NHS Resolution

24 October 2024

REF: SHA/26281

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APPEAL AGAINST NHS HAMPSHIRE & ISLE OF WIGHT ICB DECISION TO REFUSE AN APPLICATION BY PHARMAETHICAL LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT FAREHAM INNOVATION CENTRE, UNIT 15, 4 METEOR WAY, OFF BROOM WAY, LEE ON THE SOLENT, PO13 9FU 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:

Pharmaethical Ltd
L Rowland & Co (Retail) Ltd
PCSE on behalf of Hampshire & Isle of Wight ICB

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1 The Application

By application dated 24 November 2023, Pharmaethical Ltd ("the Applicant") applied to Hampshire & Isle of Wight ICB ("the Commissioner") for inclusion in the pharmaceutical list at Fareham Innovation Centre, Unit 15, 4 Meteor Way, Off Broom Way, Lee on the Solent, PO13 9FU 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 "none".

1.2 In response to why the application should not be refused pursuant to Regulation 31 the Applicant stated: "not applicable".

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

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 "7.1 (a) The pharmacy will secure the uninterrupted provision of essential services during the opening hours of the premises to any patient that requires it across England, by having the following steps in place:

1.5.1 Maintaining an appropriate number of qualified, trained and registered pharmacy staff and ensuring there are enough personnel to meet the demand for essential services during opening hours. This includes the Responsible Pharmacist (RP) who shall remain in the pharmacy during the entire proposed opening hours in accordance with RP regulations as detailed by General Pharmaceutical Council.

1.5.2 Staff schedules will be managed to guarantee continuous coverage, even during breaks or shift changes, to respond to requests for essential services.

1.5.3 Several full-line and short-line wholesalers will be used to maintain adequate stock of essential medications and medical supplies to meet patient needs without interruptions. If necessary, we can source medicines from other pharmacies within our organisation to maintain adequate stock levels.

1.5.4 Patients from anywhere in England may contact the pharmacy to request NHS Essential Services by phone, email, website, and by letter during the entire proposed opening hours, without face-to face contact.

1.5.5 Service Maintenance Contracts will be place [sic] to maintain communication equipment and PMR systems to secure uninterrupted provision of essential services.

1.5.6 As a Distance Selling Pharmacy we will offer remote prescription services, such as online or phone prescription renewals and medication consultations. This will ensure access to essential services from anywhere in England.

1.6 7.1 (b) The pharmacy will provide all NHS Essential Services in a safe and effective manner without face-to-face contact between any person receiving the services, whether on their own or someone else's behalf, and the pharmacy or the staff during the opening hours of the premises by following the pharmacy SOP's and the following points:

1.6.1 Offering secure, private consultations and services where patients can communicate with the Responsible Pharmacist or pharmacy staff via phone or video calls. This will allow us to counsel patients regarding their medication, renew their prescriptions and offer other advice as required to safeguard and meet the needs of our patients.

1.6.2 Allowing patients to request prescriptions and essential services online, which can be processed and prepared for delivery without the need for physical presence at the pharmacy.

1.6.3 Offering a safe, secure and reliable delivery service for essential medications and supplies by following the pharmacy SOP on Delivering Medicines and the Professional Guidance on the Safe Handling of Medicines by the Royal Pharmaceutical Society of Great Britain (RPSGB) to patients homes anywhere within England.

1.6.4 The pharmacy systems and processes will be regularly audited by the pharmacy team. Risk assessments and a risk register will be maintained to ensure the pharmacy services remain safe and effective.

1.6.5 Ensure Information Governance SOP is followed, where procedures and management accountability and structures are in place within the pharmacy to safeguard the movement of personal data when providing essential services by the pharmacy.

1.6.6 Staff will have data security training and understand the need for good record keeping to maintain integrity and the pharmacy remain GDPR compliant.

1.6.7 Our pharmacy team will be trained to deliver NHS Essential services, including Continued Professional Development (CPD) where appropriate. In addition, all staff will follow and adhere to the current legislation, policies, procedures and guidance as set out in our pharmacy quality management system.

1.7 7.2 When a patient attends the premises and requests essential services, the pharmacy team will follow the steps outlined below ensuring that no element of essential services is offered or provided to a person attending the pharmacy:

1.7.1 Greet and welcome the patient or their representative at the pharmacy entrance.

1.7.2 A member of the trained pharmacy team will direct the patient to contact the pharmacy via the telephone or website and inform them that no essential services can be provided by a face-to-face interaction.

1.7.3 The patient or their representative can discuss via the telephone or video call about any pharmacy service matter with the trained pharmacy team or the Responsible Pharmacist.

1.7.4 If the matter or query is deemed important then it will be documented on the patient's PMR record for future reference.

1.8 7.3 The pharmacy intends to provide the NHS Advanced Service called the NEW MEDICINE SERVICE once patient consent is gained. During the none face-to-face dispensing process if a patient is identified as requiring this advanced service, the patient will be contacted by telephone or video call by the Responsible Pharmacist (RP). The RP will follow the New Medicine Service and Remote Consultation SOPs. These procedures will ensure both the person providing the service and the person receiving it can see and hear each other via telephone or another live audio/video link, without any other person (including pharmacy staff) overhearing the conversation.

1.9 When providing this advanced service or any other in the future, no element of the essential services which requires a direct face-to-face will be permitted."

Further information in support of the application Question 4 – Essential Services Statement. Distance selling application by Pharmaethical Ltd to Hampshire & IOW ICB.

This document details how we intend to provide Essential services without face-to-face access:

Clinical Governance (CG) & Continuous Professional Development (CPD)

1.10 The superintendent pharmacist (SIP) will act as the Clinical Governance (CG) Lead and be responsible for meeting information and clinical governance requirements and ensure standards are met. This will be performed by applying the principles of CG and following the General Pharmaceutical Council guidance for registered pharmacies providing pharmacy services at a distance, including on the internet.

1.11 The pharmacy will have governance arrangements in place that safeguard the health, safety and wellbeing of patients and the public. Fully trained staff will be both empowered and competent to comply with the pharmacy Clinical Governance SOP. All essential services will be provided from our premises, facilities and also using equipment that are fit for purpose to comply with the principles of good clinical practice.

1.12 Risk management will be reviewed and monitored by the CG Lead who will maintain a risk register.

1.13 The pharmacy processes will be reviewed at regular intervals and audited. All reported incidents and customer complaints will be reviewed and addressed and SOPs amended to improve patient safety and prevent future reoccurrence.

1.14 All staff including the Responsible Pharmacist and the SIP will participate in regular Continual Professional Development (CPD) by using the CPD toolkit. This will ensure that the entire pharmacy team has the knowledge and competence to comply with Good Practice Criteria and provide essential services in a safe and secure manner.

Dispensing of Medicines

1.15 Essential services will be performed without any face-to-face contact once the patient has been registered or nominated by the pharmacy. Prescription requests can be sent online via our website, by email, post or by direct telephone call and by using the Electronic Prescription Service 2 (EPS 2). Emergency prescriptions can be sent to the pharmacy via EPS or email or by any other electronic form with the aim to deliver them as soon as possible.

1.16 Dispensed prescriptions will be delivered directly to patient's registered home/address anywhere in England (including controlled drugs and fridge lines) using a variety of secure and confidential methods such as our delivery staff, courier and appropriate Royal Mail services. All prescription items handled and delivered by a courier service or our delivery driver will comply with the delivery SOP's and follow the Professional Guidance on the Safe Handling of Medicines by the Royal Pharmaceutical Society of Great Britain (RPSGB).

1.17 In the case of Controlled Drugs (CD) couriers/drivers shall be informed that they are carrying a CD and to ensure secure transport in accordance with guidance and pharmacy CD SOP. An audit trail will be kept of CD deliveries.

1.18 Temperature sensitive medicines (fridge-lines) will be transported safely and securely in line with our Transport SOP. Where MHRA approved transport couriers are used to deliver fridge lines, cold chain environment will be maintained and the temperature of the delivery will be traceable. For all local deliveries the pharmacy delivery drivers will maintain cold chain conditions by the using appropriate containers and equipment and keep a temperature audit trail in line with the pharmacy SOP's.

1.19 Each step of the Dispensing Process is outlined in our Dispensing SOP's, from the point that the prescription is received at the registered pharmacy and until the prescription is ready for delivery. To ensure patient safety all prescriptions will be legally and clinically assessed by the Responsible Pharmacist to determine if they can be dispensed. If there is doubt or error, this will be clarified with the prescriber. The accuracy of the prescription will also be checked by the Accuracy Checking Technician/Dispenser or RP prior to dispatch of the item to the patient.

1.20 Procedures will be implemented to ensure that the pharmacist and patient can contact each other where it is necessary, anywhere in England, by using various communication methods such as e-mail, telephone, text messaging and the pharmacy website. This will allow both the pharmacy and the patients an opportunity to ask questions or clarify any queries thus ensuring and maintaining patient safety.

1.21 In the event that a patient needs a prescription item urgently, the pharmacist will prioritise the prescription. The pharmacist will make all the necessary arrangements, acceptable to the patient, in order to meet the needs of the patient. This would include arrangements for an Urgent Delivery.

Repeat Dispensing

1.22 This service is for patients with long term, stable conditions who require medicines and whose condition is not likely to change in the short to medium term. The management and dispensing of repeat prescriptions will follow the REPEAT DISPENSING SOP. Repeatable prescriptions will be securely and confidentially stored, dispensed only when required by the patient. The relevant patients will be contacted by telephone, e-mail or text message before each prescription dispensing to verify a repeat prescription is required, and that the patient is taking their medication as prescribed. The pharmacy team will check and ensure that there has been no alteration to the patient's medication regime or medical circumstances since the last point of dispensing. The records will be securely kept to facilitate a full audit and ensure smooth continuity of the service.

1.23 Where advice is sought by the patient with regards to their repeat prescription, the Responsible Pharmacist will conduct that conversation over the telephone.

1.24 To promote the Repeat Dispensing service if the patient has a long-term condition and is suitable for Repeat Dispensing, then the pharmacy team will inform both the patient and the prescriber of the benefits of this service in order to enlist them onto it.

Provision of Compliance Aids

1.25 This optional service can be provided, if requested by the patient, in accordance with the Disability Discrimination Act (DDA) 1995. Reasonable adjustments will be made to the service provided to aid those with disabilities to access and use them within their own capabilities.

Disposal of Unwanted Medicines/ Waste Management

1.26 The disposal of unwanted medicines will comply with all relevant waste management legislation and the pharmacy Disposal of Unwanted Medicines SOP. Once a request is made by the patient to return unwanted medicines, arrangements (as per SOP) are made to securely collect them from patients' home and transported back to the pharmacy via a courier service or pharmacy delivery driver.

1.27 Upon return to the pharmacy the unwanted medicine will be safely sorted and securely stored in disposal units ready for collection by a specialist waste management company such as the PHS Group Healthcare Waste Management.

1.28 Controlled Drugs (Schedule 2 and 3) will be made irretrievable and steps will be put in place to make a record of the disposal, with respect to safe custody regulations. The pharmacy will collect unwanted and out of date Controlled Drugs from the patient's home via a designated delivery driver if local or by a courier company that provides a tracked and secure delivery service.

Promotion of Healthy Lifestyles & Public Health Campaigns/Healthy Living Pharmacy

1.29 The pharmacy will promote Healthy Living Pharmacy and Healthy lifestyle advice to patients anywhere in England both verbally and in writing (by e-mail, text etc) as well as on the pharmacy website. We intend to embrace a broader range of health issues reflecting the wider patient base.

1.30 Communication will be recorded on the Patient's Medical Record (PMR) in order to monitor and audit the service.

1.31 Patient experience surveys together with patient profile data and long-term conditions such as Diabetes, Hypertension and COPD/ Asthma will be used to actively target lifestyle advice and interventions. Any local or national healthy lifestyle or health awareness campaigns will be proactively supported by the pharmacy.

Signposting

1.32 The pharmacy website will hold information and guidance that will assist patients to various organisations such as NHS Choices, Patient Forums and Chronic Disease organisations such as Diabetes UK, Heart and Stroke Foundation. The website will also contain a list of useful contacts for out of hours advice and links to NHS 111.

1.33 Where patients request specific health or medical information the pharmacy will assist and direct them to seek the relevant information and how to access additional healthcare services. This Information will be made available verbally or by phone, e-mail, text and not by face-to-face contact. If a patient contacts the pharmacy via phone outside the opening hours or when the pharmacy is closed, they will be given an option

to leave a message for the pharmacy team for non-urgent matters or to contact NHS 111 service if it is urgent or call 999 if it life threatening.

1.34 If a referral or intervention is made for the patient and it is deemed important by the RP, a record will be made on the PMR system.

Support for Self-Care

1.35 The pharmacy will provide advice to people, carers; who request help with the treatment of minor ailments and long-term conditions including general information and lifestyle changes on how best to manage their illness. This advice will be provided over the phone, emails and leaflets (sent via post) without face-to-face contact.

1.36 The verbal and written information provided by the pharmacy will include advice on managing long term conditions, how to maximise the benefits from their medication and how to lead a healthy lifestyle. Advice will also be provided on the use of Over-The-Counter (OTC) medication either supplied by the pharmacy or from elsewhere by patients.

Electronic Prescription Service

1.37 Prior to opening, the pharmacy will be equipped to securely receive and process electronic prescriptions by using an ETP compliant PMR software system such as WebRx Pharma. Only registered users with NHS smart cards and PIN numbers will be able to operate the service."

2 **The Decision**

The Commissioner considered and decided to refuse the application. The decision letter dated 22 July 2024 states:

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

2.1 "Hampshire and the Isle of Wight ICB has considered the above application and I am writing to confirm that it has been refused. Please see the enclosed report for the full reasoning."

Extract from the Pharmaceutical Services Regulations Committees meeting in common for Buckinghamshire, Oxfordshire and Berkshire West ICB, Hampshire & IoW ICB & Frimley ICB

"The Application

2.2 An application from Pharmaethical Ltd for a Distance Selling Premises Application was received on 15 November 2023. The Committee was now required to consider the application in accordance with Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended.

Consideration

2.3 The Committee considered the following:

2.3.1 The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended.

2.3.2 Department of Health guidance on Distance Selling Premises.

2.3.3 The application form provided by the Applicant.

2.3.4 Representations made by Boots UK Ltd, Rowland & Co (Retail) Ltd and Community Pharmacy South Central LPC.

2.3.5 Community Pharmacy South Central LPC stated "*that the applicant has failed to provide information on how they will provide the Discharge Medicine Service and further specific information on arrangements on disposal of hazardous waste from patients on cytotoxic medications.*"

2.3.6 Boots UK Ltd and Rowland & Co (Retail) Ltd did not support nor oppose the application.

2.3.7 The Committee decided it was not necessary to hold an oral hearing before determining the application.

2.3.8 A map of the locality showing the nearest community pharmacies and GP Surgeries, in relation to the proposed premises for the Distance Selling pharmacy.

2.3.9 The Committee noted that a site visit had not been undertaken as this application for a distance selling pharmacy is not visited by members of public.

Regulation 31 – Refusal: same or adjacent premises

2.4 The Committee noted that it was required to refuse an excepted application, if the two conditions under paragraph 31(2) applied. These conditions are –

2.4.1 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 the premises to which the application relates, or adjacent premises; and

2.4.2 The NHSCB 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).

2.5 The Committee was satisfied there is no pharmacy providing pharmaceutical services at the same or adjacent premises. The application did not therefore need to be refused in accordance with Regulation 31.

2.6 The Committee noted that the Applicant stated on the application form that it does intends [sic] to provide advanced services (NMS) remotely with consent where required.

2.7 The Committee noted that the pharmacy intends to open for 40 core hours per week.

2.8 The Committee went on to consider the reasons provided by the Applicant as to why the application should not be refused.

Regulation 25(1)

2.9 The Committee noted that as this was a distance selling application Regulation 25(1) indicates that section 129(2A) of the National Health Service Act 2006 does not apply, provided that Regulation 25(2) does not require the application to be refused.

Regulation 25(2)(a)

2.10 The Committee noted the proposed address and that it is not in the same site or building as a provider of primary medical services with a patient list. The Committee therefore did not have to refuse the application under Regulation 25(2)(a).

Regulation 25(2)(b)

2.11 The Committee noted that it had to be satisfied that services would be provided on an uninterrupted basis to patients anywhere in England who request those services and that essential services would be provided safely and effectively 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.

2.12 The Committee noted that the applicant had stated that: all essential services would be delivered in accordance with the relevant regulations, professional standards and company standard operating procedures and that "*Maintaining an appropriate number of qualified, trained and registered pharmacy staff and ensuring there ae enough personnel to meet the demand for essential services during opening hours. This included the Responsible Pharmacist (RP) who shall remain in the pharmacy during the entire proposed opening hours in accordance with RP regulations as detail by the General Pharmaceutical Council.*

2.13 *Staff schedules will be managed to guarantee continuous cover, even during breaks or shift changes, to respond to requests for essential services.*

2.14 *Patients from anywhere in England may contact the pharmacy to request NHS Essential Services by phone, email, website and by letter during the entire proposed opening hours, without face-to-face contact.*

2.15 *Services Maintenance Contracts will be in place to maintain communication equipment and PMR systems to secure uninterrupted provision of essential services.*"

2.16 The Committee noted the proposed audit procedures and that there will always be a responsible pharmacist on site during opening hours with accountability set out by the superintendent pharmacist. The Committee noted the details relating to the website and the offer of services to patients via that means.

2.17 The Committee was satisfied that, based on the information provided, there would be uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services during the stated opening hours.

2.18 The Committee went on to consider whether essential services would be provided safely and effectively 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.

2.19 The Committee was satisfied that there would be uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services as the opening hours stated.

2.20 The Applicant had confirmed that essential services will be provided without face-to face contact between anyone receiving the services, whether on their own or someone else's behalf, and the pharmacy staff. The pharmacy will operate from secure premises, with a controlled entry system, to which members of the public will not have access. Any patient that requests essential services to be provided at the premises will be informed that the pharmacy is not permitted to provide those services at the premises. Access to information about Essential Services will be achieved by using telephone, Live Video Call, the website, email and postal services. Essential services would be delivered via a number of methods including telephone, EPS, website, email, postal

services, courier services, specialist waste management services, video services and specialist cold chain courier services.

Schedule 4 Terms of service of NHS pharmacists

2.21 The Committee took the view that where compliance with the Terms of Service would ordinarily require face to face contact, the Applicant must explain how it is going to achieve compliance (and therefore safe and effective provision) without face-to-face contact.

2.22 The Committee considered Schedule 4 to the Regulations having regard to the additional information supplied by the Applicant in support of the application.

2.23 Schedule 4, paragraph 5(2) & (3) - the Committee considered whether the Applicant had explained how patients would present prescriptions. The Committee noted the Applicant's comments which stated:

2.24 "*Patients from anywhere in England may contact the pharmacy to request NHS Essential Services by phone, email, website, and by letter during the entire proposed opening hours, without face-to-face contact.*

2.25 *Prescription requests can be sent via our website, by email, post or by direct telephone call and by using the Electronic Prescription Service (EPS). Emergency prescriptions can be sent to the pharmacy via EPS or email or by any other electron from with the aim to deliver them as soon as possible."*

2.26 The Committee was satisfied that paragraph 5(2) & (3) would be complied with effectively without face-to-face contact.

2.27 Schedule 4, paragraph 6 - the Committee considered whether the Applicant had explained how in a case of urgency at the request of a prescriber drug or appliance would be provided to a patient. The Committee noted the Applicant's supporting information which stated:

2.28 *"Emergency prescriptions can be sent to the pharmacy via EPS or email or by any other electronic form with the aim to deliver then as soon as possible. Dispensed prescriptions will be delivered directly to patient's registered home/address anywhere in England (including controlled drugs and fridge lines) using a variety of secure and confidential methods such as our delivery staff, courier and appropriate Royal Mail services.*

2.29 *In the event that a patient needs a prescription urgently, the pharmacist will prioritise the prescription. The pharmacist will make all the necessary arrangements, acceptable to the patient, in order to meet the needs of the patient. This would include arrangements for an Urgent Delivery."*

2.30 The Committee was satisfied that paragraph 6 would be complied with effectively.

2.31 Schedule 4, paragraph 7 – the Committee considered whether the Applicant had explained how evidence would be sought and provided about the patient's entitlement to exemption from NHS Charges. The Applicant had not evidenced this in the application.

2.32 The Committee was not satisfied that paragraph 7 would be complied with effectively.

2.33 Schedule 4, paragraph 8(1) – the Committee considered whether the applicant had explained how items would be provided to patients including protection of the cold chain and requirements of the misuse of drugs act. The Committee noted the Applicant's comments which stated:

2.34 *"Dispensed prescriptions will be delivered directly to patient's registered home/address anywhere in England (including controlled drugs and fridge lines) using a variety of secure and confidential methods such as our delivery staff, courier and appropriate Royal Mail services. All prescription items handled and delivered by a courier service or our delivery driver will comply with the delivery SOP's and follow the Professional Guidance on the Safe Handling of Medicines by the Royal Pharmaceutical Society of Great Britain (RPSGB).*

2.35 *Temperature sensitive medicines (Fridge-lines) will be transported safely and securely in line with our Transport SOP. Where MHRA approved transport couriers are used to deliver fridge lines, cold chain environment will be maintained, and the temperature of the delivery will be traceable. For all local deliveries the pharmacy delivery drivers will maintain cold chain conditions by the using appropriate containers and equipment and keep a temperature audit trail in line with the pharmacy SOP's.*

2.36 *In the case of Controlled Drugs (CD) couriers/drivers shall be informed that they are carrying a CD and to ensure secure transport in accordance with guidance and pharmacy CD SOP. An audit trail will be kept of CD deliveries."*

2.37 The Committee was satisfied that paragraph 8(1) would be complied with effectively.

2.38 The Committee was satisfied that paragraph 8 of Schedule 4 would be complied with effectively.

2.39 Schedule 4, paragraph 8(15) – the Committee considered whether the applicant had explained how drugs would be provided in a suitable container suitable for posted/delivered items. The Committee noted the Applicant's comments which stated:

2.40 *"For all local deliveries, the pharmacy delivery drivers will maintain cold chain conditions by using appropriate containers and equipment and keep a temperature audit trial in line with the pharmacy SOP's*."

2.41 The applicant did not evidence sufficient information regarding suitable containers for non-cold chain items.

2.42 The Committee was not satisfied that paragraph 8(15) would be complied with effectively.

2.43 Schedule 4, paragraph 9(4) – the Committee considered whether the applicant had explained how for repeatable prescriptions they would assess that the patient is taking/using the item(s) appropriately and is not suffering from any side effects. The Committee noted the Applicant's comments which stated: *"This service is for patients with long term, stable conditions who require medicines and whose condition is not likely to change in the short to medium term. The management and dispensing condition is not likely to change in the short to medium term. The management and dispensing of repeat prescriptions will follow the REPEAT DISPENSING SOP.*

2.44 *Repeatable prescriptions will be securely and confidentially stored, dispensed only when required by the patient. The relevant patients will be contacted by telephone, email or text message before each prescription dispensing to verify a repeat prescription is required, and that the patient is taking their medication as prescribed. The pharmacy team will check and ensure that there has been no alteration to the patient's medication regime or medical circumstances since the last point of dispensing. The records will be securely kept to facilitate a full audit and ensure smooth continuity of the service.*

2.45 *Where advice is sought by the patient with regards to their repeat prescription, the Responsible Pharmacist will conduct that conversation over the telephone.*

2.46 *To promote the Repeat Dispensing service if the patient has a long-term condition and is suitable for Repeat Dispensing, then the pharmacy team will inform both the patient and the prescriber of the benefits of this service in order to enlist them onto it."*

2.47 The Committee was satisfied that paragraph 9(4) would be complied with effectively.

2.48 Schedule 4, paragraph 10(1) – the Committee considered whether the applicant had explained how it would provide appropriate advice about the use of drugs/appliances, safe keeping of items and returning of unwanted items be given. How it would advise regarding importance of only ordering items actually needed (repeatable prescriptions and appliances).

2.49 The applicant stated that for ensuring patients only ordering items actually needed "*The relevant patients will be contacted by telephone, e-mail or text message before each prescription dispensing to verify a repeat prescription is required, and that the patient is taking their medication as prescribed. The pharmacy team will check and ensure that there has been no alteration to the patient's medication regime or medical circumstances since the last point of dispensing.*"

2.50 However, the Applicant had not evidenced how it would provide appropriate advice about the use of drugs/appliances, safe keeping of items and returning unwanted items this in the application.

2.51 The Committee was not satisfied that paragraph 10(1) would be fully complied with safely and effectively.

2.52 Schedule 4, paragraph 14 - The Committee considered whether the Applicant had explained how it would accept unwanted drugs from patients and how patients will be advised on returning unwanted items. The Committee noted the Applicant's comments which stated:

2.53 *"The disposal of unwanted medicines will comply with all relevant waste management legislation and the pharmacy Disposal of Unwanted Medicines SOP. Once a request is made by the patient to return unwanted medicines, arrangements (as per SOP) are made to securely collect them from patients' home and transported back to the pharmacy via a courier service or pharmacy delivery driver*.

2.54 *Upon return to the pharmacy the unwanted medicine will be safely sorted and securely stored in disposal units ready for collection by a specialist waste management company such as the PHS Group Healthcare Waste Management. Controlled Drugs (Schedule 2 and 3) will be made irretrievable and steps will be put in place to make a record of the disposal, with respect to safe custody regulations. The pharmacy will collect unwanted and out of date Controlled Drugs from the patient's home via a designated delivery driver if local or by a courier company that provides a tracked and secure delivery service.*"

2.55 The Applicant had not evidenced how patients would be advised on returning unwanted items this in the application.

2.56 The Committee took into account the other comments made by the Applicant and concluded that it was not satisfied that the requirement of paragraph 14 would be fully complied with safely and effectively.

2.57 Schedule 4, paragraph 17 – The Committee considered whether the Applicant had explained or otherwise demonstrated 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.

2.58 The Committee noted information provided in the application which states that The Committee noted the Applicant's comments which stated:

2.59 *"Patient experience surveys together with patient profile data and long-term conditions such as Diabetes, Hypertension and COPD/ Asthma will be used to actively target lifestyle advice and interventions. Any local or national healthy lifestyle or health awareness campaigns will be pro-actively supported by the pharmacy.*

2.60 *The pharmacy will provide advice to people, carers; who request help with the treatment of minor ailments and long-term conditions including general information and lifestyle changes on how best to manage their illness. This advice will be provided over the phone, emails and leaflets (sent via post) without face-to-face contact*."

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

2.62 Schedule 4, paragraph 18 – The Committee considered whether the Applicant had explained how it would participate in health campaigns. The Committee noted the Applicant's comments which stated:

2.63 *"The pharmacy will promote Healthy Living Pharmacy and Healthy lifestyle advice to patients anywhere in England both verbally and in writing (by e-mail, text etc) as well as on the pharmacy website. We intend to embrace a broader range of health issues reflecting the wider patient base. Communication will be recorded on the Patient's Medical Record (PMR) in order to monitor and audit the service*.

2.64 *Patient experience surveys together with patient profile data and long-term conditions such as Diabetes, Hypertension and COPD/ Asthma will be used to actively target lifestyle advice and interventions. Any local or national healthy lifestyle or health awareness campaigns will be pro-actively supported by the pharmacy.*"

2.65 The application had not evidence [sic] how it would participate in health campaigns in the application.

2.66 The Committee considered it had not been provided with sufficient information and was satisfied that paragraph 18 would be complied with safely and effectively.

2.67 Schedule 4, paragraph 20 – The Committee considered whether the Applicant had demonstrated how it would assess patients' need before signposting them in order to minimise inappropriate use of health or social care services. The Committee noted the Applicant's comments which stated:

2.68 *"The pharmacy website will hold information and guidance that will assist patients to various organisations such as NHS Choices, Patient Forums and Chronic Disease organisations such as Diabetes UK, Heart and Stroke Foundation. The website will also contain a list of useful contacts for out of hours advice and links to NHS 111*.

2.69 *Where patients request specific health or medical information the pharmacy will assist and direct them to seek the relevant information and how to access additional healthcare services. This Information will be made available verbally or by phone, email, text and not by face-to-face contact if a patient contacts the pharmacy via phone outside the opening hours or when the pharmacy is closed, they will be given an option to leave a message for the pharmacy team for non-urgent matters or to contact NHS 111 service if it is urgent or call 999 if it life threatening*.

2.70 *If a referral or intervention is made for the patient and it is deemed important by the RP, a record will be made on the PMR system*."

2.71 The Committee concluded the Applicant had demonstrated how it would assess patients' need before signposting them to minimise inappropriate use of health or social care services.

2.72 Schedule 4, paragraph 21 – The Committee considered whether the Applicant had demonstrated how it would provide advice or support for people caring for themselves or their families. The Committee noted the Applicant's comments which stated:

2.73 "*The pharmacy will provide advice to people, carers, who request help with the treatment of minor ailments and long-term conditions including general information and lifestyle changes on how best to manage their illness. This advice will be provided over the phone, emails and leaflets (sent via post) without face-to-face contact*.

2.74 *The verbal and written information provided by the pharmacy will include advice on managing long term conditions, how to maximise the benefits from their medication and how to lead a healthy lifestyle. Advice will also be provided on the use of Over-The - Counter (OTC) medication either supplied by the pharmacy or from elsewhere by patients*."

2.75 The Committee concluded the Applicant had demonstrated how it would provide advice or support for people caring for themselves or their families.

2.76 Schedule 4, paragraph 22(b) & 22(c) - 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

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

2.76.2 or (b) who is otherwise referred to P for advice, assistance and support in respect of the patient's medication regiment by the staff of an NHS trust or NHS foundation trust as part of arrangement linked to the transfer of care between different providers of NHS services.

2.77 Further the Committee considered whether the Applicant had explained what procedures it had in place for checking referrals for the discharge medicines services.

2.78 The Committee noted The Applicant had not evidenced this in the application.

2.79 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 22(b) and 22(c) of Schedule 4.

2.80 Schedule 4, paragraph 28 – The Committee considered whether the Applicant had demonstrated how it would comply with all components of clinical governance element of the Terms of Service. The Committee noted the Applicant's comments which stated:

2.81 *"Clinical Governance (CG) & Continuous Professional Development (CPD)*

2.82 *The superintendent pharmacist (SIP) will act as the Clinical Governance (CG) Lead and be responsible for meeting information and clinical governance requirements and ensure standards are met. This will be performed by applying the principles of CG and following the General Pharmaceutical Council guidance for registered pharmacies providing pharmacy services at a distance, including on the internet*.

2.83 *The pharmacy will have governance arrangements in place that safeguard the health, safety and wellbeing of patients and the public. Fully trained staff will be both empowered and competent to comply with the pharmacy Clinical Governance SOP. All*

essential services will be provided from our premises, facilities and also using equipment that are fit for purpose to comply with the principles of good clinical practice.

2.84 *Risk management will be reviewed and monitored by the CG Lead who will maintain a risk register. The pharmacy processes will be reviewed at regular intervals and audited. All reported incidents and customer complaints will be reviewed and addressed and SOPs amended to improve patient safety and prevent future reoccurrence*.

2.85 *All staff including the Responsible Pharmacist and the SIP will participate in regular Continual Professional Development (CPD) by using the CPD toolkit. This will ensure that the entire pharmacy team has the knowledge and competence to comply with Good Practice Criteria and provide essential services in a safe and secure manner.*"

2.86 The Committee concluded the Applicant had demonstrated how it would comply with all components of clinical governance element of the Terms of Service (paragraph 28).

2.87 Schedule 4, paragraph 28(c) - The Committee considered whether the Applicant had explained how it will ensure that it has a website for the use by the public for the purpose of accessing pharmaceutical services from those premises, on which there is an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues.

2.88 The Committee noted information provided in the application which states:

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

2.90 *The pharmacy website will hold information and guidance that will assist patients to various organisations such as NHS Choices, Patient Forums and Chronic Disease organisations such as Diabetes UK, Heart and Stroke Foundation. The website will also contain a list of useful contacts for out of hours advice and links to NHS 111.*"

2.91 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 28(c) of Schedule 4.

2.92 The Committee concluded that all essential services would not be provided safely and effectively 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.

Decision

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

2.94 The Committee determined the application as follows –

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

2.94.2 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.

2.94.3 the Committee was satisfied that all essential services were likely to be secured without interruption during the stated opening hours.

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

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

2.94.6 the Committee was satisfied that all essential services were likely to be secured without face-to-face contact.

2.94.7 the Committee was not assured that Schedule 4, paragraph 7, Schedule 4, paragraph 8(15), Schedule 4, paragraph 10(1), Schedule 4, paragraph 14, Schedule 4, paragraph 18, Schedule 4, paragraph 22(b) & 22(c) would be met.

2.95 The Committee determined to refuse the application.

Regulation 64(3)

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

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

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

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

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

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

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

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

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

2.96.5.2 the applicant is likely to refuse, for reasons other than those provided for in the applicant's terms of service, to provide drugs or appliances

ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (for example, because the availability of essential services from the applicant is limited to other categories of patients)

Third Party Rights Of Appeal

2.97 The application is refused so the applicant has the right to appeal.

2.98 The Committee decided not to grant third party rights of appeal to the decision to any of the parties that responded during the consultation period because the application had been refused."

3 The Appeal

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

3.1 "I am writing on behalf of Pharmaethical Ltd to formally appeal the decision to refuse our application for a distance selling premises, located at Fareham Innovation Centre, Unit 15, 4 Meteor Way, Off Broom Way, Lee-on the-Solent, PO13 9FU, Hampshire. This appeal addresses the grounds for refusal based on the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, and the Department of Health guidance on Distance Selling Premises as cited by the Hampshire and the Isle of Wight ICB.

3.2 Pharmaethical Ltd is committed to ensuring the provision of all essential services in a safe and effective manner without face-to-face contact. To this end, we address the specific regulatory concerns as follows:

3.2.1 Schedule 4, paragraph 7 – the Committee considered whether the Applicant had explained how evidence would be sought and provided about the patient's entitlement to exemption from NHS Charges. The Applicant had not evidenced this in the application.

3.2.2 The Committee was not satisfied that paragraph 7 would be complied with effectively.

3.3 The Pharmacist will follow the 'Exemption Checking Standard Operating Procedure' to determine the patient's entitlement to exemption from NHS charges. See Appendix A.

3.4 Before providing any drugs or appliances in accordance with a prescription form or a repeatable prescription, our pharmacist will ask any person who makes or duly completes a declaration as or on behalf of the person named on the prescription form or repeatable prescription, that the person named on the prescription form or the repeatable prescription does not have to pay the charges specified in the regulations. For those patients that are age exempt or having an oral contraceptive no exemption evidence will be sought.

3.5 Evidence of exemption entitlement will be sought from the patient or their representative via post for FP10 prescriptions and verifying the exemption part has been completed. For Electronic Prescription Service (EPS) tokens a check of electronic records for EPS prescriptions that are managed by the NHS BSA known as Real Time Exemption Check (RTEC) would be completed prior to dispensing of the prescription. Where, no exemption has been declared, the pharmacist will call the patient to determine if they are entitled to any exemptions and complete the declaration on their behalf as the patient representative. If no exemption is applicable then the patient will be advised to pay for their prescriptions.

3.6 Where the patient declares an exemption following a non-face to face communication but no satisfactory evidence has been provided, the pharmacist will not refuse the dispensing of the prescription but will mark X, in the 'evidence not seen' box on the back of the paper FP10/EPS token. As part of the terms of service the pharmacist will advise the patient that NHS checks are routinely undertaken to verify that the exemption status is correct to prevent and detect fraud or error.

3.7 Once an exemption has been declared and evidence seen by the pharmacist, a record of this is noted on the pharmacy PMR computer system along with the expiry date of the certificate.

3.7.1 Schedule 4, paragraph 8(15) – the Committee considered whether the applicant had explained how drugs would be provided in a suitable container suitable for posted/delivered items. The Committee noted the Applicant's comments which stated: "*For all local deliveries, the pharmacy delivery drivers will maintain cold chain conditions by using appropriate containers and equipment and keep a temperature audit trail in line with the pharmacy SOP's*."

3.7.2 The applicant did not evidence sufficient information regarding suitable containers for non-cold chain items.

3.7.3 The Committee was not satisfied that paragraph 8(15) would be complied with effectively.

3.8 For the purpose of clarification all non-cold chain (ambient temperature) items will posted/delivered using special tamper proof packaging, using discreet high quality polythene bags/flat cardboard boxes in large letter format for easy postage or into cardboard boxes with sufficient bubble wrap for larger items such as creams and liquid bottles.

3.8.1 Schedule 4, paragraph 10(1) – the Committee considered whether the applicant had explained how it would provide appropriate advice about the use of drugs/appliances, safe keeping of items and returning of unwanted items be given. How it would advise regarding importance of only ordering items actually needed (repeatable prescriptions and appliances).

3.8.2 The applicant stated that for ensuring patients only ordering items actually needed "The relevant patients will be contacted by telephone, e-mail or text message before each prescription dispensing to verify a repeat prescription is required, and that the patient is taking their medication as prescribed. The pharmacy team will check and ensure that there has been no alteration to the patient's medication regime or medical circumstances since the last point of dispensing."

3.8.3 However, the Applicant had not evidenced how it would provide appropriate advice about the use of drugs/appliances, safe keeping of items and returning unwanted items this in the application.

3.8.4 The Committee was not satisfied that paragraph 10(1) would be fully complied with safely and effectively.

3.9 The pharmacy will ensure that appropriate advice about the use of drugs/appliances and the safekeeping of dispensed items by following the procedures as set out in the Assembling and Labelling Prescriptions SOP (see Appendix A) and giving advice and support using non-face-to-face communication by the pharmacy team.

3.10 For clarification the pharmacy will provide advice and information on how to use the prescribed medicine or appliance by:

3.10.1 labelling the medicines/appliances with clear dosage instruction on how and when to take or use the medicine/appliance

3.10.2 adding precautions relating to the use of the medicine labels such as 'For External Use only' or 'May cause drowsiness'

3.10.3 adding storage information on the labels such as 'Store in a cool dry place' or 'Protect from sunlight'

3.10.4 including safety information on the labels such as 'Keep out of reach of children'

3.10.5 enclosing general information about the medicine/appliance using the Patient Information Leaflet (PIL) within the packaging of the dispensed drugs/appliances

3.11 In addition, the pharmacist by using professional judgement and prescription linked interventions will contact the patient either by telephone call or electronic means if they believe the patient will need additional advice or information to take or use their drugs/appliances effectively and safely.

3.12 Furthermore, a patient can contact the pharmacy either by telephone, email or video call to get further information or clarification if they require further assistance or support to take or use their medication/appliance safely and effectively.

3.13 The pharmacy will keep an electronic record of all patient details and their dispensed prescription drugs and appliances on the PMR computer system. This facilitates the continued care of the patient and allows the pharmacist to offer advice and make interventions or referrals where necessary for the patient.

3.14 Repeatable prescription and appliances are processed using the pharmacy 'Repeat Dispensing SOP' as briefly described in our application and previously accepted. For clarification all patients ordering their repeat items are informed of the importance of only requesting those items which are actually needed.

3.15 Patients will be advised about returning unwanted medicines by following the pharmacy 'Returns of Unwanted Medicines SOP' and is explained in point [3.15.1] below -[3.15.1]. Schedule 4, paragraph 14 and [3.15.6]. Please see point [3.15.1 – 3.15.3] below.

3.15.1 Schedule 4, paragraph 14 - The Committee considered whether the Applicant had explained how it would accept unwanted drugs from patients and how patients will be advised on returning unwanted items. The Committee noted the Applicant's comments which stated:

3.15.2 "The disposal of unwanted medicines will comply with all relevant waste management legislation and the pharmacy Disposal of Unwanted Medicines SOP. Once a request is made by the patient to return unwanted medicines, arrangements (as per SOP) are made to securely collect them from patients' home and transported back to the pharmacy via a courier service or pharmacy delivery driver.

3.15.3 Upon return to the pharmacy the unwanted medicine will be safely sorted and securely stored in disposal units ready for collection by a specialist waste management company such as the PHS Group Healthcare Waste Management.

3.15.4 Controlled Drugs (Schedule 2 and 3) will be made irretrievable and steps will be put in place to make a record of the disposal, with respect to safe custody regulations. The pharmacy will collect unwanted and out of date Controlled

Drugs from the patient's home via a designated delivery driver if local or by a courier company that provides a tracked and secure delivery service."

3.15.5 The Applicant had not evidenced how patients would be advised on returning unwanted items this in the application.

3.15.6 The Committee took into account the other comments made by the Applicant and concluded that it was not satisfied that the requirement of paragraph 14 would be fully complied with safely and effectively.

3.16 Patients will be advised on how to return unwanted items on our pharmacy website and our practice leaflets. To arrange the return of unwanted medicines to the Pharmacy the patient is advised to call the pharmacy and speak to a member of the dispensary team or contact them via email.

3.17 The pharmacy team will confirm and agree, with the patient, which unwanted medicines from the pharmacy need to be returned and take a brief description of the medicines. When returning any Controlled Drugs, the patient must speak with the pharmacist on duty. If Controlled Drugs (CD) or hazardous drugs (such as cytotoxic medication) are being returned special arrangements will need to be made to securely return them back to the pharmacy.

3.18 The patient will be advised that their unwanted medicines (including residential homes) will be collected by our designated driver if local or the pharmacy will post out, to the patient, suitable pre-paid packaging. The patient can then send the unwanted medicines in the packaging and use the Royal Mail pre-paid secure tracked service to send them back to the pharmacy.

3.19 Patients or their representatives will be advised that they cannot return any medicines directly to the pharmacy when speaking to them on the phone or communicating via email. The pharmacy team will inform them that contractually, as a Distance Selling Pharmacy, the pharmacy cannot provide face-to-face pharmacy services including accepting unwanted medicines.

3.20 Full details on how the pharmacy accepts unwanted medicines and how patients can return them to the pharmacy can be found on the 'Disposal of Unwanted Medicines SOPs (see Appendix A).

3.20.1 Schedule 4, paragraph 18 – The Committee considered whether the Applicant had explained how it would participate in health campaigns. The Committee noted the Applicant's comments which stated:

3.20.2 "The pharmacy will promote Healthy Living Pharmacy and Healthy lifestyle advice to patients anywhere in England both verbally and in writing (by e-mail, text etc) as well as on the pharmacy website. We intend to embrace a broader range of health issues reflecting the wider patient base. Communication will be recorded on the Patient's Medical Record (PMR) in order to monitor and audit the service.

3.20.3 Patient experience surveys together with patient profile data and long-term conditions such as Diabetes, Hypertension and COPD/ Asthma will be used to actively target lifestyle advice and interventions. Any local or national healthy lifestyle or health awareness campaigns will be pro-actively supported by the pharmacy."

3.20.4 The application had not evidenced how it would participate in health campaigns in the application.

3.21 As a distance selling pharmacy (DSP) in England the pharmacy will participate in NHS health campaigns by integrating campaign materials and messages into our digital and communication channels.

3.22 The pharmacy will display digital campaign materials on its website and social media platforms. This includes banners, informational posts, and videos that align with the NHS health campaign being promoted.

3.23 The pharmacy will use email newsletters and direct communications with patients to disseminate campaign information such as tips, advice, and links to NHS resources.

3.24 In addition, our pharmacists will provide prescription linked intervention and advice related to the campaign during remote consultations. This may involve discussing key points of the health campaign with their patients. For example, with 'STOP SMOKING HEALTH CAMPAIGN' the pharmacist would promote the benefits of smoking cessation and where to get help locally.

3.25 The pharmacy will also ensure that all digital content for any health campaign is accessible and compliant with the NHS Accessible Information Standard, making it available to all patients, including those with disabilities.

3.26 Finally, the pharmacy will record and document the participation in any health campaign as mandated in the service specifications of the campaign and submit reports to NHS England in an anonymised form detailing the requested activities providing evidence of compliance.

3.26.1 Schedule 4, paragraph 22(b) & 22(c) - 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

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

3.26.3 or (b) who is otherwise referred to P for advice, assistance and support in respect of the patient's medication regiment by the staff of an NHS trust or NHS foundation trust as part of arrangement linked to the transfer of care between different providers of NHS services.

3.26.4 Further the Committee considered whether the Applicant had explained what procedures it had in place for checking referrals for the discharge medicines services.

3.26.5 The Committee noted The Applicant had not evidenced this in the application.

3.26.6 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 22(b) and 22(c) of Schedule 4.

3.27 With respect to [3.26.4], the pharmacy will check for referrals from Hospital or NHS Trust or NHS foundation trust for a recently discharged patient from incoming NHS emails and or Pharmoutcomes at least twice a day whilst the pharmacy is open.

3.28 They will complete Stage 1 of the DMS service within 72 hours of receipt of the referral (excluding hours when the pharmacy is not open for business). When providing this service all communications with the patient/patient's carer or third parties will be non-face-to-face and via telephone or email and take place in a private area of the pharmacy to maintain confidentiality.

3.29 The pharmacy will be compliant with paragraph 22(b) and 22(c) of schedule 4 of the terms of service and provide advice, assistance and support to and in respect of a health service patient recently discharged from hospital or who is otherwise referred to the pharmacy by NHS trust or NHS foundation trust by following the pharmacy DISCHARGED MEDICINE SERVICE SOP – see Appendix A. This linked transfer of care between different providers of NHS services will enhance patient outcomes and support the continuity of care.

3.30 As a distance selling pharmacy the procedures set out in this service are provided by non-face to face communication such as via telephone calls and emails.

3.31 I hope that the evidence provided clearly demonstrates our commitment and capability to meet all essential service requirements safely and effectively and in line with the terms of service. If you require any further information or clarifications, please do not hesitate to contact me.

3.32 I respectfully request that NHS Resolution reconsider our application for a distance selling premises license in light of the evidence and assurances provided."

4 Summary of Representations

This is a summary of representations received on the appeal.

4.1 THE COMMISSIONER

4.1.1 "Thank you for your letter dated 16 August 2024 inviting representations in response to the appeal by Pharmaethical Limited against the decision made by NHS Hampshire and Isle of Wight Integrated Care Board PSRC to refuse an application for inclusion on the pharmaceutical list for a distance selling pharmacy.

4.1.2 We note the additional information that has been provided as part of the appeal an in response to the decision letter.

4.1.1 We have no other representations to make."

4.2 L ROWLAND & CO (RETAIL) LTD

4.2.1 "Thank-you for the opportunity to comment on the above appeal from Pharmaethical Ltd dated 12th August 2024. If the NHSR decide to convene an oral hearing, we are willing to attend under the provisions of Paragraph 8 of schedule 3 of the regulations.

4.2.2 We have no further comments to make at this stage.

4.2.3 Please see our previous comments enclosed."

In a letter dated 4 January 2024 addressed to PCSE on behalf of the Commissioner L Rowland & Co (Retail) Ltd stated:

4.2.4 "Thank you for informing L Rowland & Co (Retail) Ltd of the above application.

4.2.5 We note this is an excepted application and should one be required we would be willing to attend an oral hearing if NHS England deem it necessary.

4.2.6 L Rowland & Co (Retail) Ltd wishes to make the following comments:

4.2.7 As the application is in respect of distance selling premises, by virtue of regulation 64 (3) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, approval is subject to the following conditions:

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

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

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

4.2.7.4 The pharmacy procedures for the premises must be such to secure –

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

4.2.7.4.2 The safe and effective provision of essential services without face-to-face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff; and

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

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

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

4.2.7.6 We note that in SHA/24544, PCA refused a DSP application because they were not satisfied that items which require cold chain transport could be satisfactorily received by the patient. They state the following "…there was nothing provided by the Applicant to demonstrate that an audit process or appropriate system is in place which would highlight any items, which might have ceased to be refrigerated in transit and therefore be compromised, and how these would be prevented from being given to the patient. In addition, Committee noted SOP 3 specifically defines a failed delivery as one where there has been no one there to accept delivery. It therefore does not include a situation where the cold chain has been compromised in transit, and the SOP does not set out how such a situation would be recognised and dealt with. The Committee was not therefore confident, as it is required to be, that all dispensed cold chain products would be delivered in a safe

and effective manner". We trust that NHSE will consider this view when reaching their decision on this application.

4.2.8 We furthermore wish to be assured that NHS England has sufficient governance procedures in place to ensure that the criteria for the excepted application are fulfilled. We also request that NHS England keep us informed of the outcome in due course."

5 **Summary of Observations**

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

6 **Consideration**

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

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

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

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

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

6.6 The Committee noted that the Applicant had stated "not applicable" as to why the application should not be refused pursuant to Regulation 31. The Commissioner was satisfied that there is no pharmacy providing pharmaceutical services at the same or adjacent premises and that this had not been disputed either on appeal or in subsequent representations. Based on the information provided, the Committee was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

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

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

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

Regulation 25(1)

6.9 In relation to Regulation 25(1), the Applicant is applying for inclusion in the relevant pharmaceutical list, as a person not already included in a pharmaceutical list, and

paragraph (1)(a) therefore operates to disapply the specified provisions of section 129 of the National Health Service Act 2006, provided that paragraph (2) does not require the application to be refused.

Regulation 25(2)(a)

6.10 As far as Regulation 25(2)(a) is concerned, the Committee had regard to the application form in which the Applicant states "not applicable." 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)

6.11 As far as Regulation 25(2)(b) is concerned, the Committee considered the information which had been provided by the Applicant in relation to its procedures for the provision of essential services, including a selection of its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.

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

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

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

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

6.16 The Committee noted the comment from the Applicant in the application form which states "*patients from anywhere in England may contact the pharmacy to request NHS Essential Services by phone, email, website and by letter during the entire proposed opening hours, without face to face contact*." The Committee further noted the response from the Applicant to the question raised at 7.2 where they state:

6.16.1 *"7.2 When a patient attends the premises and requests essential services, the pharmacy team will follow the steps outlined below ensuring that no element of essential services is offered or provided to a person attending the pharmacy:*

Greet and welcome the patient or their representative at the pharmacy entrance.

A member of the trained pharmacy team will direct the patient to contact the pharmacy via the telephone or website and inform them that no essential services can be provided by a face to face interaction.

The patient or their representative can discuss via the telephone or video call about any pharmacy service matter with the trained pharmacy team or the Responsible Pharmacist.

If the matter or query is deemed important then it will be documented on the patient's PMR record for future reference."

6.17 The Committee further noted the document from the Applicant with the original application form which sets out how the Applicant intends to provide essential services without face to face access.

6.18 However, the Committee noted the SOP "Prescription Exemption Checking" under 'Overview' states:

"A patient's exemption status applies at the time of dispensing – the point at which the patient collects their medication …"

6.19 The Committee determined that reference to "*patient collects their medication"* implied an option for patients which was not permitted under the Regulations.

6.20 Based on the information before it, the Committee was not satisfied that the provision of essential services would be without face to face contact.

6.21 The Committee noted the various references throughout the application and supporting information to prescriptions being received electronically as well as further confirmation from the Applicant that medications would be delivered by their own delivery driver and that they would also be making use of Royal Mail and courier companies. The Committee noted that the Applicant would have a fully functioning website and would be able to contact patients online as well as by telephone, email and letter. The Applicant confirmed that they would be providing essential services to anyone anywhere in England.

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

6.23 The Committee noted in the information provided, the Applicant refers to "*Maintaining an appropriate number of qualified, trained and registered pharmacy staff and ensuring there are enough personnel to meet the demand for essential services during opening hours. This includes the Responsible Pharmacist (RP) who shall remain in the pharmacy during the entire proposed opening hours in accordance with RP regulations as detailed by General Pharmaceutical Council."* The Committee noted that there was no information provided as to how the pharmacy would operate and ensure uninterrupted services in the absence of the Responsible Pharmacist.

6.24 The Committee was of the view that it was not clear from the information provided how essential services would be provided, should they be required, during the absence of the Responsible Pharmacist. Therefore the Applicant would be unable to provide all essential services without the presence of a pharmacist on site.

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

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

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

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

6.28.1 Dispensing of drugs and appliances

6.28.2 Urgent supply without a prescription

6.28.3 Preliminary matters before providing ordered drugs or appliances

6.28.4 Providing ordered drugs or appliances

6.28.5 Refusal to provide drugs or appliances ordered

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

6.28.7 Disposal service in respect of unwanted drugs

6.28.8 Promotion of healthy lifestyles

6.28.9 Prescription linked intervention

6.28.10 Health campaigns

6.28.11 Signposting

6.28.12 Support for self-care

6.28.13 Discharge medicines service

6.28.14 Websites and health promotion zones

6.29 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:

Preliminary matters before providing ordered drugs or appliances

6.30 The Committee considered whether the Applicant had explained how charges will be paid and noted that the reference to "*ask them to pay for the prescription"* and "*you can also tell patients currently paying for their prescriptions that they may benefit from buying a Prescription Payment Certificate …"* appears in the "Prescription Exemption Checking" SOP under the heading "If the patient is unsure of their entitlement". The Committee further noted the comments from the Applicant in their appeal that "*If no exemption is applicable then the patient will be advised to pay for their prescriptions"* however, there was no further information as to how payment was to be taken by the Applicant or how they would ascertain that payment had then been made.

6.31 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(5)(b) of Schedule 4.

Providing ordered drugs or appliances

6.32 The Committee considered whether the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that (i) the 'cold chain' is maintained,

where relevant and (ii) that the requirements of the Misuse of Drugs Regulations 2001 and, in particular, Regulations 14 and 16, are met).

6.33 The Committee noted the information contained within the application form that covered the provision of drugs or appliances specifically with regard to "cold chain".

6.34 The Committee noted the statements from the Applicant that:

6.34.1 *"… All prescription items handled and delivered by a courier service or our delivery driver will comply with the delivery SOP's and follow the Professional Guidance on the Safe Handling of Medicines by the Royal Pharmaceutical Society of Great Britain (RPSGB).*

In the case of Controlled Drugs (CD) couriers/drivers shall be informed that they are carrying a CD and to ensure secure transport in accordance with guidance and pharmacy CD SOP. An audit trail will be kept of CD deliveries.

Temperature sensitive medicines (fridge-lines) will be transported safely and securely in line with our Transport SOP. Where MHRA approved transport couriers are used to deliver fridge lines, cold chain environment will be maintained and the temperature of the delivery will be traceable. For all local deliveries the pharmacy delivery drivers will maintain cold chain conditions by the using appropriate containers and equipment and keep a temperature audit trail in line with the pharmacy SOP's."

6.35 L Rowland & Co (Retail) Ltd had raised concerns regarding how the integrity of the cold chain would be maintained and monitored and whilst the Committee noted the reference in the application form to the pharmacy's SOPs for delivery, these had not been provided either on appeal or in subsequent representations and no response to the concerns raised by L Rowland & Co (Retail) Ltd had been received.

6.36 Whilst the Committee noted the references to the cold chain being maintained and there being a temperature audit, there was nothing provided as to what would happen if the temperature was not maintained. The Committee also noted that there was no information provided by the Applicant as to what would happen if there was a failed delivery by either the pharmacy's own delivery driver or, for those further afield, the courier service or Royal Mail.

6.37 In the application form under "Dispensing of Medicines" the Applicant had stated:

6.37.1 *"Dispensed prescriptions will be delivered directly to patient's registered home/address anywhere in England (including controlled drugs and fridge lines) using a variety of secure and confidential methods such as our delivery staff, courier and appropriate Royal Mail services. All prescription items handled and delivered by a courier service or our delivery driver will comply with the delivery SOP's and follow the Professional Guidance on the Safe Handling of Medicines by the Royal Pharmaceutical Society of Great Britain (RPSGB)*.

In the case of Controlled Drugs (CD) couriers/drivers shall be informed that they are carrying a CD and to ensure secure transport in accordance with guidance and pharmacy CD SOP. An audit trail will be kept of CD deliveries."

6.38 The Committee further noted that whilst the Applicant had confirmed that controlled drugs would be delivered using a variety of methods including their own delivery staff, courier or Royal Mail and that they would be delivered in accordance with the "delivery SOPs" the SOPs had not been provided and there was nothing provided as to what would happen in the event of a failed delivery.

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

6.40 The Committee noted that the Applicant had stated on the application form "none" in response to the question as to whether they were undertaking to provide appliances. The Committee was therefore of the view that, if the application was to be granted, the Applicant would not be able to provide any appliances.

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

6.41 The Committee considered whether the Applicant had explained how appropriate advice about the benefits of repeat dispensing is given to any patient who (i) has 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.

6.42 The Commissioner had not been satisfied that paragraph 10(1) would be fully complied with safely and effectively as "*the Applicant had not evidenced how it would provide appropriate advice about the use of drugs/appliances, safe keeping of items and returning unwanted items this in the application". [sic]*

6.43 The Committee noted the reference in the application form that "*the management and dispensing of repeat prescriptions will follow the REPEAT DISPENSING SOP."* However, the Committee noted that it had not been provided with this SOP. The Applicant had gone on to state "*The relevant patients will be contacted by telephone, email or test message before each prescription dispensing to verify a repeat prescription is required and that the patient is taking their medication as prescribed."*

6.44 The Applicant concluded "*To promote the Repeat Dispensing service if the patient has a long term condition and is suitable for Repeat Dispensing, then the pharmacy team will information both the patient and the prescriber of the benefits of this service in enlist them on to it."*

6.45 The Committee noted that on appeal, the Applicant had referred to the "Assembling and Labelling Prescriptions SOP" which had been provided which set out how appropriate advice about the medication as well as how it should be stored. The Committee was of the view that appropriate advice about the use of drugs/appliances, safe keeping of items and returning unwanted items was not a relevant consideration under the criteria as set out in paragraph 10(1) which was concerned with the benefits of repeat dispensing.

6.46 The Committee noted that the appeal went on to state:

6.46.1 "*Repeatable prescription and appliances are processed using the pharmacy 'Repeat Dispensing SOP' as briefly described in our application and previously accepted. For clarification all patients ordering their repeat items are informed of the importance of only requesting those items which are actually needed."*

6.47 Whilst the Committee had been provided with information as to how repeat dispensing would be carried out, it had not been provided with information regarding how the appropriate advice about the benefits of repeat dispensing would be given to a patient or how those patients who may benefit from repeat dispensing would be identified.

6.48 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.

Other considerations

6.49 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.

Preliminary matters before providing ordered drugs or appliances

6.50 The Commissioner had not been satisfied that paragraph 7 would be complied with effectively. The Applicant had provided SOPs with their appeal which included the SOP "Prescription Exemption Checking" which states:

6.50.1 *If the patient makes an exempt declaration*

Every time you receive a prescription where the patient has marked a line in one box on the back of the paper FP10/token:

ask to see evidence of their eligibility either by video call or email

ask them to sign the declaration box on the paper FP10/token

when submitting an EPS claim, make sure you specify the correct exemption category and indicate whether evidence was seen

if the patient provides a valid exemption certificate, note this on your PMR system along with the expiry date of the certificate. The pharmacy PMR dispensing system will automatically calculate the patient's exemption status.

2. If the patient does not provide evidence

If the patient does not provide evidence of their entitlement to free prescriptions:

do not refuse to dispense items

put an X in the 'Evidence not seen' box on the back of the paper FP10/token

advise the patient that NHS checks are routinely undertaken to verify that people are exempt from payment of NHS prescriptions charges to prevent and detect fraud or error – this is a legislative requirement under the pharmacy's terms of service

when submitting an EPS claim, make sure you specify the correct exemption category and indicate if evidence was seen."

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

Providing ordered drugs or appliances

6.52 The Commissioner had not been satisfied that the Applicant had provided sufficient evidence regarding suitable containers for non-cold chain items and was of the view that paragraph 8(15) would not be complied with effectively.

6.53 The Committee noted the references in the application from to "*… will maintain cold chain conditions by the using appropriate containers and equipment …".* The Applicant, on appeal, had gone on to state:

6.53.1 "*For the purpose of clarification all non-cold chain (ambient temperature) items will posted/delivered using special tamper proof packaging, using discreet high quality polythene bags/flat cardboard boxes in large letter format for easy postage or into cardboard boxes with sufficient bubble wrap for larger items such as creams and liquid bottles."*

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

Disposal service in respect of unwanted drugs

6.55 The Committee noted that the Commissioner had not been satisfied that the Applicant would comply with paragraph 14 safely and effectively.

6.56 With the letter of appeal the Applicant had provided the "Disposal of Unwanted Medicines" SOP which stated:

6.56.1 "*The disposal of unwanted medicines will comply with all relevant waste management legislation and follow this Disposal of Unwanted Medicines SOP*.

This service is advertised on the pharmacy website and on the practice leaflet. Patients or their representatives cannot return any medicines directly to the pharmacy and the team follows the procedures set out in the SOPs to avoid any face-to-face contact.

To arrange the return of unwanted medicines to the Pharmacy the patient telephones and speaks to a member of the dispensary team or contacts them via email. For controlled drugs this is always the pharmacist on duty.

Confirm and agree with the patient which unwanted medicines from Pharmacy Plus need to be returned.

Get a brief description of the medicines being returned. If Controlled Drugs (CD) or hazardous drugs (such cytotoxic medication) are being returned special arrangements need to be in place to securely return them back to the pharmacy.

The patient will be advised that their unwanted medicines (including residential homes) will be collected by our designated driver if local or the pharmacy will post out, to the patient, suitable pre-paid packaging. The patient can then send the unwanted medicines in the packaging and use the Royal Mail pre-paid secure tracked service to send them back to the pharmacy.

Returns are then stored accordingly in containers provided by the approved waste disposal contractor, contracted by the local NHS England Team. The waste contractor (PHS) collects the unwanted medicines as per their procedure.

Upon return to the pharmacy the unwanted medicine will be safely sorted and securely stored in disposal units ready for collection by a specialist waste management company.

Controlled Drugs (Schedule 2 and 3) will be made irretrievable as outlined below.

All other medicines, different formulations, will be processed as described below.

All CD's returned and destroyed will be recorded in the Controlled Drugs Patient Returns Register."

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

Promotion of healthy lifestyles

6.58 The Commissioner had concluded that the Applicant had not provided sufficient information for it to be satisfied that paragraph 18 would be complied with safely and effectively.

6.59 In the application form the Applicant had stated "*Any local or national healthy lifestyle or health awareness campaigns will be proactively supported by the pharmacy.*"

6.60 On appeal, the Applicant had expanded upon this and had stated:

6.60.1 *As a distance selling pharmacy (DSP) in England the pharmacy will participate in NHS health campaigns by integrating campaign materials and messages into our digital and communication channels.*

The pharmacy will display digital campaign materials on its website and social media platforms. This includes banners, informational posts, and videos that align with the NHS health campaign being promoted.

The pharmacy will use email newsletters and direct communications with patients to disseminate campaign information such as tips, advice, and links to NHS resources.

In addition, our pharmacists will provide prescription linked intervention and advice related to the campaign during remote consultations. This may involve discussing key points of the health campaign with their patients. For example, with 'STOP SMOKING HEALTH CAMPAIGN' the pharmacist would promote the benefits of smoking cessation and where to get help locally.

The pharmacy will also ensure that all digital content for any health campaign is accessible and compliant with the NHS Accessible Information Standard, making it available to all patients, including those with disabilities.

Finally, the pharmacy will record and document the participation in any health campaign as mandated in the service specifications of the campaign and submit reports to NHS England in an anonymised form detailing the requested activities providing evidence of compliance."

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

Discharge medicines service

6.62 It was noted by the Commissioner that the Applicant had not provided any information in relation to the Discharge Medicines service in their original application form. The Committee noted that, on appeal the Applicant had stated that the pharmacy will be compliant with paragraphs 22(b) and 22(c) of Schedule 4 and had provided a SOP entitled "Discharge Medicines Service" which stated:

6.62.1 *"PURPOSE*

To ensure:

A safe and effective operation of the NHS England Discharge Medicines Service (DMS)

The DMS is operated within the service specification for a distance selling pharmacy without face-to-face contact

Patient referred to the service receive appropriate advice

Appropriate documentation is completed to ensure accurate payment is received.

To improve patient outcomes, prevent harm and reduce hospital re-admissions

SCOPE

This standard operating procedure covers the provision of the pharmacy DMS, to patients referred by NHS trusts following discharge from hospital or another provider of NHS services.

Procedure

Preparation

Check for referrals received electronically via pharmaoutcomes, this needs to be checked regularly or at least twice daily.

Agree suitable timings within day with the pharmacist on duty

Confirm minimum requirements of information have been provided on the referral and start the DMS Stage 1. These requirements include:

1. Demographic and contact details of the person and their registered general practice (including their NHS number and their hospital Medical Record Number);

2. Medicines being used by the patient at discharge (including prescribed, over-the-counter and specialist medicines, as there may be medicines interactions), including:

i. Name
ii. Strength
iii. Form
iv. Dose incl. timing, frequency
v. Planned duration of treatment
vi. Reason for prescribing

3. How the medicines are taken and what they are being taken for

4. Changes to medicines (including medicines started or stopped /dosage changes) and reason for the change

5. Contact details for the referring clinician or hospital department, to use where the pharmacy has a query.

Ideally, the referral should also contain the hospital's Organisation Data Service (ODS) code.

If information missing contact details of referring clinician/hospital department. Or if appropriate, the pharmacist should access the patients Summary Care Record (SCR) for assistance in providing the Discharge Medicines Service.

DMS – Stage 1 "completed as soon as possible, but within 72 hours on receipt of referral"

DMS – Stage 2 "Completed when 1st Prescription received following discharge. Usually within 1 week to 1 month following discharge"

DMS – Stage 3 "Confidential discussion with patient/carer on dispensing of this 1st prescription""

6.63 Based on the information provided to it, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

6.64 In relation to all other essential services, the Committee was, on balance, satisfied that procedures adopted by the pharmacy (and general adherence to the Terms of Service) would be "likely to secure" safe and effective provision.

Summary

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

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

6.66.1 confirm the Commissioner's decision;

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

6.66.3 quash the Commissioner's decision and, if it considers that there should be a further notification to the parties to make representations, remit the matter to the Commissioner.

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

6.68 The Committee considered whether there should be a further notification to the parties detailed at paragraph 19 of Schedule 2 of the Regulations to allow them to make representations if they so wished (in which case it would be appropriate to quash the original decision and remit the matter to the Commissioner) or whether it was preferable for the Committee to reconsider the application.

6.69 The Committee noted that representations on Regulation 25 had already been made by parties to the Commissioner, and these had been circulated and seen by all parties as part of the processing of the application by the Commissioner. The Committee further noted that when the appeal was circulated representations had been sought from parties on Regulation 25.

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

7 Decision

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

7.2 Accordingly, the Committee:

7.2.1 quashes the decision of the Commissioner; and

7.2.2 redetermines the application as follows -

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

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

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

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

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

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

7.2.3 The application is refused.

Case Manager
Primary Care Appeals