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REF: SHA/ 26364

APPEAL AGAINST NHS LINCOLNSHIRE ICB DECISION TO GRANT AN APPLICATION BY DAYTOM GROUP LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 31 LONDON ROAD, GRANTHAM, NG31 6EX UNDER REGULATION 25

1 Outcome

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

1.2 The Committee determined that the application should be refused.

A copy of this decision is being sent to:
Rushport Advisory LLP on behalf of Daytom Group Ltd
PCSE on behalf of Lincolnshire ICB
SPHN&M Ltd

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1 The Application

By application dated 28 May 2024, Rushport Advisory LLP on behalf of Daytom Group Ltd ("the Applicant") applied to Lincolnshire ICB ("the Commissioner") for inclusion in the pharmaceutical list at 31 London Road, Grantham, NG31 6EX under Regulation 25. In support of the application it was stated:

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

1.1.1 *"Drug Tariff part IX* *EXCEPT items that require measuring or fitting."*

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

1.2.1 *"Not applicable as no other pharmacy in same or adjacent premises."*

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

1.3.1 *"Application is not on the same site or in the same building as the premises of a provider of primary medical services with a patient list."*

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

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

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

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

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

1.6 If you are undertaking to provide advanced services at the premises please describe how you will do so without providing any element of essential services.

1.7 “The information contained within this document has been approved by the applicant prior to submission

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

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

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

1.9 **NHS England Premises Standards**

1.10 NHS England has published premises standards that the Pharmacy will comply with, however, it should be noted that not all these standards apply directly to distance selling premises other than where a patient is accessing non-essential services.

1.11 The pharmacy will be a Healthy Living Pharmacy and comply with the change management and organisational development criteria, ensuring premises and facilities are fit for purpose and engaging with the community to deliver consistently high quality health and wellbeing services.

1.12 The pharmacy will be equipped with facilities to allow for both phone (or other live audio link) and live video communication with patients in a manner which maintains patient confidentiality.

1.13 GPhC Guidance

1.14 The Applicant will operate the pharmacy in accordance with current GPhC guidance for registered pharmacies providing pharmacy services at a distance, including on the internet. Current guidance, the content of which is considered and replicated in part below, is not intended to exhaustively replicate the entirety of the GPhC guidance which will be followed.

1.15 The Applicant will have in place, prior to opening the following;

1.16 **Risk Assessment**

1.17 A Risk Assessment document and risk matrix to help identify and manage risks. The risk assessment will look at what could cause harm to patients and people who use the pharmacy services, and what the pharmacy needs to do to minimise risk.

1.18 The risk assessment will be reviewed quarterly and when there are significant business or operational changes.

1.19 **Audit Procedures**

1.20 A regular audit programme will be in place. The audit will be an important part of the evidence which gives assurance that the pharmacy continues to provide safe pharmacy services to patients. Any issues identified will be subject to a reactive review.

1.21 The audit will, at the very least, consider;

1.21.1 staffing levels and the training and skills within the team

1.21.2 suitability of communication methods with patients, and between staff and other healthcare providers, including between hubs and spokes and with collection and delivery points (if applicable)

1.21.3 use of specialised equipment and new technology

1.21.4 records of decisions to make or refuse a sale

1.21.5 systems and processes for receiving prescriptions, including EPS records of decisions to make or refuse a sale (note that our pharmacy SOPs will require more frequent analysis of refusals to sell)

1.21.6 systems and processes for secure delivery to patients

1.21.7 any information about pharmacy services on the website

1.21.8 review of how the pharmacy adheres to the information security policy, Payment Card Industry Data Security Standard (PCI DSS) and data protection law

1.21.9 feedback from patients and people who use our pharmacy services

1.21.10 concerns or complaints received, and

1.21.11 activities of third parties, agents or contractors.

1.22 The Audit and review process will act as a Project Plan for the pharmacy to implement change and upgrades in service and training.

1.23 **Reactive Review**

1.24 A reactive review will take place if an audit identifies a problem, or if there is;

1.24.1 a change in the law affecting any part of the pharmacy service

1.24.2 a significant change in any part of the pharmacy service provided, for example an increase in the number of patients the pharmacy provides services to, or an increase in the range of services the pharmacy intends to provide

1.24.3 a data security breach

1.24.4 a change in the technology the pharmacy uses

1.24.5 concerns or negative feedback are received from patients or people who use the pharmacy services

1.24.6 a review of near misses and error logs causes a concern about an activity.

1.25 **Accountability**

1.26 During opening hours there will always be a responsible pharmacist (RP) on site. Each area of work will have clear lines of accountability that will be set out by the superintendent pharmacist.

1.27 **Record Keeping**

1.28 Records in the pharmacy will be scanned in to the pharmacy IT system (including but not limited to, patient consent forms, queries, complaints, customer logs, sale refusals, and dispensing). Records will be kept for a minimum period of 7 years or longer if specific legislation requires.

1.29 **Training**

1.30 We will ensure that all staff are properly trained and competent to provide medicines and other professional pharmacy services safely. The GPhC has produced guidance to ensure a safe and effective team and this will form the basis of the training.

1.31 **Premises**

1.32 Premises will be registered with the GPhC prior to entry to the pharmaceutical list and will therefore comply with GPhC requirements for pharmacy premises.

1.33 **Website**

1.34 The website will be secure and follow information security management guidelines and the law on data protection. The website will use secure facilities for collecting, using and storing patient details and a secure link for processing card payments.

1.35 The website will display;

1.35.1 the GPhC pharmacy registration number

1.35.2 the name of the owner of the registered pharmacy

1.35.3 the name of the superintendent pharmacist

1.35.4 the name and address of the registered pharmacy that supplies the medicines

1.35.5 details of the registered pharmacy where medicines are prepared, assembled, dispensed and labelled for individual patients against prescriptions (if any of these happen at a different pharmacy from that supplying the medicines)

1.35.6 information about how to check the registration status of the pharmacy and the superintendent pharmacist

1.35.7 details of specific services available and how to use them, ie

1.35.8 Return of unwanted medicines

1.35.9 Patient Lifestyle Questionnaire

1.35.10 How to register exemptions from NHS charges

1.35.11 Promotion of Health Lifestyles and details of campaigns being undertaken

1.35.12 Procedures for Emergency Supply

1.35.13 Explanation of rules on non face to face contact

1.35.14 Patient Information Leaflet

1.35.15 the email address and phone number of the pharmacy

1.35.16 details of how patients and users of pharmacy services can give feedback and raise concerns

1.35.17 GPhC internet logo (linked to register entry)

1.35.18 Where any medicines are sold online, the pharmacy will be registered with the appropriate agency for online pharmacies.

1.35.19 The pharmacy will display any required logo on every page of the website offering medicines for sale, even if they are already displaying the GPhC voluntary logo. The website will be regularly updated, clear and accurate and follow the GPhC guidance on websites.

1.36 The pharmacy will allow the public to access pharmaceutical services from the pharmacy premises via a website 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. NOTE - this is a new requirement under the Regulations and does not allow access to essential pharmaceutical services in a face to face manner at the premises and only applies to access via the website.

1.37 **Transparency and Choice**

1.38 Our website and materials will specify the nature and type of services we provide and who provides those services.

1.39 If any part of our pharmacy services is provided at different locations we will explain clearly to people who use pharmacy services where each part of the service is based.

1.40 **Managing Medicines Safely**

1.41 The pharmacy SOPs will provide the procedures for all staff to follow to ensure that the sale and supply of medicines in carried out in such a manner as to minimise risk to patients.

1.42 **Supplying Medicines Safely**

1.43 The SOPs for delivery of medicines will contain detailed information on the safe and effective supply of medicines via the pharmacy's own driver, Royal Mail and courier firms, including;

1.43.1 assess the suitability and timescale of the method of supply, dispatch, and delivery for all medicines and particularly refrigerated medicines and controlled drugs

1.43.2 ensuring that robust identity check processes are in place to ensure that the medicines dispensed are delivered to the correct person

1.43.3 assess the suitability of packaging (for example, packaging that is tamperproof or temperature controlled).

1.44 The pharmacy will monitor third-party providers, including analysis of patient feedback about deliveries and delivery times and processes.

1.45 **Equipment and Facilities**

1.46 All equipment used in the pharmacy will be sourced from manufacturers that have designed the equipment to be used in the manner in which the pharmacy intends to operate.

1.47 All equipment will be subject to annual performance testing and review, with specialist equipment (such as temperature monitoring) subject to monthly checks.

1.48 IT equipment will meet the latest security specifications and be regularly updated including the use of encrypted networks for wired and wireless communication. Access to records will be dependent on any given employee's level of authority and clearance which shall be determined by the superintendent pharmacist.

1.49 **Standard Operating Procedures**

1.50 If the Committee requires any further information about any aspect of the operation of the pharmacy then the relevant SOP will be provided upon request.

1.51 **PHARMACY SYSTEMS AND PROCEDURES**

1.52 All Essential Services will be delivered in accordance with:

1.53 Company Standard Operating Procedures

1.53.1 NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

1.53.2 NHS Act 2006

1.53.3 Human Medicines Regulations 2012

1.53.4 GPhC – Professional Standards and Guidance on Distance Selling Pharmacies

1.53.5 Relevant Data Protection laws

1.54 This will ensure that the Applicant provides safe, effective and uninterrupted provision of all essential services to persons anywhere in England who request those services during the opening hours of the premises. Essential Services will be provided without face to face contact between anyone receiving the services, whether on their own or someone else's behalf, and the pharmacy staff.

1.55 The Applicant's wholly Internet/Delivery Pharmacy will operate from secure premises, with a controlled entry system, to which members of the public will not have access. Any patient that requests essential services to be provided at the premises will be informed that the pharmacy is not permitted to provide those services at the premises.

1.56 Access to information about the provision of NHS Essential Services will be achieved by using:

1.56.1 Telephone

1.56.2 Live Video Call

1.56.3 The website will enable patients or their carers to communicate remotely but directly allowing quick and easy access and provide clear unambiguous details of how safe, efficient, uninterrupted NHS Essential Services will be provided by the Pharmacist and qualified, knowledgeable, experienced support staff on

duty throughout the opening hours of the pharmacy premises without having 'face to face' contact with the patient or their representative.

1.56.4 Email

1.56.5 Postal services

1.57 All NHS services will be delivered free of charge in accordance with the NHS Act 2006. Essential Services may be delivered using:

1.57.1 Telephone, including text messaging where appropriate

1.57.2 Electronic Prescription Service (EPS)

1.57.3 Website

1.57.4 Email

1.57.5 Royal Mail postal service

1.57.6 Courier service

1.57.7 Specialist Waste Management Services

1.57.8 Live video services.

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

1.58 **Provision of NHS Essential Services**

1.59 **Dispensing Services**

1.60 Prescriptions will be received by the EPS, post, or where practicable, with the patient's informed consent, collected from a surgery. Prescriptions will be clinically and legally assessed to determine if they can be dispensed.

1.61 In the event of any clinical or legal issues with the prescription, the pharmacist will follow Standing Operating Procedures to resolve these issues before dispensing items. This may involve contacting the prescriber as soon as possible to make sure the patient receives their medication without delay.

1.62 When appropriate prescription interventions take place, for example drug/drug interactions, suspected over/under prescribing, etc. the pharmacist on duty will telephone and discuss with the prescriber and patient prior to dispensing or delivering the medication.

1.63 **Repeat Dispensing Services**

1.64 The Terms of Service require pharmacy contractors to ensure that appropriate advice about the benefits of repeat dispensing is given to any patient who—

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

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

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

1.66 Dispensing of repeat NHS prescriptions including those dispensed in dosette boxes as may be required under the Equality Act 2010 will be carried out in partnership with patients, carers, pharmacists and prescribers. It will cover requirements additional to those for dispensing, assessing the patients' need for repeat supply. Any clinical issues identified will be addressed to the prescriber. Where considered necessary by a pharmacist, the patient may be contacted by telephone and given verbal advice in addition to information delivered with the repeat prescription.

1.67 Medicines will only be supplied where the pharmacist is satisfied that the patient is taking and is likely to continue to take the drug appropriately and is not suffering from any side effects which indicate the need or desirability to review the patient's treatment.

1.68 **Urgent Supply and Emergency Supply**

1.69 Whilst the Distance Selling nature of the pharmacy is such that Urgent Supply or Emergency Supply is unlikely to occur as often as in a retail pharmacy, all staff will be aware of the procedures to be followed in the event of such a request.

1.70 The request may be received from a Prescriber (Urgent Supply) or from a Patient (Emergency Supply)

1.71 The following conditions must apply to the request made by a prescriber:

1.71.1 The Pharmacist must be satisfied that the request is from the appropriate authorised prescriber, see list above.

1.71.2 The Pharmacist is satisfied that a prescription cannot be supplied immediately due to an emergency.

1.71.3 The Prescriber agrees to provide a written prescription within 72 hours.

1.71.4 The medication is supplied in accordance with the prescriber's directions.

1.71.5 The medication is permitted to be supplied on an Emergency Supply basis.

1.71.6 An emergency supply cannot be provided for a Schedule 1, 2 or 3 CD except Phenobarbital for epilepsy by a UK registered prescriber.

1.71.7 EEA prescribers cannot request an emergency supply of any Schedule 1 - 5 CD.

1.72 Full records of the supply will be kept as per the relevant SOP.

1.73 The following conditions must apply to the request made by a patient:

1.74 **Interview**

1.75 The Pharmacist must interview the patient. The interview may not be by way of face to face contact and must be by other means, e.g., telephone, Skype.

1.76 **Records**

1.77 An entry must be made in the POM register on the day of supply and record all the relevant details. The label for the dispensed medicine must contain the words “Emergency Supply”.

1.78 **Faxed Prescriptions**

1.79 A ‘faxed prescription’ or other forms of scanned prescriptions do not fall within the definition of a legally valid prescription because it is not written in indelible ink, and has not been signed by an appropriate practitioner. A faxed / scanned prescription can confirm that at the time of receipt a valid prescription is in existence, but no medicines should be supplied until the original prescription is received.

1.80 The pharmacist should not dispense against faxed prescriptions and instead should use the Emergency Supply procedures.

1.81 **Delivery of Urgent Supplies**

1.82 Given the nature of a request of this type, the Pharmacy will prioritise delivery of the medication to the patient. For local deliveries the driver should be specially informed of the fact that the items are “URGENT” and for any items delivered by courier the courier will be informed that items must be delivered ASAP by the quickest route possible. The Pharmacy will not charge additional fees to the patient even if these are incurred in the delivery process. Other than noting the urgent nature of the delivery, normal delivery procedures will apply.

1.83 **Disposal of Unwanted Medicines**

1.84 Patients will have a number of options for disposal of unwanted medicines.

1.84.1 A specialist waste management company will provide safe and secure disposal of unwanted medicines by collection of unwanted medicines from patients and residential homes.

1.84.2 Patients wishing to return unwanted medicines to the pharmacy may do so by courier, which will be provided and paid for by the pharmacy.

1.84.3 Patients in locality may contact pharmacy by phone or email to arrange collection of unwanted medicines from their home or work by pharmacy staff.

1.85 Appropriate packaging will be sent to patients in advance and details of the service and how to book a collection will be available on the Pharmacy website.

1.86 Upon return to the pharmacy unwanted medicines will be sorted and placed in disposal units ready for waste management services to collect. The disposal service will be advertised on the website and any marketing leaflets.

1.87 **Promotion of Healthy Lifestyles**

1.88 Identification of patients for promotion of healthy lifestyles can take two forms, namely, passive or active.

1.89 **Active patients** will be those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further information should be sent, or who should be called to follow up on the results and offer additional support and information.

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

1.91 All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight and also lifestyle questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.

1.92 Leaflets will be delivered to patients with their medication. Those identified (Active or Passive) as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns to increase the patient's knowledge and understanding of health issues relevant to them. The website will also be used to promote healthy lifestyles.

1.93 **Health Campaigns**

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

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

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

1.96.1 clinical audit carried out in a manner which is compatible with the ICB's arrangements for the receiving and processing of data from the audit, or

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

1.97 **Signposting and Support for Self-Care**

1.98 Patient will be signposted to health and social care providers and/or any other assistance available whenever necessary. To assess whether patients require advice to minimise inappropriate use of health or social care services the pharmacist will use the same "Active and Passive" assessment tool already set out above.

1.99 Where it appears to the pharmacist, after reviewing the assessment and having regard to the need to minimise inappropriate use of health and social care services and of support services, that a person using the pharmacy would benefit from advice to help manage their medical condition then advice will be provided via non face to face methods of communication and this will include advice on both treatment options, non prescription medicines and lifestyle advice.

1.100 If a patient;

1.100.1 requires advice, treatment or support that the pharmacy cannot provide; but

1.100.2 another provider, of which the pharmacy is aware, of health or social care services or of support services is likely to be able to provide that advice, treatment or support,

1.101 The pharmacy will provide contact details of that provider to that person and will, in appropriate cases, refer that person to that provider.

1.102 **Referral for Certain Appliances**

1.103 Where, on presentation of a prescription form or repeatable prescription, the pharmacy is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within the pharmacy's normal course of business, the pharmacist will—

1.103.1 if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; and

1.103.2 if the patient does not consent to a referral, provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the pharmacist.

1.104 In appropriate cases, the pharmacist will keep and maintain a record of any information given or referral made to facilitate auditing and follow up care.

1.105 **Support for People with Disabilities**

1.106 This service will be provided in accordance with the Equality Act 2010. The Applicant will make reasonable pharmaceutical adjustment to ensure that those who qualify for help under the Act are provided with the right compliance aids.

1.107 The Applicant will conduct an initial assessment with the patient, care or representative to assess the support required to improve medication compliance. Such assessments will be carried out without patients having to access the pharmacy premises, so that no face-to-face contact at the premises will take place.

1.108 Compliance aid systems such as blister packs/dosette boxes will be provided in compliance with both service levels 1 & 2 respectively.

1.109 **Clinical Governance**

1.110 **Note: Clinical Governance is not an 'essential service' and is therefore dealt with briefly in this submission.**

1.111 The Applicant will be involved in and comply with all the components of clinical governance including, but not limited to, compliance with standard operating procedures, patient safety incident and near miss reporting, demonstrating evidence of Pharmacist and Pharmacy Technician CPD, conducting clinical audits, workforce survey and drug recalls.

1.112 'How to Make a Complaint or compliment' will be displayed and downloadable from the pharmacy website or upon request by telephone or post a copy will be posted.

1.113 All staff will be qualified or undergoing nationally accredited training. They will be competent to deliver the highest standards of Clinical Governance. All staff will receive individual and collective training, development and education provided in-house or from accredited external providers.

1.114 All staff will have an annual appraisal, receive and provide feedback.

1.115 **Information Governance**

1.116 The pharmacy will be registered and comply with Data Protection Act and the General Data Protection Regulations (GDPR) . It will also comply with the Access to Health Records Act 1990. All patient data will be kept private and confidential in accordance with NHS and legal obligations on data security, protection and confidentiality.

1.117 The pharmacy will receive support from the PMR provide to ensure that continuous access to the Electronic Prescription System is maintained.

1.118 Two members of staff will have the ability to login to the PMS system on all days (where there are 2 or more staff members working) and the NHS mail system will be checked every day for both general emails and also for any referrals under the Discharge Medicines Service.

1.119 **Discharge Medicines Service ("DMS")**

1.120 When NHS patients are discharged from hospital or there is, for other reasons, a transfer of care of them between different providers of NHS services, community pharmacies may be asked to perform a three stage service in respect of the patient, principally linked to changes in medication. The second and third stages of this service are linked to the first prescription presented post-discharge or post-transfer. Issues of concern may be raised by the pharmacy contractor not only with the patient or their carer but also with their general practitioner.

1.121 Under the DMS the pharmacy must provide assistance and support to, and in respect of, an NHS patient:

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

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

1.122 The service allows and requires the pharmacy to help not only the patient directly, but also (within the bounds of confidentiality) their carers and also provide them with assistance and support.

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

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

1.125 If the DMS referral requesting that the pharmacy provides the DMS includes circumstances in which the pharmacy is not to provide, or is to cease to provide the DMS service, then the Pharmacy is not to, or is to cease to, provide the DMS in those circumstances (for example, X's or Y's admission or re-admission to hospital).

1.126 **Pandemic Treatment Protocol ("PTP")**

1.127 The pharmacy will provide medicines properly requested under any PTP arrangements.

1.128 The RP should (and if requested to do so by the person being supplied must)

1.128.1 Provide an estimate of the time the drug will be ready and delivered.

1.128.2 If the drug is not ready by the time then provide a revised estimate of when the drug will be ready and continue to update the patient on this time should the estimate change.

1.128.3 Contact the patient to confirm dispatch of the medication.

1.129 In addition to the normal requirements, the dispensing label on the packaging of the product supplied must also contain the additional wording shown below;

1.130 THIS PRODUCT IS BEING SUPPLIED IN ACCORDANCE WITH THE [INSERT NAME] PANDEMIC TREATMENT PROTOCOL.

1.131 And insert the name of the relevant protocol.

1.132 Refusal to Supply under PTP

1.133 The pharmacy may refuse to provide an order for a drug that is or is purportedly in accordance with a PTP where—

1.133.1 The RP reasonably believes it is not a genuine order for the person who requests ,or on whose behalf is requested, the provision of the drug;

1.133.2 providing it would be contrary to the RP's clinical judgement;

1.133.3 The RP or other persons are subjected to or threatened with violence by the person who requests the provision of the drug, or by any person accompanying (see footnote re "accompanying") that person; or

1.133.4 the person who requests the provision of the drug, or any persona accompanying (see footnote re "accompanying") that person, commits or threatens to commit a criminal offence.

1.134 The pharmacy must refuse to provide, pursuant to a PTP, an order for a drug that is or is purportedly in accordance with the PTP where P is not satisfied that it is in accordance with the PTP.

1.135 Any refusal to supply must be noted on the patient and / or pharmacy record system.

1.136 **Delivering Medicines**

1.137 The Responsible Pharmacist (RP) has overall responsibility for ensuring the delivery of medicines to intended patients. Medicines must be delivered safely and with appropriate instructions.

1.138 The RP must take adequate measures to ensure that the delivery mechanism used is secure and that medicines are delivered to the intended user promptly, safely, and in a condition appropriate for use. If the delivery to patients is local, this will be undertaken by the delivery driver except fridge lines which must be sent by courier. All other nationwide deliveries (other than fridge lines) will be delivered by Royal Mail special delivery or courier and signed for by the patient, their notified carer or other patient authorised representative. Fridge Lines will be delivered by courier (see further below).

1.139 Medicines will be packed, transported and delivered in such a way that their integrity, quality and effectiveness are preserved. The delivery mechanism used will provide a verifiable audit trail for medicine from the initial request through to its final delivery, or its return to the pharmacy in the event of a delivery failure. Packaging must maintain patient privacy and confidentiality.

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

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

1.142 Medicine for local delivery which is (A) not fragile and (B) is to be delivered by the delivery driver can be packaged in the using the normal pharmacy bags supplied for standard prescription items.

1.143 Medicines classified as non-flammable or non-toxic must be securely closed and placed in a leak-proof container such as a sealed polythene bag (for liquids) or a siftproof container (for solids). Must be tightly packed in strong outer packaging and must be secured or cushioned to prevent any damage.

1.144 This means that for postal / courier items, either:

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

1.144.2 For most items - bubble wrap and where necessary, polystyrene filler, placed within a cardboard box. Cardboard boxes must be the re-enforced type.

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

1.146 The patient, carer or notified, authorised patient representative must always sign and date a receipt to prove safe receipt of the medicines. A patient who is not at home when delivery is attempted will be informed using a non-delivery notice and an alternative delivery date will be arranged.

1.147 A list of the approved cold chain couriers will be maintained within the Pharmacy. Coldchain items will be stored in styrofoam filled cardboard boxes prior to being passed to the courier and marked with the “FRAGILE” and “FRIDGE LINE” stickers. Additional packing will not be required as the courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box and are fully monitored. Some thermolabile products can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in medicines which is damaging to them and will therefore not be used in direct contact with any medicine. The courier service will be a dedicated, fully monitored and temperature controlled delivery service. Any breach of the cold chain will be automatically notified to the driver who will then follow the failed

delivery procedure and notify the pharmacy accordingly so that re-delivery can be arranged. Where the cold chain breach notice is issued items will not be re-used.

1.148 **Controlled Drugs**

1.149 **Delivery of Controlled Drugs**

1.150 There is provision within controlled drugs legislation to cover occasions when a controlled drug (CD) may temporarily be in the possession of a third party, e.g. a delivery person or postal carrier, while it is being transferred from one authorised person to another authorised person who is entitled to be in possession of the drug. Delivery of CD will be carried out by couriers with pharma grade specialist facilities to meet specific quality and validation requirements for healthcare products. This includes Home Office licensed controlled drug stores.

1.151 **Return and Destruction of CONTROLLED DRUGS**

1.152 Appropriate packaging will be sent to patients in advance with instructions for packaging any returned medicines and this will be provided and paid for by the pharmacy. The Superintendent Pharmacist will specify the appropriate method of collection depending on the items being returned and the distance from the pharmacy. Patients may also be signposted to alternate pharmacies if they prefer to return medicines to a different pharmacy. Any ‘returned’ Controlled Drugs must not be re-used or entered into the CD register. The Applicant will denature and render them irretrievable as soon as possible in order to avoid storage problems and an increased security risk.

1.153 Destruction must be witnessed by another member of staff. If not immediately destroyed, they should be segregated from main stock, clearly marked 'Patient Returns' to minimise the risk of errors and inadvertent supply and stored securely in a CD Cabinet waiting to be denatured. A record of destruction will be recorded in a separate CD Destruction Register designated for this purpose and will be available in the pharmacy for inspection.

1.154 **Cover for Breaks / Working Time Directive**

1.155 Any breaks in working time taken by the RP will be covered by a second pharmacist who will then assume the responsibility of the RP.

1.156 **Contingency Planning**

1.157 The Applicant will have accounts direct to pharmacy manufacturers and many full-line and short-line pharmaceutical wholesalers to try and increase the availability of stock and reduce Owings. A Contingency Plan will be in place to ameliorate the effects of any disruption to provision of pharmaceutical services such as medicines shortage, postal strike, EPS systems failure, etc.

1.158 **Verification of Declarations of Prescription Exemptions**

1.159 The reverse of the prescription should be fully completed (other than age exempt patients) in black ink.

1.160 Where evidence of exemption is required or provided by the patient it can be sent to the pharmacy for verification via the delivery driver and then returned to the patient. The PMR system should be updated to reflect that necessary check has been carried out and a note of when the next check is required should be entered onto the system. The Regulations require a patient to produce ‘satisfactory evidence’ to confirm

exemption. Where appropriate (ie for deliveries made other than by the pharmacy's delivery driver), the patient may scan copies of the evidence to the pharmacy (or use the postal / courier service, but see NOTE below) and the pharmacy can record that the evidence provided was not in the original format. It is for the pharmacist in charge to determine if the evidence is satisfactory or not and, if not, then cross the 'Evidence not Seen' box.

1.161 The type of exemption and date of expiry will be recorded in their Patient Medication Record. If they are not exempted prescription charge payments will be made using a secure on-line payment method.

1.162 Exemptions may be sent to the pharmacy by post and the pharmacy will pay for postage and return the exemption to the patient free of charge. Scanned email copies of exemptions are also acceptable. The nature of any exemption will be recorded on the PMR system with a copy attached to the patient's file.

1.163 Payment for prescription charges will be received via the secure payment portal on the website and when payment is received the prescription will be marked as paid.

1.164 **Pharmacy Profile**

1.165 The pharmacy profile will be properly maintained in the NHS Digital Directory of Services

1.166 **Central Alerting System**

1.167 The pharmacy will maintain access to the MHRA Central Alerting System using the premises specific NHS mail email address which will be checked on a daily basis**.**

1.168 **Registration of the Premises with the GPhC**

1.169 It is not lawful to operate a Pharmacy without registering the premises and Superintendent Pharmacist with the GPhC. The Applicant will apply to register the premises with the GPhC following the grant of an NHS Contract application. The GPhC will send an inspector to inspect the premises for approval before commencement of any Pharmacy services. The GPhC has a team of inspectors who undertake the routine monitoring and inspection of premises.

1.170 **Practice Leaflet**

1.171 Nothing in the Applicant's practice leaflet, or publicity material in respect of the listed chemist premises, in material published on behalf of the Applicant publicising services provided at or from the listed chemist premises or in any communication (written or oral) from the Applicant or the Applicant's staff to any person seeking the provision of essential services will represent, either expressly or impliedly, that—

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

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

1.172 **Advanced or Enhanced Services**

1.173 The pharmacy will only offer services that can be delivered remotely and do not require patients to attend the premises."

1.174 [A floor plan was also provided, see appendix A].

2 **The Decision**

The Commissioner considered and decided to grant the application. The decision letter dated 7 October 2024 states:

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

2.1 "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 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 "Fitness to Practice was not applicable as the applicant is already included in the respect of other practices

2.6 The proposed premises are not in a controlled locality.

2.7 **Regulation 25 – Distance Selling Premises Application**

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

2.8.1 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.

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

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

2.9 **Daytom Group Ltd will provide the following advanced service.**

2.9.1 New Medicines Service (NMS)

2.10 **Regulation 31 – Refusal; same and adjacent premises**

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

2.12 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.

2.13 **Regulation 64 – Distance selling premises: specific conditions**

2.13.1 the committee deemed this regulation to have been met.

2.14 **Regulation 66**

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

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

2.16.1 Provide the directed services mentioned in the application and

2.16.2 Not withhold agreement to a service specification for those services unreasonably.

2.17 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).

2.18 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.

2.19 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.

2.20 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.

2.21 **Appeal Rights**

2.21.1 St Peter's Hill Pharmacy

2.22 **No appeal rights**

2.22.1 Lincolnshire HWB

2.22.2 Lincolnshire LPC

2.22.3 Lincolnshire LMC

2.22.4 Lincolnshire Healthwatch”

3 The Appeal

In a letter dated 25 October 2024, SPHN&M Ltd t/a St Peter’s Hill Pharmacy (“the Appellant”) 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 Daytom Group Ltd (CAS-310722-H6L4N5) because we feel our comments were not sufficiently addressed regarding the application for a Distance Selling Pharmacy made by Daytom Group 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 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

This is a summary of representations received on the appeal.

4.1 Rushport Advisory LLP on behalf of the Applicant

4.1.1 “I act for Daytom Group Ltd in the above application and have been instructed to submit this response to the above listed appeal.

4.1.2 The Appellant raises no specific reasons for their appeal other than saying that the Applicant should have provided more information to support their application.

4.1.3 My client has therefore instructed me to submit the attached SOPs [appendix B] which describe how my client will meet all parts of the legal test.

4.1.4 We look forward to hearing from you in due course."

4.2 The Commissioner

4.2.1 "Thank you for your letter dated 07 November 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) and 25(2) quoted in full].

4.2.3 The application by Daytom Group 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.

4.2.4 The nearest provider of primary medical services with a patient list is a 3-minute drive from the proposed premises (approximately 0.1 miles away) and therefore the application could not be refused on this element of regulation 25.

4.2.5 The applicant is not seeking to restrict the provision of essential services in any way. The applicant provided a list of Standard Operating Procedures (document titled 'Further Information in Relation to Provision of Essential Services in Accordance with the Regulatory Requirements for Distance Selling Pharmacies') which outlines how they will deliver medication to patients across the country, including details of postal services, courier services and cold chain courier services (which additionally details how the cold courier service ensures the medicines will remain at the correct temperature until they are delivered to the patient). The applicant has also specified the process in which Disposal of Unwanted Medicines is proposed to be completed, and the options available to the patient to return these medicines in a method which is best suited to them.

4.2.6 The applicant outlined in their Standard Operating Procedure document how they would provide essential services to patients without face-to-face contact and has outlined how they will utilise online resources via their website primarily to support patients with Promotions of Healthy Lifestyles, and via email and text (with consent) for Health Campaigns. The applicant has provided assurance on how they will provide services to people with disabilities in line with the Equality Act 2010 and how they will support patients with the dispensing of appliances they may not be able to provide such as Stoma appliances.

4.2.7 Additionally, the applicant provided a floor plan of the proposed premises which indicated a private consultation room from which the Pharmacist can virtually offer essential services and any enhanced or advanced services to patients.

4.2.8 The applicant provided response to representations received by St Peter's Hill Pharmacy, Boots UK Limited and Lincolnshire County Council and provided clarity on all of the comments made by interested parties supplying representation.

4.2.9 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.

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

4.2.11 [Regulation 31(1) and 31(2) quoted in full].

4.2.12 The application could not be refused with regards 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:

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

4.2.14 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).

4.2.15 We hope this satisfies any outstanding queries regarding this application but would welcome the opportunity to respond to any further representations should they arise."

4.3 The Appellant

4.3.1 "We are writing to further elaborate on our objections to the proposed application in relation to a distance selling pharmacy above, emphasizing the applicant's inability to fulfill [sic] the necessary criteria set out under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations"). Following a detailed review, we have identified several critical shortcomings in the application, which we respectfully ask the panel to take into account when deciding to decline the proposal.

4.3.2 Proposed Two-Tier Delivery System Violates Regulations

4.3.3 The applicant's proposed delivery model suggests a two-tiered system that raises serious concerns about the equitable provision of services. This arrangement would result in inconsistent service levels across England, potentially disadvantaging certain patients and undermining equal access to pharmaceutical care. Despite raising this issue previously, neither the applicant nor the committee has adequately addressed or resolved it. This ongoing non-compliance with the requirement for equitable service delivery remains a significant concern under the Regulations.

4.3.4 Induction Process Fails to Meet Compliance Standards

4.3.5 The applicant's documentation indicates that locum staff are excluded from their induction process, in breach of Schedule 4, Part 2, Paragraph 28(e)(i) of the Regulations. This omission demonstrates a failure to ensure that all staff involved in the delivery of NHS services, including locum pharmacists, are properly trained and inducted. Such non-compliance compromises the quality and safety of the services provided, putting patient trust and care at risk.

4.3.6 Lack of Continuity of Services During Responsible Pharmacist Absence

4.3.7 The applicant's Standard Operating Procedures (SOPs) raise substantial concerns about the continuity of services in the absence of the Responsible Pharmacist (RP):

4.3.8 SOP002: The absence of a second pharmacist taking on the RP role during the permitted absence of the RP prevents the pharmacy from legally carrying out essential activities such as clinical checks, dispensing prescriptions, and delivering advanced services like NMS. This violates the Regulations' requirement for uninterrupted provision of essential services.

4.3.9 SOP033: This SOP explicitly states that controlled drugs (CDs) cannot be processed or delivered during the RP's absence, further underscoring the pharmacy's inability to meet its regulatory obligations under Schedule 4.

4.3.10 These procedural gaps highlight the applicant's inability to ensure the continuous provision of services, as required by the Regulations.

4.3.11 Inconsistencies and Omissions in Refusal of Supply Procedures

4.3.12 SOP010: The inconsistencies in the language used in sections (c) and (d) regarding refusal of supply due to threats or criminal activity reveal a lack of clarity and practicality in implementing these procedures.

4.3.13 Additionally, the applicant has failed to clearly state their intention to dispense appliances as required in their original application, thereby breaching Schedule 4, Part 2, Paragraph 12. This omission casts serious doubt on their ability to meet the regulatory requirements for the provision of appliances.

4.3.14 Inability to Deliver Equitable Access to Essential Services

4.3.15 The deficiencies outlined above demonstrate that the applicant is unable to provide essential services to patients across England in a manner that is uninterrupted, equitable, and compliant with the Regulations. This inability undermines the fundamental purpose of a distance selling pharmacy and directly contravenes the standards set out in the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

4.3.16 Conclusion

4.3.17 In conclusion, the applicant has failed to demonstrate adherence to critical regulatory requirements. Their proposed delivery model, inconsistent SOPs, and inadequate staff training processes collectively highlight an inability to deliver equitable, uninterrupted, and high-quality pharmaceutical services. These significant shortcomings pose unacceptable risks to patient care and safety.

4.3.18 We respectfully request the panel to reject this application based on the substantial and unresolved issues outlined above.

4.3.19 Thank you for considering our objections. We trust that the panel will prioritize the welfare and safety of patients when making its decision."

5 Summary of Observations

This is summary of observations received.

5.1 Rushport Advisory LLP on behalf of the Applicant

5.1.1 "I act for Daytom Group Ltd in the above application and have been instructed to submit this response to the comments from interested parties on my client's appeal, specifically those from St Peter's Hill Pharmacy.

5.1.2 Using the same paragraph numbering as used by St Peter's Hill Pharmacy we reply as follows.

5.1.3 The pharmacy will use the most appropriate delivery method for each patient and what will be appropriate will depend on individual circumstances and is properly set out in the SOPs.

5.1.4 An induction process is a process used for new members of staff and does not apply to locums who are not employees.

5.1.5 It is unclear which SOP is being referred to and it may be that the Appellant has copied comments from a different appeal. The SOPs deal properly with any planned /unplanned or emergency absence.

5.1.6 It is unclear which SOP is being referred to and it may be that the Appellant has copied comments from a different appeal. The SOPs deal properly with any refusal to supply and my client will not be providing Appliances that require measuring or fitting.

5.1.7 The comments from the Appellant are simply incorrect and refuted."

6 Consideration

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

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

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

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

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

(b) NHS England is satisfied that it is reasonable to treat the services that the applicant proposes to provide as part of the same service as the existing

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

6.6 The Committee noted that the Applicant, in its application form, had stated *"Not applicable as no other pharmacy in same or adjacent premises".* In the decision letter, the Commissioner stated that *"Regulation 31 does not apply as the proposed pharmacy will not be adjacent or in close proximity to an existing pharmacy premises. 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."* The Committee noted this had not been disputed by any party.

6.7 The Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

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

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

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

Regulation 25(2)(b)

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

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

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

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

forward has taken the form of the original application, representations on the appeal and the SOPs which the Applicant has prepared or commissioned.

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

6.17 The Committee noted that the Appellant states *"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."* The Committee considered that the Appellant's grievance was cured on appeal whereby the Appellant had the opportunity to submit its grounds of appeal and other representations.

6.18 The Committee considered how the Applicant would provide essential services without interruption and noted the following raised by the Appellant in its appeal:

"The applicant's Standard Operating Procedures (SOPs) raise substantial concerns about the continuity of services in the absence of the Responsible Pharmacist (RP):

SOP002: The absence of a second pharmacist taking on the RP role during the permitted absence of the RP prevents the pharmacy from legally carrying out essential activities such as clinical checks, dispensing prescriptions, and delivering advanced services like NMS. This violates the Regulations' requirement for uninterrupted provision of essential services.

SOP033: This SOP explicitly states that controlled drugs (CDs) cannot be processed or delivered during the RP's absence, further underscoring the pharmacy's inability to meet its regulatory obligations under Schedule 4."

6.19 In response the Applicant states *"It is unclear which SOP is being referred to and it may be that the Appellant has copied comments from a different appeal. The SOPs deal properly with any planned / unplanned or emergency absence."*

6.20 The Committee noted the information in the Applicant's SOPs under the following headings:

6.21 SOP 1: "Introduction and Background to SOPs"

6.21.1 *"1.3 Overriding Provisions Applicable to All SOPs*

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

The uninterrupted provision of essential services, during the opening hours of the premises."

6.22 SOP 31: "The Responsible Pharmacist"

6.22.1 *"31.9 Absence of the RP*

As a Distance Selling pharmacy, we must provide uninterrupted service throughout the opening hours of the pharmacy. For this reason, the RP is not

allowed to leave the premises in the same way as an RP at a non-Distance Selling pharmacy is allowed to (for up to 2 hours per day) unless another pharmacist is present.

The Pharmacy will have a second pharmacist available during the core and any additional hours that it operates. If, for any reason, the RP is required to leave the premises or wishes to take a break (as per Working Time Directive) then the second pharmacist must sign in as the RP."

6.23 SOP 32: "Preparing for the absence of the RP"

6.23.1 *"32.1 During the absence of the RP*

All of the pharmacy team must adhere to the pharmacy procedures set down by the RP.

Monitor the time that the RP has been absent.

If the absence exceeds 2 hours:

The second pharmacist must assume the role of RP and the Superintendent Pharmacist should be contacted and informed that there is only one pharmacist on duty.

The pharmacy must contact the RP for additional instructions and the estimated time of return."

6.24 The above extract at 6.23 raised some concerns for the Committee as it contradicted 6.22. The Committee noted SOP 31.9 states *"As a Distance Selling pharmacy, we must provide uninterrupted service throughout the opening hours of the pharmacy. For this reason, the RP is not allowed to leave the premises in the same way as an RP at a non-Distance Selling pharmacy is allowed to (for up to 2 hours per day) unless another pharmacist is present."* Whereas SOP 32.1 states *"Monitor the time that the RP has been absent…If the absence exceeds 2 hours…The second pharmacist must assume the role of RP and the Superintendent Pharmacist should be contacted and informed that there is only one pharmacist on duty."* SOP 31.9 suggested to the Committee that the Responsible Pharmacist must not leave the premises unless another pharmacist is present to assume that role. However SOP 32.1 outlines what would happen in the event that the Responsible Pharmacist is absent. This suggested to the Committee that during a two hour period, a Responsible Pharmacist would not be present, meaning the Applicant would be unable to provide all essential services in line with the Regulations.

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

6.26 With regard to services being available to persons anywhere in England, the Committee noted the information in the Applicant's SOPs under the following headings:

6.27 SOP 1: "Introduction and Background to SOPs"

6.27.1 *"1.3 Overriding Provisions Applicable to All SOPs*

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

6.28 SOP 3: "Procedures for NHS Essential Services"

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

6.29 The Committee considered how the Applicant would provide essential services without face to face contact and noted the information in the Applicant's SOPs under the following headings:

6.30 SOP 1: "Introduction and Background to SOPs"

6.30.1 *"1.3 Overriding Provisions Applicable to All SOPs*

In order to comply with our terms of service, this pharmacy will provide; The safe and effective provision of 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 owner of this pharmacy or any member of staff either on or in the vicinity of the premises…

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

Face to face contact with patients or their representatives either at the premises is only allowed in respect of the provision of services other than Essential Services.

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

6.31 SOP 3: "Procedures for NHS Essential Services"

6.31.1 *"3.1 Communication Channels*

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

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

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

6.33 The Committee was satisfied that the provision of services would be without face to face contact and would be available to persons anywhere in England. However, based on the information provided, the Committee could not be satisfied that the provision of services would be without interruption.

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

6.35 The Committee was mindful of the Appellant's comment in their representations when considering each essential service in paragraphs 3 to 22 of schedule 4 of the Regulations ("Terms of Service") *"The deficiencies outlined…demonstrate that the applicant is unable to provide essential services to patients across England in a manner that is uninterrupted, equitable, and compliant with the Regulations. This inability undermines the fundamental purpose of a distance selling pharmacy and directly contravenes the standards set out in the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013".*

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

6.36.1 Dispensing of drugs and appliances

6.36.2 Urgent supply without a prescription

6.36.3 Preliminary matters before providing ordered drugs or appliances

6.36.4 Providing ordered drugs or appliances

6.36.5 Refusal to provide drugs or appliances ordered

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

6.36.7 Disposal service in respect of unwanted drugs

6.36.8 Promotion of healthy lifestyles

6.36.9 Prescription linked intervention

6.36.10 Health campaigns

6.36.11 Signposting

6.36.12 Support for self-care

6.36.13 Discharge medicines service

6.36.14 Websites and health promotion zones

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

Providing ordered drugs or appliances

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

6.39 In the Applicant's SOPs, the Committee noted the following:

6.40 SOP 17: "Order Delivery"

6.40.1 *"17.6 Choice of Delivery Method*

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

6.40.3 *"17.14 Delivery of a prescription via Royal Mail (Not for Cold Chain or CDs)*

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

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

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

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

Confirm details of all prescriptions to be delivered.

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

Ensure Royal Mail driver signs Delivery Log sheet for all prescriptions being accepted for delivery. Store Delivery Log sheet for a minimum of 3 months from dispatch date.

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

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

6.40.4 *"17.16 Cold chain delivery via courier*

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

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

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

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

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

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

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

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

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

Confirm details of all prescriptions to be delivered.

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

6.40.5 *"17.17 Unsuccessful cold chain delivery via courier*

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

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

6.40.6 *"17.18 Breach of Integrity of Cold Chain*

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

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

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

6.41 Whilst the Committee noted the information above indicated that cold chain items would be delivered by a specialist courier, it also had regard to 17.10 in which it states:

6.41.1 *"17.10 Transfer to the Delivery Driver*

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

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

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

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

Ensure that any deliveries for fridge items and CDs are taken out of storage when appropriate.

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

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

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

6.42 The Committee was of the view that the above extract at 6.42 was specific to the Applicant's own local delivery driver as there is a separate section for couriers. The Committee was concerned that the statement *"Ensure that any deliveries for fridge items and CDs are taken out of storage when appropriate"* under the heading "Transfer to the Delivery Driver" indicated that the local delivery driver would be handling and delivering cold chain items. As the Committee must be satisfied that the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that the 'cold chain' is maintained), the Committee considered that the wording creates sufficient ambiguity as to the Applicant's intentions. The Committee noted that the Applicant had not provided any information on the process that would be followed for deliveries of cold chain items by its own driver.

6.43 Therefore the Committee could not be satisfied, as it is required to be, that during transit, the cold chain would be monitored throughout, or what would happen in the event of a breach of cold chain or failed/missed delivery by the pharmacy's own driver.

6.44 Based on the information before it, the Committee was not satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

Other considerations

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

6.46 The Committee noted that in response to the question as to whether they were undertaking to provide appliances, the Applicant stated *"Drug Tariff part IX* *EXCEPT*

items that require measuring or fitting." In the Applicant's SOPs, the Committee noted the following under the following headings:

6.47 SOP 7: "Pharmaceutical & Legal Assessment"

6.47.1 *"7.9 Items Requiring Measuring and Fitting*

Where a prescription is received for an item that requires measuring or fitting the patient should be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients should be signposted to at least two other providers of the service in their area. (see signposting SOP).

6.48 SOP 24: "Support for Self-Care, Signposting and Health Promotion"

6.48.1 *"24.14 Items Requiring Measuring and Fitting*

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

6.49 In the event that the application is granted, the Applicant would not therefore, be able to provide such appliances to patients.

6.50 The Committee noted the Appellant's concerns in their representations *"…the applicant has failed to clearly state their intention to dispense appliances as required in their original application, thereby breaching Schedule 4, Part 2, Paragraph 12. This omission casts serious doubt on their ability to meet the regulatory requirements for the provision of appliances"* and noted the response from the Applicant *"my client will not be providing Appliances that require measuring or fitting".*

6.51 Given the information outlined at 6.46 to 6.48.1, the Committee was satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(4) of Schedule 4.

6.52 The Committee noted the comment made by the Appellant in their representations that *"The applicant's proposed delivery model suggests a two-tiered system that raises serious concerns about the equitable provision of services. This arrangement would result in inconsistent service levels across England, potentially disadvantaging certain patients and undermining equal access to pharmaceutical care. Despite raising this issue previously, neither the applicant nor the committee has adequately addressed or resolved it. This ongoing non-compliance with the requirement for equitable service delivery remains a significant concern under the Regulations".* The Committee noted the response from the Applicant states *"The pharmacy will use the most appropriate delivery method for each patient and what will be appropriate will depend on individual circumstances and is properly set out in the SOPs".*

6.53 It was unclear to the Committee which term of service the Appellant was referring to and, other than the concerns outlined above, it found no reason to refuse the application based on the delivery model proposed by the Applicant in accordance with the Regulations in the context of a distance selling pharmacy.

6.54 The Committee noted the Appellant's comment in their representations *"SOP010: The inconsistencies in the language used in sections (c) and (d) regarding refusal of supply*

due to threats or criminal activity reveal a lack of clarity and practicality in implementing these procedures".

6.55 In the Applicant's SOPs, the Committee noted the following:

6.56 SOP 33: "Repeat Dispensing"

6.56.1 "*33.10 Prescription Reception*

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

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

6.56.2 *33.11 Pharmaceutical & Legal Assessment*

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

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

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

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

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

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

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

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

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

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

6.57 Furthermore, the Committee noted the Applicant's response *"It is unclear which SOP is being referred to and it may be that the Appellant has copied comments from a different appeal. The SOPs deal properly with any refusal to supply".* It was also unclear to the Committee which section the Appellant was referring to as it noted there is no

section (c) and (d) in SOP 10. The Committee did note the "further information document" provided with the application at the top of page 13 has sections (c) and (d) under the heading "Refusal to Supply under PTP" and was of the view that these may be the sections the Appellant was referring to. Notwithstanding the ambiguity regarding the relevant section, the Committee was not persuaded by the argument raised by the Appellant.

6.58 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.

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

Summary

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

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

6.61.1 confirm the Commissioner's decision;

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

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

6.62 Given the Committee has reached a different decision to that of the Commissioner, the Committee determined that the decision must be quashed.

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

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

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

7 Decision

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

7.2 Accordingly, the Committee:

7.2.1 quashes the decision of the Commissioner; and

7.2.2 redetermines the application as follows -

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

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

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

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

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

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

7.2.3 The application is refused.

Case Manager
Primary Care Appeals