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25 April 2025

REF: SHA/26463

APPEAL AGAINST NHS MID AND SOUTH ESSEX ICB DECISION TO REFUSE AN APPLICATION BY CHELMSFORD CITY PHARMA LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT TERRACE BAR, HAMPTONS SPORTS AND LEISURE, TYDEMANS, OFF BEEHIVE LANE, GREAT BADDOW, CHELMSFORD, CM2 9FH UNDER REGULATION 25

1 Outcome

1.1 The Pharmacy Appeals Committee ("Committee"), appointed by NHS Resolution, quashes the decision of the Commissioner and redetermines the application.

1.2 The Committee determined that the application should be refused.

A copy of this decision is being sent to:

Chelmsford City Pharma Ltd
North & South Essex LMC
PCSE on behalf of Mid and South Essex ICB

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1 The Application

By application dated 15 July 2024, Chelmsford City Pharma Ltd ("the Applicant") applied to Mid and South Essex ICB ("the Commissioner") for inclusion in the pharmaceutical list at Terrace Bar, Hamptons Sports and Leisure, Tydemans, off Beehive Lane, Great Baddow, Chelmsford, CM2 9FH 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*
* 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 "N/A as no other pharmacy located on premises and meets DSP location specification"

1.3 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant stated:

1.3.1 "The DSP pharmacy premises is not located at the same site or building of a primary medical service list."

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

1.4 Please find below information to explain how the pharmacy procedures used within the premises will secure:

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

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

1.5 “I am writing to submit my application for the Distant Selling Pharmacy (DSP) designation for Chelmsford City Pharma Ltd. After a thorough review of the specifications for DSP, I am confident in our ability to meet and exceed the outlined requirements.

1.6 I would like to offer the following assurances regarding our operations:

1.7 **Compliance with SOPs**: We will fully adhere to Standard Operating Procedures (SOPs) to meet the requirements for Essential, Advanced, and Enhanced services, ensuring high-quality care and compliance.

1.8 **Essential NHS Services**: Essential NHS services will not be provided on the premises, in accordance with DSP guidelines.

1.9 **Medication Delivery**: All dispensed medications will be delivered or posted to patients, ensuring accessibility and convenience as an essential service of our DSP operations.

1.10 **Patient Sign-Posting**: For patients requiring on-site Essential services, we will sign-post them to the nearest community pharmacy providers. Additionally, options for remote consultation via telephone or video call will be provided where appropriate.

1.11 **National NHS Prescription Service & Essential service**: We will offer NHS prescription services on a national scale, extending our reach and service availability as per DSP specification.

1.12 **Website Development**: A comprehensive website will be created prior to the opening of the premises, fully compliant with GPHC standards to facilitate patient access and service provision.

1.13 **Premises Standards**: Our premises will meet NHS requirements for a DSP. This includes having a consultation room equipped for telephone or video calls, ensuring privacy and convenience for patient consultations.

1.14 **GPHC Compliance**: We will consistently meet and maintain GPHC standards, which include conducting risk assessments, audits, and upholding clinical and information governance, as well as GDPR compliance.

1.15 **Reputable Wholesalers**: We will source medications from reputable wholesalers, ensuring the highest standards in dispensing and pharmaceutical care.

1.16 **Secure Medication Dispatch**: As a DSP, we will ensure that all medications are securely posted or delivered to the correct patients. Robust measures will be in place to verify and track dispatches accurately.

1.17 **Controlled Drugs Compliance**: We will strictly adhere to the requirements for dispensing controlled drugs. A reputable postal service will be used to safely deliver medications to the intended recipients, with full audit trails available for verification.

1.18 **Healthy Living Pharmacy**: This will be promoted and encouraged on website with up to [sic] NHS resource and guideline. There will be a designated section on the website promoting this.

1.19 By adhering to these practices, we aim to provide exceptional pharmaceutical care while meeting all regulatory requirements for a Distant Selling Pharmacy. I look forward to your favourable consideration of our application.”

2 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 8 January 2025 states:

2.1 "Mid and South 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."

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

2.2 "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 and 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").

2.3 Application in respect of distance selling premises: Chelmsford City Pharma Ltd, Terrace Bar, Hamptons Sports and Leisure, Great Baddow, Chelmsford, Essex, CM2 9FH.

2.4 The Committee considered this excepted application in respect of distance selling premises.

2.5 The Committee first considered Regulation 31.

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

2.7 The Committee agreed it was therefore not required to refuse the application under the provisions of Regulation 31.

2.8 Regulation 25: Distance selling premises applications

2.9 Regulation 25(2)(a)

2.10 The Committee noted that the proposed premises is situated in a sports and leisure complex which is open to the public and 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. Information on the closest pharmacies and GP practices was distributed to the Committee prior to the meeting.

2.11 The Committee agreed it was therefore not required to refuse the application under the provisions of Regulation 25(2)(a).

2.12 Regulation 25(2)(b)

2.13 The Committee considered 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.

2.14 The Committee noted that the core opening hours declared on the application form must and do total 40 core hours per week, and are listed as:

Proposed							40:00	0:00
	S1	C1		S2	C2		S3	C3
Monday		09:00	13:00		14:00	18:00		
Tuesday		09:00	13:00		14:00	18:00		
Wednesday		09:00	13:00		14:00	18:00		
Thursday		09:00	13:00		14:00	18:00		
Friday		09:00	13:00		14:00	18:00		
Saturday								
Sunday								

2.15 There are no supplementary hours declared.

2.16 The Committee noted the information provided within the application "Supporting Documents".

2.17 With their application, the applicant states:

"After a thorough review of the specifications for DSP, I am confident in our ability to meet and exceed the outlined requirements.".

Representations

2.18 The Committee noted the following representations.

2.19 Boots:

2.19.1 "Boots UK Ltd would like to respectfully request that members of the deciding committee are satisfied that this application fully meets the criteria set out in Regulation 25 and the conditions set out in Regulation 64 when determining this application."

2.20 North and South Essex Local Medical Committee

2.20.1 "The LMC has no comments but notes that this is an excepted application and seeks assurances that NHS England will clarify that all provisions set out in Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 in respect of distance selling premises will be met before granting the application."

2.21 Day Lewis Pharmacy:

2.21.1 "Firstly, we note that the applicant has not provided a full set of detailed Standard Operating Procedures ("SOPs"). This leaves significant doubt in respect of the applicant's compliance with the requirements of an application made under Regulation 25.

2.21.2 We would suggest that the ICB will not be in a position to grant this application if it is not in possession of this information in full. Whilst the applicant has provided very limited supporting information in respect of this application there are many gaps in the information provided.

2.21.3 The ICB is being asked to determine whether the application meets the regulatory tests and can therefore be approved. This can only be determined by reviewing each and every SOP in detail to ensure that:

(a) all essential services will be provided without interruption during the proposed opening hours of the pharmacy;

(b) all essential services will be made available to anybody in England who wishes to access them;

(c) all essential services are likely to be secured in a safe and effective manner;

(d) all essential services will be provided without the face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

2.21.4 In the absence of a full set of SOPs we do not believe that the ICB can be confident that the requirements of Regulation 25(2)(b) will be met. For example:

(b) all essential services will be made available to anybody in England who wishes to access them;

2.21.5 The applicant states:

2.21.6 "Essential NHS services will not be provided on the premises".

2.21.7 If these services are not provided 'on the premises' it is not clear exactly where they will be provided. From the information provided, it is also not clear how certain patient groups such as those with severe disabilities, sight loss or hearing loss will have equal access to the services offered by this pharmacy. Where services require internet or telephone access they may discriminate against patients who are not able to make use of these communication methods for any reason.

2.21.8 The ICB will be unable to satisfy themselves that all patients will be able to access essential services unless communication methods (in the absence of face-to-face contact) are explained in detail.

2.21.9 The nature of distance selling pharmacies is that the model relies heavily on the use of either websites or apps. Whilst telephone services may be provided, many of the services referred to by the applicant appear to rely on access to the internet. This naturally excludes patients who do not have such access, through choice or lack of availability.

2.21.10 Where these patients are discriminated against, through lack of access to the pharmaceutical services provided by this pharmacy, it cannot be said that services are available to anyone in England who wants to use them.

(c) all essential services are likely to be secured in a safe and effective manner;

2.21.11 The applicant states that “all dispensed medications will be delivered or posted to patients” but no information is provided in respect of ensuring the security of controlled drugs or the stability of cold chain goods. The ICB cannot be satisfied that the safe delivery of essential services will be secured.

(d) all essential services will be provided without the face-to-face contact between any person receiving the services, whether on their own or on someone else’s behalf, and the applicant or the applicant’s staff.

2.21.12 The applicant has indicated on its application form that it will include a consultation room. This implies that there may be some patients attending the premises. If the applicant intends to provide ‘face-to-face’ advanced and enhanced services, it is not clear what protections will be in place to prevent the inadvertent provision of ‘essential’ services on a face-to-face basis.

2.21.13 The applicant has failed to provide sufficient information to enable the ICB to be confident that the application meets the requirements of Regulation 25. In fact, the information provided clearly demonstrates that those requirements will not be met. That being the case the application must be refused.”

2.22 Representations Received From Circulation of First Representations

2.23 North and South Essex Local Medical Committee

2.23.1 “The LMC has no further comments on the application and looks forward to receiving the outcome in due course.”

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

2.25 The Committee noted the following aspects of the essential services, which are considered more difficult to provide safely and effectively in a distance selling context:

2.25.1 Dispensing of drugs and appliances

2.25.2 Urgent supply without a prescription

2.25.3 Preliminary matters before providing ordered drugs or appliances

2.25.4 Providing ordered drugs or appliances

2.25.5 Refusal to provide drugs or appliances ordered

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

2.25.7 Disposal service in respect of unwanted drugs

2.25.8 Promotion of healthy lifestyles

2.25.9 Prescription linked intervention

2.25.10 Public health campaigns

2.25.11 Signposting

2.25.12 Support for self-care

Dispensing of drugs and appliances

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

2.27 The Committee noted that the applicant has not provided details relating to dispensing of drugs and appliances except to say" "We will offer NHS prescription services on a national scale, extending our reach and service availability as per DSP specification."

2.28 The Committee were not satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraph 5(2)(3) of Schedule 4.

Urgent supply without a prescription

2.29 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.

2.30 The Committee noted that the applicant has not provided details relating to urgent supply without a prescription.

2.31 The Committee were not 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

2.32 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.

2.33 The Committee noted that the applicant has not provided details relating to preliminary matters before providing ordered drugs or appliances and their process for "Verification of Declarations of Prescription Exemptions".

2.34 The Committee were not 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

2.35 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).

2.36 The Committee noted that the applicant has not provided supporting information within their application relating to providing ordered drugs or appliances.

2.37 The Committee were not 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.

2.38 The Committee considered 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.

2.39 The Committee noted that the applicant has not provided supporting information relating to the refusal to provide drugs or appliances ordered.

2.40 The Committee were not 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.

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

(ii) requires regular medicine in respect of that medical condition.

2.42 The Committee noted that the applicant has not provided any supporting information relating to further activities carried out in connection with the provision of dispensing services.

2.43 The Committee were not 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

2.44 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.

2.45 The Committee noted that the applicant has not provided any supporting information relating to the disposal service in respect of unwanted drugs.

2.46 The Committee were not 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

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

2.48 The Committee noted that the applicant has not provided any supporting information relating to the promotion of healthy lifestyles except to say "*This will be promoted and encouraged on website with upto NHS resource and guideline. There will be a designated section on the website promoting this*." [sic]

2.49 The Committee were not 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.

2.50 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.

2.51 The Committee noted that the applicant has not provided information relating to prescription linked interventions.

2.52 The Committee were not 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

2.53 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 the NHSCB.

2.54 The Committee noted that the applicant has not provided information relating to public health campaigns.

2.55 The Committee were not satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraph 18 of Schedule 4.

Signposting

2.56 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.

2.57 The Committee noted that the applicant has not provided information on signposting patients within their application except to say "*For patients requiring on-site Essential services, we will sign-post them to the nearest community pharmacy providers. Additionally, options for remote consultation via telephone or video call will be provided where appropriate*."

2.58 The Committee were not 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

2.59 The 'Discharge Medicines Service ("DMS")' described briefly:

"The service is designed in 3 Stages, where each Stage builds on the last to provide additional support if required to the patient or, where appropriate their carer.

The pharmacist must use their clinical judgement when considering their actions and recommendations in respect of the service and consider the duty of confidentiality to the patient when involving a carer in discussions about the patient and their medication regimen."

2.60 The Committee was satisfied that it was provided with information sufficient to show that there would be compliance with Paragraphs 21 – 22 of Schedule 4.

2.61 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.

2.62 The Committee was satisfied this would not be affected in granting this application.

Decision

2.63 The Committee refused the application as the requirements set out in Regulation 25 are not met.

2.64 The Committee agreed it was not required to refuse the application under the provisions of Regulation 31.

2.65 The Committee agreed it was satisfied that the proposed premises are not adjacent to or in close proximity to other chemist premises.

2.66 The Committee agreed it 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.

2.67 The Committee agreed it was satisfied that all essential services are likely to be secured without interruption during the opening hours.

2.68 The Committee agreed it was not satisfied that all essential services are likely to be secured in a safe and effective manner.

2.69 The Committee agreed that appeal rights are given to the applicant, Chelmsford City Pharma Ltd.

2.70 Regulation 66 – conditions relating to providing directed services.

2.71 The Committee agreed that as the application has been refused, it is not required to consider this regulation."

3 The Appeal

Using the online form for pharmacy application appeals dated 15 January 2025, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "I am writing in response to the Pharmaceutical Services Regulations Committee's (PSRC) decision dated 27th November 2024, which rejected the application for Chelmsford City Pharma Ltd as a distance-selling premises for the Distance selling pharmacy contract. This letter seeks to address the concerns raised and provide further supporting information to demonstrate compliance with the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

3.2 As this was my first application for a DSP contract and I did not engage external agents for support, any unintentional omissions or errors in the application were not reflective of our ability to meet the requirements of the contract. I hope this does not undermine the Committee's confidence in our capacity to operate a DSP contract effectively and in full compliance with the regulations. We fundamentally understand the requirement needed to adhered to DSP requirement for example no essential service will be provided face to face, all other route of communication such as Telephone, virtual methods.

3.3 Please consider the points below in relation to the concerns you have raised, this will cover the following points:

3.3.1 Dispensing of drugs and appliances

3.3.2 Urgent supply without a prescription

3.3.3 Preliminary matters before providing ordered drugs or appliances

3.3.4 Providing ordered drugs or appliances

3.3.5 Refusal to provide drugs or appliances ordered

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

3.3.7 Disposal service in respect of unwanted drugs

3.3.8 Promotion of healthy lifestyles

3.3.9 Prescription linked intervention

3.3.10 Public health campaigns

3.3.11 Signposting

3.3.12 Support for self-care

Dispensing of Drugs and Appliances

3.4 The PSRC expressed concerns about how non-electronic prescriptions would be presented and dispensed. As outlined in our detailed procedures:

3.5 Handling Non-Electronic Prescriptions: Non-electronic prescriptions will be handled through secure and traceable courier or postal services. These services will utilize tamper-proof packaging to ensure the integrity and confidentiality of the prescription from receipt to return. Upon receiving a non-electronic prescription, our team will immediately log the details into our Patient Medication Record (PMR) system to maintain a traceable and auditable record. Additionally, patients will be provided with clear instructions on how to securely send their prescriptions to the pharmacy using pre-approved couriers.

3.6 For local delivery, we will be using delivery tracking device such as Delivery Mate, where this will date stamp delivery together with proof of delivery. All Controlled drugs medication will be signed for, track and audited.

3.7 Electronic Prescription Service (EPS): As per current prescription trend majority of prescriptions will be received through the Electronic Prescription Service (EPS). This ensures streamlined processing, minimizes delays, and facilitates clinical checks. Patients will be informed about the benefits and ease of using EPS during initial communications. Platforms such as Healthera will be used to support patient to nominate with ease and give patients options to denominated where needed. Using such platforms will allow patients to nominate not just locally but also nationally as per DSP contract.

3.8 Non EPS Prescription: Where prescription are not available as EPS, a pharmacy stamped envelope will be provided for the GP or patients to post prescriptions to us directly. All prescriptions is and will be scrutinised for clinical and legal checks [sic].

3.9 Controlled Drugs Compliance: The handling and dispensing of Controlled Drugs (CDs) will fully adhere to the Misuse of Drugs Act 1971 and its associated regulations. Prescriptions for CDs will be processed with heightened scrutiny, ensuring compliance with all legal and professional guidelines. Medications will be delivered via a secure courier or postal service equipped with a tracking mechanism to ensure accountability.

Tamper-proof packaging will further safeguard the integrity of the medication during transit.

3.10 Standard Operating Procedures (SOPs): Comprehensive SOPs are in place to address every aspect of prescription processing. These include:

3.11 Clinical Checks: Each prescription undergoes rigorous clinical and legal review by a qualified pharmacist to identify any potential interactions, errors, or concerns.

3.12 Patient Consultations: Consultations will be conducted via secure telephone or live video calls, ensuring patients receive appropriate advice and instructions about their medications. All consultations and actions will be documented and logged in the PMR system. On NO occasion any essential service will be provided face to face.

3.13 Resolution of Concerns: Any issues identified during the review process, such as incomplete prescriptions or potential contraindications, will be directly communicated to the prescriber. These communications will be logged for transparency and audit purposes.

Urgent and Emergency Supplies

3.14 The position of DSP regarding emergency supply will be clearly presented on the website and the different solution for emergency supply or signposting will be explained. For emergency supplies a comprehensive system and protocols will be in place to ensure these requests are handled promptly and professionally. Staff members will be trained to manage both urgent supply requests from prescribers and emergency supply requests from patients, ensuring compliance with legal and professional requirements.

Urgent Supply Requests (Prescriber-Initiated)

3.15 Urgent supply requests from prescribers are managed under strict conditions to ensure patient safety and regulatory compliance. The following steps are followed:

3.16 Verification of Prescriber: The pharmacist confirms the request is from a legitimate, authorized prescriber, cross-referencing against an approved list to ensure accuracy.

3.17 Emergency Justification: The pharmacist must be satisfied that an emergency prevents the immediate provision of a valid prescription. The urgency of the situation is assessed based on the information provided by the prescriber.

3.18 Written Prescription Commitment: Prescribers are required to confirm that a written prescription will be provided within 72 hours of the request, and a robust tracking system ensures these are received within the stipulated time.

3.19 Authorized Medications Only: Only medications permitted for supply in emergency situations are provided. This excludes Schedule 1, 2, and 3 controlled drugs, except Phenobarbital for epilepsy, as prescribed by a UK-registered practitioner. Prescribers from the EEA are not permitted to request emergency supplies for any controlled drugs.

3.20 Comprehensive Record-Keeping: All supplies are documented in detail in accordance with standard operating procedures, ensuring traceability and regulatory compliance.

Emergency Supply Requests (Patient-Initiated)

3.21 Requests for emergency supplies made directly by patients are carefully assessed to ensure patient need is balanced with regulatory requirements. The following steps are undertaken:

3.22 Remote Consultation: The pharmacist conducts a structured consultation with the patient using non-face-to-face methods, such as telephone or video calls. This ensures accessibility while maintaining a professional standard of care.

3.23 Legal Documentation: An entry is made in the Prescription-Only Medicine (POM) medications include the phrase “Emergency Supply” to comply with legal obligations.

3.24 Use of Faxed or Scanned Prescriptions: Faxed or scanned prescriptions are not considered legally valid. If such documents are presented, the pharmacist does not dispense medication against them but instead uses the emergency supply procedure, ensuring medications are only supplied once all conditions are met.

3.25 Where Emergency supply cannot be fulfilled i.e. for CD prescription, patients will sign posted to relevant support such as NHS 111 , GP, AE.

Prioritization of Delivery for Urgent and Emergency Supplies

3.26 Given the critical nature of urgent or emergency requests, delivery processes are designed to prioritize speed and efficiency:

3.27 Local Deliveries: Drivers are instructed to treat these deliveries with urgency and prioritize them in their schedules. Medications are clearly marked as “URGENT” to ensure rapid handling.

3.28 Courier Services: For non-local deliveries, couriers are notified of the time-sensitive nature of the items and instructed to use the fastest available delivery methods.

3.29 No Additional Charges: Patients are not charged extra for expedited delivery, even if the pharmacy incurs additional costs to meet the urgency of the request.

Safe Disposal of Unwanted Medicines

3.30 To support environmental responsibility and patient safety, a range of services is available for the safe disposal of unwanted medications:

3.31 Specialist Waste Disposal Services: A licensed waste management company is contracted to collect and dispose of unwanted medications securely, ensuring compliance with environmental and safety regulations.

3.32 Courier Return Options: Patients can return unwanted medications using a pharmacy-provided courier service. This service is fully funded by the pharmacy, ensuring accessibility for all patients.

3.33 Local Collection Services: Patients in the surrounding area can arrange for medications to be collected from their home or workplace by contacting the pharmacy through phone or email.

3.34 Pre-Packaged Disposal Kits: Patients are provided with pre-packaged disposal materials, enabling them to securely return medicines. Clear instructions are made available on the pharmacy’s website, along with information about how to arrange

3.35 Once medicines are returned to the pharmacy, they are carefully sorted and placed in secure disposal units. Regular collections by waste management providers ensure

proper handling. This disposal service is promoted through the pharmacy's website and other informational materials, making it accessible and convenient for patients.

3.36 In no situation as per Essential service would medication be accepted in person; this will be reiterated on the website and clearly signposted so patients can choose the best suitable return method.

Preliminary Matters Before Providing Ordered Drugs or Appliances

3.37 Ensuring the accurate verification of prescription exemption status is a critical part of maintaining compliance with regulatory requirements and delivering a NHS service for patients. To facilitate this, the pharmacy will implement comprehensive systems and protocols as outlined below:

Submission of Exemption Evidence

3.38 Multiple Submission Options:

3.39 Patients can provide evidence of their exemption through several secure and accessible methods:

3.39.1 Electronic Upload: Patients can submit scanned or photographed copies of their exemption evidence through a secure online portal or via email. The pharmacy records that the evidence was provided in a digital format for transparency.

3.39.2 Postal Service: Patients may send original or photocopied exemption evidence by post. To minimize inconvenience, the pharmacy covers postage costs for both sending and returning the evidence.

3.39.3 Courier Delivery: For local patients using the pharmacy's delivery driver, exemption evidence can be handed over for verification and returned securely after processing.

3.40 Flexibility for Patients:

3.41 Verification and Assessment

3.42 Rigorous Review Process:

3.43 The pharmacist in charge is responsible for assessing the submitted exemption evidence. They must ensure it meets the regulatory standard of "satisfactory evidence" to confirm the patient's exemption status.

3.44 If the evidence provided is deemed insufficient or invalid, the "Evidence Not Seen" box is marked on the reverse of the prescription, and the patient is informed about the issue promptly.

3.45 Detailed Record-Keeping:

3.46 All verified exemptions are recorded in the Patient Medication Record (PMR) system, including:

3.46.1 The type of exemption (e.g., medical condition, maternity exemption, etc.).

3.46.2 The expiration date of the exemption.

3.46.3 The date of verification and the pharmacist's assessment.

3.47 The system also includes functionality to set reminders for follow-up checks, ensuring exemption details remain up to date.

Handling of Prescription Charges

3.48 Efficient Payment Processes:

3.49 For patients who are not exempt from prescription charges, secure payment systems are in place. Payments can be made online through a secure payment portal linked to the pharmacy's website.

3.50 Once payment is received, the prescription is marked as "paid" in the pharmacy's system, and the dispensing process is initiated without delay. This ensures that all prescriptions are processed promptly while maintaining an accurate audit trail.

Communication with Patients:

3.51 Patients are notified about the status of their prescription, including whether additional information or payments are required, to minimize delays and maintain transparency.

Cost-Free and Secure Processes

3.52 Postal Costs Covered by the Pharmacy:

3.53 When patients choose to send exemption evidence by post, the pharmacy covers all associated costs, including return postage. This ensures that patients do not face financial barriers to providing the required documentation.

3.54 Evidence is handled securely and returned promptly after verification.

Patient Privacy and Security:

3.55 All submissions, whether physical or digital, are processed in line with GDPR and data protection regulations. This ensures patient privacy is maintained at every stage of the process.

3.56 System Integration and Ongoing Updates

3.57 PMR System Optimization:

3.58 The pharmacy's PMR system is designed to integrate seamlessly with exemption verification workflows. This includes real-time updates to records, automated reminders for renewal dates, and clear flags for any outstanding evidence or payments.

3.59 This functionality reduces administrative burdens for staff while ensuring compliance with regulations and continuity of service for patients.

Training and Support:

3.60 Pharmacy staff receive regular training on exemption verification procedures, including recognizing acceptable evidence and handling patient queries effectively.

3.61 A dedicated support team is available to assist patients who have questions about their exemption status or need help submitting their evidence.

Cold Chain and Controlled Drug Compliance

3.62 Provision of Drugs and Appliances

3.63 The pharmacy has implemented robust and detailed procedures to ensure all ordered drugs and appliances are dispensed and delivered safely, efficiently, and in full compliance with applicable regulations.

Receipt and Processing of Prescriptions:

3.64 Prescriptions are received via the Electronic Prescription Service (EPS), post, or courier.

3.65 Upon receipt, prescriptions undergo a thorough clinical and legal assessment by the Responsible Pharmacist (RP). Any clinical concerns, such as potential drug interactions or dosage issues, are escalated to the prescriber for prompt resolution to avoid delays in dispensing.

Standard Operating Procedures (SOPs):

3.66 Comprehensive SOPs are in place to guide staff on every stage of the dispensing process, from receiving prescriptions to the final delivery of medicines.

3.67 SOPs include detailed protocols for handling urgent or emergency requests, managing repeat prescriptions, and maintaining compliance with the Misuse of Drugs Regulations.

Packaging Protocols:

3.68 Medications are packaged securely to protect their integrity during transportation.

3.69 Tamper-evident seals are applied to all packages to ensure security and prevent unauthorized access.

3.70 Fragile items and liquid medicines are cushioned with appropriate materials to withstand transit rigors.

Cold Chain Maintenance

3.71 Maintaining the integrity of cold chain medicines is a top priority. The pharmacy has implemented industry-standard practices to ensure the storage and transportation of thermolabile medications comply with regulatory and safety requirements.

Specialized Packaging:

3.72 Cold chain medicines are packed using insulated containers with temperature-stable cooling elements that maintain the required temperature range during transportation.

3.73 Temperature data loggers are included in each shipment to monitor real-time conditions, ensuring compliance throughout the delivery process.

Dedicated Cold Chain Couriers:

3.74 Deliveries of temperature-sensitive medicines are handled by specialist courier services equipped with temperature-controlled vehicles.

3.75 These couriers are trained in the handling of pharmaceutical products and follow stringent protocols to prevent breaches in the cold chain.

Monitoring and Incident Management:

3.76 Each shipment includes temperature monitoring devices that provide a verifiable record of conditions during transit.

3.77 If a breach in the cold chain is detected, the courier immediately notifies the pharmacy, and the affected products are returned for safe disposal. Replacement medications are dispatched promptly to avoid any disruption to the patient's treatment.

Routine Audits:

3.78 Cold chain processes are reviewed regularly as part of the pharmacy's audit program. These audits assess compliance with protocols, equipment performance, and courier reliability to ensure continuous improvement.

Compliance with the Misuse of Drugs Regulations 2001

3.79 The pharmacy is fully committed to meeting the requirements of Regulations 14 and 16 of the Misuse of Drugs Regulations 2001, ensuring the secure handling, delivery, and record-keeping of controlled drugs (CDs).

Controlled Drug Storage and Dispensing:

3.80 CDs are stored in a designated, locked cabinet that complies with regulatory requirements for secure storage. Access to this cabinet is restricted to authorized personnel only.

3.81 Dispensing of CDs is conducted by the RP, who ensures all prescriptions meet legal and clinical criteria before the medicines are supplied.

Delivery of Controlled Drugs:

3.82 CDs are transported using specialized courier services equipped to handle controlled substances securely.

3.83 Robust identity verification processes ensure that CDs are delivered only to the intended patient or their authorized representative.

3.84 Patients or representatives are required to provide a signature upon receipt, creating a verifiable audit trail for every delivery.

Record-Keeping:

3.85 All transactions involving CDs are meticulously recorded in the Controlled Drug Register, which is regularly audited to ensure accuracy and compliance.

3.86 Returns of CDs are logged separately, and unused or expired CDs are destroyed in accordance with regulatory guidelines, witnessed by a trained staff member.

Incident Management:

3.87 Any discrepancies or incidents involving CDs are documented and investigated immediately. The findings are used to refine processes and prevent recurrence.

3.88 Additional Safeguards

Risk Assessments:

3.89 Comprehensive risk assessments are conducted regularly to identify and mitigate potential risks associated with the provision of drugs, including cold chain medicines and CDs.

Training and Accountability:

3.90 All staff undergo regular training to ensure they are fully competent in handling, sensitive drugs and controlled substances.

3.91 Clear lines of accountability are established, with the RP overseeing all dispensing and delivery activities.

Audit and Continuous Improvement:

3.92 The pharmacy conducts regular audits of its processes, including the delivery of cold chain medicines and CDs, to ensure compliance with legal requirements and identify areas for improvement.

Contingency Planning:

3.93 The pharmacy has contingency plans in place to manage potential disruptions, such as courier delays, equipment failures, or medication shortages, ensuring uninterrupted service to patients.

Disposal of Unwanted Drugs

3.94 Disposal of Unwanted Medicines

3.95 The pharmacy will provide a range of convenient and secure options for patients to safely dispose of unwanted medicines, ensuring compliance with environmental regulations and promoting public health. This has been addressed earlier and the following points for the committee to consider:

3.96 Disposal Options for Patients

3.97 Specialist Waste Management Service:

3.97.1 The pharmacy partners with a licensed specialist waste management company to ensure the safe and environmentally responsible disposal of unwanted medicines.

3.97.2 This service extends to residential homes, enabling collection from patients who may have mobility or transportation challenges.

3.98 Courier Return Service:

3.98.1 Patients who wish to return unwanted medicines can do so using a dedicated courier service provided by the pharmacy.

3.98.2 This courier service is fully funded by the pharmacy, ensuring no additional costs for the patient, and adheres to strict protocols to maintain the safety and security of the returned items.

3.99 Local Collection Service:

3.99.1 For patients residing in the local area, the pharmacy offers a personalized collection home or workplace by contacting the pharmacy via phone or email.

3.100 Pre-Packaged Returns:

3.100.1 Patients who prefer to return medicines through courier or local collection will be provided with appropriate packaging materials in advance.

3.100.2 These packages are designed to ensure the safe handling and secure containment of medicines during transit.

3.101 Accessing the Disposal Service

3.102 Online Booking:

3.103 Comprehensive details about the disposal service, including instructions for booking a collection or courier return, will be available on the pharmacy's website.

3.104 Patients can access step-by-step guidance to ensure a smooth and hassle-free experience.

Community Awareness:

3.105 The pharmacy will actively promote its disposal service through multiple channels, including the website, mobile app, and marketing leaflets.

3.106 Information on the importance of safe disposal and the risks of improper handling is also shared to encourage community engagement.

Processing of Returned Medicines

3.107 Sorting and Storage:

3.108 Once unwanted medicines are received at the pharmacy, they are carefully sorted by trained staff to identify and segregate items for appropriate disposal.

3.109 These medicines are stored securely in designated disposal units to prevent unauthorized access and ensure compliance with regulatory standards.

Collection by Waste Management Services:

3.110 The waste management company collects the sorted medicines regularly, ensuring timely and safe disposal in accordance with environmental and pharmaceutical regulations.

Documentation and Compliance:

3.111 A detailed log of returned CD medicines will be maintained to track the disposal process and ensure full compliance with regulatory requirements.

Routine audits will be conducted on return

3.112 Risk assessment of returns will be established

Promotion of Healthy Lifestyles

3.113 Comprehensive Strategy for Promoting Healthy Lifestyles

3.114 The pharmacy is fully committed to promoting healthy lifestyles as part of its essential services, aligning with NHS guidelines and national health objectives. The strategy is designed to provide accessible, engaging, and evidence-based support to patients across England. Below are the key elements of the plan:

Dedicated Healthy Lifestyle Resources on the Website

3.115 The pharmacy's website will feature a fully developed and dedicated section promoting healthy lifestyles.

Content and Tools:

3.116 A wide range of evidence-based resources aligned with NHS guidelines will be provided, covering key health topics such as smoking cessation, alcohol reduction, weight management, mental health, and physical activity.

3.117 Interactive tools, including online lifestyle questionnaires and health assessments, will enable patients to assess their habits and receive tailored advice based on their responses.

Regular Updates:

3.118 The content will be reviewed and updated regularly to reflect the latest public health campaigns, seasonal health concerns (e.g., winter flu prevention), and emerging healthcare priorities.

Patient-Friendly Navigation:

3.119 The section will be designed for ease of access, ensuring patients of all demographics can locate and utilize resources effectively.

National Health Campaigns

3.120 The pharmacy will actively participate in and support national health campaigns initiated by NHS England, ensuring compliance with Paragraph 17 of Schedule 4.

Integration with Services:

3.121 Campaigns will be integrated into essential service delivery by distributing promotional materials, such as leaflets and posters, with medication deliveries.

3.122 Digital materials, including videos and infographics, will be shared via the pharmacy's website, emails and SMS to maximise patient engagement.

Targeted Outreach:

3.123 Patients with specific health risks, such as those managing chronic conditions like diabetes or hypertension, will receive tailored messages and resources to address their needs.

3.124 For example, a patient identified as a smoker during a consultation will receive resources on smoking cessation, including links to local cessation services and advice on nicotine replacement therapies.

Proactive Patient Engagement

3.125 The pharmacy will employ proactive methods to engage patients and encourage participation in healthy lifestyle initiatives.

Lifestyle Questionnaires:

3.126 Patients will be invited to complete lifestyle questionnaires provided online or sent with their prescriptions. These questionnaires will assess key health factors such as diet, exercise, smoking, alcohol consumption, and mental well-being.

3.127 Responses will be analysed to identify at-risk individuals and provide them with tailored advice and resources.

Non-Face-to-Face Consultations:

3.128 Pharmacists and trained staff will engage with patients via phone, video calls, or email to discuss health concerns and provide guidance on improving their lifestyle habits.

3.129 These consultations will be conducted confidentially, with records securely maintained in the Patient Medication Record (PMR) system.

Health Education and Support Materials

3.130 Patients will have access to a broad range of educational materials to support their health journey.

Example of topics Covered:

3.131 Resources will address smoking cessation, healthy eating, exercise routines, stress management, and alcohol moderation, among other areas.

3.132 Special focus will be placed on managing chronic conditions such as diabetes, cardiovascular disease, and asthma through lifestyle modifications.

Modes of Delivery:

3.133 Information will be presented through multiple channels, including website content, downloadable guides, video tutorials, and links to NHS-endorsed apps and tools. Patients will be signposted to local smoking cessation programs, weight management clinics, and mental health support services as appropriate.

3.134 Contact details and guidance for accessing these services will be provided through the website and during consultations.

3.135 The pharmacy will leverage email newsletters and social media platforms to share information about upcoming campaigns, health observances, and resources.

3.136 Feedback will be collected through surveys, questionnaires, and direct patient communication. This information will be used to refine resources and campaigns to better address patient needs.

3.137 Audits will be conducted to assess the impact of healthy lifestyle campaigns and ensure compliance with NHS requirements.

3.138 Metrics such as patient engagement rates, resource utilization, and reported behaviour changes will be analysed.

3.139 Insights from audits and feedback will inform future strategies, ensuring the pharmacy remains effective in promoting healthy lifestyles.

Community Integration

3.140 While operating as a distance-selling pharmacy, the pharmacy will maintain a strong connection to the community by promoting health initiatives and collaborating with local healthcare providers.

3.141 Collaboration with Local Services:

3.141.1 Awareness Campaigns:

3.141.2 Monitoring and Feedback

3.142 The effectiveness of the pharmacy's healthy lifestyle promotion initiatives will be continually monitored and improved.

3.143 Patient Feedback:

3.143.1 Clinical Audits:

3.144 Continuous Improvement:

Compliance with Paragraphs 16–18 of Schedule 4

3.145 The outlined strategy ensures the pharmacy meets the requirements of Paragraphs 16–18 of Schedule 4 by:

3.146 Providing resources and tools that are accessible to all patients, regardless of location, through a comprehensive online platform (Paragraph 16).

3.147 Actively engaging with patients to address health concerns and encourage positive lifestyle changes through non-face-to-face methods, including consultations and targeted campaigns (Paragraph 17).

3.148 Promoting public health and supporting national health initiatives in alignment with NHS priorities, ensuring that the pharmacy contributes to improving health outcomes across England (Paragraph 18).

3.149 To support public health initiatives:

3.149.1 The pharmacy's website will host a dedicated section for healthy lifestyle resources, incorporating NHS-approved materials.

3.149.2 Leaflets and targeted campaigns will accompany prescription deliveries, addressing conditions like diabetes, coronary heart disease, and smoking cessation.

Public Health Campaigns

3.150 The pharmacy is committed to actively supporting and participating in NHS-mandated public health campaigns. These initiatives are designed to raise awareness, educate patients, and promote positive health behaviours across a broad spectrum of health issues. The pharmacy's approach includes a comprehensive, multi-channel strategy to ensure maximum engagement and impact. This has been discussed earlier, but this is some areas for the committee to consider:

Distribution of Campaign Materials

3.151 With Prescriptions:

3.151.1 Physical campaign materials, such as leaflets and brochures, will be included with medication deliveries to ensure patients receive timely and relevant health information.

3.151.2 Materials will be tailored to align with national campaigns and specific health conditions, such as smoking cessation, flu vaccination, or diabetes awareness.

3.152 Digital Communication:

3.152.1 Campaign information will be shared through electronic means, including emails, SMS alerts, and notifications via the pharmacy's mobile app or website.

3.152.2 Digital assets, such as downloadable guides, infographics, and links to trusted NHS convenience.

3.153 Proactive Promotion of Campaigns

3.154 Targeted Outreach:

3.154.1 The pharmacy will use patient data, such as medication history and lifestyle information, to identify individuals who may benefit most from specific campaigns. Personalized messages and resources will be provided to these patients.

3.154.2 For example, patients prescribed antihypertensive medications may receive targeted materials on managing cardiovascular health.

3.155 Social Media and Online Platforms:

3.155.1 Campaigns will be actively promoted through the pharmacy's social media channels, using engaging posts, videos, and infographics to reach a wider audience.

3.155.2 Blog posts and articles related to the campaign themes will be published on the pharmacy's website, offering in-depth insights and actionable tips.

3.156 Integration with Pharmacy Services

3.157 Routine Consultations:

3.157.1 Campaign messages will be integrated into patient interactions, such as medication reviews and consultations, ensuring that public health advice is embedded into routine care.

3.157.2 Pharmacists will proactively discuss campaign topics relevant to the patient's condition or lifestyle, such as discussing smoking cessation during a prescription consultation for nicotine replacement therapy.

3.158 Health Questionnaires:

3.158.1 Patients will be encouraged to complete health questionnaires related to the campaign themes, helping identify those who may benefit from additional advice or resources.

Signposting

3.159 Commitment to Public Health

3.160 Through these activities, the pharmacy demonstrates its commitment to supporting NHS public health objectives and fostering a culture of health awareness and improvement among patients. By leveraging both digital and traditional communication methods, the pharmacy ensures that campaign messages reach patients effectively and make a meaningful impact on their health and well-being.

3.161 Active and Passive Patient Assessments

3.162 Active Assessments:

3.162.1 Patients who engage with the pharmacy through consultations, lifestyle questionnaires, or health campaigns are actively assessed to identify potential needs for referral to additional services.

3.162.2 For example, a patient reporting frequent chest infections during a consultation may be referred to a respiratory health specialist or signposted to smoking cessation services if appropriate.

3.163 Passive Assessments:

3.163.1 During routine interactions, such as medication reviews or repeat dispensing, the pharmacy team is trained to identify potential unmet needs, even if the patient does not explicitly seek assistance.

3.163.2 For instance, the prescription history of a patient receiving multiple cardiovascular medications might trigger a conversation about additional services, such as dietary advice or a heart health program.

3.164 Provision of Contact Details and Tailored Advice

3.165 Relevant Service Referrals:

3.166 The pharmacy maintains an up-to-date database of local and national health, social care, and support services. This database includes contact details for organizations such as smoking cessation programs, weight management services, mental health helplines, and social care providers.

3.167 Patients are provided with clear, actionable guidance on how to access these services, including phone numbers, email addresses, and website links.

3.168 Tailored Recommendations:

3.168.1 Based on the patient's individual circumstances and health needs, the pharmacy team provides personalized advice and explains the benefits of engaging with the recommended service.

3.168.2 For example, a patient struggling with anxiety might be directed to both a local counseling [sic] service and NHS-approved mental health resources available online.

3.169 Non-Face-to-Face Signposting

3.170 Digital Accessibility:

3.170.1 Patients can access signposting services remotely via phone, email, or the pharmacy's website. The website features a dedicated section with categorized links need.

3.171 Proactive Outreach:

3.171.1 For patients who have been identified as needing additional support, the pharmacy team follows up with tailored information via email or SMS, ensuring continuity of care.

3.172 Integration with Essential Services

3.173 Clinical Context:

3.173.1 Signposting is seamlessly integrated into essential pharmaceutical services. For instance:

3.173.2 During medication reviews, pharmacists identify potential unmet needs and offer information on additional support services.

3.173.3 Patients presenting with minor ailments are signposted to appropriate services, such as walk-in centres or their GP.

3.174 Supporting Chronic Disease Management:

3.174.1 Patients managing chronic conditions such as diabetes or COPD are referred to disease-specific support programs, improving health outcomes and reducing the burden on other healthcare providers.

3.175 Monitoring and Feedback

3.176 Patient Follow-Up:

3.176.1 Where appropriate, the pharmacy follows up with patients to ensure they have successfully accessed the referred service and received the necessary support.

3.177 Quality Assurance:

3.177.1 Regular audits of the signposting process are conducted to ensure the accuracy and effectiveness of referrals. Patient feedback is used to refine and enhance the service over time.

Support for Self-Care

3.178 Via the Website and other social media platforms , the pharmacy is committed to delivering a robust and patient-centered [sic] approach to providing advice and educational resources that empower individuals to manage their health effectively. Below is an expanded description of the support and educational services that will be available:

3.179 Personalized Advice and Support

3.179.1 Patients will have access to comprehensive, tailored advice delivered through various secure, non-face-to-face communication channels:

3.180 Telephone Consultations:

3.180.1 Patients can speak directly with a qualified pharmacist or trained team member for personalized advice on managing their health concerns, understanding their medications, or addressing any side effects they may experience.

3.180.2 Calls are conducted in a professional, confidential manner to ensure patient privacy and trust.

3.181 Email Correspondence:

3.181.1 For patients who prefer written communication, email provides a convenient option for queries about medications, health concerns, or recommendations for additional services.

3.181.2 Responses will be timely and detailed, ensuring patients receive clear, actionable information.

3.182 Video Consultations:

3.182.1 Secure video consultations will allow pharmacists to engage with patients in a more interactive and visual manner, particularly useful for discussing lifestyle modifications, medication usage, or assessing specific health concerns.

3.182.2 Video consultations ensure accessibility for patients who may benefit from visual aids, such as demonstrations or shared screens for educational resources.

3.183 Educational Materials for Self-Care

3.183.1 To encourage informed self-care decisions, the pharmacy will provide an extensive range of educational materials tailored to individual patient needs:

3.184 Digital Resources:

3.184.1 Patients will have access to downloadable guides, infographics, and videos on topics such as managing chronic conditions, maintaining a healthy diet, and incorporating exercise into daily routines.

3.184.2 Resources are designed to be engaging, easy to understand, and aligned with NHS-approved guidelines to ensure accuracy and reliability.

3.185 Condition-Specific Information:

3.185.1 For patients managing chronic conditions, targeted educational materials will be provided, covering areas such as blood sugar monitoring for diabetes, inhaler

3.186 Health Campaign Integration:

3.186.1 Educational materials will align with ongoing NHS health campaigns, ensuring patients receive timely and relevant information, such as flu prevention tips during the winter or smoking cessation support during targeted campaigns.

3.187 Promoting Lifestyle Improvements:

3.187.1 Resources will address key areas of public health, including smoking cessation, weight management, alcohol moderation, and stress reduction,

empowering patients to take proactive steps toward improving their overall well-being.

3.188 Accessibility and Follow-Up Support

3.188.1 The pharmacy's commitment extends beyond the initial interaction to ensure patients feel supported throughout their health journey:

3.189 Accessibility Across Platforms:

3.189.1 Educational materials and advice will be accessible through the pharmacy's website, mobile app, or upon request during consultations. Patients can choose their preferred method of communication for convenience.

3.190 Ongoing Follow-Up:

3.190.1 For patients requiring additional support, follow-up consultations will be arranged to monitor progress, answer further questions, and provide additional resources as needed.

3.191 Patient-Centered Approach [sic]:

3.192 All advice and educational content will be tailored to individual circumstances, taking into account the patient's medical history, current health concerns, and personal preferences.

Conclusion and Request for Reconsideration

3.193 We believe the additional information provided herein demonstrates our commitment to meeting the regulatory requirements for a distance-selling pharmacy. Our comprehensive SOPs, risk assessments, and operational procedures ensure the safe and effective provision of essential services to all patients across England. We also wish to comply with regulation 66, by informing the Market entry team that we aim to commence services approximately within 12 months of accreditation from the NHS. This will give us ample time to retrofit the pharmacy to our needs and no ensure zero compromise in our service delivery.

3.194 We kindly request the PSRC [sic] to reconsider its decision based on this new information. Should you require further clarification or documentation, please do not hesitate to contact us."

4 Summary of Representations

This is a summary of representations received on the appeal.

4.1 THE COMMISSIONER

4.1.1 "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.

4.1.2 Thank you for your letter dated 27 January 2025 advising us that Chelmsford City Pharma Ltd (the Appellant) have submitted an appeal against the decision by Mid and South Essex ICB to refuse their application for a Distance Selling Premises (DSP).

4.1.3 We note that the Appellant has recognised that their application did not contain the necessary information to meet the tests as out in the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the Regulations).

4.1.4 On appeal, the Appellant has provided further additional information to demonstrate compliance with the Regulations. This information was not available to the Pharmaceutical Services Regulations Committee (PSRC) 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.

4.1.5 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."

4.2 NORTH AND SOUTH ESSEX LMC

4.2.1 "The LMC notes that the applicant has now submitted further details in support of the application which we trust will provide the necessary assurances that all provisions set out in Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 in respect of distance selling premises will be met."

5 **14 day comments to PCSE**

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 to circulate the comments received in response to the representations made to the Commissioner on the application as these had not been seen by parties prior to the decision being made by the Commissioner.

5.1 THE APPLICANT

5.1.1 "Thank you for your letter dated 30th September 2024. I would like to write a response to the feedback provided by the local contractors. Given this, we'll focus our reply on addressing the comments they've raised.

Standard Operating Procedures (SOPs)

5.1.2 We note the concern expressed about the absence of a full set of detailed Standard Operating Procedures (SOPs) in our application. As NHSE and the Integrated Care Board (ICB) are aware, there is no requirement under Regulation 25 to provide full SOPs at the application stage. Instead, the applicant is required to demonstrate, through appropriate information, how they will comply with all relevant regulations and ensure safe and effective service delivery.

5.1.3 I believe we have provided sufficient information part of our application on how we intend to comply with regulatory requirements, which includes maintaining a full set of SOPs to be made available for inspection as part of our contractual requirements. These SOPs will cover all aspects of service provision, ensuring safe, compliant, and uninterrupted services, including the delivery of essential services without face-to-face contact, as required by Regulation 25.

Access to Essential Services

5.1.4 Day Lewis questions where essential services will be provided if they are not offered on the premises. To clarify, as a distance-selling pharmacy, Chelmsford City Pharma Ltd will provide all essential NHS services remotely, as required. Patients will access services through a variety of methods, including telephone consultations, email, and online platforms, depending on their preferences and needs. This fully aligns with the nature of distance-selling pharmacies, which are specifically designed to deliver services without patients physically visiting the premises.

5.1.5 As the objection references concerns about access for specific patient groups, such as those with disabilities or sensory impairments, we would like to emphasize that Chelmsford City Pharma Ltd will provide tailored communication methods to accommodate all patients, including those who may have difficulty accessing digital services. For instance, patients who are blind or have hearing impairments can be supported via telephone, braille leaflets, or through family members or carers acting on their behalf.

5.1.6 Importantly, it must be remembered that patients choosing a distance-selling pharmacy are aware of the non-face-to-face nature of the service and select this option based on their individual circumstances and preferences.

Security and Delivery of Medications

5.1.7 Regarding the security and delivery of medications, Chelmsford City Pharma Ltd takes these responsibilities very seriously. All dispensed medications, including controlled drugs and cold chain goods, will be delivered to patients through secure, tracked delivery methods. We will ensure that all necessary protocols for the safe handling, packaging, and delivery of medicines are strictly adhered to, including the use of temperature controlled packaging for cold chain items. Our SOPs address the safe and compliant delivery of medications, and the ICB can be assured that all procedures will be fully compliant with NHS and regulatory standards.

Face-to-Face Contact

5.1.8 Another concern raised regarding the inclusion of a consultation room in our application, suggesting this implies face-to-face services. We would like to clarify that the consultation room is intended for advanced and enhanced services that may be offered at a future stage, in line with NHS regulations. However, we reaffirm that no essential services will be provided face-to-face at our premises, as required under Regulation 25 for distance-selling pharmacies.

5.1.9 We understand and fully comply with the restriction that prohibits face-to-face provision of essential NHS services at the premises. There will be clear procedures in place to ensure that essential services are delivered solely through remote means, as required.

Compliance with Regulation 25

5.1.10 In summary, Chelmsford City Pharma Ltd has provided detailed information demonstrating how we will meet the requirements of Regulation 25. All essential services will be provided without interruption, made accessible to all patients across England, and delivered safely and effectively. The distance-selling model is specifically designed to offer flexibility, choice, and convenience, and our approach ensures that no patient group is excluded.

5.1.11 We are confident that our application meets the regulatory tests and fully complies with all requirements.

5.1.12 Thank you for your time, and we look forward to progressing further with the application."

6 Summary of Observations

This is summary of observations received.

6.1 THE COMMISSIONER

6.1.1 "One observation in relation to the representations made by Chelmsford City Pharma Ltd in relation to the provision of SOPs – the ICB was not concerned about the absence of a full set of SOPs. The ICB is aware that there is no requirement to provide SOPs under regulation 25 and agree that the applicant is required to demonstrate through appropriate information how they will comply with the relevant regulations. At the point of application and at the time of the decision made by the Pharmaceutical Services Regulations Committee (PSRC), the applicant had not provided information to satisfy the PSRC that the requirements of the regulations had been met.

6.1.1 On appeal, the applicant has provided additional information which was not available to the ICB and PSRC at the point of the decision."

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") 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 "*N'/a as no other pharmacy located on premises and meets DSP location specification"* as to why the application should not be refused pursuant to Regulation 31. The Committee noted that the Commissioner 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.

7.7 Based on the information provided, the Committee was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

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

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

Additional information to be included with excepted applications

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

(a) A's belief that the application satisfies the criteria included in one of the regulations in Part 4 which need to be satisfied if section 129(2A) and

(2B) of the 2006 Act (regulations as to pharmaceutical services) are not to apply in relation to that application; and

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

7.11 As far as Regulation 25(2)(a) is concerned, the Committee had regard to the application form in which the Applicant states *"The DSP pharmacy premises is not located at the same site or building of a primary medical service list".* 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)

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

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

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

7.15 The Committee has asked itself whether it has sufficient information and documentation which would address the criteria in Regulation 25(2)(b). If the Committee is to be satisfied of the matters in that paragraph, the Committee must be provided with evidence to demonstrate these matters.

7.16 The Committee noted the comments from parties with regard to the absence of Standard Operating Procedures (SOPs) and the Commissioner's response on this

point. The Committee was of the view that there are many ways in which an applicant can choose to organise itself in order to comply with the various requirements of the Regulations and that SOPs do not necessarily have to be provided if the information provided by the Applicant in their original application form and any subsequent representations provides the assurance that the Commissioner, or the Committee, is seeking that there will be compliance with Regulation 25 and the relevant criteria as set out in the Regulations.

7.17 The Committee has sought evidence within the information provided (the original application form and the subsequent appeal) in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.

7.18 The Committee noted the references from the Applicant to prescriptions being received electronically and had confirmed in the application form that "*All dispensed medication will be delivered or posted to patients*" and further that "*we will offer NHS prescription services on a national scale…"* The Committee noted the confirmation in representations to the Commissioner that "*patients will access services through a variety of methods including telephone consultations, email and online platforms*." On appeal, the Applicant had confirmed that they would be using couriers as well as postal services. In addition, for local delivery the Applicant confirms that they will be using delivery tracking devices such as "Delivery Mate".

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

7.20 The Committee noted references throughout the appeal and application form to services being provided other than by face to face and that "contact" would also not be face to face either on or in the vicinity of the premises.

7.21 The Committee noted the comments regarding the consultation room, however was mindful that the Applicant had stated that this was for the provision of advanced and enhanced services "at a later date". The Committee also noted that the consultation room was to be used for telephone or video calls to ensure privacy whilst services were being delivered.

7.22 The Committee noted the information contained within the application form which sets out how the Applicant intends to provide essential services without face to face contact but using permissible methods of communication with patients, including communicating with patients by email, telephone or video calls.

7.23 In the application form the Applicant had stated

7.23.1 "*Patient sign posting: For patients requiring on-site Essential services, we will sign-post them to the nearest community pharmacy providers …*"

and further:

7.23.2 "*Essential Services: Essential NHS Services will not be provided on the premises, in accordance with DSP guidelines*."

7.24 The Applicant went on to confirm, in their appeal, that "*no essential services will be provided face to face, all other route of communication such as telephone, virtual methods*."

7.25 However, the Committee noted the location of the pharmacy was the "Terrace Bar, Hamptons Sports and Leisure".

7.26 The Committee considered that by virtue of the fact that the premises were proposed to be located at the address indicated by the Applicant, which appears to be the "Terrace Bar" within a sports and leisure complex, then this could increase the risk of face to face services being provided as the complex is open to the public. The Committee had regard to the fact that a member of the public encountering the pharmacy within a public setting, may assume that face to face services would be provided from the pharmacy.

7.27 The Committee noted that there was no information provided by the Applicant as to how, apart from the statement "*Essential NHS Services will not be provided on the premises in accordance with DSP guidelines*" it would ensure that there would be limited access to the pharmacy area. The Committee had no information before it as to how the Applicant would ensure that the pharmacy, being located within a sports and leisure facility, would mitigate the additional risks created by its location. Specifically there was no information on how it would ensure that patients or their representatives were aware that they could not attend the pharmacy, as part of their visit to the Terrace Bar within the sports and leisure facility, to receive essential pharmaceutical services and how the two services would be separate.

7.28 Based on the higher level of risk created by the location, the Committee considered that it was reasonable to expect a higher level of information than may be the case for other settings, to satisfy it that provision of services would be without face to face contact. The lack of detailed information before the Committee as to how the pharmacy would operate in this particular setting in compliance with this aspect of the Regulations, led the Committee to determine that it was not satisfied that the provision of services would be without face to face contact.

7.29 The Committee noted that there was no information provided with regard to the Responsible Pharmacist and how the Applicant would ensure that there would be uninterrupted provision of essential services at the pharmacy, should they be required, during the absence of the Responsible Pharmacist.

7.30 Based on the lack of information before it, the Committee was not satisfied that the provision of services would be without interruption.

7.31 The Committee went on to consider whether safe and effective provision of essential services was likely to be secured.

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

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

7.33.1 Dispensing of drugs and appliances

7.33.2 Urgent supply without a prescription

7.33.3 Preliminary matters before providing ordered drugs or appliances

7.33.4 Providing ordered drugs or appliances

7.33.5 Refusal to provide drugs or appliances ordered

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

7.33.7 Disposal service in respect of unwanted drugs

7.33.8 Promotion of healthy lifestyles

7.33.9 Prescription linked intervention

7.33.10 Health campaigns

7.33.11 Signposting

7.33.12 Support for self-care

7.33.13 Discharge medicines service

7.33.14 Websites and health promotion zones

7.34 The Committee noted that the Applicant had stated *"Drug Tariff part IX* (*except items that require measuring or fitting)"* in response to the question as to whether they were undertaking to provide appliances. The Committee noted that the Applicant did not intend to provide appliances which required measuring or fitting. In the event that the application was granted, the Applicant would not therefore be able to provide these appliances, as listed in the application form, to patients.

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

Providing ordered drugs or appliances

7.36 The Committee considered whether the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that (1) 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).

7.37 Whilst the Applicant had provided very little information in its application form, the Committee noted that, in subsequent correspondence to the Commissioner, it had stated:

7.37.1 *"Regarding the security and delivery of medications, Chelmsford City Pharma Ltd takes these responsibilities very seriously. All dispensed medications, including controlled drugs and cold chain goods, will be delivered to patients through secure, tracked delivery methods. We will ensure that all necessary protocols for the safe handling, packaging, and delivery of medicines are strictly adhered to, including the use of temperature controlled packaging for cold chain items. Our SOPs address the safe and compliant delivery of medications, and the ICB can be assured that all procedures will be fully compliant with NHS and regulatory standards."*

7.38 On appeal, the Applicant had provided further information.

7.38.1 *"For local delivery we will be using delivery tracking device such as Delivery mate, where this will date stamp delivery together with proof of delivery. All controlled drugs will be signed for, track and audited.*

7.39 The Applicant had gone on to expand upon how drugs or appliances will be provided to patients and stated:

7.39.1 "*Cold Chain Maintenance*

Maintaining the integrity of cold chain medicines is a top priority. The pharmacy has implemented industry-standard practices to ensure the storage and transportation of thermolabile medications comply with regulatory and safety requirements.

Specialized Packaging:

Cold chain medicines are packed using insulated containers with temperature-stable cooling elements that maintain the required temperature range during transportation.

Temperature data loggers are included in each shipment to monitor real-time conditions, ensuring compliance throughout the delivery process.

Dedicated Cold Chain Couriers:

Deliveries of temperature-sensitive medicines are handled by specialist courier services equipped with temperature-controlled vehicles.

These couriers are trained in the handling of pharmaceutical products and follow stringent protocols to prevent breaches in the cold chain.

Monitoring and Incident Management:

Each shipment includes temperature monitoring devices that provide a verifiable record of conditions during transit.

If a breach in the cold chain is detected, the courier immediately notifies the pharmacy, and the affected products are returned for safe disposal. Replacement medications are dispatched promptly to avoid any disruption to the patient's treatment.

Routine Audits:

Cold chain processes are reviewed regularly as part of the pharmacy's audit program. These audits assess compliance with protocols, equipment performance, and courier reliability to ensure continuous improvement.

Compliance with the Misuse of Drugs Regulations 2001

The pharmacy is fully committed to meeting the requirements of Regulations 14 and 16 of the Misuse of Drugs Regulations 2001, ensuring the secure handling, delivery, and record-keeping of controlled drugs (CDs).

Controlled Drug Storage and Dispensing:

CDs are stored in a designated, locked cabinet that complies with regulatory requirements for secure storage. Access to this cabinet is restricted to authorized personnel only.

Dispensing of CDs is conducted by the RP, who ensures all prescriptions meet legal and clinical criteria before the medicines are supplied.

Delivery of Controlled Drugs:

CDs are transported using specialized courier services equipped to handle controlled substances securely.

Robust identity verification processes ensure that CDs are delivered only to the intended patient or their authorized representative.

Patients or representatives are required to provide a signature upon receipt, creating a verifiable audit trail for every delivery.

Record-Keeping:

All transactions involving CDs are meticulously recorded in the Controlled Drug Register, which is regularly audited to ensure accuracy and compliance.

Returns of CDs are logged separately, and unused or expired CDs are destroyed in accordance with regulatory guidelines, witnessed by a trained staff member."

7.40 The Committee noted that whilst the Applicant had provided some information regarding the various delivery methods, there was limited information provided as to what would happen for a missed or failed delivery of a controlled drug.

7.41 Taking all of the information before it into account, the Committee was of the view that the Applicant had not provided sufficient information for it to be satisfied that there would be compliance with paragraph 8(1) of Schedule 4.

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

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

7.43 The Commissioner had not been satisfied that that paragraph 10(1) would be fully complied with safely and effectively as "*the applicant has not provided any supporting information relating to further activities carried out in connection with the provision of dispensing services.*"

7.44 The Committee noted the Applicant had stated "*SOPs include detailed protocols for handling urgent or emergency requests, managing repeat prescriptions, and maintaining compliance with the Misuse of Drugs Regulations*". The Committee noted that whilst it had not been provided with these SOPs, it noted that the SOP referred to was "managing repeat prescriptions" but the Applicant had not given any further information as to how it would offer appropriate advice about the benefits of repeat dispensing in the first instance.

7.45 The Committee noted the further comments from the Applicant with regard to "repeat dispensing" in its appeal however, this had been in the context of identification of patients who were already receiving repeat dispensing as part of "Signposting".

7.46 The Committee noted that there was no information provided by the Applicant as to how it would give advice about the benefit of repeat dispensing to a patient who was not currently receiving this service, but had a long term, stable medical condition and would benefit from this service.

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

Discharge medicine service

7.48 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 or NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.

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

7.50 The Committee noted that no information had been provided by the Applicant either in its original application or in its subsequent appeal with regard to the Discharge Medicine Service and no explanation had been given as to how the Applicant was proposing to provide advice, assistance or support and that there was also no explanation regarding any procedures in place for checking referrals for the discharge medicine service.

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

Other considerations

7.52 The Committee noted that the Commissioner had refused the application on the basis that they were not satisfied that the Applicant had provided information to show that there would be compliance with the Terms of Service. The Committee, taking into account the additional information provided by the Applicant on appeal, considered these areas of the Terms of Service in more detail.

Dispensing of drugs and appliances

7.53 The Committee noted that the Commissioner had not been satisfied that the Applicant would comply with paragraph 5(2)(3) of Schedule 4 safely and effectively.

7.54 The Committee noted in the appeal the comments from the Applicant that

7.54.1 *"Non-electronic prescriptions will be handled through secure and traceable courier or postal services. These services will utilize tamper-proof packaging to ensure the integrity and confidentiality of the prescription from receipt to return. Upon receiving a non-electronic prescription, our team will immediately log the details into our Patient Medication Record (PMR) system to maintain a traceable and auditable record. Additionally, patients will be provided with clear instructions on how to securely send their prescriptions to the pharmacy using pre-approved couriers.*

…

Non EPS Prescription: Where prescription are not available as EPS, a pharmacy stamped envelope will be provided for the GP or patients to post prescriptions to us directly. All prescriptions is and will be scrutinised for clinical and legal checks. [sic]*"*

7.55 The Applicant had gone on to state:

7.55.1 "*For local delivery, we will be using delivery tracking device such as Delivery Mate, where this will date stamp delivery together with proof of delivery. All Controlled drugs medication will be signed for, track and audited.*

7.56 The Committee was of the view that the Applicant had provided sufficient information for it to be satisfied that there would be compliance with paragraph 5(2)(3) of Schedule 4.

Urgent Supply without a prescription

7.57 The Commissioner had not been satisfied that the Applicant had provided sufficient information regarding urgent supply without a prescription and was of the view that paragraph 6 of Schedule 4 would not be complied with effectively.

7.58 The Committee noted that in their application form, the Applicant had provided no information in respect of this aspect of the Terms of Service, however on appeal the Applicant had provided further information regarding urgent supply without a prescription.

7.59 The Applicant stated:

7.59.1 "*The position of DSP regarding emergency supply will be clearly presented on the website and the different solution for emergency supply or signposting will be explained …*

7.60 The Applicant had gone on to state:

7.60.1 *"Verification of Prescriber: The pharmacist confirms the request is from a legitimate, authorized prescriber, cross-referencing against an approved list to ensure accuracy.*

Emergency Justification: The pharmacist must be satisfied that an emergency prevents the immediate provision of a valid prescription. The urgency of the situation is assessed based on the information provided by the prescriber.

Written Prescription Commitment: Prescribers are required to confirm that a written prescription will be provided within 72 hours of the request, and a robust tracking system ensures these are received within the stipulated time.

Authorized Medications Only: Only medications permitted for supply in emergency situations are provided. This excludes Schedule 1, 2, and 3 controlled drugs, except Phenobarbital for epilepsy, as prescribed by a UK-registered practitioner. Prescribers from the EEA are not permitted to request emergency supplies for any controlled drugs."

7.61 The Committee noted the comments from the Applicant regarding "Prioritisation of Delivery for Urgent and Emergency Supplies" which stated:

7.61.1 *"Given the critical nature of urgent or emergency requests, delivery processes are designed to prioritize speed and efficiency:*

Local Deliveries: Drivers are instructed to treat these deliveries with urgency and prioritize them in their schedules. Medications are clearly marked as "URGENT" to ensure rapid handling.

Courier Services: For non-local deliveries, couriers are notified of the time-sensitive nature of the items and instructed to use the fastest available delivery methods.

No Additional Charges: Patients are not charged extra for expedited delivery, even if the pharmacy incurs additional costs to meet the urgency of the request."

7.62 The Committee was of the view that the Applicant had provided sufficient information for it to be satisfied that there would be compliance with paragraph 6 of Schedule 4.

Preliminary matters before providing ordered drugs or appliances

7.63 The Commissioner had not been satisfied that paragraph 7 would be complied with effectively. The Applicant, on appeal, had provided more information which included:

7.63.1 *"Patients can provide evidence of their exemption through several secure and accessible methods:*

Electronic Upload: Patients can submit scanned or photographed copies of their exemption evidence through a secure online portal or via email. The pharmacy records that the evidence was provided in a digital format for transparency.

Postal Service: Patients may send original or photocopied exemption evidence by post. To minimize inconvenience, the pharmacy covers postage costs for both sending and returning the evidence.

Courier Delivery: For local patients using the pharmacy's delivery driver, exemption evidence can be handed over for verification and returned securely after processing."

7.64 The Applicant went on to state:

7.64.1 *"The pharmacist in charge is responsible for assessing the submitted exemption evidence. They must ensure it meets the regulatory standard of "satisfactory evidence" to confirm the patient's exemption status.*

If the evidence provided is deemed insufficient or invalid, the "Evidence Not Seen" box is marked on the reverse of the prescription, and the patient is informed about the issue promptly."

7.65 Under "Efficient Payment Processes", the Applicant had stated:

7.65.1 "*For patients who are not exempt from prescription charges, secure payment systems are in place. Payments can be made online through a secure payment portal linked to the pharmacy's website.*

Once payment is received, the prescription is marked as "paid" in the pharmacy's system, and the dispensing process is initiated without delay. This ensures that all prescriptions are processed promptly while maintaining an accurate audit trail."

7.66 Based on the information before it, the Committee was of the view that the Applicant had provided sufficient information for it to be satisfied that there would be compliance with paragraph 7 of Schedule 4.

Providing ordered drugs or appliances

7.67 The Committee went on to consider whether the Applicant had explained what containers would be suitable for posted/delivered items.

7.68 The Committee noted the comments from the Applicant that:

7.68.1 *"Packaging Protocols:*

Medications are packaged securely to protect their integrity during transportation.

Tamper-evident seals are applied to all packages to ensure security and prevent unauthorized access.

Fragile items and liquid medicines are cushioned with appropriate materials to withstand transit rigors."

7.69 The Committee was of the view that the Applicant had provided sufficient information for it to be satisfied that there would be compliance with paragraph 8(15) of Schedule 4.

Refusal to provide drugs or appliances

7.70 The Commissioner had not been satisfied that paragraph 9(4) would be fully complied with.

7.71 The Committee noted that, on appeal, the Applicant had stated:

7.71.1 "Patient Consultations: Consultations will be conducted via secure telephone or live video calls, ensuring patients receive appropriate advice and instructions about their medications. All consultations and actions will be documented and logged in the PMR system. On NO occasion any essential service will be provided face to face."

7.72 And further:

7.72.1 "*Patients can speak directly with a qualified pharmacist or trained team member for personalized advice on managing their health concerns, understanding their medications, or addressing any side effects they may experience.*"

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

Disposal service in respect of unwanted drugs

7.74 The Committee noted that the Commissioner had not been satisfied that the Applicant would comply with paragraphs 13 – 15 of Schedule 4 safely and effectively.

7.75 On appeal, the Applicant had stated:

7.75.1 *"To support environmental responsibility and patient safety, a range of services is available for the safe disposal of unwanted medications:*

Specialist Waste Disposal Services: A licensed waste management company is contracted to collect and dispose of unwanted medications securely, ensuring compliance with environmental and safety regulations.

Courier Return Options: Patients can return unwanted medications using a pharmacy-provided courier service. This service is fully funded by the pharmacy, ensuring accessibility for all patients.

Local Collection Services: Patients in the surrounding area can arrange for medications to be collected from their home or workplace by contacting the pharmacy through phone or email.

Pre-Packaged Disposal Kits: Patients are provided with pre-packaged disposal materials, enabling them to securely return medicines. Clear instructions are made available on the pharmacy's website, along with information about how to arrange

Once medicines are returned to the pharmacy, they are carefully sorted and placed in secure disposal units. Regular collections by waste management providers ensure proper handling. This disposal service is promoted through the pharmacy's website and other informational materials, making it accessible and convenient for patients.

In no situation as per Essential service would medication be accepted in person; this will be reiterated on the website and clearly signposted so patients can choose the best suitable return method."

7.76 The Applicant went on to state:

7.76.1 "The pharmacy will provide a range of convenient and secure options for patients to safely dispose of unwanted medicines, ensuring compliance with environmental regulations and promoting public health. This has been addressed earlier and the following points for the committee to consider:

Disposal Options for Patients

Specialist Waste Management Service:

The pharmacy partners with a licensed specialist waste management company to ensure the safe and environmentally responsible disposal of unwanted medicines.

This service extends to residential homes, enabling collection from patients who may have mobility or transportation challenges.

Courier Return Service:

Patients who wish to return unwanted medicines can do so using a dedicated courier service provided by the pharmacy.

This courier service is fully funded by the pharmacy, ensuring no additional costs for the patient, and adheres to strict protocols to maintain the safety and security of the returned items.

Local Collection Service:

For patients residing in the local area, the pharmacy offers a personalized collection home or workplace by contacting the pharmacy via phone or email.

Pre-Packaged Returns:

Patients who prefer to return medicines through courier or local collection will be provided with appropriate packaging materials in advance.

These packages are designed to ensure the safe handling and secure containment of medicines during transit.

Accessing the Disposal Service

Online Booking:

Comprehensive details about the disposal service, including instructions for booking a collection or courier return, will be available on the pharmacy's website.

Patients can access step-by-step guidance to ensure a smooth and hassle-free experience."

7.77 The Committee was of the view that the Applicant had provided sufficient information for it to be satisfied that there would be compliance with paragraphs 13 – 15 of Schedule 4.

Promotion of healthy lifestyles

7.78 The Committee noted that the Commissioner had not been satisfied that the Applicant would comply with paragraphs 16 – 18 of Schedule 4 safely and effectively.

7.79 On appeal, the Applicant had stated:

7.79.1 "*Promotion of Healthy Lifestyles*

Comprehensive Strategy for Promoting Healthy Lifestyles

The pharmacy is fully committed to promoting healthy lifestyles as part of its essential services, aligning with NHS guidelines and national health objectives. The strategy is designed to provide accessible, engaging, and evidence-based support to patients across England. Below are the key elements of the plan:

Dedicated Healthy Lifestyle Resources on the Website

The pharmacy's website will feature a fully developed and dedicated section promoting healthy lifestyles.

Content and Tools:

A wide range of evidence-based resources aligned with NHS guidelines will be provided, covering key health topics such as smoking cessation, alcohol reduction, weight management, mental health, and physical activity.

Interactive tools, including online lifestyle questionnaires and health assessments, will enable patients to assess their habits and receive tailored advice based on their responses.

Regular Updates:

The content will be reviewed and updated regularly to reflect the latest public health campaigns, seasonal health concerns (e.g., winter flu prevention), and emerging healthcare priorities."

7.80 The Committee was of the view that the Applicant had provided sufficient information for it to be satisfied that there would be compliance with paragraphs 16 – 18 of Schedule 4.

Prescription linked intervention

7.81 The Committee noted that the Commissioner had not been satisfied that the Applicant would comply with paragraph 17 of Schedule 4 safely and effectively.

7.82 The Committee noted, in its appeal, under "Compliance with Paragraphs 16 – 18 of Schedule 4" the Applicant stated:

7.82.1 *"Actively engaging with patients to address health concerns and encourage positive lifestyle changes through non-face-to-face methods, including consultations and targeted campaigns (Paragraph 17)."*

…

Leaflets and targeted campaigns will accompany prescription deliveries, addressing conditions like diabetes, coronary heart disease, and smoking cessation."

7.83 The Committee was of the view that the Applicant had provided sufficient information for it to be satisfied that there would be compliance with paragraph 17 of Schedule 4.

Health Campaigns

7.84 The Committee noted that the Commissioner had not been satisfied that the Applicant would comply with paragraph 18 safely and effectively.

7.85 The Committee noted, in its Appeal the assurance from the Applicant that it would:

7.85.1 "actively participate in and support national health campaigns initiated by NHS England, ensuring compliance with Paragraph 17 of Schedule 4."

7.86 The Applicant went on to state:

7.86.1 "The pharmacy is committed to actively supporting and participating in NHS-mandated public health campaigns. These initiatives are designed to raise awareness, educate patients, and promote positive health behaviours across a broad spectrum of health issues. The pharmacy's approach includes a comprehensive, multi-channel strategy to ensure maximum engagement and impact. This has been discussed earlier, but this is some areas for the committee to consider: …"

7.87 The Applicant concluded:

7.87.1 *"Proactive Promotion of Campaigns*

Targeted Outreach:

The pharmacy will use patient data, such as medication history and lifestyle information, to identify individuals who may benefit most from specific campaigns. Personalized messages and resources will be provided to these patients."

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

Signposting

7.89 The Committee noted that the Commissioner had not been satisfied that the Applicant would comply with paragraphs 19 – 20 of Schedule 4 safely and effectively.

7.90 On appeal, the Applicant stated:

7.90.1 *"Commitment to Public Health*

Through these activities, the pharmacy demonstrates its commitment to supporting NHS public health objectives and fostering a culture of health awareness and improvement among patients. By leveraging both digital and traditional communication methods, the pharmacy ensures that campaign messages reach patients effectively and make a meaningful impact on their health and well-being.

Active and Passive Patient Assessments

Active Assessments:

Patients who engage with the pharmacy through consultations, lifestyle questionnaires, or health campaigns are actively assessed to identify potential needs for referral to additional services.

For example, a patient reporting frequent chest infections during a consultation may be referred to a respiratory health specialist or signposted to smoking cessation services if appropriate.

Passive Assessments:

During routine interactions, such as medication reviews or repeat dispensing, the pharmacy team is trained to identify potential unmet needs, even if the patient does not explicitly seek assistance.

For instance, the prescription history of a patient receiving multiple cardiovascular medications might trigger a conversation about additional services, such as dietary advice or a heart health program.

Provision of Contact Details and Tailored Advice

Relevant Service Referrals:

The pharmacy maintains an up-to-date database of local and national health, social care, and support services. This database includes contact details for organizations such as smoking cessation programs, weight management services, mental health helplines, and social care providers.

Patients are provided with clear, actionable guidance on how to access these services, including phone numbers, email addresses, and website links.

…

Patients can access signposting services remotely via phone, email, or the pharmacy's website. The website features a dedicated section with categorized links need."

7.91 Based on the information before it, the Committee was of the view that the Applicant had provided sufficient information for it to be satisfied that there would be compliance with paragraphs 19 – 20 of Schedule 4.

Support for self care

7.92 The Committee noted that the Commissioner had not been satisfied that the Applicant would comply with paragraphs 2 21 – 22 of Schedule 4 safely and effectively.

7.92.1 *"Support for Self-Care*

Via the Website and other social media platforms , the pharmacy is committed to delivering a robust and patient-centered [sic] approach to providing advice and educational resources that empower individuals to manage their health effectively. Below is an expanded description of the support and educational services that will be available:

Personalized Advice and Support

Patients will have access to comprehensive, tailored advice delivered through various secure, non-face-to-face communication channels:

Telephone Consultations:

Patients can speak directly with a qualified pharmacist or trained team member for personalized advice on managing their health concerns, understanding their medications, or addressing any side effects they may experience.

Calls are conducted in a professional, confidential manner to ensure patient privacy and trust."

7.93 Based on the information before it, the Committee was of the view that the Applicant had provided sufficient information for it to be satisfied that there would be compliance with paragraphs 21 – 22 of Schedule 4.

Website and health promotion zone

7.94 The Committee noted that their application form, the Applicant had stated:

7.94.1 "*Website Development: A comprehensive website will be created prior to the opening of the premises, fully compliant with GPhC standards to facilitate patient access and service provision."*

7.95 Throughout its appeal, the Applicant had expanded on this and stated:

7.95.1 *"The pharmacy's website will feature a fully developed and dedicated section promoting healthy lifestyles.*

Information will be presented through multiple channels, including website content, downloadable guides, video tutorials, and links to NHS-endorsed apps and tools

The pharmacy's website will host a dedicated section for healthy lifestyle resources, incorporating NHS-approved materials

Accessibility Across Platforms:

Educational materials and advice will be accessible through the pharmacy's website, mobile app, or upon request during consultations"

7.96 The Committee was of the view that the Applicant had provided sufficient information for it to be satisfied that there would be compliance with paragraph 28C of Schedule 4.

Summary

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

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

7.98.1 confirm the Commissioner's decision;

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

7.98.3 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.

7.99 In those circumstances, given that the Committee had additional information which was not available to the Commissioner, the Committee determined that the decision of the Commissioner must be quashed.

7.100 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.

7.101 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.

7.102 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 Accordingly, 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 there was not already a person on the pharmaceutical list providing pharmaceutical services from the proposed premises and the proposed premises were not adjacent to other chemist premises',

8.2.2.2 the Committee was satisfied that the premises of the Applicant are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list,

8.2.2.3 the Committee was not satisfied that all essential services were likely to be secured without interruption during the opening hours,

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

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

8.2.2.6 the Committee was not satisfied that all essential services were likely to be secured without face to face contact;

8.2.3 The application is refused.

Case Manager
Primary Care Appeals