28 August 2026

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REF: APL-4430 [SHA/26819]

APPEAL AGAINST NORTH EAST AND NORTH CUMBRIA ICB DECISION TO REFUSE AN APPLICATION BY FREEMAN PHARMA LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 1 STATION ROAD, NEWCASTLE UPON TYNE, NE15 8LS UNDER REGULATION 25

1 Outcome

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

1.2 The Committee determined that the application should be refused.

A copy of this decision is being sent to:

Freeman Pharma Ltd
PCSE on behalf of North East and North Cumbria ICB
Rushport Advisory representing Newburn Pharmacy, Throckley Chemist and Lemington Pharmacy
Boots
Community Pharmacy North of Tyne

NHS Resolution

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1 The Application

By application dated 21 June 2025, Freemanpharma Ltd ("the Applicant") applied to North East and North Cumbria ICB ("the Commissioner") for inclusion in the pharmaceutical list at 1 Station Road, Newcastle upon Tyne, NE15 8LS 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:

1.2 [Left blank].

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

1.4 [Left blank].

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

1.6 [Left blank].

Pharmacy procedures

1.7 Please 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.

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

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

1.10 You must ensure that you provide sufficient information within this application form to satisfy NHS England or the relevant delegated integrated care board on the above points. You are not required to submit your standard operating procedures for the premises but if you do they will be circulated to interested parties unless NHS England or the relevant delegated integrated care board is satisfied that the full disclosure principle does not apply.

1.11 “There will be a responsible pharmacist on duty during the opening hours of the premises. The pharmacy will serve anywhere in England who request the services.

1.12 The pharmacy will not allow face to face contact for essential services. There will be a controlled door entry system to prevent people from accessing essential services face to face. There be an SOP that explains to the team how to refuse a request for face to face essential services.

1.13 There will [sic] a sign outside the pharmacy that indicates that this is a distance selling pharmacy and essential services cannot be accessed in person in the pharmacy.

1.14 We have attached a document called Station Road supporting information which details how we are going to provide essential services to anywhere in England during the opening hours of the pharmacy. This document also gives more details on all aspects of this question.”

“Station Road Premises Supporting Information

NHS England Premises Standards

1.15 NHS England has published 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.

1.16 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 delivery consistently high quality health and wellbeing services.

1.17 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.

GPhC Guidance

1.18 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.

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

Risk Assessment

1.20 A Risk Assessment document and risk matrix to help identify and manage risks.

1.21 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.

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

Audit Procedures

1.23 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 services to patients. Any issues identified will be subject to a reactive review.

1.23.1 The audit will, at the very least, consider:

1.23.2 Staffing levels and the training and skills within the team;

1.23.3 Suitability of communication methods with patients, and between staff and other healthcare providers.

1.23.4 Use of specialised equipment and new technology;

1.23.5 Records of decisions to make or refuse a sale;

1.23.6 Systems and processes for receiving prescriptions, including EPS records of decisions to make or refuse a sale.

1.23.7 Systems and processes for secure delivery to patients;

1.23.8 Any information about pharmacy services on the website;

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

1.23.10 Feedback from patients and people who use the pharmacy services;

1.23.11 Concerns or complaints received; and

1.23.12 3 [sic]

1.23.13 Activities of third parties, agents or contractors.

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

Reactive Review

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

1.25.1 A change in the law affecting any part of the pharmacy service;

1.25.2 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;

1.25.3 A data security breach;

1.25.4 A change in the technology the pharmacy uses;

1.25.5 Concerns or negative feedback are received from patients or people who use the pharmacy services;

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

Accountability

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

Record Keeping

1.27 Records in the pharmacy will be scanned into 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.

Training

1.28 The Applicant 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.

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.

Website

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

1.31 The website will display:

1.31.1 The GPhC pharmacy registration number;

1.31.2 The name of the owner of the registered pharmacy;

1.31.3 The name of the superintendent pharmacist;

1.31.4 The name and address of the registered pharmacy that supplies the medicines;

1.31.5 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);

1.31.6 Information about how to check the registration status of the pharmacy and the superintendent pharmacist;

1.31.7 Details of specific services available and how to use them, i.e.;

1.31.7.1 Return of unwanted medicines;

1.31.7.2 Patient Lifestyle Questionnaire;

1.31.7.3 How to register exemptions from NHS charges;

1.31.7.4 Promotion of Health Lifestyles and details of campaigns being undertaken;

1.31.7.5 Procedures for Emergency Supply;

1.31.7.6 Explanation of rules of non-face to face contact;

1.31.7.7 Patient Information Leaflet;

1.31.7.8 The email address and phone numbers of the pharmacy;

1.31.7.9 Details of how patients and users of pharmacy services can give feedback and raise concerns;

1.31.7.10 GPhC internet logo (linked to register entry);

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

1.31.7.12 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.

1.32 The pharmacy will allow the public to access pharmaceutical services from the pharmacy premises via a website on which there is a health promotion 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 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.

Transparency and Choice

1.33 The Applicant's website and materials will specify the nature and type of services it provides and who provides those services.

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

5 [sic] Managing Medicines Safely

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

Supplying Medicines Safely

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

1.36.1 Assess the suitability and timescale of the method of supply, dispatch, and delivery for all medicines and particularly refrigerated medicines and controlled drugs;

1.36.2 Ensuring that robust identity check processes are in place to ensure that medicines dispensed are delivered to the correct person;

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

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

Equipment and Facilities

1.38 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.

1.39 All equipment will be subject to annual performance testing and review.

1.40 IT equipment will meet the latest security specifications and be regularly updated including the use of encrypted networks for wired and wireless

communication. Access to records will be dependent on any given employee's level of authority and clearance which shall be determined by the superintendent pharmacist.

Standard Operating Procedures

1.41 If NHS England requires any further information about any aspect of the operation of the pharmacy then the relevant SOPs will be provided upon request.

PHARMACY SYSTEMS AND PROCEDURES

1.42 All Essential Services will be delivered in accordance with:

1.42.1 Company Standard Operating Procedures;

1.42.2 NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013;

1.42.3 NHS Act 2006;

1.42.4 Human Medicines Regulations 2012;

1.42.5 GPhC – Professional Standards and Guidance on Distance Selling Pharmacies;

1.42.6 Relevant Data Protection laws.

1.43 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.

1.44 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.

1.45 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.

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

1.46.1 Telephone;

1.46.2 Live video call;

1.46.3 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;

1.46.4 Email;

1.46.5 Postal services.

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

1.48 Essential Services may be delivered using:

1.48.1 Telephone, including text messaging where appropriate;

1.48.2 Electronic Prescription Service (EPS);

1.48.3 Website;

1.48.4 Email;

1.48.5 Royal Mail postal service;

1.48.6 Courier service;

1.48.7 Specialist Waste Management Services;

1.48.8 Live video services.

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

Provision of NHS Essential Services

Dispensing Services

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

1.51 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.

1.52 When appropriate prescription interventions take place, for example drug/drug use 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.

Repeat Dispensing Services

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

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

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

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

1.55 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.

1.56 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.

Urgent Supply and Emergency Supply

1.57 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.

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

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

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

1.59.2 The Pharmacist is satisfied that a prescription cannot be supplied immediately due to an emergency;

1.59.3 The Prescriber agrees to provide a written prescription within 72 hours;

1.59.4 The medication is supplied in accordance with the prescriber's directions;

1.59.5 The medication is supplied in accordance with the prescriber's directions;

1.59.6 The medication is permitted to be supplied on an Emergency Supply basis;

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

1.59.7 EEA prescribers cannot request an emergency supply of any Schedule 1 – 5 CD.

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

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

1.61.1 Interview;

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

1.61.2 Records;

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

1.61.2.2 The label for the dispensed medicine must contain the words 'Emergency Supply'.

1.61.3 Faxed prescription;

1.61.3.1 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.

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

Delivery of Urgent Supplies

1.62 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.

Disposal of Unwanted Medicines

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

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

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

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

1.67 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.

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

Promotion of Healthy Lifestyles

1.69 We will promote healthy lifestyle advice both to those who we know have issues and those who have no known issues.

1.70 Patients with known issues will be given information relevant to their needs via e-mail, video link or by post.

1.71 Patients with no known issues will be proactively provided with general healthy lifestyle information via the website, e-mail, video link or by post.

1.72 We will collect information on peoples lifestyles and needs to help us better support them.

1.73 Leaflets will be delivered to patients with their medication for conditions relevant to them such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc, and those 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.

Health Campaigns

1.74 The Pharmacy will take part in national health campaigns to promote health messages to the Applicant's 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.

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

1.76 Patients should also be assessed for participation in at least one clinical audit and whichever of the following that the NHS specifies –

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

1.78 (ii) a policy based audit (to support the development of the commissioning policies of the NHS carried out in a manner which is compatible with the NHS arrangements for the receiving and processing of data from the audit.

Signposting and Support for Self-Care

1.79 Patient will be signposted to health and social care providers and/or any other assistance available whenever necessary.

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

1.81 If a patient;

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

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

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

Referral for Certain Appliances

1.85 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 –

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

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

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

Support for People with Disabilities

1.89 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.

1.90 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.

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

Clinical Governance

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

1.93 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.

1.94 '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.

1.95 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.

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

Information Governance

1.97 The pharmacy will be registered and comply with Data Protection Act and the General Data Protection Regulation (GPDR). It will also comply with the Access to Health Records Act 1990. It will publish its Freedom of Information Act Publication Scheme on its website and copies will be made available on request. All patient data will be kept private and confidential in accordance with NHS and legal obligations on data security, protection and confidentiality.

1.98 The pharmacy will receive support from the PMR provider to ensure that Continuous access to the Electronic Prescription System is maintained.

1.99 Two members of staff will have the ability to login to the PMR 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.

Discharge Medicines Service ("DMS")

1.100 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 and 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.

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

1.102 (a) 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

1.103 (b) 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.

1.104 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.

1.105 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.

1.106 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.

1.107 If the DMS referral can no longer be done e.g. patient back in hospital the referral should be declined.

1.108 The pharmacy will provide medicines properly requested under any Pandemic arrangements.

1.109 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.

1.110 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).

1.111 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.

1.112 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.

1.113 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.

1.114 Medicines for local delivery which is (a) not fragile and (b) is to be delivered by the delivery driver can be packaged in the normal pharmacy bags supplied for standard prescription items.

1.115 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 sift proof container (for solids). Must be tightly packed in strong outer packaging and must be secured or cushioned to prevent any damage.

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

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

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

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

1.117 The patient, carer or notified, authorised patient representative must also 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.

1.118 A list of the approved cold chain couriers will be maintained within the Pharmacy. Cold chain 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 redelivery can be arranged. Where the cold chain breach notice is issued items will not be re-used.

Controlled Drugs

Delivery of Controlled Drugs

1.119 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.

Return and Destruction of CONTROLLED DRUGS

1.120 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 reused 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.

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

Cover for Breaks / Working Time Directive

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

Contingency Planning

1.123 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.

Verification of Declarations of Prescription Exemptions

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

1.125 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 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.

1.126 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.

1.127 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.

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

Pharmacy Profile

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

Central Alerting System

1.130 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.

Registration of the Premises with the GPhC

1.131 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.

Practice Leaflet

1.132 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—

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

1.132.2(ii) 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).

1.133 Advanced or Enhanced Services

1.133.1The pharmacy will only offer services that can be delivered remotely and do not require patients to attend the premises."

2 Comments to the Commissioner

On reviewing the paperwork provided by PCSE, it was noted that the comments made by the Applicant to the representations on the application, had not been circulated or seen by parties.

In the interests of transparency and fairness, NHS Resolution sought to rely on the discretion afforded in paragraph 7 of Schedule 3 of the Regulations to vary the normal procedures and circulate these comments to parties for them to make observations on them if they so wished.

2.1 THE APPLICANT

2.1.1 "I wish to thank the three respondents to the application. I have the following points to make in response to the application:

2.1.2 1. In response to Mr. Mehdi's comment regarding the need for an additional pharmacy in the area of Newcastle. This is a DSP application using regulation 25 and as the committee for Community pharmacy North of Tyne acknowledges there is no primary medical service provider with a patient list on the same site or in the same building, we do not need to show a pharmaceutical need in Newcastle.

2.1.3 2. In response to Mr Mehdi's comment: "The supporting information talks about patients accessing the pharmacy for non-essential services which we presume means for NMS or pharmacy first?"

2.1.4 I think Mr Medhi has misread the supporting information it states: "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."

2.1.5 The application also lists the following advanced NHS services that will be provided by the pharmacy. New Medicine Service and Pharmacy First.

2.1.6 Remote Provision Advanced Services

2.1.7 All advanced services listed in the application will be delivered in strict compliance with the following legislation:

2.1.8 Regulation 25 of the 2013 Regulations with affect from 24 June 2025.

2.1.9 NHS Terms of Service for Distance Selling Premises

2.1.10 General Pharmaceutical Council Standards for Registered Pharmacies

2.1.11 UK GDPR and NHS Data Security and Protection Toolkit requirements

2.1.12 Relevant Patient Group Directions (PGDs)

2.1.13 NHS England service specifications.

2.1.14 No member of the public will have physical access to the premises for NHS services, and no NHS consultations will occur in person at or near the site.

2.1.15 **New Medicine Service (NMS)**

2.1.16 Conducted via NHS-compliant secure video platforms (e.g., MS Teams, AccuRx) or telephone from a dedicated, soundproofed consultation room.

2.1.17 Identity verification will be carried out before the consultation using patient demographics and/or photographic ID via video.

2.1.18 Explicit informed consent will be recorded in the PMR in accordance with NHS guidance.

2.1.19 **NHS Pharmacy First Service**

2.1.20 Six of the current seven NHS Pharmacy First Service clinical pathways will be provided. Acute Otitis media clinical pathway will not be provided as the legislation requires the patient to be physically present in the pharmacy which is not permitted from a distance selling pharmacy.

2.1.21 All consultations conducted by secure video call only, in accordance with NHS England Pharmacy First Service Specification.

2.1.22 Clinical assessment and preparation for supply under the relevant PGDs will be completed during the video consultation.

2.1.23 Medicines supplied will be dispatched via tracked courier or postal delivery.

2.1.24 3. In response to Mr Medhi's question "What the pharmacy would do if the responsible pharmacist was not available?" Mr Medhi also questioned "How the pharmacy would deal with patient enquiries during the absence of the pharmacist."

2.1.25 As this is a distance selling application there must be a responsible pharmacist available physically on the premises at all times the pharmacy operates. The pharmacy would not operate without the presence of a pharmacist at any time.

2.1.26 I have attached the draft SOP RP1 to detail the answer to what the pharmacy would do if the Responsible Pharmacist was not available and how the pharmacy would deal with patient queries during the absence of the pharmacist.

2.1.27 4. Mr Medhi questioned "What the pharmacy would do It is also not clear what the pharmacy would do if they were delivering prescriptions such as insulin or other items that need to be refrigerated and the patient was not at home when the delivery was being made. If a patient lived in Cornwall and the pharmacy is in Newcastle how will they deal with these missed deliveries? What will the patient do if they run out" of medicine because they were not at home? Will they just put the delivery in the letterbox if the patient is not in?

2.1.28 My understanding of the above exert from the response is that Mr Medhi wants to understand:

2.1.28.1 What the cold chain procedure will be for the delivery of fridge lines.

2.1.28.2 How missed deliveries will be handled.

2.1.28.3 How deliveries will be handled if the patient is not in

2.1.28.4 How failed deliveries will be handled that result in the patient being without medication.

2.1.29 In response to the question on cold chain procedure for fridge lines and how to handle missed fridge line deliveries please see Draft SOP CC1 which includes the procedure for delivery and handling missed Fridge line deliveries.

2.1.30 In response to how missed deliveries will be handled and how deliveries will be handled if the patient is not in please see draft SOP D1.

2.1.31 In response to how failed deliveries will be handled that result in the patient being without medication please see draft SOP D2.

2.1.32 5. In response to Mr Medhi's comment "The information does not show that the pharmacy will provide safe services and the ICB should not allow this pharmacy to open."

2.1.33 In this letter and the SOPs specified I have answered every one of Mr Medhi's concerns. I provided a lot of supporting information with the application to demonstrate how this pharmacy will provide safe services. In addition should this application be successful it will need to satisfy the GPhC that it is set up to provide safe services before it is allowed to open.

2.1.34 6. In response to Jo Severn, Boots NHS Contract Lead comment:

2.1.35 Boots UK Ltd would 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.

2.1.36 This application meets the criteria set out in regulation 25 and the conditions set out in Regulation 64.

2.1.37 7. In response to North Tyne LPC Committees comment:

2.1.38 "Under Regulation 25, part 2(a), the application can be approved because there is no primary medical services provider with a patient list on the same site or in the same building."

2.1.39 I agree with this comment.

2.1.40 8. In response to North Tyne LPC Committees comment:

2.1.41 "Under Regulation 25, part 2(b), the application can be approved because the contractor has provided information to support their provision of services to patients anywhere within England without face to face contact between the patient or their representative and the applicant's staff."

2.1.42 I agree with this comment.

2.1.43 9. "In response to North Tyne LPC Committees comment:

2.1.44 The applicant has provided a floor plan to accompany their application. This provides space for multiple consultation tooms. The LPC accepts a consultation room is required to provide a confidential space to allow the pharmacist and support team to have confidential conversations with patients via telephone or video conference. Given the pharmacy is unable to provide any face to face NHS services following the forthcoming update to the regulations, the LPC requests that upon commencement of trading, that NHSE&I assure themselves that services are being provided from secure premises which do not permit any face to face contact with patients other than for private services."

2.1.45 The building we are using was an old bank and the consultation rooms were already in place. As detailed in the application we have systems in place to ensure NHS interactions are conducted at a distance only."

2.1.46 [Appendix A for Committee:

2.1.46.1SOP CC1, Version 1 - Cold Chain Medicines – Storage, Packing, Delivery and Handling Failed Deliveries

2.1.46.2D2 - Failed Delivery Patient Call SOP – DSP (Staff & RP Actions)

2.1.46.3Standard Operating Procedure (SOP): Responsible Pharmacist (RP) – Distance Selling Pharmacy SOP Number: RP1 DRAFT – Version 1.2

2.1.46.4Standard Operating Procedure (SOP): Delivery & Dispatch – Distance Selling Pharmacy (DSP) SOP: D1 - Version: 1.1.]

3 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 12 November 2025 states:

3.1 "North East and North Cumbria ICB has considered the above application and I am writing to confirm that it has been refused. Please see the enclosed report for the full reasoning.

3.2 You have a right of appeal to the Secretary of State against North East and North Cumbria ICB's decision. Should you choose to appeal then you should either complete the online form available on the NHS Resolution website or send a concise and reasoned statement of the grounds for your appeal within 30 days of the date of this letter to nhsr.appeals@nhs.net or:

3.3 Primary Care Appeals, NHS Resolution, 8th Floor, 10 South Colonnade, Canary Wharf, London, E14 4PU."

Decision Report:

3.4 "**APPLICATION: CAS-370449-C3F4M4- for inclusion in a pharmaceutical list:**

3.5 **Distance Selling Premises (Excepted Application)** by **Freemanpharma Ltd at 1, STATION ROAD , NEWCASTLE UPON TYNE , NE15 8LS**

3.6 On 29th October 2025, the Pharmaceutical Services Regulations Committee (PSRC) **refused** this **Distance Selling Premises Application** on the following basis:

3.7 **Regulation 25(2)(a)** does not apply as no primary care provider with a patient list is present within the same premises as the proposed site – **Regulation not applicable.**

3.8 **Regulation 25(2)(b)(i) -** Regulation not met as the applicant has not demonstrated how services will be provided remotely, and without interruption throughout the given opening hours - **Regulation not met.**

3.9 **Regulation 25(2)(b)(ii) -** Regulation not met as the applicant has not demonstrated how the safe and effective provision of pharmaceutical services

without face to face contact at the pharmacy premises between any person receiving the services - **Regulation not met.**

3.10 **Regulation 31** does not apply as there is no pharmacy at the same or adjacent premises to the proposed site – **Regulation not applicable.**

3.11 **Regulation 64 –** has not been met as the application does not fully meet the below specific conditions to be met by applications for Distance Selling Premises: **Regulation not met.**

3.11.1 The applicant must not offer to provide pharmaceutical services to persons who are present at (which includes in the vicinity of) the proposed premises.

3.11.2 The means by which the applicant provides pharmaceutical services must be such that any person receiving those services does so otherwise than at the proposed premises.

3.11.3 The proposed premises must not be on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

3.11.4 The pharmacy procedures for the premises must be such as to secure:

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

3.11.4.2and

3.11.4.3– 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; and

3.11.5 Nothing in the applicant's practice leaflet, in the applicant's publicity material in respect of the proposed premises, in material published on behalf of the applicant publicising services provided at or from the proposed 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 from the applicant must represent, either expressly or impliedly, that:

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

3.11.5.2– 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 (eg because the availability of essential services from the applicant is limited to other categories of patients).

3.11.6 **Regulation 64(4)** is satisfied as the NENC ICB will not vary or remove the conditions set out in paragraph 64(3) - **Regulation met.**

3.11.7 The HWB's **Pharmaceutical Needs Assessment** is not relevant to this application as DSP applications are excepted.

3.11.8 **Consultation** – Objections were received from Newburn Pharmacy, Throckley Chemists and Lemington Pharmacy.

3.11.9 **Appeal Rights: Applicant."**

4 The Appeal

In a letter dated 7 December 2025, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

4.1 "We are writing to formally appeal the decision of the North East and North Cumbria ICB Pharmaceutical Services Regulations Committee (PSRC), dated 29th October 2025, to refuse the application by Freemanpharma Ltd for inclusion in the pharmaceutical list for a Distance Selling Pharmacy (DSP) at the above address.

4.2 We have reviewed the decision notice and the grounds for refusal. While we respect the committee's role, we believe their decision was based on an incomplete understanding of the robustness of our proposed service, which was a direct result of our failure to provide sufficient detail in the initial application.

4.3 In this appeal, we will provide comprehensive, detailed evidence and procedures that directly address the committee's concerns and demonstrate that our application fully meets all necessary requirements of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

4.4 The premises have been carefully chosen to be located in Newburn, chosen for its excellent logistical access to the A1, A69, and the Newburn bridge, facilitating rapid, nationwide delivery. The premises will have clear markings indicating it is a Distance Selling Pharmacy (DSP). Access to the building will be strictly restricted to pharmacy staff only via a locked door and intercom system for deliveries. Clear signage will indicate that service is provided via telephone or website only, with no face-to-face provision of essential pharmaceutical services. This controlled access ensures the physical environment supports the provision of essential services without face-to-face contact, as required by Regulation 64.

4.5 Our grounds for appeal are structured to directly rebut the specific regulations the PSRC found were not met.

4.6 **Ground 1: Regulation 25(2)(b)(i) – Uninterrupted Provision of Services**

4.7 The PSRC was not satisfied that we had demonstrated how services would be provided remotely and without interruption throughout our opening hours. We acknowledge that our initial application lacked the specific, granular detail required to provide this assurance. We have now rectified this by developing a

comprehensive suite of Standard Operating Procedures (SOPs) and operational plans.

4.8 **To demonstrate our commitment to uninterrupted service, we have enclosed the following new evidence:**

4.8.1 **SOP 303 - Business Continuity & Disaster Recovery:** This details our proactive and reactive strategies for all foreseeable interruptions, including power outages (backup generator), internet failure (redundant fibre lines from two different providers), PMR system failure (offline working protocols and data backup), and staff shortages.

4.8.2 **SOP 112 and Detailed 12 week staff rota - Staffing, Training, and Competency:** This includes a detailed staffing rota for the first three months of operation, demonstrating that a Responsible Pharmacist and sufficient support staff will be onsite at all times during our 43 core opening hours. It also outlines our comprehensive training plan and competency assessments.

4.8.3 **SOP 307 - IT Systems, Security, and Failure Protocol:** This document outlines our robust IT infrastructure, including our Pharmacy Manager PMR system, encrypted data handling, and clear protocols for staff to follow during any system downtime to ensure continuity of patient care.

4.9 These documents prove that we have a resilient operational model designed to provide a consistent and uninterrupted service to patients anywhere in England, fully meeting the requirements of this regulation.

4.10 **Ground 2: Regulation 25(2)(b)(ii) – Safe and Effective Remote Provision**

4.11 The PSRC was not satisfied that we had demonstrated how the safe and effective provision of pharmaceutical services would be achieved without face-to-face contact. We understand this is the cornerstone of a DSP application and our initial submission was not detailed enough.

4.12 We have now produced an exhaustive set of procedures that demonstrate a robust and secure patient journey.

4.13 **To demonstrate our commitment to safe and effective remote provision, we have enclosed our key SOPs:**

4.13.1 **SOP 615 - Verifying Addresses Before Delivery:** Our enhanced, multi-stage verification process ensures medicines are only sent to the correct, verified address. This includes initial verification against the NHS Spine, secondary checks for new patients, and enhanced identity verification (e.g., photo ID check) for high-risk and Controlled Drug deliveries.

4.13.2 **604 D1: Delivery & Dispatch:** This details our partnership with Royal Mail (for standard deliveries) and City Sprint (for refrigerated items and Controlled Drugs), including secure packaging, tracking, signature-on-

receipt requirements, and a strict prohibition on delivery to "safe places.".

4.13.3 **SOP 619 - Medication Waste Disposal:** Our updated procedure details a safe, nationwide service for patients to return unwanted medicines, including a secure courier collection service for Controlled Drugs, ensuring full compliance with all environmental and pharmaceutical regulations.

4.13.4 **SOP 111 - Patient Communication & Remote Consultation:** This outlines how patients can easily contact a pharmacist via telephone, secure video call, or email during all opening hours, ensuring they receive the same quality of advice and support as they would in a community pharmacy.

4.14 These procedures, taken together, create a closed-loop system that guarantees the safe and effective provision of services, from prescription receipt to delivery and aftercare, without any need for face-to-face contact.

4.15 **Ground 3: Regulation 64 – Conditions for Distance Selling Premises**

4.16 The PSRC found that we did not fully meet the specific conditions of Regulation 64. Our enhanced evidence pack now comprehensively addresses every point of this regulation.

4.16.1 **No Face-to-Face Service:** We reiterate that no pharmaceutical services will be offered or provided to any person present at or in the vicinity of the premises. Our SOPs and staff training make this an absolute and non-negotiable rule.

4.16.2 **Uninterrupted Nationwide Service:** As detailed under Ground 1, our business continuity plans, staffing levels, and robust delivery network ensure we can provide essential services to **any person, anywhere in England** who requests them, without interruption.

4.16.3 **Safe & Effective Remote Service:** As detailed under Ground 2, our comprehensive SOPs ensure the safe and effective provision of all services remotely.

4.16.4 **Website Compliance and Content**: Our website design reflects available guidance and provides an easy-to-follow layout. As demonstrated in Screenshot 05 (Health Information Top), the website provides access to a reasonable range of up-to-date materials that promote healthy lifestyles (e.g., High Blood Pressure, Stop Smoking Support, Diabetes Management), all linked directly to trusted NHS resources. All relevant pharmacy details, including the Newburn address, GPhC registration (pending), and compliance statements (Data Protection Act 2018, UK GDPR), are prominently displayed on the homepage (Screenshot 01 & 02) in full compliance with the GPhC guidance on providing services at a distance [1]. To ensure website content contains up-to-date materials that promote healthy lifestyles, a designated staff member will update the website on a regular basis.

4.16.5 **No Geographical Limitation in Publicity:** We have updated our draft website and practice leaflet to explicitly and prominently state that our services are available to all patients throughout England. We have removed any language that could possibly imply a local focus. We enclose screenshots of this updated material.

4.17 We are confident that this new body of evidence demonstrates that Freemanpharma Ltd has the procedures, resources, and commitment to operate a safe, effective, and compliant Distance Selling Pharmacy that fully meets all conditions of Regulation 64.

4.18 We respectfully request that the committee considers this new, detailed evidence and overturns the original decision. We believe we have now demonstrated, beyond doubt, our capability to provide a high-quality, safe, and uninterrupted pharmaceutical service to patients across England."

4.19 [Enclosures: Appendix B for Committee

4.19.1 Pages 1 -5 Screen shots of Website

4.19.2 Pages 6 – 291 Freeman Pharma Standard Operating Procedures.]

5 Additional Information

The following letter was provided by the Applicant by email on 8 January 2026 part way through the circulation period of the appeal:

5.1 THE APPLICANT

5.1.1 **"Notification of governance changes - FreemanPharma Ltd (Distance Selling Pharmacy Appeal)**

5.1.2 **Re: FreemanPharma Ltd - Distance Selling Pharmaceutical List Application**

5.1.3 **NHS England Ref: CAS-370449-C3P4M4**

5.1.4 **NHS Resolution Ref: SHA/26819**

5.1.5 I write on behalf of FreemanPharma Ltd to notify NHS Resolution, and NHS England, of governance changes occurring during the pendency of the above appeal. This notification is provided in accordance with Regulation 66 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and the NHS Pharmaceutical Services Manual.

5.1.6 1. Change of Director

5.1.7 With effect from 16 December 2025, the following change to the board of directors took place:

5.1.7.1 Outgoing Director: Caroline Freeman.

5.1.7.2 Incoming Director: Thomas William McCullough.

5.1.8 The applicant remains FreemanPharma Ltd, the same legal entity, with no change to the company name or registration number. The update to the company's record of directors was formally filed and recorded at Companies House on 7 January 2026.

5.1.9 The incoming director confirms that he is not subject to any current or ongoing fitness to practise investigations, regulatory proceedings, interim orders, conditions or restrictions by any professional or regulatory body.

5.1.10 2. Change of Intended Superintendent Pharmacist

5.1.11 With effect from 16 December 2025:

5.1.11.1 Outgoing Intended Superintendent Pharmacist: Caroline Freeman. GPhC 2082209.

5.1.11.2 Incoming Intended Superintendent Pharmacist: Thomas William McCullough. GPhC 2056528.

5.1.12 As FreemanPharma Ltd does not currently hold an NHS pharmaceutical services contract, there is no active Superintendent Pharmacist registration recorded with the GPhC. Formal notification will be made if and when the appeal is successful.

5.1.13 The incoming intended Superintendent Pharmacist confirms that he is not subject to any current or ongoing fitness to practise investigations or regulatory proceedings.

5.1.14 3. Confirmation regarding the appeal

5.1.15 The applicant company remains unchanged. The appeal grounds remain unchanged. These governance changes do not amount to a new or materially different application."

6 Application placed on hold

On 14 January 2026, NHS Resolution sent the following letter to the Commissioner and the Applicant:

6.1 "The Applicant has provided the enclosed information confirming the change of Director and change of intended Superintendent Pharmacist from 16 December 2025.

6.2 In accordance with paragraph 5A of Schedule 2 relating to 'Updating of information about or relating to a superintendent' it states:

5A.—*(1) Where, in the case of a body corporate making an application for inclusion in a pharmaceutical list, there is a change to the superintendent of the body corporate before the applicant is included in a pharmaceutical list or the*

application cannot be further proceeded with, the applicant must update the application as soon as is reasonably practicable with—

(a)the details about that superintendent that the applicant would have been required to submit under paragraph 3; and

(b)the details about any other body corporate that the applicant would have been required to submit under paragraph 4 because of that superintendent being that other body corporate's superintendent,

had the superintendent been in post at the time the application was submitted.

(2) If—

(a)the application has been determined by NHS England but—

(i)there are proceedings relating to the application that have not yet reached their final outcome, or

(ii)in the case of an application that has been granted, there are no such proceedings but the applicant has not yet been included in a pharmaceutical list; and

(b)NHS England is satisfied, on the basis of the information provided or required to be provided under sub-paragraph (1), that there are grounds for refusing the application under regulation 33 or imposing a condition under regulation 35,

NHS England may redetermine the application, but only for the purpose of refusing it under regulation 33 or imposing a condition under regulation 35 (so there may still be a purpose to any proceedings that have not yet reached their final outcome).

6.3 Accordingly, we respectfully request that the Commissioner conduct fitness to practise checks at the earliest opportunity and provide confirmation of the outcome prior to Primary Care Appeals progressing with the appeal."

By email dated 10 March 2026, the Commissioner provided the following update:

6.4 "Apologies for the delay, we have been asked to relay this information on to the appeals authority.

6.5 I am writing to advise you that FreemanPharma Ltd has notified the North East and North Cumbria ICB, in accordance with paragraph 5A of Schedule 2, that a new superintendent pharmacist has been appointed. The required fitness information for the new superintendent has now been provided to the ICB.

6.6 In line with the Regulations, the ICB will now undertake a fresh consideration of the application, specifically whether:

6.6.1 there are grounds to refuse the application under Regulation 33 (fitness), or

6.6.2 the applicant should be conditionally included under Regulation 35.

6.7 Please note that any appeal arising from this forthcoming decision would fall under the jurisdiction of the First-tier Tribunal.

6.8 We will update you further once the Primary Care Services Regulatory Committee (PSRC) has completed its assessment and determined the outcome."

6.9 [All parties were informed of the delay by email dated 12 March 2026.]

By email dated 29 May 2026, the Commissioner provided the following update:

6.10 "Further to previous correspondence, I am writing to provide an update following consideration by the Primary Care Services Regulatory Committee (PSRC).

6.11 The PSRC has now reviewed the fitness information relating to the Superintendent Pharmacist and has determined that:

6.11.1 *"There are no grounds to refuse the application under Regulation 33 (fitness), nor to impose conditional inclusion under Regulation 35 on fitness grounds."*

6.12 This completes the ICB's consideration of the fitness aspects of the application.

6.13 Please can you ensure that this update is shared with the Primary Care Appeals team / NHS Resolution to support their ongoing consideration of the appeal.

6.14 Please let me know if any further information is required."

7 Summary of Representations

This is a summary of representations received on the appeal.

7.1 RUSHPORT ADVISORY LLP REPRESENTING NEWBURN PHARMACY, THROCKLEY CHEMIST AND LEMINGTON PHARMACY

7.1.1 "I act for Mohamed Mehdi who owns:

7.1.1.1 Newburn Pharmacy, 1 Newburn Road, Newburn, Newcastle Upon Tyne NE15 8LX

7.1.1.2 Throckley Chemist, Throckley Primary Care Center, Tillmouth Park Road, Throckley, Newcastle Upon Tyne NE15 9PA

7.1.1.3 Lemington Pharmacy, 3 Tyne View, Lemington, Newcastle Upon Tyne NE15 8DE

7.1.2 I am instructed to submit this reply to the appeal submitted by Freemanpharma Ltd in the above listed application.

7.1.3 My client continues to object to this application and we submit that it should be refused for the following reasons.

7.1.4 The Applicant has provided 295 pages of information in its appeal document circulated by Primary Care Appeals. The document contains a range of SOPs from a Chaperone Policy to Hand Washing Policy but fails to properly address how the services that it proposes to provide will in fact be delivered.

7.1.5 Little or no information is provided in respect of many services and where information is provided it is deficient. Examples of this are;

7.1.6 Page 78 appeal document – delivery of CDs – simply states that a courier will be used and that the courier will confirm patient details and that failed deliveries will "immediately returned to the pharmacy's secure storage. It is not clear how a courier would be expected to do this for deliveries that could be hundreds of miles from the proposed pharmacy premises.

7.1.7 Page 177 – Cold Chain – states that the pharmacy should – "*Select validated insulated container and pre-conditioned gel packs/phase-change packs*" and "*Place packs around the medicine*.". After this the Applicant mentions elsewhere in their SOPs, but not in the delivery SOP that a courier will be used to deliver medicines. However, if a medicine is packaged with cool packs and then independently delivered via courier in a temperature controlled van, there is no way to know what the temperature of the actual medicine is as it will be lower than the temperature recorded in the courier's van due to the use of *pre-conditioned gel packs/phase-change packs.*

7.1.8 Page 220 – Supply of Lithium – this SOP appears to have come from the NPA and is dated June 2021 and is out of date and no longer reflects current guidance.

7.1.9 Page 223 – Supplying insulin SOP – does not say how insulin should be delivered other than saying "*Deliveries of insulin must be checked of the delivery note and placed in the fridge as soon as possible*."

7.1.10 We submit that the appeal should be refused and look forward to hearing from you in due course."

7.2 BOOTS

7.2.1 "Boots UK Ltd have no further comments to make but respectfully ask that NHS Resolution inform us of the decision in due course."

7.3 COMMUNITY PHARMACY NORTH OF TYNE

7.3.1 "Following receipt of the above application, members of Community Pharmacy North of Tyne were consulted. Members decided they have no further comments to make on the application as above.

7.3.2 We would be grateful if you could keep us informed of the progress and outcome of the appeal in due course."

8 Summary of Observations

This is summary of observations received.

8.1 THE APPLICANT

8.1.1 **"Rebuttal to Third-Party Objections**

8.1.2 **To:** Primary Care Appeals, NHS Resolution **From:** FreemanPharma Ltd **Date:** 11 June 2026 **Reference:** SHA/26819 – FREEMAN PHARMA LTD – APPLICATION FOR INCLUSION IN THE PHARMACEUTICAL LIST FOR A DISTANCE SELLING PHARMACY AT 1 STATION ROAD, NEWCASTLE UPON TYNE, NE15 8LS

8.1.3 **1. Introduction**

8.1.4 This letter is submitted on behalf of FreemanPharma Ltd ("the Applicant") in response to the representations made by Rushport Advisory LLP (acting for Mr Mohamed Mehdi), Boots UK Ltd, and Community Pharmacy North of Tyne regarding the above-referenced appeal.

8.1.5 We note that Boots UK Ltd and Community Pharmacy North of Tyne have confirmed they have no further comments to make.

8.1.6 The Applicant draws the Committee's attention to a material change in the application since the original submission. The Superintendent Pharmacist (SP) for FreemanPharma Ltd changed on 16 December 2025 from Ms Caroline Freeman to Mr Tom McCullough (GPhC: 2056528). This change was duly notified and has been formally authorised by the relevant authorities. All updated SOPs enclosed with this rebuttal have been authored and approved by Mr McCullough as the current SP. The case, which was briefly placed on hold pending the ICB fitness-to-practise assessment of Mr McCullough, is now confirmed as live and proceeding.

8.1.7 The sole substantive objection is from Rushport Advisory LLP, dated 19 January 2026. Rushport raises four specific criticisms regarding the Applicant's Standard Operating Procedures (SOPs).

8.1.8 The Applicant has carefully considered these criticisms. While we maintain that the original application demonstrated a commitment to safe and effective service provision, we recognise the Committee's expectation for absolute clarity in DSP procedures. Therefore, the Applicant has proactively reviewed and updated the relevant SOPs to address every point raised by Rushport, drawing directly on current NHS clinical guidance and the standards explicitly validated by NHS Resolution in recent successful DSP appeals.

8.1.9 The updated SOPs, which supersede the versions submitted with the original application, are enclosed with this rebuttal. As established in *Wakefield (SHA/26600)* and numerous other decisions, it is entirely permissible for an applicant to provide new or updated information during the appeal process to cure alleged defects.

8.1.10 **2. Response to Specific Objections**

8.1.11 **Objection 1: Delivery of Controlled Drugs (CDs)**

8.1.12 **Rushport's claim:** *The SOP simply states that a courier will be used and that failed deliveries will be "immediately returned to the pharmacy's secure storage." Rushport questions how a courier could do this for deliveries "hundreds of miles from the proposed pharmacy premises."*

8.1.13 **The Rebuttal:** 2.1. This objection relies on a hypothetical scenario (a failed delivery hundreds of miles away) rather than assessing the actual procedures the Applicant has put in place.

8.1.14 To remove any ambiguity, the Applicant has submitted an updated **SOP 604 D1 (Delivery & Dispatch, v6)** and **SOP 604.2 (Delivery by CitySprint, v3)**. These SOPs now explicitly confirm that the Applicant holds an active, contracted account with **CitySprint Healthcare** (Account No. C3139341), operating from their Newcastle Service Centre (Tel: 0191 226 0005). A copy of the account confirmation is attached as **Exhibit A**.

8.1.15 The updated SOPs implement a strict, three-tier "Failed Delivery Hierarchy" for Controlled Drugs, which directly addresses Rushport's concern: * **Primary Obligation:** Same-day return to the pharmacy wherever operationally possible. Given that CitySprint operates from Newcastle, same-day return is highly achievable for the vast majority of the Applicant's expected patient base. * **Contingency (Overnight Storage):** Where the timing or distance of the attempted delivery precludes same-day return, CitySprint will store the CD securely overnight at their approved, MHRA-compliant warehouse facilities. * **Absolute Maximum:** Under no circumstances will a CD be retained by the courier for more than 48 hours.

8.1.16 This exact protocol—relying on CitySprint's MHRA-compliant overnight storage as a contingency for failed deliveries—was explicitly quoted and validated by the Committee in **Oldbury (SHA/26675)** as satisfying the requirements of paragraph 8(1) of Schedule 4. The Applicant has adopted this gold-standard approach.

8.1.17 **Objection 2: Cold Chain Temperature Monitoring**

8.1.18 **Rushport's claim:** *The Cold Chain SOP mentions using pre-conditioned gel packs. Rushport argues that if a medicine is packaged with cool packs and delivered in a temperature-controlled van, "there is no way to know what the temperature of the actual medicine is as it will be lower than the temperature recorded in the courier's van."*

8.1.19 **The Rebuttal:** This objection demonstrates a misunderstanding of validated pharmaceutical cold chain packaging. The purpose of phase-change materials (gel packs) inside a validated insulated container is to *maintain* the internal temperature at 2-8°C, not to freeze the product.

8.1.20 Nevertheless, to provide the Committee with absolute assurance, the Applicant has submitted an updated **SOP 608 (Cold Chain, v8)**. This SOP incorporates the most robust cold chain protocols validated in recent NHSR decisions, including **Gateshead (SHA/26620)** and **London (SHA/26080)**.

8.1.21 Crucially, SOP 608 now mandates the use of **calibrated temperature data loggers placed inside the insulated packaging with the medication**. The temperature is recorded at the point of dispatch and again at the point of delivery (or upon return to the pharmacy in the event of a failed delivery). This guarantees that the temperature of the *actual medicine* is known and recorded, entirely resolving Rushport's theoretical concern about van temperatures.

8.1.22 **Objection 3: Supply of Lithium SOP**

8.1.23 **Rushport's claim:** *The Lithium SOP "appears to have come from the NPA and is dated June 2021 and is out of date and no longer reflects current guidance."*

8.1.24 **The Rebuttal:** The Applicant accepts that clinical guidance evolves and that the 2021 SOP (which included temporary COVID-19 monitoring extensions) required updating.

8.1.25 The Applicant has therefore submitted a fully rewritten **SOP 702 (Supplying Lithium Therapy, v2)**. This SOP has been authored by the Superintendent Pharmacist and explicitly incorporates the current **NHS SPS guidance (March 2026: *Supporting lithium safety across the system*)**.

8.1.26 Furthermore, the updated SOP 702 now includes a detailed, DSP-specific protocol for remote verification of blood test results (via the Summary Care Record or prescriber contact) and remote checking of the patient's lithium therapy record book (via video consultation or secure photo upload). It also explicitly states that "as directed" dosage instructions are clinically unacceptable for lithium, mandating prescriber contact. This demonstrates the Applicant's proactive engagement with current clinical governance standards in a remote dispensing context.

8.1.27 **Objection 4: Supplying Insulin SOP**

8.1.28 **Rushport's claim:** *The Insulin SOP "does not say how insulin should be delivered other than saying 'Deliveries of insulin must be checked of the delivery note and placed in the fridge as soon as possible.'"*

8.1.29 **The Rebuttal:** The Applicant acknowledges that the previous iteration of the SOP focused primarily on the receipt of insulin into the pharmacy rather than its dispatch to the patient.

8.1.30 To rectify this, the Applicant has submitted an updated **SOP 704 (Supplying Insulin, v5)**, which now includes a comprehensive "Section 5: Delivery of Insulin – Distance Selling Pharmacy Protocol".

8.1.31 This new section details a robust, multi-layered safety protocol for remote insulin delivery, including: * A pre-dispatch pharmacist counselling call for all new patients or product changes. * A **photo verification step**, where a photograph of the packaged insulin (showing brand, strength, and device) is sent to the patient for approval *before* dispatch, replicating the face-to-face safety check. * Strict adherence to the cold chain delivery and failed delivery protocols set out in SOP 608 and SOP 611 D2.

8.1.32 **3. Conclusion**

8.1.33 Rushport's objections, while highlighting areas where the original SOPs could be strengthened, do not represent fatal flaws in the Applicant's proposed operating model.

8.1.34 The Applicant has engaged constructively with every criticism raised. The updated SOPs submitted with this rebuttal are comprehensive, bespoke to the DSP model, aligned with current NHS clinical guidance, and directly mirror the procedures explicitly validated by NHS Resolution in recent successful appeals (such as *Oldbury* and *Gateshead*).

8.1.35 The Applicant has demonstrated exactly how the safe and effective provision of pharmaceutical services will be secured without face-to-face contact, fully satisfying the requirements of Regulation 25(2)(b) and Regulation 64.

8.1.36 We therefore respectfully request that the Committee overturns the initial refusal and grants the application."

8.1.37 [Appendix C – for Committee

8.1.37.1 Pages 1 - 2 - EXHIBIT A: Specialist Courier Account Confirmation

8.1.37.2 Pages 3 – 8 Standard Operating Procedures Index

8.1.37.3 Pages 9 – 13 - 604 D1: Delivery & Dispatch – Distance Selling Pharmacy (DSP)

8.1.37.4 Pages 14 – 15 - SOP 604.1: Delivery by Local Driver (DSP)

8.1.37.5 Pages 16 – 17 - SOP 604.2: Delivery by Specialist Courier (CitySprint)

8.1.37.6 Pages 18 – 23 - SOP 608: Cold Chain

8.1.37.7 Pages 24 – 26 - SOP 611 D2: Failed Delivery Call or Message

8.1.37.8Pages 27 – 31 – SOP 702: Supply of Lithium Therapy

8.1.37.9Pages 32 – 35 -SOP 704: Supplying Insulin

8.1.37.10Pages 36 – 37 - SOP 720 Uncomplicated UTI Service

8.1.37.11Pages 38 – 39 - SOP 721 Sinusitis Service

8.1.37.12Pages 40 – 41 - SOP 722 Sore Throat Service

8.1.37.13Pages 42 – 43 -SOP 723 Infected Insect Bites Service

8.1.37.14Pages 44 - 45 SOP 724 Impetigo Service

8.1.37.15Pages 46 -47 - SOP 725 Shingles Service.]

9 Comments on Observations

In accordance with Schedule 3, Part 3, paragraph 7 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as the Applicant had provided new information in its observations, these were circulated and parties given the opportunity to comment upon them. These comments were circulated to parties for information. This is summary of comments on observations received:

9.1 RUSHPORT ADVISORY LLP REPRESENTING NEWBURN PHARMACY, THROCKLEY CHEMIST AND LEMINGTON PHARMACY

9.1.1 “I act for Mr Mohamed Mehdi in connection with the above appeal.

9.1.2 Freeman Pharma Ltd has updated a number of SOPs in direct response to the objections raised in my letter of 19 January 2026 and these comments address the updated SOPs.

9.1.3 The Committee is reminded that the legal test is not whether the Applicant has satisfactorily answered the specific criticisms raised by any objector. The test is whether the Applicant has demonstrated, to the Committee’s satisfaction, that the safe and effective provision of pharmaceutical services will be secured without face-to-face contact, and that services will be provided on an uninterrupted basis to persons anywhere in England. The burden of satisfying that test rests on the Applicant.

9.1.4 Whilst the Committee has exercised its discretion to permit these further amendments to the Applicant’s SOPs, we trust that the Committee will follow its normal procedure from this point and not permit any further evidence from the Applicant. The Applicant has already been afforded an additional opportunity to submit new evidence despite having received a letter from PCA that would have stated that no new matters could be raised.

9.1.5 For the reasons set out below, we submit that the Applicant still does not meet the legal test.

9.1.6 **Absence of Any Emergency Supply Procedure**

9.1.7 Neither the original December 2025 appeal bundle nor the June 2026 rebuttal bundle contains any Standard Operating Procedure governing emergency supply — whether at the request of a prescriber or at the request of a patient.

9.1.8 The Applicant's SOP index lists SOP 726 as "Pharmacy First Urgent Supply Service (NUMSAS)". This is a specific commissioned service arrangement and does not constitute a procedure for statutory emergency supply. The two are distinct obligations and the former does not satisfy the latter.

9.1.9 **Absence of an EPS Nomination Management Procedure**

9.1.10 SOP 603 (Receiving Prescriptions) in the original bundle adequately addresses the downloading and initial processing of EPS prescriptions once received. However, there is no SOP anywhere in either bundle governing the management of EPS nominations — specifically: the process for capturing patient nominations, advising which patients are or are not suitable for nomination, changing nominations at a patient's request, and cancelling nominations.

9.1.11 A Distance Selling Pharmacy generates its prescription volume almost entirely through EPS nominations. The Terms of Service impose specific obligations in this regard.

9.1.12 The Applicant has not demonstrated any proper process for managing nominations, including how patients will be informed of their nomination options, how the pharmacy will ensure nominations are not inappropriately captured or retained, and how cancellation requests will be handled in a timely fashion.

9.1.13 **Absence of a Prescription Charge Exemption Checking Procedure**

9.1.14 SOP 603 (Receiving Prescriptions) in the original bundle addresses the receipt and initial validation of prescriptions but contains no procedure governing prescription charge exemption checking, real-time exemption checking ("RTEC"), or the management of mixed HRT prescriptions. These are mandatory obligations under the Terms of Service.

9.1.15 The Terms of Service impose a positive obligation on the contractor to take reasonable steps to prevent fraudulent exemption claims, to use RTEC where available, and to manage the specific requirements applicable to HRT prepayment certificates and mixed prescriptions. None of this is addressed in the Applicant's SOPs.

9.1.16 **Failure to Provide Patients with an Estimate of Delivery Time**

9.1.17 Schedule 4 to the Regulations requires a pharmacy contractor to provide pharmaceutical services with reasonable promptness and imposes an obligation to provide patients with an estimate of when their

medicine will be ready and delivered, together with a revised estimate if that time changes.

9.1.18 The principal delivery SOP — SOP 604 D1, both in its original form (v2) and in the updated version submitted with the rebuttal (v6) — provides only that patients will be notified by SMS or email when their order has been dispatched and when it is out for delivery. This is a dispatch notification, not an estimate of delivery and does not satisfy the Terms of Service obligation.

9.1.18.1 It provides no information to the patient as to when they should expect their medicines.

9.1.18.2 It contains no obligation to communicate proactively with the patient if the 48-hour turnaround target referenced in SOP 603 will not be met. The 48-hour target is an

9.1.18.3 internal operational benchmark; it is not communicated to patients, and no procedure exists for notifying patients when it will be exceeded.

9.1.18.4 It contains no requirement to provide a revised estimate if there is a delay, whether due to stock availability, courier issues, or any other reason.

9.1.19 The sole SOPs in the bundle that contain any reference to communicating an expected delivery time to the patient are the Pharmacy First clinical pathway SOPs 720 to 725, each of which states that “the RP ensures the patient is aware of the expected delivery time.” This obligation is therefore confined, in the Applicant’s procedures, to cases where a Pharmacy First consultation has taken place. It does not apply to routine dispensing, which will constitute the overwhelming majority.

9.1.20 **Cold Chain**

9.1.21 The SOPs relating to cold chain delivery remain deficient.

9.1.22 SOP 7 refers to “Cold Chain Deliveries by Local Driver” and states that;

9.1.23 “*cold chain deliveries must be packaged and monitored in strict accordance with SOP 608 (Cold Chain)”*

9.1.24 And,

9.1.25 *“The driver must use pharmacy-provided, temperature-controlled containers with a calibrated temperature data logger”*

9.1.26 It is not clear which deliveries would be via courier and which by CitySprint, but it is clear that a local delivery driver will be used for some cold chain deliveries.

9.1.27 Turning to SOP 608 Cold Chain the Applicant's submissions are contradictory and unsafe. For example SOP 608 s3.1 states;

9.1.28 "*Courier companies are equipped to transport these items in monitored cold chain sections of their vans, commonly maintaining a temperature range of 2-8°C, thereby ensuring the integrity of the cold chain from pharmacy to recipient*."

9.1.29 However, SOP 608 s3.3 states that ice packs / gels will be added for deliveries of over 3 hours. Adding ice packs / gels will likely cause freezing of the medicine that is already being transported in "cold chain sections" of the courier's van. This would be unknown to the courier as their own temperature controlled environment would remain in the correct range whilst the individual medicines freeze.

9.1.30 SOP 608 s3.3 also refers to "validated medical cool boxes" being used for "short" journey times but with no detail about this system.

9.1.31 Then at SOP 608 s3.4 the Applicant provides further contradictory information and states;

9.1.32 *Temperature will be recorded at the beginning of the journey and again at the point of delivery to ensure it stays between 2-8°C. Thermometer(s) will be calibrated annually against a certified standard to ensure safe and effective use.*

9.1.33 This contradicts SOP 608 s3.1 and also means that the only temperatures being monitored are the points at the beginning and end of the journey. The use of a thermometer contradicts the earlier reference to "calibrated temperature probes".

9.1.34 It is not clear what the delivery driver or courier would do with these readings or what action they would take if the correct temperature range was not maintained or if a driver would be aware of a deviation in temperature that occurred between the beginning and end of a journey.

9.1.35 SOP 608 s4.5 then provides a completely new process suggesting that "*The cold chain service is a dedicated, fully monitored, and temperature-controlled delivery service*."

9.1.36 This is clearly not correct as deliveries by the local driver are not covered, nor is their [sic] any explanation for the requirement in SOP 608 s3.3 to add ice packs or the thermometers / probes from SOP 608 s3.3

9.1.37 In summary, the Applicant still fails the legal test as they have not demonstrated that services will provided in a safe and effective manner.

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

10 Consideration

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

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

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

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

Regulation 31

10.5 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).

10.6 The Committee noted that the Applicant had not provided any information in the application form on this point but the Committee noted that the wording of the application form only required the Applicant to include information in the relevant section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee considered it reasonable to determine that the lack of information in the application form on this point when read with the wording of the application form allowed it to be reasonably satisfied that the Applicant considered that the proposed premises were not adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Commissioner had determined that "*Regulation 31 does not apply as there is no pharmacy at the same or adjacent premises to the proposed site*" which had not been disputed by any party. The Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

10.7 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."

10.8 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)

10.9 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)

10.10 The Committee noted that the Applicant had not included any information in the relevant section of the application form that deals with this point. The Committee noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Commissioner in its decision report stated that "*Regulation 25(2)(a) does not apply as no primary care provider with a patient list is present within the same premises as the proposed site*". Based on the information available to it, which had not been disputed, the Committee determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

10.11 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.

10.12 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.

10.13 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.

10.14 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 along with the revised SOPs which the Applicant has prepared or commissioned.

10.15 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 application along with the revised SOPs in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.

10.16 The Committee first considered how the Applicant would provide essential services without interruption and noted the following information provided by the Applicant in its application, 14 day comments, its appeal and in SOPs in appendices A and B. SOP 111 Patient Communication & Remote Consultation states:

10.16.1"*A pharmacist will be available for consultation during all pharmacy opening hours (Monday to Friday, 9:00am-1pm and 1.30pm - 5:30 pm)*."

10.17 SOP 112 Staffing, Training, and Competency states:

10.17.1"*Monday to Friday: 9:00 am - 1:00 pm, then 1:30 pm - 5:30 pm (8 hours/day)*

10.17.2 *Saturday: 9:00 am - 12:00 pm (3 hours)*

10.17.3 *Lunch Break: 1:00 pm - 1:30 pm (pharmacy closed)*

10.17.4 *Total Weekly Opening Hours: 43 hours Core Staffing*:

10.17.5 *1 x Pharmacist Manager (Responsible Pharmacist) - 43 hours/week (present all opening hours)*

10.17.6 *2 x Dispensary Assistants/Technicians (NVQ2/3 qualified) - 40 hours/week each*

10.17.7 *Superintendent Pharmacist - Available for cover as needed*"

10.18 SOP 306 Operation of the Distance Selling Pharmacy With and Without a Responsible Pharmacist states:

10.18.1"*Scope***:**

10.18.2….. *This SOP covers*:

10.18.3 *Conditions for operating when the RP is signed in*

10.18.4 *Conditions for periods when the RP is not signed in …..*

10.18.5 *Although the Human Medicines Regulations allow up to 2 hours of RP absence per day, this does not apply during NHS DSP opening hours*.

10.18.6 *Reason*:

10.18.6.1 DSPs must provide continuous pharmaceutical services throughout all core hours

10.18.6.2 No DSP services can legally take place without a pharmacist

10.18.6.3 Therefore, any RP absence during NHS opening hours would result in an immediate breach of NHS Terms of Service

10.18.7 *Therefore: An RP must be signed in continuously during all DSP NHS opening hours, and the 2-hour RP absence provision cannot be used*.

10.18.8 *This applies Monday–Friday 09:00–17:30 (excluding lunch closure) and Saturday 09:00–12:00*. ……

10.18.98. *Communication During RP Unavailability*

10.18.10 *If the RP signs out or becomes unavailable unexpectedly (e.g. emergency)*:

10.18.10.1 All dispensing and clinical activity must stop immediately

10.18.10.2 No despatch may occur

10.18.10.3 EPS queue must be frozen

10.18.10.4 *Website/telephone script must state: "A pharmacist is not currently available. We cannot process or despatch prescriptions at this time*."

10.18.11 *If unavailability occurs during NHS core hours, NHS England must be notified if pharmaceutical services cannot be restored promptly*."

10.19 The Committee accepted that the Applicant had stated that a Responsible Pharmacist would be physically present whenever the pharmacy was operating and that the pharmacy would not operate in the absence of a pharmacist. The Committee noted a slight inconsistency in that SOP 111 referred only to Monday to Friday opening hours, whereas SOP 112 and SOP 306 referred to Saturday opening. SOP 306 addressed the position if the Responsible Pharmacist became unexpectedly unavailable, by requiring dispensing, clinical activity and dispatch to cease immediately and by requiring NHS England to be notified if pharmaceutical services could not be restored promptly. The Committee considered that whilst these provisions were intended as emergency contingency arrangements rather than routine operation without a

Responsible Pharmacist, the Regulations contained no such distinction. Therefore, the Committee was not satisfied that the Applicant had provided sufficient assurance on Responsible Pharmacist presence and staffing cover during opening hours. In particular, SOP 306 asserted that the statutory provision permitting a Responsible Pharmacist to be absent for up to two hours but this did not apply to distance selling pharmacies. The Committee therefore considered that the Applicant had not provided a clear and coherent procedure explaining how services would remain uninterrupted if the Responsible Pharmacist became absent during opening hours.

10.20 With regard to essential services being available to persons anywhere in England, the Committee noted the following information in the Applicant's appeal:

10.20.1"***Uninterrupted Nationwide Service:*** *As detailed under Ground 1, our business continuity plans, staffing levels, and robust delivery network ensure we can provide essential services to* ***any person, anywhere in England*** *who requests them, without interruption*. ….

10.20.2***No Geographical Limitation in Publicity:*** *We have updated our draft website and practice leaflet to explicitly and prominently state that our services are available to all patients throughout England. We have removed any language that could possibly imply a local focus. We enclose screenshots of this updated material*."

10.21 The Applicant had provided screenshots of its Preview mode web pages which is not yet live in Appendix B which states:

10.21.1"*FreemanPharma is a registered Distance selling Pharmacy providing services remotely to patients anywhere is England. All services are accessed via telephone, email secure messaging and delivery*.

10.21.2*! Important: Patients are not permitted to attend the premises in person. All services are delivered remotely*."

10.22 In SOP 607 Repeat Dispensing Service states:

10.22.1"*SCOPE This procedure covers Repeat Dispensing services operated between the pharmacy and local GP practices for both paper and electronic prescriptions*. …..

10.22.2*KNOWN RISKS*

10.22.3….. *Poor communication between pharmacy and local surgeries*. …."

10.23 In SOP 706 Signposting states:

10.23.1"*SCOPE This SOP includes contact details for local signposting services*."

10.24 The Committee noted the Applicant's evidence that its services would be available remotely to patients anywhere in England, and that its draft publicity

material had been updated to make clear that there was no geographical limitation. However, the Committee also noted that SOP 607 referred to repeat dispensing services operated with "local GP practices" and to the risk of poor communication with "local surgeries". The Applicant's Signposting SOP (706) included details of Northumberland, North Tyneside and Newcastle Sexual Health Services. The Committee considered that this was inconsistent with the Applicant's stated position that essential services would be available nationally. Even if the wording was unintended, it created uncertainty as to the scope of the procedures relied upon. The Committee was therefore not satisfied that the Applicant had provided sufficient assurance that essential services would be available to persons anywhere in England who requested them.

10.25 The Committee next considered how the Applicant would provide pharmaceutical services without face to face contact. The Committee noted the following information in the application:

10.25.1 "*The pharmacy will not allow face to face contact for essential services. There will be a controlled door entry system to prevent people from accessing essential services face to face. There be an SOP that explains to the team how to refuse a request for face to face essential services*."

10.26 Further:

10.26.1 "*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*. ….

10.26.2 *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*.

10.26.3 *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*."

10.27 In its appeal, the Applicant refers to SOP 111 Patient Communication & Remote Consultation states:

10.27.1 "*SCOPE This SOP applies to all patient communication at FreemanPharma Ltd, covering telephone, secure email, and video consultations during all opening hours. It ensures patients receive timely pharmaceutical care without face-to-face contact*."

10.28 The SOP 403 Dealing with Dispensing Errors states:

10.28.1 "**4. Secure the Evidence**

10.28.1.1 *Ask to inspect the incorrect medicine*.

10.28.1.2 *If the patient does not wish to hand over the medicine, then suggest that an independent body such as the GPhC could hold the medicine safely*."

10.29 The Committee noted the Applicant's evidence that services would be provided remotely, using telephone, secure email and video consultation, and that members of the public would not have access to the premises for the provision of pharmaceutical services. However, the reference to a SOP "*that explains to the team how to refuse a request for face to face essential services"* was not made available to the Committee. Further, with regard to SOP 403 there is no reference to how the incorrect medicine will be retrieved from the patient or action to resolve the error to ensure the correct medicines have been supplied. The Committee was of the view that this overall alludes to dispensing errors being handled in person. The Committee was therefore not satisfied that the Applicant had provided sufficient assurance that pharmaceutical services would be provided without face to face contact at the pharmacy premises.

10.30 The Committee was mindful of the regulatory changes as of 1 October 2025 and 31 March 2026, that distance selling pharmacies can no longer provide Directed services (Advanced, National Enhanced and Enhanced Services) face to face with the patient at the pharmacy premises. As a result of this amendment, the Committee noted that the Applicant would not be able to provide any pharmaceutical services to patients present at its premises.

10.31 In its application the Applicant stated that it intended to provide New Medicine Service and noted in its 14 day comments on the application states:

10.31.1"***New Medicine Service (NMS)***

10.31.2*Conducted via NHS-compliant secure video platforms (e.g., MS Teams, AccuRx) or telephone from a dedicated, soundproofed consultation room*.

10.31.3*Identity verification will be carried out before the consultation using patient demographics and/or photographic ID via video*.

10.31.4*Explicit informed consent will be recorded in the PMR in accordance with NHS guidance*."

10.32 Further in its SOP 716 New Medicine Service (NMS) it states:

10.32.1"*Patient Identification: Contact the patient by telephone or video call from a private consultation room. Before proceeding with the NMS consultation, verify the patient's identity using a two-factor verification process*."

10.33 The Committee was aware that if 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.

10.34 The Committee was not satisfied that the provision of essential services would be without interruption, that pharmaceutical services would be provided without face to face contact or that the provision of essential services would be available to persons anywhere in England. The Committee went on to consider whether the safe and effective provision of pharmaceutical services was likely to be secured.

10.35 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.

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

10.36.1 Dispensing of drugs and appliances

10.36.2 Urgent supply without a prescription

10.36.3 Preliminary matters before providing ordered drugs or appliances

10.36.4 Providing ordered drugs or appliances

10.36.5 Refusal to provide drugs or appliances ordered

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

10.36.7 Disposal service in respect of unwanted drugs

10.36.8 Promotion of healthy lifestyles

10.36.9 Prescription linked intervention

10.36.10 Health campaigns

10.36.11 Signposting

10.36.12 Support for self-care

10.36.13 Discharge medicines service

10.36.14 Websites and health promotion zones.

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

Urgent supply without a prescription

10.38 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.

10.39 The Applicant in its application states:

10.39.1 "*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*.

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

10.40 It lists the conditions which must apply to the request made by a prescriber and if a request is made by a patient.

10.41 The Applicant then states:

10.41.1 "*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*."

10.42 In its SOP 726 Urgent Repeat Medicine Supply Service (NUMSAS) the Applicant states:

10.42.1 "*Scope: This SOP covers the remote clinical assessment, consultation, and supply/referral process for patients presenting with symptoms of **Urgent supply of repeat medication or appliance** (Age: All eligible patients) to FreemanPharma Ltd, a Distance Selling Pharmacy (DSP)*."

10.43 Rushport Advisory LLP state:

10.43.1 **"***Neither the original December 2025 appeal bundle nor the June 2026 rebuttal bundle contains any Standard Operating Procedure governing emergency supply — whether at the request of a prescriber or at the request of a patient*.

10.43.2 *The Applicant's SOP index lists SOP 726 as "Pharmacy First Urgent Supply Service (NUMSAS)". This is a specific commissioned service arrangement and does not constitute a procedure for statutory emergency supply. The two are distinct obligations and the former does not satisfy the latter*."

10.44 The Committee noted Rushport Advisory LLP's submission that SOP 726 related to a commissioned urgent repeat medicine supply service and did not amount to a statutory emergency supply procedure. The Committee accepted that SOP 726 did not answer the issue under paragraph 6 of Schedule 4.

10.45 The Committee also noted that the Applicant's application contained a section on "Urgent Supply and Emergency Supply" which referred to requests from prescribers and listed a number of conditions to be satisfied before supply. However, the Committee considered that this information was limited and was not supported with a detailed procedure explaining how such requests would be received, assessed, recorded and delivered safely and effectively in practice.

10.46 The Committee was therefore not satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 6 of Schedule 4 in relation to urgent supply requests from prescribers.

Preliminary matters before providing ordered drugs or appliances

10.47 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.

10.48 The Committee noted in its application, the Applicant states:

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

10.48.2*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 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*.

10.48.3*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*.

10.48.4*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*."

10.49 In its SOP 610 Care Homes - How to Dispense Procedure the Applicant states:

10.49.1"*17. Ensure that the prescription is fully endorsed if applicable, stamped with the correct date and that the back of the prescription is signed and the correct exemption is crossed*.

10.49.2*18. Check that the exemption is completed accurately on the back of the prescription. If needed contact the home to check which exemption applies and update PMR*."

10.50 SOP 612 Dosette Boxes – How to Dispense Procedure the Applicant states:

10.50.1 "*9. Ensure the prescription is fully endorsed, stamped with the correct date and that the back of the prescription is signed, and the correct exemption is crossed*."

10.51 The Applicant, in observations states:

10.51.1 "*The updated SOPs, which supersede the versions submitted with the original application, are enclosed with this rebuttal. As established in Wakefield (SHA/26600) and numerous other decisions, it is entirely permissible for an applicant to provide new or updated information during the appeal process to cure alleged defects*."

10.52 Rushport Advisory LLP states in response to the Applicant's observations:

10.52.1 "*SOP 603 (Receiving Prescriptions) in the original bundle addresses the receipt and initial validation of prescriptions but contains no procedure governing prescription charge exemption checking, real-time exemption checking ("RTEC"), or the management of mixed HRT prescriptions. These are mandatory obligations under the Terms of Service*.

10.52.2 *The Terms of Service impose a positive obligation on the contractor to take reasonable steps to prevent fraudulent exemption claims, to use RTEC where available, and to manage the specific requirements applicable to HRT prepayment certificates and mixed prescriptions. None of this is addressed in the Applicant's SOPs*."

10.53 The Committee noted the Applicant's statement that the updated SOPs submitted with its rebuttal superseded the versions submitted with the original application, and that an applicant may provide updated information during the appeal process. The Committee accepted that it was entitled to consider updated material. However, it remained for the Applicant to provide a clear and coherent explanation of the procedures that would apply in practice.

10.54 In relation to prescription charge exemptions, the Committee noted that the application material contained some information about how evidence could be obtained, checked and recorded. However, the Committee also noted that the operative SOPs did not set out a clear procedure dealing with prescription charge exemption checking. Given that the Applicant stated that its updated SOPs superseded earlier versions, the Committee was not satisfied that it was clear which parts of the application material remained operative and how they were to be applied in practice.

10.55 The Committee was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.

Providing ordered drugs or appliances

10.56 The Committee considered whether the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that (i) the 'cold chain' is maintained, where relevant, and (ii) that the requirements of the

Misuse of Drugs Regulations 2001 and, in particular, Regulations 14 and 16, are met).

10.57 The Committee noted the Applicant had provided information in its application and on appeal however in observations stated:

10.57.1 "*The updated SOPs, which supersede the versions submitted with the original application, are enclosed with this rebuttal*…

10.57.2 *To remove any ambiguity, the Applicant has submitted an updated SOP 604 D1 (Delivery & Dispatch, v6) and SOP 604.2 (Delivery by CitySprint, v3).* ….

10.57.3 *The updated SOPs implement a strict, three-tier 'Failed Delivery Hierarchy' for Controlled Drugs*…

10.57.4 *SOP 608 now mandates the use of calibrated temperature data loggers placed inside the insulated packaging with the medication*. …

10.57.5 *The Applicant has therefore submitted a fully rewritten SOP 702 (Supplying Lithium Therapy, v2).* ….

10.57.6 *The Applicant has submitted an updated SOP 704 (Supplying Insulin, v5), which now includes a comprehensive 'Section 5: Delivery of Insulin – Distance Selling Pharmacy Protocol'*."

10.58 Rushport Advisory LLP in response to the latest SOPs states:

10.58.1 "*SOP 604 D1 … provides only that patients will be notified by SMS or email when their order has been dispatched and when it is out for delivery. This is a dispatch notification, not an estimate of delivery*…

10.58.2 *It contains no requirement to provide a revised estimate if there is a delay*…

10.58.3 *It is not clear which deliveries would be via courier and which by CitySprint*…

10.58.4 *It is not clear what the delivery driver or courier would do with these readings or what action they would take if the correct temperature range was not maintained*…"

10.59 The Committee reviewed the latest SOPs which the Applicant had provided with its observations. SOP 604 D1: Delivery & Dispatch – Distance Selling Pharmacy (DSP) states:

10.59.1 "*…. Scope: This SOP covers all procedures for the dispatch and delivery of medicines, including ambient, controlled drug (CD), and cold chain items. It outlines the principles, pre-dispatch checks, delivery modes, proof of receipt requirements, management of failed deliveries, and record-keeping. …..*

10.59.2 *1.4 Cold Chain Medicines: All medicines requiring temperature-controlled storage and transport must be handled in strict accordance with SOP 608 (Cold Chain). …..*

10.59.3 *2.3 Cold Chain Deliveries: Cold chain deliveries are made via CitySprint Healthcare or the pharmacy's local trained driver. All cold chain deliveries, regardless of the delivery method, must be packaged, monitored, and logged in strict accordance with SOP 608 (Cold Chain). Same-day delivery is used wherever possible to ensure temperature integrity. Full temperature tracking is maintained until the patient receives the package. …..*

10.59.4 *5.4 Controlled Drugs (CDs) Failed Delivery Protocol: In the event of a failed delivery of a Controlled Drug by either CitySprint or the local driver, the CD must be returned to the pharmacy on the same day wherever operationally possible. Upon same-day return, the CD must be accurately re-entered into the Controlled Drug register with a clear explanation of the failed delivery, and immediately secured in the designated Controlled Drug cabinet.*

10.59.5 *5.5 Overnight Storage Contingency (CitySprint only): Where the timing of the attempted delivery by CitySprint precludes same-day return to the pharmacy, the courier is responsible for storing the CD securely overnight at their approved, MHRA-compliant warehouse facilities until it can be returned to the pharmacy. (Note: Local drivers must always return CDs to the pharmacy on the same day; overnight retention by local drivers is strictly prohibited). The pharmacy must be notified immediately of any failed delivery. The tracking service will notify both the pharmacy and the patient of the failed delivery, enabling the arrangement of a re-delivery at a mutually convenient time or the return of the medication to the pharmacy."*

10.60 SOP 604.1: Delivery by Local Driver (DSP) states:

10.60.1 "*2.3 Drivers must use pharmacy-provided, temperature-controlled containers for all cold chain items, with a recorded temperature log for the duration of the route.*

10.60.2 *6. Controlled Drug (CD) Deliveries by Local Driver*

10.60.3 *6.1 Controlled Drugs may be delivered by the local driver for urgent or local supplies.*

10.60.4 *6.2 The driver must only deliver the CD to the named recipient and must ask for photographic proof of ID before handover.*

10.60.5 *6.3 In the event of a failed CD delivery, the driver must not leave the package unattended. The CD must be returned to the pharmacy on the same day…..*

10.60.6 *7. Cold Chain Deliveries by Local Driver*

10.60.7*7.1 Cold chain items may be delivered by the local driver for urgent or local supplies.*

10.60.8*7.2 All cold chain deliveries must be packaged and monitored in strict accordance with SOP 608 (Cold Chain).*

10.60.9*7.3 The driver must use pharmacy-provided, temperature-controlled containers with a calibrated temperature data logger.*

10.60.10*7.4 In the event of a failed delivery, the cold chain item must be returned to the pharmacy on the same day. The maximum and minimum temperatures must be recorded on return. If the temperature has breached the 2-8°C range, the item must be quarantined and destroyed as per SOP 608."*

10.61 SOP 604.2: Delivery by Specialist Courier (CitySprint) states:

10.61.1*"2.3 Cold chain items must be handed over in pre-conditioned, validated temperature-controlled packaging (e.g., cool boxes) provided by the pharmacy or the courier, with a data logger included. …..*

10.61.2*3.2 The courier service must provide real-time tracking and a pre-determined delivery time agreed with the patient. In the event of a failed delivery, the tracking service will notify both the pharmacy and the patient, enabling the arrangement of a re-delivery at a mutually convenient time….*

10.61.3*4.4 Controlled Drug Deliveries: Controlled Drugs will be delivered to patients at a pre-determined time and must be signed for on receipt. CitySprint drivers will only deliver the CD to the named recipient and will require photographic proof of ID before handover.*

10.61.4*In the event of a failed CD delivery, the CD must be returned to the pharmacy on the same day wherever operationally possible. Upon same-day return, the CD must be re-entered into the Controlled Drug register with an explanation of the failed delivery and immediately secured in the Controlled Drug cabinet.*

10.61.5*Where the timing of the attempted delivery precludes same-day return, CitySprint will store the CD securely overnight at their approved, MHRA-compliant warehouse facilities. The pharmacy will be notified immediately and a re-delivery will be arranged with the patient at a mutually convenient time. All failed CD deliveries must be recorded in the CD Delivery Log and reviewed by the Responsible Pharmacist."*

10.62 SOP 608: Cold Chain states:

10.62.1"***3.4 Temperature Monitoring:*** *Temperatures will be strictly controlled and monitored with calibrated temperature probes to provide temperature data for the entire journey. Temperature will be recorded at the beginning of the journey and again at the point of delivery to ensure it stays between 2-8°C. Thermometer(s) will be calibrated*

annually against a certified standard to ensure safe and effective use. ….

10.62.2***7.1 Daily:*** *RP checks fridge temperatures*.

10.62.3***7.2 Monthly:*** *Random sample cross-check. The pharmacy team will send dummy parcels to various locations with a recording temperature control device to check if cold storage has been maintained. A staff member will collect the parcel and record the results. The Responsible Pharmacist will ensure this is actioned monthly and the results recorded in the Cold Chain Log. If there has been a breach of cold chain, the courier must be contacted and an investigation carried out immediately. All further cold chain orders must be kept on hold until the courier can guarantee cold chain delivery*."

10.63 The Committee accepted that the Applicant had provided substantially more detail in the updated SOPs and had sought to address the objections raised. In particular, the Committee noted the updated arrangements for controlled drug deliveries, including the proposed use of CitySprint, requirements for photographic identification, same-day return wherever operationally possible, and secure overnight storage by CitySprint where same-day return was not possible. The Committee also noted the references to cold chain packaging, temperature-controlled containers, data loggers, same-day return by local drivers, and quarantine/destruction where the required temperature range had not been maintained. However the Committee was concerned whether these devices are reconciled with the courier delivery process and are not single use which was initially indicated in the original cold chain SOP as part of Appendix B. If they are not single use, the Committee was unclear as to how devices are returned and reviewed or how the data is reviewed. With regard to the dummy parcels, the Committee considered that this is potentially a useful control, but the SOP does not specify the locations of the testing, if members of staff are going to collect the dummy parcel nationwide, what would be considered successful testing and who would provide assurance .

10.64 Therefore, the Committee was not satisfied that the procedures, read as a whole, provided a sufficiently clear and coherent process for the provision of ordered drugs and appliances. In this regard, the Committee remained concerned that the cold chain arrangements were not sufficiently clear, including as to the circumstances in which CitySprint or a local driver would be used, how temperature would be sufficiently maintained if medicines are not in refrigerated vehicles, when temperature is monitored throughout the route and at delivery stage, and what action would be taken during delivery if a temperature issue arose.

10.65 The Committee considered that these matters went directly to the safe and effective provision of ordered drugs and appliances. Although the Applicant had provided additional information and updated SOPs, the Committee was not satisfied that the information provided was sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

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

10.66 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.

10.67 SOP 607 Repeat Dispensing System states:

10.67.1 "*SCOPE This procedure covers Repeat Dispensing services operated between the pharmacy and local GP practices for both paper and electronic prescriptions*. ….

10.67.2 *For patients whose medication is stable, GPs may issue a Repeat Dispensing (RD) batch of prescriptions*. ….

10.68 The Committee noted SOP 607 describes the process but it only addresses stable medicines but not long term conditions.

10.69 The Committee noted that SOP 607 provided for confirmation that the repeat supply was required and that there had been no change to the patient's medicines since the previous supply; the recording of each supply on the Repeat Dispensing Record Sheet to provide an audit trail; notification to the patient when the final supply in a batch was issued; explicit patient consent to be obtained and recorded in the PMR; advice on the operation of repeat dispensing; and checks by the Responsible Pharmacist before each batch issue. However, although SOP 607 addressed patients whose medicines were stable, it did not explain how the pharmacy would identify patients who also had a long-term, stable medical condition or ensure that appropriate advice about the benefits of repeat dispensing was given to those patients.

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

Prescription linked intervention

10.71 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.

10.72 The Committee noted in its application, the Applicant states:

10.72.1 "*When appropriate prescription interventions take place, for example drug/drug use 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*."

10.73 On appeal the Applicant states:

10.73.1"***Website Compliance and Content**: Our website design reflects available guidance and provides an easy-to-follow layout. As demonstrated in Screenshot 05 (Health Information Top), the website provides access to a reasonable range of up-to-date materials that promote healthy lifestyles (e.g., High Blood Pressure, Stop Smoking Support, Diabetes Management), all linked directly to trusted NHS resources. ….*"

10.74 The Applicant had also provided SOP 405 Interventions and Problem Solving which states:

10.74.1"*PURPOSE SCOPE*

10.74.2*To ensure all dispensing and clinical interventions are identified, resolved, and documented effectively to maintain patient safety and compliance. ……*

10.74.3*PROCEDURE/PROCESS*

10.74.4*1. Identification and Recording of Interventions*

10.74.4.1*1.1. During the dispensing process (prescription receipt, data entry, assembly, or accuracy check), any issue that requires a change to the prescribed item or dose, or a clinical decision, is considered an intervention.*

10.74.4.2*1.2. Interventions include, but are not limited to: drug-drug interactions, dose queries, therapeutic duplication, allergy checks, illegible prescriptions, and supply issues.*

10.74.4.3*1.3. All interventions must be immediately referred to the Responsible Pharmacist (RP). …..*

10.74.5*2.3. Handling Remote Patient Queries: …..*

10.74.5.1*b. Queries relating to medication use, side effects, or clinical advice must be handled exclusively by the RP via a secure remote consultation (telephone or video). …..*"

10.75 The Committee noted that the Applicant had provided information on prescription interventions generally, including that the pharmacist would contact the prescriber and patient where issues such as drug interactions or suspected over/under-prescribing arose. The Committee also noted that SOP 405 described the recording and management of dispensing and clinical interventions. However, the Committee was not satisfied that the Applicant had explained with sufficient clarity how it would assess whether individual patients required prescription-linked intervention advice specifically because they had diabetes, were at risk of coronary heart disease, smoked or were overweight. The material referred to general health promotion and website resources, but did not set out a clear process for identifying those patients and linking that assessment to prescription-linked intervention advice.

10.76 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

Other considerations

Absence of an EPS Nomination Management Procedure

10.77 The Committee noted Rushport Advisory LLP's comment in its observations that SOP 603 Receiving Prescriptions dealt with the receipt and processing of EPS prescriptions but did not address the management of EPS nominations. The Committee reviewed SOP 603 and accepted that it contained a process for checking the PMR system for new EPS prescriptions, downloading prescriptions, noting prescriber alerts or messages, and documenting prescription-related communications in the PMR.

10.78 However, the Committee considered that this did not amount to a procedure for managing EPS nominations. SOP 603 did not explain how the Applicant would obtain and record a patient's nomination, ensure that the patient had been informed of their choice of pharmacy, deal with requests to change or cancel a nomination, or ensure that nominations were not inappropriately captured or retained.

10.79 The Committee therefore accepted Rushport's comment to this extent. While SOP 603 provided some assurance in relation to the processing of EPS prescriptions once received, it did not provide sufficient assurance that the Applicant had a clear process for managing EPS nomination.

Anti-Coagulation SOP

10.80 The Committee noted SOP 614 Dispensing of Anti Coagulants states:

10.80.1"*PROECDURE/PROCESS*

10.80.2*Dispense prescription following 'Assembling and Labelling' SOP.*

10.80.3*Contact patient to verify if have had a recent INR test. If possible can they send a photo of latest page of yellow book. The INR clinic may also offer support where needed.*

10.80.4*Does the dose as described by patient correspond with what has been prescribed in the yellow anti-coagulant book?*

10.80.5*If no recent check, INR out of range with no retest within two weeks or dose patient taking is different to dose prescribed, contact prescriber."*

10.81 The Committee was of the view that the process relies on the patient providing information rather than the pharmacist independently verifying the current INR result and dosing instructions which the Committee considered was a safety concern with regard to the provision of pharmaceutical services in a safe and effective manner.

10.82 The Committee noted that the application form was left blank in response to the question asking the Applicant to specify the appliances it undertook to provide, or to write "none" if it did not intend to provide appliances. The Committee also noted the Applicant's supporting information, which addressed the referral process to be followed where the pharmacy was unable to provide an appliance or stoma appliance customisation because it was not within its normal course of business. Reading the application form and supporting information together, the Committee was satisfied that the Applicant was not proposing to provide appliances. Accordingly, the Committee did not consider compliance with paragraph 8(4) of Schedule 4 insofar as it relates to the measuring and fitting of appliances requiring such services.

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

Summary

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

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

10.85.1 confirm the Commissioner's decision;

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

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

10.86 The Commissioner had not given reasons for its decision other than broad statements that the Applicant had not demonstrated how the relevant requirements would be met. The Commissioner's decision did not identify the specific deficiencies relied upon, explain why the information provided was insufficient, or show how the relevant statutory tests had been applied to the information before it. In those circumstances, as the Committee was not satisfied that the Commissioner had given adequate reasons for refusing the application, it determined that the decision must be quashed.

10.87 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.

10.88 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.

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

11 Decision

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

11.2 The Committee:

11.2.1 quashes the decision of the Commissioner; and

11.2.2 redetermines the application as follows -

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

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

11.2.2.3 the Committee was not satisfied that all essential services were likely to be secured for persons anywhere in England;

11.2.2.4 the Committee was not satisfied that pharmaceutical services were likely to be secured in a safe and effective manner; and

11.2.2.5 the Committee was not satisfied that pharmaceutical services were likely to be secured without face to face contact.

11.2.3 The application is refused.

Case Manager
Primary Care Appeals