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5 December 2024

REF: 26317

APPEAL AGAINST NHS LINCOLNSHIRE ICB DECISION TO GRANT AN APPLICATION BY K2 INNOVATIONS LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 10 CHANDLERS YARD BUSINESS PARK, GREYFRIARS, GRANTHAM, NG31 6PG UNDER REGULATION 25

1 Outcome

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

1.2 The Committee determined that the application should be granted.

A copy of this decision is being sent to:

K2 Innovations Ltd (the Applicant)
St Peter's Hill Pharmacy (the Appellant)
PCSE for the Commissioner
Community Pharmacy Lincolnshire

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1 The Application

By application dated 4 March 2024, K2 Innovations Ltd ("the Applicant") applied to Lincolnshire ICB ("the Commissioner") for inclusion in the pharmaceutical list at 10 Chandlers Yard Business Park, Greyfriars, Grantham, NG31 6PG under Regulation 25. In support of the application it was stated:

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 section of the application form blank.

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

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

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

1.1 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.

1.2 "See attached document titled 'NHS Contract' which outlines this answer as there is not enough space in this section."

NHS Contract

1.3 "The responsible pharmacist (RP) will remain on the premises during the opening hours of the pharmacy, in accordance with the RP regulations as outlined by the GPhC. Dispensing of medications will be completed during all of the time that the pharmacy is open and will be completed under the supervision of a pharmacist. During the opening hours of the pharmacy any patient can request support or advice from the pharmacist, to be delivered via the telephone or video links. These consultations will take place in a private office, located away from the main dispensary to allow for a truly confidential consultation. Patients from anywhere in the UK can request NHS essential services by phone, email, website and writing during the entire proposed opening hours, without direct face-to-face contact. The pharmacy website will be available to access 24 hours a day, 365 days a year. All NHS essential services will be delivered during the full opening hours of the pharmacy, without interruption and without face-to-face contact between the patient or their representative and the pharmacist or pharmacy staff. There will be no patient contact on the site of the pharmacy.

1.4 Listed below are statements highlighting provisions that will be made to ensure all essential services are delivered to anyone in England without any face-to-face contact:

1.5 Discharge Medicines Service (DMS) – The DMS will be provided to all referred patients. The three stages will be completed via either telephone or video link to the patient, to ensure that there is no face-to-face contact. Throughout the DMS service, the pharmacist will use their clinical judgment when considering recommendations or actions that should be completed. The consultation will be completed away from the main dispensary and in a private office to ensure adequate confidentiality when completing this service remotely.

1.6 Dispensing Medicines – Prescriptions can be received by the pharmacy via EPS and/or post from patients anywhere in the UK. There will be no collection of prescriptions from surgeries and prescriptions will not be accepted if delivered to the unit by the patient themselves, as there will be strictly no patients on the pharmacy site. Dispensed prescriptions will be delivered via two means, delivery driver and postal courier.

1.6.1 Patients within a 35-mile radius of the pharmacy (extended at the discretion of the pharmacist) will have their prescription delivered to them, including fridge and controlled drug items.

1.6.2 If the patient is outside of this radius, a nominated courier will be used to deliver the medication to them, including a cold-chain courier for fridge items and a tracked delivery service for controlled drugs.

1.7 Should the exemption status not be signed by the patient/representative, pharmacy staff must confirm exemption via telephone or email and sign accordingly. NHS charges will be collected electronically, over the phone or via the website. No cash or card transactions will be permitted on the premises.

1.8 Repeat Dispensing – Once a specified number of repeat prescriptions have been issued, the prescription will be dispensed and delivered to the patient in the same manner as above. Advice about the benefits of repeat dispensing will be given to patients who have stable, long-term health conditions and require regular medication, via the telephone or video link, to advise that they discuss repeat dispensing with their GP surgery.

1.9 Disposal of Unwanted Medicines – Patients wanting to return unused medication to the pharmacy will be able to do so via the pharmacy delivery driver (for patients within the specified radius) or the courier, the service being provided and funded by the pharmacy. Packaging equipment will be sent to the patients and details of how to book a collection (if in the specified radius) or to obtain a free courier label, will be clearly available on the pharmacy website. The return of medicines is to be completed solely via remote means; patients will not be able to physically bring them to the pharmacy. Once the medicines have been returned to the pharmacy, the unwanted medicines will be sorted and placed in disposal units, ready for a specialist waste management company to collect.

1.10 Promotion of Healthy Lifestyles and Public Health Campaigns – All patients will be asked to fill out a healthy lifestyle questionnaire, which can be returned via email, post or through a form on the website. Once the pharmacy has received this questionnaire, results will be analysed, relevant patients contacted and provided with additional information and support. Patients can also be identified through the type of medication dispensed; specific material regarding their condition can be provided, in the form of a leaflet with their medication or a phone call/video call between the pharmacist and the patient. On the pharmacy website, there will be a specific section related to healthy lifestyles, public health campaigns, medication related FAQs, self-care advice and condition-related FAQs. The website will be accessible during all hours, 365 days a year. Patients can also telephone/arrange a video call to discuss anything in more detail, during the opening hours of the pharmacy. The pharmacy will pro-actively take

part in national health campaigns to promote public health messages to patients. Leaflets will be sent to patients with their prescriptions during specific target campaign periods.

1.11 All of the NHS essential services listed above will be provided without face-to-face contact during all of the pharmacy opening hours, to allow for the uninterrupted provision.

1.12 No services, both NHS and private will be conducted physically on the premises, therefore there is no risk of providing an essential service physically on the premises. There are currently no private services offered. The only NHS advanced service proposed is the New Medicines Service (NMS), which will be completed entirely via telephone and/or video link."

2 **The Decision**

The Commissioner considered and decided to grant the application. The decision letter dated 28 August 2024 states:

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

2.1 "NHS Lincolnshire 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.

2.2 The report details the conditions that will be placed upon your inclusion in the relevant pharmaceutical list should a valid notice of commencement be received. Enclosed is a form confirming acceptance of these conditions. It should be completed by an authorised person and returned to me with your notice of commencement.

2.3 Also enclosed is a template of the notice of commencement which you are required to submit to us. Please note that if this is submitted before the end of the 30 day appeal period and a valid notice of appeal is then received by the Secretary of State, the notice of commencement will cease to have effect. This means that if you have opened your new premises then you will be required to close with immediate effect.

2.4 Please note that you must submit the notice of commencement no fewer than 30 days before the date you intend to start service provision. If it is received fewer than 30 days in advance it is not a valid notice of commencement and will not be accepted by NHS Lincolnshire ICB unless you successfully ask to give a shorter notice period. Should you wish to ask to give a shorter notice period please complete the enclosed application form."

Decision Report

2.5 K2 Innovations Ltd, Distant Selling Pharmacy at Unit 10, Chandlers Yard, Greyfriars, Grantham, Lincolnshire, NG31 6PG (2013 Regulations – Regulation 25 (Lincolnshire))

2.6 Re: ME3277 CAS-282520-W8H5F5

2.7 Fitness to Practice criteria has been reviewed by East Midlands Primary Care Team Clinical Advisor.

2.8 The proposed premises are not in a controlled locality.

2.9 Regulation 25 – Distance Selling Premises Application

2.10 The application meets the criteria for a distance selling application - Regulation 25

2.10.1 The proposed premises in respect of which the application is made on the same site or in the same building as the premises of a provider of primary medical services with a patient List.

2.10.2 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 in accordance with

2.10.2.1 The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

2.11 K2 Innovations Ltd will provide the following advanced service.

2.11.1 New Medicines Service (NMS)

2.12 Regulation 31 – Refusal; same and adjacent premises

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

2.14 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.

2.15 Regulation 64 – Distance selling premises: specific conditions

2.16 The Committee deemed this regulation to have been met.

2.17 Regulation 66

2.18 Regulation 66(4) applies and the inclusion of the applicant and the pharmacy premises in the pharmaceutical list for the area of Leicestershire Health and Wellbeing board would be subject to the condition set out in regulation 66(5).

2.19 The condition is that, at the pharmacy premises, the applicant must:

2.19.1 a) Provide the directed services mentioned in the application and

2.19.2 b) Not withhold agreement to a service specification for those services unreasonably

2.20 If the ICB commissions the services from the applicant within three years of the date of either the grant of the application or, if later, the listing in relation to the applicant of the pharmacy premises, unless thereafter the ICB ceases to commission the services (if it has commissioned them).

2.21 The committee have requested that to satisfy the elements of regulation 66 the pharmacy must supply the East Midlands Primary Care Team with Signed SLAs for all enhanced services and complete MYS registration for those advanced services commissioned by Lincolnshire ICB that are detailed within the application within 8 weeks of the date of commencement.

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

2.23 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.

2.24 Appeal Rights

2.24.1 St Peter's Hill Pharmacy, 15 St Peter's Hill, Grantham, Lincolnshire, NG31 6QA.

2.24.2 Lincoln Co-Op Chemists, 176 Winchester Road, Grantham, Lincolnshire, NG31 8RX."

3 The Appeal

In a letter received on 20 September 2024, St Peter's Hill Pharmacy appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "I am writing to appeal the decision on the application for Distance selling pharmacy by K2 Innovations Ltd (Ref:ME3277 - CAS-282520-W8H5F5) because we feel our comments were not sufficiently addressed regarding the application for a Distance Selling Pharmacy made by K2 Innovations Ltd.

3.2 Any reference to regulations will exclusively mean The National Health Service (Pharmaceutical and Local Pharmaceutical Regulations) 2013, as amended, unless otherwise stated. We also reserve the right to attend any oral hearing deemed necessary.

3.3 We believe that our legitimate concerns around the lack of detail on the following points were not addressed. We could not add any objectivity or value to the Market Entry process because we were not given the information we would have needed to understand how they meet the regulatory standard.

3.4 Regulation 64 consider matters that NHS need to consider the following:

3.5 Application fulfils Regulation 25. We have not been given sufficient information from the application to objectively respond. This requires detail on how the applicant intends to deliver essential services, at a distance, uninterrupted, to anyone in England. We have been advised that the application suffices but have not seen the detail ourselves.

3.6 64(3)(d) requires that the pharmacy procedures for the premises must be such as to secure uninterrupted, safe services- in the absence of any sight of procedures, detailed floor plans or any insight into public communications (e.g. Practice leaflets, website shells, Business Continuity Plans) we have not been afforded a fair chance to comment. Because of this, we have not been able to objectively respond to the application simply because we have not seen any detail.

3.7 Therefore, we wish our appeal to be heard by the appeals body and that the decision is quashed and redetermined, allowing interested parties their rights to inform and input to any market entry application. We feel this has been a 'closed' process and therefore we cannot support a decision that we have not been close enough to the detail to make sure this is a legitimate DSP application."

4 Summary of Representations

It came to NHS Resolution's attention that a document entitled "NHS Contract 2024-02-29T15 50 36 513" was provided by the Applicant to the Commissioner with its application however it was not circulated prior to the application being considered. NHS Resolution used its discretion under Schedule 3, Part 3, paragraph 7 and allowing all parties, including the Appellant and Community Pharmacy Lincolnshire, to make representations on this previously unseen document.

This is a summary of representations received on the appeal.

4.1 K2 INNOVATIONS LTD (THE APPLICANT)

Email dated 30 October 2024:

4.1.1 “Please see the attached documents relating to appeal listed in the subject of this email.

4.1.2 Within the documents we have redacted the couriers which we are using, however please see them listed below:

4.1.3 Specialist Cold Chain Courier – PDQ Specialist Courier Services. They deliver nationally.

4.1.4 Specialist Controlled Drug Courier – PDQ Specialist Courier Services. They deliver nationally.

4.1.5 We have a variety of encrypted video calling software that we have available to interact with our patients without face-to-face contact, the main example being Zoom, which can be used for live video and audio calling, as well as live audio calling. These consultations will take place in the confidential consultation space as outlined in the attached floor plan.

4.1.6 Please note that all mention of contact in the SOPs refer to a method of non-face to face communication.

4.1.7 As mentioned in the attached letter, I am more than happy to provide additional clarification or email further SOPs/company specific policies or procedures if requested to do so.

4.1.8 I have attached the following documents to this email: [See Appendix A for Committee]

4.1.8.1 SOP 000 – Review of SOPs

4.1.8.2 SOP 001 – Assuming and Ceasing the role of the RP

4.1.8.3 SOP 002 – Absence of the RP

4.1.8.4 SOP 006 – Dispensing Prescription Items

4.1.8.5 SOP 007 – Accuracy Checking and Bagging Up of Prescriptions

4.1.8.6 SOP 008 – Patient Return and Disposal of Medicines

4.1.8.7 SOP 009 – Delivering Pharmacy Items

4.1.8.8 SOP 010 – Legal and Clinical Check

4.1.8.9 SOP 012 – Owing Prescriptions

4.1.8.10 SOP 013 – Receipt and Storage of Pharmacy Items

4.1.8.11 SOP 014 – Repeat Dispensing

4.1.8.12 SOP 015 – Discharge Medicines Service

4.1.8.13 SOP 018 – Date Checking

4.1.8.14 SOP 019 – Measuring and Recording Fridge Temperatures

4.1.8.15 SOP 021 – Serious Shortage Protocol (SSP)

4.1.8.16 SOP 024 – Sorting and Submission of Prescriptions

4.1.8.17 SOP 025 – Summary Care Records

4.1.8.18 SOP 027 – Electronic Prescription Service (EPS)

4.1.8.19 SOP 028 – EPS Nomination

4.1.8.20 SOP 031 – EPS Submission

4.1.8.21 SOP 032 – Dealing with a CD Incident

4.1.8.22 SOP 033 – Delivery of CDs

4.1.8.23 SOP 038 – Receipt and Storage of Schedule 2 and 3 Controlled Drugs

4.1.8.24 SOP 042 – Dealing with an Incident

4.1.8.25 SOP 043 – Complaints

4.1.8.26 SOP 044 – Valproate Containing Medicines (High Risk Drug SOP)

4.1.8.27 SOP 045 – Methotrexate (High Risk Drug SOP)

4.1.8.28 SOP 046 – Lithium (High Risk Drug SOP)

4.1.8.29 SOP 047 – Isotretinoin (High Risk Drug SOP)

4.1.8.30 SOP 049 – Safeguarding Vulnerable Adults and Children

4.1.8.31 SOP 052 – Pandemic Treatment Protocols, Pandemic Treatment Patient Group Directions, LPIV

4.1.8.32 SOP 053 – Cold Chain

4.1.8.33 SOP 057 – Healthy Living, Lifestyle and Health Campaigns

4.1.8.34 SOP 058 – Self-care, Signposting and Health Promotion

4.1.8.35 SOP 067 – Emergency/Urgent Supply at Request of Prescriber/Patient

4.1.8.36 SOP 079 – Drug Recall

4.1.8.37 SOP 085 – Interventions and Prescription Queries

4.1.8.38 SOP 087 – Prescription Exemption

4.1.8.39 SOP 099 – Patient Return and Disposal of CDs

4.1.8.40 SOP 103 – Communication

4.1.8.41 SOP – Near Miss

4.1.8.42 Business Continuity Plan

4.1.8.43 Cleaning Matrix

4.1.8.44 Equality Act and Reasonable Adjustments

4.1.8.45Extract from Google Profile

4.1.8.46Floor Plan

4.1.8.47GPhC Registration Screenshot

4.1.8.48Information Governance Overview

4.1.8.49Photos of the Pharmacy

4.1.8.50Practice Leaflet

4.1.8.51Response to Appeal

4.1.8.52Website Shell

4.1.9 Many thanks."

Letter dated 30 October 2024:

4.1.10 "I am writing to you in response to your letter dated 01 October 2024, concerning appeals received from interested parties, in relation to our above application which was approved by Lincolnshire Integrated Care Board on 28 August 2024. All mention of 'regulations' in this letter and attached documents standard operating procedures (SOPs) relate to the National Health Service (Pharmaceutical and Local Pharmaceutical) Regulations 2013, unless stated explicitly. Please see below our comments regarding the points raised in the appeal received from St Peter's Hill Pharmacy, in addition to the attached documents and SOPs to highlight our compliance with the regulations.

4.1.11 The SOPs attached as part of our response to this appeal are to show how we are intending on providing:

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

4.1.11.2(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

4.1.12 All NHS Essential services will be delivered to patients in accordance with the SOPs, The Medicines Act, The Misuse of Drugs Act, The Responsible Pharmacist Regulations, The National Health Service (Pharmaceutical and Local Pharmaceutical) Regulations, Data Protection Laws and GPhC guidance.

4.1.13 Regarding marketing and advertising, we wish to make it clear that we do not intend to promote or advertise our services specifically for those located in the Grantham area or indeed any specific geographic region and are fully aware that this is prohibited under the regulations, which our operations will strictly adhere to. As we are not operational at present, we do not have any active marketing materials to share, but have included a screenshot of our Google profile, and website home page which clearly indicates that the services provided by Newton Pharmacy are for all in England. We are also not situated in a premises on the same site or in the same building of a provider of primary medical services with a patient list.

4.1.14 Newton Pharmacy is currently registered with the General Pharmaceutical Council (GPhC) as a distance selling pharmacy (GPhC Registration 9012439) and the GPhC inspector was satisfied that we were compliant with the GPhC standards for registered pharmacies and adhering to the "guidance for registered pharmacies providing pharmacy services at a distance, including on the internet" document. It is important to note, that we are **not** intending to sell any General Sale List (GSL) or Pharmacy (P) medications, nor offer a prescribing service of any description, therefore sections within the GPhC guidance that relate to this are not relevant to our pharmacy.

4.1.15 As a distance selling pharmacy it is important to understand the risk associated with providing pharmacy services at a distance. As such, we have completed a risk assessment for all pharmacy activities, which identifies the likelihood and impact of a given risk, which includes arrangements for ensuring that all stock is procured and handled in an appropriate way, arrangements for ensuring that all equipment used in the provision of pharmaceutical services is maintained appropriately, an approved incident reporting system (together with arrangements for analysing and responding to critical incidents), record keeping arrangements, arrangements for dealing appropriately and timeously with any communications concerning patient safety from the Secretary of State and NHS England, SOPs, waste disposal arrangements for clinical and confidential waste, safeguarding procedures and monitoring arrangements in respect of compliance with the Health and Safety Act 1974.

4.1.16 Principle 1 of the GPhC standards outlines the necessity to have such an assessment completed, which the GPhC inspector has viewed during their initial inspection. All the SOPs provided have been created in line with this assessment and is read alongside the SOP before staff signing. Within Newton Pharmacy, there is also a Clinical Governance Lead (the Superintendent Pharmacist).

4.1.17 We conduct regular audits quarterly as well as when there are operational changes to ensure the safe and effective running of the pharmacy. Newton Pharmacy has an audit procedure (which includes risk reviews), which does not form part of the SOPs attached. However, this audit document covers these areas: review of SOPs, monitoring arrangements for owings, monitoring arrangements in respect of compliance with The Equality Act 2010, staffing levels, training and skills within the team, suitability of communication methods – between pharmacy staff and between the pharmacy and patients/healthcare professionals/third parties (e.g.wholesalers) via non face-to-face methods, systems and processes for receiving prescriptions, including the electronic prescription service (EPS), records of decisions/interventions/referrals, systems and processes for secure delivery to patients via delivery driver or courier(s), information about the pharmacy on the website, adherence to the information security policy, to the Payment Card Industry Data Security Standard (PCI DSS) and to data protection law, feedback from people who use our pharmacy services, including any concerns or complaints received and activities of third parties, agents or contractors. We also ensure that appropriate non face- to-face advice is given in respect of the provision of medicines, including repeat and acute medications, in addition to self-care advice as necessary. We also will complete the approved workforce survey annually and are aware, compliant, and willing to adhere to all of the particulars listed in Schedule 4 of the regulations. A reactive review will take place if the audit identifies any areas of deficiency, for example if there is a data security breach, patient complaints, near miss logs identifies a specific issue, a change in the law or best practice requirements or a change in the way the pharmacy operates. Records that are kept in the pharmacy are kept securely on the dispensing computers or in the lockable filing cabinet, which are retained as per legal or best practice requirements.

4.1.18 All pharmaceuticals are sourced from reputable wholesalers who hold a wholesaler dealers license (WDL). All equipment within the pharmacy is sourced from reputable manufacturers and will be assessed by the Superintendent Pharmacist for testing and review annually (monthly for more specialist equipment such as temperature probes). All IT equipment is encrypted, has the latest security features downloaded, with access password protected and limited to specific members of staff who are required to change their individualised login credentials periodically. All access will be removed once the staff member leaves the company. The DSP toolkit will be completed annually by the Superintendent Pharmacist. The premises themselves are secure and locked at all times, meaning members of the public cannot enter the pharmacy at all.

4.1.19 Staff are trained on the specifics of the distance selling pharmacy regulations, in order to comply with the terms of service. All staff (including locums) qualifications and references are verified before working with Newton Pharmacy and staff have a thorough induction, which includes reading all SOPs, risk assessments, terms of service and policies, in addition to specific training (e.g. on remote consultation skills, safeguarding, confidentiality, consent) and a discussion with the Superintendent Pharmacist to ensure that this is all fully understood and to reinforce the specifics of the distance selling pharmacy regulations and terms of service.

4.1.20 They are aware that we must offer:

4.1.20.1 The uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services (all staff are aware of which services are classed as essential)

4.1.20.2 The safe and effective provision of essential services without face-to-face contact between any person receiving the service.

4.1.21 As there are no private or face to face consultations occurring at the pharmacy at all, there is no risk of inadvertently providing an essential service face-to-face as there is never a situation whereby a patient or their representative would be asked to come physically to the pharmacy; everything is conducted via a non-face-to face communication method. Nothing in our practice leaflet, publicity material published by ourselves or on our behalf, or in any communication (written or oral) from the pharmacy or pharmacy staff to any person seeking the provision of essential services from the pharmacy represent, either expressly or implied that the essential services provided at or from the premises are only available to persons in particular areas of England.

4.1.22 The pharmacy is equipped with facilities to allow for both confidential phone (or other live audio link) and confidential live video communication. Patients from anywhere in England can use our service, for **all** types of medication (e.g. fridge, controlled drugs) and all types of NHS prescription (e.g. FP10 posted to us, EPS prescriptions, repeat prescriptions), dispatched with reasonable promptness.

4.1.23 The delivery methods used are either via a delivery driver or courier, meaning that all patients in England can receive any type of medication from Newton Pharmacy. All medication (including controlled drugs but excluding cold chain products) for patients within a 35-mile radius will be delivered via a delivery driver. All cold-chain products will be couriered to the patient by a specialist national cold-chain courier, regardless of proximity to the pharmacy. Since submitting the application, a further risk assessment has been completed and demonstrated that potential cold-chain breaches can be minimised by using a specialist cold-chain courier as they have a full temperature audit trail. Using a

delivery driver makes this is harder to achieve, hence has been changed to minimise the risk of a cold chain breach. For patients outside of the 35-mile radius of the pharmacy, controlled drugs will be couriered by a specialist national controlled drugs courier and all other non-cold-chain and non-controlled drug medication will be couriered via a tracked Royal Mail Health service, which delivers nationally. All courier methods used are compliant with the GPhC standards. The Superintendent Pharmacist will monitor the third-party couriers, including assessing patients feedback regarding the deliveries and time taken for deliveries, to ensure that they are being completed in a timely fashion.

4.1.24 The website shell attached as part of this appeal, highlights our compliance with the website requirements outlined by the regulations as well as by the GPhC, which includes an interactive healthy living and promotion zone. Please note that this shell is not exhaustive and relevant examples of content have been provided to highlight our compliance. This website contains an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up-to-date materials that promote healthy lifestyles by addressing a reasonable range of health issues. The website will secure and follow information security management guidelines and data protection laws. The website will use secure facilities for processing card payments.

4.1.25 The standard operating procedures (SOPs) attached are not exhaustive but are intended to highlight how the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services will be provided without any face-to-face contact with the patient or their representative. Should any further evidence be required, including SOPs for specific activities or company specific policies/procedures, I would be more than happy to provide these if requested.

4.1.26 I trust that the SOPs and additional information provided addresses the concerns raised in the appeal and reinforces our commitment to providing safe and compliant NHS Essential Services safely at a distance."

4.2 THE COMMISSIONER

4.2.1 "Thank you for your letter dated 01 October 2024; the East Midlands Primary Care Team (EMPCT) on behalf of Lincolnshire ICB would like to make the following representations.

4.2.2 Regulation 25(1) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended states that Section 129(2A) of the 2006 Act (regulations as to pharmaceutical services) does not apply to an application—

4.2.3 [Quotes Regulation 25(1) in full]

4.2.4 Regulation 25(2) states that in respect of pharmacy premises that are distance selling premises the commissioner must refuse the application to which paragraph (1) applies.

4.2.5 [Quotes Regulation 25(2) in full]

4.2.6 The application by K2 Innovations Limited was for a distance selling premises and as such is an accepted application under regulation 25 of the National Health Services (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended.

4.2.7 The nearest provider of primary medical services with a patient list is a 3-minute drive from the proposed premises (approximately 0.2 miles away) and therefore the application could not be refused on this element of regulation 25.

4.2.8 The applicant is not seeking to restrict the provision of essential services in any way. The applicant provided a list of Standard Operating Procedures including process of delivering medications to patients within a 35-mile radius (via local delivery) and outside of the 35-mile radius (via a nominated courier, a specified cold chain courier where required and a tracked delivery service for controlled drug delivery). The applicant has also specified the process in which Disposal of Unwanted Medicines is proposed to be completed, via a prebooked courier collection service paid for by the Distance Selling Pharmacy in packaging equipment provided to the patient.

4.2.9 The applicant outlined in their Standard Operating Procedure document how they would provide essential services to patients without face-to-face contact, in the form of a video or telephone consultation in a private office away from the main dispensary to allow for a confidential consultation.

4.2.10 This was further reinforced in the representation response from the applicant in which they noted that they had identified a specific private room for virtual consultations, as opposed to a consultation room found in a patient facing Pharmacy.

4.2.11 It was brought to our attention that the document outlining the proposed Standard Operating Procedures was not distributed by Primary Care Support England as part of the 45-day circulation for representations. This document outlined the ways in which the Pharmacy would interact with patients virtually and ensure no face-to-face contact. This was then reiterated in the response to representations by the applicant.

4.2.12 The applicant provided response to representations received by St Peter's Hill Pharmacy, Boots UK Limited, Lincolnshire County Council and Lincolnshire Cooperative Limited and provided clarity on all of the comments made by interested parties supplying representation. There was a further representation by Community Pharmacy Lincolnshire, but this fell outside the regulatory 45-day window for representations and therefore was discounted from discussion but included in the paper presented to committee for transparency.

4.2.13 In summary the contractor provided additional information to show compliance with all the elements of regulation 25, as they have provided evidence and further clarification as to how they will provide essential services to the population without face-to-face contact.

4.2.14 Regulation 31 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended requests consideration will be given as to whether:

4.2.15 [Quotes Regulation 31 in full].

4.2.16 The application could not be refused with regards [sic] to regulation 31 as there are no persons on the pharmaceutical list (which may or may not be the applicant) providing or having undertaken to provide pharmaceutical services from:

4.2.16.1 The premises to which the application relates, or adjacent premises and

4.2.16.2 The Integrated Care Board is satisfied that it is reasonable to treat the services that the applicant proposes to provide as part of the service

as the existing services (and so the premises to which the application relates, and the existing listed chemist's premises should be treated as the same site).

4.2.17 It is important to note that the paper presented to committee recommended that the application be refused on the grounds of the failure to supply the Standard Operating Procedures, however the quorate members of the committee noted that the applicant had detailed how they would deliver the essential services within their supporting document and therefore agreed that the application could be supported."

4.3 COMMUNITY PHARMACY LINCOLNSHIRE

4.3.1 "We appreciate you exercising your discretion to allow us to make representations on the application referred to in the subject title.

4.3.2 All references to Regulations herein relate to the National Health Service (Pharmaceutical and Local Pharmaceutical) Regulations 2013, as amended. As a committee, we wish to reserve the right to participate in any oral hearings should the committee identify this as necessary.

4.3.3 It is important to note that the process surrounding this application is concerning, which has required you to exercise discretion. For this, we are grateful; however, we respectfully place on record our concerns that due process appears not to have been followed by the NHS Commissioning Board in this matter. As always, we remain available to support our colleagues in upholding due process, given the importance of making the correct decisions.

4.3.4 Using the information available, we wish to make the following comments:

4.3.5 **Regulation 31**

4.3.6 If this is a determination that you are to quash and redetermine under the Regulations, it is difficult to provide full comments without the original version of the application form that aided the initial decision. Although the committee had sight of the original application at the beginning of the process, Lincolnshire Co-operative Chemists Limited identified a discrepancy in the form, particularly regarding the following statement: "Paragraph 2 of Schedule 2 describes what must be included in any routine or excepted application. Sub-paragraph (3)(c) requires the applicant to provide the address of their registered office. This is missing from the application form; therefore, we cannot be satisfied this has been provided in any Fitness to Practise declarations, as we are not privy to this separate form. Consequently, we cannot be satisfied that the application meets the minimum prescribed requirements of the Regulations."

4.3.7 We have no assurances that this issue was rectified, and in the absence of confirmation, we believe the application was granted outside the scope of the Regulations. Paragraph 10 of Schedule 2 makes clear that the absence of the registered office address renders the application invalid. Without the application form included in the document bundle, this requirement remains unsatisfied.

4.3.8 **Regulations 25 and 64**

4.3.9 Essential services must be provided at a distance, accessible to patients throughout England.

4.3.10 While it is beyond the remit and expectation of NHS Resolution and Community Pharmacy Lincolnshire to verify the applicant's SOPs, in their absence, we cannot have full assurance that the following points are addressed:

4.3.10.1 **Controlled Drugs**: There are no assurances that Controlled Drugs are supplied in a manner compliant with the Misuse of Drugs Regulations. There is no guarantee that supply is secured and monitored to ensure appropriate and lawful distribution. The use of 'tracked' supply does not confirm the identity of the end recipient. To satisfy the Regulations, we believe the name and signature of the recipient are required.

4.3.10.2 **Returned Waste**: The applicant references the use of specialist waste management companies to uplift waste from the site, but there are no assurances that the applicant's obligations to the patient are met by using couriers (or themselves) that are registered Tier 1 or 2 waste carriers.

4.3.10.3 **Reasonable Promptness**: The proposal of a two-tiered delivery system based on geographical location may expose patients further afield to varying lead times for their supply. This could potentially expose the NHS and/or the contractor to claims of discrimination under the Equalities Act 2010 for granting and operating a licence for a distance-selling pharmacy without assurances that patients can access essential services equitably, regardless of distance from the site.

4.3.10.4 **Healthy Living Pharmacy**: Compliance with the Healthy Living Pharmacy requirement, which has been a Term of Service since October 2020, is not assured.

4.3.10.5 **Business Continuity Planning**: This is a Clinical Governance requirement integral to ensuring that services supplied fulfil Regulations 25 and 64. Without assurances that such planning exists, we believe the applicant cannot meet the regulatory test.

4.3.10.6 **Other Essential Services**: There are no assurances that services such as PTP supplies, LPIV provision, SSP supplies, and urgent supplies without a prescription are provided by the applicant.

4.3.10.7 **Appliances**: There are no assurances that the particulars of patient orders for appliances are met as per the Regulations.

4.3.10.8 **Signposting**: The applicant does not provide assurances regarding signposting.

4.3.10.9 **Support for Self-Care**: The applicant does not provide assurances regarding support for self-care.

4.3.10.10 **Clinical Governance**: The applicant does not provide assurances regarding the particulars of clinical governance.

4.3.11 We thank you for the opportunity to provide our comments on the application and respectfully advise the committee to decline the application based on the points raised above."

5 **Late Representations**

5.1 ST PETERS HILL PHARMACY (THE APPELLANT)

5.1.1 “Please find the comments below regarding the proposed distance selling pharmacy application by K2 innovations Ltd.

5.1.2 Comments on the Distance Selling Pharmacy Application

5.1.3 1. Uninterrupted Provision of Services:

5.1.4 The application states that the responsible pharmacist (RP) will remain on the premises during opening hours and that medications will be dispensed under the pharmacist's supervision. However, it is crucial to clarify how this physical presence of the RP translates into the uninterrupted provision of services when all patient interactions are conducted remotely. The effectiveness of remote services should not compromise the quality of care that is typically provided in person.

5.1.5 2. Remote Consultations and Patient Care:

5.1.6 While the pharmacy proposes consultations via telephone and video links, the absence of face-to-face contact may limit the pharmacist's ability to adequately assess patient needs. Many health conditions require non-verbal cues or physical assessments that cannot be captured through remote interactions. It is important to consider how the pharmacy will ensure comprehensive evaluations in cases where physical examination may be necessary.

5.1.7 3. Accessibility for Vulnerable Groups.

5.1.8 The reliance on technology raises concerns about access for vulnerable populations, including the elderly and those without adequate technological resources. The application should detail how it plans to support these individuals to ensure they can still access essential services effectively.

5.1.9 4. Delivery of Medicines:

5.1.10 The proposal outlines a structured delivery system for medications, including coldchain and tracked services for controlled drugs. However, the application should address how the pharmacy will mitigate risks associated with delivery errors, especially for sensitive medications. Details on protocols for confirming receipt of medications by patients and handling delivery issues would strengthen this section.

5.1.11 5. Medication Disposal Procedures:

5.1.12 The process for the disposal of unwanted medications relies heavily on remote collection. While the logistics are outlined, the application should clarify how the pharmacy will ensure safe handling and environmental compliance during the return and disposal of medicines. Details about training for delivery staff on handling hazardous materials would enhance this section.

5.1.13 6. Promotion of Healthy Lifestyles:

5.1.14 The approach to promoting healthy lifestyles and public health campaigns is commendable. However, the application should clarify how the pharmacy will engage with patients to ensure that health promotions are effective. For instance, how will the pharmacy ensure that patients actively participate in health initiatives if all communication is remote?

5.1.15 7. Quality Assurance and Compliance:

5.1.16 The application lacks detail on how the pharmacy will maintain quality assurance and compliance with NHS regulations while operating as a distance

selling pharmacy. Regular audits, patient feedback mechanisms, and protocols for continuous professional development for staff should be outlined to ensure ongoing compliance with standards.

5.1.17 8. Risk Management:

5.1.18 The absence of direct patient contact on the pharmacy premises raises potential concerns regarding risk management. The application should outline how the pharmacy plans to handle complaints, medication errors, or adverse reactions that may arise from remote consultations or deliveries.

5.1.19 9. Service Interruptions:

5.1.20 Although the application claims that all essential services will be provided without interruption, it should also address how the pharmacy will respond to unforeseen disruptions, such as technology failures or supply chain issues. Clear contingency plans are essential for ensuring patient safety and continuity of care.

5.1.21 While the application presents a comprehensive framework for a distance selling pharmacy, it is crucial to address the highlighted areas to ensure compliance with the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013."

6 Summary of Observations

This is summary of observations received.

6.1 K2 INNOVATIONS LTD (THE APPLICANT)

6.1.1 "I am writing to you in response to your letter dated 15 November 2024, concerning representations received from St Peters Hill Pharmacy and Community Pharmacy Lincolnshire, in relation to our above application which was approved by Lincolnshire Integrated Care Board on 28 August 2024. All mention of 'regulations' in this letter relate to the National Health Service (Pharmaceutical and Local Pharmaceutical) Regulations 2013, unless stated explicitly. I will address each interested party individually and specifically address the issues raised. Please note that no new information is being included at this stage.

6.1.2 St Peters Hill Pharmacy

6.1.3 Although St Peters Hill Pharmacy submitted their representations after the consultation period had ended with their representations being made on 4 November 2024, when in fact the consultation period had terminated on 31 October 2024, I will still address the issues raised as it will be down to NHS Resolution as to whether this is included at the committee meeting.

6.1.3.1 Uninterrupted Provision of Services – The uninterrupted provision of essential services will take place during all opening hours, to anyone in England who may request them. I am confused as to the point raised here, as by having a responsible pharmacist (RP) signed in and a pharmacist present, both dispensing and remote consultations can take place. This is evidenced in standard operating procedures (SOPs) 001 and 002.

6.1.3.2 Remote Consultations and Patient Care – This is a criticism of the distance selling model itself and not specifically to our proposed operation. All staff have completed remote consultation training, and a risk assessment has been completed for providing pharmacy services

at a distance. Should a consultation not be able to be conducted via remote means, then the signposting SOP (SOP 058) would be followed, which is compliant with the regulations as a distance selling pharmacy (DSP).

6.1.3.3 Accessibility for Vulnerable Groups – This is predominately a criticism of the DSP model itself as opposed to our proposed operation. Pharmacy services are provided via a variety of means e.g. website, phone, video link, post and email which are not all "technological". We are compliant with the Equality Act and make reasonable adjustments to cater for patients and their representatives to enhance inclusivity.

6.1.3.4 Delivery of Medicines – We have a robust delivery procedure for both controlled and non-controlled drugs as per SOP 009 and 033 as well as a risk assessment completed for the delivery of medicines. Delivery drivers are enrolled on an accredited pharmacy delivery driver course.

6.1.3.5 Medication Disposal Procedures – We have a robust disposal procedure in place for both controlled and non-controlled drugs as per SOP 008 and 099. All staff are adequately trained to perform medicine disposal tasks, in addition to a risk assessment completed.

6.1.3.6 Promotion of Healthy Lifestyles – We have SOPs in place to ensure that we are compliant with the regulations as demonstrated in SOP 057 and 058. We also have a website which contains an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up-to-date materials that promote healthy lifestyles by addressing a reasonable range of health issues.

6.1.3.7 Quality Assurance and Compliance – We conduct regular audits in a variety of areas that are dictated by the regulations, GPhC as well as best practice guidance. This is demonstrated throughout the submitted SOPs and have a robust complaints procedure (SOP 043). All staff (both registered and unregistered pharmacy professionals) complete regular Continuing Professional Development that are submitted to the GPhC as part of the registered professionals revalidation process. All staff however, (both registered and unregistered) are required to bring 2 CPD records to their yearly appraisal as per company policy, which is discussed, and a learning plan developed to enhance their skills.

6.1.3.8 Risk Management – This is addressed in point 7 above.

6.1.3.9 Service Interruptions – We have submitted our business continuity plan which covers how we respond to unforeseen disruptions, such as technology failures or supply chain issues.

6.1.4 Community Pharmacy Lincolnshire

6.1.5 Community Pharmacy Lincolnshire has mentioned that the application form that they have seen is missing the address of our registered office. K2 Innovations Ltd included this information on the application form submitted to PCSE, which was anonymised by PCSE prior to distribution to interested parties. I have attached a screenshot of the form we submitted, and the form distributed by PCSE in Appendix A [Appendix B for Committee] of this letter for reference. I will list our responses to the issues raised by Community Pharmacy Lincolnshire below:

6.1.5.1 Controlled Drugs – All deliveries of controlled drugs are compliant with the Misuse of Drugs Regulations, as outlined in SOP 033. Both the

courier and delivery driver confirm the identity of the end recipient, which does include recording the name, signature and date of the recipient.

6.1.5.2 Returned Waste – The return of unwanted medicines is compliant with all relevant legislation as per SOP 008 and 099.

6.1.5.3 Reasonable Promptness – There has been a precedent set among DSPs that deliveries are made by either a delivery driver or a courier, both of which provide prompt delivery of medicines to patients regardless of their location. Royal Mail Health is a 24-hour tracked service, with our delivery driver delivering same or next day to the patient. The cold chain and controlled drug courier are same or next day delivery, demonstrating that delivery is prompt, regardless of location.

6.1.5.4 Healthy Living Pharmacy – Please refer to SOP 057 which outlines how we are compliant with this requirement of the regulations.

6.1.5.5 Business Continuity Planning – We have attached a copy of our business continuity plan along with our SOPs, which outline how we respond to unforeseen events and are therefore complaint with this particular of the regulations.

6.1.5.6 Other Essential Services – We have SOPs in place to provide medication supplied against PTP, LPIV and PTPGDs as per SOP 052 and the urgent provision of medication without a prescription in SOP 067.

6.1.5.7 Signposting – Please refer to SOP 058 which highlights how we are compliant with this particular of the regulations.

6.1.5.8 Support for Self-Care – Please refer to SOP 058 which details our process for providing self-care advice.

6.1.5.9 Clinical Governance – Details of our clinical governance arrangements are in the respective SOP in which the governance arrangement applies to, which highlights our compliance with the regulations.

6.1.6 I trust that the attached SOPs and various other policies/procedures outline our compliance with the regulations and our commitment to providing safe and effective pharmaceutical services at a distance. I look forward to hearing from you in due course."

6.2 LINCOLNSHIRE COMMUNITY PHARMACY

6.2.1 "We are writing to provide additional responses to the application for a distance selling pharmacy, reiterating our concerns and observations regarding the applicant's ability to meet the requirements under the **NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013** ("the Regulations").

6.2.2 1. Two-Tier Delivery System

6.2.3 We reiterate our original concern that the applicant appears to be proposing a **two-tier delivery system**, which would result in unequal delivery services for patients in England. This issue has not been addressed adequately by either the committee or the applicant. We respectfully request that the panel give due consideration to our previously submitted comments on this matter. The applicant had not addressed this point in their response to our comments.

6.2.4 2. Induction Process Non-Compliance

6.2.5 The applicant's documentation indicates that only employed colleagues are subject to an induction process, while locums are excluded. This contravenes **Schedule 4, Part 2, Paragraph 28(e)(i)** of the Regulations, which requires that all staff engaged in the provision of NHS services, including locums, are adequately trained and inducted.

6.2.6 3. Responsible Pharmacist (RP) and Continuity of Services

6.2.7 **SOP002**: The applicant's SOP suggests that in the absence of the RP, a second pharmacist does not automatically assume the RP role, and therefore the pharmacy cannot meet the regulatory requirements.

6.2.8 While the RP may be absent for up to 2 hours as permitted under the **Regulations**, specific activities requiring the RP's legal oversight (e.g., clinical checks on prescriptions, dispensing medicines, and advanced services like MURs and NMS) cannot be performed during their absence. This means the pharmacy cannot provide uninterrupted essential services.

6.2.9 Additionally, without a formally recorded RP in the RP log, another pharmacist present cannot legally assume responsibility for pharmacy operations.

6.2.10 **SOP033**: This SOP states that the RP must be signed in and in charge of the pharmacy to process and hand out controlled drugs (CDs). If the RP is absent as described, CDs cannot be processed or handed out, which also means they cannot be delivered. This further highlights the inability to maintain uninterrupted service provision during the RP's absence.

6.2.11 **4. Inconsistencies in Refusal of Supply SOP**

6.2.12 **SOP010**: This SOP raises concerns about the clarity and practicality of the refusal process.

6.2.13 Specifically:

6.2.13.1 Section (c) mentions that "pharmacy staff are subjected to or threatened with verbal violence by a patient *or* someone contacting the pharmacy via non-face-to face communication on their behalf."

6.2.13.2 Section (d) refers to "a patient or their representative committing or threatening to commit a criminal offence via non-face-to-face communication."

6.2.13.3 This difference in phrasing between (c) and (d) implies the potential presence of patients in the pharmacy, which contradicts the fundamental requirement for distance selling pharmacies to operate without direct patient access.

6.2.14 Furthermore, this SOP references the times where they may refuse to supply appliances, indicating that appliances will be dispensed. In their original application form, the form clearly states that the applicant needed to have written 'not dispensing appliances' or words to that effect which was left blank. With this in mind, the applicant has not demonstrated compliance with **Schedule 4, Part 2, Paragraph 12** of the Regulations, which specifies additional terms of service for the provision of appliances. This omission suggests that the regulatory requirements for dispensing appliances are not being met.

6.2.15 **5. Essential Services Delivery**

6.2.16 Given the issues outlined above, we believe the applicant cannot ensure the provision of essential services to all patients in England in an uninterrupted manner and without face-to-face contact. This contravenes the requirements for distance selling pharmacies as defined in the **NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013**.

6.2.17 **Conclusion**

6.2.18 In light of these significant concerns, we respectfully request that the application be refused. The applicant has not demonstrated compliance with the necessary regulatory requirements to ensure equitable, uninterrupted, and fully compliant pharmaceutical services for all patients in England.

6.2.19 Thank you for considering our observations."

7 Consideration

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

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

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

7.4 The Committee noted the application form had been submitted by K2 Innovations Limited. The SOPs provided by the Applicant give the pharmacy name as "*Newton Pharmacy, Unit 10 Chandlers Yard, Grantham, Lincolnshire, NG31 6PG*". Also included in the SOPs bundle is the pharmacy leaflet which states "K2 Innovations Ltd (trading as Newton Pharmacy), Unit 10 Chandlers Yard, Grantham, Lincolnshire, NG31 6PG." The Committee is satisfied that the SOPs relate to the Applicant's pharmacy.

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

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

7.7 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, states that "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" which had not been disputed by any party.

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

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

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

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

Additional information to be included with excepted applications

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

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

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

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

7.12 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 representations stated "*The nearest provider of primary medical services with a patient list is a 3-minute drive from the proposed premises (approximately 0.2 miles away) and therefore the application could not be refused on this element of regulation 25*." The Committee noted that this information had not been disputed by parties. 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)

7.13 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.

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

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

7.16 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.

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

7.18 The Committee noted the Appellant's comments regarding the Commissioner not providing the information (at paragraphs 1.7 to 1.17 above). The Committee noted the Commissioner, in its representations, states "It was brought to our attention that the document outlining the proposed Standard Operating Procedures was not distributed by Primary Care Support England as part of the 45-day circulation for representations. This document outlined the ways in which the Pharmacy would interact with patients virtually and ensure no face-to-face contact. This was then reiterated in the response to representations by the applicant." The Committee was puzzled as to why the Commissioner did not circulate the missing information on realising its mistake. However, using its discretion under Schedule 3, Part 3, paragraph 7 NHS Resolution allowed all parties who made comments on the application, including the Appellant and Community Pharmacy Lincolnshire to make representations on this previously unseen document. See representations at paragraph 4 above.

7.19 With regard to the uninterrupted provision of services, the Committee noted comments from the Appellant in its representations with regard to "*it is crucial to clarify how this physical presence of the RP translates into the uninterrupted provision of services when all patient interactions are conducted remotely*."

7.20 The Applicant states in its application:

7.20.1 "*The responsible pharmacist (RP) will remain on the premises during the opening hours of the pharmacy, in accordance with the RP regulations as outlined by the GPhC*. …..

7.20.2 *All NHS essential services will be delivered during the full opening hours of the pharmacy, without interruption …….*"

7.21 Further in the Applicant's observations:

7.21.1 "…. *by having a responsible pharmacist (RP) signed in and a pharmacist present, both dispensing and remote consultations can take place*."

7.22 The Applicant refers to SOP 001 "Assuming and Ceasing the Role of the Responsible Pharmacist" and SOP 002 "Absence of the RP"

7.23 SOP 001 states:

7.23.1 "*The RP must be aware of the differences between a non-distance selling pharmacy (DSP) and a DSP. Newton Pharmacy is a DSP and therefore must provide uninterrupted NHS essential services during the opening hours of the premises, therefore the RP is not allowed to leave the pharmacy (for 2 hours) as would be permitted in a non-DSP unless another pharmacist is present. The pharmacy will have a second pharmacist available during all opening hours*

that the DSP operates, for if any reason the RP needs to leave, then the second pharmacist must sign in as RP."

7.24 SOP 001 provides a checklist with the process for Assuming the duties of the RP and ceasing the duties of the RP.

7.24.1 SOP 002 provides a check list with the process for preparing for the absence of the RP and concludes:

7.24.2 "*If the RP returns within 2 hours*:

7.24.2.1 *The RP should make an entry in the pharmacy record indicating their time of return*

7.24.2.2 *Staff should be made aware of their return*

7.24.3 *If RP is still absent at 1 hour 45 minutes after their departure*:

7.24.3.1 *Contact should be made with the RP for an estimated return time*

7.24.3.2 *If this exceeds a total absence of more than 2 hours, then the 2nd pharmacist must assume the role of RP and the initial RP signed out (with their consent). Follow the assuming and ceasing the role of the responsible pharmacist SOP*

7.24.3.3 *The superintendent pharmacist must be informed*."

7.25 With regard to NHS essential services to be provided without face to face contact, the Committee noted comments from the Appellant in its representations with regard to "*the absence of face-to-face contact may limit the pharmacist's ability to adequately assess patient needs*." The Appellant's arguments were misconceived as the criteria in the Regulations which it needed to be satisfied with refers to:

7.25.1 "*the safe and effective provision of essential services without face to face contact between any person receiving the services ….."*

7.26 The Applicant states in its application:

7.26.1 "*Patients from anywhere in the UK can request NHS essential services by phone, email, website and writing during the entire proposed opening hours, without direct face-to-face contact*."

7.26.2 "*The three stages will be completed via either telephone or video link to the patient, to ensure that there is no face-to-face contact."*

7.27 The Applicant in its representations states:

7.27.1 "*We have a variety of encrypted video calling software that we have available to interact with our patients without face-to-face contact, the main example being Zoom, which can be used for live video and audio calling, as well as live audio calling*"

7.28 The Committee noted throughout the Applicant's SOPs there are references as to how a patient could make contact with the pharmacy. For example:

7.28.1 SOP 008 Patient Return of and Disposal of Medicines

7.28.2 "*Patients may call, email (or any other method of communication other than face-to-face) the pharmacy to be advised to the method of how to return*

unwanted medicines. There is also a disposal of medicines section on our website which outlines how patients can go about returning medicines."

7.28.3 SOP 009 Delivery of Medicines to Patient

7.28.4 "*Send the tracking number to the patient using their preferred method of non-face-to-face communication*."

7.28.5 SOP10 Legal and clinical check

7.28.6 *"… consult the patient via a non face to face method of communication*."

7.29 With regard to NHS essential services to be provided to any patient living in England, the Committee noted the Applicant states in its application:

7.29.1 "*Patients from anywhere in the UK can request NHS essential services by phone, email, website and writing during the entire proposed opening hours, without direct face-to-face contact*."

7.30 The Committee noted throughout the SOPs the Applicant states that essential services will be provided without face to face contact anywhere in England. For example:

7.30.1 SOP 006 Dispensing Prescription Items

7.30.2 "*To safely and accurately dispense medications against a prescription, to ensure the uninterrupted provision of dispensing (NHS essential service) during the opening hours of the premises, to persons anywhere in England who may request those services*."

7.31 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.

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

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

Dispensing of drugs and appliances

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

7.35 In its application, the Applicant states:

7.35.1 "*Prescriptions can be received by the pharmacy via EPS and/or post from patients anywhere in the UK. There will be no collection of prescriptions from surgeries and prescriptions will not be accepted if delivered to the unit by the patient themselves, as there will be strictly no patients on the pharmacy site. Dispensed prescriptions will be delivered via two means, delivery driver and postal courier*."

7.36 In SOP 024 Sorting and Submission of Non-EPS NHS Prescriptions, the Applicant provides a checklist of the process in place.

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

Urgent supply without a prescription

7.38 The Committee noted Community Pharmacy Lincolnshire's comments:

7.38.1 "*There are no assurances that services such as PTP supplies, LPIV provision, SSP supplies, and urgent supplies without a prescription are provided by the applicant*."

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

7.40 The Committee had regard to SOP 067 Emergency / Urgent Supply at the Request of Patient / Prescriber which describes how the Applicant will process such a request from either a patient or a prescriber.

7.40.1 "*The prescriber must agree to provide a prescription within **72 hours** of the request being made*

7.40.1.1 *The prescription can be sent via the EPS or if it is a physical prescription be posted to the pharmacy*."

7.41 With reference to patient requests, SOP 067 provides a comprehensive checklist which includes:

7.41.1 "*The pharmacist should check this by asking the patient to send an email with a photo of a previous prescription box or visually on video call if possible*."

7.42 With regard to Pandemic Treatment Protocol (PTP supplies), Listed Prescription items voucher (LPIV provision), Serious Shortage Protocols (SSP supplies) as mentioned by Community Pharmacy Lincolnshire, the Applicant has provided SOP 021 Serious Shortage Protocol and SOP 052 Pandemic Treatment Protocols (PTP), Pandemic Treatment Patient Group Direction (PTPGD) and Listed Prescription Items Voucher (LPIV).

7.43 The Committee noted SOP 021 provides a comprehensive process regarding SSP.

7.44 The Committee noted SOP 052 states:

7.44.1 "*The medicine should then be delivered/couriered to the patient in accordance with the "delivery" SOP **as soon as possible** and contacted via phone/video to inform them that the medication has been dispatched as well as the estimated delivery date*.

7.44.2 *The patient should then be contacted via phone/video to confirm receipt of the package*."

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

Preliminary matters before providing ordered drugs or appliances

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

7.47 In its application, the Applicant states:

7.47.1 "*Should the exemption status not be signed by the patient/representative, pharmacy staff must confirm exemption via telephone or email and sign accordingly*."

7.48 SOP 087 Prescription Exemptions states the Applicant's process including:

7.48.1 "*If the prescription has arrived via post, check the back of the prescription to see whether the patient/representative has already completed the reverse of the prescription outlining their exemption status*." ….

7.48.2 "*Satisfactory evidence includes proof from the RTEC (real time exemption checking) system as per the Charges Regulations within the dispensing software, which is available in Newton Pharmacy*. ….

7.48.3 *If the evidence has been sent into the pharmacy and has an expiry date, it is not necessary to request the same piece of evidence for the duration of the exemption, however, should still be contacted to confirm exemption status. Income support or Jobseekers Allowance exemptions should be asked for evidence every time as this exemption status can change frequently*."

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

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

7.51 In its application, the Applicant states:

7.51.1 "*NHS charges will be collected electronically, over the phone or via the website. No cash or card transactions will be permitted on the premises*."

7.52 SOP 087 Prescription Exemptions states the Applicant's process including:

7.52.1 *The patient "should be directed to the website where there is a payment section, allowing for the number of charges to be entered and paid for using a VISA, Mastercard, Paypal or AMEX card. Once the payment has been processed, a receipt is delivered to the patient and the pharmacy via email, indicating that the payment has been made*.

7.52.2 *Alternatively, payment can be taken over the phone/video call using the "customer not present" setting*."

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

Providing ordered drugs or appliances

7.54 The Committee noted Community Pharmacy Lincolnshire stated:

7.54.1 "*There are no assurances that Controlled Drugs are supplied in a manner compliant with the Misuse of Drugs Regulations. There is no guarantee that supply is secured and monitored to ensure appropriate and lawful distribution. The use of 'tracked' supply does not confirm the identity of the end recipient. To satisfy the Regulations, we believe the name and signature of the recipient are required*" and

7.54.2 "*The proposal of a two-tiered delivery system based on geographical location may expose patients further afield to varying lead times for their supply. This could potentially expose the NHS and/or the contractor to claims of discrimination under the Equalities Act 2010 for granting and operating a licence for a distance-selling pharmacy without assurances that patients can access essential services equitably, regardless of distance from the site*."

7.55 The Appellant stated:

7.55.1 "*the application should address how the pharmacy will mitigate risks associated with delivery errors, especially for sensitive medications. Details on protocols for confirming receipt of medications by patients and handling delivery issues would strengthen this section*."

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

7.57 The Applicant, in its observations refers to SOP 009 and SOP 033 in this regard.

7.58 In SOP 009 Delivery of Medicines to Patient, the Applicant describes how it will deliver prescriptions via delivery driver including the process for successful and unsuccessful deliveries. Deliveries via Royal Mail and its process for unsuccessful deliveries by Royal Mail. Also the process for cold chain delivered by Courier and unsuccessful delivery attempts.

7.58.1 "*Patients within a 35-mile radius of the pharmacy (extended at the discretion of the responsible pharmacist) will have all of their medications delivered by a delivery driver apart from cold-chain products, which will be sent via the cold-chain courier*.

7.58.2 *Patients outside of this area will have all of their medications delivered via Royal Mail Tracked except for*:

7.58.2.1*Fridge Items – cold-chain courier should be used*

7.58.2.2*Controlled Drugs – controlled drug courier should be used (as per Controlled Drug Delivery SOP)*.

7.58.3 *The Royal Mail Tracked courier service is run as part of Royal Mail Health through Charac. This is a specialist platform that has been endorsed by the NPA for the delivery of medications. The reason for this is that a signature is required and CANNOT be left in a safe place. This is fully compliant with the GPhC guidance on delivery of medicines*. …..

7.58.4 *Hand the delivery driver record sheet to the delivery driver which contains the list of addresses to deliver to*. ….

7.58.4.1*The delivery driver should sign against each patient to confirm acceptance*. ….

7.58.5 *Transfer the tote box(es) to the delivery van*

7.58.5.1 *Ensure all medication is securely stored out of sight from the general public*

7.58.5.2*The vehicle must be locked when unattended. ……*

7.58.6 *Driver to inform pharmacist of successful delivery, enabling the prescription to proceed to the claiming process – follow Claiming SOP. …*

7.58.7 *If there has been no answer after five minutes, proceed to post a "missed delivery" card through the letterbox which informs the patient/representative of how to contact the pharmacy to rearrange the delivery*.

7.58.8 *Return the prescription bags to the pharmacy and inform the RP of the missed delivery*. ……"

7.59 The Committee noted with regard to Cold Chain delivery by Courier, SOP 009 states:

7.59.1 *"The cold chain provider that is used is Redacted for appeal, which is an approved cold chain courier, they meet a strict criteria ensuring a fully compliant and monitored cold chain, specifically for pharmaceuticals and specialists in healthcare*. …….

7.59.2 *Book a delivery online and select the 2-8^{o}C option. The box requiring delivery should be left in the fridge until the courier arrives to collect the box*.

7.59.2.1 *The patient should be contacted via phone/video call to enquire as to when they would like the parcel to be delivered. Select the day before for courier collection as it is next day delivery*. …..

7.59.3 *The cold chain courier requires a signature upon delivery.* ***The patient must be contacted via a non-face to face method of communication to confirm that they have successfully received the parcel****. The parcel cannot be left in a safe space or with an alternative address (unless informed by the pharmacy when booking) by the courier as per the terms of service*. ……"

7.60 The Committee noted that should the delivery of cold chain be unsuccessful, SOP 009 states:

7.60.1 "*Courier will leave a missed delivery card at the address with information of how to rearrange a delivery via the phone or on the couriers website*. …..

7.60.2 *If there is no contact in terms of rearranging the delivery within two days of the attempted delivery, then the parcel will be returned to the pharmacy. The cold chain is maintained in the delivery vans and in storage throughout*. ……

7.60.3 *The cold chain service is fully monitored and consists of temperature-controlled delivery and storage. Redacted for appeal is routinely used in the pharmaceutical and healthcare industry to transport cold chain products, such as vaccines, cold chain pharmaceuticals and wholesalers registered with the MHRA*. …..

7.60.4 *The courier ensures temperature integrity throughout the whole chain, including storage, delivery and pick up from the pharmacy. If there is ever a breach in the cold chain at any point the company are made aware automatically by their temperature monitoring system (both in delivery vans and storage). …….*"

7.60.5 *"Process – Cold Chain Delivery via Courier (Fridge Items) – Unsuccessful Delivery*

7.60.6 *Courier will leave a missed delivery card at the address with information of how to rearrange a delivery via the phone or on the couriers website*.

7.60.7 *If there is no contact in terms of rearranging the delivery within two days of the attempted delivery, then the parcel will be returned to the pharmacy. The cold chain is maintained in the delivery vans and in storage throughout*.

7.60.8 *Once the parcel is back at the pharmacy, re-attach prescription. The parcel is to go straight into the delivery fridge and the patient contacted to re-arrange a new delivery date*."

7.60.9 "*How can the cold chain be guaranteed? And what happens if there is a breach in the cold chain*?

7.60.10 *….*

7.60.11 *When there has been a breach in the cold chain, the parcel is to be returned to the pharmacy, with details of the cold chain breach along with a phone call/email from the courier that the parcel is going to be returned. The pharmacy can then inform the patient via phone/video call of the breach and re-arrange another delivery using re-dispensed product and dispatch as soon as possible*.

7.60.12 *Once the product is received back in the pharmacy, this must be disposed of as per medicines disposal SOP*."

7.61 The Committee noted in SOP 033 Delivery and Courier of Controlled Drugs the Applicant describes "*the processes to be followed when delivering Schedule 2 and 3 Controlled Drugs (CDs) to patients/authorised representatives.*"

7.61.1 "*Controlled Drugs are to be gathered and stored in the to be delivered box of the CD cabinet*. …….

7.61.2 *For Controlled Drugs the CD Delivery Record Book needs to be completed* [listing several field of information including patient details, signatures and ID confirmation] …..

7.61.3 *The delivery driver should also sign the CD Delivery Record Book to confirm receipt of that medication, double-checking patient name, quantity, and medication before signing. The pharmacist must perform a check to confirm the product matches the prescription in terms of patient name, address, medication particulars (drug, brand, strength, form, quantity) and sign the CD Delivery Record Book before handing to the driver*.

7.61.4 *Transfer the controlled drugs to the delivery van in the locked safe*

7.61.4.1 *Ensure all medication is securely stored out of sight from the general public*

7.61.4.2*The vehicle must be locked when unattended*. …….

7.61.5 *Driver to inform pharmacist of successful delivery*. ……..

7.61.6 *Delivery of Controlled Drugs to Patient or Representative Address – Unsuccessful Delivery*

7.61.7 *If there has been no answer after 5 minutes, proceed to post a "missed delivery" card through the letterbox which informs the patient/representative of how to contact the pharmacy to rearrange the delivery*. …..

7.61.8 *Place prescription bags back into their respective areas in the delivery vehicle and controlled drugs back into the safe*. ……..

7.61.9 *Unsuccessful controlled drug deliveries sent via courier will be returned to the pharmacy within 1 day and when received must be entered back into the controlled drugs register and placed back in the CD cabinet, with the prescription attached*

7.61.9.1 *The parcel is stored in their controlled drug warehouse prior to dispatch and when being stored*

7.61.10 *When a failed delivery occurs, the courier will notify the patient and the pharmacy so that a re-delivery can be booked at a more convenient time*.

7.61.10.1 *If the re-delivery is within 24 hours this can be re-booked directly with the courier and delivery re-attempted*

7.61.10.2 *Otherwise, the pharmacy is to make contact with the patient/representative and re-organise the delivery*."

7.62 Based on the information before it, the Committee was satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

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

7.64 In relation to appliances, the Committee noted that the Applicant in its application form had left this section blank. The Committee noted in SOP 058 SelfCare, Signposting and Health Promotion, the Applicant states:

7.64.1 "*As a distance selling pharmacy there is no face-to-face contact with any patient. Therefore, if a prescription is received for an item that requires fitting/measuring, the patient should be contacted via phone/video call as this is not available at this pharmacy. The prescription form or repeatable prescription should be referred to another NHS pharmacy or NHS appliance contractor, chosen by the patient with the consent of the patient obtained. If the patient does not consent to a referral, provide the patient with contact details of at least 2 NHS pharmacies or NHS appliance contractors who are able to provide this service*."

7.65 The Committee was satisfied that it was not the Applicant's intention to provide appliances if they require measuring and fitting. The Committee therefore did not need to be satisfied that there would be compliance with paragraph 8(4) of Schedule 4. In the event that the application is granted, the Applicant would not therefore, be able to provide to patients appliances that require measuring or fitting.

7.66 The Committee considered whether the Applicant had explained what containers would be suitable for posted/delivered items.

7.67 The Applicant provided SOP 007 Accuracy Checking and Bagging up of prescriptions which stated:

7.67.1 " ….. *place each medication in*:

7.67.1.1 *A paper prescription bag for non controlled drugs*

7.67.1.2 *Clear bag with 'controlled drug' sticker which has the expiry date of prescription (28 days for schedule 2, 3 and 4) on for controlled drugs*. …….

7.67.2 *Delivery via Courier packaging*

7.67.3 *No fridge items*

7.67.4 *Delivery cardboard boxes (reinforced), specifically designed for transportation purposes sealed with anti-tamper tape*

7.67.5 *Brown packing paper to fill the remaining space in the cardboard box*

7.67.6 *For fragile items – wrap in bubble tape*

7.67.7 *Fridge items*

7.67.8 *Cold chain products must be placed in bubble wrap and placed in specifically designs Styrofoam lined cardboard boxes and stored in the "to be dispatched fridge" rather than the stock fridge*

7.67.9 *Box sealed with anti-tamper tape."*

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

Refusal to provide drugs or appliances ordered

7.69 Community Pharmacy Lincolnshire, in its observations, states:

7.69.1 "***SOP010****: This SOP raises concerns about the clarity and practicality of the refusal process*.

7.69.2 *Specifically*

7.69.3 *Section (c) mentions that "pharmacy staff are subjected to or threatened with verbal violence by a patient or someone contacting the pharmacy via non-face-to face communication on their behalf*."

7.69.4 *Section (d) refers to "a patient or their representative committing or threatening to commit a criminal offence via non-face-to-face communication*."

7.69.5 *This difference in phrasing between (c) and (d) implies the potential presence of patients in the pharmacy, which contradicts the fundamental requirement for distance selling pharmacies to operate without direct patient access*."

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

7.71 The Committee was of the view that the Applicant's SOPs clearly state at section c and d as is quoted above and throughout its SOPS that it will serve patients via non face to face communication.

7.72 The Applicant provided SOP 010 Legal and clinical check. In section 4 it states for example:

7.72.1 "*If the item(s) are not appropriate, consult the patient via a non face to face method of communication as they may be able to provide relevant information*."

7.73 Point "j" of SOP 010 states:

7.73.1 "*The pharmacist must only provide the medications (as requested by a patient/their representative) ordered on a repeatable prescription if the patient is taking/using and is likely to continue to take or use the medication appropriately and is not suffering from any side effects, that the regimen has not altered in a way which indicates the need or desirability of reviewing the patients treatment and there have been no changes to the health of the patient to whom the prescription relates*. …..

7.73.2 *Whenever there is a refusal to supply professional judgment should be used to try and minimise the delay/disruption to the patient, for example the prescriber/patient must be contacted via phone to try to resolve/clarify the query – follow the intervention and signposting SOPs. All refusals to supply must be approved by the RP and documented in the pharmacy communication book*."

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

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

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

7.76 The Applicant, in its application, states:

7.76.1 "*Once a specified number of repeat prescriptions have been issued, the prescription will be dispensed and delivered to the patient in the same manner as above. Advice about the benefits of repeat dispensing will be given to patients who have stable, long-term health conditions and require regular medication, via the telephone or video link, to advise that they discuss repeat dispensing with their GP surgery*."

7.77 In SOP 044 Repeat Dispensing, the Applicant states:

7.77.1 "*Repeat dispensing is a method of a patient receiving repeat medications, without having to get a prescription from their GP surgery every time they need a further supply of medication. The pharmacy manages the repeat supply of the medicines, for the duration specified by the prescriber*. …..

7.77.2 *Pharmacy teams need to identify appropriate patients and provide them with information about Repeat Dispensing, with the aim that there is an increase in the use of the service by patients*.

7.77.3 *Appropriate advice can be given verbally (over the phone or via video call) to patients. The decision to proceed with repeat dispensing is dependent upon approval from the prescriber. The decision to start repeat dispensing must be made by the patient, with their consent*."

7.78 Given the above, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.

Disposal service in respect of unwanted drugs

7.79 The Committee noted the Appellant states:

7.79.1 "*The process for the disposal of unwanted medications relies heavily on remote collection. While the logistics are outlined, the application should clarify how the pharmacy will ensure safe handling and environmental compliance during the return and disposal of medicines. Details about training for delivery staff on handling hazardous materials would enhance this section*."

7.80 The Committee noted Community Pharmacy Lincolnshire states:

7.80.1 "*The applicant references the use of specialist waste management companies to uplift waste from the site, but there are no assurances that the applicant's obligations to the patient are met by using couriers (or themselves) that are registered Tier 1 or 2 waste carriers*."

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

7.82 In its application, the Applicant states

7.82.1 "*Patients wanting to return unused medication to the pharmacy will be able to do so via the pharmacy delivery driver (for patients within the specified radius) or the courier, the service being provided and funded by the pharmacy. Packaging equipment will be sent to the patients and details of how to book a collection (if in the specified radius) or to obtain a free courier label, will be clearly available on the pharmacy website. The return of medicines is to be completed solely via remote means; patients will not be able to physically bring them to the pharmacy. Once the medicines have been returned to the pharmacy, the unwanted medicines will be sorted and placed in disposal units, ready for a specialist waste management company to collect*."

7.83 In SOP 008 Patient Return of and Disposal of Medicines, the Applicant states:

7.83.1 "*Patient makes contact with the pharmacy via non face to face methods (email or phone for example) enquiring about the disposal of medicines*. ……

7.83.2 *Ask the patient which medicines they wish to return*

7.83.2.1 *Confirm there are no needles or sharps (if there are refer to their local authority guidance online for how to dispose of sharps)*

7.83.2.2 *Confirm that there are only medicines being returned*

7.83.2.3 *Go through each medication and confirm they are eligible to be returned*

7.83.2.4 *If there are CD's, these must be segregated and returned using the CD returns SOP. All other medicines must be returned using this method*.

7.83.3 *Patients should be advised to contact their local council for advice on the disposal of products that we cannot accept*

7.83.4 *Staff should confirm with the pharmacist that we are unable to accept something before advising the patient as to not breach the terms of the NHS contract*. …….

7.83.5 *Advise the patient of the options available (that have been approved by the pharmacist)*:

7.83.5.1 *Collected by the delivery driver*

7.83.5.2*To be couriered back to the pharmacy via Royal Mail*

7.83.5.3*Collected via Specialist waste management contractor*

7.83.6 *If the patient does not want to proceed with any of the following, then they must be signposted to at least two pharmacies local to them*."

7.84 The Applicant describes the process of collection via Royal Mail and via courier.

7.85 The Applicant describes how it will dispose of unwanted medicines in the pharmacy including

7.85.1 "*Staff member to don PPE, including gloves, apron and mask …..*"

7.86 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 13-15 of Schedule 4.

Promotion of healthy lifestyles

7.87 The Committee noted the Appellant states:

7.87.1 "…. *how will the pharmacy ensure that patients actively participate in health initiatives if all communication is remote*."

7.88 The Applicant, in its application, states:

7.88.1 "*All patients will be asked to fill out a healthy lifestyle questionnaire, which can be returned via email, post or through a form on the website. Once the pharmacy has received this questionnaire, results will be analysed, relevant patients contacted and provided with additional information and support. Patients can also be identified through the type of medication dispensed; specific material regarding their condition can be provided, in the form of a leaflet with their medication or a phone call/video call between the pharmacist and the patient. On the pharmacy website, there will be a specific section related to healthy lifestyles, public health campaigns, medication related FAQs, self-care advice and condition-related FAQs*. ….."

7.89 In SOP 057 Healthy Living and Health Campaigns the Applicant states:

7.89.1 *There are 3 main ways that a patient can be identified, which include through engagement, passively or via the dispensing process*.

7.89.2 *Passive – Identification of the patient has occurred as a result of a non-face to face interaction between a member of pharmacy staff and the patient, where the patient has not actively been looking for assistance, for example smoking status determined as a result of completing an NMS consultation, revealed as a result of the pharmacist asking the patient*.

7.89.3 *Via Engagement – Patients who have chosen to fill in the 'lifestyle questionnaire' provided by the pharmacy to all patients when they have their prescriptions dispensed by Newton Pharmacy. This questionnaire includes sections such as: smoking status, how much alcohol is drunk on average in a week, how much exercise they do per week on average, weight, height, and pre-existing medical conditions. This questionnaire is available on the website and can be returned via pre-paid postage or email. In addition, a printed questionnaire is provided to each new patient (upon their first dispensing) and then yearly thereafter for patients, which can be returned via email or in the prepaid envelope. Patients are identified from the completed questionnaires and contacted via phone to follow up the results and offer support and*

associated information. Results and consultations must be uploaded to the PMR.

7.89.4 *Dispensing/Repeat Dispensing – Where the dispensing/repeat dispensing of a prescription identifies a patient as having diabetes for example. Staff must record the information provided on the PMR*.

7.89.5 *Any patient that is identified that they would benefit from healthy living/lifestyle advice must be recorded and information relevant to them must be provided*.

7.89.6 *Records of advice and support given/provided must be recorded on the PMR. Where verbal advice is given over the phone/video call, written advice (sent via post or email) should be provided (if consent has been obtained to do so*)

7.89.7 *Printed leaflets will be provided with the patients prescription which is delivered/couriered to the patient. Patients identified as or at risk of having certain conditions such as hypertension, diabetes, asthma, smokers, overweight patients for example will also receive targeted resources via email and printed resources with their prescription*.

7.89.8 *Healthy living and lifestyle promotion will be provided on the website in the Healthy Living and Promotion section of the website*."

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

7.91 In SOP 057 Healthy Living and Health Campaigns the Applicant states:

7.91.1 "*Patients will be made aware of all campaign-based services and healthy living resources via nonface- to-face methods, for example updates on the website, printed materials and information in prescription bags that are to be delivered to the patient, SMS (with consent) for example. Help and support will be available on the website, which is clearly available when you first access the website so all patients regardless of location are able to see the health promotion, campaigns etc at all times*.

7.91.2 *Newton Pharmacy will take part in national health campaigns to support and promote public health messages to patients everywhere in England. The terms of service require participation in up to 6 campaigns per financial year, but we will take part in all campaigns that are possible. Printed leaflets will be sent with prescriptions to be delivered/couriered to patients during specific targeted campaign periods. The Healthy Living and Promotion section of the website will also be updated to provide additional resources and support for that specific campaign*."

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

Prescription linked intervention

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

7.94 The Committee noted SOP 057 as quoted above and, in addition, the Applicant states:

7.94.1 ""*Where the pharmacy identifies a patient (via the above processes) that*:

7.94.1.1 *Has diabetes*,

7.94.1.2 *Is at risk of coronary heart disease, especially those with high blood pressure, or*

7.94.1.3 *Smokes or is overweight*

7.94.2 *The pharmacy must provide advice via the phone/video call to that patient with the aim of increasing that person's knowledge and understanding of the health issues with are relevant to that persons personal circumstances. The advice given must be backed up by providing written material (for example printed leaflets with their prescription) or information leaflets emailed to the patient and refer the patients to at least 2 other sources of information and advice. All staff members have training on this area. The staff member must fill in the 'referral and intervention' book so that follow up care can be provided via non face to face methods as well as be able to conduct audits in the provision of advice provided by the pharmacy*."

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

Health campaigns

7.96 The Committee noted Community Pharmacy Lincolnshire states:

7.96.1 "*Compliance with the Healthy Living Pharmacy requirement, which has been a Term of Service since October 2020, is not assured*."

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

7.98 The Committee was mindful of the Applicant's SOP 057 Healthy Living and Health Campaigns extracts of which have been quoted above. The Committee noted the Applicant has described how it will identify patients, participate in campaigns, support patients with long term conditions and complete prescription linked interventions.

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

Signposting

7.100 The Committee noted Community Pharmacy Lincolnshire states:

7.100.1 "*The applicant does not provide assurances regarding signposting*."

7.101 The Applicant in response refers to SOP 058 which it says "*highlights how we are compliant with this particular of the regulations*."

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

7.103 The Committee noted that SOP 58 Self Care, Signposting and Health Promotion states:

7.103.1 "*Signposting*

7.103.2 *Service Description – The provision of information to patients (via remote means) who require further support, advice or treatment which cannot be provided by the pharmacy, on other health and social care providers or support organisations who may be able to assist the person. Where appropriate, this*

may take the form of a referral, alternatively a patient must be given the contact information to be able to access those services.

7.103.3 *Aims and Intended Service Outcomes*

7.103.3.1 *To inform or advice people who require assistance, which cannot be provided by the pharmacy, of other appropriate health and social care providers or support organisations*

7.103.3.2 *To enable people to contact and/or access further care and support appropriate to their needs*

7.103.3.3 *To minimise inappropriate use of health and social care services*. …….

7.103.4 *The patient must be signposted if they require further advice, treatment, or support that the pharmacy cannot provide but we are aware of another provider of health/social care services who is like to be able to provide that advice, treatment, or support. Where that patient is signposted to an alternative provider of health/social care services the patient must be provided with what the service provides as well as their contact details.* ***At least 2 providers*** *should be identified and provided to the patient/representative every time signposting is provided*."

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

Support for self-care

7.105 The Committee noted Community Pharmacy Lincolnshire states:

7.105.1 "*The applicant does not provide assurances regarding support for self-care*."

7.106 In response, the Applicant states:

7.106.1 "*Please refer to SOP 058 which details our process for providing self-care advice*."

7.107 The Committee considered whether the Applicant had explained how it will provide advice and support to people caring for their families by reviewing SOP 058 Self Care, Signposting and Health Promotion which states:

7.107.1 "*Aims and intended service outcomes*:

7.107.1.1 *To enhance access and choice for people who wish to care for themselves or their families*

7.107.1.2 *People, including carers, should be provided with appropriate advice to help them self manage a self-limiting or long-term condition, including advice on and the use of appropriate medicines*

7.107.1.3 *People, including carers, are opportunistically provided with health promotion advice when appropriate, in line with the promotion of healthy lifestyles service*

7.107.1.4 *People, including carers are better able to care for themselves to manage a condition both immediately and in the future, by being more knowledgeable about the treatment options they have, including non-pharmacological ones*

7.107.1.5 *To minimise inappropriate use of health and social care services"*

7.108 The Applicant describes in detail how it will identify patients via engagement, or via the dispensing process, including the use of a patient questionnaire which is available on the Applicant's website.

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

Discharge medicines service

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

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

7.112 The Applicant provided SOP 015 NHS Discharge Medicines Service (DMS) – Essential Service which states:

7.112.1 "*Where a patient has been discharged from hospital or there has been a transfer of care between various NHS providers, we can be asked to conduct a DMS for that patient. It is a 3-stage service, primarily related to the changes in medicines, where queries can be raised with the patient or GP surgery (via remote means).*"

7.113 The SOP explains a step by step process to preparing to provide the service and then three stages

7.113.1 Stage 1 what to do when a discharge referral is received by the pharmacy.

7.113.2 Stage 2 first prescription is received post discharge and

7.113.3 Stage 3 patient engagement to check their understanding of their medication regime following first prescription received post discharge.

7.114 The SOP has an Appendix 1 to cover its procedure on occasions where all stages of the service cannot be provided because either

7.114.1 The patient is uncontactable for different reasons or

7.114.2 Switches to another pharmacy

7.114.3 Or if received in error.

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

Websites and health promotion zones

7.116 The Committee considered whether the Applicant had explained how it will ensure that it has a website for use by the public for the purpose of accessing pharmaceutical services from those premises, on which there is an interactive page, clearly promoted

to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues

7.117 In its application, the Applicant states:

7.117.1 "*The pharmacy website will be available to access 24 hours a day, 365 days a year*."

7.118 The Committee reviewed SOP 058 Self Care, Signposting and Health Promotion which states:

7.118.1 "*We also have an interactive Healthy Living and Promotion zone on our website which provides healthy living advice to patients. This Healthy Living and Promotion zone is clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues*."

7.119 Further, the Applicant has provided some photographs of website shells stating:

7.119.1 "*The website shell attached as part of this appeal, highlights our compliance with the website requirements outlined by the regulations as well as by the GPhC, which includes an interactive healthy living and promotion zone. Please note that this shell is not exhaustive and relevant examples of content have been provided to highlight our compliance. This website contains an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up-to-date materials that promote healthy lifestyles by addressing a reasonable range of health issues. The website will secure and follow information security management guidelines and data protection laws*."

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

7.121 The Committee noted the Appellant and Community Pharmacy Lincolnshire had made a number of comments which each considered required assurances from the Applicant regarding the running of a pharmacy in a distance selling environment. The Committee was mindful that a number of these criteria are not listed under the heading of Essential Service in Part 2 of Schedule 4 of the Regulations. The Committee noted for example that clinical governance is listed in Part 4 of Schedule 4 and relates to all pharmaceutical services provided by a pharmacy which would include essential services. However, it also noted the Applicant had provided information in response as follows.

7.122 Under the heading Regulation 31, the Committee noted the Community Pharmacy Lincolnshire refer to:

7.122.1 "*a discrepancy in the form, particularly regarding the following statement: "Paragraph 2 of Schedule 2 describes what must be included in any routine or excepted application. Sub-paragraph (3)(c) requires the applicant to provide the address of their registered office*. *This is missing from the application form; therefore, we cannot be satisfied this has been provided in any Fitness to Practise declarations, as we are not privy to this separate form*."

7.123 The Committee noted that the Applicant, in its observations had provided a copy of the form which had been redacted and circulated by the Commissioner and also the original form it had sent to the Commissioner.

7.124 Both the Appellant and Community Pharmacy Lincolnshire had requested assurances regarding quality assurance and compliance, risk management, service interruptions, business continuity and clinical governance.

7.125 The Committee noted the Applicant, in Appendix A, had provided several SOPs and documents in this regard including:

7.125.1.1 SOP 103 – Communication

7.125.1.2 SOP – Near Miss

7.125.1.3 Business Continuity Plan

7.125.1.4 Cleaning Matrix

7.125.1.5 Equality Act and Reasonable Adjustments

7.125.1.6 GPhC Registration Screenshot

7.125.1.7 Information Governance Overview

7.125.1.8 Photos of the Pharmacy

7.125.1.9 Practice Leaflet

7.126 The Committee has not quoted information from the above sources as they contain matters over and above the detail it requires to review under the criteria of Regulation 25(2)(b). The Committee was mindful that the information within these documents had been seen by all parties on circulation of representations by NHS Resolution. As such, the Committee was of the view that it had been provided with sufficient information to demonstrate how the Applicant will deal with quality assurance and compliance, risk management, service interruptions, business continuity and clinical governance in respect of the activities raised by the Appellant and Community Pharmacy Lincolnshire.

7.127 Community Pharmacy Lincolnshire, in its observations, states:

7.127.1 "*The applicant's documentation indicates that only employed colleagues are subject to an induction process, while locums are excluded. This contravenes Schedule 4, Part 2, Paragraph 28(e)(i) of the Regulations, which requires that all staff engaged in the provision of NHS services, including locums, are adequately trained and inducted*."

7.128 The Committee noted that the Applicant, in its representations, states:

7.128.1 "*Staff are trained on the specifics of the distance selling pharmacy regulations, in order to comply with the terms of service. All staff (including locums) qualifications and references are verified before working with Newton Pharmacy and staff have a thorough induction, which includes reading all SOPs, risk assessments, terms of service and policies, in addition to specific training (e.g. on remote consultation skills, safeguarding, confidentiality, consent) and a discussion with the Superintendent Pharmacist to ensure that this is all fully understood and to reinforce the specifics of the distance selling pharmacy regulations and terms of service*."

7.129 The Committee was satisfied that this would be no different to that of a traditional bricks and mortar pharmacy and therefore it was satisfied that locum staff were not excluded from training or inductions.

Summary

7.130 On the information before it, the Committee was satisfied that there are procedures likely to secure safe and effective provision of essential services as required by Regulation 25(2)(b).

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

7.131.1 confirm the Commissioner's decision;

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

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

7.132 As the Commissioner made a determination using information that it knowingly had not circulated to interested parties to comment upon and further did not provide reasons in its determination to explain how it had reached its conclusion, the Committee determined that the decision of the Commissioner must be quashed.

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

7.134 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, the information which the Commissioner had omitted to circulate was circulated and representations had been sought from parties on Regulation 25.

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

8 Decision

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

8.2 Accordingly, the Committee:

8.2.1 quashes the decision of the Commissioner; and

8.2.2 redetermines the application as follows -

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

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

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

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

8.2.2.5 the Committee was satisfied that all essential services were likely to be secured in a safe and effective manner,

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

8.2.3 The application is granted.

Case Manager
Primary Care Appeals