address a reasonable range of health issues.

The health promotion zone may also includes [sic] details of current health campaigns and other information to promote healthy lifestyle choices as well as providing access to the Lifestyle Questionnaire that is used to target health information to patients."

- 7.102 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 28C of Schedule 4.

Summary

- 7.103 On the information before it, the Committee could be satisfied that there are procedures likely to secure the safe and effective provision of pharmaceutical services as required by Regulation 25(2)(b).

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

- 7.104.1 confirm the Commissioner's decision;
 - 7.104.2 quash the Commissioner's decision and redetermine the application;
 - 7.104.3 quash the Commissioner's decision and, if it considers that there should be a further notification to the parties to make representations, remit the matter to the Commissioner.
- 7.105 In those circumstances, given that the Committee has reached a different conclusion to the Commissioner for the reasons set out above, the Committee determined that the decision of the Commissioner must be quashed.
- 7.106 The Committee considered whether there should be a further notification to the parties detailed at paragraph 19 of Schedule 2 of the Regulations to allow them to make representations if they so wished (in which case it would be appropriate to quash the original decision and remit the matter to the Commissioner) or whether it was preferable for the Committee to reconsider the application.
- 7.107 The Committee noted that representations on Regulation 25 had already been made by parties to the Commissioner, and these had been circulated and seen by all parties as part of the processing of the application by the Commissioner. The Committee further noted that when the appeal was circulated representations had been sought from parties on Regulation 25.
- 7.108 The Committee concluded that further notification under paragraph 19 of Schedule 2 would not be helpful in this case.

8 Decision

- 8.1 The Committee concluded that it was not required to refuse the application under the provisions of Regulation 31.
- 8.2 The Committee:
- 8.2.1 quashes the decision of the Commissioner; and
 - 8.2.2 redetermines the application as follows -
 - 8.2.2.1 the Committee was satisfied that the premises of the Applicant are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list;
 - 8.2.2.2 the Committee was satisfied that all essential services were likely to be secured without interruption during the opening hours;
 - 8.2.2.3 the Committee was satisfied that all essential services were likely to be secured for persons anywhere in England;
 - 8.2.2.4 the Committee was satisfied that pharmaceutical services were likely to be secured in a safe and effective manner; and

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

8.2.3 The application is granted.

Case Manager
Primary Care Appeals