NHS Resolution

18 March 2026

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REF: SHA/26809

APPEAL AGAINST BEDFORDSHIRE, LUTON AND MILTON KEYNES ICB DECISION TO REFUSE AN APPLICATION BY CONNECT AF PHARMA LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT OFFICE 148, 960 CAPABILITY GREEN, LUTON, LU1 3PE 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:

PCSE on behalf of Bedfordshire, Luton and Milton Keynes ICB
Connect AF Pharma Ltd

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1 The Application

By application dated 21 June 2025, Connect AF Pharma Ltd, ("the Applicant") applied to Bedfordshire, Luton and Milton Keynes ICB ("the Commissioner") for inclusion in the pharmaceutical list at Office 148, 960 Capability Green, Luton, LU1 3PE under Regulation 25. In support of the application it was stated:

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

1.2 "NONE"

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

1.4 [This was left blank.]

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

1.6 [This was left blank.]

Pharmacy procedures

1.7 Please explain how the pharmacy procedures used within the premises will secure:

> (a) the uninterrupted provision of essential services during the opening hours of the premises, to persons anywhere in England who request those services, and
>
> (b) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or someone else's behalf, and the applicant or the applicant's staff.

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

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

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

1.11 “Please see attached pharmacy procedures and Draft SOPs documentation”

1.12 “Connect AF Pharma 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.

1.13 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.

1.14 Connect AF Pharma Ltd will have a website which facilitates the following:

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

1.14.2 Patient provides details of prescription,

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

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

1.14.5 Item is dispensed and details added to PMR.

1.14.6 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.

1.15 The website has been built by a company called The Pharmacy Centre 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.

1.16 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.

1.17 Connect AF Pharma Ltd has decided to use Proscript Connect as the software provider which will be a key tool in providing a safe and effective provision of service.

1.18 Connect AF Pharma 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.

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

1.20 Connect AF Pharma Ltd is comprised of one director, [AT]. [AT] is the nominated superintendent and has suitable pharmacy experience. [AT] 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.

1.21 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.

1.22 Essential Service – Dispensing

1.23 Uninterrupted service

1.24 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. This also includes any unforeseen circumstances in which case a pharmacist will be able to step in without notice to cover the opening hours and to ensure that the service is not interrupted.

1.25 Persons anywhere in England

1.26 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.

1.27 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.

1.28 Safe and effectively

1.29 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.

1.30 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)

1.31 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.

1.32 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.

1.33 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.

1.34 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.

1.35 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.

1.36 Without face-to-face contact

1.37 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.

1.38 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.

1.39 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.

1.40 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.

1.41 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.

1.42 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.

1.43 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.

1.44 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.

1.45 Essential Service - Disposal of Unwanted Medication

1.46 Uninterrupted Service

1.47 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.

1.48 Persons anywhere in England

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

1.50 Safe and Effectively

1.51 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.

1.52 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.

1.53 Without face-to-face contact

1.54 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.

1.55 Essential Service – Signposting

1.56 Uninterrupted Service

1.57 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.

1.58 Persons anywhere in England

1.59 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.

1.60 Safe and Effectively

1.61 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.

1.62 Without face-to-face contact

1.63 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.

1.64 Essential Service - Repeat Dispensing

1.65 Uninterrupted Service

1.66 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.

1.67 Persons anywhere in England

1.68 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.

1.69 Safe and Effectively

1.70 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.

1.71 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.

1.72 Without face-to-face contact

1.73 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.

1.74 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.

1.75 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.

1.76 Essential Service – Discharge Medicine Service

1.77 Uninterrupted Service

1.78 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.

1.79 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.

1.80 Persons anywhere in England

1.81 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.

1.82 Safe and Effectively

1.83 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.

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

1.85 Without face-to-face contact

1.86 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.

1.87 Essential Service - Public Health (Promotion of Healthy Lifestyles)

1.88 Prescription linked intervention

1.89 Uninterrupted service

1.90 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.

1.91 Persons anywhere in England

1.92 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.

1.93 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.

1.94 Safe and effectively

1.95 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.

1.96 Without face-to-face contact

1.97 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.

1.98 National Health Campaign

1.99 Uninterrupted Service

1.100 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.

1.101 Persons anywhere in England

1.102 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.

1.103 Safe and Effectively

1.104 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.

1.105 Without face-to-face contact

1.106 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

1.107 Essential Service - Support for Self Care

1.108 Uninterrupted Service

1.109 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.

1.110 Persons anywhere in England

1.111 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.

1.112 Safe and Effectively

1.113 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.

1.114 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.

1.115 Without face-to-face contact

1.116 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.

1.117 Essential Service - Clinical Governance

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

1.119 Patient and public involvement

1.120 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.

1.121 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.

1.122 Clinical audit

1.123 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.

1.124 Risk management

1.125 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.

1.126 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.

1.127 Connect AF Pharma 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.

1.128 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.

1.129 Staffing and staff management

1.130 There will be a set of induction packs at the pharmacy to ensure that all have access to all necessary Clinical Governance information. 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.

1.131 Education, training and continuing professional and personal development

1.132 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.

1.133 Use of information to support clinical governance and health care delivery

1.134 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. Connect AF Pharma 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 Connect AF Pharma 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.

1.135 Pharmacists will be using their own professional judgement to make records of interventions they have made and any advice they may have given. Connect AF Pharma 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.

1.136 Proof of exemption/prescription charges

1.137 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.

1.138 Additional Information

1.139 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."

2 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]

2.1 “Bedfordshire, Luton and Milton Keynes 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.

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

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

Extract from PSRC decision report

2.4 “The Pharmaceutical Services Regulations Committee (hereafter referred to as “the Committee”) considers all pharmaceutical services applications for the 6 Integrated Care Boards (ICB) within the East of England footprint. NHS Hertfordshire & West Essex ICB (HWE ICB) hosts the meeting on behalf of the 6 ICBs, in accordance with the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended (hereafter referred to as “the Regulations”).

2.5 **Application in respect of distance selling premises:** Connect AF Pharma Ltd, Office 148, 960 Capability Green, Luton, Bedfordshire, LU1 3PE.

2.6 The Committee considered this excepted application in respect of distance selling premises, which was determined under the following Regulations:

2.7 **Regulation 31: Refusal: same or adjacent premises**

2.8 The Committee noted there is no person on the pharmaceutical list providing or undertaking to provide pharmaceutical services from or adjacent to the premises.

2.9 The Committee agreed it was not required to refuse the application under the provisions of Regulation 31.

2.10 **Regulation 25: Distance selling premises applications**

2.11 The Committee noted that the application was made before 23rd June 2025.

2.12 **Regulation 25(2)(a)**

2.13 The Committee noted that where the application asks at section 6.1, “*In my/our view this application should not be refused pursuant to Regulation 25(2)(a) for the following reasons:,”* the applicant did not provide a response.

2.14 The Committee noted that the premises in respect of which the application is made, is not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

2.15 The Committee agreed it is not required to refuse the application under the provisions of Regulation 25(2)(a).

2.16 **Regulation 25(2)(b)**

2.17 The Committee considered the information which had been provided by the applicant in relation to its procedures for the provision of essential services, including any Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.

2.18 The Regulations require the Committee to be satisfied as to a number of matters, including that essential services will be provided on an uninterrupted basis, in a safe and effective way, across England, and without face-to-face contact. As of June 2025, the Regulations were amended and therefore also required the Committee to be satisfied the pharmacy premises are likely to secure the safe and effective provision of all pharmaceutical services (not just essential services) without face-to-face contact at the pharmacy premises.

2.19 The Committee considered the documents provided in the committee report, namely:

2.19.1 Annex 1 Application Form

2.19.2 Connect AF Pharma Ltd – SOP

2.19.3 Connect AF Pharma Ltd – Pharmacy Procedure

2.20 **Representations**

2.21 The Committee noted that no representations/comments were made.

2.22 The Committee considered each essential service in paragraphs 3 to 22 of Schedule 4 of the Regulations.

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

2.23.1 Dispensing of drugs and appliances

2.23.2 Urgent supply without a prescription

2.23.3 Preliminary matters before providing ordered drugs or appliances

2.23.4 Providing ordered drugs or appliances

2.23.5 Refusal to provide drugs or appliances ordered

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

2.23.7 Disposal service in respect of unwanted drugs

2.23.8 Promotion of healthy lifestyles

2.23.9 Prescription linked intervention

2.23.10 Public health campaigns

2.23.11 Signposting

2.23.12 Support for self-care

2.24 **Dispensing of drugs and appliances**

2.25 The Committee considered whether the applicant had explained how non-electronic prescriptions will be presented by the patient and how products will be provided.

2.26 The Committee noted the information contained in the Connect AF Pharma Ltd Pharmacy Procedure document:

2.26.1 *"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.*

Essential Service – Dispensing

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.

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.

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.

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."

2.27 Page 1 of the safe and effective supply of medicinal products SOP provided further information.

2.28 The delivering medicines safely and effectively SOP provided further detail.

2.29 The Committee were satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 5 of Schedule 4.

2.30 **Urgent supply without a prescription**

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

2.32 The Committee noted that on pages 7 and 8 of the safe and effective supply of medicinal products SOP, the applicant provided information on how they propose to safely and effectively receive requests from prescribers for urgent supplies of drugs and appliances.

2.33 Information contained in the Connect AF Pharma Ltd Pharmacy Procedure document also stated:

> *"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."*

2.34 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.

2.35 **Preliminary matters before providing ordered drugs or appliances**

2.36 The Committee considered whether the applicant has explained how evidence will be sought and provided with regards to the patients' entitlement to exemption or remissions from NHS Charges.

2.37 The Committee noted that on page 1 of the safe and effective supply of medicinal products SOP and page 2 of Delivering medicines safely and effectively SOP, information was provided on exemption checking.

2.38 The Committee noted the information contained in the Connect AF Pharma Ltd Pharmacy Procedure document:

2.38.1 *"Proof of exemption/prescription charges*

> *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 contact 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."

2.39 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.

2.40 **Providing ordered drugs or appliances**

2.41 The Committee considered whether the applicant had explained how drugs/appliances would 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).

2.42 The fridge temperature monitoring SOP, the delivering medicines safely and effectively SOP and dispensing of controlled drugs SOP provided further information.

2.43 The Committee noted the information contained in the Connect AF Pharma Ltd Pharmacy Procedure document, where the applicant stated:

2.43.1 *"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 predetermined 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.

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.

2.44 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance to this regard.

2.45 **Refusal to provide drugs or appliances ordered**

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

2.47 The Committee noted the Repeat Dispensing SOP.

2.48 The Committee noted the information contained in the Connect AF Pharma Ltd Pharmacy.

2.49 Procedure document:

2.49.1 *"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.

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."

"Procedure covers repeat dispensing services operated between this pharmacy and participating local GP Practices for those patients who wish to take advantage of them."

2.50 Based on the information before it, the Committee were not satisfied that it has been provided with information sufficient to show that there would be compliance with paragraph 9(4) of Schedule 4,

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

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

2.53 The Committee noted the information contained in the Connect AF Pharma Ltd Pharmacy Procedure document, where the applicant stated:

2.53.1 *"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. 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."*

2.54 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with 10(1) of Schedule 4.

2.55 **Disposal service in respect of unwanted drugs**

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

2.57 The safe and effective disposal of medicines SOP and the destruction of controlled drugs SOP described this.

2.58 The Committee noted the information contained in the Connect AF Pharma Ltd Pharmacy Procedure document and noted the applicant stated:

2.58.1 *"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.*

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. 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."

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

2.60 **Promotion of healthy lifestyles**

2.61 The Committee considered whether the applicant had explained how it will safely and effectively promote healthy lifestyles.

2.62 The Self-care and healthy lifestyle promotion SOP described this. Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with paragraph 16 – 18 of Schedule 4.

2.63 **Prescription linked intervention**

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

2.65 The Self-care and healthy lifestyle promotion SOP described this.

2.66 The Committee noted the information contained in the Connect AF Pharma Ltd Pharmacy Procedure document:

2.66.1 *"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.

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."

2.67 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

2.68 **Public health campaigns**

2.69 The Committee considered whether the applicant had explained how it will safely and effectively participate in public health campaigns, if and to the extent required by the NHSCB.

2.70 The Committee noted the information contained in the Connect AF Pharma Ltd Pharmacy Procedure document:

2.70.1 *"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.*

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."

2.71 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with paragraph 18 of Schedule 4.

2.72 **Signposting**

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

2.74 The Self-care and healthy lifestyle promotion SOP had information included.

2.75 The Committee noted the information contained in the Connect AF Pharma Ltd Pharmacy Procedure document:

2.75.1 *"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.*

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."

2.76 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with paragraphs 19 – 20 of Schedule 4.

2.77 **Support for self-care**

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

2.79 This has been addressed within the self-care and healthy lifestyle promotion SOP.

2.80 The Committee noted the information contained in the Connect AF Pharma Ltd Pharmacy Procedure document:

2.80.1 *"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. 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. 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."

2.81 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with paragraphs 21 – 22 of Schedule 4.

2.82 The applicant has not listed any advanced or enhanced services to be undertaken.

2.83 **Regulation 25 – Distance Selling Premises Requirements**

2.84 Regulation 25 requires that NHS England must refuse an application for a distance selling pharmacy unless it is satisfied that:

2.84.1 The pharmacy will provide uninterrupted essential services during opening hours to persons anywhere in England.

2.84.2 The pharmacy will provide safe and effective pharmaceutical services without face to-face contact at the pharmacy premises between the patient (or their representative) and the pharmacy staff.

2.85 **Consider impact of decision on those with protected characteristics under the Equalities Act 2010 and is this in accordance with NHS England/the ICB's Public Sector Equality Duty**

2.86 Consider impact of decision on NHS England/the ICB's duty on health inequality

2.87 The Committee agreed this would not be affected if granting this application.

2.88 All decision makers agreed that the applicant had not provided evidence to demonstrate that their application meets the requirements of Regulation 25.

2.89 **Decision**

2.90 The Committee refused the application as not all the requirements set out in Regulation 25 have been met.

2.90.1 The Committee was not required to refuse the application under the provisions of Regulation 31 as the proposed premises are not adjacent to or in close proximity to other chemist premises.

2.90.2 The Committee were satisfied that the premises of the applicant are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

2.90.3 The Committee were satisfied that all essential services are likely to be secured without interruption during the opening hours.

2.90.4 The Committee were not satisfied that all essential services are likely to be secured for persons anywhere in England.

2.90.5 The Committee were satisfied that all pharmaceutical services are likely to be secured in a safe and effective manner.

2.90.6 The Committee were satisfied that all pharmaceutical services are likely to be secured without face-to-face contact.

2.91 The Committee agreed that Connect AF Pharma Ltd has the right to appeal the decision."

3 The Appeal

In a letter dated 3 December 2025, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "In response to your decision I am sending an appeal in relation to the above application.

3.2 I have attached a copy of the amended SOPs to cover the issues raised during the decision.

3.3 In response to paragraph 9(4) of Schedule 4 the SOPS given were in draft form to clarify the new SOP will be amended as below to make sure they conform with the regulations:

3.4 "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.

3.5 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. During this consultation the pharmacist will make sure that

adherence to the drug/appliance is appropriate and also make sure that the patient is not suffering from any side effects which will highlight the need to review the patients treatment. During this consultation it will be confirmed with the patient that the medication regimen or manner of utilisation of the appliance by the patient has not been altered in anyway which will also prompt a review required by the prescriber. In addition to this it will be confirmed with the patient that there has been no changes to the health of the patient to which the prescription relates to. This again will prompt a review of the patient's treatment

3.6 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.

3.7 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."

3.8 Procedure covers repeat dispensing services operated between this pharmacy and participating GP Practices across England for those patients who wish to take advantage of them."

4 Summary of Representations

This is a summary of representations received on the appeal.

4.1 The Commissioner

4.1.1 "Please note that from the 1 April 2023, community pharmacy contracting and commissioning has been delegated to Integrated Care Boards (ICBs). Hertfordshire and West Essex (HWE) ICB are hosting the function on behalf of the six East of England ICBs. The six ICBs have formed one Pharmaceutical Services Regulation Committee (PSRC) which is also hosted by HWE ICB.

4.1.2 Thank you for your letter dated 11 December 2025 advising that Connect AF Pharma Ltd (the Appellant) has submitted an appeal against the decision to refuse their application for inclusion in the pharmaceutical list to provide pharmaceutical services as a distance selling pharmacy under Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the Regulations).

4.1.3 We note that on appeal, the Appellant has provided additional information to demonstrate compliance with the Regulations. This information was not available to the ICB when the original decision was made. The PSRC notes that had this information been provided by the Appellant as part of the application process, the decision made by PSRC may have been different.

4.1.4 We note that NHS Resolution will have regard to all information provided to date including the revised and additional information submitted by the Appellant as part of this appeal."

5 **Summary of Observations**

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

6 **Consideration**

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

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

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

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

Regulation 31

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

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

(2) This paragraph applies where -

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

6.6 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.

6.7 The Commissioner in its decision noted that "*there is no person on the pharmaceutical list providing or undertaking to provide pharmaceutical services from or adjacent to the premises*" which has not been disputed by any party. The Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

(ii) the safe and effective provision of 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."

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

6.11 As far as Regulation 25(2)(a) is concerned, the Committee 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 is decision report, stated that "*the premises in respect of which the application is made, is not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee agreed it is not required to refuse the application under the provisions of Regulation 25(2)(a)*." Based on the information available to it, which has not been disputed, 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)

6.12 As far as Regulation 25(2)(b) is concerned, the Committee considered the information which had been provided by the Applicant in relation to its procedures for the provision of essential services and pharmaceutical services,

including its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.

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

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

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

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

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

6.18 Under the following heading in the application form, “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*”. The Committee noted that the Applicant had stated that:

6.18.1 “*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. 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*.”

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

Essential services will be provided on an uninterrupted basis

6.20 The Committee considered how the Applicant would provide essential services without interruption and noted the following information in the application under the heading "Connect AF Pharma Ltd Pharmacy Procedures":

6.20.1 "*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*."

6.21 And further, under the heading "Essential Service – Dispensing", "Uninterrupted service", the Applicant states:

6.21.1 "*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. 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. This also includes any unforeseen circumstances in which case a pharmacist will be able to step in without notice to cover the opening hours and to ensure that the service is not interrupted*."

6.22 Under the headings "Essential Service - Disposal of Unwanted Medication, Uninterrupted Service", the Applicant states:

6.22.1 "*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*."

6.23 The Committee noted that throughout the application form, the Applicant sets out how essential services will be delivered without interruption through the use of, "*email, phone, fax, email, post, website or webcam*." The Committee also noted references to the availability of a second pharmacist and fully trained support staff throughout the pharmacy's opening hours. The Committee was therefore satisfied that essential services would be provided without interruption.

Provision of services across England

6.24 In relation to the provision of essential services to persons anywhere in England, the Committee noted the comments from the Commissioner that it

was "*not satisfied that all essential services are likely to be secured for persons anywhere in England*." The Committee noted that the Commissioner did not expand on this in the decision.

6.25 With regard to services being available to persons anywhere in England, the Committee noted the following information in the Applicant's application form:

6.25.1 *"Essential Service – Dispensing, 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."

6.26 Under the heading "Essential Service – Dispensing, Without Face to Face Contact", the Applicant states:

6.26.1 "*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*.

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."

6.26.2 "*Essential Service - Disposal of Unwanted Medication Persons anywhere in England*

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

6.26.3 "*Safe and Effectively*

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."

6.26.4 "*Essential Service – Signposting, Persons anywhere in England*

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."

6.26.5 "*Essential Service - Repeat Dispensing, Persons anywhere in England*

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 [sic] 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."

6.26.6 "*Essential Service – Discharge Medicine Service, Persons anywhere in England*

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."

6.26.7 "*Essential Service - Public Health (Promotion of Healthy Lifestyles) Persons anywhere in England*

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."

6.26.8 *"National Health Campaign, Persons anywhere in England*

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."

6.26.9 *"Essential Service - Support for Self Care, Persons anywhere in England*

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."

6.27 While the Committee acknowledged the references to a nationwide service, including the use of national couriers such as CitySprint and non-face-to-face communication methods (for example, via the pharmacy website and telephone), it also noted that the "Repeat Dispensing" SOP, under the heading "Scope", states that the "*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.

6.28 The Committee was therefore not satisfied that the provision of essential services would be available to persons anywhere in England.

Without Face to Face Contact

6.29 In its supporting information, the Applicant states:

6.29.1 "*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.*

…

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

…

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."

6.30 Further, the Applicant states under the heading "Essential Service – Dispensing":

6.30.1 "*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.*

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.

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.

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."

6.31 The Committee was mindful of the change to the wording of the Regulations which now states:

"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." [emphasis added]

6.32 The Committee was of the view that there was nothing provided in the information submitted by the Applicant which demonstrated that "pharmaceutical services" would be provided by face to face contact at the pharmacy premises.

6.33 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. As a result of this amendment, the Committee noted that the Applicant would not be able to provide any pharmaceutical services to patients present at its premises.

6.34 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.

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

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

6.36.1 Dispensing of drugs and appliances

6.36.2 Urgent supply without a prescription

6.36.3 Preliminary matters before providing ordered drugs or appliances

6.36.4 Providing ordered drugs or appliances

6.36.5 Refusal to provide drugs or appliances ordered

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

6.36.7 Disposal service in respect of unwanted drugs

6.36.8 Promotion of healthy lifestyles

6.36.9 Prescription linked intervention

6.36.10 Health campaigns

6.36.11 Signposting

6.36.12 Support for self-care

6.36.13 Discharge medicines service

6.36.14 Websites and health promotion zones

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

Providing ordered drugs or appliances

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

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

6.39 The Committee noted, under the heading, “Essential Service – Dispensing”, the Applicant states:

6.39.1 “*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.

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.”

6.40 The Committee noted that the above references items that are being delivered by “City Sprint” and that the Applicant has also made reference to the use of local delivery drivers for the delivery of cold chain items. By way of example, within the SOP entitled “Delivering Medicines Safely and Effectively”, the Applicant refers to the delivery driver handling and delivering fridge line items. Under “P4 Preparation for Delivery”, it states:

6.40.1 "***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

Travel to the correct address

Politely introduce yourself and explain why you are present

Confirm your identity and hand over the medicines to the patient/carer or authorised designated person. ***Do Not*** *hand over medicines to someone who is not the patient/carer or authorised designated person*

Ask the patient to check the name, address, and number of packages. Confirm exemption evidence if necessary

Ask the patient to check that the medicines received are required by the patient to help minimise wastage

Ask the patients if they will require their repeats again next month

Ask the patient to write their name and sign to indicate receipt of the medication in the Driver's delivery record book – where this isn't possible, the reason should be recorded by the delivery driver

Return the Delivery Record book to authorised pharmacy staff."

6.41 Further, under the heading "P5 Deliver", "Delivery Driver", the SOP states that delivery drivers are to request any refrigerated packages from dispensary staff. In addition, "P5 Delivery" states that medicines requiring refrigerated storage must be transported in a cool box:

6.41.1 *"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

Travel to the correct address

Politely introduce yourself and explain why you are present

Confirm your identity and hand over the medicines to the patient/carer or authorised designated person. Do Not hand over medicines to someone who is not the patient/carer or authorised designated person

Ask the patient to check the name, address, and number of packages. Confirm exemption evidence if necessary

Ask the patient to check that the medicines received are required by the patient to help minimise wastage

Ask the patients if they will require their repeats again next month

Ask the patient to write their name and sign to indicate receipt of the medication in the Driver's delivery record book – where this isn't possible, the reason should be recorded by the delivery driver

Return the Delivery Record book to authorised pharmacy staff

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

6.42.1 "*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."

6.43 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.

6.44 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.

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

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

6.46 The Committee noted that the Applicant's SOP titled 'Repeat Dispensing' states:

6.46.1 "*Purpose*

To provide a framework for a safe ongoing repeat dispensing service which includes prompt attention to medication changes or any other known changes in patent need. To ensure that the master repeatable prescription and batch issues are stored safely. To ensure there is an effective audit trail for each master repeatable prescription and its associated batch issues. To ensure that all regular dispensary staff are appropriately trained in accordance with the local PCO arrangements, and that all part-time pharmacists, relief pharmacists and locum pharmacist who work in the pharmacy have also received appropriate training. To increase convenience for patients on regular repeat medication and to decrease drug wastage.

6.46.2 *Scope*

Procedure covers repeat dispensing services operated between this pharmacy and participating local GP Practices for those patients who wish to take advantage of them

6.46.3 *Before Providing the First and Subsequent Repeat Items to the Patient:*

6.46.3.1 Contact the patient via their preferred method of none face to face contact. Check whether the patient:

Is taking or using the medicines, appliances or reagents properly

Requires each item to be dispensed

Is not suffering from any side-effects that suggest a need for review

Is taking any OTC medicines which could cause problems

Whether there are any other reasons why the items should not be supplied

The GP should be informed promptly if items are not supplied or if there are any problems

6.46.4 *Before Supplying Subsequent Batch Issues*

6.46.5 *Check:*

The pharmacy holds the master repeatable prescription

The master repeatable prescription is in date

Pharmacy holds the batch issue, or the patient sends it in

Batch issues are presented in numerical order (batch issues are indicated as number 1 of 12, 2 of 12 etc.) in the space normally used for signing There is no legal requirement to dispense in numerical order, but it is good practice and helps avoid confusion

Any problems on the original master repeatable prescription are corrected and reflect in batch issue

If the patient requires all items, is using medicines, appliances or reagents properly, and is not suffering any side-effects

There have been no changes in patient's circumstances since the last supply, e.g.:

Hospital admission

Hospital outpatient clinic visit

New symptoms

Taking OTC medicines

6.46.6 *If there is any concern about the safety or appropriateness of a repeat prescription:*

Contact the patient and advise them to make an appointment with the GP

Contact the GP (or other health care provider) directly

If the patient doesn't want all items or the full quantity, record what has been given via:

PMR

Endorsing batch issue appropriately

Endorsing the master repeatable prescription with the date of supply."

6.47 Whilst the Committee noted the information provided on how the repeat dispensing service would be delivered to existing patients, there was no information explaining how patients who may benefit from the service would be identified or informed.

6.48 The Committee was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 9(4) of Schedule 4.

Prescription linked intervention

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

6.50 The Committee noted that SOP, 'Self Care and Healthy Lifestyle Promotion' states:

6.50.1 "*Ensure that customers and their families are given the most appropriate advice to support their own health and wellbeing, including signposting to appropriate organisations and promotion of a healthy lifestyle*

…

All advice will be provided via email, telephone or using leaflets

…

Healthy Lifestyle

Check if it is appropriate to give advice and support

Yes – identify relevant PCT campaign

Provide leaflets and advice on campaign issues, and record advice provided via email or telephone on the PMR

If no PCT campaign is running, provide relevant advice or supply leaflets

No – refer to relevant health or social care provider or support organisation and made a record on the PMR."

6.51 The Committee noted that although the Applicant does mention providing interventions to those patients with underlying health conditions, the Committee noted the information provided does not show how patients will be identified as being eligible for prescription linked intervention or specifically how any interventions will be discussed with them.

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

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

Summary

6.54 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).

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

6.55.1 confirm the Commissioner's decision;

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

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

6.56 Although the decision reached by the Committee is ultimately the same as the Commissioner, it has reached that decision for different reasons. Therefore, the Committee determined that the decision must be quashed.

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

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

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

7 Decision

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

7.2 The Committee:

7.2.1 quashes the decision of the Commissioner; and

7.2.2 redetermines the application as follows -

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

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

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

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

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

7.2.3 The application is refused.

Case Manager
Primary Care Appeals