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27 May 2025

REF: SHA/26555

APPEAL AGAINST HAMPSHIRE AND ISLE OF WIGHT ICB DECISION TO REFUSE AN APPLICATION BY COLLIMATION LIMITED FOR INCLUSION IN THE PHARMACEUTICAL LIST AT UNIT 3&4, HOME FARM BUSINESS CENTRE, EAST TYTHERLEY ROAD, LOCKERLEY, ROMSEY, SO51 0JT 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:

Collimation Limited
PCSE on behalf of Hampshire & Isle of Wight ICB

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1 The Application

By application dated 5 November 2024, Collimation Ltd ("the Applicant") applied to Hampshire and Isle of Wight ICB ("the Commissioner") for inclusion in the pharmaceutical list at Units 3&4, Home Farm Business Centre, East Tytherley Road, Lockerley, Romsey, SO51 0JT 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 "All items listed in the drug tariff part IX."

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

1.2.1 "n/a"

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

1.3.1 "n/a"

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.

Supporting information provided by the Applicant

1.5 "The information contained within this document has been approved by the Amber Pharmacy prior to submission

1.6 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 Amber Pharmacy or the Amber Pharmacy's staff.

GPhC Guidance

1.7 The Amber Pharmacy will operate the pharmacy in accordance with the “Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet” issued in April 2015.

1.8 Specifically, but not exhaustively, the Amber Pharmacy will have in place, prior to opening.

Risk Assessment

1.9 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 keep the risk as low as possible.

1.10 The risk assessment will include consideration of;

1.10.1 how staff tell patients and the public about the pharmacy services they will receive, and how they get their consent

1.10.2 how staff communicate between different locations (if applicable)

1.10.3 medicines supply, including counselling and delivery

1.10.4 The pharmacy’s capacity to provide the proposed services, and

1.10.5 Business continuity plans, including website and data security

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

Audit Procedures

1.12 A regular audit programme will be in place with initial frequency of quarterly audits. 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.

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

1.13.1 staffing levels and the training and skills within the team

1.13.2 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)

1.13.3 use of specialised equipment and new technology

1.13.4 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)

1.13.5 systems and processes for secure delivery to patients

1.13.6 any information about pharmacy services on the website

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

1.13.8 feedback from patients and people who use our pharmacy services

1.13.9 concerns or complaints received, and

1.13.10 activities of third parties, agents or contractors

1.14 The Audit and review process will act of [sic] a Project Plan for the pharmacy to implement change and upgrades in service and training.

Reactive Review

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

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

1.15.2 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

1.15.3 a data security breach

1.15.4 a change in the technology the pharmacy uses

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

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

Accountability

1.16 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.

Record Keeping

1.17 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.

Premises

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

Website

1.19 The only website used to sell P medicines will be the website associated with the pharmacy.

1.20 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.

1.21 The website will display;

1.21.1 the GPhC pharmacy registration number

1.21.2 the name of the owner of the registered pharmacy

1.21.3 the name of the superintendent pharmacist

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

1.21.5 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)

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

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

1.21.7.1 Return of unwanted medicines

1.21.7.2 Patient Lifestyle Questionnaire

1.21.7.3 How to register exemptions from NHS charges

1.21.7.4 Promotion of Health Lifestyles and details of campaigns being undertaken

1.21.7.5 Procedures for Emergency Supply

1.21.7.6 Explanation of rules on non-face to face contact

1.21.7.7 Annual patient survey

1.21.7.8 Patient Information Leaflet

1.21.8 the email address and phone number of the pharmacy

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

1.21.10 GPhC internet logo (linked to register entry)

1.21.11 The pharmacy will be registered with the Medicines and Healthcare products Regulatory Agency (MHRA) and to be on the MHRA's list of UK registered online retail sellers.

1.21.12 EU common logo

1.21.12.1 The pharmacy will display the new EU common logo on every page of the website offering medicines for sale, even if they are already displaying the GPhC voluntary logo. The registered EU common logo will also be linked to the entry in the MHRA's list of registered online sellers.

Patient Consent

1.22 Patients will be asked to provide informed consent for any pharmacy services that the pharmacy provides to them. Patient consent forms for services will be stored as part of the PMR record created for all patients that use the pharmacy services.

Managing Medicines Safely

1.23 The pharmacy SOPs provide the procedures for all staff to follow to ensure that the sale and supply of medicines in done in such a manner as to minimise risk to patients. The supply or sale of any new medicine must be approved by the superintendent pharmacist as suitable for sale via distance selling.

Supplying Medicines Safely

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

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

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

1.25 Prior to contracting with any carrier the pharmacy will check the terms, conditions and restrictions of the carrier.

1.26 Where any recipient is outside the UK the pharmacy will check the laws covering the export or import of medicines from the UK to that country.

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

Equipment and Facilities

1.28 ll [sic] 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.

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

1.30 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.

Standard Operating Procedures

1.31 The Amber Pharmacy has already developed a draft suite of operating procedures to cover all aspects of the operations of this distance selling contract. If NHS England requires any further information about any aspect of the operation of the pharmacy then the relevant SOP will be provided upon request. We have not provided all SOPs with this application as they contain commercially sensitive material.

1.32 It should be noted that NHS England's national policy document, "Policy for monitoring compliance with the terms of service for pharmacy and dispensing appliance contractors" (published 5 April 2013) contains a section on SOPs that states:

-2.11

"The essential service and clinical governance specifications require pharmacies to have appropriate standard operating procedures for dispensing, repeat dispensing and support for self- care.

Monitoring compliance requires only the determination of whether the pharmacy has an appropriate SOP.

It does not require NHS England to carry out a detailed analysis of the content of the SOPs. Indeed, it would be unwise for an NHS England employee to carry out any detailed examination because he or she will be unable to determine what is appropriate for the individual pharmacy concerned.

Any shortcomings not identified, or suggestions made which themselves cause problems in delivery of the services could lead to NHS England itself being involved in litigation."

1.33 The Amber Pharmacy however notes that there may be occasions where NHS England would wish to see specific SOPs if particular concerns are raised and in any such instance we would be happy to provide a copy of any requested SOPs.

Pharmacy Systems and Procedures

1.34 All Essential Services will be delivered in accordance with:

1.34.1 Company Standard Operating Procedures

1.34.2 NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 NHS Act 2006

1.34.3 RPSGB - Professional Standards and Guidance for Internet Pharmacy Services

1.34.4 PSNC - Guidance on Internet Selling Pharmacies

1.34.5 GPhC – Professional Standards and Guidance on Distance Selling Pharmacies

1.35 This will ensure that the Amber Pharmacy 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.

1.36 The Amber Pharmacy'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.

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

1.37.1 Telephone

1.37.2 Website/ Pharmacy App on mobile phones

1.37.3 The 'E Commerce' 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.

1.37.4 Email

1.37.5 Postal services

1.38 All NHS services will be delivered free of charge in accordance with the NHS Act 2006.

1.39 Essential Services will be delivered by using:

1.39.1 Telephone, including text messaging where appropriate

1.39.2 Electronic Prescription Service (EPS)

1.39.3 Website

1.39.4 Email

1.39.5 Royal Mail postal service

1.39.6 Courier service

1.39.7 PHS Group Healthcare Waste Management Services (or equivalent)

1.39.8 The Amber Pharmacy also intends to promote the use of free video-conferencing services such as Skype so that patients have a better chance of getting to know their pharmacy staff. Such services do not constitute ‘face-to-face’ contact under the Regulations and can be a particularly efficient way of interacting with patients and gaining rapport, as they are more personal than a basic telephone service. Many people now have the ability to use services like this via their mobile phones at any location where they can find a wireless internet signal.

1.39.9 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 is always preserved. This will be a dedicated, fully monitored and temperature controlled delivery service.

Provision of NHS Essential Services

1.40 The Amber Pharmacy will provide all the Essential Services as outlined in the NHS contractual framework.

Dispensing Services

1.41 Prescriptions will be received by the EPS, post, and fax 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.

1.42 In the event that they are not clinically or legally correct, pharmacists will follow Standing Operating Procedures to resolve clinical or legal issues before dispensing items. This may involve contacting the prescriber as soon as possible to make sure the patient receives their medication without delay.

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

Repeat Dispensing Services

1.44 From March 1 2015, Terms of Service require the Pharmacy to ensure that appropriate advice about the benefits of repeat dispensing is given to any patient who—

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

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

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

1.46 Dispensing of repeat NHS prescriptions including those dispensed in dosette boxes as may be required under the Disability Discrimination Act will be done 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.

1.47 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.

Urgent Supply

1.48 Whilst the Distance Selling nature of the pharmacy is such that 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.

1.49 The request may be received from a Prescriber (check list of authorised Prescribers) of from a Patient [sic].

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

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

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

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

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

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

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

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

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

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

1.52.1 Interview

1.53 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.

1.53.1 Records

1.54 An entry must be made in the POM register on the day of supply and record all the relevant details.

1.55 The label for the dispensed medicine must contain the words "Emergency Supply".

1.55.1 Faxed Prescriptions

1.56 A 'faxed prescription' does 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 practitioner. A faxed prescription can confirm that at the time of receipt a valid prescription is in existence.

1.57 Any pharmacist who decides to dispense a prescription only medicine against a faxed prescription without sight of the original prescription must ensure that adequate safeguards exist to ensure that the original prescription will be in their possession within a short period and not more than 72 hours. Any doubt as to the content of the original prescription caused by poor reproduction must be overcome before the medicine is supplied by contacting the prescriber.

1.58 Other than in emergency situations it is recommended that the pharmacist does not dispense against faxed prescriptions and instead uses the Emergency Supply procedures.

1.59 As it is possible to fax a prescription many times the pharmacist is advised to ensure that no dispensing against a fax takes place unless the system used for the sending or receipt of faxes is secure.

1.60 Schedule 1, 2, or 3 CDs (except Phenobarbital for the treatment of epilepsy) must not be supplied against a faxed prescription.

1.61 As detailed above the patient should be interviewed over the phone. Payment can be processed via the website or over the phone. The pharmacist may wish to consider the following before providing an emergency supply at the request of the patient:

Delivery of Urgent Supplies

1.62 Given the nature of a request of this type, the Pharmacy should 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 company must be informed that items must be delivered ASAP by the quickest route possible. The Pharmacy must 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 SOPs apply.

Disposal of Unwanted Medicines

1.63 PHS Group Healthcare Waste Management Services (or another similar company which may be appointed as required from time to time) will provide safe and secure disposal of unwanted medicines by collection of unwanted medicines from patients and residential homes.

1.64 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/app and marketing leaflets.

1.65 Patients wishing to return unwanted medicines to the pharmacy may do so by courier, which will be provided and paid for by the pharmacy. Patients in locality may contact pharmacy by phone or email to arrange collection of unwanted medicines from their home or work by pharmacy staff.

1.66 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.

Public Health (Promotion of Healthy Lifestyles)

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

1.68 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.

1.69 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.

1.70 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.

1.71 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. The website, app and email newsletters will also be used to promote healthy lifestyles.

Public Health Campaigns

1.72 The Pharmacy will take part in national health campaigns to promote public 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.

1.73 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.

1.74 From 1 March 2015 patients should also be assessed for participation in at least one clinical audit and whichever of the following that the NHSCB specifies—

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

(ii) 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 NHSCB's arrangements for the receiving and processing of data from the audit.

Signposting and Assessment of whether patients require advice to minimise inappropriate use of health or social care services

1.75 Any help or advice that cannot be accessed on the website and app links will be available by telephoning the pharmacy and asking for advice. The patient will then be signposted to health and social care providers and/or any other assistance available. 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.

1.76 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—

(a) requires advice, treatment or support that the pharmacy cannot provide; but

(b) 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,

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

1.78 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—

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

(b) 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.

1.79 Where appropriate, a referral can be made by means of a written referral note.

1.80 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.

Support for Self-Care

1.81 Information about support organisations, the treatment of common illnesses, minor ailments, long term medical conditions and appropriate usage of OTC medications will be available on the website, app and email newsletter. The pharmacist on duty can be contacted by telephone for more advice and drug interactions.

1.82 There will also be pharmacist selected web links and 'downloads' to print off.

Support for People with Disabilities

1.83 This service will be provided in accordance with the Disability Discrimination Act (DDA). The Amber Pharmacy will make reasonable pharmaceutical adjustment to ensure that those who qualify for help under the DDA are provided with the right compliance aids.

1.84 The Amber Pharmacy 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.

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

Clinical Governance

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

1.87 The Amber Pharmacy 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 Pharmacists and Pharmacy Technician CPO, conducting clinical audits and patient satisfaction surveys, and drug recalls.

1.88 '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.

1.89 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.

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

1.91 The Pharmacy will conduct an annual PSS based on the template recommended by the PSNC.

1.92 Details of the survey (as per PSNC website) can be found at http://psnc.org.uk/contract-it/essentialservice-clinical-governance/cppq/

1.93 The survey will be adapted to reflect the operation of a distance selling pharmacy, ie

1.93.1 Distributed via email, post and with delivery drivers / couriers

1.93.2 References to “visiting” the pharmacy changes to reflect non face to face contact methods used.

1.93.3 Ratings for the pharmacy based on physical characteristics changed to reflect actual method of use, ie ease of use of website as opposed to “comfort and convenience of the waiting areas”.

Information Governance

1.94 The pharmacy will be registered and comply with Data Protection Act. It will also comply with the Access to Health Records Act. It will publish its Freedom of Information Act Publication Scheme on its website and copies will be made available on request. All patient data will be kept private and confidential in accordance with NHS and legal obligations on data security, protection and confidentiality.

Delivering Medicines

1.95 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.

1.96 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 done by the delivery driver. All other nationwide delivery will be delivered by special delivery and signed for by the patient, their notified carer or other patient authorised representative.

1.97 The patient will be provided with a tracking number to track the status of the delivery online. A text messaging system will inform the patient about their delivery.

1.98 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.

1.99 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.

1.100 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.

1.101 Medicine for local delivery which is not fragile and to be delivered by the delivery driver can be packaged in the using the pharmacy bags supplied for standard prescription items.

1.102 Medicines classified as non-flammable or non-toxic must be securely closed and placed in a leakproof 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.

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

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

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

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

1.104 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.

1.105 A list of the approved cold chain couriers is available within the Pharmacy. Coldchain items should 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. Pharmacy staff should be aware that 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. The courier service is a dedicated, fully monitored and temperature controlled delivery service. Any breach of the cold chain is 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 may not be re-used.

Controlled Drugs

1.106 Delivery of Controlled Drugs

1.107 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. The couriers will have the following UK Licenses and Standards:

1.107.1 MHRA Wholesale Dealer License

1.107.2 MHRA Manufacturer's lmporters License

1.107.3 GAMP 4 Systems Validation

1.107.4 MHRA IMP License

1.107.5 MHRA Manufacturer's "Specials" License

1.107.6 ISO 9001: 2000 Certified

1.107.7 Clinical trials audited to GMP Annexe 13 standards

1.107.8 FDA audited

1.107.9 Meet all Home Office safe custody and record keeping requirements

1.107.10 (Current proposed courier: DHL)

Return and Destruction of CD

1.108 Patients wishing to return CDs to the pharmacy may do so by making an appointment in advance with the pharmacy. 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 Amber Pharmacy will denature and render them irretrievable as soon as possible in order to avoid storage problems and an increased security risk.

1.109 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.

Cover for Breaks / Working Time Directive

1.110 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.

Contingency Planning

1.111 The Amber Pharmacy 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 .

Verification of Declarations of Prescription Exemptions

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

1.113 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 or fax copies of the evidence to the pharmacy (or use the postal / courier service, but see NOTE below) and the pharmacy can note that the evidence provided was not in 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.

1.114 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.

1.115 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. Faxed and 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.

1.116 Payment for prescription charges will be received via the secure payment portal on the website (eg Sagepay) and when payment is received the prescription will be marked as paid.

Registration of the Premises with the GPhC

1.117 It is illegal to operate a Pharmacy without registering the premises and Superintendent Pharmacist with the GPhC. The Amber Pharmacy 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 business. The GPhC has a team of inspectors who undertake the routine monitoring and inspection of premises.

Practice leaflet

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

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

(ii) the Amber Pharmacy is likely to refuse, for reasons other than those provided for in the Amber Pharmacy'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 Amber Pharmacy is limited to other categories of patients)."

2 **The Decision**

The Commissioner considered and decided to refuse the application. The decision letter dated 11 March 2025 states:

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

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

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

2.2 "The Application

2.3 An application from Collimation Limited for a Distance Selling Premises Application was received on 12th November 2024. The Committee was now required to consider the application in accordance with Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended.

2.4 Consideration

2.5 The Committee considered the following:

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

2.5.2 Department of Health guidance on Distance Selling Premises.

2.5.3 The application form provided by the Applicant.

2.5.4 No representations were received from interested parties.

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

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

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

Regulation 31 – Refusal: same or adjacent premises

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

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

services") from the premises to which the application relates, or adjacent premises; and

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

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

2.8 The Committee noted that the Applicant stated on the application form that it intends to provide advanced services (NMS, Pharmacy First and CPCS). The Committee noted that although the applicant stated CPCS on the application form the service has been superseded by Pharmacy First.

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

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

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

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

Regulation 25(1)

2.13 The Committee noted that it had to be satisfied that services would be provided on an uninterrupted basis to patients anywhere in England who request those services and that essential services would be provided safely and effectively without face-to-face contact between any person receiving the services whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

Regulation 25(2)(a)

2.14 The Committee noted that the applicant had stated that: all essential services would be delivered in accordance with the relevant regulations, professional standards and company standard operating procedures and that provision would be uninterrupted to persons anywhere in England who request those services during the opening hours of the premises.

Regulation 25(2)(b)

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

2.16 The Committee was satisfied that, based on the information provided, there would be uninterrupted provision of essential services, during the opening hours of the premises,

to persons anywhere in England who request those services during the stated opening hours.

2.17 The Committee went on to consider whether essential services would be provided safely and effectively without face-to-face contact between any person receiving the services whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

2.18 The Applicant had confirmed that essential services will be provided without face-to-face contact between anyone receiving the services, whether on their own or someone else's behalf, and the pharmacy staff. The pharmacy will operate from secure premises, with a controlled entry system, to which members of the public will not have access. Any patient that requests essential services to be provided at the premises will be informed that the pharmacy is not permitted to provide by using telephone, the website/pharmacy App, the 'E Commerce' website, email and postal services. Essential services would be delivered via a number of methods including telephone, EPS, website, email, postal services, courier services, specialist waste management services, video services and specialist cold chain courier services.

Schedule 4 Terms of service of NHS pharmacists

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

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

2.21 **Schedule 4, paragraph 5(2) & (3)** - the Committee considered whether the Applicant had explained how patients would present prescriptions. The Committee noted the Applicant's comments which stated that prescriptions will be received by the EPS, post, or where practicable, with the patient's informed consent, collected from a surgery. They had also described the means of supplying dispensed prescriptions.

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

2.23 **Schedule 4, paragraph 6** - the Committee considered whether the Applicant had explained how in a case of urgency at the request of a prescriber, a drug or appliance would be provided to a patient. The Committee noted the Applicant's supporting information which acknowledged that such requests would be unlikely to occur often in a distance selling pharmacy. However, they had gone on to describe the processes and had described the way the legal requirements would be met in terms of the patient interview and records. They had also described that such requests would be prioritised for urgent local or courier delivery.

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

2.25 **Schedule 4, paragraph 7** – the Committee considered whether the Applicant had explained how evidence would be sought and provided about the patient's entitlement to exemption from NHS Charges. The Applicant had explained that for local patients, 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. Exemptions may also 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. In all instances. The PMR system would 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.

2.26 The Committee was satisfied that paragraph 7 would be complied with effectively.

2.27 **Schedule 4, paragraph 8(1)** – the Committee considered whether the applicant had explained how items would be provided to patients including protection of the cold chain and requirements of the misuse of drugs act. The Committee noted the Applicant's comments which included information about deliveries. They stated that medicines will be packed, transported, and delivered in such a way that their integrity, quality and effectiveness is 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. They went on to describe management of the cold drugs will be carried out by couriers with pharma grade specialist facilities to meet specific quality and validation requirements.

2.28 The Committee noted that in addition to the broader information provided as part of the application, that very specific details were also available in the SOPs

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

2.30 **Schedule 4, paragraph 8(4)** – the Committee considered whether the applicant had explained how the measurement and fitting of appliances under Part IX of the Drug tariff would be carried out safely and effectively carried out. No information had been provided about this matter.

2.31 The Committee considered that it had not been provided with sufficient information to be satisfied that paragraph 8 of Schedule 4 would be complied with safely and effectively.

2.32 **Schedule 4, paragraph 8(15)** – the considered [sic] whether the applicant had explained how drugs would be provided in a suitable container suitable for posted/delivered items. The Committee noted the Applicant's comments which confirmed that suitable package would be used for deliveries and that there would be differentiation in terms of the packaging used for different medicine types and delivery methods.

2.33 The Committee was satisfied that paragraph 8(15) would be complied with effectively.

2.34 **Schedule 4, paragraph 9(4)** – the Committee considered whether the applicant had explained how for repeatable prescriptions they would assess that the patient is taking/using the item(s) appropriately and is not suffering from any side effects. The Committee noted the Applicant's comments which stated that the advice required for repeat dispensing would be provided using its non-face to face methods for communication. The SOPs covered this in more detail, stating that the pharmacist would telephone the patient to ask the relevant questions and provide advice before issuing the prescription.

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

2.36 **Schedule 4, paragraph 10(1)** – the Committee considered whether the applicant had explained how it would provide appropriate advice about the use of drugs/appliances, safe keeping of items and returning of unwanted items be given. How it would advise

regarding importance of only ordering items actually needed (repeatable prescriptions and appliances). The Committee noted the Applicant's comments which stated the advice required for repeat dispensing would be provided using its non-face to face methods for communication.

2.37 The Committee considered that it had not been provided with sufficient information to be satisfied that paragraph 10(1) would be complied with effectively.

2.38 **Schedule 4, paragraph 14** - The Committee considered whether the Applicant had explained how it would accept unwanted drugs from patients and how patients will be advised on returning unwanted items. The Committee noted the Applicant's comments which outlined the options for disposal of unwanted medicines – i.e., a specialist waste management company for residential homes, return via a courier (paid for by the pharmacy) or local collection. Appropriate packaging will be made available, and the service will be advertised on the website/app and pharmacy leaflets.

2.39 The Committee took into account the other comments made by the Applicant and concluded that it was satisfied that the requirement of paragraph 14 would be complied with safely and effectively.

2.40 **Schedule 4, paragraph 17** – The Committee considered whether the Applicant had explained or otherwise demonstrated how it will assess whether persons require prescription linked intervention advice because they have diabetes, are at risk of coronary heart disease, smoke or are overweight.

2.41 The Committee noted information provided in the application which states that there will be "active" and "passive" approaches. A questionnaire will be available via the website which would identify whether further information was required. In some cases, patients will choose to complete the questionnaire without being asked to and others will be identified and asked to complete the questionnaire. Leaflets will be delivered with medication and there will also be targeted campaigns.

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

2.43 **Schedule 4, paragraph 18** – The Committee considered whether the Applicant had explained how it would participate in health campaigns. The Committee noted the Applicant's comments which confirmed that the pharmacy would participate in the national health campaigns and that this would be done by sending out leaflets during the period of the campaign and providing additional advice and learning resources via the website. Patients would be directed to the resources via email, text and other non-face to face communication so that they are aware of the campaign.

2.44 The Committee considered it had been provided with sufficient information and was satisfied that paragraph 18 would be complied with safely and effectively.

2.45 **Schedule 4, paragraph 20** – The Committee considered whether the Applicant had demonstrated how it would assess patients' needs before signposting them in order to minimise inappropriate use of health or social care services. The Committee noted the Applicant's comments which stated that the same active and passive assessment tool (as set out above) would be used. If the pharmacy is not able to provide the appropriate advice, treatment, or support, they will provide contact details of another suitable provide and in some cases refer the patient to that provider. Advice would be provided via non face to face methods.

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

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

"Information about support organisations, the treatment of common illnesses, minor ailments, long term medical conditions and appropriate usage of OTC medications will be available on the website, app and email newsletter. The pharmacist on duty can be contacted by telephone for more advice and drug interactions.

There will also be pharmacist selected web links and 'downloads' to print off."

2.48 The Committee concluded that it had not been provided with sufficient information to be satisfied that paragraph 21 would be complied with safely and effectively.

2.49 **Schedule 4, paragraph 22(b) & 22(c)** - The Committee considered whether the Applicant had explained how it will provide advice, assistance and support to and in respect of a health service patient

> (a) recently discharged from hospital who is referred to P for advice, advice and support in respect of the patient's medication regimen by the staff of the hospital in which the patient stayed;
>
> or (b) who is otherwise referred to P for advice, assistance and support in respect of the patient's medication regiment by the staff of an NHS trust or NHS foundation trust as part of arrangement linked to the transfer of care between different providers of NHS services. Further the Committee considered whether the Applicant had explained what procedures it had in place for checking referrals for the discharge medicines services.

2.50 The Committee noted the Applicant had made no comments in regard to Schedule 4, paragraph 22(b) & 22(c)

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

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

2.53 Information has been provided to indicate that the pharmacy will have a website. However, it was not clear from the information provided that there would be "an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues".

2.54 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 28(c) of Schedule 4.

2.55 The Committee concluded that essential services would not all be provided safely and effectively without face-to-face contact between any person receiving the services whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

Decision

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

2.57 The Committee determined the application as follows – the Committee was satisfied that the proposed premises were not adjacent to or in close proximity to other chemist premises.

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

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

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

2.57.4 the Committee was not satisfied that all essential services were likely to be secured in a safe and effective manner without face to face contact.

2.58 The Committee determined to refuse the application.

Third Party Rights Of Appeal

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

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

3 The Appeal

In an undated letter received by email on 12 March 2025, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "Responses:

[2.13 above] The Committee noted that it had to be satisfied that services would be provided on an uninterrupted basis to patients anywhere in England who request those services and that essential services would be provided safely and effectively without face-to-face contact between any person receiving the services whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

3.2 ANSWER: Patients across England can access our pharmaceutical services by calling our pharmacy directly or, for added convenience, by using our website to request any of the services we offer. We have established clear protocols to ensure that staff avoid face-to-face contact with patients or their representatives, in line with our safety and service standards. These Standard Operating Procedures (SOPs) have been developed by our Superintendent Pharmacist, who brings over 16 years of extensive

experience in the pharmacy sector and is highly skilled in upholding regulatory and professional standards.

[2.8 above] The Committee noted that the Applicant stated on the application form that it intends to provide advanced services (NMS, Pharmacy First and CPCS). The Committee noted that although the applicant stated CPCS on the application form the service has been superseded by Pharmacy First.

3.3 ANSWER: I would like to kindly clarify that in my application, I referred to the service as “CPCS” instead of “Pharmacy First.” Please accept my sincere apologies for this oversight.

3.4 We are still in the habit of referring to the service as CPCS, as it has been commonly used within our team and practice. I hope you will kindly overlook this and understand that it was unintentional.

[2.30 above]. Schedule 4, paragraph 8(4) – the Committee considered whether the applicant had explained how the measurement and fitting of appliances under Part IX of the Drug tariff would be carried out safely and effectively carried out. No information had been provided about this matter.

[2.31 above]. The Committee considered that it had not been provided with sufficient information to be satisfied that paragraph 8 of Schedule 4 would be complied with safely and effectively.

3.5 ANSWER: The measurement and fitting of appliances under Part IX of the Drug Tariff will be carried out by the patient themselves. Clear and self-explanatory templates and proformas are provided for the patient to complete and return. If the patient is unable to do this independently, a relative or carer may assist on their behalf. For care home residents, carers or nursing staff can support the process as needed.

[2.36 above]. Schedule 4, paragraph 10(1) – the Committee considered whether the applicant had explained how it would provide appropriate advice about the use of drugs/appliances, safe keeping of items and returning of unwanted items be given. How it would advise regarding importance of only ordering items actually needed (repeatable prescriptions and appliances). The Committee noted the Applicant’s comments which stated the advice required for repeat dispensing would be provided using its non-face to face methods for communication.

[2.37 above]. The Committee considered that it had not been provided with sufficient information to be satisfied that paragraph 10(1) would be complied with effectively.

3.6 Answer: We will ensure that all advice and communications are conducted through appropriate non-face-to-face methods. Specifically:

3.6.1 Communication Channels: We will use telephone calls and video consultations to discuss and provide advice on the use of drugs and appliances, as well as guidance on safe storage and the return of unwanted items.

3.6.2 Unwanted Medicines Collection: Unwanted medications will be collected by our driver, with clear instructions printed on the pharmacy bags or bag labels. For care home residents, we will designate specific collection days for unwanted medicines, and these arrangements will be communicated through informative leaflets and standard introductions.

3.6.3 Repeatable Prescriptions and Appliances: Discussions regarding repeatable prescriptions and the ordering of appliances will be conducted via telephone or video call, ensuring that only the necessary items are ordered.

3.7 This comprehensive non face-to-face approach allows us to maintain high service standards while ensuring patient safety and clear communication.

[2.50 above]. Schedule 4, paragraph 21 – The Committee considered whether the Applicant had demonstrated how it would provide advice or support for people caring for themselves or their families. The Committee noted the Applicant's comments which stated: "Information about support organisations, the treatment of common illnesses, minor ailments, long term medical conditions and appropriate usage of OTC medications will be available on the website, app and email newsletter. The pharmacist on duty can be contacted by telephone for more advice and drug interactions. There will also be pharmacist selected web links and 'downloads' to print off."

[2.48 above]. The Committee concluded that it had not been provided with sufficient information to be satisfied that paragraph 21 would be complied with safely and effectively.

3.8 Answer: Queries related to self-treatment, minor ailments, or long-term conditions can be easily addressed over the phone when needed. If the inquiry is made online or via email, the pharmacist will respond accordingly. Additionally, relevant literature provided by the NHS can be emailed upon request. This information can also be printed and delivered along with the medications. Care home residents can receive this information in printed form or via email whenever requested.

[2.49 above] Schedule 4, paragraph 22(b) & 22(c) - The Committee considered whether the Applicant had explained how it will provide advice, assistance and support to and in respect of a health service patient

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

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

3.9 Answer:

3.9.1 Online/Video Consultation: Patients and customers can connect with our pharmacy team via secure video consultations to discuss any health concerns. Comprehensive advice and assistance are provided throughout the consultation.

3.9.2 Pharmacy Website & Mobile App: Our online platform and mobile application offer user-friendly access to support and guidance regarding medication management and other pharmaceutical advice.

3.9.3 E-Commerce Services: Our website features an integrated e-commerce option that allows for the purchase of prescription lines (P-Lines), over-the-counter (OTC) medications, and other pharmaceutical products. Orders can be delivered via Royal Mail or by our driver for local deliveries.

3.9.4 Care-Home and Telephone Orders: Care-home operators, as well as individual patients and customers, can utilize the same ordering methods. Alternatively, they may call our pharmacy directly to place orders or seek advice regarding their treatment.

[2.55 above]. The Committee concluded that essential services would not all be provided safely and effectively without face-to-face contact between any person receiving the services whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

3.10 Answer: As previously mentioned, all staff members are required to strictly adhere to the Standard Operating Procedures (SOPs) established by our Superintendent Pharmacist. These SOPs have been carefully developed to ensure full compliance with regulatory requirements and best practices within the pharmacy sector. Our Superintendent Pharmacist brings over 16 years of experience and in-depth knowledge of pharmaceutical laws, guidelines, and professional standards. Their expertise ensures that our protocols are not only legally compliant but also aligned with the highest standards of patient care and safety."

4 Summary of Representations

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

5 Consideration

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

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

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

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

Regulation 31

5.5 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).

5.6 The Committee noted that the Applicant had not provided any information in the application form on this point stating "n'/a" but the Committee noted that the wording of the application form only required the Applicant to include information in the relevant section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee considered it reasonable to determine that the lack of information in the application form on this point when read with the wording of the application form allowed it to be reasonably satisfied that the Applicant considered that the proposed premises were not adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises.

5.7 The Committee noted that the Commissioner had determined that it was not required to refuse the application under the provisions of Regulation 31 and that this had not been disputed on appeal.

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

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

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

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

5.12 The Committee noted that the Applicant had not included any information in the relevant section of the application form that deals with this point except to write "n/a". The Committee noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Commissioner in it is decision report stated that "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."

5.13 Based on the information available to it, the Committee therefore determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

5.14 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.

5.15 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.

5.16 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.

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

5.18 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.

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

5.20 The Committee noted the references from the Applicant to prescriptions being received electronically and had confirmed in the application form that as well as local delivery drivers they would also be using Royal Mail and couriers which would ensure that the provision of services was to all of England. The Committee was satisfied, based on the information before it, that the provision of services would be available to persons anywhere in England.

5.21 The Committee noted the references throughout the appeal and application form which sets out how the Applicant intends to provide essential services without face to face contact but using permissible methods of communication. The Committee noted the comments from the Applicant that “contact” would be via telephone, email or other permissible methods.

5.22 The Committee noted in the SOP “Receiving NHS Prescriptions” it states:

5.22.1 *“Ensure NHS prescriptions are never accepted from members of the public at the premises of the pharmacy in any circumstance*

Prescriptions may be:

Collected from the surgery

Posted to the pharmacy

Electronically transferred via EPS (preferred method)

Faxed – the original prescriptions must have been received at the point of Accuracy Checking

To ensure the products supplied match the original prescription (before sending to patient)"

5.23 However, it goes on to state:

5.23.1 *"Only those members of staff trained in handling prescriptions eg medicines counter assistants, dispensing technicians or pharmacists* ***should take in*** *the prescription. They should check and confirm the patients details.* [emphasis added]

Patients/representatives must be asked to sign the reverse of NHS prescriptions."

5.24 The Committee also noted that in the SOPs for "Labelling", "Assembly" and "Accuracy checking" under "Procedure: WHY?" each SOP stated:

5.24.1 *"Ensure there is no face to face Essential Service offered at the distance selling pharmacy premises"*

5.25 However under "Purpose" in each of these SOPs it stated:

5.25.1 *"Labelling*

Purpose: This covers the labelling of any kind of prescription brought to the counter by a patient or representative

…

"Assembly

Purpose: This covers the assembly of any kind of prescription brought to the counter by a patient or representative

…

"Accuracy Checking

"Purpose: This covers the prescription final check of any kind of prescription brought to the counter by a patient or representative.

…"

5.26 The Committee also noted in the "Controlled Drugs" SOP under the heading "Return and Destruction of CD" it states:

5.26.1 *"Patients wishing to return CDs to the pharmacy may do so by making an appointment in advance with the pharmacy."*

5.27 Whilst the SOP goes on to state "*Appropriate packaging will be sent to patients in advance with Instructions for packaging any returned medicines [sic] …"* the Committee was of the view that there was conflicting information regarding the making of the appointment with the pharmacy and whether or not this would involve the patient attending the pharmacy and therefore receiving essential services at the pharmacy premises.

5.28 The Committee was of the view, given the conflicting information contained within the SOPs, that it could not be satisfied that the provision of services would be without face to face contact.

5.29 The Committee noted the comments from the Applicant that

5.29.1 "*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"*.

5.30 The Committee was satisfied that the provision of essential services would be without interruption and would be available to persons anywhere in England.

5.31 However, the Committee was not satisfied that the provision of essential services would be without face to face contact.

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

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

5.34 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:

5.34.1 Dispensing of drugs and appliances

5.34.2 Urgent supply without a prescription

5.34.3 Preliminary matters before providing ordered drugs or appliances

5.34.4 Providing ordered drugs or appliances

5.34.5 Refusal to provide drugs or appliances ordered

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

5.34.7 Disposal service in respect of unwanted drugs

5.34.8 Promotion of healthy lifestyles

5.34.9 Prescription linked intervention

5.34.10 Health campaigns

5.34.11 Signposting

5.34.12 Support for self-care

5.34.13 Discharge medicines service

5.34.14 Websites and health promotion zones

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

Providing ordered drugs or appliances

5.36 The Committee considered whether the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that (1) the 'cold chain' is maintained, where relevant, and (ii) that the requirements of the Misuse of Drugs Regulations 2001 and, in particular, Regulations 14 and 16, are met).

5.37 In the SOPs, provided by the Applicant, entitled "Pharmacy Systems and Procedures" it stated:

5.37.1 *"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 is always preserved. This will be a dedicated, fully monitored and temperature-controlled delivery service."

5.38 In the SOP "Delivery of Medicines and Appliances" it goes on to state:

5.38.1 *"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 done by the delivery driver. All other nationwide delivery will be delivered by special delivery and signed for by the patient, their notified carer or other patient authorized representative.*

The patient will be provided with a tracking number to track the status of the delivery online. A text messaging system will inform the patient about their delivery.

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.

…

The patient, carer or notified, authorized 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.

…

Procedure: HOW?

Medication will be delivered by our approved contracted medication courier

Delivery vans have a locked Controlled Drugs cabinets with full audit trail

Delivery van have a locked temperature controlled refrigerator with full audit trail and remote

temperature monitoring

Our contract is for same day or next day deliveries (any temperature-controlled items or controlled

drugs should be sent as same day)

Drivers will always wear identifiable name tags

Drivers will remain contactable in a safe and legal manner through the control office

Deliveries will be trackable by our staff and the end customer

All deliveries will be signed at all points of hand-over including (but not limited to):

Any relevant information that is placed on the bag will be transferred to the end customer

Follow-up any important information with a phone call to the customer once delivery is

marked 'Delivered'

Controlled Drug and Temperature Sensitive items require an extra signature to ensure the product Is received satisfactorily by the customer."

5.39 The Committee also noted the SOP entitled "Delivery of Controlled Drugs" however this provided generic information regarding the provision within the relevant legislation for controlled drugs to be delivered and then listed the UK Licenses and Standards which a courier delivering controlled drugs should have. The Committee noted that the SOP then went on to provide information regarding the "Return and Destruction of CD", which is repeated in the supporting information contained within the application form.

5.40 The Committee noted that if the delivery to patients is local then this will be carried out by their own delivery driver. The Committee noted that there appeared to be no exceptions to this and that the pharmacy's own delivery driver could also therefore be delivering thermolabile medications. The Committee noted that the Applicant had not provided any information as to how the local delivery driver would ensure that the cold chain was maintained or, if there was a breach in the cold chain, how they would become aware of this and what the process was for the return of any medication either where the integrity of the cold chain had been compromised or as a result of there being a missed or failed delivery.

5.41 The Committee noted that whilst the Applicant had provided some information regarding the various delivery methods, and had made reference to the failed delivery procedure being followed, there was limited information provided as to what this procedure involved and what would happen for a missed or failed delivery of a controlled drug.

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

5.43 The Committee noted that on the application form the Applicant had confirmed that they were proposing to undertake to provide appliances "All items listed in the drug tariff part IX". Therefore, the Committee considered whether the Applicant had explained the arrangements that it will have in place to ensure that for appliances which require fitting/measuring, a registered pharmacist measures/fits them.

5.44 The Committee noted that the Commissioner had not been satisfied that paragraph 8(4) would be fully complied with safely and effectively.

5.45 In its application form, which was also repeated in the SOPs at page 35 "Promotion of Healthy Lifestyles (Public Health)" the Applicant had stated:

5.45.1 *"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—*

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

(b) 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."

5.46 On appeal the Applicant had expanded further on this point and stated:

5.46.1 *"The measurement and fitting of appliances under Part IX of the Drug Tariff will be carried out by the patient themselves. Clear and self-explanatory templates and proformas are provided for the patient to complete and return. If the patient is unable to do this independently, a relative or carer may assist on their behalf. For care home residents, carers or nursing staff can support the process as needed."*

5.47 The Committee was of the view that the information from the Applicant was not sufficient and a patient, or a relative or carer assisting them, using a template for an appliance which requires measuring/fitting, even with explanatory templates and proformas, was not the same as the registered pharmacist measuring/fitting the appliance. The Committee concluded that there was very little information provided in the way of advising how the pharmacist was going to actually fit the appliance.

5.48 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(4) of Schedule 4.

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

5.49 The Committee considered whether the Applicant had indicated how appropriate advice about the benefits of repeat dispensing is given to any patient who (i) has a long term, stable medical condition (that is a medical condition that is unlikely to change in

the short to medium term), and (ii) requires regular medicine in respect of that medical condition.

5.50 The Commissioner had not been satisfied that paragraph 10(1) would be fully complied with effectively.

5.51 In the application form the Applicant had stated that “such advice will be provided by the Pharmacy using its permissible methods of non-face-to-face contact with patients”.

5.52 The Committee noted SOP 28 “Repeat Dispensing” had expanded upon this further and stated:

5.52.1 *“Such advice will be provided by the pharmacy using its permissible methods of non-face-to face contact with patients.*

Dispensing of repeat NHS prescriptions including those dispensed in dossette boxes as may be required under the Disability Discrimination Act will be done in partnership with patients, carers, pharmacists and prescribers. It will cover requirements additional to those for dispensing, assessing, and 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 with the repeat prescription.

Purpose:

Ensure there is no face to face Essential Service offered at the distance selling pharmacy premises

Provide a repeat dispensing service that is operated in a safe and secure method with all members of the pharmacy team and locums aware of the scheme

Objective:

The procedure covers repeat dispensing operating between the pharmacy, participating local surgeries and consenting patients.

Procedure: HOW & WHY?

Receive Repeat Dispensing (RD) prescriptions in batch issues

Batches could be issued from 3 to 12 months' worth of batches at once

Check name and address of patient, clarifying any incorrect or incomplete details and ensure patient consent.

Check if first presentation of a repeat prescription and batch issues that patient is aware that information on the use of their medication and arrangements may be passed between the pharmacist and the prescriber and vice-versa.

Check the repeatable prescription for usual details-patient name, address, age, date of birth, prescriber details, signature and date.

Check the repeatable prescription (RA) is not more than 6 months old. N.B the repeatable prescription (RA) does not need the declaration on reverse side to be completed.

Check the repeatable prescription (RA) and batch issue prescriptions (RD) relate to one another and that the number of batch prescriptions presented matches the number issued.

Check batch prescriptions (RD) are not more than 12 months old.

Annotate patient medication record with a 'repeat dispensing' tag.

Dispense the first batch prescription (RD) and endorse date and quantity on repeatable prescription or attached sheet

The endorsed batch prescription should be submitted to the PPA at the end of the month in which it was dispensed. Retain repeatable prescription (RA) in the pharmacy in the repeat dispensing filing system.

After dispensing all batches, the RA prescriptions should be submitted to the PPA

Any unused RD scripts must be destroyed (shredding). Ensure a record is kept for destroyed batches"

5.53 On appeal, the Applicant had addressed this further and stated:

5.53.1 *"We will ensure that all advice and communications are conducted through appropriate non-face-to-face methods. Specifically:*

Communication Channels: We will use telephone calls and video consultations to discuss and provide advice on the use of drugs and appliances, as well as guidance on safe storage and the return of unwanted items.

Unwanted Medicines Collection: Unwanted medications will be collected by our driver, with clear instructions printed on the pharmacy bags or bag labels. For care home residents, we will designate specific collection days for unwanted medicines, and these arrangements will be communicated through informative leaflets and standard introductions.

Repeatable Prescriptions and Appliances: Discussions regarding repeatable prescriptions and the ordering of appliances will be conducted via telephone or video call, ensuring that only the necessary items are ordered."

5.54 The Committee was of the view that, whilst the Applicant had again provided assurances that any interaction would not be via face to face contact, there was no information provided by the Applicant as to how it would give advice about the benefit of repeat dispensing to a patient who was not currently receiving this service, but had a long term, stable medical condition and would benefit from this service.

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

Discharge Medicine Service

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

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

5.58 The Committee noted that the Commissioner had not been satisfied that paragraphs 22(B) and 22(C) would be fully complied with safely and effectively.

5.59 The Committee noted that this had not been addressed by the Applicant in their original application, however on appeal, the Applicant had stated:

5.59.1 *"Online/Video Consultation: Patients and customers can connect with our pharmacy team via secure video consultations to discuss any health concerns. Comprehensive advice and assistance are provided throughout the consultation.*

Pharmacy Website & Mobile App: Our online platform and mobile application offer user-friendly access to support and guidance regarding medication management and other pharmaceutical advice.

E-Commerce Services: Our website features an integrated e-commerce option that allows for the purchase of prescription lines (P-Lines), over-the-counter (OTC) medications, and other pharmaceutical products. Orders can be delivered via Royal Mail or by our driver for local deliveries.

Care-Home and Telephone Orders: Care-home operators, as well as individual patients and customers, can utilize the same ordering methods. Alternatively, they may call our pharmacy directly to place orders or seek advice regarding their treatment."

5.60 The Committee was of the view that the information provided by the Applicant on appeal confirmed that they would carry out the process via permissible methods of communication and whilst they advised that they would provide "comprehensive advice and assistance" throughout the consultation, there was no explanation as to how the Applicant was proposing to provide the advice, assistance or support. Further, the Committee noted that there was also no explanation regarding any procedures in place for checking referrals for the discharge medicine service.

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

Other considerations

5.62 The Committee noted that the Commissioner had refused the application on the basis that they were not satisfied that the Applicant had provided information to show that there would be compliance with the Terms of Service. The Committee, taking into

account the additional information provided by the Applicant on appeal, considered these areas of the Terms of Service in more detail.

Support for Self-care

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

5.64 In its application form the Applicant had stated, under the heading "Support for Self-care":

5.64.1 Information about support organisations, the treatment of common illnesses, minor ailments, long term medical conditions and appropriate usage of OTC medications will be available on the website, app and email newsletter. The pharmacist on duty can be contacted by telephone for more advice and drug interactions.

There will also be pharmacist selected web links and 'downloads' to print off."

5.65 The Committee also noted the SOPs provided with the application form and in particular the SOPs headed "Support for Self-Care" and "Self-care Advice, including management of minor ailments & long-term conditions" which as well as reiterating the information provided in the application form stated:

5.65.1 "*WHY?*

To provide advice on minor ailments and long-term conditions

To provide advice on the use of non-prescription medicines

To give opportunistic or requested advice to patients without face-to-face contact on the pharmacy

premises to anyone In the United Kingdom To receive self-care referrals from NHS Direct [sic]

To signpost to other health and Social care providers

To make a record of advice given"

5.66 On appeal, the Applicant had stated:

5.66.1 *"Queries related to self-treatment, minor ailments, or long-term conditions can be easily addressed over the phone when needed. If the inquiry is made online or via email, the pharmacist will respond accordingly. Additionally, relevant literature provided by the NHS can be emailed upon request. This information can also be printed and delivered along with the medications. Care home residents can receive this information in printed form or via email whenever requested."*

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

Website and health promotion zones

5.68 The Commissioner had not been satisfied that the Applicant had provided sufficient information to show that there would be compliance with paragraph 28(c) of Schedule 4.

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

5.69.1 *"The website will display:*

…

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

Return of unwanted medicines

Patient Lifestyle Questionnaire

How to register exemptions from NHS charges

Promotion of Health Lifestyles and details of campaigns being undertaken

Procedures for Emergency Supply

Explanation of rules on non-face to face contact

Annual patient survey

Patient Information Leaflet"

5.70 The Applicant had also gone on to state:

5.70.1 *"The 'E Commerce' 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."*

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

5.72 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

5.73 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).

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

5.74.1 confirm the Commissioner's decision;

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

5.74.3 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.

5.75 In those circumstances, given that the Committee had additional information which was not available to the Commissioner and whilst it had reached the same conclusion as the Commissioner it had done so for different reasons, the Committee determined that the decision of the Commissioner must be quashed.

5.76 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.

5.77 The Committee noted that representations on Regulation 25 had already been sought as part of the processing of the application by the Commissioner, however no representations had been made by any statutory party. The Committee further noted that when the appeal was circulated representations had been sought from parties on Regulation 25.

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

6 Decision

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

6.2 Accordingly, the Committee:

6.2.1 quashes the decision of the Commissioner; and

6.2.2 redetermines the application as follows -

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

6.2.2.2 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,

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

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

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

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

6.2.3 The application is refused.

Case Manager
Primary Care Appeals