NHS Resolution

26 March 2026

REF: SHA/26823

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APPEAL AGAINST GREATER MANCHESTER ICB DECISION TO REFUSE AN APPLICATION BY MOSOAR LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT HUB 14 PEPPER HOUSE, HAZEL GROVE, STOCKPORT, SK7 5DP 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:

Pharmaceutical Defence on behalf of Mosoar Ltd
Rowland Pharmacy
PCSE on behalf of Greater Manchester ICB

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1 The Application

By application dated 14 June 2025, Mosoar Ltd ("the Applicant") applied to Greater Manchester ICB ("the Commissioner") for inclusion in the pharmaceutical list at Hub 14, Pepper House, Hazel Grove, Stockport, SK7 5DP 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 "NONE".

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

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

Pharmacy procedures

1.4 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.

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

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

1.7 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.

1.8 “Please see attached pharmacy procedures

1.9 Please see attached draft SOPs” [see Appendix A]

Mosoar Ltd Pharmacy Procedures

1.10 “Mosoar Ltd has prepared a draft of their initial Quality Management System and SOPs in preparation for securing the distance selling contract and to support this application. These DRAFT SOPs cover the essential services as required to be delivered by NHS pharmacy contractors and have been written to suit the Distance Selling model. The Superintendent Pharmacist will be responsible for the management of the SOPs and for training all staff on the SOPs according to their role within the pharmacy. After induction training, understanding of the SOPs will be validated by the Superintendent Pharmacist before new staff commence their shift.

1.11 The pharmacy will have SOPs in place for the provision of essential services. It is pertinent to know that only some of the SOPs have been provided to help facilitate the application, any specific SOP can be provided if requested.

1.12 Mosoar Ltd will have a website which facilitates the following:

1.12.1 Patient accesses website via a secure log-in procedure;

1.12.2 Patient provides details of prescription,

1.12.3 Patient will be contacted by the pharmacy and medical history assessed.

1.12.4 Patient posts prescription to pharmacy and/or prescription received via EPS.

1.12.5 Item is dispensed and details added to PMR.

1.12.6 The medication is delivered nationwide via a tracked delivery service. There will be no charge to the patient for delivery of medication dispensed against NHS prescriptions. Any costs incurred for delivery will be met by the pharmacy.

1.13 The website has been built by a company called Healthera who are web developers that have experience within the pharmacy web development market. Each patient will have their own personal login account once registered which will include their own personalised password for added security. Upon patient consent the pharmacy will then nominate them for EPS. This will then enable us to deliver a service safely and effectively to anyone in England without face to face contact.

1.14 Communication between the pharmacy and patients will be facilitated by phone, fax, email and webcam. Records of all patient interactions will be maintained on the PMR in use at the pharmacy. Mosoar Ltd has decided to use Titan PMR as the software provider which will be a key tool in providing a safe and effective provision of service.

1.15 Mosoar Ltd is committed to having all staff trained by the National Pharmaceutical Association at a level suitable to their role. All training will need to be recognised and accredited by the GPhC and all staff will hold NVQ qualifications in Pharmacy Services. Staff and Responsible Pharmacists will also be provided with training on the SOPs relevant to their role. By following a set of SOPs, the pharmacy will be able to provide a safe and effective service that is patient-centric and outcome focussed.

1.16 The Superintendent Pharmacist will train all the staff members on the conditions of being a distance selling contractor. They will receive specific training on speaking to patients without face-to-face contact, an example being how to elicit a comprehensive medical history by telephone or webcam.

1.17 Mosoar Ltd is comprised of one director, [SA]. [SA] is the nominated superintendent and has suitable pharmacy experience. [SA] will act in overseeing the operations of the pharmacy and will maintain role of the Information Governance Lead, Clinical Governance Lead and Smartcard Sponsor. A full-time Responsible Pharmacist will be employed to be in attendance during the opening hours. He will be supported by a staff team of one full- time and one part-time dispenser. This level of staff will be able to cover initial trade levels once the pharmacy is open and will ensure an uninterrupted provision of essential services during the opening hours. The team is expected to grow with the business and new members will be added as and when required.

1.18 The premises have been carefully chosen to prevent face to face contact for any person seeking the provision of essential services, in, or within the vicinity of the premises. No person who is seeking essential services under the NHS contract will be allowed entry to the premises. All entrances and exits will remain inaccessible to members of the public who are seeking the provision of essential services. An alarm system will cover the pharmacy premises which will notify the owner of unauthorised access when the premises are closed. All access routes will always be secured and kept locked when the premises not in use. Keys to the pharmacy premises will only be kept with authorised persons employed by the company. Schedule 1, 2 and relevant 3 drugs will always be stored in a locked CD cabinet. Security of premises will be reviewed regularly. A chosen member of staff will be available for emergency outcall in case of a breach.

Essential Service – Dispensing

Uninterrupted service

1.19 Provision of service through the opening hours of the pharmacy will be maintained by having a Responsible Pharmacist present at all times during the pharmacy opening hours and having sufficient support staff at all times. The

pharmacy website will run throughout these hours together with a phone, fax, email and webcam service. If the responsible pharmacist is required to leave the premises, a further pharmacist will be on hand to ensure that there is no break in pharmacist cover during the opening hours.

Persons anywhere in England

1.20 Patients anywhere in England can access these services via our pharmacy website a direct phone line to the pharmacy, fax, email as well as webcam. Internet connections at the pharmacy will be provided by the NHS HSCN network via BT.

1.21 All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint (www.citysprinthealth.co.uk). This will include the delivery of prescriptions received via post, fax and EPS. City Sprint will also be delivering cold chain items and CDs. This is addressed in the SOPs which have been included.

Safe and effectively

1.22 The service will be delivered safe and effectively by using SOPs to manage the process. Please see the attached SOPs provided to show examples of how the pharmacy will be managed safely and efficiently at all times.

1.23 We will have a suitable number of staff who will be trained to a minimum of an NVQ level 2 standards. This training will be undertaken by National Pharmaceutical Association (NPA) (www.npa.co.uk)

1.24 Requests from patients to show the Pharmacist visual symptoms of conditions will be done via a secure video link. All conversations will be recorded on the PMR in detail.

1.25 If patient counselling is required for any dispensed medication, the pharmacy will have procedures so this can be done via the telephone, videoconferencing or email before dispatch of medication. The pharmacy will require acknowledgment from the patient or another person that the counselling points have been understood. Patient interactions will be recorded on the PMR. A label will also be attached to the packaging asking the patient to contact the pharmacy for further details.

1.26 Prior to medication being delivered, staff will contact patient to confirm delivery address, date and time. Deliveries will be monitored with the online courier tracking service which will give real-time information and is also available as an app for smart phone and tablets.

1.27 All medication will be delivered in tamper-proof and seal-proof packaging. Several companies who produce packaging material have been researched with a view to order corrugated cardboard boxes and 5-panel wraps which are able to withstand a single trip. It will be packed so it is protected from the environment which may include using a double walled package design or using waterproofing on the packaging material. This will also ensure that the delivery person is protected from cytotoxics and sharps.

Without face-to-face contact

1.28 This service will be delivered without face-to-face contact via the pharmacy website as a communication link as well as telephone post/email/fax/webcam. A courier service will provide a third-party delivery if this is required when it would not be practicable to use the in-house delivery service.

1.29 If needed, Controlled Drug (CD) deliveries will be undertaken by City Sprint who are accredited to handle and transport CDs. Their drivers will deliver to patients at a pre-determined time and the CD's must be signed for on receipt. Their drivers will only deliver the CD to the named recipient and they will ask for photographic proof of ID. In the instance of a failed delivery attempt, City Sprint will return any CDs to their overnight safe storage facility and the pharmacy will be contacted to arrange alternative delivery date to patient.

1.30 City Sprint is approved by the MHRA and has fully trained couriers to deal with all pharmacy deliveries including controlled drugs and fridge items. As well as collecting prescriptions from surgeries and collection of unwanted waste medication from patients. This will ensure there is no face to face contact.

1.31 Delivery of Refrigerated Medicinal Products - For cold chain products, delivery times will always be pre-arranged with the patient to minimise the risk of failed delivery. The patient's contact number will be given to the City Sprint delivery driver so they can again call the patient approximately 15-30 minutes prior to so they can check that somebody will be at the address to receive the medication. Cold chain products will be packed in such a way as to ensure that the required temperatures are maintained throughout the journey and the medicines are transported in accordance with their labelling requirements to maintain product integrity.

1.32 For delivery of medication with short journey times of less than 3 hours, validated medical cool boxes will be used as recommended by the MHRA. For extended journeys, gels/ ice packs will be added to the packaging to maintain appropriate temperatures throughout. Extra caution will be taken with regards to the positioning of these packs within the consignments as this would be deemed extremely important as they must not be allowed to come into direct contact with the medicines being delivered. Temperatures will be strictly controlled and monitored with calibrated temperature probes to provide temperature data for the entire journey. This will be done by the courier driver. Temperatures will be recorded at the beginning of the journey and again at the point of delivery to ensure it stays between 2-8°C. If the temperature is outside of the required range, then the product will be deemed unsafe to deliver, marked as waste and returned to the pharmacy for destruction. Thermometer(s) will be calibrated annually against a certified standard to ensure safe and effective use. When used to deliver medication, the City Sprint delivery driver must only remove the item from cold storage once the patient has answered the door and verified their identity. In the event of failed delivery, the cold storage item must be returned to the pharmacy as soon as possible, with the maximum and minimum temperatures again being recorded at the point of return. Once again, if temperature monitoring suggests that the medication may have been transported outside of the required range, then the product will be destroyed by the pharmacy and then item will be re-dispensed

by the pharmacy. Once again, a new delivery will be agreed with the patient prior to redelivery.

1.33 Acute or Urgent Dispensing Requests – Any acute, urgent medication received by ETP or directly via courier from a surgery for patients anywhere in England can be dispensed and dispatched the same day using City Sprint who offer a 24 hour, 365 day service for any type of delivery.

1.34 If a prescription is received for an appliance which requires measuring and fitting, the patient will be telephoned and emailed to state that the pharmacy cannot provide this service because the pharmacy must operate without face to face contact. The patient will then be advised that they would need to have the prescription dispensed by a pharmacy where a pharmacist would be able to measure and fit the appliance. We would facilitate this by gaining the permission of the patient to contact their nominated pharmacy and explaining the situation. We would then return the prescription to the patient or to the NHS spine so that the prescription can be dispensed.

Essential Service - Disposal of Unwanted Medication

Uninterrupted Service

1.35 Provision for disposal of unwanted medications can be requested by any patients during the core opening hours of the pharmacy. This can be requested via telephone, fax, email or webcam. All staff will be trained to deal with such enquiries.

Persons anywhere in England

1.36 Patients anywhere in England can request for safe disposal of their unwanted medication from our pharmacy via phone, fax, email, post or webcam.

Safe and Effectively

1.37 Patients, anywhere in England, can contact the pharmacy for collection of their unwanted medicines. We will take details of medication being returned by patients and assess if we are allowed to take them. We would provide patients with adequate packaging so medication can be returned securely via City Sprint couriers at no charge to the patient. All legal records will be kept and we would have procedures in place to comply with Hazardous Waste Regulations and we would keep any additional legal records such as those required for Controlled Drugs. Returned medication can be collected from patients' homes and residential homes but we will not be accepting from nursing homes. Returned medication will be stored in UN type containers provided by PHS.

1.38 Returned medication will be stored in UN type containers provided by PHS. Returned solid medicines/ ampoules, liquids and aerosols will be separated. Schedule 2 and 3 Controlled Drugs that are subject to safe custody regulations which are returned by patients will be segregated from other returned medicines and stored in compliance with the Safe Custody Regulations until they have been rendered irretrievable. As the Environment Agency has suggested that the denaturing of CDs is likely to constitute a waste treatment, the pharmacy will hold a waste management license. We will ensure that the

courier collecting returned medication is registered as a waste carrier with each local environmental agency office that it operates in. We will keep full records of any waste collected and disposed of for at least three years.

Without face-to-face contact

1.39 Disposal of unwanted medication will be delivered without face-to-face contact via City Sprint couriers or, for local requests, out in-house delivery service. This courier service will provide a third party delivery. Patients would communicate with the pharmacy via phone, fax, email website, post or webcam. We have SOPs in place to ensure this service is offered without having them to be present the pharmacy.

Essential Service – Signposting

Uninterrupted Service

1.40 Provision of signposting can be done through the opening hours of the pharmacy via phone, fax, email, post, website or webcam. Staff will be trained to assess the need for signposting and if any doubt will refer the matter to the pharmacist.

Persons anywhere in England

1.41 Patients anywhere in England would be able to access the signposting service from the pharmacy via phone, website, email, post or webcam. During communication the pharmacy staff will assess the need for signposting and if any doubt will refer the matter to the pharmacist.

Safe and Effectively

1.42 We would contact the relevant NHS organisations in Scotland. Wales and Northern Ireland to obtain resources. Furthermore, we would have access to Macmillan, NHS Choices and NHS Direct websites, as well as full internet access to further on-demand resources. Depending on the nature of patient queries and assessment of the information provided by the patient we could then either contact patients for further information refer them to their GP or signpost them to a local NHS or non NHS service as appropriate. We will provide referral notes by email, fax and post to the appropriate health and social care providers in cases where the pharmacy is unable to meet the needs of the patient. We will aim to ensure that patients are referred correctly to minimise inappropriate use of health and social care services. We will keep records of all referrals made on the PMR including any advice given to maintain audit trails.

Without face-to-face contact

1.43 Signposting will be delivered without face-to-face contact via the website email phone, post fax or webcam. All patients will communicate with the pharmacy via these methods and as such there will be no face-to-face patient interaction. The SOPs in place ensure we can deliver the service without face to face contact in a distance selling model.

Essential Service - Repeat Dispensing

Uninterrupted Service

1.44 Provision of repeat dispensing throughout the opening hours of the pharmacy will be maintained by phone, fax, email, post or webcam. The Responsible Pharmacist will have undertaken the necessary training and is competent to provide the repeat dispensing service. The CPPE certificate of the Responsible Pharmacist will be provided to the local NHS team for their records. During the opening hours the Responsible Pharmacist will be supported by a suitable trained team sufficient to deliver the repeat dispensing. The pharmacy IT system will be ETP compliant to allow for repeat prescriptions to be received electronically from surgeries anywhere in England that are ETP release 2 compliant. This will be promoted to patients as a quick way to receive prescriptions from participating surgeries for nominated patients repeat and acute prescriptions for quick despatch of medicines without any delay.

Persons anywhere in England

1.45 Patients anywhere in England can access the Repeat Dispensing service by signing consent form which is available on the website for anyone wishing to use the service. This consent from can be emailed, faxed or posted directly to the pharmacy. Patients from surgeries that are ETP 2 compliant will have their prescriptions sent and received at the pharmacy electronically almost instantly after the Doctor signs off the electronic prescription. The prescriptions medicines will be dispensed and despatched for delivery by our in-house delivery service or the courier without any delay.

Safe and Effectively

1.46 Repeat Dispensing will be delivered safe and effectively via the staff completing sufficient clinical and legal assessments before dispensing the medicine. Once a patient signs up we will obtain the batch prescription (both the Repeat Authorising Prescription RA and the Repeat Dispensing Prescriptions RD) either from the surgery, electronically or via post. Either the patient will contact the pharmacy via phone, email post, website or webcam to dispense the next RD instalment prescription or the pharmacy contacts the patient when they are due their next RD instalment.

1.47 Before each RD dispensing activity we will contact the patient to clarify which items are required and whether or not there has been a change in medical condition. If treatment needs to be reviewed by the prescriber, the patient will be notified by telephone and/or email. We will keep records of dates of dispensing for each individual batch for each patient, to monitor compliance. Records of interventions made by the pharmacist considered by the pharmacist to be clinically significant will be maintained on the PMR. These actions will ensure a safe and effective service is delivered for patients using the repeat dispensing service.

Without face-to-face contact

1.48 All repeat dispensing patients will be communicated without face-to-face contact via phone, email, post, fax or webcam. All medications will be delivered

using our in-house delivery service or the City Sprint courier service and will maintain service delivery without face-to-face contact. We have SOPs in place to manage these services without face-to-face contact.

1.49 For patients who request our service and who are NOT signed up to the repeat dispensing service, we will request that they contact the pharmacy so that we can discuss their suitability for the service but also provide further information on the benefits of the service. The initial contact with the patient will be via a leaflet which will be included within their dispensed medication. Benefits will include saving time for the patient and the prescriber due to a decreased workload on both parties.

1.50 A further benefit will include an improvement of medication safety as the pharmacy will check each and every request to ensure that the medication is still suitable before dispensing. During these checks, if a medication is flagged as being unsuitable or there are side effects, then the patient will be referred to the prescriber for discussion.

Essential Service – Discharge Medicine Service

Uninterrupted Service

1.51 Provision of discharge medicine service throughout the opening hours of the pharmacy will be maintained by phone, fax, email, post or webcam. The Responsible Pharmacist will have undertaken the necessary training and is competent to provide the discharge medicine service. The CPPE certificate for the Responsible Pharmacist will be provided to the local NHS team for their records.

1.52 During the opening hours the Responsible Pharmacist will be supported by a suitable trained team sufficient to deliver the discharge medicine service. The pharmacy IT system will be compliant to allow for discharge medicine service to be undertaken via Pharmoutcomes website or the pharmacy dedicated NHS mailbox.

Persons anywhere in England

1.53 Patients anywhere in England can access the discharge medicine service via the phone, email, chat, video link. When the pharmacist identifies an intervention on the service he/she will communicate with the patient and other healthcare professionals. All interventions will be documented on their PMR record.

Safe and Effectively

1.54 Discharge Medicine service will be delivered safe and effectively via the staff completing sufficient clinical and legal training to provide the service. Hospitals will identify patients who will benefit from discharge medicine service and will send a referral to the patient's pharmacy via secure electronic system. When a referral is received, the pharmacist will review the information in the referral, including comparing the revised medicines prescribed to those the patient used before being admitted to hospital. If any issues are identified, these will be queried with the hospital or the general practice. Pharmacy team members will

check whether there are any existing dispensed prescriptions waiting for the patient or any electronic repeat dispensing prescriptions on the NHS spine. If there are, these need to be checked to see if they are still appropriate for the patient. The pharmacist will have a consultation with the patient and/or their carer to check their understanding of what medicines they should now be using and to provide further advice. If there are medicines the patient is no longer using, we will offer to dispose of them, to avoid potential confusion in the future. When the first prescription for the patient is received by the pharmacy following discharge, there will be a check to compare the medicines prescribed by the hospital and those prescribed by the GP. If there are discrepancies or other issues, the pharmacist will try to resolve them with the general practice. 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.

1.55 Relevant information will be documented on the PMR/IT System for Stage 1, 2 and 3 to ensure continuity of the service.

Without face-to-face contact

1.56 All discharge medicine service patients will be communicated without face-to-face contact via phone, email, post, fax or webcam. All medications will be delivered using our in-house delivery service or the City Sprint courier service and will maintain service delivery without face-to-face contact. If medicines need to be returned, this will be done in accordance to disposal of unwanted medication. We have SOPs in place to manage these services without face-to-face contact. This discharge medicine service will ensure better communication of changes to a patient's medication when they leave hospital and to reduce incidences of avoidable harm caused by medicines.

Essential Service - Public Health (Promotion of Healthy Lifestyles)

1.57 Prescription linked intervention

Uninterrupted service

1.58 Provision of service through the core opening hours of the pharmacy will be maintained by having a Responsible Pharmacist rostered on for all opening hours and having sufficient support staff at all times. Provision of service through the core opening hours of the pharmacy will be maintained by the pharmacy website email and telephone.

Persons anywhere in England

1.59 Patients anywhere in England can access these services via the pharmacy website, phone, email, chat, video link or distribution of leaflets within the prescription that is delivered to the patient. When the pharmacist identifies an intervention on a prescription he/she will communicate with the patient and other healthcare professionals. All interventions will be documented on their PMR record.

Safe and effectively

1.60 This service will be delivered safe and effectively by pharmacists and appropriately trained staff. At risk patients will be targeted through prescription linked intervention. Opportunistic advice will be given by the pharmacist on specified healthy living/public health topics to patients who have their prescriptions fulfilled by the pharmacy. Staff will be trained to assess for prescription linked interventions and if any doubt will refer the matter to the pharmacist. In particular, patients with diabetes, coronary heart disease, high blood pressure, smokers and obesity. These patients will be identified through the type of medication being requested the patients PMR, or the online questionnaire completed by new patients. Once a prescription linked intervention has been made, a note will be made on the patient's PMR. This note will ensure continuity of advice and as a reference for future interactions with the patients.

Without face-to-face contact

1.61 The service will be delivered without face-to-face contact via telephone, email, live chat or video link. Any educational material relating to certain conditions can also be sent in the post or inserted into the packaging of any dispensed prescriptions. We have SOPs in place to manage these services without face-to-face contact.

1.62 National Health Campaign

Uninterrupted Service

1.63 Provision of service through the core opening hours of the pharmacy will be maintained by the pharmacy website, telephone, fax email, web chat or video link. Promotional material prepared by the Local Area Team and/or Public Health England will be made available for any patients. Trained staff will be available at the pharmacy to run the campaigns during the opening hours.

Persons anywhere in England

1.64 Patients anywhere in England can access these services via the pharmacy website, telephone, email, live chat, video link as well as sending out printed leaflets. The website will have a specific area for current health campaigns and allow outbound links to accredited organisations and clear routes to further resources.

Safe and Effectively

1.65 This service will be delivered safe and effectively. The pharmacy will contribute in up to 6 campaigns as directed by NHS England and Public Health England. Other campaigns may be advised by the Local Area Team/Health and Wellbeing Board. Throughout the campaigns the pharmacy will maintain a record of the number of people that receive the advice to ensure traceability. The pharmacy will use the approved content provided by the relevant bodies. This may include briefing packs, patient literature, NHS funded merchandise or services.

Without face-to-face contact

1.66 The service will be delivered without face-to-face contact via the pharmacy website telephone, email or live chat. We have SOPs in place to manage these services without face to face contact.

1.67 Essential Service - Support for Self-Care

Uninterrupted Service

1.68 Provision of service through the core opening hours of the pharmacy will be maintained by having a Responsible Pharmacist rostered on for all opening hours and having sufficient support staff at all times. Communication links to maintain the service through the core opening hours of the pharmacy will be via the pharmacy website, telephone, email, live chat or video link.

Persons anywhere in England

1.69 Patients anywhere in England can access these services via the pharmacy website, telephone, email, live chat or video link. The majority of interactions will come whilst giving advice to the patient using these methods.

Safe and Effectively

1.70 Support for self-care will be delivered safe and effectively. Pharmacy staff will provide advice to patients including carers requesting help with the treatment of minor illness and long term conditions, including general information and advice on how to manage illness. Using website or telephone consultation, we can assess patients using a protocol based on the WWHAM model.

1.71 Visual symptoms can be accessed via a video link if necessary. The pharmacy staff will advise on the appropriate use of the wide range of non-prescription medicines which can be used in the self-care of minor illness and long term conditions. When appropriate pharmacy staff will make healthy interventions in a similar manner to that provided in promotions of healthy lifestyle service. When appropriate and where necessary, pharmacy staff will signpost patients to other health and social care providers. Records of advice given, products purchased or referrals made will be put on to the patients PMR when the pharmacist deems it to be of clinical significance. Any medication sold online will be sent to the patient via City Sprint couriers.

Without face-to-face contact

1.72 This service will be delivered without face-to-face contact via telephone, email, live chat or video link. Support for Self-Care will be prevalent in all patient interactions which will be maintained using these methods. Any deliveries of OTC products will be made using City Sprint courier who will act as a third party. We have SOPs in place to manage these services without face-to-face contact.

1.73 Essential Service - Clinical Governance

1.74 There will be a named Clinical Governance Lead who will also be the Superintendent Pharmacist, [SA]

Patient and public involvement

1.75 A practice leaflet will be easily accessible on the front page of the pharmacy website and we will also supply a paper copy to all patients when first delivering to them. Updated leaflets will sent to all registered patients should there be any significant changes. All services provided by the pharmacy will be listed on the leaflet and whether the service is funded by the NHS or privately. In addition, the pharmacy will produce an annual patient satisfaction survey presented to patients who use our service electronically and along with delivery of medication. Patients will have the option to return the satisfaction surveys electronically or through the post via a pre-paid envelope. The results of the patient satisfaction survey will be published on the pharmacy website and practice leaflet. The results will feed into the pharmacy's continuous quality improvement scheme.

1.76 The pharmacy will also have in place procedures to deal with complaints which will be regularly reviewed to allow us to improve our performance compliant with GPhC guidance. The employed Pharmacy Manager will deal with any complaints. Procedures to deal with medication owed to patients will also be in place and patients given a written note either via email or along with their delivery of medication to inform them of exactly what is owed and when the medication is expected to be supplied. Notes of medication owed will be kept on the PMR and regularly reviewed so stock levels can be adjusted appropriately.

Clinical audit

1.77 The pharmacy will participate in a minimum of two clinical audits annually. At least one practice based audit and one multidisciplinary audit determined by NHS England, the Area Team or any other relevant organisation. Suitable personnel will be made available to ensure these audits are carried out.

Risk management

1.78 All incident reporting will be carried out in the pharmacy and this will involve near misses using the GPhC near miss template and help identify trends or highlight weaknesses in pharmacy systems and procedures and would be rectified promptly. Any patient safety incidents will be reported to the National Patient Safety Agency (NPSA) online. We will analyse and learn from any patient safety incidents through a system of regular reviews. In addition, the pharmacist will be proactive in considering and preventing potential risks. This will include competence in risk management and the application of Root Cause Analysis. Health and Safety legislation will be complied with in order to reduce the risk of harm to pharmacy staff and the public.

1.79 All patient safety communications received at the pharmacy either by fax, email or post will be actioned by the Pharmacist and pharmacy staff promptly and records of this will be kept at the pharmacy for audit purposes. We will have adequate facilities in place to be able to dispose of any confidential waste. NHS Code of Practice on Confidentiality will also be met.

1.80 Mosoar Ltd have produced DRAFT- Standard Operating Procedures (SOPs) at this point in time to cover the Essential Services. These procedures will

continue to be developed up until when we secure the contract and commence trading. The SOPs will be reviewed at a minimum annually or a result of changes in best practice, new regulations or as a corrective action following any adverse incidents. The Superintendent Pharmacist will be responsible for the maintenance of the SOPs and training all staff in the SOPs relevant to their role.

1.81 All pharmacy staff will be trained in and aware of child and vulnerable adult safeguarding procedures, and have access to safeguarding arrangements and reporting to all areas of United Kingdom via access to internet at the pharmacy. Any documentation will be kept for audit purposes.

Staffing and staff management

1.82 There will be a set of induction packs at the pharmacy to ensure that all have access to all necessary

1.83 Clinical Governance information.

1.84 Appropriate training will be given to all staff relevant to their positions in the pharmacy. Staff appraisals will be conducted regularly to ensure that all members of staff meet GPhC standards. If standards are not met then support will be offered and remedial action taken. We would expect Pharmacists and any registered technicians to demonstrate continual professional development and keep records of events to meet GPhC requirements.

Education, training and continuing professional and personal development

1.85 All pharmacists working at the pharmacy are able to demonstrate a commitment to continuing professional development (CPD), via a CPD record and this will be in line with the national RPSGB scheme. Any necessary accreditation will be achieved prior to provision of any advanced or enhanced services.

Use of information to support clinical governance and health care delivery

1.86 Pharmacy staff will have full access to up to date reference sources such as the BNF and Drug Tariff and with appropriate IT links with electronic reference sources. Mosoar Ltd will ensure all employees will comply with data protection and confidentiality, including the Data Protection Act 2018, Human Rights Act 1998 and common law of confidentiality Mosoar Ltd will ensure that all employees will conform to the NHS Code of Practice on confidentiality and will have systems and policies in place to support this including ensuring all staff are appropriately trained. Employee contracts will include a duty of confidence as a specific requirement linked to disciplinary procedures.

1.87 Pharmacists will be using their own professional judgement to make records of interventions they have made and any advice they may have given. Mosoar Ltd will ensure that NHS direct are aware of the pharmacy's actual working hours so that they can provide appropriate information to members of the public.

Proof of exemption/prescription charges

1.88 If the patient is under 16 or over 60 years of age and the date of birth is printed on the front of the prescription then no check of exemption status is required. The pharmacy will make use of real time exemption checking (RTEC) via the PMR system if appropriate. For all other exemptions, the pharmacy will make contact with the patient and ask them for proof of their exemption. The pharmacy will ask patients to send proof of exemption to the pharmacy via post, fax or as an email attachment. The exemption details can also be updated on the secure pharmacy website. The pharmacy will keep records of exemption on the PMR, including when the exemption runs out or expires. On each dispensing occasion, we would verify exemption details and seek explicit permission from the patient if they would like the pharmacy to fill in the back of the prescription on their behalf. We would make a record each time the patient gave us permission to fill in the back of the prescription on their behalf so there is an audit trail. If the patient wishes to fill in the back of the prescriptions themselves we would send the prescription to the patient via courier for them to fill in and return to us. This could be done at the same time as the medication is being delivered or prior to delivery depending on patient preference. If patient is unable to provide proof of exemption, the pharmacy would mark the back of the prescription to indicate that the exemption has not been seen. Where prescription charge(s) need to be taken, the pharmacy will have facilities in place whereby card details can be taken over the telephone or via a secure internet site. The pharmacy will cover the cost of postage by arranging for an insured courier to collect prescription charges nationally via a tracked service.

Additional Information

1.89 We will maintain a high level of standards regarding the premises in terms of cleanliness in order to ensure good working conditions and minimise risks of infections. This will be covered in our SOPs and also by having a cleaning rota that is monitored. All staff will be trained on basic hygiene and hand washing issues and appropriate materials will be provided to promote this."

1.90 [SOPs provided]

2 Comments to the Commissioner

On reviewing the paperwork provided by PCSE, it was noted that the comments made by Pharmaceutical Defence on behalf of the Applicant in response 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 PHARMACEUTICAL DEFENCE ON BEHALF OF THE APPLICANT

2.1.1 "We refer to the attached letter of authorisation.

2.1.2 We have received the representations from other contractors/ interested parties regarding the proposed DSP.

2.1.3 The objections raised in the response by Mai's Pharmacy appear to be financially motivated responses which the committee will be fully aware is not one of tests that needs to be satisfied under Regulation 25 or 64. Furthermore, the response does not address any of the tests that need to be satisfied under Regulation 25 or 64. Finally, we note that there are 2 CAS reference numbers written within this response. The committee must only be concerned with deciding the application with the reference CAS-340740-N5D1W9. We say the representations made by Mai's Pharmacy are borne not out of altruist intentions but are out of fear of losing NHS Market Share to another provider. We ask the committee to fully disregard the rather self-serving response from Mai's Pharmacy.

2.1.4 With reference to the response by Rowlands Pharmacy, this again does not address, significantly, any of the tests in Regulation 25 and 64. The committee will be aware that the reference CAS number written in the response is not the CAS number for this application. Therefore, we urge the committee to disregard this response in its entirety as the committee must only be concerned with deciding the application with the reference CAS-340740- N5D1W9.

2.1.5 Turning to the response from Community Pharmacy Greater Manchester (herein referred to as CPGM), we say that this response does not add any significant information over and above the evidence that the committee have in front of them. It is for the committee to decide upon all of the evidence before it, including evidence within the SOPs, and of course SOPs can be amended. The committee can direct that the SOPs are amended if they see fit and sent to the ICB for review before the NHS contract, if awarded, begins to operate. Further addressing the comments made by CPGM regarding the DSP application, we note that although they have mentioned the SOPs, the committee are reminded that it is not the function of the committee to approve or disapprove of the SOPs as there are various ways that the applicant could organise itself in order to comply with the various requirements of the Regulations.

2.1.6 Finaly, [sic] we would point out that the location of the DSP is an irrelevant concern as the committee have already been given reassurances that ALL NHS services under a DSP contract, if awarded, would be offered remotely i.e. not face to face.

2.1.7 We ask the committee to assess the application on the evidence presented already by ourselves. We urge the committee to find that ALL NHS services would be delivered without face-to-face contact and that this service would be uninterrupted during the core hours stipulated. Finally, we urge the committee to find that the services would be delivered in a safe, secure and effective manner."

3 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 13 November 2025 states:

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

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

Extract from the Committee Report from the NHS Greater Manchester Integrated Care Board (NHS GM) Pharmaceutical Services Regulations Committee (PSRC)

3.2 "CAS reference number: CAS-370740-N5D1W9

3.3 Name of applicant: Mosoar Ltd

3.4 Fitness to practise: Fitness deemed suitable for inclusion in the Stockport HWB area Pharmaceutical List by PSRC 29/08/2025

3.5 Address of proposed premises: Hub 14 Pepper House, Hazel Grove, Stockport, SK7 5DP

3.6 Status of location: Non-controlled locality.

3.7 Relevant regulations and guidance

3.7.1 Regulations 25 – distance selling premises.

3.7.2 Regulation 31 – refusal: same or adjacent premises.

3.7.3 Regulation 66 – conditions relating to providing directed services. (The

3.8 PSRC noted that Regulation 66 is not applicable in this case, as the applicant is not undertaking to provide directed services) DHSC market entry guidance chapter 11.

3.9 Regulation 31 considerations

3.10 The PSRC noted the proposed location of the distance selling premises (DSP) is Hub 14 Pepper House Hazel Grove, Stockport, SK7 5DP:

3.11 Proposed location is shown below (source: Google Maps): [see Appendix B]

3.12 The nearest pharmacy is Rowlands Pharmacy, 61 Arundel Avenue, Hazel Grove, Stockport, SK7 5LD, 0.9 mile away (19-minute walk) (source: the NHS Site):

3.13 Based on all available information, the PSRC was satisfied that the application should not be refused under Regulation 31, as there is no other provider of pharmaceutical services either in the same premises or adjacent premises to the proposed location.

3.14 Regulation 25 considerations

Are the premises listed in the application on the same site or in the same building as a provider of primary medical services with a patient list? (Regulation 25(2)(a))

3.15 Based on all available information, the PSRC was satisfied that the proposed location is not on the same site or in the same building as a provider of primary medical services with a patient list.

Will the applicant provide uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services? (Regulation 25(2)(b)(i)); and

Will the applicant ensure 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? (Regulation 25(2)(b)(ii))

3.16 The applicant has declared it will provide:

3.17 Core opening hours of 09:00-13:00, 13:30-17:30 Monday to Friday and total opening hours 09:00-13:00, 13:30-17:30 Monday to Friday

3.18 Opening Hours

Proposed core opening hours

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total
0900 – 1300 1330 - 1730	0900 – 1300 1330 - 1730	0900 – 1300 1330 - 1730	0900 – 1300 1330 - 1730	0900 – 1300 1330 - 1730	Closed	Closed	40

Total proposed opening hours

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total
0900 – 1300 1330 - 1730	0900 – 1300 1330 - 1730	0900 – 1300 1330 - 1730	0900 – 1300 1330 - 1730	0900 – 1300 1330 - 1730	Closed	Closed	40

3.19 Proposed services [this was left blank in the Commissioner's decision letter]

Service	Accredited to provide (Y/N/NA)	Premises accredited (Y/N/NA)

3.20 The PSRC noted that the applicant had provided information in the application with regards to Regulation 25:

3.21 The applicant has submitted in support of his application:

3.22 In section 7 of the application:

3.23 Pharmacy procedures, 12 pages (see Section 1 above)

"Essential Service • Dispensing

Uninterrupted service

Provision of service through the opening hours of the pharmacy will be maintained by having a Responsible Pharmacist present at all times during the pharmacy opening hours and having sufficient support staff at all times. The pharmacy website will run throughout these hours together with a phone, fax, email and webcam service. If the responsible pharmacist is required to leave the premises, a further pharmacist will be on hand to ensure that there is no break in pharmacist cover during the opening hours.

Persons anywhere in England

Patients anywhere in England can access these services via our pharmacy website a direct phone line to the pharmacy, fax, email as well as webcam. Internet connections at the pharmacy will be provided by the NHS HSCN network via BT.

All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint (www.citysprinthealth.co.uk). This will include the delivery of prescriptions received via post, fax and EPS. City Sprint will also be delivering cold chain items and CDs. This is addressed in the SOPs which have been included."

3.24 It is unclear what happens in the event of responsible pharmacist being absent, etc.

"Without face-to-face contact

This service will be delivered without face-to-face contact via the pharmacy website as a communication link as well as telephone post/email/fax/webcam. A courier service will provide a third-party delivery if this is required when it would not be practicable to use the in-house delivery service.

If needed, Controlled Drug (CD) deliveries will be undertaken by City Sprint who are accredited to handle and transport CDs. Their drivers will deliver to patients at a pre-determined time and the CD's must be signed for on receipt. Their drivers will only deliver the CD to the named recipient and they will ask for photographic proof of ID. In the instance of a failed delivery attempt, City Sprint will return any CDs to their

overnight safe storage facility and the pharmacy will be contacted to arrange alternative delivery date to patient.

City Sprint is approved by the MHRA and has fully trained couriers to deal with all pharmacy deliveries including controlled drugs and fridge items. As well as collecting prescriptions from surgeries and collection of unwanted waste medication from patients. This will ensure there is no face to face contact.

Delivery of Refrigerated Medicinal Products - For cold chain products, delivery times will always be pre-arranged with the patient to minimise the risk of failed delivery. The patient's contact number will be given to the City Sprint delivery driver so they can again call the patient approximately 15-30 minutes prior to so they can check that somebody will be at the address to receive the medication. Cold chain products will be packed in such a way as to ensure that the required temperatures are maintained throughout the journey and the medicines are transported in accordance with their labelling requirements to maintain product integrity."

3.25 Very general description of cold chain/fridge items handling, no description of what happens in the event of unsuccessful delivery, etc.

3.26 The PSRC noted that the applicant has submitted no floor plan:

3.26.1 *Floor plan showing consultation area:*

The floor plan is still being finalised by the architects and will be made available to NHSE and ICB."

3.27 The applicant has also submitted Draft SOPs, 76 pages [see Appendix A]

"MOSOAR LTD

THESE ARE SOPs THAT ARE DRAFT IN NATURE NO FACE-TO-FACE CONTACT WITH PATIENTS OR THEIR REP REPRESENTATIVES IS PERMITTED WHEN DELIVERING ANY NHS SERVICES UNLESS DIRECTED BY THE ICB / LOCAL AREA TEAM

While care has been taken to remove any suggestion of face-to-face contact while delivering NHS Pharmacy Services, there may still be references to this. In the Final SOP bundle, all references to face-to-face contact for NHS services will be removed."

3.28 These draft SOPs have been scrutinized by the panel:

"P2 Legal and clinical assessment

Pharmacist only

Check that the prescription is legal, particularly careful with Controlled Drug (CD) Prescriptions and Prescriptions written by an EEA doctor or

dentist not registered in the UK. (If in doubt, your professional indemnity insurance provider helpline)

The following factors are thought to be significant in assess the prescription for clinical appropriateness:

Age of patient

Sex of patient

Weight of patient

Pregnant or breastfeeding?

Relevant clinical condition

Patient Medication Record (PMR)

Interactions with other drugs, foods, supplements, or disease states

Dose and dose changes

Strength and strength changes

Formulation

Route of administration

Contra-indications

…"

"P6 Failure to deliver

Driver

If the patient is not home during the agreed delivery slot:

Complete a 'Not at Home' Card detailing information about arranging a re-delivery

Post the pharmacy card through the letter box

Do NOT push through medicines through the letterbox

Do NOT leave the medicines outside the door

Inform the authorised pharmacy staff upon return to the pharmacy

Where schedule 2 or 3 CDs or fridge lines are not delivered, inform the pharmacist upon return to the pharmacy

Responsible pharmacist or second pharmacist

For CDs subject to safe custody

Return undelivered CDs to the CD Cupboard

For Schedule 2 CDs, re-enter the drug(s) back into the CD register with an explanation

Note – attempted deliveries by staff who are not employed by the pharmacy may not be entered back into the CD register and must be treated as a patient return"

3.29 The submitted SOPs don't address the procedure in the event of unsuccessful delivery with regards to what happens with medicines and what pharmacy staff should do about it.

3.30 The application and the submitted information do not address comprehensively how the applicant aims to provide services without face-to-face contact and in uninterrupted manner. Neither does it specify the operating procedures for handling cold chain deliveries, what happens in the event of unsuccessful deliveries, responsible pharmacist presence/absence, etc.

3.31 Therefore, we do not have enough assurances that services will be provided in a safe and effective manner with no face-to-face contact in an uninterrupted manner.

3.32 The PSRC noted that the information provided by the applicant neither specified sufficiently nor contained adequate assurances relating to the safe and effective provision of pharmaceutical services without face-to face contact.

3.33 In light of the above, PSRC was not satisfied that the services will be provided in a safe and effective manner with no face-to-face contact in an uninterrupted manner.

3.34 Therefore, the PSRC was not adequately assured that its procedures would enable the DSP to meet the requirements of Regulation 25(2), in addition to the ongoing requirements set out under Regulation 64 – which are:

3.34.1 that the applicant does not offer to provide pharmaceutical services, other than directed services, to persons who are present at (which includes in the vicinity of) the listed chemist premises;

3.34.2 that the means by which the applicant provides pharmaceutical services, other than directed services, must be such that any person receiving those services does so otherwise than at the listed chemist premises;

3.34.3 that the DSP 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;

3.34.4 that the applicant secures the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services,

3.34.5 that the applicant ensures 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 applicant's staff; and

3.34.6 that nothing in the applicant's practice leaflet, publicity material in respect of the listed DSP, in material published on behalf of the applicant publicising services provided at or from the listed DSP or in any communication (written or oral) from the applicant or applicant's staff to any person seeking the provision of essential services from the applicant must represent, either expressly or impliedly, that the essential services provided at or from the premises are only available to persons in particular areas of England, or that the applicant is likely to refuse, for reasons other than those provided for in its 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 applicant is limited to other categories of patients).

3.35 The applicant is reminded that the commissioner (NHS GM) may not vary or remove any of the above conditions.

3.36 The following interested parties within a 2km radius of the proposed premises location were notified of the application:

Rowlands Pharmacy	61 Arundel Avenue	Hazel Grove	SK7 5LD
Well	114 London Road	Hazel Grove	SK7 4AG
Well	221 London Road	Hazel Grove	SK7 4HS
Mai's Pharmacy	373 Buxton Road	Great Moor	SK2 7EY
Fir Road Pharmacy	8 Fir Road	Bramhall	SK7 2NP
Scorah Chemists Hazel Grove	87 Macclesfield Road	Hazel Grove	SK7 6BG
Scorah Chemists Bramhall	61 North Park Road	Bramhall	SK7 3LQ
Dial House Pharmacy	144 Dialstone Lane	Offerton	SK2 6AP
Davenport Pharmacy	191 Bramhall Lane, Davenport, Stockport, SK2 6JA		

3.37 The following organisations were also informed of the application

3.37.1 CPGM

3.37.2 Stockport Local Medical Committee

3.37.3 Stockport Health & Wellbeing Board

3.37.4 Healthwatch Stockport

3.38 Representations received from interested parties:

3.39 Well Pharmacy comment:

3.39.1 Application by Mosoar Ltd for inclusion in, the Pharmaceutical List at Hub 14 Pepper House, Hazel Grove, Stockport. SK7 5DP in respect of distance selling premises.

3.39.2 Thank you for informing Well of the above application and for inviting written representations. We are willing to attend an oral earing if the Area Team deem it necessary to hold one.

3.39.3 The ICB must be assured that this application fully satisfies Regulation 25 and Regulation 64 oft e NHS i(Pharmaceutical Services) Regulations 2013 before it should be granted.

3.39.4 The ICB should have regard to regulation 25(2) which states that the NHSCB must re-fuse the application unless it is satisfied that the procedures of the proposed pharmacy premises will allow for the uninterrupted provision of essential services during the opening hours stated on the application form from anywhere in England. Furthermore, the safe and effective provision of essential services must be assured without face- to-face contact with the patient or the patient's representative.

3.40 Rowlands Pharmacy Comment:

3.40.1 RE: APPLICATION FOR INCLUSION IN A PHARMACEUTICAL LIST AT HUB 14 PEPPER HOUSE, HAZEL GROVE, STOCKPORT, SK7 5DP IN RESPECT OF DISTANCE SELLING PREMISES BY MOSOAR LTD.

3.40.2 We note this is a Distance Selling excepted application and should one be required we would be willing to attend any oral hearing in relation to the above application to express our written comments verbally.

3.40.3 L Rowland & Co (Retail) Ltd wishes to make the following comments:

3.40.4 As the application is in respect of distance selling premises, by virtue of regulation 64 (3) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, approval is subject to the following conditions:

3.40.5 The applicant must not offer to provide pharmaceutical services to persons who are present at (which includes in the vicinity of) the proposed premises. As the proposed premises currently has a shop front it is even more important that assurances are sought to ensure no face to face services are able to take place.

3.40.6 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.

3.40.7 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.

3.40.8 The pharmacy procedures for the premises must be such to secure –

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

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

3.40.9 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 –

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

3.40.10 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).

3.40.11 We note that in SHA/24544, PCA refused a DSP application because they were not satisfied that items which require cold chain transport could be satisfactorily received by the patient. They state the following "…there was nothing provided by the Applicant to demonstrate that an audit process or appropriate system is in place which would highlight any items, which might have ceased to be refrigerated in transit and therefore be compromised, and how these would be prevented from being given to the patient. In addition, Committee noted SOP 3 specifically defines a failed delivery as one where there has been no one there to accept delivery. It therefore does not include a situation where the cold chain has been compromised in transit, and the SOP does not set out how such a situation would be recognised and dealt with. The Committee was not therefore confident, as it is required to be, that all dispensed cold chain products would be delivered in a safe and effective manner." We trust that NHSE will consider this view when reaching their decision on this application.

3.40.12 Also when reviewing the draft SOPs we do not believe they are detailed enough to ensure the safe delivery of medication to patients via a courier service.

3.40.13 We note that the SOPs mention the pharmacy delivery driver or delivery of CDs by a competent member of staff this then surely implies that the deliveries will be local.

3.40.14 We would like to comment on the recent regulatory changes concerning Distance Selling Pharmacy (DSP) applications, which came into effect on 23 June 2025. This information was taken from the Community Pharmacy England website Contract changes: DSP regulatory FAQs - Community Pharmacy England.

3.40.15 The primary reason for these changes is the current saturation of the DSP market, with approximately 400 such pharmacies already operating in England. The Department of Health and Social Care has expressed concerns that further expansion of DSPs could undermine the integrity of the pharmacy sector. Specifically, it is believed that new DSPs may divert premises and resources away from traditional community pharmacies, potentially reducing access to face-to-face pharmaceutical services for local populations.

3.40.16 Additionally, from October 2025, new regulations will restrict DSPs to providing services exclusively through remote means. Previously, DSPs were permitted to offer Advanced and Enhanced services, including face-to face consultations, at their premises. Under the new rules, only COVID-19 and influenza vaccinations may continue to be delivered onsite until 31 March 2026.

3.40.17 The community pharmacy landscape has undergone significant changes in recent years. As the NHS increasingly relies on community pharmacies to deliver National, Advanced, and Enhanced Services, it is essential to stabilise the sector. Any threat to the viability of local pharmacies could negatively impact pharmaceutical provision at the community level.

3.40.18 We furthermore wish to be assured that the ICB has sufficient governance procedures in place to ensure that the criteria for the excepted application are fulfilled. We also request that PCSE keep us informed of the outcome at the proper time.

3.41 CPGM comment:

3.41.1 Re: Application for inclusion in a pharmaceutical list at Hub 14 Pepper House, Hazel Grove, Stockport , SK7 5DP in respect of distance selling premises by Mosoar Ltd Thank you for your letter dated 25th July 2025 regarding the above application, and for the opportunity to submit representations.

3.41.2 Community Pharmacy Greater Manchester (CPGM) subgroup would like to note that the SOPs submitted related to Grange Pharmacy rather than the applicant. Furthermore, the SOPs reference PCTs (which ceased to exist in 2013) in several places.

3.41.3 The CPGM applications subgroup is of the opinion that the applicant does not provide sufficient detail regarding the safe delivery of medicines requiring refrigeration items and controlled drugs.

3.41.4 The sub- group is concerned that the SOP states medicines should only be couriered when it is impractical to deliver via the delivery driver. For a DSP application, the service is expected to operate on a national basis, which would ordinarily rely on courier provision. The SOP wording therefore suggests a more locally focused service model, which appears inconsistent with the requirements of a national DSP. The applicant has also not demonstrated within the provided SOPs how healthy lifestyles will be provided digitally.

3.41.5 CPGM applications subgroup would welcome continued communication on the progress of this application and request that we are kept informed of any developments.

3.42 Opposition from Mai's Pharmacy:

3.42.1 "While I support consumer choice in healthcare delivery, these new proposed models raise several concerns that merit careful consideration before approval is granted.

3.42.2 On-line pharmacies operate under a significantly different cost structure and business model, often bypassing many physical infrastructure and staffing requirements that community pharmacies are obligated to maintain. Allowing a business with such a model to open in the immediate vicinity undermines fair competition and threatens the financial viability of traditional pharmacies like ours, which offer critical in-person services. In addition to this, there are already, that we know of, online pharmacies in Stockport; these being Stockport Pharmacy in Edgeley and iPharmacy in Hazel Grove.

3.42.3 My pharmacy has served the local community for 30 years, providing not only dispensing services, but also face-to-face consultations, medication reviews, vaccinations and other public health support. The presence of a nearby online-only option operation could dilute foot traffic and revenues, jeopardizing the sustainability of these essential in-person services.

3.42.4 Online pharmacies often lack the capacity for integrated, ongoing and personalized patient engagement. Patients may experience fragmented care without continuity, which increases the risk of medication errors, lack of adherence monitoring and poor health outcomes - especially in vulnerable populations such as elderly and those with chronic conditions.

3.42.5 There are ongoing public concerns around online pharmacies' oversight and accountability, particularly in relation to prescription verification, patient identity and misuse of medications. Locating such a business near a trusted, community - centered pharmacy may create confusion and diminish public trust. I respectfully urge you to consider the broader implications of these applications - not just in terms of market

competition, but in relation to community health, equitable service provision and long-term sustainability of in person pharmaceutical care.

3.42.6 Lastly, these new businesses do not meet the requirement of the pharmaceutical needs assessment in our area, in relation to opening hours as they do not open when all the local pharmacies are closed.

3.42.7 Thank you for your time and for considering the perspective of local providers who are deeply committed to the well-being of the communities we serve".

3.43 Representations received outside the 45 day notification period: None

3.44 Representations received from circulation of first representations

3.45 Comment by the applicant's representative: (see Section 2 above)

3.45.1 Turning to the response from Community Pharmacy Greater Manchester (herein referred to as CPGM), we say that this response does not add any significant information over and above the evidence that the committee have in front of them. It is for the committee to decide upon all of the evidence before it, including evidence within the SOPs, and of course SOPs can be amended. The committee can direct that the SOPs are amended if they see fit and sent to the ICB for review before the NHS contract, if awarded, begins to operate. Further addressing the comments made by CPGM regarding the DSP application, we note that although they have mentioned the SOPs, the committee are reminded that it is not the function of the committee to approve or disapprove of the SOPs as there are various ways that the applicant could organise itself in order to comply with the various requirements of the Regulations.

3.45.2 Finaly, we would point out that the location of the DSP is an irrelevant concern as the committee have already been given reassurances that ALL NHS services under a DSP contract, if awarded, would be offered remotely i.e. not face to face.

3.45.3 We ask the committee to assess the application on the evidence presented already by ourselves. We urge the committee to find that ALL NHS services would be delivered without face-to-face contact and that this service would be uninterrupted during the core hours stipulated. Finally, we urge the committee to find that the services would be delivered in a safe, secure and effective manner.

3.46 The PSRC reviewed the representations and was not satisfied that it meets all the requirements of Regulation 25(2)(b), in addition to the ongoing requirements set out under Regulation 64.

3.47 The PSRC determined the application does not meet the requirements of Regulation 25(2)(b)(i) and Regulation 25(2)(b)(ii).

3.48 The PSRC also considered the impact of decision on those with protected characteristics under the Equalities Act 2010, in accordance with NHS England/ICB's Public Sector Equality Duty and its duties on health inequality.

3.49 It was noted that from 01/01/2021 for all face-to-face community pharmacies (and 01/04/2021 for all distance selling premises), the system of clinical governance within the Terms of Service was expanded to include the promotion of healthy living. The Healthy Living Pharmacy (HLP) framework is aimed at achieving consistent provision of a broad range of health promotion interventions through community pharmacies to meet local need, improving the health and wellbeing of the local population and helping to reduce health inequalities. NHS Greater Manchester is committed to support its community pharmacies in achieving and maintaining compliance with this framework.

3.50 Decision Based on all available information, the PSRC refused the application, as it concluded that the application did not meet the requirements of Regulation 25(2)(b)(i) and Regulation 25(2)(b)(ii).

3.51 Appeal rights are awarded to the applicant.

3.52 The Pharmaceutical Services Regulations Committee (PSRC) makes decisions on applications made under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended.

3.53 The above decision does not, at this point, constitute a contractual change. However, should the applicant commence pharmaceutical services following this grant, its inclusion in the Pharmaceutical List as a new contractor would constitute a contractual change.

3.54 Under NHS Greater Manchester governance this determination by the PSRC is to be authorised for and on behalf of Greater Manchester Integrated Care by: [BS], Director of Primary Care NHS Greater Manchester".

4 The Appeal

In an online form dated 12 December 2025, Pharmaceutical Defence on behalf of the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

4.1 "The decision letter and attached decision report did not contain any information so that the applicant could be satisfied that the application had been fully considered.

4.2 Both the decision letter and reasons are attached. [see Section 3 above]

4.3 It is submitted that the decision letter and decision report provided by NHS Greater Manchester ICB:

4.3.1 Is woefully inadequate in that it contains little information as to why the committee reached the refusal decision AND / OR

4.3.2 Is woefully inadequate in that it contains very little information as to why the application does not meet the requirements of Regulation 25 AND / OR

4.3.3 The decision report appears to have:

4.3.3.1 Failed to take into account the full suite of SOPs provided by the applicant AND / OR

4.3.3.2 Failed to give adequate explanation that the committee have considered all of the SOPs AND/ OR

4.3.3.3 Primarily focused on areas which appear to have been predetermined by the committee namely unsuccessful delivery and cold chain AND / OR

4.3.3.4 Explain how the committee applied the law to the application that they were tasked with deciding on AND / OR

4.3.3.5 Contained a predetermined decision which was to refuse the application AND / OR

4.3.3.6 Took into account representations from Rowlands Pharmacy which was submitted by Rowlands with a different CAS number to that of the application being considered. The representations from Rowlands should have been dismissed due to this and not taken into account AND / OR

4.3.3.7 Taken into account matters which it should not have done so namely the current saturation of the DSP market. This does not form part of the tests laid out in Regulations 25 or 64 AND / OR

4.3.3.8 Commented on the viability of other providers in the community pharmacy landscape and the potential impact of a DSP application upon such. This does not form part of the tests laid out in Regulations 25 or 64 AND / OR

4.3.3.9 Failed to take into account that it is not the committees function to approve or disapprove of the applicants SOPs

4.4 No person, be that the applicant or a member of the public, could be satisfied that the committee reached the correct decision based on the woefully inadequate information provided in the refusal decision and letter.

4.5 The decision is therefore:

4.5.1 Unsafe as no person, be that the applicant or a member of the public, could be satisfied that the committee reached the correct decision based on the inadequate provided in the refusal decision and letter AND / OR

4.5.2 Unlawful as the committee have misdirected themselves on the correct interpretation of the tests laid down in Regulations 25 and 64

4.6 The applicant requests that the committee hear the appeal and consider the application afresh."

4.7 [Revised SOPs were provided and these are at Appendix C]

5 Summary of Representations

This is a summary of representations received on the appeal.

Representations were also sought from the Applicant on the amendments to Regulation 25 as the Commissioner considered the application against the previous regulatory test.

5.1 PHARMACEUTICAL DEFENCE ON BEHALF OF THE APPLICANT

5.1.1 "We refer to the above and to the letter dated 7 January 2026.

5.1.2 Within our letter dated 14 September 2025, we addressed the amended test to regulation 25 which stated:

"… as the committee have already been given reassurances that ALL NHS services under a DSP contract, if awarded, would be offered remotely i.e. not face to face.

We ask the committee to assess the application on the evidence presented already by ourselves. We urge the committee to find that ALL NHS services would be delivered without face-to-face contact and that this service would be uninterrupted during the core hours stipulated. Finally, we urge the committee to find that the services would be delivered in a safe, secure and effective manner."

5.2 ROWLANDS PHARMACY

5.2.1 "Thank-you for the opportunity to comment on the above appeals. If the NHSR decide to convene an oral hearing, we are willing to attend under the provisions of Paragraph 8 of schedule 3 of the regulations.

5.2.2 We have no further comments to make at this stage but include our previous comments which we still believe are relevant with the correct CAS number.

5.2.3 We respectfully request that NHSR inform us of the outcome in due course."

In a letter addressed to the Commissioner dated 30 July 2025, Rowlands Pharmacy stated:

5.2.4 "We note this is a Distance Selling excepted application and should one be required we would be willing to attend any oral hearing in relation to the above application to express our written comments verbally.

5.2.5 L Rowland & Co (Retail) Ltd wishes to make the following comments:

5.2.6 As the application is in respect of distance selling premises, by virtue of regulation 64 (3) of the NHS (Pharmaceutical and Local Pharmaceutical

Services) Regulations 2013, approval is subject to the following conditions:

5.2.6.1 The applicant must not offer to provide pharmaceutical services to persons who are present at (which includes in the vicinity of) the proposed premises. As the proposed premises currently has a shop front it is even more important that assurances are sought to ensure no face to face services are able to take place.

5.2.6.2 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.

5.2.6.3 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.

5.2.6.4 The pharmacy procedures for the premises must be such to secure –

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

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

5.2.6.5 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 –

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

5.2.6.5.2 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 (for example, because the availability of essential services from the applicant is limited to other categories of patients).

5.2.6.6 We note that in SHA/24544, PCA refused a DSP application because they were not satisfied that items which require cold chain transport could be satisfactorily received by the patient. They state the following "…there was nothing provided by the Applicant to demonstrate that an audit process or appropriate system is in place which would highlight any items, which might have ceased to be refrigerated in transit and therefore be compromised, and how these would be prevented from being given to the patient. In addition, Committee noted SOP 3 specifically defines a failed delivery as one where there has been no one there to accept delivery. It therefore does not include a situation where the cold chain has been compromised in transit, and the SOP does not set out how such a situation would be recognised and dealt with. The Committee was not therefore confident, as it is required to be, that all dispensed cold chain products would be delivered in a safe and effective manner." We trust that NHSE will consider this view when reaching their decision on this application.

5.2.6.7 Also when reviewing the draft SOPs we do not believe they are detailed enough to ensure the safe delivery of medication to patients via a courier service.

5.2.6.8 We note that the SOPs mention the pharmacy delivery driver or delivery of CDs by a competent member of staff this then surely implies that the deliveries will be local.

5.2.6.9 We would like to comment on the recent regulatory changes concerning Distance Selling Pharmacy (DSP) applications, which came into effect on 23 June 2025. This information was taken from the Community Pharmacy England website Contract changes: DSP regulatory FAQs - Community Pharmacy England.

5.2.6.10 The primary reason for these changes is the current saturation of the DSP market, with approximately 400 such pharmacies already operating in England. The Department of Health and Social Care has expressed concerns that further expansion of DSPs could undermine the integrity of the pharmacy sector. Specifically, it is believed that new DSPs may divert premises and resources away from traditional community pharmacies, potentially reducing access to face-to-face pharmaceutical services for local populations.

5.2.6.11 Additionally, from October 2025, new regulations will restrict DSPs to providing services exclusively through remote means. Previously, DSPs were permitted to offer Advanced and Enhanced services, including face-to-face consultations, at their premises. Under the new rules, only COVID-19 and influenza vaccinations may continue to be delivered onsite until 31 March 2026.

5.2.6.12 The community pharmacy landscape has undergone significant changes in recent years. As the NHS increasingly relies on community pharmacies to deliver National, Advanced, and Enhanced Services, it is essential to stabilise the sector. Any threat to the viability of local pharmacies could negatively impact pharmaceutical provision at the community level.

5.2.7 We furthermore wish to be assured that the ICB has sufficient governance procedures in place to ensure that the criteria for the excepted application are fulfilled. We also request that PCSE keep us informed of the outcome at the proper time."

6 Summary of Observations

This is summary of observations received.

6.1 PHARMACEUTICAL DEFENCE ON BEHALF OF THE APPLICANT

6.1.1 "I am writing on behalf of the Appellant, Mosoar Ltd, in response to the representations received regarding the above appeal.

6.1.2 Our responses to the specific points raised are detailed below.

Response to Representations

6.1.3 The Appellant has provided a robust suite of Standard Operating Procedures that cover all essential services, including Dispensing, Delivery, Cold Chain integrity, and Discharge Medicines Service. We submit that the "Draft" status of these documents is a prudent approach to pre-opening governance and does not constitute a failure to meet the regulatory test.

6.1.4 The Appellant is committed to providing a safe, effective service that is available to all persons in England. We confirm that we are content for the appeal to be determined on the papers, or we are willing to attend an oral hearing should the Committee deem it necessary.

6.1.5 We ask the committee to assess the application on the evidence presented already by ourselves. We urge the committee to find that ALL NHS services would be delivered without face-to-face contact and that this service would be uninterrupted during the core hours stipulated. Finally, we urge the committee to find that the services would be delivered in a safe, secure and effective manner."

[Pharmaceutical Defence included a further copy of the Applicant's original application form and supporting information which can be found above at Section 1.]

7 Consideration

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

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

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

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

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

7.6 The Committee noted that 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.

7.7 The Committee noted the Commissioner "*was satisfied that the application should not be refused under Regulation 31, as there is no other provider of pharmaceutical services either in the same premises or adjacent premises to the proposed location*". The Committee noted that this had not been disputed either on appeal or in subsequent representations. The Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

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

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

7.11 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 "*the PSRC was satisfied that the proposed location is not on the same site or in the same building as a provider of primary medical services with a patient list.*" The Committee noted that this had not been disputed either on appeal or in subsequent representations. Based on the information available to it, the Committee therefore determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

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

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

7.14 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicates that the obligation is only discharged if the information or documentation provided is sufficient to

satisfy the Commissioner in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the Commissioner may need to make of the information or documentation when carrying out its functions.

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

7.16 It is not for the Committee to 'approve' or 'disapprove' of these SOPs (as they may contain matters not relevant to the Committee's consideration, and there are many ways an applicant can choose to organise itself in order to comply with the various requirements of the Regulations) and the Committee has not sought to do so. The Committee noted that the Applicant has not requested that the SOPs provided with its appeal should supersede those provided with its application instead it states that "*We ask the committee to assess the application on the evidence presented already by ourselves"*. The Committee has therefore sought evidence from within both sets of SOPs provided, the application and appeal in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.

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

7.18 The Committee noted that, in the application form, in response to the question as to whether they were undertaking to provide appliances, the Applicant had left this blank.

7.19 The Committee noted in the application form, the Applicant had stated:

7.19.1 *"If a prescription is received for an appliance which requires measuring and fitting, the patient will be telephoned and emailed to state that the pharmacy cannot provide this service because the pharmacy must operate without face to face contact. The patient will then be advised that they would need to have the prescription dispensed by a pharmacy where a pharmacist would be able to measure and fit the appliance …"*

7.20 The Committee was of the view, in the event that the applicant is granted, the Applicant would not be able to provide any such appliances that require measuring and/or fitting to patients.

7.21 The Committee first considered how the Applicant would provide essential services without interruption. The Committee noted the comments of the Commissioner that "*it is unclear what happens in the event of responsible pharmacist being absent etc."* and further "*The application and the submitted information do not address comprehensively how the applicant aims to provide services … in uninterrupted manner …".*

7.22 In the application form, the Applicant had stated:

7.22.1 *"Provision of service through the opening hours of the pharmacy will be maintained by having a Responsible Pharmacist present at all times during the pharmacy opening hours and having sufficient support staff at all times."*

7.23 The Committee noted the following information in the SOP provided by the Applicant on appeal headed "Provision of Essential, Advanced and Enhanced Services without face to face contact" which states:

7.23.1 *"Purpose*

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

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

7.24 SOP "Operating in the Absence of a Responsible Pharmacist" states:

7.24.1 *"As a Distance Selling pharmacy, we are required to offer continuous service during our operating hours. Therefore, the Responsible Pharmacist (RP) must remain on the premises at all times during working hours.*

The Pharmacy will have a second pharmacist available during both core and additional operating hours. If the RP needs to leave the premises or take a break on an ad-hoc basis or planned, the second pharmacist must sign in as the RP."

7.25 Based on the information before it, the Committee was of the view that the provision of essential services would be without interruption.

7.26 With regard to services being available to persons anywhere in England, the Committee noted the following information in the supporting information with the application form:

7.26.1 *"The medication is delivered nationwide via a tracked delivery service."*

7.27 And further:

7.27.1 *"Persons anywhere in England*

Patients anywhere in England can access these services via our pharmacy website a direct phone line to the pharmacy, fax, email as well as webcam. Internet connections at the pharmacy will be provided by the NHS HSCN network via BT.

All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint (www.citysprinthealth.co.uk). This will

include the delivery of prescriptions received via post, fax and EPS. City Sprint will also be delivering cold chain items and CDs. This is addressed in the SOPs which have been included."

7.28 The Committee noted the SOP "Provision of Essential, Advanced and Enhanced Services without face to face contact" which states:

7.28.1 "*All pharmacy staff must note that this pharmacy operates in accordance with specific approval under the Regulations and these premises are 'Distance Selling Premises'. In order to comply with our terms of service, this pharmacy will provide;*

The uninterrupted provision of essential, advanced and enhanced services, during the opening hours of the premises, to persons anywhere in England who request those services."

7.29 As well as the statements above, the Committee further noted the references throughout the application form and SOPs with regard to delivery being made by couriers and Royal Mail as well as the Applicant's own delivery driver and that this would be provided on a nationwide basis to any patient living in England.

7.30 Whilst the Committee acknowledge the references to a nationwide service, as set out above, it also noted that the "Repeat Dispensing" SOP, as provided with the application form, under the heading "Scope" states *"Procedure covers repeat dispensing services operated between this pharmacy and participating local GP Practices …*". This suggested an intention to operate at a local level, with no explanation of how patients registered with GP practices outside the local area would be able to access the same service.

7.31 The Committee was of the view, based on the information before it, that essential services would not be provided to persons anywhere in England, who requested those services.

7.32 The Committee next considered how the Applicant would provide pharmaceutical services without face to face contact. The Committee noted the comments of the Commissioner that "*The application and the submitted information do not address comprehensively how the applicant aims to provide services without face-to-face contact …*" and "*The PSRC noted that the information provided by the applicant neither specified sufficiently nor contained adequate assurances relating to the safe and effective provision of pharmaceutical services without face-to face contact*."

7.33 The Committee noted the statements in the application form that:

7.33.1 *"Communication between the pharmacy and patients will be facilitated by phone, fax, email and webcam…"*

7.34 The Applicant went on to state:

7.34.1 *"The premises have been carefully chosen to prevent face to face contact for any person seeking the provision of essential services, in, or within the vicinity of the premises. No person who is seeking essential*

services under the NHS contract will be allowed entry to the premises. All entrances and exits will remain inaccessible to members of the public who are seeking the provision of essential services. An alarm system will cover the pharmacy premises which will notify the owner of unauthorised access when the premises are closed. All access routes will always be secured and kept locked when the premises not in use …"

7.35 The Committee noted SOP Provision of Essential, Advanced and Enhanced Services without face to face contact" which states:

7.35.1 "*All pharmacy staff must note that this pharmacy operates in accordance with specific approval under the Regulations and these premises are 'Distance Selling Premises'. In order to comply with our terms of service, this pharmacy will provide;*

…

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

…

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

…

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

Provision of NHS Essential Services without face-to-face contact within premises will be achieved by using:

Telephone, including text messaging where appropriate

Live Video Call

Website inbox (through contact us)

Real-time chat box on website

Email

Electronic Prescription Service (EPS)

Royal Mail postal service

Courier service

Specialised cold chain courier services e.g. DHL COLDCHAIN"

7.36 The Committee was of the view, based on the information before it, that there was nothing provided which demonstrates that pharmaceutical services would be provided by face to face contact at the pharmacy premises. Further, the Committee noted the information contained within the SOPs with regard to the access to and security of the premises and was of the view that there was nothing provided which demonstrated that this would not be maintained, if the application was granted and once the pharmacy was open.

7.37 Further, the Committee was mindful of the regulatory changes as of 1 October 2025, that distance selling pharmacies can no longer provide Directed services (Advanced, National Enhanced and Enhanced Services, with the exception of Covid-19 and Flu vaccination services) face to face with the patient at the pharmacy premises. The Committee noted the reference in the SOPs on appeal that "*In line with the service specifications, the pharmacy will only offer Advanced and Enhanced services that can be delivered remotely without requiring patients to attend the premises"*. However, the Committee noted that the Applicant, in its original application form, was not proposing to offer any Advanced or Enhanced services.

7.38 The Committee was of the view that as a result of this amendment, the Applicant would not be able to provide any pharmaceutical services to patients present at its premises.

7.39 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.

7.40 The Committee was satisfied that essential services would be provided without interruption and that pharmaceutical services would be provided without face to face contact. The Committee was not satisfied 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.

7.41 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.

7.42 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:

7.42.1 Dispensing of drugs and appliances

7.42.2 Urgent supply without a prescription

7.42.3 Preliminary matters before providing ordered drugs or appliances

7.42.4 Providing ordered drugs or appliances

7.42.5 Refusal to provide drugs or appliances ordered

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

7.42.7 Disposal service in respect of unwanted drugs

7.42.8 Promotion of healthy lifestyles

7.42.9 Prescription linked intervention

7.42.10 Health campaigns

7.42.11 Signposting

7.42.12 Support for self-care

7.42.13 Discharge medicines service

7.42.14 Websites and health promotion zones

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

Providing ordered drugs or appliances

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

7.45 The Committee noted the comments from the Commissioner that "*The submitted SOPs don't address the procedure in the event of unsuccessful delivery with regards to what happens with medicines and what pharmacy staff should do about it.*" and further *"The Application and submitted information do not address comprehensively how the application aims to provide services without face-to-face contact and in an uninterrupted manner. Neither does it specify the operating procedures for handling cold chain deliveries, what happens in the event of unsuccessful deliveries, … etc."*

7.46 The Committee noted, SOP "Dispensing of Prescriptions" under the heading "Transferring the finished prescription to the patient" it states:

7.46.1 *"FOR ALL PRESCRIPTIONS*

1. Check the fridge.

Check for items in the fridge or CD cabinet as indicated by the appropriate sticker. Always have a second check before send out for delivery through courier packaging.

2. Check for CDs.

If there is a label denoting inclusion of a schedule 4 CD, check that the whole prescription can be delivered by confirming with the Pharmacist. If the prescription is a schedule 2 or 3 CD and has been removed from the CD cabinet, check that the prescription date is not more than 28 days ago. Give the prescription to the Pharmacist to check before delivery. The delivery driver/courier should sign the back of the prescription as the representative when accepting the CD for delivery. The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative (passport, driving licence or government approved photo ID card are acceptable forms of ID). A delivery cannot be left with anyone who is not the patient or their authorised representative."

7.47 The Committee noted SOP "The Delivery of Medicines" which states:

7.47.1 *"1. Obtain authorisation of request for delivery*

Confirm and record patient consent specifically for delivery before items are dispatched, ensuring it includes authorisation details if a representative will accept the medication. It can be done through verbal or by obtaining a signature from patient/carer via post or by delivery driver. …"

7.48 The SOP went on to state:

7.48.1 *"Local and Nationwide deliveries*

To ensure the safe and appropriate delivery of medicines, local deliveries will be handled by pharmacy own delivery driver. If our delivery driver is unavailable for their shift, we will utilise City Sprint as a backup to ensure uninterrupted delivery services. Nationwide deliveries will be sent via recorded delivery from Royal Mail, requiring a signature from the patient, their notified carer, or an authorised representative. Patients will receive a tracking number to monitor their delivery status online and will be informed about their delivery through a text messaging system.

6. Driver arrival.

Ensure the Responsible Pharmacist (RP) is signed in during all stages where dispensed items are handed over to the delivery driver. Deliveries must not be prepared or dispatched without an RP in charge. When the driver arrives, confirm with patient/representative for their name and address, check the label on the bag against the prescription, branch record sheet and book. File prescriptions. Cold chain medications will be separated from local delivery and to be done via courier. Check and tick against the branch record sheet label when transferring items to the delivery driver. The driver signs and dates the branch record sheet at this stage to confirm the pickup. Ask the patient or representative to sign their details on the delivery sheet.

7. Controlled drugs delivery.

If a CD is included, phone the patient beforehand to confirm they are in. The driver should sign the blue box on the back of the script and write 'delivery' to complete the audit trail. The driver's name and 'delivery' is written in the CD register as the person collecting the medication. If delivery is unsuccessful, the CD is returned to the pharmacy, booked back into the CD register and signed out again on retry.

IF THE PATIENT IS IN:

1. The driver should state that he is delivering medication from the pharmacy and check the patient's name and address. The number of packages to be delivered should be confirmed against the entry in the delivery record book.

2. The patient must sign the delivery record book on receipt of their medication. The driver should not enter the patient's house if possible.

3. The book must be returned to the pharmacy as proof of delivery before the close of business that day.

4. The driver should not offer medical advice unless qualified to do so. If the patient has a query about their delivered medication, the driver can provide the telephone number of the pharmacy (which is printed on all medication labels) and ask the patient to phone the pharmacy for advice. If the driver is asked to give written advice to a patient in the form of a note or letter from the pharmacy, then the pharmacy should phone the patient after delivery to ensure the note has been received and understood. Medicines should be kept securely in the vehicle, and doors and windows are closed/locked at all times. The medication should be kept out of sight, e.g. in the boot.

IF THE PATIENT IS OUT:

1. In the event of an unsuccessful delivery, the driver will leave a failed delivery card at the delivery address specifying the date and time of the attempted delivery and providing clear instructions and contact details for the patient to contact the pharmacy and reschedule the delivery.

2. Undelivered medicines must be reconciled against the delivery record on return to the pharmacy to ensure nothing has been lost, tampered with, or left unattended.

3. Redelivery attempts should be documented, including patient contact, revised delivery date/time, and confirmation of patient availability.

4. If multiple delivery attempts fail or the patient remains unreachable, staff should escalate to the pharmacist for clinical review. Pharmacist should assess risk associated with delayed therapy and consider notifying GP or care provider if patient safety is potentially compromised.

DO NOT- Leave the delivery items.

• unattended in porches or on doorsteps

• with children

• neighbours - Unless arrangements have been made by the patient/carer"

7.49 And further:

7.49.1 *"To ensure the safe and appropriate delivery of medicines, local deliveries (apart from cold chain deliveries) will be handled by pharmacy own delivery driver. Nationwide deliveries will be sent via recorded delivery, requiring a signature from the patient, their notified carer, or an authorised representative. Patients will receive a tracking number to monitor their delivery status online and will be informed about their delivery through a text messaging system. Medicines will be packed, transported, and delivered to preserve their integrity, quality, and effectiveness. The delivery process will provide a verifiable audit trail from the initial request to final delivery or return to the pharmacy in case of delivery failure. Post delivery items will not be put through letter boxes or left unattended in porches on doorsteps, with children or with neighbours, unless arrangements have been made by patient/carer. This request would be obtained in writing from the patient/carer with a signature authorising delivery to another address. A signature is always required from the recipient to indicate safe receipt. For postal/courier items, at a minimum, use padded envelopes for non-fragile items to protect the manufacturer's packaging. For most items, use bubble wrap and, if necessary, polystyrene filler inside a reinforced cardboard box. The patient, carer, or authorised representative must always sign and date a receipt to confirm safe receipt of the medicines. If the patient is not at home during the delivery attempt, they will be notified with a non-delivery notice, and an alternative delivery date will be arranged.*

Provisions such as DHL COLDCHAIN (or a similar specialist cold chain courier service) will ensure the integrity of the cold chain and the maximum stability of temperature-sensitive drugs by packing, transporting, and delivering them in a manner that preserves their integrity, quality, and effectiveness. This is a dedicated, fully monitored, and temperature-controlled delivery service. In the event of an unsuccessful delivery, DHL COLDCHAIN will leave a 'Missed Delivery' card, stating the date and time of the attempted delivery. The patient can then rearrange delivery for a convenient time by telephone or Internet. DHL COLDCHAIN will keep the cold chain intact until successful delivery."

7.50 The SOP went on to state:

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

• The pharmacist should contact patients before delivery to confirm dispatch and provide any necessary counselling.

• Ensure that the RP is available to oversee the handover of all items for delivery.

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

• Clearly print a return address on the outer packaging.

• Verify the details of all prescriptions to be delivered.

• Record all tracking numbers for prescriptions being delivered via Royal Mail on the Delivery Log sheet.

• Ensure the Royal Mail driver signs the Delivery Log sheet for all prescriptions accepted for delivery. Retain the Delivery Log sheet for at least 3 months from the dispatch date.

• Email patients with dispatch confirmation and their tracking number once the prescriptions have left the premises.

• All deliveries will require a patient signature to confirm receipt of their prescription.

Unsuccessful Delivery via Royal Mail

If a delivery attempt is unsuccessful, Royal Mail will leave a 'Sorry We Missed You' card, indicating the date and time of the attempt. The patient can then either choose to collect and sign for their medication at their local post office or reschedule the delivery for a convenient time by phone or email.

Pharmacy Actions following a failed attempt:

• Record the failed delivery in the pharmacy Delivery Log, including the date of attempted delivery and tracking number.

• Staff should check the online tracking status periodically until the item is delivered or returned to the pharmacy. Any change in status must be logged in the patient's PMR.

• Contact the patient within 48 hours if no action has been taken by them, to avoid delays in medication adherence. This is particularly important for essential, high-risk, or time-sensitive medications.

• Advise the patient that Royal Mail will hold their parcel for a limited period (normally 18 days). If uncollected, the medication will be returned to the pharmacy.

• Undelivered medicines must be reconciled against the delivery record on return to the pharmacy to ensure nothing has been lost, tampered with, or left unattended

• Store items appropriately upon return and contact the patient to arrange redelivery

• Incident escalation – any failed delivery involving urgent, end-of-life, or critical medicines must be reviewed by the pharmacist the same working day.

• Do not reattempt postal delivery until updated consent and delivery instructions have been confirmed with the patient."

7.51 The Committee went on to note SOP "Cold Chain Delivery" which states:

7.51.1 *4. Product dispatch*

Ensure any items for cold chain delivery via courier are stored in the fridge and accompanying items are appropriately marked with a fridge line sticker. Accompanying items should include a note to explain that fridge items will be delivered separately to the rest of their items to enable the cold chain to be maintained. Patients will be contacted to inform and arrange for cold chain deliveries. All cold chain deliveries should be booked on courier specific portal. The cold chain medication should be kept in the fridge until the courier arrives to accept the delivery. Verify courier vehicle temperature before transfer. The vehicle must be within 2–8°C at the point of loading. Details of all prescriptions scheduled for delivery will be confirmed with courier driver. The courier must scan a barcode sticker for each item, with the pharmacy retaining a copy of the barcode, which also serves as the tracking number. Ensure the on-duty pharmacist is available to oversee the handover of all items for delivery and match against the delivery log and prescription. Pharmacy staff record all tracking numbers for prescriptions being delivered by the courier on the Delivery Log sheet and confirm the courier signs the Delivery Log sheet for all prescriptions accepted for delivery. Patients will be contacted with dispatch confirmation with their Tracking number when the prescriptions have left the premises. Live tracking with estimated ETA is available via the courier website. All deliveries will require a signature from the patient to confirm receipt of their prescription. Delivery log is stored for a minimum of 3 months from dispatch date.

5. Using courier service

All cold chain deliveries must be done via specialist medical cold chain courier service. Provisions such as DHL COLDCHAIN (or a similar specialist cold chain courier service) maintain the integrity, quality, and effectiveness of temperature-sensitive medications. These services ensure proper packing, transportation, and delivery under fully monitored, temperature controlled conditions. Real-time monitoring devices are used to track temperature, humidity, and other environmental factors, alongside GPS tracking for precise location updates as well as electronic proof of delivery. Vehicles are equipped with built-in refrigeration systems to maintain the necessary temperature throughout transit. Courier operates under an ISO

9001:2015 certified Quality Management System, ensuring robust processes and quality oversight. In addition, all pharmaceutical warehousing and cold chain distribution used for this service are fully MHRA licensed under Wholesale Distribution Authorisation (WDA(H)) and GDP-compliant, ensuring full regulatory compliance for the storage and distribution of temperature-sensitive medicinal products.

Each cold chain product will be individually bagged, sealed with tamper-evident packaging, and clearly labelled with a "fridge item" sticker to ensure all handlers are aware that it requires cold chain management. The pharmacist will only remove the item from cold storage once the delivery courier is present. The pharmacist or trained staff will oversee the transfer of the item to the temperature-controlled vehicle, ensuring that the cold chain is maintained throughout the handover process. Delivery drivers are properly trained and would only remove the item from their vehicle upon arrival when the patient has answered the door and verified their identity.

During the transit, temperature alarms must be logged, investigated, and retained as part of GDP documentation. In the event of a cold chain breach, the driver will be immediately notified, and any affected delivery will be cancelled. The pharmacy will be promptly informed of the breach. Medications are stored in temperature-controlled warehouses for interim storage or in cases of failed deliveries.

A list of approved cold chain couriers is maintained by the Pharmacy and will be periodically updated. Each approved courier meets strict criteria to guarantee a fully monitored and dedicated cold chain service.

In case of delay, if the estimated time of arrival changes by more than 4 hours, the courier must notify the pharmacy so the Responsible Pharmacist can assess clinical urgency, contact the patient if required, and document any risk mitigations.

Patient should be advised to immediately refrigerate the medicine, inspect packaging for tamper-evidence, and contact the pharmacy immediately if the product feels warm or frozen at delivery.

Courier delivery DO NOT- Leave the delivery items.

• unattended in porches or on doorsteps

• with children

• neighbours - Unless arrangements have been made by the patient/carer

6. Unsuccessful cold chain delivery via courier

If a delivery attempt fails, the cold chain courier (e.g., DHL COLDCHAIN) will leave a 'Missed Delivery' card with the date, time, and instructions to reschedule. Medications will not be left unattended if the patient is unavailable to receive the delivery. Patients can

rearrange delivery via phone or online. Medications are stored in temperature-controlled warehouses in the interim and maintained for up to 48 hours. Staff should check the online tracking status periodically until the item is delivered or returned to the pharmacy. Any change in status must be logged in the patient's PMR. Contact the patient within 48 hours if no action has been taken by them, to avoid delays in medication adherence. This is particularly important for essential, high-risk, or time-sensitive medications. Advise the patient that cold chain courier (DHL COLDCHAIN) will hold their parcel for a limited period (normally 48 hours). If uncollected, the medication will be returned to the pharmacy. If undelivered within this period, items are returned to the pharmacy with the cold chain maintained throughout the journey, which will contact the patient to arrange a new delivery. The entire journey, from transfer within the warehouse to loading onto the transport vehicle, and throughout transit, is continuously monitored with real-time temperature tracking and alarm systems to ensure the cold chain is consistently maintained. If temperature excursion data cannot be validated, the medicine must be destroyed and recorded in waste logs. Any failed delivery involving urgent, end of-life, or critical medicines must be reviewed by the Responsible Pharmacist (RP) on the same working day. The RP will then use their clinical judgment to decide whether it is appropriate to wait for a rescheduled delivery or to release the prescription to the patient's local pharmacy for collection or delivery, with the patient's consent.

7. Breach of Integrity of Cold Chain

DHL vehicles are equipped with built-in refrigeration systems to ensure the required temperature is maintained during road transportation. The system automatically alerts the delivery driver that the cold chain has been breached and affected deliveries will be cancelled. The patient and pharmacy will be promptly informed of the breach, or the patient will receive a 'Missed Delivery' card.

The pharmacy must arrange for an immediate re-delivery of the items via courier and ensure the return of undelivered items to the pharmacy. Items compromised by a cold chain breach are not reused and must be segregated from the pharmacy stock upon their return. If the breach of the cold chain is discovered after the medication has been given to the patient, then the Incident Reporting Policy should be followed. The patient must be referred to the responsible pharmacist for review. Regularly review and audit on courier temperature and tracking data to identify patterns of risk or non-compliance. Conduct stimulated drills or mock scenarios at least once a year to test protocols and response times for breaches or equipment failures."

7.52 SOP "Balance Check and Record-Keeping" states:

7.52.1 *"3. Identity check*

On delivery of prescribed CDs, the driver must ask the person receiving whether they are the patient, a representative or a healthcare

professional receiving on the patient's behalf. Proof of identity is required if the receiver is not known to pharmacy staff. The name and type of ID (preferably with a photo) requested are entered into the CD register, as part of the CD audit trail. If a healthcare professional is receiving the medicine, then the pharmacist must enter their name and address into the CD register.

Delivery of Prescriptions

• The delivery driver is considered to be the nominated person receiving the Controlled Drug for all delivery prescriptions, and their name is entered into the CD register when the medication is taken from the branch, with the word 'delivery'. They must also sign the back of the CD prescription in the blue box, adding the word 'delivery'.

• The prescription does not go to the patient's house with the delivery driver but is retained in pharmacy.

• Each branch should have a delivery record book (see delivery SOP). Every CD prescription to be delivered should have the patient's name, address, and a CD sticker entered in the book and also into the branch delivery record sheet. The delivery driver signs and dates the branch record sheet entry, which stays in the pharmacy. The driver takes the delivery records book on their round and the patient signs the book on receipt of the medicine. The delivery record book is returned to the pharmacy after delivery. If there is a delivery failure, then the medicine is returned to the pharmacy and booked back into the CD register running balance."

7.53 SOP "Delivering Controlled Drugs" states:

7.53.1 *"1. Organise CD deliveries.*

Indicate whether delivery to a specified person other than the patient or carer has been authorised onto the PMR. Where the patient is exempt, record details of the exemption, including the expiry date for any exemption certificate onto the PMR.

Where exemption status has expired contact the patient to provide new evidence of exemption status. Where the patient is not exempt, mark 'to pay' on the prescription. For each patient, the pharmacist should clinically assess the prescription.

Controlled drugs should be given extra caution when delivering extra care and record-keeping is required. Figure out which drugs need to be delivered and signed for. Make sure when dispensing CD's the SOP for dispensing controlled drugs is followed.

…

2. Dispatch the item.

Give the correctly labelled and bagged item to the driver along with the delivery sheet. Make sure that the driver understands that this is not a regular delivery and needs to be signed for. Make sure that the deliverer understands that CDs and any other medicines on that patient's delivery must be stored in the lockable compartment of the delivery van and not out of sight. The delivery van must be kept locked at all times when the driver is not in the vehicle and will not be left unattended. Ensure that the RP is available to oversee the handover of all items for delivery.

3. Driver delivers the item.

The person who is delivering the controlled drug should double-check the address to be delivered to and ask the person who is present for identification if necessary. A signature should be obtained from the patient who receives their item. Where the recipient is not the patient, their full name should be recorded on the delivery record form, along with their signature. If the patient has a carer and is incapable of signing then the delivery driver is effectively the patient's nominated representative authorised to collect the CD on their behalf. As such the driver should sign the 'collected by' section on the reverse of the prescription. The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative (passport, driving licence or government approved photo ID card are acceptable forms of ID). A delivery cannot be left with anyone who is not the patient or their authorised representative.

4. Report back to the pharmacist.

The pharmacist has a legal responsibility to make sure that the patient has received their medication. If the patient/carer is home to accept the delivery, the driver must confirm the patient details and ensure the delivery record form is signed by the recipient. Once delivered, the driver must return the signed delivery note to the pharmacy. File the delivery record form as evidence of successful delivery of the controlled drug. The forms should be stored for a minimum of six months in case the delivery is later queried.

5. Entry into the CD register

This should be exclusively be performed by the Responsible Person. This is a legal requirement for specific controlled drugs.

6. CD delivery with Courier

Delivery of controlled drugs in local area will be managed by pharmacy delivery driver, otherwise will be handled by DHL, which has pharma-grade specialist facilities meeting specific quality and validation requirements for healthcare products, including Home Office licensed controlled drug stores. …

DHL meets all Home Office safe custody and record-keeping requirements. Controlled drugs delivered by DHL Courier Services are

all being tracked, with verifiable audit trails. GPS, image & signature data would be checked by the pharmacy team after delivery to ensure that the patient has received the CD delivery.

• The pharmacist should contact patients before delivery to confirm dispatch and provide any necessary counselling.

• Ensure that the RP is available to oversee the handover of all items for delivery.

• Print and securely attach the appropriate DHL Signed For delivery labels to the outer packaging.

• Clearly print a return address on the outer packaging.

• Verify the details of all prescriptions to be delivered.

• Record all tracking numbers for prescriptions being delivered via DHL on the Delivery Log sheet.

• Ensure the DHL driver signs the Delivery Log sheet for all prescriptions accepted for delivery. Retain the Delivery Log sheet for at least 3 months from the dispatch date.

• Email patients with dispatch confirmation and their tracking number once the prescriptions have left the premises.

• All deliveries will require a patient signature to confirm receipt of their prescription.

7. Unsuccessful CD Delivery

If a delivery attempt is unsuccessful, our own delivery driver or DHL (if courier is used) will leave a 'Sorry We Missed You' card, indicating the date and time of the attempt. For local deliveries, the card will provide clear instructions and contact details for the patient to contact the pharmacy and reschedule the delivery. For courier delivery, the patient can then either choose to collect and sign for their medication at their local post office or reschedule the delivery for a convenient time by phone or email. For local deliveries, if the patient is not home during the agreed delivery slot– the CD must be returned to the pharmacy on the same day by the driver and at the earliest opportunity. Unsuccessful deliveries sent with a courier should be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate. Where the time of attempted delivery means that the return cannot be made on the same day, the courier will store the drugs at their approved warehouse overnight and return the next day.

DO NOT- Leave the delivery items.

• unattended in porches or on doorsteps

• with children

• neighbours - Unless arrangements have been made by the patient/carer

For local unsuccessful deliveries, driver will inform the authorised pharmacy staff upon return to the pharmacy. The CD register entry for failed CD deliveries should be annotated by marginal note or footnote to state that the delivery was not made and the CD entry is not accurate. If the pharmacist is satisfied that the product has been stored correctly and is suitable to be issued to the patient at a later date the item should be re-entered in the supplied section of the CD register.

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

Pharmacy Actions following a failed attempt:

• Record the failed delivery in the pharmacy Delivery Log, including the date of attempted delivery and tracking number.

• Staff should check the online tracking status periodically until the item is delivered or returned to the pharmacy. Any change in status must be logged in the patient's PMR.

• Contact the patient within 48 hours if no action has been taken by them, to avoid delays in medication adherence. This is particularly important for essential, high-risk, or time-sensitive medications.

• Advise the patient that DHL will hold their parcel for a limited period. If uncollected, the medication will be returned to the pharmacy.

• Undelivered medicines must be reconciled against the delivery record on return to the pharmacy to ensure nothing has been lost, tampered with, or left unattended

• Store items appropriately upon return and contact the patient to arrange redelivery

• Incident escalation – any failed delivery involving urgent, end-of-life, or critical medicines must be reviewed by the pharmacist the same working day.

• Pharmacist should assess risk associated with delayed therapy and consider notifying GP or care provider if patient safety is potentially compromised.

• The RP will then use their clinical judgment to decide whether it is appropriate to wait for a rescheduled delivery or to release the prescription to the patient's local pharmacy for collection or delivery, with the patient's consent.

• Do not reattempt postal delivery until updated consent and delivery instructions have been confirmed with the patient.

8. Following delivery or attempted delivery

Check the Driver's delivery schedule against the detached prescriptions. Prescriptions for packages which been successfully delivered may be treated as completed and filed. Prescriptions for packages which have not been delivered should be reattached to the package. Contact the patient to confirm the next details for the next delivery. Return the prescription and package to the delivery storage area if applicable."

7.54 SOP "Security and Storage of Controlled Drugs" states:

7.54.1 *"5. When delivering Controlled Drugs.*

When delivering CDs to patient's homes, the CD is kept in the CD cabinet until the delivery driver is about to depart from the pharmacy on their delivery rounds. The CD prescription is signed on the back in the blue box by the delivery driver, stating 'delivery' and the medicine is signed out of the CD register, naming the delivery driver with the word 'delivery' as the person collecting the CD. If the delivery is unsuccessful, the CD medicine is returned to the pharmacy, put back in the CD cabinet straight away and signed back into the running balance for that particular medicine's entry in the CD register."

7.55 The Committee noted the information contained in the original application form which states:

7.55.1 *"For delivery of medication with short journey times of less than 3 hours, validated medical cool boxes will be used as recommended by the MHRA. For extended journeys, gels/ ice packs will be added to the packaging to maintain appropriate temperatures throughout. Extra caution will be taken with regards to the positioning of these packs within the consignments as this would be deemed extremely important as they must not be allowed to come into direct contact with the medicines being delivered. Temperatures will be strictly controlled and monitored with calibrated temperature probes to provide temperature data for the entire journey. This will be done by the courier driver. Temperatures will be recorded at the beginning of the journey and again at the point of delivery to ensure it stays between 2-8°C. If the temperature is outside of the required range, then the product will be deemed unsafe to deliver, marked as waste and returned to the pharmacy for destruction. Thermometer(s) will be calibrated annually against a certified standard to ensure safe and effective use. When used to deliver medication, the City Sprint delivery driver must only remove the item from cold storage once the patient has answered the door and verified their identity. In the event of failed delivery, the cold storage item must be returned to the pharmacy as soon as possible, with the maximum and minimum temperatures again being recorded at the point of return. Once again, if temperature monitoring suggests that*

the medication may have been transported outside of the required range, then the product will be destroyed by the pharmacy and then item will be re-dispensed by the pharmacy. Once again, a new delivery will be agreed with the patient prior to redelivery."

7.56 The Committee noted the above reference to medicines being delivered by "City Sprint", however the Committee also noted references, in the original SOPs as provided with the application, to the use of local delivery drivers for the delivery of cold chain items. In this regard, the SOP "Delivery Medicines Safely and Effectively" under "P5 Delivery" states:

7.56.1 "*P5 Delivery*

Delivery Driver

While in transit, medicines must always be secured and remain in your possession or left in the vehicle. The vehicle must be locked, the windows must be closed, and the medicines should be kept out of sight, e.g. the boot of a car

Medicines usually requiring storage in a fridge must be kept in a cool box during transit.

…"

7.57 Further, under the heading "P6 Failure to Deliver" the Applicant sets out the procedure to be followed where delivery is unsuccessful, stating:

7.57.1 "*Driver*

If the patient is not home during the agreed delivery slot:

Complete a 'Not at Home' Card detailing information about arranging a re-delivery

Post the pharmacy card through the letter box

Do NOT push through medicines through the letterbox

Do NOT leave the medicines outside the door

Inform the authorised pharmacy staff upon return to the pharmacy

Where schedule 2 or 3 CDs or fridge lines are not delivered, inform the pharmacist upon return to the pharmacy."

7.58 The Committee noted the above references to in-house delivery drivers delivering cold-chain items. Whilst the Applicant proposes to use a "cool-box" during transit, for cold chain items that are delivered by the Applicant's own delivery drivers, the Committee was not satisfied that sufficient information had been provided by the Applicant to show how the temperature would actually be monitored during transit and what would be done in a situation where the cold

chain was compromised during transit, or what would happen in the event of a missed/failed delivery.

7.59 The Committee was not therefore confident, as it is required to be, that all dispensed products would be delivered in a safe and effective manner. The Committee was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

7.60 In relation to all other 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

7.61 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).

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

7.62.1 confirm the Commissioner's decision;

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

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

7.63 Although the decision reached by the Commissioner is the same as that of the Committee, it has reached that decision for different reasons, as set out above. In those circumstances, the Committee determined that the decision of the Commissioner must be quashed.

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

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

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

8 Decision

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

8.2 The Committee:

8.2.1 quashes the decision of the Commissioner; and

8.2.2 redetermines the application as follows -

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

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

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

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

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

8.2.3 The application is refused.

Case Manager
Primary Care Appeals