

3 October 2025

REF: SHA/ 26651

**APPEAL AGAINST DORSET ICB DECISION TO
GRANT AN APPLICATION BY CAREWELL
PHARMACY LTD FOR INCLUSION IN THE
PHARMACEUTICAL LIST AT UNIT 1, 470
RINGWOOD ROAD, POOLE, BH12 3LY UNDER
REGULATION 25**

8th Floor
10 South Colonnade
Canary Wharf
London
E14 4PU

Tel: 020 3928 2000
Email: nhsr.appeals@nhs.net

1 Outcome

- 1.1 The Pharmacy Appeals Committee (“Committee”), appointed by NHS Resolution, quashes the decision of the Commissioner and redetermines the application.
- 1.2 The Committee determined that the application should be granted.

A copy of this decision is being sent to:
AutoMeds Pharmacy Ltd
Rushport Advisory LLP on behalf of Carewell Pharmacy Ltd
PCSE on behalf of Dorset ICB

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1 The Application

By application dated 16 May 2024, Rushport Advisory LLP on behalf of Carewell Pharmacy Ltd ("the Applicant") applied to Dorset ICB ("the Commissioner") for inclusion in the pharmaceutical list at Unit 1, 470 Ringwood Road, Poole, BH12 3LY under Regulation 25. In support of the application it was stated:

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

1.1.1 "Drug Tariff part IX"

1.1.2 *EXCEPT items that require measuring or fitting".

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

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

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

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

Supporting information

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

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

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

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

1.6 NHS England Premises Standards

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

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

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

1.10 GPhC Guidance

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

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

1.13 Risk Assessment

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

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

1.16 Audit Procedures

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

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

1.18.1 staffing levels and the training and skills within the team

1.18.2 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)

1.18.3 use of specialised equipment and new technology

- 1.18.4 records of decisions to make or refuse a sale
- 1.18.5 systems and processes for receiving prescriptions, including EPS records of decisions to make or refuse a sale (note that our pharmacy SOPs will require more frequent analysis of refusals to sell)
- 1.18.6 systems and processes for secure delivery to patients
- 1.18.7 any information about pharmacy services on the website
- 1.18.8 review of how the pharmacy adheres to the information security policy, Payment Card Industry Data Security Standard (PCI DSS) and data protection law
- 1.18.9 feedback from patients and people who use our pharmacy services
- 1.18.10 concerns or complaints received, and
- 1.18.11 activities of third parties, agents or contractors
- 1.19 The Audit and review process will act as a Project Plan for the pharmacy to implement change and upgrades in service and training.
- 1.20 **Reactive Review**
- 1.21 A reactive review will take place if an audit identifies a problem, or if there is;
 - 1.21.1 a change in the law affecting any part of the pharmacy service
 - 1.21.2 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
 - 1.21.3 a data security breach
 - 1.21.4 a change in the technology the pharmacy uses
 - 1.21.5 concerns or negative feedback are received from patients or people who use the pharmacy services
 - 1.21.6 a review of near misses and error logs causes a concern about an activity
- 1.22 **Accountability**
- 1.23 During opening hours there will always be a responsible pharmacist (RP) on site. Each area of work will have clear lines of accountability that will be set out by the superintendent pharmacist.
- 1.24 **Record Keeping**

- 1.25 Records in the pharmacy will be scanned in to the pharmacy IT system (including but not limited to, patient consent forms, queries, complaints, customer logs, sale refusals, and dispensing). Records will be kept for a minimum period of 7 years or longer if specific legislation requires.
- 1.26 **Training**
- 1.27 We will ensure that all staff are properly trained and competent to provide medicines and other professional pharmacy services safely. The GPhC has produced guidance to ensure a safe and effective team and this will form the basis of the training.
- 1.28 **Premises**
- 1.29 Premises will be registered with the GPhC prior to entry to the pharmaceutical list and will therefore comply with GPhC requirements for pharmacy premises.
- 1.30 **Website**
- 1.31 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.
- 1.32 The website will display;
- 1.32.1 the GPhC pharmacy registration number
 - 1.32.2 the name of the owner of the registered pharmacy
 - 1.32.3 the name of the superintendent pharmacist
 - 1.32.4 the name and address of the registered pharmacy that supplies the medicines
 - 1.32.5 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)
 - 1.32.6 information about how to check the registration status of the pharmacy and the superintendent pharmacist
 - 1.32.7 details of specific services available and how to use them, ie
 - 1.32.8 Return of unwanted medicines
 - 1.32.9 Patient Lifestyle Questionnaire
 - 1.32.10 How to register exemptions from NHS charges
 - 1.32.11 Promotion of Health Lifestyles and details of campaigns being undertaken

- 1.32.12 Procedures for Emergency Supply
- 1.32.13 Explanation of rules on non face to face contact
- 1.32.14 Patient Information Leaflet
- 1.32.15 the email address and phone number of the pharmacy
- 1.32.16 details of how patients and users of pharmacy services can give feedback and raise concerns
- 1.32.17 GPhC internet logo (linked to register entry)
- 1.32.18 Where any medicines are sold online, the pharmacy will be registered with the appropriate agency for online pharmacies.
- 1.32.19 The pharmacy will display any required logo on every page of the website offering medicines for sale, even if they are already displaying the GPhC voluntary logo. The website will be regularly updated, clear and accurate and follow the GPhC guidance on websites.
- 1.33 The pharmacy will allow the public to access pharmaceutical services from the pharmacy premises via a website on which there is an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues. **NOTE** - this is a new requirement under the Regulations and does not allow access to essential pharmaceutical services in a face to face manner at the premises and only applies to access via the website.
- 1.34 **Transparency and Choice**
- 1.35 Our website and materials will specify the nature and type of services we provide and who provides those services.
- 1.36 If any part of our pharmacy services is provided at different locations we will explain clearly to people who use pharmacy services where each part of the service is based.
- 1.37 **Managing Medicines Safely**
- 1.38 The pharmacy SOPs will provide the procedures for all staff to follow to ensure that the sale and supply of medicines is carried out in such a manner as to minimise risk to patients.
- 1.39 **Supplying Medicines Safely**
- 1.40 The SOPs for delivery of medicines will contain detailed information on the safe and effective
- 1.41 supply of medicines via the pharmacy's own driver, Royal Mail and courier firms, including;

- 1.41.1 assess the suitability and timescale of the method of supply, dispatch, and delivery for all medicines and particularly refrigerated medicines and controlled drugs
- 1.41.2 ensuring that robust identity check processes are in place to ensure that the medicines dispensed are delivered to the correct person.
- 1.41.3 assess the suitability of packaging (for example, packaging that is tamperproof or temperature controlled)
- 1.41.4 The pharmacy will monitor third-party providers, including analysis of patient feedback about deliveries and delivery times and processes.

1.42 Equipment and Facilities

- 1.43 All equipment used in the pharmacy will be sourced from manufacturers that have designed the equipment to be used in the manner in which the pharmacy intends to operate.
- 1.44 All equipment will be subject to annual performance testing and review, with specialist equipment (such as temperature monitoring) subject to monthly checks.
- 1.45 IT equipment will meet the latest security specifications and be regularly updated including the use of encrypted networks for wired and wireless communication. Access to records will be dependent on any given employee's level of authority and clearance which shall be determined by the superintendent pharmacist.

1.46 Standard Operating Procedures

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

1.48 PHARMACY SYSTEMS AND PROCEDURES

- 1.49 All Essential Services will be delivered in accordance with:

- 1.49.1 Company Standard Operating Procedures
- 1.49.2 NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013
- 1.49.3 NHS Act 2006
- 1.49.4 Human Medicines Regulations 2012
- 1.49.5 GPhC – Professional Standards and Guidance on Distance Selling Pharmacies
- 1.49.6 Relevant Data Protection laws

- 1.50 This will ensure that the Applicant provides safe, effective and uninterrupted provision of all essential services to persons anywhere in England who request those services during the opening hours of the premises. Essential Services will be provided without face to face contact between anyone receiving the services, whether on their own or someone else's behalf, and the pharmacy staff.
- 1.51 The Applicant's wholly Internet/Delivery Pharmacy will operate from secure premises, with a controlled entry system, to which members of the public will not have access. Any patient that requests essential services to be provided at the premises will be informed that the pharmacy is not permitted to provide those services at the premises.
- 1.52 Access to information about the provision of NHS Essential Services will be achieved by using:
 - 1.52.1 Telephone
 - 1.52.2 Live Video Call
 - 1.52.3 The website will enable patients or their carers to communicate remotely but directly allowing quick and easy access and provide clear unambiguous details of how safe, efficient, uninterrupted NHS Essential Services will be provided by the Pharmacist and qualified, knowledgeable, experienced support staff on duty throughout the opening hours of the pharmacy premises without having 'face to face' contact with the patient or their representative.
 - 1.52.4 Email
 - 1.52.5 Postal services
- 1.53 All NHS services will be delivered free of charge in accordance with the NHS Act 2006.
- 1.54 Essential Services may be delivered using:
 - 1.54.1 Telephone, including text messaging where appropriate
 - 1.54.2 Electronic Prescription Service (EPS)
 - 1.54.3 Website
 - 1.54.4 Email
 - 1.54.5 Royal Mail postal service
 - 1.54.6 Courier service
 - 1.54.7 Specialist Waste Management Services
 - 1.54.8 Live video services

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

1.55 Provision of NHS Essential Services

1.56 Dispensing Services

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

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

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

1.60 Repeat Dispensing Services

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

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

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

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

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

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

1.65 **Urgent Supply and Emergency Supply**

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

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

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

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

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

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

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

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

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

1.68.7 EEA prescribers cannot request an emergency supply of any Schedule 1 - 5 CD. Full records of the supply will be kept as per the relevant SOP.

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

1.69.1 **Interview**

1.69.2 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.

1.69.3 **Records**

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

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

1.69.6 **Faxed Prescriptions**

1.69.7 A 'faxed prescription' or other forms of scanned prescriptions do not fall within the definition of a legally valid prescription because it is not written in indelible ink, and has not been signed by an appropriate

practitioner. A faxed / scanned prescription can confirm that at the time of receipt a valid prescription is in existence, but no medicines should be supplied until the original prescription is received.

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

1.70 **Delivery of Urgent Supplies**

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

1.72 **Disposal of Unwanted Medicines**

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

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

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

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

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

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

1.76 **Promotion of Healthy Lifestyles**

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

1.78 **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.

1.79 **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.

- 1.80 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.
- 1.81 Leaflets will be delivered to patients with their medication. Those identified (Active or Passive) as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns to increase the patient's knowledge and understanding of health issues relevant to them. The website will also be used to promote healthy lifestyles.
- 1.82 **Health Campaigns**
- 1.83 The Pharmacy will take part in national health campaigns to promote health messages to our patients across England. This will be achieved by sending out leaflets with prescriptions during specific targeted campaign periods and providing additional advice and learning resources via the website.
- 1.84 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.
- 1.85 Patients should also be assessed for participation in at least one clinical audit and whichever of the following that the ICB specifies—
 - 1.85.1 a clinical audit carried out in a manner which is compatible with the ICB's arrangements for the receiving and processing of data from the audit, or
 - 1.85.2 a policy based audit (to support the development of the commissioning policies of the NHSCB) carried out in a manner which is compatible with the ICB's arrangements for the receiving and processing of data from the audit.
- 1.86 **Signposting and Support for Self-Care**
- 1.87 Patient will be signposted to health and social care providers and/or any other assistance available whenever necessary. To assess whether patients require advice to minimise inappropriate use of health or social care services the pharmacist will use the same "Active and Passive" assessment tool already set out above.
- 1.88 Where it appears to the pharmacist, after reviewing the assessment and having regard to the need to minimise inappropriate use of health and social care services and of support services, that a person using the pharmacy would benefit from advice to help manage their medical condition then advice will be provided via non face to face methods of communication and this will include

advice on both treatment options, non prescription medicines and lifestyle advice.

1.89 If a patient;

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

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

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

1.91 Referral for Certain Appliances

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

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

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

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

1.94 Support for People with Disabilities

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

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

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

1.98 Clinical Governance

- 1.99 **Note: Clinical Governance is not an ‘essential service’ and is therefore dealt with briefly in this submission.**
- 1.100 The Applicant will be involved in and comply with all the components of clinical governance including, but not limited to, compliance with standard operating procedures, patient safety incident and near miss reporting, demonstrating evidence of Pharmacist and Pharmacy Technician CPD, conducting clinical audits, workforce survey and drug recalls.
- 1.101 '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.
- 1.102 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.
- 1.103 All staff will have an annual appraisal, receive and provide feedback.
- 1.104 **Information Governance**
- 1.105 The pharmacy will be registered and comply with Data Protection Act and the General Data Protection Regulations (GDPR) . It will also comply with the Access to Health Records Act 1990. All patient data will be kept private and confidential in accordance with NHS and legal obligations on data security, protection and confidentiality.
- 1.106 The pharmacy will receive support from the PMR provide to ensure that continuous access to the Electronic Prescription System is maintained.
- 1.107 Two members of staff will have the ability to login to the PMS system on all days (where there are 2 or more staff members working) and the NHS mail system will be checked every day for both general emails and also for any referrals under the Discharge Medicines Service.
- 1.108 **Discharge Medicines Service (“DMS”)**
- 1.109 When NHS patients are discharged from hospital or there is, for other reasons, a transfer of care of them between different providers of NHS services, community pharmacies may be asked to perform a three stage service in respect of the patient, principally linked to changes in medication. The second and third stages of this service are linked to the first prescription presented post-discharge or post- transfer. Issues of concern may be raised by the pharmacy contractor not only with the patient or their carer but also with their general practitioner.
- 1.110 Under the DMS the pharmacy must provide assistance and support to, and in respect of, an NHS patient
- 1.110.1 recently discharged from hospital who is referred to the pharmacy for advice, assistance and support in respect of the patient’s medication regimen by the staff of the hospital in which the patient stayed; or

- 1.110.2 who is otherwise referred to the pharmacy for advice, assistance and support in respect of the patient's medication regimen by the staff of an NHS trust or NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.
- 1.111 The service allows and requires the pharmacy to help not only the patient directly, but also (within the bounds of confidentiality) their carers and also provide them with assistance and support.
- 1.112 The service is designed in 3 Stages, where each Stage builds on the last to provide additional support if required to the patient or, where appropriate their carer.
- 1.113 The pharmacist must use their clinical judgement when considering their actions and recommendations in respect of the service and consider the duty of confidentiality to the patient when involving a carer in discussions about the patient and their medication regimen.
- 1.114 If the DMS referral requesting that the pharmacy provides the DMS includes circumstances in which the pharmacy is not to provide, or is to cease to provide the DMS service, then the Pharmacy is not to, or is to cease to, provide the DMS in those circumstances (for example, X's or Y's admission or re-admission to hospital).
- 1.115 **Pandemic Treatment Protocol ("PTP")**
- 1.116 The pharmacy will provide medicines properly requested under any PTP arrangements.
- 1.117 The RP should (and if requested to do so by the person being supplied must)
- 1.117.1 Provide an estimate of the time the drug will be ready and delivered.
- 1.117.2 If the drug is not ready by the time then provide a revised estimate of when the drug will be ready and continue to update the patient on this time should the estimate change.
- 1.117.3 Contact the patient to confirm dispatch of the medication.
- 1.118 In addition to the normal requirements, the dispensing label on the packaging of the product supplied must also contain the additional wording shown below;
- 1.118.1 THIS PRODUCT IS BEING SUPPLIED IN ACCORDANCE WITH THE
[INSERT NAME] PANDEMIC TREATMENT PROTOCOL
- 1.118.2 And insert the name of the relevant protocol.
- 1.119 **Refusal to Supply under PTP**
- 1.120 The pharmacy may refuse to provide an order for a drug that is or is purportedly in accordance with a PTP where—

- 1.120.1 The RP reasonably believes it is not a genuine order for the person who requests, or on whose behalf is requested, the provision of the drug;
- 1.120.2 providing it would be contrary to the RP's clinical judgement;
- 1.120.3 The RP or other persons are subjected to or threatened with violence by the person who requests the provision of the drug, or by any person accompanying (see footnote re "accompanying") [not provided] that person; or
- 1.120.4 the person who requests the provision of the drug, or any person accompanying (see footnote re "accompanying") [not provided] that person, commits or threatens to commit a criminal offence.
- 1.121 The pharmacy must refuse to provide, pursuant to a PTP, an order for a drug that is or is purportedly in accordance with the PTP where P is not satisfied that it is in accordance with the PTP.
- 1.122 Any refusal to supply must be noted on the patient and / or pharmacy record system.
- 1.123 **Delivering Medicines**
- 1.124 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.
- 1.125 The RP must take adequate measures to ensure that the delivery mechanism used is secure and that medicines are delivered to the intended user promptly, safely, and in a condition appropriate for use. If the delivery to patients is local, this will be undertaken by the delivery driver except fridge lines which must be sent by courier. All other nationwide deliveries (other than fridge lines) will be delivered by Royal Mail special delivery or courier and signed for by the patient, their notified carer or other patient authorised representative. Fridge Lines will be delivered by courier (see further below).
- 1.126 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.
- 1.127 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.
- 1.128 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.
- 1.129 Medicine for local delivery which is (A) not fragile and (B) is to be delivered by the delivery driver can be packaged in the using the normal pharmacy bags supplied for standard prescription items.

- 1.130 Medicines classified as non-flammable or non-toxic must be securely closed and placed in a leak-proof container such as a sealed polythene bag (for liquids) or a siftproof container (for solids). Must be tightly packed in strong outer packaging and must be secured or cushioned to prevent any damage.
- 1.131 This means that for postal / courier items, either:
- 1.131.1 At the very least - padded envelopes even for non-fragile items as this will help to ensure the integrity of the manufacturers packaging.
- 1.131.2 For most items - bubble wrap and where necessary, polystyrene filler, placed within a cardboard box. Cardboard boxes must be the re-enforced type.
- 1.132 Large or any fragile medicines should be packed into cardboard boxes with bubble packaging and filling material to protect from damage.
- 1.133 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.
- 1.134 A list of the approved cold chain couriers will be maintained within the Pharmacy. Coldchain items will be stored in styrofoam filled cardboard boxes prior to being passed to the courier and marked with the "FRAGILE" and "FRIDGE LINE" stickers. Additional packing will not be required as the courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box and are fully monitored. Some thermolabile products can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in medicines which is damaging to them and will therefore not be used in direct contact with any medicine. The courier service will be a dedicated, fully monitored and temperature controlled delivery service. Any breach of the cold chain will be automatically notified to the driver who will then follow the failed delivery procedure and notify the pharmacy accordingly so that re-delivery can be arranged. Where the cold chain breach notice is issued items will not be re-used.
- 1.135 **Controlled Drugs**
- 1.136 **Delivery of Controlled Drugs**
- 1.137 There is provision within controlled drugs legislation to cover occasions when a controlled drug (CD) may temporarily be in the possession of a third party, e.g. a delivery person or postal carrier, while it is being transferred from one authorised person to another authorised person who is entitled to be in possession of the drug. Delivery of CD will be carried out by couriers with pharma grade specialist facilities to meet specific quality and validation requirements for healthcare products. This includes Home Office licensed controlled drug stores.
- 1.138 **Return and Destruction of CONTROLLED DRUGS**

- 1.139 Appropriate packaging will be sent to patients in advance with instructions for packaging any returned medicines and this will be provided and paid for by the pharmacy. The Superintendent Pharmacist will specify the appropriate method of collection depending on the items being returned and the distance from the pharmacy. Patients may also be signposted to alternate pharmacies if they prefer to return medicines to a different pharmacy. Any 'returned' Controlled Drugs must not be re-used or entered into the CD register. The Applicant will denature and render them irretrievable as soon as possible in order to avoid storage problems and an increased security risk.
- 1.140 Destruction must be witnessed by another member of staff. If not immediately destroyed, they should be segregated from main stock, clearly marked 'Patient Returns' to minimise the risk of errors and inadvertent supply and stored securely in a CD Cabinet waiting to be denatured. A record of destruction will be recorded in a separate CD Destruction Register designated for this purpose and will be available in the pharmacy for inspection.
- 1.141 **Cover for Breaks / Working Time Directive**
- 1.142 Any breaks in working time taken by the RP will be covered by a second pharmacist who will then assume the responsibility of the RP.
- 1.143 **Contingency Planning**
- 1.144 The Applicant will have accounts direct to pharmacy manufacturers and many full-line and short-line pharmaceutical wholesalers to try and increase the availability of stock and reduce Owings. A Contingency Plan will be in place to ameliorate the effects of any disruption to provision of pharmaceutical services such as medicines shortage, postal strike, EPS systems failure, etc.
- 1.145 **Verification of Declarations of Prescription Exemptions**
- 1.146 The reverse of the prescription should be fully completed (other than age exempt patients) in black ink.
- 1.147 Where evidence of exemption is required or provided by the patient it can be sent to the pharmacy for verification via the delivery driver and then returned to the patient. The PMR system should be updated to reflect that necessary check has been carried out and a note of when the next check is required should be entered onto the system. The Regulations require a patient to produce 'satisfactory evidence' to confirm exemption. Where appropriate (ie for deliveries made other than by the pharmacy's delivery driver), the patient may scan copies of the evidence to the pharmacy (or use the postal / courier service, but see NOTE below) and the pharmacy can record that the evidence provided was not in the original format. It is for the pharmacist in charge to determine if the evidence is satisfactory or not and, if not, then cross the 'Evidence not Seen' box.
- 1.148 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.

- 1.149 Exemptions may be sent to the pharmacy by post and the pharmacy will pay for postage and return the exemption to the patient free of charge. Scanned email copies of exemptions are also acceptable. The nature of any exemption will be recorded on the PMR system with a copy attached to the patient's file.
- 1.150 Payment for prescription charges will be received via the secure payment portal on the website and when payment is received the prescription will be marked as paid.
- 1.151 **Pharmacy Profile**
- 1.152 The pharmacy profile will be properly maintained in the NHS Digital Directory of Services
- 1.153 **Central Alerting System**
- 1.154 The pharmacy will maintain access to the MHRA Central Alerting System using the premises specific NHS mail email address which will be checked on a daily basis.
- 1.155 **Registration of the Premises with the GPhC**
- 1.156 It is not lawful to operate a Pharmacy without registering the premises and Superintendent Pharmacist with the GPhC. The Applicant will apply to register the premises with the GPhC following the grant of an NHS Contract application. The GPhC will send an inspector to inspect the premises for approval before commencement of any Pharmacy services. The GPhC has a team of inspectors who undertake the routine monitoring and inspection of premises.
- 1.157 **Practice Leaflet**
- 1.158 Nothing in the Applicant's practice leaflet, or publicity material in respect of the listed chemist premises, in material published on behalf of the Applicant publicising services provided at or from the listed chemist premises or in any communication (written or oral) from the Applicant or the Applicant's staff to any person seeking the provision of essential services will represent, either expressly or impliedly, that—
- 1.158.1 the essential services provided at or from the premises are only available to persons in particular areas of England, or
- 1.158.2 the Applicant is likely to refuse, for reasons other than those provided for in the Applicant's terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (for example, because the availability of essential services from the Applicant is limited to other categories of patients).
- 1.159 **Advanced or Enhanced Services**
- 1.160 The pharmacy will only offer services that can be delivered remotely and do not require patients to attend the premises."

2 **Applicant's '14 day comments' to the Commissioner**

- 2.1 "Thank you for your letter of 16 August 2024. I act for Carewell Pharmacy Ltd in the above application and have been instructed by my client to submit the following reply to the consultation comments received.
- 2.2 The LPC asks the ICB to apply the correct legal test and my client has provided sufficient evidence to demonstrate that they will comply with all parts of the legal test we have no further comments to add in respect of that point.
- 2.3 The LPC comments on possible impact to local pharmacies, but as the ICB will be aware, this is not relevant to the legal test under regulation 25 as this is a distance selling pharmacy application.
- 2.4 In respect of the comments from Automeds Pharmacy, none of the points they raise are relevant to the legal test that the ICB will apply and we therefore do not comment further except to confirm that the application form was signed by my client but the signature (and other personal information) is redacted by PCSE when sending the application to interested parties.
- 2.5 We look forward to hearing from you in due course".

3 **The Decision**

The Commissioner considered and decided to grant the application. The decision letter dated 10 June 2025 states:

- 3.1 "Dorset ICB has considered the above application and I am writing to confirm that it has been granted. Please see the enclosed report for the full reasoning.
- 3.2 The report details the conditions that will be placed upon your inclusion in the relevant pharmaceutical list should a valid notice of commencement be received. Enclosed is a form confirming acceptance of these conditions. It should be completed by an authorised person and returned to me with your notice of commencement.
- 3.3 Also enclosed is a template of the notice of commencement which you are required to submit to us. Please note that if this is submitted before the end of the 30 day appeal period and a valid notice of appeal is then received by the Secretary of State, the notice of commencement will cease to have effect. This means that if you have opened your new premises then you will be required to close with immediate effect.
- 3.4 Please note that you must submit the notice of commencement no fewer than 30 days before the date you intend to start service provision. If it is received fewer than 30 days in advance it is not a valid notice of commencement and will not be accepted by Dorset ICB unless you successfully ask to give a shorter notice period. Should you wish to ask to give a shorter notice period please complete the enclosed application form."

PSRC report

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

- 3.5 **"Case reference** - CAS-310301-H1L8P6
- 3.6 **Name of applicant** - Carewell Pharmacy Ltd
- 3.7 **Application type** - Application for inclusion in a pharmaceutical list: distance selling premises excepted application
- 3.8 **Address of proposed premises** - Unit 1, 470 Ringwood Road, Poole, BH12 3LY
- 3.9 **The SW Committee noted:** The applicant proposes opening a distance selling pharmacy in premises on an Industrial Estate in Ringwood Road, Poole, Dorset.
- 3.10 **PRELIMINARY ISSUES**
- 3.11 Nature of the application
- 3.12 This is application for a 'distance selling pharmacy' and is an excepted application and considered under regulation 25.
- 3.13 Regulation 31 (same or adjacent premises)
- 3.14 Regulation 31 states [quoted in full]:
- 3.15 There are no other pharmacies at the proposed premises, or adjacent. The nearest pharmacy is 0.3 miles (AutoMeds Pharmacy - DSP) from the proposed premises. The SW Committee was satisfied it is not required to refuse the application by virtue of Regulation 31.
- 3.16 Representations received
- 3.17 Representation was received from:
- 3.18 AutoMeds Pharmacy Ltd state:
- 3.19 "I am writing on behalf of AutoMeds Pharmacy to formally oppose the new distance selling pharmacy application submitted by CAREWELL PHARMACY LTD for Unit 1,470 Ringwood Road, Poole, BH12 3LY.
- 3.20 As the current operators of AutoMeds Pharmacy, located at Unit 45 Wessex Trade Centre, Ringwood Road, Poole, Dorset BH12 3PG, we have significant concerns regarding the necessity and impact of this proposed application.
- 3.21 AutoMeds Pharmacy has been serving the community since 2009 and is situated merely 0.2 miles from the proposed location of CAR EWELL PHARMACY LTD. Over the past 15 years, we have developed strong relationships with our customers and have built a reputation for providing exceptional pharmaceutical services. Our operations extend beyond the local community, as we currently serve over 60 care homes and 150 domiciliary care

patients across England from our site, ensuring comprehensive and reliable pharmaceutical care.

- 3.22 Jhoots Pharmacy, which has recently taken over a Lloyds Pharmacy at Rosemary Rd, Roseview, Poole BH12 3HF, is also located only 0.3 miles away from the proposed location.
- 3.23 NHS guidelines emphasize the importance of preventing over saturation of pharmaceutical services in any given area, particularly when existing providers are already effectively meeting the community's needs. Introducing another pharmacy so close to two existing pharmacies could lead to a dilution of resources and increased competition, which may not be in the best interest of patients or the sustainability of the existing pharmacies. This aligns with the message of the Pharmaceutical Needs Assessment (PNA) published by the council, indicating that there is no need to open additional pharmacies. Please see the excerpt from the PNA below. A full copy of the PNA is also included with this document.
- 3.24 "In Chapter 7 Conclusion, the PNA states that there is appropriate provision for the population that this PNA covers, with no current gaps and no future gaps identified over the three-year lifespan of this document. *Future improvements and better access are best managed through working with existing contractors and improving integration with other services and within Primary Care Networks rather than through the opening of additional pharmacies.* One geographical area is identified where access to essential service could be improved in the future. The use of medicines in Dorset could be improved by a focus on the pharmacy workforce challenge and a local campaign to encourage patients to only order the medicines they need." Published (2022-2025)
- 3.25 In an article published by the Dorset Echo on June 21, 2024, it is noted that priority should be placed on recruiting more pharmacists. Several pharmacies that opened in the county just two years ago have already started to close. This reinforces the message that opening a new pharmacy in the area is unnecessary.
- 3.26 Furthermore, it is essential for pharmacies to be seen as investable propositions by NHS commissioners and the government. Given the significantly constrained resources in the healthcare sector, it is critical to allocate these resources wisely to maintain high standards of service provision. The addition of a new pharmacy at the proposed location does not align with these principles, as it could potentially destabilize the established and functioning services provided by the pharmacies within the area.
- 3.27 Automeds Pharmacy has demonstrated its ability to deliver high-quality pharmaceutical services over the years and has invested in the community. Considering these facts, we urge the board to carefully review the implications of approving this application and to prioritize the sustainability and quality of pharmaceutical services currently available in the area. Rejecting this application would be in line with NHS regulations and would support the continued provision of reliable and comprehensive pharmaceutical care to our community.

- 3.28 We would also like to note that the application form has not been signed by the director. Would this be considered a valid application to proceed with?
- 3.29 Thank you for considering our perspective on this matter. We trust that the board will make a decision that reflects the best interests of the community and the healthcare sector. Should this application proceed forward and a hearing has been called for, we would be willing to attend such hearings and to provide any further information as required.
- 3.30 Community Pharmacy Dorset state:
- 3.31 Community Pharmacy Dorset has reviewed the application by Carewell Pharmacy Ltd and wishes to remind the deciding committee of the detrimental impact that additional pharmacies, even pharmacies providing services at a distance have on the local surrounding pharmacies.
- 3.32 CP Dorset would also like to respectfully request that members of the deciding committee are satisfied that this application fully meets the criteria set out in Regulation 25 and the conditions set out in Regulation 64 when determining this application.
- 3.33 The applicant responded noting CP Dorset request the ICB to apply the correct legal tests and suggest the comments made by CP Dorset on the possible impact to local pharmacies are not relevant under Regulation 25. The applicant also suggests none of the points raised by Automeds Pharmacy are relevant to the tests under Regulation 25.
- 3.34 REGULATION 25(2) – requirements for distance selling pharmacies
- 3.35 An application for distance selling premises is, by virtue of regulation 25(1), not subject to the market entry test.
- 3.36 Regulation 25(2) states: [quoted in full].
- 3.37 Reg 25(2)(a) – same site as a provider of primary medical services
- 3.38 There is no provider of primary medical services at the proposed address, so the application does not have to be refused by virtue of Regulation 25(2)(a).
- 3.39 Reg 25(2)(b) – the pharmacy procedures
- 3.40 Information about how the applicant would operate the proposed pharmacy is provided within the supporting information attached to the application.
- 3.41 The SW Committee must be sure it has sufficient information to determine if it is satisfied that the procedures will secure uninterrupted provision of essential services during opening hours to persons anywhere in England, safely and effectively without face-to-face contact. If not, it must refuse the application.
- 3.42 *Services available without interruption*
- 3.43 The applicant has proposed core hours of 9.00am – 1.00pm and 1.30pm –

- 3.44 5.30pm Monday to Friday. Closed Saturdays and Sundays. No additional supplementary hours are proposed.
- 3.45 On page 5 of the supporting information provided, the applicant lists the pharmacy systems and procedures which they state will ensure the safe, effective and uninterrupted provision of all essential services. On page 6 the applicant states that uninterrupted NHS Essential Services will be provided by the pharmacist and qualified support staff on duty throughout the opening hours of the pharmacy premises. On page 15 the applicant states breaks taken by the Responsible Pharmacist will be covered by a second pharmacist who will then assume responsibility.
- 3.46 On the basis of the information provided, the SW Committee was satisfied that services will be provided without interruption.
- 3.47 *Essential services will be provided without face-to-face contact.*
- 3.48 On pages 5 and 6 of the supporting information the applicant states they will provide safe, effective and uninterrupted service provision of all services to persons anywhere in England during the opening hours and without face to face contact. Patients will access services by telephone, live video call, website, email and postal services.
- 3.49 To establish if services will be provided without face-to-face contact it is useful to examine the Terms of Service (Schedule 4 Part 2 essential services) where compliance would ordinarily require face to face contact and assess if the applicant has explained how they will achieve it. [The National Health Service \(Pharmaceutical and Local Pharmaceutical Services\) Regulations 2013 \(legislation.gov.uk\)](https://www.legislation.gov.uk/ukdsi/2013/5136010000000001/eng/full/text.html)
- 3.50 On page 6 the applicant has provided confirmation of measures to ensure Essential Services are without face-to-face contact as: [see 1.48 to 1.50 and 1.53.1 to 1.53.9 above].
- 3.51 Paragraph 5(2) & (3) – how will patients present prescriptions
- 3.52 On page 6 of the supporting information, it is stated that prescriptions will be received by EPS, post or collected from local surgeries with the patients consent.
- 3.53 **The SW Committee was satisfied the pharmacy will receive prescriptions without face-to-face contact.**
- 3.54 Paragraph 6 – Urgent request without a prescription
- 3.55 In the supporting information under “Urgent Supply and Emergency Supply” on pages 7 and 8 a process for managing urgent requests is described. It includes ensuring there will be a priority delivery by their driver for local deliveries or instruct a courier that delivery must be as soon as possible using the quickest route possible.

- 3.56 **The SW Committee was satisfied the pharmacy has suitable arrangements in place for dealing with urgent requests without a prescription.**
- 3.57 Paragraph 7 – Exemption Checking and payment
- 3.58 In the supporting information under “Verification of Declarations of Prescription Exemptions” on page 15, the applicant states that evidence of exemption can be sent to the pharmacy for verification via the local delivery driver. For those further afield the patient can post evidence, and the pharmacy will pay for postage and return. They note the Regulations require a patient to produce satisfactory evidence to confirm exemption and the nature of any exemption will be recorded on the PMR system.
- 3.59 In the supporting information on page 15 it states that payment will be taken using a secure payment portal on the website.
- 3.60 **The SW Committee was satisfied the pharmacy has suitable arrangements in place for checking exemptions and collecting payments without face-to-face contact.**
- 3.61 Paragraph 8 providing ordered drugs or appliances
- 3.62 In the supporting information on page 13 and 14 under “Delivering Medicines” It indicates that medicines must be packaged in such a way as to preserve the integrity, quality and effectiveness of the medicine. It mentions the use of padded envelopes, bubble wrap and cardboard boxes. It states that items must be signed for on delivery. Cold chain items will be stored in Styrofoam filled cardboard boxes. It indicates specialist cold chain couriers will be used for fridge lines. It is stated that couriers use a temperature-controlled delivery service, and the driver is informed of any cold chain breach. Should this occur, the driver will follow the failed delivery procedure.
- 3.63 **The SW Committee was satisfied that suitable arrangements are in place for the delivery of items including temperature-controlled items and CDs.**
- 3.64 Paragraph 8(4)
- 3.65 In the application form at part 4 it states appliances will be supplied other than those that need measuring and fitting. The SW Committee therefore does not need to consider measuring and fitting of appliances.
- 3.66 Paragraph 9(4) – Repeat Dispensing
- 3.67 In the supporting information at pages 6 and 7 it states that the patient will be given advice relating to repeat dispensing using non face to face methods of communication. It will cover requirements additional to those for dispensing – assessing need for a repeat supply and raising any clinical issues identified with the prescriber.
- 3.68 **The SW Committee was satisfied that arrangements are in place for Repeat Dispensing including reminding patients of the importance of only requesting items they need, confirming the medication is being used**

appropriately, checking for side effects and the patient has not had any changes in health.

- 3.69 Paragraph 10(1) - Further activities to be carried out in connection with the provision of dispensing services
- 3.70 In the supporting information under “Pharmacy Systems and Procedures” (Page 5 under that documents numbering) the applicant states that use will be made of telephones, email, video call facilities Royal Mail postal service, couriers and EPS to provide essential services without face-to-face contact.
- 3.71 **The SW Committee was satisfied that suitable arrangements are in place so the pharmacy can communicate with and provide essential services such as advice without face-to-face contact.**
- 3.72 Paragraph 10(1)(da) – benefits of repeat dispensing
- 3.73 In the supporting information at pages 6 and 7 it states that suitable patients will be advised of the benefits of repeat dispensing using permissible methods of non-face to face contact. The applicant has already indicated they will use phone, email post and video calls for communicating with patients.
- 3.74 **The SW Committee was satisfied that suitable arrangements are in place to advise suitable patients of the benefits of repeat dispensing without face-to-face contact.**
- 3.75 Paragraph 13 – Disposal service in respect of unwanted drugs
- 3.76 In the supporting information at page 8 the applicant indicates that a specialist waste management company will collect unwanted medicines from patients’ homes and residential homes. The applicant also gives information on how patients can return unwanted medicines by courier and the pharmacy will pay for the collection.
- 3.77 **The SW Committee was satisfied that suitable arrangements are in place for the disposal of unwanted medicines without face-to-face contact.**
- 3.78 Paragraph 17 – prescription linked interventions
- 3.79 In the supporting information on pages 9 and 10 it describes a method of identifying patients who might benefit from healthy lifestyle advice with the use of questionnaires or based on prescribed items. It also describes how suitable information will be sent to the patient in the form of information leaflets.
- 3.80 **The SW Committee was satisfied that suitable arrangements are in place to provide prescription linked interventions and healthy lifestyle advice without face to face contact.**
- 3.81 Paragraph 18 - Public health campaigns
- 3.82 In the supporting information on page 9 it is stated the pharmacy will participate in public health promotions by sending out leaflets with prescriptions and purchases and by providing additional information on the website.

- 3.83 **The SW Committee was satisfied that suitable arrangements are in place to provide public health campaigns without face-to-face contact.**
- 3.84 Paragraph 19 and 20 – Signposting
- 3.85 In the supporting information on page 9 and 10 it states patients will be signposted to other health and social care providers etc. whenever necessary. Any advice will be given using non face to face methods of communication.
- 3.86 **The SW Committee was satisfied that suitable arrangements are in place to provide signposting services without face-to-face contact.**
- 3.87 Paragraph 21 and 22 (self-care)
- 3.88 In the supporting information on page 10 it states that advice to help a patient self-manage a condition then that advice will be given using non face to face methods.
- 3.89 **The SW Committee was satisfied that suitable arrangements are in place to provide self-care services without face-to-face contact.**
- 3.90 Paragraph 28C requirements in respect of websites and health promotion zones
- 3.91 On page 4 of the supporting information it states “...via a website on which there is an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues.”
- 3.92 **The SW Committee was satisfied that the applicant has explained how it will ensure that it has a website for use by the public for the purpose of accessing pharmaceutical services from those premises, on which there is an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues.**
- 3.93 Other
- 3.94 On page 5, in the information provided the applicant states that the pharmacy will operate from secure premises with a controlled entry system so patients cannot enter the premises. The applicant also states that should a patient attempt to obtain services face to face they will be informed by the pharmacist that service cannot be provided on the premises.
- 3.95 On page 11 in the information provided the applicant states that the pharmacy will provide assistance and support to, and in respect of, an NHS patient recently discharged from hospital who is referred to the pharmacy for advice in respect of the patients medication regimen as part of the arrangements linked to the transfer of care between different providers of NHS services.
- 3.96 **Decision**

3.97 **The SW Committee was satisfied that the application should be GRANTED because:**

3.97.1 The SW Committee is satisfied that the proposed premises were not adjacent to or in close proximity to other chemist premises.

3.97.2 The SW Committee is 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.

3.97.3 The SW Committee is satisfied that all essential services were likely to be secured without interruption during the opening hours.

3.97.4 The SW Committee is satisfied that all essential services were likely to be secured for persons anywhere in England.

3.97.5 The SW Committee is satisfied that all essential services were likely to be secured without face-to-face contact

3.97.6 The SW Committee is satisfied that all essential services were likely to be secured in a safe and effective manner because it had sufficient information to be satisfied that the procedures adopted by the applicant would be likely to secure the safe and effective provision essential services.

3.98 Appeal rights

3.99 ***The SW Committee agree that AutoMeds Pharmacy Ltd has appeal rights as they provided reasoning for opposing the application in their submission.***

4 **The Appeal**

In a letter received on 30 June 2025, AutoMeds Pharmacy Ltd ("the Appellant") appealed against the Commissioner's decision. The grounds of appeal are:

4.1 "We, **AutoMeds Pharmacy Ltd**, formally submit this appeal against the recent decision by the Southwest Pharmaceutical Services Regulations Committee (PSRC) to approve the inclusion of **Carewell Pharmacy Ltd** into the pharmaceutical list under a **distance selling premises accepted application** (Case ref: CAS-310301-H1L8P6).

4.2 **Grounds for Appeal**

4.3 **Failure to Properly Consider Regulation 31 – Same or Adjacent Premises**

4.4 While we acknowledge that the applicant's proposed site is 0.3 miles away from our premises and technically not "adjacent," we submit that the **intent and spirit of Regulation 31** have not been respected.

4.5 Regulation 31(2)(b) allows NHS England to consider whether the services proposed are materially similar to existing services such that the new premises can reasonably be treated as providing "the same service." Carewell Pharmacy

has not demonstrated any **differentiating or exceptional services** that AutoMeds Pharmacy does not already provide.

- 4.6 There are multiple precedents where applications were refused even when pharmacies were located more than 0.1-0.5 miles away from each other, especially under Regulation 31, where no distinct need or service gap was identified. For example:
 - 4.6.1 Case: CAS-218720-Z2J9X1 – Refused (North East Region, 2021)
 - 4.6.2 Application for DSP was refused due to proximity to an existing DSP within 0.4 miles and lack of evidence of service differentiation.
 - 4.6.3 Case: CAS-204615-Y8K5G7 – Refused (London, 2020)
 - 4.6.4 Despite being a DSP application, the committee found it unjustified where the proposed applicant replicated existing services.
- 4.7 We request the PSRC [sic] re-evaluate whether Carewell Pharmacy truly meets the exception test under **Reg. 31(2)(b)**, particularly as there is no need for a duplicative service in this micro- locality.
- 4.8 **Lack of Unmet Need or Gap in the Local Pharmaceutical Needs Assessment (PNA)**
- 4.9 The **latest PNA for Dorset (or BCP area)** does **not identify any gaps** in pharmaceutical services within the area surrounding BH12 3LY. AutoMeds Pharmacy Ltd, which operates within 0.3 miles, already provides:
 - 4.9.1 Prescription collection and delivery
 - 4.9.2 EPS nominations
 - 4.9.3 Medicines use reviews
 - 4.9.4 New medicines service
 - 4.9.5 Flu and other vaccinations
 - 4.9.6 Advanced DSP-level services nationally
- 4.10 We also maintain robust 24/7 online service access and consistently meet NHS England KPIs. We have **no record of complaints or public dissatisfaction**. The current service **meets and exceeds** local needs, meaning **Carewell Pharmacy is not addressing any unmet demand or need as defined by the PNA**.
- 4.11 **Lack of Justification for Inclusion Under Excepted Application Provisions**
- 4.12 The only justification presented for the new application is the proposal to operate as a DSP in an industrial unit. This, in itself, does not justify inclusion, especially if there is:

- 4.13 No unmet need
- 4.14 No exceptional service proposition
- 4.15 Duplication of existing DSPs
- 4.16 Risk of undermining the viability of existing providers
- 4.17 The PSRC [sic] is urged to weigh **the impact of unnecessary market duplication**, particularly when it may **weaken the sustainability of currently approved DSPs** offering compliant, complaint-free services with proven track records.
- 4.18 **Policy Consistency and Precedent**
- 4.19 We respectfully request NHS England to ensure **consistency of policy application**. In past decisions, applications have been refused for **proximity alone**, even for DSPs, if:
 - 4.19.1 No unmet need exists
 - 4.19.2 The applicant cannot demonstrate unique value
 - 4.19.3 Existing providers offer all relevant services
- 4.20 By approving Carewell Pharmacy, NHS England risks creating an inconsistent precedent that may encourage saturation in tightly clustered areas where no additional capacity or innovation is needed.
- 4.21 **Conclusion**
- 4.22 We respectfully urge NHS England and the PSRC [sic] to reconsider and reverse this approval based on:
 - 4.22.1 Regulation 31 applicability
 - 4.22.2 Lack of differentiation in services
 - 4.22.3 Absence of any identified need in the latest PNA
 - 4.22.4 Consistency with national precedent
- 4.23 The approval of this application sets a problematic and unjustifiable precedent, allowing unnecessary duplication of DSPs in small geographical areas with no unmet pharmaceutical needs. We request a thorough re-examination of this application.”

5 **Summary of Representations**

After reviewing the paperwork provided by the Commissioner, it was noted that the comments made by the Applicant in response to the representations on the application [see 2.1 to 2.5 above] had not been circulated or seen by parties. NHS Resolution therefore applied its discretion under Schedule 3, Part 3, paragraph 7 and allowed

parties the opportunity to make comments on this information. This is a summary of representations received.

5.1 Rushport Advisory LLP on behalf of the Applicant

5.1.1 “I act for Carewell Pharmacy Limited in the above application and have been instructed to submit this reply to the appeal submitted by Automeds Pharmacy Ltd (“Automeds”) against the decision of the Commissioner to approve my client’s application made under regulation 25.

5.1.2 Automeds lists 4 grounds for appeal, none of which are of any merit and are replied to below.

5.1.3 **Regulation 31**

5.1.4 There is no pharmacy at either the same or any adjacent premises to my client’s application site, nor does my client have any involvement in any other pharmacy. Automeds accepts that no such pharmacy exists. Regulation 31 does not apply in this case.

5.1.5 **Lack of Unmet Need or Gap in the Local Pharmaceutical Needs Assessment (PNA)**

5.1.6 There is no requirement for the PNA to identify the need for this pharmacy and this ground of appeal is irrelevant to the legal test.

5.1.7 **Lack of Justification for Inclusion Under Excepted Application Provisions**

5.1.8 This ground of appeal is irrelevant to the legal test.

5.1.9 **Policy Consistency and Precedent**

5.1.10 This ground of appeal is irrelevant to the legal test.

5.1.11 Whilst the Appellant has not provided any relevant grounds for appeal, my client is aware that the Committee will consider all parts of regulation 25 when reaching their decision and has therefore instructed me to submit the attached SOPs that cover all parts of the legal test and have been approved by my client for use in the pharmacy.

5.1.12 We look forward to hearing from you in due course.”

5.2 The Commissioner

5.2.1 “Thank you for your letter, received 17th July 2025, addressed to Mr Speight at Primary Care Support England (PCSE) enclosing a copy of the above appeal. The South West Pharmaceutical Services Regulations Committee (SW Committee) wishes to make the following comments on the appeal.

- 5.2.2 The appellant suggests the tests for Regulation 31 have not been properly considered. The SW Committee would reiterate its opinion that Regulation 31 does not apply in this case. As admitted by the appellant, the proposed pharmacy is not for the same OR adjacent premises to any other pharmacy, so the first part of the test is not met. The SW Committee notes the applicants' proposed premises are separate from those in which the appellant is operating, and they are separate legal entities. There is no evidence to suggest the premises to which the application relates, and the existing listed chemist premises should be treated as the same site. The SW Committee note Regulation 31 2 a and b are to be considered together and not as separate tests, as suggested by the appellant.
- 5.2.3 The SW Committee noted this is an application for a 'distance selling pharmacy' and is an excepted application and therefore not subject to the market entry test.
- 5.2.4 The SW Committee noted the application must be approved unless the Commissioner is not satisfied that the pharmacy procedures for the pharmacy premises are likely to secure:
- 5.2.5 *(i) the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and*
- 5.2.6 *(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.*
- 5.2.7 The appellant suggests the latest PNA does not identify any gaps in pharmaceutical services within the area, however as mentioned above, the SW Committee notes this is not a test for applications made under Regulation 25.
- 5.2.8 Following consideration of the information provided by the applicant the SW Committee was satisfied that the application should be granted as:
- 5.2.8.1 the proposed premises were not adjacent to or in close proximity to other chemist premises.
- 5.2.8.2 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.
- 5.2.8.3 all essential services were likely to be secured without interruption during the opening hours.
- 5.2.8.4 all essential services were likely to be secured for persons anywhere in England.
- 5.2.8.5 all essential services were likely to be secured without face to face contact.

5.2.8.6 all essential services were likely to be secured in a safe and effective manner because it had sufficient information to be satisfied that the procedures adopted by the applicant would be likely to secure the safe and effective provision essential services.

5.2.9 The SW Committee looks forward to receiving the Primary Care Appeals' decision in due course."

5.3 The Appellant

5.3.1 "We, AutoMeds Pharmacy Ltd, formally submit this appeal against the decision to approve the inclusion of Carewell Pharmacy Ltd into the pharmaceutical list under a distance selling premises accepted application (Case ref: CAS-310301-H1L8P6).

5.3.2 Grounds for Appeal

5.3.3 Failure to Properly Consider Regulation 31 – Same or Adjacent Premises

5.3.4 While we acknowledge that the applicant's proposed site is 0.3 miles away from our premises and technically not "adjacent," we submit that the intent and spirit of Regulation 31 have not been respected.

5.3.5 Regulation 31(2)(b) allows NHS England to consider whether the services proposed are materially similar to existing services such that the new premises can reasonably be treated as providing "the same service." Carewell Pharmacy has not demonstrated any differentiating or exceptional services that AutoMeds Pharmacy does not already provide.

5.3.6 There are multiple precedents where applications were refused even when pharmacies were located more than 0.1-0.5 miles away from each other, especially under Regulation 31, where no distinct need or service gap was identified. For example:

5.3.6.1 Case: CAS-218720-Z2J9X1 – Refused (North East Region, 2021)

5.3.6.2 Application for DSP was refused due to proximity to an existing DSP within 0.4 miles and lack of evidence of service differentiation.

5.3.6.3 Case: CAS-204615-Y8K5G7 – Refused (London, 2020)

5.3.6.4 Despite being a DSP application, the committee found it unjustified where the proposed applicant replicated existing services.

5.3.7 We request the PSRC [sic] re-evaluate whether Carewell Pharmacy truly meets the exception test under Reg. 31(2)(b), particularly as there is no need for a duplicative service in this micro- locality.

- 5.3.8 Lack of Unmet Need or Gap in the Local Pharmaceutical Needs Assessment (PNA)
- 5.3.9 The latest PNA for Dorset (or BCP area) does not identify any gaps in pharmaceutical services within the area surrounding BH12 3LY. AutoMeds Pharmacy Ltd, which operates within 0.3 miles, already provides:
- 5.3.10 Prescription collection and delivery
- 5.3.11 EPS nominations
- 5.3.12 Medicines use reviews
- 5.3.13 New medicines service
- 5.3.14 Flu and other vaccinations
- 5.3.15 Advanced DSP-level services nationally
- 5.3.16 We also maintain a robust online service and consistently meet NHS England KPIs. We have no record of complaints or public dissatisfaction. The current service meets and exceeds local needs, meaning Carewell Pharmacy is not addressing any unmet demand or need as defined by the PNA.
- 5.3.17 Lack of Justification for Inclusion Under Excepted Application Provisions
- 5.3.18 The only justification presented for the new application is the proposal to operate as a DSP in an industrial unit. This, in itself, does not justify inclusion, especially if there is:
- 5.3.19 No unmet need
- 5.3.20 No exceptional service proposition
- 5.3.21 Duplication of existing DSPs
- 5.3.22 Risk of undermining the viability of existing providers
- 5.3.23 The PSRC [sic] is urged to weigh the impact of unnecessary market duplication, particularly when it may weaken the sustainability of currently approved DSPs offering compliant, complaint-free services with proven track records.
- 5.3.24 Policy Consistency and Precedent
- 5.3.25 We respectfully request the NHS England [sic] to ensure consistency of policy application. In past decisions, applications have been refused for proximity alone, even for DSPs, if:
- 5.3.26 No unmet need exists

- 5.3.27 The applicant cannot demonstrate unique value
- 5.3.28 Existing providers offer all relevant services
- 5.3.29 By approving Carewell Pharmacy, NHS England risks creating an inconsistent precedent that may encourage saturation in tightly clustered areas where no additional capacity or innovation is needed.
- 5.3.30 Conclusion
- 5.3.31 We respectfully urge NHS England and the PSRC [sic] to reconsider and reverse this approval based on:
- 5.3.32 Regulation 31 applicability
- 5.3.33 Lack of differentiation in services
- 5.3.34 Absence of any identified need in the latest PNA
- 5.3.35 Consistency with national precedent
- 5.3.36 The approval of this application sets a problematic and unjustifiable precedent, allowing unnecessary duplication of DSPs in small geographical areas with no unmet pharmaceutical needs. We request a thorough re-examination of this application.”

6 **Summary of Observations**

This is summary of observations received.

6.1 The Appellant

- 6.1.1 “I write further to our original appeal to reinforce why Carewell Pharmacy Ltd’s application should not be approved.
- 6.1.2 Such an application should only be considered if it demonstrably strengthens, rather than weakens, the stability of existing pharmaceutical provision. In this locality, where services are already fragile, introducing another distance selling pharmacy (DSP) in such close proximity risks undermining the sustainability of care that patients depend on.
- 6.1.3 Jhoots Pharmacy, located beside Rosemary Medical Practice and within 0.3 miles of the proposed Carewell site, has already faced repeated closures due to pharmacist shortages. This clearly illustrates the vulnerability of local provision. Approving another DSP so close by, just 0.3 miles from AutoMeds Pharmacy, would further fragment prescription volumes and EPS nominations, directly threatening the financial viability of both community and distance-selling providers. Such dilution places essential services under greater strain, making it harder to maintain safe staffing and reliable access for patients. If established pharmacies are destabilised financially, these frontline services are the first to disappear to the detriment of the community.

6.1.4 For these reasons, we respectfully submit that the Carewell Pharmacy application does not meet the spirit or conditions of the Regulations. It offers no added assurance of safe, effective, and uninterrupted services; instead, it risks destabilising compliant, complaint-free providers already serving the area.

6.1.5 We therefore urge the Committee to give serious weight to these sustainability concerns and to refuse this application”.

7 Consideration

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

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

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

7.4 The Committee had regard to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (“the Regulations”).

Regulation 31

7.5 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”) at or from -

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

(ii) adjacent premises; and

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

7.6 The Committee noted that in response to the question in the application on this point, the Applicant stated “Not applicable as no other pharmacy in same or adjacent premises”.

7.7 The Commissioner in its decision letter stated that “The SW Committee was satisfied it is not required to refuse the application by virtue of Regulation 31”.

- 7.8 In its appeal, the Appellant had stated that:

“While we acknowledge that the applicant’s proposed site is 0.3 miles away from our premises and technically not “adjacent,” we submit that the intent and spirit of Regulation 31 have not been respected.

Regulation 31(2)(b) allows NHS England to consider whether the services proposed are materially similar to existing services such that the new premises can reasonably be treated as providing “the same service.” Carewell Pharmacy has not demonstrated any differentiating or exceptional services that AutoMeds Pharmacy does not already provide.

There are multiple precedents where applications were refused even when pharmacies were located more than 0.1-0.5 miles away from each other, especially under Regulation 31, where no distinct need or service gap was identified. For example:

Case: CAS-218720-Z2J9X1 – Refused (North East Region, 2021). Application for DSP was refused due to proximity to an existing DSP within 0.4 miles and lack of evidence of service differentiation.

Case: CAS-204615-Y8K5G7 – Refused (London, 2020). Despite being a DSP application, the committee found it unjustified where the proposed applicant replicated existing services.

We request the PSRC re-evaluate whether Carewell Pharmacy truly meets the exception test under Reg. 31(2)(b), particularly as there is no need for a duplicative service in this micro- locality.”

- 7.9 In response, the Applicant stated that *“There is no pharmacy at either the same or any adjacent premises to my client’s application site, nor does my client have any involvement in any other pharmacy. Automeds accepts that no such pharmacy exists. Regulation 31 does not apply in this case.”*
- 7.10 The Committee noted that Regulation 31(2)(b) only applies if 31(2)(a) is satisfied. The Committee noted that there is no dispute that 31(2)(a) is not satisfied as there is currently no pharmacy on the same or adjacent premises as the proposed site. It therefore appeared to the Committee that this element of the appeal was based on the Appellant’s misunderstanding of how Regulation 31 is considered. Further, the Committee noted the Appellant’s reference to case precedent. The Committee noted that the case reference numbers appeared to be for applications as opposed to appeals so the Committee had no background knowledge of these cases.
- 7.11 Taking the above into account, the Committee was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

- 7.12 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 pharmaceutical services without face to face contact at the pharmacy premises between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff."

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

Additional information to be included with excepted applications

8. *If the applicant (A) is making an excepted application, A must include in that application details that explain—*
- (a) *A's belief that the application satisfies the criteria included in one of the regulations in Part 4 which need to be satisfied if section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) are not to apply in relation to that application; and*
 - (b) *if the regulation includes reasons for which the application must be refused, why the application should not be refused for those reasons.*

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

- 7.15 As far as Regulation 25(2)(a) is concerned, the Committee had regard to the application form in which the Applicant states "*Application is not on the same site or in the same building as the premises of a provider of primary medical services with a patient list*". The Commissioner in its decision report stated that "*There is no provider of primary medical services at the proposed address, so the application does not have to be refused by virtue of Regulation 25(2)(a)*". The Committee noted that this had not been disputed and that it had not been provided with any information to persuade it otherwise. The Committee was therefore satisfied that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

- 7.16 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 and pharmaceutical services, including its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.
- 7.17 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, across England, and that pharmaceutical services will be provided in a safe and effective way without face to face contact.
- 7.18 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicates that the obligation is only discharged if the information or documentation provided is sufficient to satisfy the Commissioner in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the Commissioner may need to make of the information or documentation when carrying out its functions.
- 7.19 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.

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

7.21 The Committee considered how the Applicant would provide essential services without interruption and noted the information in the Applicant's SOPs under the following headings:

7.22 SOP 1: "Introduction and Background to SOPs"

7.22.1 "1.3 Overriding Provisions Applicable to All SOPs

The uninterrupted provision of pharmaceutical services, during the opening hours of the premises, to persons anywhere in England who request those services.

The safe and effective provision of pharmaceutical services without face-to-face contact between any person receiving the services, whether on their own or on someone else's behalf, and the owner of this pharmacy or any member of staff either on or in the vicinity of the premises."

7.23 SOP 34: "The Responsible Pharmacist"

7.23.1 "34.9 Absence of the RP

As a Distance Selling pharmacy, we must provide uninterrupted service throughout the opening hours of the pharmacy. Whilst the GPhC permits the absence of the RP from the pharmacy in particular situations, the NHS Terms of Service still require a pharmacist to be present so that services are not interrupted.

If, for any reason, the RP wishes to leave the premises or wishes to take a break then the second pharmacist must sign in as the RP and arrangements must be made for this prior to one RP leaving the premises and another RP signing in."

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

7.25 SOP 1: "Introduction and Background to SOPs"

7.25.1 "1.3 Overriding Provisions Applicable to All SOPs

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

7.26 SOP 3: “Procedures for NHS Pharmaceutical Services”

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

7.27 The Committee considered how the Applicant would provide pharmaceutical services without face to face contact and noted the information in the Applicant’s SOPs under the following headings:

7.28 SOP 1: “Introduction and Background to SOPs”

7.28.1 *“1.3 Overriding Provisions Applicable to All SOPs*

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

The safe and effective provision of pharmaceutical services without face-to-face contact between any person receiving the services, whether on their own or on someone else’s behalf, and the owner of this pharmacy or any member of staff either on or in the vicinity of the premises...

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

Any reference to ‘contact’ with or ‘contacting’ a patient in relation to these SOPs means contact other than face-to-face contact either on or in the vicinity of the premises.”

7.29 SOP 3: “Procedures for NHS Pharmaceutical Services”

7.29.1 *“3.1 Communication Channels*

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

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

7.30 Further the Committee was mindful of the regulatory changes as of 1 October 2025, that distance selling pharmacies can no longer provide Directed services (Advanced, National Enhanced and Enhanced Services, with the exception of Covid-19 and Flu vaccination services) face-to-face with the patient at the pharmacy premises.

- 7.31 In its application, which the Committee acknowledged was completed before the amendment came into force, the Applicant had stated that it intended to provide “NMS [New Medicines Service] (*remotely with consent where required*)”. As a result of this amendment, the Committee noted that the Applicant would not be able to provide any pharmaceutical services at its premises.
- 7.32 The Committee was aware that when the pharmacy opens, it will be the responsibility of the Commissioner, in keeping with Regulation 64, to ensure that services are provided other than with face to face contact.
- 7.33 The Committee was satisfied that the provision of essential services would be without interruption, would be available to persons anywhere in England and pharmaceutical services would be without face to face contact. The Committee went on to consider whether safe and effective provision of pharmaceutical services was likely to be secured.
- 7.34 The Committee considered pharmaceutical services including each essential service in paragraphs 3 to 22 of schedule 4 of the Regulations (“Terms of Service”) in turn.

Dispensing of drugs and appliances

- 7.35 The Committee considered whether the Applicant had explained how non-electronic prescriptions will be presented by the patient and how products will be provided.
- 7.36 In the Applicant's SOPs, the Committee noted the following:
- 7.37 SOP 3: “Procedures for NHS Pharmaceutical Services”
- 7.37.1 *“...Patients who wish to send paper prescriptions to the pharmacy by post should be sent stamped addressed envelopes to enable them to do so.”*
- 7.38 SOP 6: “Online Order Receipt & Exemption Checking”
- 7.38.1 *“6.2 Scope*
- All online services including the following:*
- ...Requests to collect and dispense NHS Prescriptions.*
- Requests to dispense a prescription received in the post.*
- Any requests from the “contact us” section of the website.”*
- 7.39 SOP 20 “Order Delivery”
- 7.39.1 *“20.6 Choice of Delivery Method*
- For items other than cold chain / “fridge line” items, local deliveries (up to 30 miles radius, but may be extended at the discretion of the RP) the*

delivery driver should deliver medication. Outside this area Royal Mail should be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier must be used (see SOP for Delivery of Controlled Drugs), or the items are fridge lines, in which case the cold chain courier must be used (see below). [Applicant's emphasis]".

7.40 The Committee was satisfied that the Applicant was proposing to offer the service to all of England, as per the information contained in the SOPs.

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

Urgent supply without a prescription

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

7.43 The Committee noted the information in the Applicant's SOPs under the heading "Emergency Supply and Urgent Supply" which describes how the Applicant will process such a request. The Committee noted that the SOPs refer to pharmaceutical services being delivered by several means of non-face-to-face communication including telephone and email, and considered that it was reasonable to infer that these methods would be used to receive requests from prescribers for the urgent supply of drugs.

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

Preliminary matters before providing ordered drugs or appliances

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

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

7.47 SOP 6: "Online Order Receipt & Exemption Checking"

7.47.1 "6.11 Exempt NHS Prescriptions

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 (i.e., 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."

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

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

7.50 SOP 6: "Online Order Receipt & Exemption Checking"

7.50.1 "6.14 Paid NHS Prescription

Check the prescription to confirm how many charges are due.

Check to see if any fees have been paid and if so, was the correct amount paid?

Contact the patient to arrange payment using the secure payments system using the "customer not present" option.

If no fees have been paid or there is a discrepancy between fees paid and those due, the patient should be contacted and directed to pay the appropriate fees via the online payment system."

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

Providing ordered drugs or appliances

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

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

7.54 SOP 20: "Order Delivery"

7.54.1 "20.10 Transfer to the Delivery Driver

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

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

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

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

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

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

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

7.54.2 “20.14 Delivery of a prescription via Royal Mail (Not for Cold Chain or CDs)

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

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

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

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

Confirm details of all prescriptions to be delivered.

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

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

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

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

7.54.3 “20.16 Cold chain delivery via courier

All cold chain deliveries must be carried out by couriers with verified and approved cold chain procedures. A list of approved cold chain couriers is available within the Pharmacy and will be updated from time to time.

Each approved courier meets stringent criteria to ensure a fully monitored and dedicated cold chain service.

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

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

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

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

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

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

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

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

Confirm details of all prescriptions to be delivered.

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

7.54.4 "20.17 Unsuccessful cold chain delivery via courier

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

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

7.54.5 “20.18 Breach of Integrity of Cold Chain

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

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

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

7.55 SOP 24: “Controlled Drugs: Delivery”

7.55.1 “24.5 Delivery of Schedule 2 & 3 CDs

A robust audit trail is essential when controlled drugs are involved. The delivery can be made to a person who is not the patient (the patient must have given authorisation for a representative to take receipt of CDs on their behalf). A Controlled Drugs Delivery Sheet must also be filled in for CD deliveries in addition to the Delivery Log sheet.

CDs must be in a separate bag to any other medication being delivered and the bags should be attached together.

CDs and any other medicines on that patient’s delivery must be stored in the lockable compartment of the delivery van and out of sight.

The delivery van must be kept locked at all times when the driver is not in the vehicle.

The delivery driver/courier must sign the back of the prescription as the representative when accepting the CD for delivery.

The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative (passport, driving licence or government approved photo ID card are acceptable forms of ID). A delivery cannot be left with anyone who is not the patient or their authorised representative.

Any falsified medicines rules introduced by the UK must be followed

All entries in the CD register must be made when the medication leaves the pharmacy premises. The delivery driver/courier must be entered as the ‘person collecting’.

The prescription must be retained in the pharmacy until the delivery driver returns the appropriate paperwork signed by the patient or representative to confirm successful delivery or the patient signature is confirmed online if delivered by courier."

7.55.2 "24.6 Successful Schedule 2 & 3 Delivery

The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative. A delivery cannot be left with anyone who is not the patient or their authorised representative.

For all successful deliveries the Controlled Drug delivery sheet signed by the patient or online courier delivery record should be cross-referenced with the prescription and CD register prior to the prescription being processed as part of the end of day procedure."

7.55.3 "24.7 Unsuccessful Schedule 2 & 3 Delivery via pharmacy driver

Unsuccessful deliveries sent with a pharmacy driver must be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate."

7.55.4 "24.8 Unsuccessful Schedule 2 & 3 Delivery via courier

Unsuccessful deliveries sent with a courier must be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate. Where the time of attempted delivery means that the return cannot be made on the same day, the courier will store the drugs at their approved warehouse overnight.

When a failed delivery occurs, the tracking service will notify the pharmacy and the patient of the failed delivery so that delivery can be re-arranged for the patient at the next convenient time or returned to the pharmacy."

7.55.5 "24.9 Note re Use of Couriers for Controlled Drugs Deliveries

The courier has pharma grade specialist facilities to meet specific quality and validation requirements for healthcare products. This includes Home Office licensed controlled drug stores."

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

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

7.58 In the application, the Committee noted that in response to the question as to whether they were undertaking to provide appliances, the Applicant stated “*Drug Tariff part IX**EXCEPT items that require measuring or fitting*”. In the Applicant’s SOPs, the Committee noted the following under the following headings:

7.59 SOP 10: “Pharmaceutical & Legal Assessment”

7.59.1 “10.9 Items Requiring Measuring and Fitting

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

7.60 SOP 27: “Support for Self-Care, Signposting and Health Promotion”

7.60.1 “27.14 Items Requiring Measuring and Fitting

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

7.61 In the event that the application is granted, the Applicant would not therefore, be able to provide such appliances that require measuring and/or fitting to patients.

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

7.63 The Committee considered whether the Applicant had explained what containers will be “suitable” for posted/delivered items.

7.64 In the Applicant’s SOPs, the Committee noted the following:

7.65 SOP 19: “Bagging-Up”

7.65.1 “19.7 Choice of Packaging

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.

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.

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.

DO NOT use normal cardboard boxes. When cardboard boxes are required ALWAYS use the re-enforced boxes that are purchased for delivery purposes.

For postal items, either:

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

*For most items - bubble wrap and where necessary, polystyrene filler, placed within a cardboard box. **use the re-enforced cardboard boxes***

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

Coldchain items should be bubble wrapped and placed in Styrofoam filled re-enforced cardboard boxes and kept in the DELIVERIES FRIDGE (rather than the storage fridge) with the “FRAGILE” and “FRIDGE LINE” stickers attached. The courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box (“cold ship” packaging) and are fully monitored – typically at 2 to 8 degrees Celsius range- (see delivery SOP). 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 and such items must not be used.” [Applicant’s emphasis].

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

Refusal to provide drugs or appliances ordered

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

- 7.68 In the Applicant’s SOPs, the Committee noted the following:

- 7.69 SOP 35: “Repeat Dispensing”

7.69.1 “35.10 Prescription Reception

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

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

7.69.2 "35.11 Pharmaceutical & Legal Assessment

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7.73 SOP 35: "Repeat Dispensing"

7.73.1 "35.10 Prescription Reception

Appropriate advice about the benefits of repeat dispensing must be given to any patient who:

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

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.

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

On receipt of a repeatable prescription from the patient, either in the post or collected from the surgery for the first time, the pharmacy staff should ensure that the patient fully understands the Repeat Dispensing Process and is provided with a patient information leaflet that outlines the benefits of the service.

Check to confirm if the patient has a long term, stable medical condition that requires regular medicine in the short to medium term and ensure relevant patients have the scheme explained to them."

7.73.2 "35.11 Pharmaceutical & Legal Assessment

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

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

7.74 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.

Disposal service in respect of unwanted drugs

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

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

7.77 SOP 25: "Controlled Drugs: Collection and Disposal of Patient Returns"

7.77.1 "25.5 Patient Returned Medication

This service is available to all patients living in England.

Patients or their representatives may not return and medicines directly to the pharmacy and must follow the procedures set out in this SOP.

Patients should be referred to the 'Returning unwanted medication' page on the website for information.

To arrange the return of unwanted medicines to the Pharmacy the patient must telephone and speak to a member of the dispensary team. For controlled drugs this must always be the pharmacist on duty.

The process for returning medication must be explained to the patient.

Each return will be made by booking an appointment for the pharmacy's driver to visit the patient's home to collect the returned medication or by sending the appropriate packaging to the patient to arrange for return by Royal Mail – Note the Royal Mail website refers to a prohibition on carrying "controlled drugs" but this refers only to illicit controlled drugs and not those supplied under the direction of a physician."

7.77.2 "25.7 Return by Royal Mail

The pharmacist must

Speak to the patient about the return and clarify the items being returned.

Assess the items for suitability for return by Royal Mail

If items are suitable for return by Royal Mail then make a note on the PMR and arrange to send the appropriate packaging to the patient for safe return (refer to bagging up SOP for appropriate packaging)

If items are not suitable for return by Royal Mail (eg clinical or contaminated waste) then provide the patient with details of their local procedures for disposal.

Send the packaging to the patient along with the instructions for appropriate packing of the goods

Contact the patient to ensure that the packaging has been received

Provide signposting to other pharmacies where the patient prefers to dispose of unwanted medicines locally."

7.77.3 "25.8 Handling Patient-Returned CDs from Delivery Driver

Drivers need to:

Be aware that they cannot accept patient returns from patients without prior arrangement. The driver must notify the patient to follow the "returning unwanted medication" process as set out on the website.

Ensure that appropriate packaging is within the van prior to starting the journey as the patient may not have requested the correct type or there may be a requirement for additional packaging.

Pharmacy staff need to:

If CDs have been identified, immediately on receipt from the driver, secure them in a bag, clearly marking on 'Patient-returned CDs for destruction' and include the date of return; place the bag in the CD cabinet away from pharmacy stock until they can be destroyed.

As soon as possible, Refer to the 'Returned medicines form' to make the entry in the 'Patient returned CD register', to record the CD that require destruction at a later date."

7.78 SOP 26: "The Safe and Effective Receipt and Disposal of Medicines"

7.78.1 "26.6 Process for Patients to Return Medication

Patient Returned Medication

Patients or their representatives MAY NOT return and medicines directly to the pharmacy and must follow the procedures set out in this SOP.

This service is available to all patients living in England.

Patients can be referred to the 'Returning unwanted medication' page on the website for information.

To arrange sending medication back to the Pharmacy the patient must telephone and speak to a member of the dispensary team.

Patients may

Arrange collection by the Pharmacy driver at an appointed time, or

Send unwanted medication back to the Pharmacy via courier (at the pharmacy's cost), or Royal Mail (subject to risk assessment of contents by the RP in advance) or,

The Pharmacy can arrange for medication to be collected by our specialist waste management contractor.

Advise patient of their other options to dispose of unwanted or expired medication if none of these options is suitable for them (signposting to local pharmacies).

Explaining the Process to Patients

Check which patient or patients the medication belonged to.

Check the relevant PMR to identify any hazardous / dangerous drugs or items that have been dispensed and could potentially form part of the return.

Ask the patient to identify the type of medication being returned.

If there is any item considered dangerous, such as a cytotoxic, inform the patient that we will collect items using the specialist waste management contractor and arrange for that collection to take place at a convenient time.

Go through the "unwanted medicines card" (available from the CPE website) over the phone with the patient."

7.78.2 "26.7 Process for accepting patient returns by the Driver

Confirm that a collection of unwanted medication for disposal has been booked. Returns without a booking should only happen in exceptional circumstances as this increases the chance that the proper process for segregation of medicine has not been followed.

Ensure you are fully equipped with the utensils in your vehicle to accept unwanted medication as patients may have placed unwanted medication into incorrect bags

Wear appropriate protective clothing where there is a requirement to handle any returned waste.

Identify any controlled drugs (check with the pharmacist if necessary); segregate these and place in a labelled clear bag for the pharmacist for denaturing and disposal. For further guidance read SOP Controlled Drugs: Disposal of Patient returned medication'.

Identify any sharps and ask the customer to take these back if it safe to do so, signposting to the most appropriate route of disposal.

Identify any cytotoxic or other hazardous waste (check with the pharmacist where necessary).

Identify any flammable waste and store separately until this can be removed by the waste contractor.

Where large quantities of the same medicine are being returned, then report this to the pharmacist as this could indicate a compliance issue requiring intervention.

Complete the 'Patients Returns Sheet' detailing the patients name and address, also if relevant their representatives name.

Store returned medicines in the quarantine area of the van for transport.

The returnable items can be taken back to the pharmacy for destruction.

Ensure medicines are not visible in the vehicle at all times."

7.78.3 "26.9 Return by Royal Mail

The pharmacist must

Speak to the patient about the return and clarify the items being returned.

Assess the items for suitability for return by Royal Mail

If items are suitable for return by Royal Mail then make a note on the PMR and arrange to send the appropriate packaging to the patient for safe return (refer to bagging up SOP for appropriate packaging)

If items are not suitable for return by Royal Mail (eg clinical or contaminated waste) then provide the patient with details of their local procedures for disposal.

Send the packaging to the patient along with the instructions for appropriate packing of the goods

Contact the patient to ensure that the packaging has been received

Provide signposting to other pharmacies where the patient prefers to dispose of unwanted medicines locally."

7.78.4 "26.10 Disposal of returned medicines

Use the specialist waste management company to provide safe and secure disposal of unwanted medicines by collection of unwanted medicines from patients and residential homes.

Unwanted medicines collected by the driver must be sorted and placed in disposal units / containers provided by the NHSCB or a waste contractor retained by the NHSCB ready for waste management services to collect.”

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

Promotion of healthy lifestyles

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

- 7.81 In the Applicant's SOPs, the Committee noted the following:

- 7.82 SOP 28: “Promotion of Healthy Living, Lifestyle & Health Campaigns”

7.82.1 “28.3 Identification of patients for promotion of Healthy Lifestyles

Identification can take three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process.

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. 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.

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 / diabetes etc.

As part of repeat dispensing process (or during any other interaction with a patient) staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from promotion of healthy lifestyles they should be recorded as a ‘target patient’ and the appropriate information that is relevant to them should be provided.

Leaflets will be delivered to patients with their medication. Those identified 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 via the health promotion zone.”

7.82.2 “28.4 Health Campaigns & Community Engagement Exercise

Terms of Service require participation in up to 6 campaigns per financial year, but you should agree to take part in all campaigns where practicable.

The Pharmacy will take part in national health campaigns to promote public health messages to 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 on the health promotion zone...

... We will also offer help and support on our website and direct patients to appropriate links for the health campaigns. This will ensure that patients across the UK are able to easily access information about health campaigns at all times.”

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

Prescription linked intervention

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

- 7.85 In the Applicant's SOPs, the Committee noted the following:

- 7.86 SOP 28: “Promotion of Healthy Living, Lifestyle & Health Campaigns”

7.86.1 “28.7 Long Term Conditions

If it is appropriate to provide advice the pharmacist should provide any advice necessary and within their area of competency. Where advice is provided it should be recorded on an Intervention & Referral form. Any advice given should always aim to include counselling on healthy lifestyle as well as management of the long-term condition.

If it is not appropriate to provide advice the patient should be referred to the appropriate health or social care provider or support organisation (see Signposting SOP). Where advice cannot be provided it should be recorded on an Intervention & Referral form along with the referral organisation.

For specific groups of patients (those with diabetes, at risk of coronary heart disease, especially those with high blood pressure, and patients who smoke or who are overweight) the pharmacists must provide advice without face-to face interaction (eg telephone, Live video, via the

website). Such advice should be backed up, as appropriate, by the provision of written material such as leaflets.”

7.86.2 “28.8 Identification of patients for Support with Long Term Conditions

Identification can take three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process.

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. 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.

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 / diabetes etc.

As part of repeat dispensing process (or during any other interaction with a patient) staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from promotion of healthy lifestyles they should be recorded as a ‘target patient’ and the appropriate information that is relevant to them should be provided.

Leaflets will be delivered to patients with their medication. Those identified 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.”

- 7.87 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.

Health campaigns

- 7.88 The Committee considered whether the Applicant had explained how it will safely and effectively participate in public health campaigns, if and to the extent required by the Commissioner.
- 7.89 In the Applicant’s SOPs, the Committee noted the following:
- 7.90 SOP 28: “Promotion of Healthy Living, Lifestyle & Health Campaigns”

7.90.1 “28.4 Health Campaigns & Community Engagement Exercise

The Pharmacy will take part in national health campaigns to promote public health messages to 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 on the health promotion zone.

The pharmacy will also take part in at least one approved community engagement exercise in relation to the promotion of health living each financial year.

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.

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.

We will also offer help and support on our website and direct patients to appropriate links for the health campaigns. This will ensure that patients across the UK are able to easily access information about health campaigns at all times.

The Pharmacy will use the opportunity when dispensing prescriptions for patients who have conditions such as diabetes, heart disease, obesity and high blood pressure, to offer health advice over the phone or provide them with leaflets about their conditions. Patients will also be able to speak to the pharmacist regarding information about the campaigns. Advice and help will be available to patients during opening hours of the pharmacy and patients can access information on our pharmacy website at all times. This ensures the uninterrupted provision of the service to patients across England.”

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

Signposting

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

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

7.94 SOP 27: "Support for Self-Care, Signposting and Health Promotion"

7.94.1 "27.10 Other Provider Organisations and Support Details

Details of local health and social care providers to whom patients can be referred as well as contact details for local patient and support groups can should [sic] be provided to patients via written mailshots, flyers sent with prescription deliveries, our website and by telephone or email."

7.94.2 "27.12 Signposting

Service Description

To minimise inappropriate use of health and social care services and support services, patients who require further support, advice or treatment which cannot be provided by the pharmacy, on other health and social care providers or support organisations who may be able to assist the person must be given sufficient information to enable them to access those services. Where appropriate, this may take the form of a referral."

7.94.3 "27.13 Patient Identification

Identification can take place during any interaction that the patient has with the pharmacy staff. In particular, staff should consider the results from the identification of patients for the promotion of healthy lifestyles and those who have filled in the Lifestyle Questionnaire on the website.

Staff should always consider that in order to minimise inappropriate use of health and social care services and of support services and person who:

*requires advice, treatment or support that we cannot provide;
but*

we are aware of another provider of health services who is likely to be able to provide that advice, treatment or support.

We must provide the patient with contact details of that provider and, where appropriate, refer the person to the provider. At least two providers should be identified if this is possible."

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

Support for self-care

7.96 The Committee considered whether the Applicant had explained how it will provide advice and support to people caring for their families.

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

7.98 SOP 27: "Support for Self-Care, Signposting and Health Promotion"

7.98.1 "27.8 Patient Identification

As part of repeat dispensing process / medicine sale or during any other interaction with a patient staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from support for self-care they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided and should include:

treatment options, including advice on the selection and use of appropriate drugs which are not prescription only medicines; and

on changes to the patient's lifestyle."

7.98.2 "27.9 Service outline

Upon receipt of a request for help with the Support for Self-Care, including treatment of minor illness and long-term conditions, pharmacy staff should consider available resources and provide general information and advice on how to manage illness.

If appropriate, access the patient's Summary Care Record / National Care Records Service to see if it assists in delivery of the service...

...The pharmacist should provide advice on the appropriate use of non-prescription medicines which can be used in the self-care of the relevant minor illness and / or long-term conditions."

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

Discharge medicines service

7.100 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 and NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.

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

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

7.103 SOP 29: "Discharge Medicines Service ("DMS")"

7.103.1 "29.3 Process

Every day the RP must check the pharmacy's NHS mail system, PharmOutcomes and Refer to Pharmacy for referrals to the DMS. Pharmacy contractors must consider any communication in the following form and manner as constituting a referral: "Any written patient information received by a community pharmacy via secure electronic message from an NHS trust or other provider of NHS services concerning a patient's discharge to usual primary care services and their medicines regimen".

7.103.2 "29.4 Consent

Obtain and record the informed consent from the patient prior to provision of the service using the consent form. As part of obtaining consent discuss the requirements for data sharing. Inform the patient that any information discussed as part of the service may be shared with their GP."

7.103.3 "29.5 DMS Stages

It is expected that all patients referred to the pharmacy will receive all three stages of the service. Note that stages 1, 2 and 3 of the service may occur in parallel and first contact with the patient (as defined in the NHS Discharge Medicines Service toolkit) could happen at any stage in the process."

7.103.4 "29.6 DMS Stage 1

The community pharmacy receives a discharge referral. A clinical review is undertaken by a community pharmacist following receipt of a patient referral. The community pharmacy team may contact the referring NHS trust contact or the PCN pharmacy team to discuss any concerns (eg an important medicine the patient usually takes is omitted on the discharge referral) and to seek clarification about the discharge referral."

7.103.5 "29.7 Considering the appropriateness of any medication changes prior to discharge

DMS requests will not necessarily all be in the same form.

Summary Care Record / National Care Records Service Access - If appropriate, access the patient's Summary Care Record / National Care Records Service to see if it assists in providing the service

The pharmacist must review the actions requested in the DMS and consider whether the actions requested are, in the pharmacists clinical judgement, appropriate.

For actions that are considered appropriate the pharmacist must;

Use the information in the referral, to compare (as far as possible) the patient's medicines at discharge to those they were taking before admission to hospital.

Check any prescriptions issued to be dispensed to assess whether any changes are appropriate and identify any areas of concern.

Where necessary, discuss changes that may be appropriate or raise any issues of concern identified, to the extent that in accordance with the pharmacist's clinical judgement, it appropriate to do so with—

(i) the staff of the hospital or other provider of NHS services that made the referral, and

(ii) any provider of primary medical services on whose patient list the patient is; and

keep and maintain records of the DMS referrals received and of any actions taken, as appropriate (in particular, to support delivery of stages 2 and 3 of the service).

REQUIRED ACTIONS AS PER NHS GUIDANCE.”

7.103.6“29.8 DMS Stage 2

The community pharmacy receives the first prescription following discharge. The pharmacist or pharmacy technician will ensure medicines prescribed post-discharge take account of the appropriate changes made during the hospital admission. If there are discrepancies, the pharmacy team will try to resolve them with the general practice, utilising existing communication channels. Alternatively, the community pharmacist may refer the patient to the PCN pharmacy team for a Structured Medication Review or other intervention.

If the pharmacy receives either a written or electronic prescription (or repeatable prescription) or EPS token and the pharmacy has received a request for Stage 2 of the DMS service either from Stage 1 or

Even without a referral to Stage 2, the pharmacy receives such a prescription as described above and the pharmacy is aware as a result of an earlier referral to Stage 2 or Stage 3 that this is the first prescription for a medicinal product following the patient's discharge from hospital, or a transfer of the patient's care from another NHS service provider, AND

The pharmacy is aware that either the patient, or their carer wishes the pharmacy to provide Stage 2 of the DMS service then the pharmacy must provide the following service as part of Stage 2

Then the pharmacist must:

Review / perform a further review of any prescription

*Summary Care Record / National Care Records Service Access
- If appropriate, access the patient's Summary Care Record / National Care Records Service to see if it assists in providing the service.*

Specifically consider if in your clinical judgement appropriate account has been taken to any changes in the medication regimen during the patient's stay in hospital or prior to the transfer of the DMS from another pharmacy.

Where you see areas of concern, raise those issues as appropriate with the patient's GP

Keep and maintain records of the DMS referrals received and of any actions taken, as appropriate (in particular, to support delivery of stage 3 of the service)."

7.103.7 "29.9 DMS Stage 3

The NHS Discharge Medicines Service should also be used as an opportunity to engage with patients about their medicines on a shared decision-making basis. Whether the patient or their carer makes contact themselves for advice, a referral is received from an NHS trust on discharge or a prescription is received following prescribing changes, the pharmacist or pharmacy technician should take the opportunity to establish the patient's understanding of their condition(s), their associated medications and how each medicine can be best administered to get optimum benefit and reduce unwanted side effects.

The community pharmacy checks the patient's understanding of their medicines regimen. The pharmacist or pharmacy technician will hold a discussion, adopting a shared decision-making approach, with the patient (or the carer if appropriate) to check their understanding of their post-discharge medicines' regimen. The pharmacist or pharmacy technician will identify any adherence, clinical issues, outstanding questions or needs the patient may have regarding their medicines."

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

Websites and health promotion zones

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

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

7.107 SOP 27: "Support for Self-Care, Signposting and Health Promotion"

7.107.1 "27.11 Health promotion zone on our website

The website allows patients to access pharmaceutical services via our interactive page.

Explaining the Interactive Page to Patients

The interactive page is promoted on the website so that when a patient first visits the website they are signposted to a range of up to date materials that promote healthy lifestyles.

The Superintendent Pharmacist is responsible for ensuring that a reasonable range of materials are accessible via the interactive page and that they address a reasonable range of health issues.

The health promotion zone may also includes [sic] details of current health campaigns and other information to promote healthy lifestyle choices as well as providing access to the Lifestyle Questionnaire that is used to target health information to patients."

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

Other considerations

7.109 The Committee noted the Appellant's reference to a "*Lack of Unmet Need or Gap in the Local Pharmaceutical Needs Assessment (PNA)... No exceptional service proposition, Duplication of existing DSPs and Risk of undermining the viability of existing providers*" as reasons why the application should be refused. However, the Committee noted that these are not relevant considerations under the provision of Regulation 25.

Summary

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

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

7.111.1 confirm the Commissioner's decision;

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

7.111.3quash the Commissioner's decision and, if it considers that there should be a further notification to the parties to make representations, remit the matter to the Commissioner.

7.112 Although the Committee had reached the same conclusion as the Commissioner, it was mindful that it had been provided with more information on appeal, such as the Applicant's SOPs. In those circumstances the Committee determined that the decision of the Commissioner must be quashed.

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

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

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

8 Decision

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

8.2 The Committee:

8.2.1 quashes the decision of the Commissioner; and

8.2.2 redetermines the application as follows -

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

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

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

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

8.2.2.5 the Committee was satisfied that pharmaceutical services were likely to be secured in a safe and effective manner; and

8.2.2.6 the Committee was satisfied that pharmaceutical services were likely to be secured without face to face contact.

8.2.3 The application granted.

Case Manager
Primary Care Appeals