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21 March 2024

REF: SHA/26126

APPEAL AGAINST NHS DERBY AND DERBYSHIRE ICB DECISION TO GRANT AN APPLICATION BY QUALITY CARE HEALTH LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT UNIT 101, CONEY GREEN BUSINESS CENTRE, CLAY CROSS, CHESTERFIELD, DERBYSHIRE, S45 9JW 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:

Quality Care Health Ltd
PCT Healthcare Ltd
PCSE on behalf of Derby and Derbyshire ICB

NHS Resolution

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1 The Application

By application dated 9 May 2023, Quality Care Health Ltd ("the Applicant") applied to Derby and Derbyshire ICB for inclusion in the pharmaceutical list at Unit 101, Coney Green Business Centre, Clay Cross, Chesterfield, Derbyshire, S45 9JW under Regulation 25. In support of the application it was stated:

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

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

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

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

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

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

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

1.5 Please see the document attached.

1.6 "As a distance selling pharmacy, we will ensure the safe and effective delivery of uninterrupted essential services during the core opening hours, to any person in England who request those services. See how we plan to provide each of the services below: -

Dispensing

1.7 We aim to dispense any medication ordered on a paper or electronic NHS prescription (Prescription only medication, Controlled drugs, appliance and other substance that may be ordered only in certain circumstances (i.e. medication on Selected List Scheme)), together with information and advice to enable safe and effective use by patients. Any patient, anywhere in England who would like us to dispense their medications can request their GP to send the prescription to us electronically (EPS Service) and can choose to nominate us as their preferred

pharmacy, enabling all future prescriptions to be sent to us electronically. Patients who are in possession of a paper prescription such as an FP10, can post it to us via secure mail.

1.8 Prior to dispensing an acute or a new repeat prescription, a pharmacist will complete a clinical check to ensure that the medication is appropriate and safe for the patient. If necessary, the prescriber will be contacted prior to dispensing to ensure safety and suitability, (See SOP 'Dispensing of medication'). When dispensing a repeatable prescription on any occasion other than the first time, the patient will be contacted by the pharmacist and the supply will only be made if satisfied that the patient is using it appropriately, had no changes to their health, and not suffering from any side effects. If needed, they will be referred to the GP for review.

1.9 If the pharmacist believes that the order on the prescription or the repeat prescription is not genuine (i.e. Forged/ Stolen), then the medication will not be supplied until the validity of the prescription is confirmed by contacting the prescriber. If the pharmacist believe that the prescription is not clinically/legally appropriate or if an error has been made on the prescription, the medication will not be dispensed until after a discussion with the prescriber and the pharmacist is satisfied, or until a new clinically/ legally appropriate prescription is supplied. Supply will also be refused if a prescription only medication has been prescribed, which the specific prescriber was not entitled to prescribe.

1.10 Pharmacy will have accounts with multiple medication suppliers such as Alliance, AAH, Phoenix etc, all of which will have good standing with the MHRA. This will ensure that we can obtain medications from multiple verified suppliers to provide all medications on a prescription. We will be able to obtain the medication from another supplier if a certain item is out of stock at our regular supplier. If an item is unavailable from all suppliers, we will contact the patient to discuss their options. Options include sign posting the patient to another pharmacy, contacting the prescriber to arrange a suitable alternative or following the Serious shortage protocol (SSP) if applicable. When sign posting, the patient will be given contact details of at least two pharmacies in their local area, where they will be able to obtain the required service. We will contact these pharmacies prior to passing details to the patient to ensure that they are able to offer the required service promptly.

1.11 Suitable containers will be used for all medication, such as plastic bottles for split quantities of tablets/ capsules and glass bottles for liquids. Child resistant caps will be used in any bottles supplied if appropriate, (See 'Assembling and labelling Prescriptions' SOP). Patients will also be contacted to provide appropriate advice and guidance regarding correct usage, possible side effects, storage and how to return their unwanted medication for safe destruction.

1.12 If a new prescription for an appliance, which needs to be fitted is received, an appliance measurement sheet will be sent electronically or physically to the patient, which instructs how the patient can take the required measurements themselves. If required, a pre-recorded video of a measurement being taken will be sent, however, if insufficient, a live video consultation will be performed with the Responsible Pharmacist to aid the patient in the measurements.

1.13 In the event of a repeat prescription for an appliance, we will check the patient's PMR history as to whether they have had the appliance before and as such confirm with the patient that there are no changes to the size that is needed, (See SOP 'Remote appliance fitting').

Repeat Dispensing (RD)

1.14 If a patient is identified as being suitable for repeat dispensing (See 'Repeat dispensing' SOP), we will explain to the patient (via the phone/ video link) the benefits of RD/ eRD service and gain their consent before referral. We will explain to the

patient that eRD allows the GP to send a series of repeat prescriptions to the pharmacy in one go, so there's no need for patients to order them each time. It's reliable, secure, and confidential. Their regular prescriptions are stored securely on the NHS database, so they'll be ready for delivery from the pharmacy each time they need them. Repeat dispensing will also be promoted on our website. Patients will be given the opportunity to register on the website for free repeat dispensing service in order to ensure that repeat dispensing service is available nationwide without face to face contact.

1.15 At each repeat dispensing, patients will be contacted by phone or email (NHS mail) to confirm that they still need the medication and to see if any circumstances have changed. Additionally, patients will be contacted to make sure they are using the medication properly, are not experiencing any side effects, and/or their situations have not changed which may impact their medication usage. Any feedback that is clinically significant will be noted in the patient's PMR and, if required, reported to their doctor, (See SOP 'Repeat dispensing').

Checking Exemption and taking payment

1.16 NHS Exemptions will be checked to ensure that patients do not claim an NHS exemption fraudulently or accidentally. In regards to [sic] paper prescriptions, the patient or their representative must have completed the relevant sections of the reverse of the token prior to posting it to us. This will be checked before dispensing the prescription. In regards to [sic] electronic prescriptions, patients can update their exemption on the website, which will be checked with the RTEC functionality to prevent fraudulent claims. If exempt, the patient will be asked to send us the proof of their exemption via post or send us a copy via NHS mail. If patients do not have proof of exemption, but insist that they have a valid exemption, then double check their exemption and tick this along with 'Evidence not seen' at the back of the prescription. If evidence is seen, it will be noted on their PMR along with its expiry date. We will check this every time before any prescription is dispensed to ensure that the exemption is still valid. NHS will be contacted if any doubt to confirm the validity of the exemption, (See SOP 'Checking NHS Exemption with no contact').

1.17 Prior to supply, a prescription charge will be taken from all patients who are not deemed to be exempt. Patients will be encouraged to check that they are entitled to claim free prescriptions before completing the declaration on the website/ prescription form. If payment is required, this will be taken using our secure payment system. This can either be performed automatically online or over the phone manually using the 'customer not present' functionality of our card processing provider, (See 'Taking an NHS payment charge' SOP).

Delivery of medication

1.18 Any electronic or paper NHS prescription will be dispensed and delivered for patients on demand, with reasonable promptness. The method of delivery will depend upon the distance of the patients address from the pharmacy. If the patient lives within a 25-mile radius of the premises, their medication will be delivered by our delivery driver. If a patient lives outside of this area, their medication will be delivered by 'Royal Mail'. Items that require extra care including controlled drugs and fridge lines will be delivered by 'City Sprint', in a secure and tamper proof packaging for free. 'City Sprint' will be our chosen company for delivering Controlled Drugs and Fridge lines as they are validated and regulated to provide courier delivery of patient's medication. They will also be used to deliver other medication if Royal Mail is unavailable to make deliveries. 'Igloo-thermo' will also be used as back up if any issues arise with 'City Sprint', ensuring uninterrupted delivery of medication, to anywhere in England without face to face contact, (See 'Postal Delivery' SOP).

1.19 Dispensed items including fridge lines and Controlled drugs will be delivered directly to the patient's home/ address using the Courier, or our own delivery staff. In the case

of carrying a controlled drug or fridge items, driver/ courier will be informed that they are carrying a controlled drug or a fridge item to ensure secure transport in accordance with guidance (i.e. Secure containers/ Cold transport) and where appropriate will ensure an auditable cold chain. Both CDs and Cold lines are tracked through transit. Sufficient auditing processes will be in place when employing a company to do deliveries, so that all medications will be tracked appropriately, (Refer to 'delivery of medication', 'Security and Storage of Controlled Drugs', 'Delivering Controlled Drugs', 'Cold Chain delivery' SOPs).

Emergency Supplies

1.20 The Responsible Pharmacist will use their professional judgement when determining the necessity of the request for an emergency supply by a patient or prescriber. If an emergency supply is necessary, the pharmacist will provide the least amount of medication required to cover the patient's emergency (Maximum 30 days for POM, or 5 days in case of phenobarbitone and schedule 4 or 5 drugs). Pharmacist shall make a supply, in accordance with Human Medicines Regulations, in properly labelled container, and a record of supply will be kept, (See SOP 'Emergency Supply')

Business Continuity

1.21 Plans are in place to ensure the uninterrupted provision of all essential services during the core opening hours of the business. The Business Continuity Plan encompasses a diverse range of potential emergencies, outlining the necessary actions to be taken in response to each specific scenario. It effectively addresses a wide spectrum of emergencies, providing clear guidance on the appropriate course of action to be followed (See 'Business Continuity' SOP). We will also implement a robust strategy to optimise our team availability and coverage. This includes careful team profiling to account for holidays, sickness, and emergencies, effectively increasing the core hours by almost double the required amount. Additionally, when necessary, we will proactively secure shifts from self - employed professionals through multiple agencies, arranging them 3 to 6 months in advance. By adopting these measures, we will ensure sufficient staffing and mitigate any concerns that may arise. Urgent shifts will be advertised at a higher rate to attract locums in an emergency such as sickness. Locums will be required to read all the required SOPs (See 'Locum Induction' SOP) prior to starting any work.

Serious Shortage Protocol

1.22 The Responsible Pharmacist will use clinical judgement alongside other health care professionals such as GPs to decide whether it is reasonable and appropriate to substitute patients order based on the active SSP. Patients will also have to agree to the alternative before the supply can be made. The pharmacist will actively check the NHSBSA website for the latest information on each SSP as they can change (See 'Serious Shortage Protocol (SSP)' SOP).

Disposal of unwanted medication

1.23 Patients will be advised that they can return their unwanted medication to a local NHS pharmacy who are legally obliged to accept it back for safe disposal regardless of whether that pharmacy dispensed those medications initially. This will be particularly emphasised to patients who live outside of the pharmacy's vicinity (25 miles). However, if that is not possible, our organisation has the capacity to accept unwanted medication from individuals or households to dispose of it safely if needed. If the patient lives within 25 miles from the pharmacy, we will arrange next day collection from their home. We will obtain an upper tier 'Waste Carriers License' for our driver to transit waste medication from the patient's home to pharmacy. In the event that the patient lives more than 25 miles from the pharmacy, we have the ability to make arrangements for the medication to be posted back to us. Waste medication will be sorted and stored according to the SOP (See 'Remote disposal of Unwanted

medication' SOP). We will also have arrangements with NHS commissioning board (NHSCB) for regular collection of waste medication from the pharmacy for safe disposal. All colleagues in the pharmacy will be aware of risks associated with handling of waste medication. We will have appropriate protective equipment's including gloves and other materials to safely segregate waste and to deal with any spillages.

Public Health Promotion

1.24 Promotion of healthy lifestyle will be achieved through our website and through prescription linked interventions. The Well-Being section on our website will provide public health advice/support and targets the main health campaigns as set out by NHS England. Prescription linked interventions will be spotted in the pharmacy and patient contact will be made via phone or video consult. If the patient is suffering from diabetes, is at risk of coronary heart disease, or smokes, or is overweight, the pharmacist will provide advice with the aim of increasing patient knowledge and understanding of the health issues which are relevant to that individuals circumstances. If appropriate, relevant health promotion leaflets will also be supplied. We will pro-actively participate in national/ local campaigns to promote public health messages using our website and leaflets during specific targeted campaign periods.

Signposting

1.25 Our pharmacy considers it the duty of any Responsible Pharmacist working for us to minimise inappropriate use of health and social care services. Patients can contact the pharmacist at any time during the core opening hours via telephone, email or via live video link for advice/ guidance and support. All patients that cannot be provided with adequate help and support will be signposted to other health and social care providers or support organisations, who may be able to assist the person accordingly. The pharmacist will make a note of the referral or advice provided on the patients PMR if necessary. We will have a list of local services available and if the patient is not a local, we can assist them by pointing out those services closest to them through the NHS Choices website or the NHS 111 service if necessary. There will also be links to main health topics on the NHS Choices website through the pharmacy website. (See 'Remote Signposting' and 'signposting' SOP).

Healthy Living Pharmacy

1.26 We will work through PSNC's Healthy Living Pharmacy portfolio workbook to ensure that the pharmacy meets all the requirements and collate evidence required to prove that service specifications has been met.

1.26.1 Work force development – The team will be trained to pro-actively support and promote behaviour change and improve health and well-being. All pharmacy staff will understand the basic principles of health and well-being, and that every interaction (via phone/ Email etc) is an opportunity for a health promotion intervention. All staff will be able to use public health information sources such as the NHS website to provide advice on health issues via telephone or video consult. As online pharmacies have a greater geographical reach, rather than a specific local area, we will reflect on the broader health needs of patients throughout the UK, for example, by seeking information on the health profiles of the patients when undertaking patient experience surveys or similar, or using the health profiles reflecting a broader area as per service specifications.

1.26.2 Engagement – We will collate a list of local/national health and social care providers to direct patients to where they have enquiries or need healthy living support, including smoking cessation, drug/ alcohol services, weight management services, mental health services, sexual health clinics and health trainer service.

1.26.3 Environmental – We will have a website with interactive pages that can be accessed by patients and the public accessing our service. The pages will be clearly promoted when accessing the website and will provide a range of up-to-date materials that promote healthy lifestyles and advice on a range of health issues. We will also ensure that there are arrangements in the pharmacy which will enable staff and patients to communicate confidentially via audio link or live video link.

Discharge Medicines Service

1.27 We will comply with the below pre-requisitions to provide the service; -

1.27.1 Staff Competency – All pharmacists and pharmacy technicians delivering the service will complete the 'CPPE NHS Discharge Medicines service' training to reinforce their knowledge. If there are any doubts that the staff are not competent to provide the service, then we will arrange further training.

1.27.2 Premises requirement – Pharmacists will be able to communicate confidentially with the patient via telephone or a live video link.

1.27.3 Standard Operating Procedure – We have an SOP in place for the provision of DMS, which will be signed by all members providing the service. (See 'Discharge Medicines service' SOP).

Clinical Governance

1.28 We will be accountable for continually improving the quality of the services and safeguarding high standards of care by cultivating an atmosphere that fosters clinical excellence. The superintendent pharmacist, Hanson Lukose will be the Clinical governance lead in the pharmacy.

1.28.1 Patient and public involvement

1.28.1.1 A practice leaflet will be produced and displayed on our website, which will inform patients about the pharmacy and the services we provide. The practice leaflet will be kept up to date to ensure that patients receive the correct information. Information of all essential services and advanced services we provide will be available on the website and we will make it clear that the services are funded as part of the health service.

1.28.2 Patient satisfaction survey

1.28.2.1 Patient satisfaction surveys will be carried out on an annual basis according to the approved particulars of department of health. The survey will be a valuable opportunity for us to assess how well the pharmacy is doing from a patient's perspective and to improve our services. The patient satisfaction survey will be available from the website, via e-mail or via post using third party courier should the patients wish. The feedback can be delivered back by email (NHS mail), secure post, website or telephone. We will meet the minimum sample size required (based on our monthly dispensing volume) and will review survey findings, allowing us to consider changes that might enhance service provision. The pharmacy will share with the Primary care organisation, the areas with the greatest room for development identified by the survey, the performance-improving measures being taken, as well as the areas in which the pharmacy is performing well. Results of the survey will be displayed on the pharmacies website.

1.28.3 Monitoring owed drugs

1.28.3.1 If we are unable to supply an item on the patients prescription, the patient will be supplied with an owing note, detailing the medicines owned and the quantity outstanding. Patient will be contacted to inform them of the owing and when/if it's expected to arrive. All details of the Owings will be recorded on the patients PMR. Pharmacy will have a system in place to review and to redeem owings on a daily basis. If we find it difficult to obtain the owing, the prescriber will be contacted to arrange an alternative, or patient will be signposted to another pharmacy where they can obtain their medication from.

1.28.4 Complaints

1.28.4.1 A complaints form will be available on our website for patients to use if required. Patients can also raise complaints via phone, post or email. Information will be available online. All complaints will be taken seriously, and appropriate actions will be taken promptly on individual complaints. Patients will be informed of all investigations being carried out as well as the outcome of the investigation. All complaints will be logged and reviewed monthly, and any changes that could improve service will be considered.

1.28.4.2 Pharmacy will cooperate with primary care organisations (PCO) and other external bodies on monitoring and auditing of pharmacy services. Furthermore, we will cooperate with any local patient and public involvement forum visits and take appropriate actions as advised.

1.28.5 Clinical Audits

1.28.5.1 We will participate in at least one practice-based audit and a multidisciplinary audit as determined by PCO annually. Audits will be carried out remotely using the resources available without face to face contact with any patients.

1.28.6 Risk Management

1.28.6.1 SOP's- We will have SOPs in place to cover all processes and procedures in the pharmacy. This will standardise procedures and will act as a reference for all staff members to follow and ensure compliance with NHS and GPHC guidelines. SOPs will be reviewed at least every 2 years in accordance with changes and best practice. All staff members will be required to read and sign relevant SOPs before they can undertake a specific task.

1.28.7 Equipment maintenance

1.28.7.1 We will make arrangements with service contractors for routine maintenance of the equipment used in the delivery of pharmaceutical services in order to guarantee that all such equipment's are secure and suitable for its intended usage.

1.28.8 Incident Reporting

1.28.8.1 All patient safety incidents, at all stages of the medication process, will be recorded and maintained. All patient safety incidents and prevented patient safety incidents (Near Misses) will be recorded using the reporting form available on PSNC website, which

corresponds to mandatory information required by National Patient Safety Agency's (NPSA), allowing us to submit the report to National Reporting and Learning System (NRLS) via their website. Information collected will be used to identify opportunities to improve patient safety every month, using root cause analysis to reduce the risk of recurrence.

1.28.9 Waste Management

1.28.9.1 Unwanted medication will be collected, separated, stored and destroyed in accordance with the SOP (See 'Remote disposal of unwanted medication'). Confidential waste will be shredded and disposed of using 'Restore' Recycling (www.restore.co.uk).

1.28.10 Health and safety

1.28.10.1 We will comply with all health and safety legislations to reduce risk of harm to pharmacy staff. For example, recommendations and best practices set out by public health England will be followed to reduce the risk of Coronavirus and other pathogens. We will continually carry out risk assessments for all our staff members and have in place the necessary cleaning and personal protective equipment (PPE) in order to minimise risk of catching and spreading diseases. Cleaning rota will be in place to ensure that worktops/ floors etc are cleaned regularly using appropriate cleaning materials. With regards to child protection act, all staff will all be briefed and shall comply with local and national guidance relating to child protection procedures and safeguarding policies.

1.28.11 Promoting self- care

1.28.11.1 We will endeavour to provide maximum support from the pharmacy to enable people to care for themselves or their families. There will be a range of topics ranging from long-term conditions to minor ailments on the website in the well-being section that aims to provide information and advice in support of patient's conditions. This information is also linked to the NHS Choices website for up-to-date information and support (See 'Remote support for self-care' SOP). Self-care will also be promoted opportunistically i.e. when a patient or carer telephones the pharmacy for advice.

1.28.12 Repeat Dispensing

1.28.12.1 Repeat dispensing will be promoted and patients who are eligible will be identified. We will manage and dispense repeatable NHS prescriptions continuously throughout the core pharmacy opening hours. Enabling patients to acquire their regularly prescribed medications directly from the pharmacy, ultimately improving the clinical effectiveness of prescribing. (See 'Repeat Dispensing' SOP).

1.28.13 Staff Management and development

1.28.13.1 Valid DBS and qualification checks will be completed prior to hiring any staff members. Each staff member will be enrolled in a GPHC accredited NVQ training such as the accredited independent training company Buttercups if they are not already qualified for their role. Support will be provided to everyone to meet their developmental needs. All pharmacists will be required to complete their continuing professional development (CPDs) as required.

1.28.13.2 All staff members, including locums will be given relevant induction prior to starting work, ensuring that they are adequately informed about the processes and workings of the pharmacy, (See 'Locum Induction' and 'Staff Induction' SOP).

1.28.14 Support for clinical governance and health care delivery

1.28.14.1 Pharmacy will have access to up-to-date resources such as BNF (hard copy and online access), Electronic medicines compendium, Drug Tariff, Chemist and druggist, NHS choices etc to support with health care delivery. Appropriate training will be provided, and systems will be in place to ensure that the NHS code of practice on confidentiality, data protection act- 1998, Human rights act 1998 and common laws of confidentiality are always adhered to. Pharmacy core opening hours will be displayed clearly on our website to inform the public. All essential services will be provided during these hours without interruption, to any persons anywhere in England without face to face contact.

Avoiding face to face contact

1.29 Essential services will only be provided to patients remotely. No essential services will be provided to any patient at the premises. We will emphasise that we are an online only pharmacy and that we do not allow face to face contact on the premises or within the vicinity of the premises to all new patients requesting our services. In the event a patient/ patients representative comes to the pharmacy and makes a request for an essential service, we will explain to them that we are unable to provide the requested service due to the nature of the business and they will be signposted to the nearest retail pharmacy, where they will be able to obtain the required service if urgent. If the patient would like us to provide them with any essential service in the future, they will be advised to contact us via phone/email/website which will enable us to provide those services remotely. If a patient comes to the pharmacy to collect their medication, they will be advised that their medication will be delivered to their preferred address and due to the nature of the business, we are unable to hand over the medication to them at or in the vicinity of the premises. If patients have any queries, they must contact either by phone, email or using the contact form available on our website.

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

1.30 The pharmacy is located within a business centre, with no access to public and no passing foot traffic. Key codes and keys are required to access the pharmacy premises. Only customers with pre-booked appointments for an advanced service will be allowed into the premises. Patients will be advised to wait at the main reception area of the business centre and to text the number we have provided when they arrive for their appointment. A member of our team will then accompany that patient to the pharmacy and the service will be provided. If a patient arrives at the premises and asks for one or more of the essential services such as dispensing or waste disposal, we will apologise and explain to the patient that we are unable to provide the service due to the nature of the business. If they require the service urgently, they will be signposted to the nearest local pharmacy. They will also be advised that if they would like us to dispense their medication in the future, they can either post us the prescription in case of a paper prescription or request their prescriber to send it to us as an Electronic Prescription. In case of disposal of unwanted medication or any other essential service, they can contact us, and we will make arrangements for the service.

7.3) If you are planning to provide advanced services at the premises please describe how you will do so without providing any element of essential services

1.31 When the patient makes an appointment for a specific service via website, phone or email, they will be informed that we will not provide any other service when they attend their appointment. When the patient attends the pharmacy for an advanced service such flu vaccination service, we will ensure that no essential service such as dispensing or waste management is provided, even if the patient makes a request for an essential service. For example, if the patient brings with them some unwanted medication and requests us to dispose of it, we will refuse to do so and explain to the patient that, due to the nature of the business, we are unable to offer them the service. They will then be sign posted to the nearest local pharmacy."

1.32 SOPs were provided by the Applicant and these were circulated to interested parties with the application form. The SOPs are contained in Appendix A.

2 The Decision

Derby and Derbyshire ICB ("the Commissioner") considered and decided to grant the application. The decision letter dated 28 November 2023 states:

2.1 "Derby and Derbyshire ICB has considered the above application and I am writing to confirm that it has been granted. Please see the enclosed report for the full reasoning."

Extract from the decision report

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

2.2 "The application meets the criteria for a distance selling application – Regulation 25.

2.3 Regulation 31

2.4 Regulation 31 does not apply as the proposed pharmacy will not be adjacent or in close proximity to an existing pharmacy premises.

2.5 There are no existing pharmacies operating from the proposed best estimate location and therefore, under this provision, Regulation 31 would not cause the application to be refused.

2.6 Fitness to practise

2.6.1 The fitness to practise criteria has been reviewed and approved by NHS England's Clinical Adviser (or whichever area team has approved the FTP).

2.7 Regulation 66

2.7.1 Regulation 66 does not apply as there are no conditions relating to providing directed services.

2.8 Regulation 25

2.8.1 The proposed premises are not listed on the same site or in the same building as a GP practice.

2.8.2 The Committee is satisfied that the uninterrupted provision of essential services will be provided during the opening hours of the premises, to persons anywhere in England.

2.9 The Committee agreed that the approval of the application will have no impact on those with protected characteristics or on NHS England's duty on health inequality.

2.10 The Committee was satisfied that the applicant meets all of the criteria for opening a wholly internet/mail order-based distance selling premises and therefore determined to grant this application.

2.11 Appeal Rights

2.12 PCT Healthcare Ltd"

3 **The Appeal**

In a letter dated 20 December 2023, PCT Healthcare Ltd t/a Peak Pharmacy ("the Appellant") appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "Further to the letter dated 28 November 2023 regarding the above application. PCT Healthcare Ltd, trading as Peak Pharmacy in this locality, wish to appeal the decision by Derby and Derbyshire ICB to grant this application.

3.2 We operate three pharmacies on the distribution list:

3.2.1 PCT Healthcare Ltd t/a Peak Pharmacy, Unit 9 Retail Park, New Bridge Street, Clay Cross, Chesterfield, Derbyshire S45 9NG (ODS Code FHA96)

3.2.2 PCT Healthcare Ltd t/a Peak Pharmacy, 14 The Green, North Wingfield, Chesterfield, Derbyshire S42 5LQ (ODS Code FJ057)

3.3 Please note in addition that we also operate:

3.3.1 PCT Healthcare Ltd, t/a Peak Pharmacy, 7-9 Market Street, Clay Cross, Chesterfield, Derbyshire S45 9JE (ODS Code FRK32)

3.4 The reason for this appeal is that none of the specific issues raised in our comments to Derby and Derbyshire ICB from the applicant's SOPs submitted with the application were addressed in the report for the full reasoning to grant the application dated 28 November 2023.

3.5 Regulation 64(3) sets out conditions that distance selling premises must comply with. One of those is that the pharmacy procedures for the premises must secure the uninterrupted provision of essential services during core and supplementary opening hours to persons anywhere in England who request those services, the application does not fully explain how this will take place.

3.6 Essential pharmacy services cannot be provided to patients who are present at a distance selling pharmacy premises. This applicant does not satisfy the criteria that there would be safe and effective provision of essential services without face-to-face contact with patients or carers.

3.7 Within the Standard Operating Procedures (SOPs) provided by Quality Care Health Limited there are details of patients being on site for essential services:

3.8 SOP for Dispensing of Prescriptions, on page 6 under Section 5. Take Payment.

"payment, or payment can be taken over the telephone (see 'Taking an NHS payment charge' SOP). Indicate the payment status on the top left hand corner of the prescription as PAID. Mark the quantity paid. In the box on the back of the prescription before the patient signs it. Ensure the staff know which items incur double charges (See Drug Tariff) or have an unusual payment regime e.g. one charge for two"

3.9 On page 32 of the SOP for Dispensing of Prescriptions

"For all prescriptions

1. Check the fridge

Check for items in the fridge or CD cabinet as indicated by the appropriate sticker. If the prescription is for insulin, show the product to the patient (should be in clear plastic bag) and ask the patient to confirm that it is the correct brand/preparation. If there is any doubt, check with the Pharmacist.

2. Check for CDs

If there is a label denoting inclusion of a schedule 4 CD, check that the whole prescription can be given out by confirming with the Pharmacist. If the prescription is schedule 2 or 3 CD and has been removed from the CD cabinet, check that the prescription date is not more than 28 days ago. Give the prescription to the Pharmacist to check before handing out. The status of the person collecting must be known (patient, representative, healthcare professional), their ID checked and the blue box on the back of the prescription is signed by them. Give the CD prescription to the Pharmacist afterwards so that the CD register entry can be completed if applicable."

3.10 The above paragraphs indicate that patients shall be on site for essential services, which is contrary to Regulation 25(2)(b)(ii) for Distance Selling Pharmacies, the details provided by the applicant in the NHS Application Questions differs from the SOPs provided.

3.11 For Distance Selling Pharmacy services cannot be limited to a locality and must be available on a nationwide basis.

3.12 Within the SOP for Delivering Controlled Drugs there is mention of using "own delivery driver" where the patient lives within twenty-five miles from the proposed pharmacy. For patients outside this radius City Sprint should be used. Within section 5 of this SOP a "drop sheet" is mentioned which should be returned before close of business to the pharmacy, what will happen if City Sprint are delivering to St Ives to the "drop sheet" from a GDPR perspective.

3.13 In addition, there is no mention of what the procedure is where there is failure to deliver by a courier, please see below from the Delivering Controlled Drugs SOP.

7. Failure to deliver

If the patient is not home during the agreed delivery slot – complete a not at home postcard detailing information about re-delivery or collection from the pharmacy Post the pharmacy card through the letterbox Do NOT push the medicines through the letterbox Do NOT leave the medicines outside the door Inform the authorised pharmacy staff upon return to the pharmacy The pharmacist should then do the following: For controlled drugs subject to safe custody Return undelivered controlled drugs to the controlled drugs cabinet For schedule 2 CDs re-enter the drug back into the CD register with an explanation.

8. Following delivery or attempted delivery

Check the Driver's delivery schedule against the detached prescriptions. Prescriptions for packages which have been successfully delivered may be treated as completed and filed. Prescriptions for packages which have not been delivered should be reattached to the package. Contact the patient to confirm the next details for the next delivery. Return the prescription and package to the delivery storage area or the fridge if applicable.

3.14 With regards to the SOP for Cold Chain delivery there is mention of freezers and dry ice, the temperatures for both these items are well below the recommended temperature for pharmacy refrigerated items.

5. Temperature deviation due to freezer malfunction

If the temperature has deviated during a freezer malfunction, move the samples to an alternate freezer and give a list of the affected boxes, and the temperature at the time of the move then document this discrepancy in the bunet.io error log and follow the steps below.

6. Temperature deviation due to power outage

If a power outage occurs, and the generator (if available) does not kick in to restore power to the freezers, alternative arrangements for cold storage must be deployed. This includes, but is not limited to, finding another facility with suitable cold chain maintenance ability to house the product temporarily. This error will need to be logged in the hubnet.io error log and follow the subsequent steps below.

7. Temperature deviation due to dry ice

If a shipment temperature has deviated during shipment (ie a shipment has warmed because all of the dry ice has sublimated due to a delayed shipment) document this discrepancy in the error log and follow the steps below.

3.15 Regarding the SOP for Owing Medication Supply this section is not correct for a distance selling pharmacy, why would an owing not be with the patient, 3 months after preparation of the prescription?

14. If any Owings are not delivered 3 months after they were prepared, put the medication back into stock, ensuring that the dispensing label is removed. (Dispose of the mediation if there is no expire/batch information on it or it is short dated/expired). Removed dispensing labels and address labels should be stuck into a notebook to make a record of uncollected items/date of initial dispensing/name and address of patient. This notebook is the uncollected medication record and can then be used to re-dispense the item from the PMR records if the patient contacts the pharmacy after 3 months and request the medication, redispense and arrange delivery (as long as it is legally possible to do this, i.e. not a schedule 2,3 or 4 CD).

3.16 This application is required to fully meet the criteria within Regulation 25, and we wish NHS Resolution to specifically consider Regulation 25(2)(b)(ii) regarding this application.

3.17 Additionally, we trust that the SOPs will satisfy NHS Resolution in other key areas such as:

3.17.1 The manner in which the applicant would communicate and action drug recalls and alerts.

3.17.2 Action the applicant will take in the event of being unable to fulfil a prescription completely (i.e., how they will deal with 'owings').

3.18 We also ask NHS Resolution to satisfy themselves that the applicant, from the evidence within the application will ensure that all communication, whether on their website, practice leaflet or via mailshots / local advertising and the like, complies with GPhC's "Guidance for Registered Pharmacies Providing Pharmacy Services at a Distance, Including on the Internet" Principle 4.1 in relation to transparency and choice.

3.19 PCT Healthcare Limited t/a Peak Pharmacy would like to be informed of the outcome of this appeal and we would wish to attend the Oral Hearing, should one be deemed necessary."

4 Summary of Representations

This is a summary of representations received on the appeal.

4.1 THE APPLICANT

4.1.1 "Thank you for your email and for sharing the details of the appeal with us. I would like to bring to your attention that the points raised by Peak Pharmacy in this appeal are identical to those highlighted by them during the application process.

4.1.2 I have attached our original response letter and associated documents we submitted. These documents comprehensively address and provide detailed responses to each concern raised by Peak Pharmacy.

4.1.3 We trust that the information provided in our previous response adequately addresses the concerns raised and supports the approval of our application. If there are any additional details required or further clarification is needed, please do not hesitate to contact us.

4.1.4 We remain committed to ensuring a transparent and thorough resolution to this matter and appreciate your attention to the attached documents.

4.1.5 Thank you for your understanding."

In a letter to the Commissioner the Applicant stated:

4.1.6 "I hope this letter finds you well. We are writing this letter in response to the comments received from PCT Healthcare Limited. We wish to express our commitment and dedication to providing exceptional pharmacy services to patients across England through our distance selling pharmacy. At Quality Care Pharmacy, our mission is to ensure that every individual, regardless of their location in England, has access to high-quality pharmaceutical services and health-related information.

Response to the comment from PCT regarding the pharmacies they operate in the locality.

4.1.7 We understand that the landscape of healthcare delivery is constantly evolving, and distance selling pharmacies play a crucial role in meeting the healthcare needs of individuals who may face geographical barriers or require convenient and accessible pharmaceutical services. As a distance selling pharmacy, we are dedicated to serving as a reliable healthcare partner for individuals across England. Our vision is to contribute to the well-being and health of communities by providing accessible and high-quality pharmaceutical services. All patients regardless of their location in England will be able to access our services.

4.1.8 As mentioned above, our focus is the provision of our services nationally, however we believe that our DSP will also be very beneficial to the local community. As mentioned in the comments received from PCT Healthcare Limited, currently, a few community pharmacies have established a monopoly in the local area, which, while providing valuable services, can also lead to challenges such as limited choices for patients, extended waiting times, and potential gaps in service provision. Hence, we believe that the introduction of our distance selling pharmacy will not only provide residents of

the local area with more choices but will also support the overall healthcare ecosystem by promoting healthy competition, improving accessibility, and enhancing the quality of pharmaceutical services available to the community locally and nationally.

Response to the comments regarding providing essential services at the premises.

4.1.9 We would like to address a critical aspect of our commitment to patient safety and adherence to regulations as a distance selling pharmacy. While we acknowledge the importance of our physical location, we want to emphasise our firm commitment to adhering to the following principles to ensure no essential services are provided on-site:

4.1.9.1 Dispensing Medication: We will strictly adhere to the regulations of 'Distance selling pharmacy'. While prescriptions are dispensed on the premises, medications will never be handed over to patients at our physical location.

4.1.9.2 Online Ordering and Delivery: All prescriptions will have to be received electronically or via post. Once the prescription is received, we will process the prescription and arrange for secure and discreet delivery to the patient's preferred address.

4.1.9.3 Patient communication: All Patient communication will be conducted remotely using secure channels such as confidential telephone line to ensure confidentiality.

4.1.9.4 No Walk-In Services: We do not entertain walk-in patients or on-site visits for any essential pharmaceutical services. All interactions occur through our designated confidential channels. The location of the premises is not accessible to the public. Security key cards are required to enter the business centre in which our premises is located. This prevents patients coming to the pharmacy and requesting essential services. Further actions we will take to prevent the provision of essential services at the premises are highlighted in the application.

4.1.9.5 Compliance: We are committed to strict compliance with all relevant laws and regulations governing distance selling pharmacies. Our policies and procedures align with the requirements set forth by regulatory authorities to prevent on-site provision of essential services.

4.1.10 By strictly adhering to these principles, we aim to eliminate any potential confusion or misconception regarding the provision of essential services at our physical premises. Our focus remains on providing secure, efficient, and high-quality pharmaceutical services to patients across England while upholding the highest standards of regulatory compliance.

4.1.11 Most of our SOPs are provided by 'Hubnet', a pharmacy quality management system that helps us to ensure that we provide up-to-date, high-quality services to our patients. We invested significant amount of time and effort into developing, editing, and refining our SOPs to ensure that they meet the requirements set out by the NHS for distance selling pharmacies. Unfortunately, due to an oversight, an unedited SOP was uploaded with the application, and we wish to offer our sincere apology for this error. We hold ourselves to the highest standards of professionalism, quality, and precision in our work, especially when it comes to the documentation and dissemination of important materials like SOPs. We understand the

importance of accuracy and adherence to established procedures, and we take full responsibility for the error that occurred. The unedited SOP document should not have been uploaded, and we understand that this may have raised questions or concerns. Please allow us to assure you that this incident is not reflective of our usual practices, and we have taken the following steps to rectify the situation and to ensure regulatory compliance:

4.1.11.1 Immediate Removal: We have promptly removed the unedited SOP.

4.1.11.2 Review and Editing: We have initiated a thorough review of all our SOPs to ensure that they meet the required standards of accuracy, clarity, and completeness. The edited SOP has been attached to this letter [see Appendix B].

4.1.11.3 Revised Procedures: We are implementing additional checks and quality assurance measures to prevent similar incidents in the future. We are committed to maintaining the integrity of our documentation.

Response to comments on delivery of medication by own driver and courier service: -

4.1.12 We wish to take great care to ensure the efficient and secure delivery of our products to our valued customers. To maintain the highest standards of quality control and accountability, we employ a drop sheet system for tracking deliveries. It is important to note that this drop sheet is solely for our internal audit purposes and is applicable only to deliveries completed by our designated delivery drivers.

4.1.13 Our policy can be summarised as follows:

4.1.13.1 Drop Sheet for Internal Audit Purposes: The drop sheet is a tool used by our organisation to track deliveries carried out by our dedicated delivery drivers. It is employed primarily for internal auditing and quality control purposes.

4.1.13.2 Exemption for Courier Services: Deliveries conducted by courier services are exempt from the drop sheet requirement. This exemption is due to the nature of courier services, which operate independently of our internal delivery team.

4.1.13.3 Missed Deliveries: In cases of missed deliveries by our own driver, a note will be left through the letter box to inform them of our attempt to deliver. Drugs will then be returned to the pharmacy, and we will attempt to arrange redelivery. In case of authorised courier services, courier company-specific procedures will be diligently followed. These procedures are designed to address missed deliveries, including re-scheduling, communication with customers, and any necessary corrective actions.

4.1.14 We believe that this policy provides the necessary flexibility to differentiate between our internal delivery operations and external courier services while maintaining the high standards of accountability and customer service that our customers expect from us.

Response to comments on Cold Chain delivery

4.1.15 We are committed to maintaining the cold chain integrity while delivering temperature-sensitive medications. We understand the critical importance of safeguarding the efficacy and safety of these vital medications throughout the supply chain.

4.1.16 The medical cool boxes we intend to use in our delivery van for cold chain deliveries will be purchased from ‘The Cool Ice Box Company’, who are an NHS certified medical cooler supplier. We would like to highlight some key attributes of their medical cool boxes that will help us maintain the integrity of cold chain medication, while in transit:

4.1.16.1 Internal Temperature Probe: An internal temperature probe in the cooler allows us to monitor and verify the temperature inside the cooler accurately. This capability gives us the assurance that our temperature-sensitive medical supplies are consistently stored within the required range of 2-8 degrees Celsius.

4.1.16.2 External LED Temperature Display: The external LED temperature display adds another layer of transparency to our cold chain management. It enables our driver to quickly check the current temperature of the cooler without opening it, reducing the risk of temperature fluctuations.

4.1.16.3 Extended Temperature Maintenance: The Medical cool boxes we intend to use has the capability to maintain temperatures between 2-8 degrees Celsius for up to 18 hours. This is more than adequate to ensure that the cold chain is maintained throughout the duration of the transit process, ensuring that temperature-sensitive medical supplies reach their destination in pristine condition.

4.1.17 We have updated the language in the 'SOP for Cold Chain Delivery' and have altered terms such as ‘freezers’ and ‘dry ice’ to eliminate any potential confusion and to provide clearer instructions for maintaining temperatures between 2-8 degrees Celsius and maintaining integrity of cold chain medication. Updated copy of the SOP is attached to this response letter. [see Appendix B].

Response to comments on the inclusion of ‘dealing with Owings that are not delivered within 3 months’ in the SOP.

4.1.18 In cases where a patient is unavailable to receive their owed medication during the initial delivery attempt, and all reasonable efforts to contact the patient for redelivery coordination have been exhausted, our standard operating procedure (SOP) mandates the following protocol. While the likelihood of being unable to successfully deliver medication within a three-month timeframe remains relatively low, it is not entirely negligible. Therefore, it is our considered opinion that the inclusion of this procedure within our SOP is imperative for comprehensive and responsible operational guidance.

Response to comments on communicating recalls and alerts.

4.1.19 See our procedures for communicating product alerts and recalls below: -

4.1.19.1 Email Notifications: We will use this channel to send detailed information about product alerts and recalls directly to patients. Our email notifications will include the reason for the alert or recall, affected product details, potential risks, and instructions for any action required.

4.1.19.2 Website Notifications: For immediate access to critical information, we will post alert and recall notices on our website's homepage. This ensures that anyone visiting our website is promptly informed of any product-related issues.

4.1.19.3 Phone Calls: In rare cases where a recall poses an immediate health risk, we will make direct phone calls to affected customers. This approach is reserved for situations where urgent action is necessary.

4.1.19.4 Follow-Up Communications: Throughout the recall process, we will maintain open lines of communication with the patient. We will send follow-up messages to keep them informed of any updates, including when the issue is resolved.

4.1.19.5 Record Keeping: For transparency and regulatory compliance, we will maintain thorough records of all communications related to alerts and recalls.

Response to comments about actions we will take in the event of being unable to fulfil prescriptions completely.

4.1.20 If we are unable to fulfil a prescription completely for any reason, here are the actions we will take:

4.1.20.1 Prompt Communication: We will reach out to the patient as soon as we become aware that their prescription cannot be fully filled.

4.1.20.2 Explanation: We will provide a clear and honest explanation for the situation, including the reason why we cannot fulfil the entire prescription. This may be due to factors such as medication shortages, stock issues, or regulatory restrictions.

4.1.20.3 Alternatives: We will discuss potential alternatives with the patient. This could involve:

4.1.20.3.1 Getting a new prescription for a suitable alternative.

4.1.20.3.2 Partially filling the prescription and arranging for the remaining quantity to be supplied as soon as possible.

4.1.20.3.3 Recommending nearby pharmacies or healthcare facilities where they can obtain the missing medication.

4.1.20.4 Billing Adjustments: If the patient has already been charged for the medication that cannot be supplied, we will promptly adjust the invoice or refund the corresponding amount.

4.1.20.5 Timely Fulfilment: If part of the prescription can be supplied immediately, we will ensure that it is delivered as soon as possible.

4.1.20.6 Documentation: We will maintain thorough records of the situation, including all communications and actions taken. This documentation will help us ensure compliance with regulatory requirements and improve our processes.

4.1.20.7 Support and Follow-Up: We will continue to support the patient throughout the process, providing updates and addressing any concerns the patient may have.

Response to comment about our communications being complaint with GPHC standards 4.1 regarding transparency and choice.

4.1.21 We recognise that transparency and choice are not just regulatory requirements but essential pillars of patient-centered care and trust. Ensuring that our patients have access to clear information and a wide array of choices is fundamental to our mission. To align with GPhC Standard 4.1, we have implemented the following initiatives:

4.1.21.1 Website Transparency: Our website will provide patients with transparent, accurate and non-misleading information such as:-

4.1.21.1.1 Our pharmacy's registration details, including name and address, will be prominently displayed on our website.

4.1.21.1.2 Simple and accurate descriptions of our range of services, guaranteeing clarity and comprehensiveness.

4.1.21.2 Patient Choice and Consent: We respect patient autonomy and will always be honest and transparent with patients in all communication channels such as our website, practice leaflet, and advertisements. This prevents misleading information/ confusion and allows the patient to make an informed decision as to whether our pharmacy is appropriate for them. The same information will be provided verbally (phone call) if required.

4.1.21.3 Advertising Compliance: All our advertising materials will comply with GPhC guidelines.

4.1.22 We will refrain from making any misleading or exaggerated claims about the services we provide.

4.1.23 We trust that NHS England will find our responses to the comments from PCT Healthcare ltd to be comprehensive and well-considered. We respectfully urge NHS England to take into careful consideration the information we have furnished in conjunction with our application during the decision-making process. Your thorough review is greatly appreciated."

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").

6.5 The Committee noted the decision report from the Commissioner stated "*There are no existing pharmacies operating from the proposed best estimate location…*".

6.6 Paragraph 1 of Schedule 2 refers to information that must be included in routine and/or excepted applications. Paragraph 1(7)(a) states:

"If A is seeking the listing of the premises not already listed in relation to A (whether or not A is already listed) -

(a) either:

(i) the address of the premises, or

(ii) if the address is not known and it is a routine application, A's best estimate of where the proposed premises will be."

6.7 The Committee considered that the Regulations are clear that both routine and excepted applications must include the address for the proposed premises, however in the case of a routine application, a best estimate of the address may be provided instead.

6.8 As the application is not a routine application, a best estimate cannot be provided.

6.9 The Committee went on to consider whether the address provided in the application is an "address" or a "best estimate" of an address.

6.10 The Committee noted that there is no definition of "address" in the Regulations therefore the Committee considered that "address" must be interpreted in accordance with its plain and straightforward meaning.

6.11 The Committee noted that standard wording on the application from states "*A full address must be provided – 'best estimates' are not acceptable…"* The Applicant, in completing the application form had provided an exact location. The Committee was of the view that the Applicant had given a full address and not a best estimate.

6.12 The Committee was unsure why the Commissioner had chosen to use this particular phrase in its decision. The Committee determined that a full address had been provided and therefore the application had been made in accordance with the Regulations.

6.13 The Committee went on to consider the application before it.

Regulation 31

6.14 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) 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).

6.15 The Committee noted that the Applicant had not provided any information in the application form on this point but the Committee noted that the wording of the application form only required the Applicant to include information in the relevant section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee considered it reasonable to determine that the lack of information in the application form on this point when read with the wording of the application form allowed it to be reasonably satisfied that the Applicant considered that the proposed premises were not adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Commissioner in its decision report considered Regulation 31, concluding that "*Regulation 31 would not cause the application to be refused*" which the Committee noted had not been disputed by any party.

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

Regulation 25

6.17 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) The NHSCB 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 the NHSCB 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."

6.18 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 the NHSCB in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the NHSCB may need to make of the information or documentation when carrying out its functions.*

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

6.19.1 confirm the Commissioner's decision;

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

6.19.3 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.

Regulation 25(1)

6.20 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)

6.21 The Committee noted that the Applicant had not included any information in the relevant section of the application form that deals with this point. The Committee noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Commissioner in its decision report stated that "*The proposed premises are not listed on the same site or in the same building as a GP practice*" which had not been disputed by any party. Based on the information available to it, the Committee therefore determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

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

6.23 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.

6.24 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.

6.25 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.

6.26 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 in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.

6.27 The Committee noted the comments from the Appellant in their appeal that "*this applicant does not satisfy the criteria that there would be safe and effective provision of essential services without face to face contact with patients or carers."*

6.28 The Committee noted in the information provided with the application form under "Avoiding face to face contact", the Applicant states that essential services will only be provided to patients remotely. Further, the Applicant states "*If patients have any queries they must contact either by phone, email or using the contact form available on our website."*

6.29 The Applicant states "*The pharmacy is located within a business centre, with no access to public and no passing foot traffic. Key codes and keys are required to access the pharmacy premises. Only customers with pre-booked appointments for an advance service will be allowed into the premises. … If a patient arrives at the premises and asks for one or more of the essential services such as dispensing or waste disposal, we will apologise and explain to the patient that they are unable to provide the service due to the nature of the business. If they require the service urgently, they will be signposted to the nearest local pharmacy. …"*

6.30 The Committee noted the reference in the SOP for Dispensing of Prescriptions which the Appellant had raised on appeal, had been amended by the Applicant and a revised SOP had been submitted with their representations. The Committee noted that the revised SOP had removed the references as quoted by the Appellant and that there would be no face to face contact. The Committee also noted the assurance from the Applicant that "*Dispensing Medication: We will strictly adhere to the regulations of 'Distance selling pharmacy'. While prescriptions are dispensed on the premises, medications will never be handed over to patients at our physical location."*

6.31 Based on the information before it, including the revised SOPs, the Committee was satisfied that the provision of essential services would be without face to face contact.

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

6.33 The Committee noted the comments from the Appellant, raised on appeal that the Applicant must secure uninterrupted provision anywhere in England to those who requested those services and that they were of the view that the application does not explain how this will take place.

6.34 The Committee noted the comment from the Appellant that "*For distance selling pharmacy services cannot be limited to a locality and must be available on a nationwide basis*."

6.35 The Committee noted the references throughout the information provided by the Applicant that "*all medications are delivered to patients homes*" and that the delivery method will depend on the distance of the patients address from the pharmacy. The Committee noted that the Applicant is proposing to use a combination of their own delivery driver for those within a 25 mile radius. For those who live further afield, the Applicant states that medication will be delivered by Royal Mail. In addition to this, the Applicant is also proposing to use couriers for controlled drugs and fridge lines and that they will also use couriers if Royal Mail is unavailable. The Applicant confirms that they will be providing essential services to anyone anywhere in England.

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

6.37 The Committee noted the comments from the Applicant in the SOPs with regard to the Responsible pharmacist. The Committee noted the "SOP for Operating in the Absence of a Responsible Pharmacist" which states:

6.37.1 "*1. The Responsible Pharmacist realises that they need to leave the premises.*

Make sure that the RP tells staff well in advance that they are going to leave the premises. make sure that the RP has already signed the Pharmacy Record and that they understand they should not be absent for more than 2 hours. make sure all staff understand what the legislation means. The pharmacist must abide by certain rules if they are to leave the premises these include:

- *The designated RP may not leave the premises for more than 2 hours in any 24 hours period.*
- *The RP must remain contactable ie must leave a working mobile phone number.*

2. The RP leaves the Pharmacy.

When this occurs make sure staff know to act appropriately when the pharmacist is off the premises. Make an appropriate record in the pharmacy record. P medicines and POM's cannot be handed over to the driver for delivery whilst the RP is absent. When the RP leaves the pharmacy make sure they sign the Pharmacy Record, filing the appropriate fields. Designated staff may offer advice over the phone if deemed fit. Make sure that there is an adequate record of who is deemed qualified.

3. After 1 and a half hours of the absence.
If the pharmacist has not returned after one hour. A designated member of staff should contact the pharmacist immediately to ascertain when they will return. If the pharmacist cannot return within 2 hours of absence then the superintendent should be telephoned to ascertain what is the best course of action. This may involve closing the pharmacy.

4. Absence of the RP after 2 hours.

If the pharmacist has not returned within two hours then the pharmacy cannot undertake any essential services.

5. The return of the RP.

Make sure the RP signs into the pharmacy record noting the duration of absence and reason (GP). If the RP returns the next working day then they should sign in a soon as possible. The Pharmacy Record should be kept for a minimum of 5 years."

6.38 The Committee noted that there was no further information provided as to how the pharmacy would operate and ensure uninterrupted services in the absence of the Responsible Pharmacist or if a second pharmacist would be available at short notice should the Responsible Pharmacist be absent.

6.39 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.

6.40 Based on the information provided to it, the Committee was not satisfied that the provision of services would be without interruption.

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

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

6.43 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:

6.43.1 Dispensing of drugs and appliances

6.43.2 Urgent supply without a prescription

6.43.3 Preliminary matters before providing ordered drugs or appliances

6.43.4 Providing ordered drugs or appliances

6.43.5 Refusal to provide drugs or appliances ordered

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

6.43.7 Disposal service in respect of unwanted drugs

6.43.8 Promotion of healthy lifestyles

6.43.9 Prescription linked intervention

6.43.10 Health campaigns

6.43.11 Signposting

6.43.12 Support for self-care

6.43.13 Discharge medicines service

6.43.14 Websites and health promotion zones

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

Providing ordered drugs or appliances

6.45 The Committee considered whether the Applicant had explained the arrangements which ensure that, for appliances which require fitting/measuring, a registered pharmacist measures/fits them.

6.46 The Committee noted that the Applicant had not completed this section of the application form and therefore no appliances were specified, however the Committee noted the supporting information with the application form, where the Applicant stated:

6.46.1 *"If a new prescription for an appliance, which needs to be fitted is received, an appliance measurement sheet will be sent electronically or physically to the patient, which instructs how the patient can take the required measurements themselves. If required, a pre-recorded video of a measurement being taken will be sent, however, if insufficient, a live video consultation will be performed with the Responsible Pharmacist to aid the patient in the measurements*.

In the event of a repeat prescription for an appliance, we will check the patient's PMR history as to whether they have had the appliance before and as such confirm with the patient that there are no changes to the size that is needed, (See SOP 'Remote appliance fitting')"

6.47 The "Remote Appliance Fitting Standard Operating Procedure" states:

6.47.1 ***"Scope***

This SOP covers all appliances which may need to be fitted as per the NHS contract.

1. *Receiving a Repeat Appliance Prescription*
   In the event that a prescription for an appliance which needs fitting is received from a patient, before ordering the medicine Focal Point will check the patient's PMR history as to whether they have had the appliance before and as such confirm with the patient that there is no change to the size that is needed.

2. *Receiving a New Appliance Prescription*
   In the event that there is a new prescription for an appliance which needs to be fitted, an appliance measurement sheet will be sent electronically or physically to the patient which instructs how the patient can measure themselves. In this event, a pre-recorded video of a measurement being taken is sent. Lastly, if this is not sufficient a live video teleconsult will be performed with the Responsible Pharmacist to aid the patient in the measurements."

6.48 The Committee noted the information in the SOP, including the use of an appliance measurement sheet including instructions, a pre-recorded video and a teleconsult. However, the Committee was of the view that this was not sufficient and a patient using a template for an appliance which requires measuring/fitting, even with

guidance from a pharmacist, was not the same as the registered pharmacist measuring/fitting the appliance.

6.49 The Committee was therefore not satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(4) of Schedule 4.

Other considerations

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

6.51 The Committee noted the comments from the Appellant with regard to the "drop sheet" which the Applicant had referred to. In addition the Appellant had raised a query with regard to the procedure where there is failure to deliver by a courier.

6.52 The Committee noted, in their representations, the clarification provided by the Applicant with regard to the "drop sheet" which states:

6.52.1 *"To maintain the highest standards of quality control and accountability, we employ a drop sheet system for tracking deliveries. It is important to note that this drop sheet is solely for our internal audit purposes and is applicable only to deliveries completed by our designated drivers.*

Our policy can be summarised as follows:

- *Drop Sheet for Internal Audit Purposes: The drop sheet is a tool used by our organisation to track deliveries carried out by our dedicated delivery drivers. It is employed primarily for internal auditing and quality control purposes.*
- *Exemption for Courier Services: Deliveries conducted by courier services are exempt from the drop sheet requirement. This exemption is due to the nature of courier services, which operate independently of our internal delivery team.*
- *Missed Deliveries: In cases of missed deliveries by our own driver, a note will be left through the letter box to inform them of our attempt to deliver. Drugs will then be returned to the pharmacy, and we will attempt to arrange redelivery. In case of authorised courier services, courier company-specific procedures will be diligently followed. These procedures are designed to address missed deliveries, including re-scheduling, communication with customers, and any necessary corrective actions.*

We believe that this policy provides the necessary flexibility to differentiate between our internal delivery operations and external courier services while maintaining the high standards of accountability and customer service that our customers expect from us."

6.53 Whilst the Committee noted the comments from the Appellant with regard to freezers and dry ice, the Committee noted that a revised "SOP for Cold Chain Delivery" had been provided with the Applicant's representations. The Committee noted the comment from the Applicant in their supporting information which stated:

6.53.1 "*We have updated the language in the 'SOP for Cold Chain Delivery' and have altered terms such as 'freezers' and 'dry ice' to eliminate any potential confusion and to provide clearer instructions for maintaining temperatures between 2-8 degrees Celsius and maintaining integrity of cold chain medication. Updated copy of the SOP is attached to this response letter*."

6.54 The Committee noted the revised SOP states:

6.54.1 *"Delivery Temperature Deviation Procedure*

If it is found during delivery that the maximum/minimum thermometer readings are outside the ideal 8C and 2C and there is a concern that there has been a breach in the cold chain then this should be brought to the attention of the named person responsible for the storage of medicines. In this event, please follow these procedures.

5. Temperature deviation due to fridge malfunction

If the temperature has deviated during a fridge malfunction, move the samples to an alternate fridge and give a list of the affected boxes, and the temperature at the time of the move then document this discrepancy in the hubnet.io error log and follow the steps below.

6. Temperature deviation due to power outage

If a power outage occurs, and the generator (if available) does not kick in to restore power to the fridge, alternative arrangements for cold storage must be deployed. This includes, but is not limited to, finding another facility with suitable cold chain maintenance ability to house the product temporarily. This error will need to be logged in the hubnet.io error log and follow the subsequent steps below."

6.55 In addition, the Committee noted the representations from the Applicant which had gone into further detail and stated:

6.55.1 *"The medical cool boxes we intend to use in our delivery van for cold chain deliveries will be purchased from 'The Cool Ice Box Company', who are an NHS certified medical cooler supplier. We would like to highlight some key attributes of their medical cool boxes that will help us maintain the integrity of cold chain medication, while in transit:*

- *Internal Temperature Probe: An internal temperature probe in the cooler allows us to monitor and verify the temperature inside the cooler accurately. This capability gives us the assurance that our temperature-sensitive medical supplies are consistently stored within the required range of 2-8 degrees Celsius.*
- *External LED Temperature Display: The external LED temperature display adds another layer of transparency to our cold chain management. It enables our driver to quickly check the current temperature of the cooler without opening it, reducing the risk of temperature fluctuations.*
- *Extended Temperature Maintenance: The Medical cool boxes we intend to use has the capability to maintain temperatures between 2-8 degrees Celsius for up to 18 hours. This is more than adequate to ensure that the cold chain is maintained throughout the duration of the transit process, ensuring that temperature-sensitive medical supplies reach their destination in pristine condition."*

6.56 Based on the information before it, including the additional information from the Applicant and the revised SOPs, the Committee was satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

6.57 The Committee noted the comments from the Appellant with regard to "owings" and further noted the explanation from the Applicant in subsequent representations:

6.57.1 "*In cases where a patient is unavailable to receive their owed medication during the initial delivery attempt, and all reasonable efforts to contact the patient for redelivery coordination have been exhausted, our standard operating procedure (SOP) mandates the following protocol. While the likelihood of being unable to successfully deliver medication within a three-month timeframe remains relatively low, it is not entirely negligible. Therefore, it is our considered opinion that the inclusion of this procedure within our SOP is imperative for comprehensive and responsible operational guidance."*

6.58 Based on the further information and explanation provided, the Committee was satisfied that it had been provided with sufficient information to show how the Applicant would deal with any "owings" that may arise.

6.59 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.

6.60 The Committee noted the comments from the Appellant that they "*trust that the SOPs will satisfy NHS Resolution in other key areas such as: the manner in which the applicant would communicate and action drug recalls and alerts*".

6.61 The Committee was mindful that drug recalls and alerts are not listed under the heading of Essential Services in Part 2 of Schedule 4 of the Regulations. The Committee noted the response from the Applicant in paragraph 4.1.19 above under "Response to comments on communicating recalls and alerts" in which the Applicant set out how they would deal with recalls and alerts using various notifications including email, the website and phone calls.

6.62 The Committee noted that the Appellant had not indicated any specific issues relating to drug recalls and alerts, just that they trusted that NHS Resolution would be satisfied. The response from the Applicant provided information on how they would action drug recalls and alerts and how these would be carried out. As such, the Committee was of the view that it had been provided with sufficient information to demonstrate how the Applicant will deal with and communicate to their patients in respect of the activities raised by the Appellant.

Summary

6.63 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).

6.64 In those circumstances, as the Committee has reached a different decision to that of the Commissioner, the Committee determined that the decision of the Commissioner must be quashed.

6.65 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.

6.66 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.

6.67 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 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