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16 October 2025

REF: SHA/26675

APPEAL AGAINST BLACK COUNTRY ICB DECISION TO REFUSE AN APPLICATION BY 365MED LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT UNIT 18, PHOENIX WORKS, DUDLEY ROAD, WEST TIVIDALE, OLDBURY, B69 2PJ 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 granted.

A copy of this decision is being sent to:

365Med Ltd
PCSE on behalf of Black Country ICB

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1 The Application

By application dated 5 October 2024, 365Med Ltd ("the Applicant") applied to Black Country ICB ("the Commissioner") for inclusion in the pharmaceutical list at Unit 18, Phoenix Works, Dudley Road, West Tividale, Oldbury, B69 2PJ 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 left this blank.

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

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

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

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

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

365Med Pharmacy Procedures

1.4 "365Med 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.

1.5 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.

1.6 365Med will have a website which facilitates the following:

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

1.6.2 Patient provides details of prescription,

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

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

1.6.5 Item is dispensed and details added to PMR.

1.6.6 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.

1.7 The website has been built by the Superintendent Pharmacist. 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.

1.8 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.

1.9 365Med has decided to use Titan PMR (https://www.titanpmr.com) as the software provider which will be a key tool in providing a safe and effective provision of service.

1.10 365Med 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.

1.11 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.

1.12 365Med is comprised of one director, [MZ]. Mr [Z] is the nominated superintendent and has suitable pharmacy experience. Mr [Z] 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/she 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.

1.13 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 and this will be made clear by the positioning of posters on any outward facing window and door of the premises. All entrances and exits will remain inaccessible to members of the public who are seeking the provision of essential services. An alarm system will cover the pharmacy premises which will notify the owner of unauthorised access when the premises are closed. All access routes will always be secured and kept locked when the premises not in use. Keys to the pharmacy premises will only be kept with authorised persons employed by the company. Schedule 1, 2 and relevant 3 drugs will always be stored in a locked CD cabinet. Security of premises will be reviewed regularly. A chosen member of staff will be available for emergency outcall in case of a breach.

Essential Service – Dispensing

1.14 Uninterrupted service

1.15 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.

1.16 Persons anywhere in England

1.17 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 HSCN network via BT.

1.18 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 at the current release

version. City Sprint will also be delivering cold chain items and CDs. This is addressed in the SOPs which have been included.

1.19 Safe and effectively

1.20 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.

1.21 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)

1.22 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.

1.23 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.

1.24 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.

1.25 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.

1.26 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.

1.27 Without face-to-face contact

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

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

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

1.31 Delivery of Refrigerated Medicinal Products - For cold chain products, delivery times will always be pre-arranged with the patient to minimise the risk of failed delivery. The patient's contact number will be given to the City Sprint delivery driver so they can again call the patient approximately 15-30 minutes prior to so they can check that somebody will be at the address to receive the medication.

1.32 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.

1.33 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.

1.34 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.

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

to measure and fit the appliance. We would facilitate this by gaining the permission of the patient to contact their nominated pharmacy and explaining the situation. We would then return the prescription to the patient or to the NHS spine so that the prescription can be dispensed.

Essential Service - Disposal of Unwanted Medication

1.36 Uninterrupted Service

1.37 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.

1.38 Persons anywhere in England

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

1.40 Safe and Effectively

1.41 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.

1.42 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.

1.43 Without face-to-face contact

1.44 Disposal of unwanted medication will be delivered without face-to-face contact via City Sprint couriers or, for local requests, out [sic] 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 [sic].

Essential Service – Signposting

1.45 Uninterrupted Service

1.46 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.

1.47 Persons anywhere in England

1.48 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.

1.49 Safe and Effectively

1.50 We would contact the relevant NHS organisations 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.

1.51 Without face-to-face contact

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

Essential Service - Repeat Dispensing

1.53 Uninterrupted Service

1.54 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 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.

1.55 Persons anywhere in England

1.56 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. [sic] This consent from can be emailed, faxed or posted directly to the pharmacy. Patients from surgeries that are ETP compliant will have their prescriptions sent and received at the pharmacy electronically almost instantly after the appropriate prescribing practitioner 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.

1.57 Safe and Effectively

1.58 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.

1.59 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.

1.60 Without face-to-face contact

1.61 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.

1.62 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.

Essential Service – Discharge Medicine Service

1.63 Uninterrupted Service

1.64 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. 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.

1.65 Persons anywhere in England

1.66 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.

1.67 Safe and Effectively

1.68 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.

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

1.70 Without face-to-face contact

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

Essential Service - Public Health (Promotion of Healthy Lifestyles)

Prescription linked intervention

1.72 Uninterrupted service

1.73 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.

1.74 Persons anywhere in England

1.75 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.

1.76 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.

1.77 Safe and effectively

1.78 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.

1.79 Without face-to-face contact

1.80 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.

National Health Campaign

1.81 Uninterrupted Service

1.82 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.

1.83 Persons anywhere in England

1.84 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.

1.85 Safe and Effectively

1.86 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.

1.87 Without face-to-face contact

1.88 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.

Essential Service - Support for Self-Care

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. 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.

1.91 Persons anywhere in England

1.92 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.

1.93 Safe and Effectively

1.94 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.

1.95 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.

1.96 Without face-to-face contact

1.97 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

Essential Service - Clinical Governance

1.98 There will be a named Clinical Governance Lead who will also be the Superintendent Pharmacist, Mr [Z].

Patient and public involvement

1.99 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.

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

Clinical audit

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

Risk management

1.102 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.

1.103 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.

1.104 365Med 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.

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

Staffing and staff management

1.106 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.

Education, training and continuing professional and personal development

1.107 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.

1.108 Use of information to support clinical governance and health care delivery 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. 365Med 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. 365Med 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.

1.109 Pharmacists will be using their own professional judgement to make records of interventions they have made and any advice they may have given. 365Med will ensure that NHS direct are aware of the pharmacy's actual working hours so that they can provide appropriate information to members of the public.

Proof of exemption/prescription charges

1.110 If the patient is under 16 or over 60 years of age and the date of birth is printed on the front of the prescription then no check of exemption status is required. The pharmacy will make use of real time exemption checking (RTEC) via the PMR system if appropriate. For all other exemptions, the pharmacy will make contact with the patient and ask them for proof of their exemption. The pharmacy will ask patients to send proof of exemption to the pharmacy via post, fax or as an email attachment. The exemption details can also be updated on the secure pharmacy website. The pharmacy will keep records of exemption on the PMR, including when the exemption runs out or expires. On each dispensing occasion, we would verify exemption details and seek explicit permission from the patient if they would like the pharmacy to fill in the back of the prescription on their behalf. We would make a record each time the patient gave us permission to fill in the back of the prescription on their behalf so there is an audit trail. If the patient wishes to fill in the back of the prescriptions themselves we would send the prescription to the patient via courier for them to fill in and return to us. This could be done at the same time as the medication is being delivered or prior to delivery depending on patient preference. If patient

is unable to provide proof of exemption, the pharmacy would mark the back of the prescription to indicate that the exemption has not been seen. Where prescription charge(s) need to be taken, the pharmacy will have facilities in place whereby card details can be taken over the telephone or via a secure internet site. The pharmacy will cover the cost of postage by arranging for an insured courier to collect prescription charges nationally via a tracked service.

Additional Information

1.111 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 Applicant's '14 day comments' to the Commissioner

2.1.1 "I have reviewed the 45 day consultation comments and I wanted to address and expand on the point raised by Community Pharmacy Sandwell about the consultation room entrance being through the dispensary.

2.1.2 Given that most of our consultations will be online, this should help mitigate any potential confidentiality breaches related to patient flow through the dispensary area.

2.1.3 However, if there are specific concerns regarding in-person services, such as vaccinations, we are prepared to adapt the consultation room to include a separate entrance. This modification will ensure that we meet the required standards and address any confidentiality concerns.

2.1.1 I thank you for forwarding these comments for our attention. We are committed to providing the best service possible and are open to any further suggestions you might have."

3 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 23 June 2025 states:

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

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

Extract from the Pharmacy Services Regulations Committee 8 April 2025

3.2 "Decision:

Regulation 31 – refusal: same or adjacent premises

3.3 Regulation 31 (1) A routine or excepted application, other than a consolidation application, must be refused where paragraph (2) applies.

3.4 Regulation 31(2)(a) (i) (ii) There is no pharmacy providing pharmaceutical services at the same or adjacent premises.

3.5 As Regulation 31(2)(a) does not apply, the committee is not required to consider Regulation 31(2) (b)

3.6 Therefore, the committee concluded that it was not required to refuse the application under the provisions of Regulation 31.

3.7 The Committee then went on to consider Regulation 25.

Regulation 25 – Distance Selling Premises Applications

3.8 Regulation 25(2)(a) – The NHSCB must refuse an application to which paragraph 1 applies –

3.9 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.

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

3.11 The applicant did not provide details within the application form, however the proposed premises are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

3.12 This is confirmed with information available on the NHS.UK website where the nearest general practice is located 0.7 miles away.

3.13 Therefore, the Committee concluded that it is not required to refuse the application under Regulation 25(2)(a).

3.14 Regulation 25(2)(b)(i) – The uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.

3.15 The Committee was not satisfied that pharmacy procedures meet the standard required to satisfy the regulatory requirements of the uninterrupted provision of essential services to anyone in England who request such services. SOP statements indicate that during a two hour period, a Responsible Pharmacist may not be present, with no reference given to a second pharmacist meaning the Applicant would be unable to provide all essential services in line with the Regulations.

3.16 With regards to deliveries, no assurance is given as to the procedures to be used to secure the safe and effective delivery of medicines to anyone in England. There are only references to 'the delivery driver', and with no information about national couriers, it is assumed that the delivery driver is

directly employed by the pharmacy. This would make it impractical to provide a national service. Therefore, this regulation is deemed to have not been met.

3.17 Regulation 25(2)(b)(ii) – The safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

3.18 The Committee was not satisfied that the pharmacy procedures meet the standard required to satisfy the regulatory requirements of the provision of essential services without face to face contact. There are multiple references throughout the SOPs that do not give assurance that the applicant procedures reflect that face to face consultations for Essential Services are not permitted Therefore, this regulation is deemed to have not been met.

3.19 The committee refused the application.

3.20 The Committee determined that the applicant has been granted appeal rights.

Specific conditions – Distance Selling Premises

3.21 As the application is in respect of distance selling premises, by virtue of Regulation 64(3) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, if the applicant is subsequently included in the pharmaceutical list for the area of Sandwell Health and Wellbeing board in respect of the premises included in the application, that inclusion will be subject to the following conditions:

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

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

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

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

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

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

3.21.5 Nothing in the applicant's practice leaflet, in the applicant's publicity material in respect of the proposed premises, in material published on

behalf of the applicant publicising services provided at or from the proposed premises or in any communication (written or oral) from the applicant or the applicant's staff to any person seeking the provision of essential services from the applicant must represent, either expressly or impliedly, that:

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

3.21.5.2 the applicant is likely to refuse, for reasons other than those provided for in the applicant's terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (eg because the availability of essential services from the applicant is limited to other categories of patients)."

4 The Appeal

In an online form for pharmacy application appeals dated 20 July 2025, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

4.1 "365Med Ltd appeals the rejection of its pharmacy application. Our revised SOPs and supplementary documentation fully address concerns under Regulation 25(2)(b)(i) and (ii) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, ensuring compliant, secure, and uninterrupted non-face-to-face pharmacy services in England.

4.2 Initial ambiguities, previously attributed to an external agent, have been rectified. While SOPs are revised, other verified supporting documents remain unaltered.

4.3 Addressing Regulation 25(2)(b)(i) – Uninterrupted Essential Services:

4.3.1 Responsible Pharmacist Coverage: New SOPs outline robust procedures for continuous Responsible Pharmacist presence and availability, including contingency plans and remote supervision.

4.3.2 National Delivery: Updated SOPs detail reliance on reputable national couriers (e.g.,CitySprint) for secure medicine delivery, including handling, packaging, tracking, and exception management.

4.4 Addressing Regulation 25(2)(b)(ii) – Safe Provision Without Face-to-Face Contact:

4.4.1 Exclusion of Face-to-Face Contact: Our model explicitly precludes face-to-face interaction. Revised SOPs remove all references to in-person interactions, ensuring clarity on remote service delivery.

4.4.2 Remote Consultation: SOPs reinforce remote consultation via telephone, video, and online messaging. Procedures detail stringent protocols for identity verification, confidentiality, and emergency escalation, ensuring patient safety and privacy. Previous interpretations suggesting physical interaction were erroneous.

4.5 We are confident our updated SOPs and consistent supporting documentation fully address all concerns, ensuring complete adherence to Regulation 25(2)(b)(i) and (ii). We respectfully request reconsideration. The "365 Med Procedures" document consistently covered these crucial points, despite initial ambiguities in preceding SOPs.

4.6 The Management Team, 365Med Ltd,

4.7 Supporting Documentation Supplied:

4.7.1 365 Med SOPS (NEW REPLACEMENT SET)

4.7.2 365 Med Procedures (Original Unaltered Document) [as set out above at section 1]"

5 Amendments to Regulation 25

On 23 June 2025, amendments to Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 came into force which affect this application. Given the amendments represent a new test the Applicant was given the opportunity to make comments in support of its application and parties given the opportunity to provide comments in response.

5.1 THE APPLICANT

5.1.1 "We've received your letter from 29th July 2025, concerning the recent amendments to Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and the upcoming changes for Directed Services for Distance Selling Pharmacies (DSPs). These legislative changes, detailed in The National Health Service (Charges, Remission of Charges and Pharmaceutical Services etc.) (Amendment and Transitional Provisions) Regulations 2025 (SI 2025/636), are central to how we operate.

5.1.2 We acknowledge the amendments to Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 which came into force, specifically:

5.1.2.1 In paragraph (1), after "to an application" insert "to relocate to different premises"; and omit sub-paragraph (a).

5.1.2.2 In paragraph (2)(b)(ii), for "essential services" substitute "pharmaceutical services"; and after "contact" insert "at the pharmacy premises".

5.1.3 We confirm that our application, SHA/26675, fully satisfies the requirements of the revised Regulation 25(2)(b) and aligns precisely with the new operational mandates for DSPs, which come into effect from 1st October 2025.

5.1.4 Here's how our application addresses these points:

5.1.4.1 Regulation 25(2)(b)(i) – Uninterrupted Provision of Essential Services: Our operational model is designed to seamlessly provide essential services to people across England during all opening hours, exclusively remotely from our pharmacy premises. This is backed by a robust IT infrastructure and an efficient pharmaceutical logistics network, supported by reliable pharmacy suppliers who ensure consistent and secure medicine and appliance delivery. Our online platform provides 24/7 access to information and remote consultation booking, facilitating continuous service provision.

5.1.4.2 Regulation 25(2)(b)(ii) – Safe and Effective Remote Provision of Pharmaceutical Services: We're committed to safely and effectively delivering all pharmaceutical services without requiring face-to-face contact at the pharmacy premises. Our application thoroughly details our protocols for remote consultation, secure dispensing, and safe delivery, all of which prioritise patient safety and service effectiveness. Our secure online patient portal allows for remote consultations via video or chat, prescription management, and direct communication with pharmacists, ensuring safe and effective remote service delivery.

5.1.5 Regarding the changes to Directed Services effective from 1st October 2025:

5.1.5.1 We understand that DSPs will no longer be able to deliver in-person Directed Services (Advanced, National Enhanced, and Enhanced Services) on-site (meaning no face-to-face patient interactions at the pharmacy). This means DSPs can only provide Advanced, National Enhanced, and Enhanced Services remotely from their premises, aligning with the original intent for DSPs to be national remote providers, as outlined by Community Pharmacy England (CPE) and the Department of Health and Social Care (DHSC).

5.1.5.2 Our operational model is fully set up for this new directive. We've established secure systems to provide:

5.1.5.2.1 Remote consultations from our premises, adhering to relevant professional standards and data security, facilitated by our online consultation platform.

5.1.5.2.2 Off-site, face-to-face provision of a service, where a service specification allows and with explicit ICB approval, ensuring this provision is not at our pharmacy premises. This may involve mobile outreach services coordinated through our online scheduling system.

5.1.6 We assure you that our Standard Operating Procedures (SOPs) are either already fully compliant with these updated regulations and directives or are undergoing immediate revision to ensure complete

adherence before the 1st October 2025 implementation. Plus, we have a dedicated SOP in place specifically for continuously reviewing and immediately updating all relevant internal procedures whenever legislative changes occur, ensuring perpetual compliance. Our online SOP management system ensures that all team members have immediate access to the latest versions. If any existing SOP inadvertently suggests face-to-face contact for services now restricted to remote delivery, it's immediately rectified during this revision process to reflect the updated legislation.

5.1.7 Our application, supported by our robust SOPs and integrated online systems, clearly demonstrates that we meet all current and upcoming regulatory requirements for inclusion in the Pharmaceutical List as a distance selling pharmacy. This reinforces our commitment to patient care and adherence to the evolving NHS framework.

5.1.8 Thank you for your careful consideration. We anticipate a positive resolution for our application."

6 Summary of Representations

After reviewing the paperwork provided by the Commissioner, it was noted that the comments made by the Applicant in response to the representations on the application [see section 2 above] had not been circulated or seen by parties. NHS Resolution therefore applied its discretion under Schedule 3, Part 3, Paragraph 7 and allowed parties the opportunity to make comments on this information.

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

7 Consideration

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

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

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

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

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

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

7.7 The Committee noted the conclusion of the Commissioner that Regulation 31 does not apply as "*there is no pharmacy providing pharmaceutical services at the same or adjacent premises*" and that this had not been disputed either on appeal or in subsequent representations. Based on the information before it, the Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

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

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

7.11 The Committee noted that the Applicant had not included any information in the relevant section of the application form that deals with this point. The Committee noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Commissioner in its decision report was satisfied that the proposed premises 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 and that "*this is confirmed with information available on the NHS.uk website where the nearest general practice is located 0.7 miles away*." The Committee noted that this had not been disputed either on appeal or in subsequent representations. Based on the information available to it, the Committee therefore determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

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

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

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

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

7.16 It is not for the Committee to 'approve' or 'disapprove' of these SOPs (as they may contain matters not relevant to the Committee's consideration, and there

are many ways an applicant can choose to organise itself in order to comply with the various requirements of the Regulations) and the Committee has not sought to do so. The Committee has sought evidence within the SOPs and application in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.

7.17 In relation to the provision of essential services to persons anywhere in England, the Committee noted the comments from the Commissioner and that it was not satisfied with regard to a national service being offered by the Applicant.

7.18 The Committee noted the Applicant had stated, in its procedures that:

7.18.1 *"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 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 at the current release version. City Sprint will also be delivering cold chain items and CDs. This is addressed in the SOPs which have been included."

7.19 Further, the Applicant on appeal stated:

7.19.1 *"National Delivery: Updated SOPs detail reliance on reputable national couriers (e.g.,CitySprint) for secure medicine delivery, including handling, packaging, tracking, and exception management."*

7.20 The Committee also noted the SOPs provided on appeal and in particular the SOP "Order Delivery – Delivering dispensed medication to the Patient or their representative" which states:

7.20.1 *"Choice of Delivery Method*

*For items **other than** cold chain / "fridge line" items, local deliveries (up to 30 miles radius, but may be extended at the discretion of the RP) the delivery driver should deliver medication. Outside this area CitySprint should be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier should be used (see SOP for Delivery of Controlled Drugs), or the items are fridge lines, in which case the cold chain courier should be used (see below)."*

7.21 Based on the information before it, the Committee was satisfied that the provision of essential services would be available to persons anywhere in England.

7.22 With regard to the uninterrupted provision of essential services, the Committee noted the decision of the Commissioner that it was "*not satisfied that pharmacy procedures meet the standard required to satisfy the regulatory requirements*

of the uninterrupted provision of essential services to anyone in England who request such services".

7.23 The Committee noted that the Applicant's procedures state:

7.23.1 "*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*."

and

7.23.2 "*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*."

7.24 The Committee noted in the appeal, the Applicant states:

7.24.1 *"Responsible Pharmacist Coverage: New SOPs outline robust procedures for continuous Responsible Pharmacist presence and availability, including contingency plans and remote supervision."*

7.25 The Committee further noted the SOP, as provided on appeal, entitled "The Responsible Pharmacist SOP" which states:

7.25.1 ***"Procedures for the Responsible Pharmacist's Absence in a Distance Selling Pharmacy***

As a Distance Selling pharmacy, it is imperative to provide uninterrupted service throughout operating hours. Consequently, the Responsible Pharmacist is not permitted to leave the premises in the same manner as an RP at a non-Distance Selling pharmacy (who may leave for up to two hours daily) ***unless another pharmacist is present****. This requirement is a direct response to GPhC guidance emphasizing continuous professional oversight in distance selling models. This pharmacy will ensure a second pharmacist is available during both core and any additional operating hours. Should the RP be required to leave the premises for any reason, or wish to take a break (in accordance with the Working Time Directive), the second pharmacist must formally sign in and assume the duties of the Responsible Pharmacist, thereby maintaining continuous pharmacist oversight as expected by the GPhC for distance selling operations."*

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

7.27 With regard to the safe and effective provision of pharmaceutical services without face to face contact, the Committee noted that the Commissioner had not been satisfied that "*the pharmacy procedures meet the standard required to satisfy the regulatory requirements of the provision of essential services without face to face contact*". The Commissioner had gone on to state "*There are multiple references throughout the SOPs that do not give assurance that the applicant procedures reflect that the face to face consultations for Essential Services are not permitted. Therefore this regulation is deemed to have not been met."*

7.28 The Committee noted the Applicant, in its procedures provided with the application form, had referred to communication with patients by phone, fax, email and webcam.

7.29 The Committee noted on appeal the Applicant had stated:

7.29.1 "*Addressing Regulation 25(2)(b)(ii) – Safe Provision Without Face-to-Face Contact:*

> *Exclusion of Face-to-Face Contact: Our model explicitly precludes face-to-face interaction. Revised SOPs remove all references to in-person interactions, ensuring clarity on remote service delivery.*
>
> *Remote Consultation: SOPs reinforce remote consultation via telephone, video, and online messaging. Procedures detail stringent protocols for identity verification, confidentiality, and emergency escalation, ensuring patient safety and privacy. Previous interpretations suggesting physical interaction were erroneous."*

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

7.31 In its application, which the Committee acknowledged was completed before the amendment came into force, the Applicant had stated that it intended to provide "New Medicines Service, Pharmacy first and Community Pharmacy Seasonal Influenza Service". As a result of this amendment, the Committee noted that the Applicant would not be able to provide any pharmaceutical services at its premises.

7.32 The Committee further noted the comments from the Applicant with regard to the regulatory changes:

7.33 *"Regarding the changes to Directed Services effective from 1st October 2025:*

> *We understand that DSPs will no longer be able to deliver in-person Directed Services (Advanced, National Enhanced, and Enhanced Services) on-site (meaning no face-to-face patient interactions at the pharmacy). This means DSPs can only provide Advanced, National*

Enhanced, and Enhanced Services remotely from their premises, aligning with the original intent for DSPs to be national remote providers, as outlined by Community Pharmacy England (CPE) and the Department of Health and Social Care (DHSC).

Our operational model is fully set up for this new directive. We've established secure systems to provide:

Remote consultations from our premises, adhering to relevant professional standards and data security, facilitated by our online consultation platform.

Off-site, face-to-face provision of a service, where a service specification allows and with explicit ICB approval, ensuring this provision is not at our pharmacy premises. This may involve mobile outreach services coordinated through our online scheduling system."

7.34 The Committee was aware that when the pharmacy opens, it will be the responsibility of the Commissioner, in keeping with Regulation 64, to ensure that services are provided other than with face to face contact.

7.35 The Committee was satisfied that the provision of essential services would be without interruption, would be available to persons anywhere in England and that pharmaceutical services would be provided without face to face contact. The Committee went on to consider whether safe and effective provision of pharmaceutical services was likely to be secured.

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

Dispensing of drugs and appliances

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

7.38 In the Applicant's procedures, the Committee noted the following:

7.38.1 "*Patient posts prescription to pharmacy …"*

7.39 In the SOP "Electronic Prescription Service (EPS) Dispensing" it states:

7.39.1 ***"Scanning Prescription Token Barcode:** If a patient submits their token to the pharmacy (either by post or collection from the surgery), the barcode on the prescription token can be scanned to "pull down" the prescription to the pharmacy system. This method is particularly common for acute prescriptions, allowing for quick processing upon the token's arrival.*

*…**The following steps apply when a patient or healthcare provider posts a prescription token to the nominated pharmacy:***

3.2.1. Handling Mailed Prescription Tokens

Upon receipt of a mailed prescription token, the prescription may have already been downloaded, dispensed, and be awaiting delivery, or the barcode may need to be scanned to retrieve the prescription from the NHS spine. If the prescription has already been downloaded, the system will notify the user upon scanning the barcode. The pharmacy should determine whether staff should first check if the prescription is already prepared for delivery or if the token should be scanned first to locate the prescription using the system."

7.40 The Committee also noted the SOP "Order Delivery – Delivering dispensed medication to the Patient or their representative" which states

7.40.1 *Choice of Delivery Method*

*For items **other than** cold chain / "fridge line" items, local deliveries (up to 30 miles radius, but may be extended at the discretion of the RP) the delivery driver should deliver medication. Outside this area CitySprint should be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier should be used (see SOP for Delivery of Controlled Drugs), or the items are fridge lines, in which case the cold chain courier should be used (see below)."*

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

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

Urgent supply without a prescription

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

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

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

Preliminary matters before providing ordered drugs or appliances

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

7.47 The Committee noted the Applicant's procedures under 'Proof of exemption/prescription charges' which state:

7.47.1 *"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. … The pharmacy will cover the cost of postage by arranging for an insured courier to collect prescription charges nationally via a tracked service.*"

7.48 The SOP "Online Order Receipt & Exemption Checking: SOP" states:

7.48.1 "*1. Objective:*

…

1.4 Exemption Validation: Thoroughly validating prescription charge exemptions using scanned or posted evidence and maintaining meticulous records.

…"

7.49 "Product Selection, Labelling and Assembly SOP" under 'Prescription Verification' states:

7.49.1 **"*Examination of Prescription:*** *Conduct a comprehensive examination of the prescription, ensuring the following:*

Patient Information Verification: *Verify the patient's full name, address, and date of birth against official identification where possible, and double-check these details within the PMR system before selecting*

a patient from the PMR list. This is crucial to prevent misidentification and ensure patient safety.

Prescriber's Signature Confirmation: *Confirm the clear presence and legibility of the prescriber's signature, validating its authenticity as per regulatory requirements.*

Reverse of Prescription Completion : *If relevant ensure all required sections on the reverse of the prescription have been completed accurately and appropriately, including any patient declarations or exemption details.*

Identification of Anomalies and Missing Information: *Diligently identify and address any discrepancies, missing information, or additional notes on the prescription. Any identified issues must be resolved with the prescriber or patient as per established protocols."*

7.50 Further, the SOP "Dispensing Controlled Drugs" under 'Receiving Prescriptions' states:

7.50.1 "Ensure the reverse of the prescription is completed with payment/exemption details. If incomplete, refer to the patient's registration documentation and sign as the representative if applicable. If proof of exemption is not provided, contact the patient to obtain a copy for records."

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

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

7.53 The Committee noted the Applicant's procedures under Proof of exemption/prescription charges which state:

7.53.1 *"... 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. .."*

7.54 Within the "Introduction and Background to SOPs" it states:

7.54.1 ***"Information Security and Data Protection:*** *A rigorous audit of adherence to the pharmacy's internal information security policy, compliance with the Payment Card Industry Data Security Standard (PCI DSS) for payment processing, and strict observance of all applicable data protection laws (e.g., GDPR). This includes assessing data encryption, access controls, and incident response procedures."*

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

Providing ordered drugs or appliances

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

7.57 The Committee considered the information before it contained in the original application form and the SOPs submitted by the Applicant.

7.58 In the procedures the Applicant states:

7.58.1 *"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 at the current release version. City Sprint will also be delivering cold chain items and CDs. This is addressed in the SOPs which have been included.*

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."

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 the patient.

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

Delivery of Refrigerated Medicinal Products - For cold chain products, delivery times will always be pre-arranged with the patient to minimise the risk of failed delivery. The patient's contact number will be given to the City Sprint delivery driver so they can again call the patient approximately 15-30 minutes prior to so they can check that somebody will be at the address to receive the medication.

Cold chain products will be packed in such a way as to ensure that the required temperatures are maintained throughout the journey and the medicines are transported in accordance with their labelling requirements to maintain product integrity.

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.

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."

7.59 The Committee noted that the Applicant had expanded upon the delivery of medication in the SOPs as provided with the appeal.

7.60 The SOP "Order Delivery – Delivering dispensed medication to the Patient or their representative' states:

7.60.1 ***"Choice of Delivery Method***

For items ***other than*** *cold chain / "fridge line" items, local deliveries (up to 30 miles radius, but may be extended at the discretion of the RP) the delivery driver should deliver medication. Outside this area CitySprint should be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier should be used (see SOP for Delivery of Controlled Drugs), or the items are fridge lines, in which case the cold chain courier should be used (see below)."*

Secure Transfer to the Delivery Driver

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

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

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

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

Ensure that any deliveries for fridge items and CDs are taken out of storage when appropriate.

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

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

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

At hand-over to the driver / courier ensure that any current falsified medicines regulation or guidance is followed.

Successful delivery Protocol

Once the deliveries are completed, return the delivery sheets to the pharmacy on the same day. The delivery sheets must be stored safely for a minimum of 3 months.

Unsuccessful Delivery Protocol

If the patient or representative is not able to receive the delivery of their medication, complete the 'attempted delivery' form and post it through the letterbox. The form will have details for arranging re-delivery.

The prescription and medication must be returned to the pharmacy on the same day and the pharmacist informed of the unsuccessful delivery.

The pharmacy should follow up the unsuccessful delivery by contacting the patient to arrange a second delivery time.

DO NOT:

i. Post the medication through the letter/post box.
ii .Leave the medication on the porch or any other out building.
iii. Leave the medication at an unauthorised address.

Delivery of a prescription via CitySprint or Chosen Courier (Not for Cold Chain or CDs)

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

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

3. Print and attach relevant CitySprint Signed For delivery labels using the CitySprint online business account and attach securely to outer packaging. For CitySprint deliveries, ensure the CitySprint label is securely attached to the outer packaging.

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

5. Confirm details of all prescriptions to be delivered.

6. Make a note of all Tracking numbers for prescriptions being delivered by CitySprint or Courier on the Delivery Log sheet.

7. Ensure the CitySprint or Courier driver signs the Delivery Log sheet for all prescriptions being accepted for delivery. Store the Delivery Log sheet for a minimum of 3 months from dispatch date.

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

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

Unsuccessful Delivery via CitySprint or Courier

1. In the event of an unsuccessful delivery by CitySprint , CitySprint will leave a 'Sorry We Missed You' card, stating the date and time of the attempted delivery. The patient can then either choose to collect and sign for their medicines at their local post office, or rearrange delivery for a convenient time by telephone or email.

2. In the event of an unsuccessful delivery by CitySprint, the CitySprint driver will attempt to contact the patient. If unsuccessful, CitySprint will return the medication to the pharmacy. The pharmacy will then contact the patient to arrange a new delivery time or collection.

Cold chain delivery via Nominated Couriers

Explanatory Note

See "Prescription Bagging and Dispatch SOP" SOP for cold chain packaging guidance. All cold chain deliveries must be carried out by couriers with verified and approved cold chain procedures. A list of approved cold chain couriers is available within the Pharmacy and will

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

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

Breaches of /cold Chain

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

Unsuccessful cold chain delivery via courier

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

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

Breach of Integrity of Cold Chain

The courier is responsible for maintaining temperature integrity throughout the supply chain, from collection and goods-in to pharmaceutical storage and final delivery.

The cold chain service is a dedicated, fully monitored, and temperature-controlled delivery service. In the event of a breach in service integrity, the system automatically alerts the delivery driver that the cold chain has not been maintained.

Should such an event occur, the courier is instructed to leave a 'Missed Delivery' card and inform the pharmacy that delivery was unsuccessful due to a cold chain breach. The pharmacy must then arrange for immediate re-delivery of the items via courier and the return of the compromised items to the pharmacy by the courier. Items subject to a cold chain breach may not be re-used and must be segregated from pharmacy stock."

7.61 The Committee noted the SOP "Secure Delivery of Controlled drugs" under the heading "Procedures for Delivering Schedule 2 & 3 Controlled drugs" states:

7.61.1 *"Maintaining a robust and comprehensive audit trail is paramount when handling Controlled Drugs. Deliveries may be made to a designated representative if the patient has provided explicit authorisation for them*

to receive the CDs on their behalf. In addition to the standard Delivery Log sheet, a dedicated Controlled Drugs Delivery Sheet must be accurately completed for all CD deliveries.

Segregation and Storage During Transit: Controlled Drugs must be placed in a separate, distinct bag from any other medications being delivered to the same patient. These bags, though separate, should be securely attached together to prevent misplacement. During transit, CDs and any other accompanying medications for that patient's delivery must be stored securely within the lockable compartment of the delivery vehicle, ensuring they are out of public sight and protected from theft or tampering, in line with MHRA and GPhC storage guidelines for medicines in transit.

Vehicle Security: The delivery vehicle must remain locked at all times when the driver is not physically present within the vehicle, reinforcing security measures for the CDs.

Proof of Collection: The delivery driver or courier must sign the back of the prescription as the authorised representative upon accepting the Controlled Drugs for delivery from the pharmacy premises.

Identity Verification at Delivery: Prior to handing over the CDs, the delivery driver or courier must rigorously verify the identity of the person accepting the delivery. Acceptable forms of identification include a valid passport, driving licence, or a government-approved photo ID card. CDs cannot, under any circumstances, be left with an individual who is not the patient themselves or their officially authorised representative. This stringent verification is a critical component of preventing diversion and ensuring patient safety, aligning with GPhC standards for dispensing and delivery.

Compliance with Falsified Medicines Rules: All regulations and guidance introduced by the UK regarding falsified medicines must be strictly adhered to during the delivery process.

CD Register Entry Prior to Dispatch: All necessary entries into the Controlled Drug register must be completed precisely at the moment the medication departs the pharmacy premises. The delivery driver or courier should be accurately recorded as the 'person collecting' the CDs.

Prescription Retention and Confirmation of Delivery: The original prescription for the CDs must be retained within the pharmacy until the delivery driver returns the signed Controlled Drug Delivery Sheet or, in the case of a courier, until the patient's signature is confirmed via the online courier delivery record, thereby validating successful delivery.

Confirmation of Successful Schedule 2 & 3 Delivery

Upon arrival at the delivery location, the delivery driver or courier is obligated to verify the identity of the recipient to confirm they are either the patient or their authorised representative. Under no circumstances

should the delivery be completed if the recipient does not meet these criteria.

For all successful deliveries, the signed Controlled Drug Delivery Sheet (or online courier delivery record) must be meticulously cross-referenced with both the original prescription and the Controlled Drug register as part of the end-of-day reconciliation procedure. This step ensures a complete and accurate audit trail, as required by MHRA and GPhC regulations.

Handling Unsuccessful Schedule 2 & 3 Deliveries by Pharmacy Staff

In instances where a delivery attempted by a pharmacy driver is unsuccessful, the Controlled Drugs must be immediately returned to the pharmacy on the same day. Upon return, the CDs must be re-entered into the Controlled Drug register, if applicable, with a clear explanation of the failed delivery. Subsequently, these returned CDs must be secured without delay in the designated Controlled Drug cabinet, in strict accordance with secure storage regulations.

Handling Unsuccessful Schedule 2 & 3 Deliveries by Courier

For unsuccessful deliveries facilitated by a courier, the Controlled Drugs should be returned to the pharmacy on the same day whenever feasible. Upon return, they must be accurately re-entered into the Controlled Drug register, if applicable, with an accompanying explanation of the failed delivery. These returned CDs must then be secured within the Controlled Drug cabinet. If the timing of the attempted delivery precludes same-day return, the courier is responsible for storing the drugs securely overnight at their approved, MHRA-compliant warehouse facilities. In the event of a failed delivery, the tracking service will notify both the pharmacy and the patient, enabling the arrangement of a re-delivery at a mutually convenient time or the return of the medication to the pharmacy."

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

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

7.64 The Committee noted that, in response to this on the application form, the Applicant had left this blank. The Committee noted the SOP "Standard Operating Procedure: Clinical and Legal Assessment of Prescriptions"

7.64.1 "6.4 Items Requiring Measuring and Fitting

Should a prescription be received for an item that explicitly necessitates measuring or fitting (e.g., certain medical devices or compression garments), the patient must be promptly contacted. They should be clearly informed that this particular pharmacy does not offer a

measuring and fitting service. Patients must then be directed to at least two alternative service providers in their local area that can provide this service, in accordance with the established signposting SOP."

7.65 The Committee noted that the Applicant did not intend to provide appliances which require measuring or fitting. In the event that the application is granted, the Applicant would not therefore be able to provide these appliances, as listed in the application form, to patients.

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

7.67 The Committee considered whether the Applicant had explained what containers would be suitable for posted/delivered items.

7.68 The Committee noted the SOP "Prescription Bagging and Dispatch" 'Optimising Packaging for Secure and Efficient Deliveries' states:

7.68.1 *"The selection of appropriate packaging for any delivered item hinges on its inherent characteristics, with the primary goal of providing ample protection against potential damage throughout the entire delivery process. A critical security measure for all pharmaceutical deliveries is the mandatory application of tamper-proof seals directly from the pharmacy. These seals serve as an essential visual indicator, enabling immediate detection of any unauthorised access or interference with the package's contents, thereby safeguarding product integrity and patient safety*.

For local deliveries, where a dedicated delivery driver is utilised, standard pharmacy prescription bags are deemed suitable for medications that are not fragile. However, it is crucial to avoid the use of generic cardboard boxes. Instead, the preferred option is to utilise reinforced cardboard boxes that have been specifically sourced for delivery purposes, offering superior structural integrity and protection compared to their generic counterparts. When preparing items for postal delivery, adherence to specific guidelines is paramount to ensure product safety:

- *Initial Layer of Protection: All items must be enclosed within padded envelopes as a baseline requirement. This crucial initial layer safeguards the manufacturer's original packaging from minor damages such as scuffs or dents, maintaining the product's aesthetic and structural integrity.*
- *Enhanced Protection for Most Items: For the majority of postal items, a more robust packaging solution is necessary. This involves comprehensively wrapping the item in bubble wrap, and where appropriate, utilising polystyrene filler to immobilise the contents within reinforced cardboard boxes. This combination provides both cushioning against impact and prevents shifting during transit, minimising the risk of damage.*

- *Fragile or Larger Medications: Larger medications or those identified as particularly fragile necessitate an even higher level of protective packaging. This involves the use of reinforced cardboard boxes, combined with ample bubble packaging, and additional filling material. This multi-layered approach is designed to absorb shocks and prevent damage during handling and transport, ensuring delicate items arrive intact.*

For items requiring strict temperature control, commonly referred to as "cold chain items," a specialised packaging protocol is absolutely essential:

- *Insulation and Cushioning: These items should first be bubble-wrapped to provide an initial layer of insulation and cushioning against physical impact.*
- *Temperature-Controlled Containment: Subsequently, they must be meticulously placed within reinforced cardboard boxes that are filled with Styrofoam. This specialised insulation is crucial for maintaining a stable temperature environment throughout the delivery process, protecting the efficacy and safety of temperature-sensitive medications.*
- *Designated Storage: It is imperative that these cold chain items are stored exclusively in the designated DELIVERIES FRIDGE within the pharmacy, and not in the general storage fridge. This segregation ensures their specific temperature requirements are consistently met, preventing degradation due to improper storage.*
- *Prominent Labelling: Furthermore, packages containing cold chain items must have "FRAGILE" and "FRIDGE LINE" stickers prominently affixed to them. These labels serve as clear indicators for handling and storage instructions, both for pharmacy staff and courier personnel.*
- *Specialised Courier Handling: Courier companies are typically equipped to transport these items in monitored cold chain sections of their vans, commonly maintaining a temperature range of 2-8°C, thereby ensuring the integrity of the cold chain from pharmacy to recipient.*
- *Caution with Cooling Agents: Pharmacy staff must also be acutely aware that certain thermolabile products are susceptible to damage from excessive cold. Therefore, extreme caution should be exercised regarding the use of cooling agents like ice packs, as their improper application can potentially cause freezing and compromise the integrity of such sensitive medications, potentially rendering them ineffective or harmful."*

7.69 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(15) of Schedule 4.

Refusal to provide drugs or appliances ordered

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

7.71 The Committee noted the SOP headed "Repeat Dispensing" as provided by the Applicant with its appeal and in particular the section 'Pharmaceutical & Legal Assessment', in which it stated:

7.71.1 *"This subsection describes the essential professional and legal checks required before dispensing*:

Patient Advice on Need: In accordance with the pharmacy's Terms of Service, patients must be advised to request only the items they genuinely need. This advice can be conveyed through telephone conversations or by including written information with delivered medication.

Pharmacist Consultation (before issuing a repeat): Before each repeat dispensing, the pharmacist is required to consult with the patient remotely to: ○ Confirm that the patient is continuing to use the medicine appropriately and effectively.

Advise the patient to only order the specific items they require, helping to prevent waste.

Enquire about any experienced side effects and provide appropriate advice or intervention.

Verify that there have been no significant changes to the patient's health condition or medication regimen since the initial authorisation of the repeat dispensing service.

Encourage the patient to discuss any concerns or questions they have about repeat dispensing directly with their prescriber.

Interventions & Referrals: Any clinically significant interventions made by the pharmacist (e.g., dosage adjustments, managing side effects), referrals to the patient's GP or other healthcare professionals, or instances where supply is refused, must be meticulously recorded. This information should also be effectively communicated to the patient's GP to ensure continuity of care.

Prescription Validity: The RA must bear the prescriber's signature to be valid. The RDs, while unsigned, are sequentially numbered. The RA explicitly outlines the total number of issues permitted and, if applicable, the specific dispensing interval (e.g., every 28 days). If no interval is specified, pharmacists should exercise their professional judgment to determine appropriate supply dates, always ensuring clinical appropriateness and patient safety."

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

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

7.73 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 a long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term), and (ii) requires regular medicine in respect of that medical condition.

7.74 The Committee noted the SOP headed "Repeat Dispensing" as provided by the Applicant with its appeal in which it stated:

7.74.1 *"Background*

The Repeat Dispensing Service is designed to streamline the prescription process for patients who are on stable, long-term medication. Its core purpose is to eliminate the need for these patients to repeatedly contact their GP for each subsequent refill, thereby simplifying access to their necessary medicines, particularly for a distant selling pharmacy model.

…

The implementation of the Repeat Dispensing Service aims to achieve several key objectives:

Safety and Responsiveness: To provide a secure and continuous supply of medication, while also maintaining the flexibility to promptly address any necessary changes in medication or evolving patient needs.

Promotion: To actively inform eligible patients about the benefits of the service and encourage their enrollment, [sic] ensuring wider adoption and patient access.

…

Prescription Reception

This subsection details the initial stages of receiving a prescription or interacting with a patient regarding repeat dispensing:

Patient Advice: Patients who have long-term, stable medical conditions and require regular medication should be proactively informed about the advantages of repeat dispensing. This advice can be provided through various remote channels to enhance accessibility.

First-Time RA: Upon the initial reception of a repeatable prescription (RA), pharmacy staff are responsible for ensuring that the patient fully

comprehends the repeat dispensing process. The patient must also be provided with a patient information leaflet (PIL) that explains the service in detail.

Key Steps:

Confirm that the patient has a long-term stable medical condition and thoroughly explain the repeat dispensing scheme, addressing any patient queries remotely.

Complete and securely attach a dedicated pharmacy record card to the RA. An entry must be made on this card each time a dispensing occurs, documenting the supply.

Accurately record any amendments or deviations from the original prescription (e.g., items that were not issued, changes to dispensing intervals) in the comment section of the pharmacy's copy of the record card.

Conduct a meticulous check of the RA for any potential errors or omissions that could hinder the dispensing of all subsequent batch prescriptions (RDs).

Retain the original RA securely within the pharmacy. Patients have the option to either leave the batch prescriptions (RDs) with the pharmacy for safekeeping or to retain them themselves."

7.75 Given the above, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.

Disposal service in respect of unwanted drugs

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

7.77 In the SOPs the Committee noted the "Management of Patient-Returned Controlled Drugs" SOP which stated:

7.77.1 *"This SOP covers the collection and disposal of patient-returned CDs, encompassing Schedule 2, 3, 4, and 5 drugs.*

This service is extended to all patients residing in England.

Crucially, patients or their representatives are not permitted to return medicines directly to the pharmacy in person. They must strictly follow the procedures outlined in this SOP, which emphasise remote processes.

Patients should be directed to the "Returning unwanted medication" page on the pharmacy website for comprehensive guidance. This aligns

with GPHC guidance for online pharmacies, which emphasises clear and accessible information for patients regarding all aspects of pharmacy services, including returns.

To arrange the return of unwanted medicines, patients must contact the dispensary team by telephone. For controlled drugs, this call must always be directed to the pharmacist on duty.

The procedure for returning medication should be thoroughly explained to the patient, reinforcing the remote nature of the process.

Returns will be facilitated either by booking an appointment for the pharmacy's driver to collect the medication from the patient's home, or by sending appropriate packaging to the patient for return via CitySprint. It is important to note that while the CitySprint website prohibits carrying "controlled drugs," this refers only to illicit controlled drugs and not those supplied under a physician's direction. This aligns with the T34 exemption under the Misuse of Drugs Regulations 2001, which allows for the lawful return of prescribed controlled drugs through authorised postal services.

Patients must understand that sharps and clinical/contaminated waste cannot be returned and they should follow local procedures for their disposal.

Patients must be informed that cytotoxic, hazardous waste, and CDs, if possible, should be separated before returning to the pharmacy.

Patients should be advised to label the unwanted medication package "Z Returns" for easy identification. The packaging must not identify the contents as controlled drugs or any other type of drug to maintain security and discretion, in line with GPHC expectations for secure handling.

Appropriate packaging must be sent to patients for the return of hazardous medicines, as inadequate packaging may compromise safety.

Patients should be informed of alternative disposal options for unwanted or expired medication if a suitable collection time cannot be arranged. Patients are permitted to return medication to their local pharmacy if necessary, but direct returns to this pharmacy are prohibited.

CitySprint Returns Process

The pharmacist must: ○ Speak with the patient to clarify the items being returned, ensuring no face-to-face contact.

Assess the items for suitability for return via CitySprint .

If items are suitable, record this on the Patient Medication Record (PMR) and arrange to send appropriate packaging for

safe return (refer to the Prescription Bagging and Dispatch SOP for packaging details).

If items are not suitable (e.g., clinical or contaminated waste), provide the patient with details of local disposal procedures.

Send the packaging to the patient along with instructions for appropriate packing.

Contact the patient to confirm receipt of the packaging.

Provide information on other pharmacies where the patient may prefer to dispose of unwanted medicines locally.

Managing Patient-Returned CDs Received from Delivery Drivers

Drivers are required to:

Be aware that they cannot accept patient returns without prior arrangement. Drivers should instruct patients to follow the "returning unwanted medication" process outlined on the website, reinforcing the no direct return policy.

Ensure appropriate packaging is available in the van before starting the journey, as the patient may not have requested the correct type or additional packaging may be required."

7.78 The Committee also noted the SOP "Safe and Effective Disposal of Returned and Expired Medicines" which states:

7.78.1 *"Patient Guidelines for Returning Medication:*

Patient-Initiated Returns:

Patients or their representatives are not permitted to return medicines directly to the pharmacy in person and must follow the procedures outlined in this SOP.

This service is available to all patients residing in England.

Patients can find further information on the "Returning unwanted medication" page of the pharmacy's website.

To arrange the return of medication, patients must contact a member of the dispensary team by telephone.

Accepted Return Methods for Patients:

Patients can schedule a collection by the Pharmacy driver at a pre-arranged time.

Patients can send unwanted medication back to the Pharmacy via courier (at the pharmacy's expense) or CitySprint (subject to a pre-assessment of contents by the Responsible Pharmacist for suitability).

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

Patients will be informed of alternative options for disposing of unwanted or expired medication if none of the above options are suitable (e.g., signposting to local pharmacies)."

7.79 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 13 – 15 of Schedule 4.

Promotion of Healthy Lifestyles

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

7.80.1 *"Patient identification can be passive, active, or occur during the repeat (or normal) dispensing process.*

***Active patients** are those who complete Lifestyle Questionnaires via the website or post. Based on the results, they are identified for further information, follow-up calls, and additional support. All patients receiving prescriptions or purchasing medicines are asked to complete this questionnaire, providing details on medical conditions, height, weight, smoking status, and exercise habits.*

***Passive patients** are identified through other interactions, such as dispensing a prescription that indicates conditions like high blood pressure or diabetes, where the patient isn't actively seeking assistance.*

***During repeat dispensing or other patient interactions**, staff should record information provided by patients on the PMR system. If the information suggests a patient would benefit from healthy lifestyle promotion, they should be marked as a "target patient" and provided with relevant information.*

Leaflets will be delivered with medication. Patients identified with or at risk of conditions like diabetes, coronary heart disease, COPD, asthma, high blood pressure, or being overweight will receive targeted campaigns. The website, app, and email newsletters will also be utilised for health promotion. If appropriate, the patient's Summary Care Record can be accessed to help identify areas for advice."

7.81 Based on the information before it, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 16 - 18 of Schedule 4.

Prescription Linked Intervention

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

7.83 The Committee noted SOP "Promoting Healthy Lifestyles and Managing Long Term Conditions" which states:

7.83.1 **"*Support for Long-Term Conditions***

If appropriate, the pharmacist should provide advice within their competency, recording it on an Intervention & Referral form. This advice should always include counselling on healthy lifestyle in addition to managing the long-term condition. If advice is not appropriate, the patient should be referred to a suitable health or social care provider or support organization (referencing the Signposting SOP), with the referral recorded on the Intervention & Referral form.

For specific patient groups (those with diabetes, at risk of coronary heart disease, especially with high blood pressure, and patients who smoke or are overweight), pharmacists must provide advice without face-to-face interaction. This includes communication via telephone, live video, or the website. Such advice should be supplemented with written materials like leaflets as appropriate.

Identifying Patients for Long-Term Condition Support

Patient identification for long-term condition support follows the same three forms: passive, active, or as part of the repeat (or normal) dispensing process.

***Active patients** are those who complete Lifestyle Questionnaires via the website or post. Based on the results, they are identified for further information, follow-up calls, and additional support. All patients receiving prescriptions or purchasing medicines are asked to complete this questionnaire, providing details on medical conditions, height, weight, smoking status, and exercise habits.*

***Passive patients** are identified through other interactions, such as dispensing a prescription that indicates conditions like high blood pressure or diabetes, where the patient isn't actively seeking assistance.*

***During repeat dispensing or other patient interactions**, staff should record information provided by patients on the PMR system. If the information suggests a patient would benefit from healthy lifestyle promotion, they should be marked as a "target patient" and provided with relevant information.*

Leaflets will be delivered with medication. Patients identified with or at risk of conditions like diabetes, coronary heart disease, COPD, asthma, high blood pressure, or being overweight will receive targeted campaigns. The website, app, and email newsletters will also be utilised

for healthy lifestyle promotion. If appropriate, the patient's Summary Care Record can be accessed to help identify areas for advice."

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

Health Campaigns

7.85 The Committee considered whether the Applicant had explained how it will safely and effectively participate in health campaigns, if and to the extent required by the Commissioner.

7.86 The Committee noted SOP "Promoting Healthy Lifestyles and Managing Long Term Conditions" under the heading 'Health Campaigns and Community Engagement' which states:

7.86.1 *"The pharmacy is required to participate in up to six campaigns per financial year and should aim to join all practicable campaigns. Participation in national health campaigns involves sending leaflets with prescriptions during targeted periods and offering additional advice and learning resources on the website's health promotion zone.*

The pharmacy will also engage in at least one approved community engagement exercise related to health promotion annually. Patients will be directed to learning resources via email, text, and other non-face-to-face communication to ensure campaign awareness.

Patients should also be assessed for participation in at least one clinical audit and any specified policy-based audit by the NHSCB, ensuring compatibility with their data processing arrangements. The pharmacy's website will offer help and support, directing patients to appropriate links for health campaigns, making information accessible across the UK at all times.

When dispensing prescriptions for patients with conditions such as diabetes, heart disease, obesity, and high blood pressure, health advice will be offered over the phone or through leaflets. Patients can also speak to the pharmacist about campaigns. Advice and help are available during opening hours, and information on the website is accessible continuously, ensuring uninterrupted service provision across England."

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

Signposting

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

7.89 The Committee noted SOP "Remote Patient Support, Self-Care, Signposting, and Health Promotion SOP" which states:

7.89.1 "*Remote Signposting: Where appropriate, the pharmacist should remotely signpost patients to other health and social care providers, in line with the "Signposting" service, ensuring patients receive comprehensive support.*

External Support Organisations and Contact Information

Details of local health and social care providers suitable for patient referrals, along with contact information for local patient and support groups, will be made available to patients through remote channels. This includes written mailshots (digital), flyers sent with prescription deliveries, the pharmacy website, and via telephone or email communication."

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

Support for Self-Care

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

7.92 The Committee noted SOP "Remote Patient Support, Self-Care, Signposting, and Health Promotion SOP" which states:

7.92.1 *"Remote Support for Self-Care: Service Overview*

This service focuses on pharmacy staff providing advice and support through remote channels to enable individuals to gain maximum benefit from self-managing their own health or that of their families. This encompasses guidance on over-the-counter medicines, lifestyle interventions, and general health information, all delivered without face-to-face interaction, adhering to GPhC guidance on remote consultations."

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

Discharge Medicines Service

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

arrangements linked to the transfer of care between different providers of NHS services.

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

7.96 The Committee noted the SOP "Discharge Medicines Service (DMS)" which stated:

7.96.1 *"The Discharge Medicines Service (DMS) outlines a comprehensive, three-stage process designed to optimise medication use, reduce harm, and improve patient understanding following discharge from NHS hospitals or transfers of care between NHS service providers. This service requires community pharmacies to provide assistance and support to referred patients, primarily focusing on medication regimen changes. Clinical judgement and patient confidentiality are paramount throughout all stages.*

Individual DMS Stages in detail:

While the service is structured in three stages, it is expected that all referred patients will receive all three. Stages may occur in parallel, and initial patient contact can happen at any point in the process.

Stage 1: Clinical Review Prior to Prescription Receipt

This initial stage focuses on a proactive clinical review by a community pharmacist upon receiving a patient referral.

Referral Analysis: The pharmacist undertakes a comprehensive clinical review of the patient referral, assessing the appropriateness of any requested actions.

Information Gathering:

The patient's Summary Care Record (SCR) should be accessed if it can aid in service provision.

Medications listed at discharge are to be compared, as far as possible, with those the patient was taking before hospital admission.

Any prescriptions already issued for dispensing, or awaiting delivery (especially electronic repeatable prescriptions), should be checked for appropriateness.

Issue Identification and Resolution: ○ The pharmacist must critically assess whether prescribed medication changes are appropriate.

Concerns, such as the omission of an important medicine, should be identified and discussed with the referring NHS trust

or the Primary Care Network (PCN) pharmacy team for clarification.

Where necessary and clinically appropriate, issues of concern should be raised with the staff of the referring hospital/NHS service provider and/or the patient's GP.

Record Keeping: Detailed records of all DMS referrals received and actions taken must be maintained to support subsequent stages of the service.

Stage 2: Review Upon First Prescription Receipt Post-Discharge

This stage commences upon the pharmacy's receipt of the patient's first prescription following discharge or care transfer, either directly referred from Stage 1 or if the pharmacy is otherwise aware of it being the first post-discharge prescription and the patient/carer desires Stage 2.

Prescription and Medication Regimen Review:

The pharmacist performs a thorough review of the prescription.

The patient's SCR should be accessed if appropriate.

Specific consideration must be given to whether appropriate account has been taken of any changes in the medication regimen during the patient's hospital stay or prior to the transfer of the DMS from another pharmacy.

The discharge referral should be compared with the first post-discharge prescription.

Actions recommended from Stage 1 should be reviewed.

Issue Resolution:

Discrepancies or areas of concern should be raised with the patient's GP, utilising existing communication channels.

Alternatively, the community pharmacist may refer the patient to the PCN pharmacy team for a Structured Medication Review or other intervention if deemed necessary.

Patient Engagement for Stage 3:

Consideration should be given to making an appointment for the Stage 3 service with the patient or carer, requesting that they have all their medicines ready for the consultation.

Record Keeping:

Comprehensive records of all actions taken during Stage 2 must be maintained, particularly to support the delivery of Stage 3.

Stage 3: Patient/Carer Engagement and Understanding Check

This stage focuses on direct patient or carer involvement, fostering shared decision-making regarding the patient's medication regimen.

Appointment Management:

The pharmacy diary should be checked daily for scheduled remote appointments and reminders.

Prior to the intervention, the patient's medication history and actions from Stages 1 and 2 should be reviewed.

The patient's SCR should be accessed if appropriate.

A reminder should be sent to the patient/carer.

Consultation Conduct:

The service should ideally be conducted via live video call; an audio call is acceptable if video is unavailable.

Discussions must occur in a private area to ensure patient confidentiality.

The patient/carer should be welcomed and made to feel at ease.

Patient identity (date of birth, postcode) and consent for information sharing and understanding of the service should be confirmed.

It should be emphasised that the service is supportive, not a test.

Medication Understanding Assessment:

The pharmacist or pharmacy technician should facilitate a discussion to assess the patient's (or carer's) understanding of their condition(s), associated medications, and optimal administration methods to maximise benefit and minimise side effects.

The patient's understanding of their medicines, how they should be taken, and any changes should be actively listened for, avoiding leading questions. Notes should be taken.

The patient's understanding of their medicines should be compared with the hospital's discharge list, and any discrepancies recorded.

All medicines and charts should be reviewed, highlighting any stopped, started, or changed medications, with particular attention to areas of poor understanding.

Issue Resolution and Support:

Any adherence issues, clinical concerns, outstanding questions, or unmet needs regarding the patient's medicines should be identified.

Action Planning:

Minor issues can be resolved directly with the patient.

The GP should be contacted if an amendment or intervention is required.

The hospital should be contacted if hospital intervention is needed.

The patient/carer must be involved in decision-making, and their agreement should be secured.

If no issues are identified, medication should be dispensed according to Standard Operating Procedures (SOP), and counselling provided on hospital-initiated changes.

The appropriateness of compliance aids should be considered.

Common or expected side effects of new medications or interactions should be discussed.

Information on other available pharmacy services (including no-cost options) should be provided.

The Unwanted Medicines Disposal Service should be explained to address medicine wastage, especially for drugs no longer prescribed but still at the patient's home.

For injectable medications, confirmation should be sought regarding appropriate self-administration training from their GP practice nurse or hospital, if applicable.

Follow-up and Documentation:

Further questions from the patient should be addressed, and agreed actions and follow-up (if necessary) confirmed.

The need for and [sic] arrangement of further reviews should be considered.

All discussions, concerns, and actions undertaken as part of this service must be accurately recorded in the patient's electronic record to assist in service evaluation processes."

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

Website and health promotion zones

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

7.99 As well as various references throughout the SOPs and procedures to having a fully functioning website for use by the public, the Committee further noted SOP "Remote Patient Support, Self-Care, Signposting and Health Promotion" which states:

7.99.1 ***"10. Digital Health Promotion Zone***

The pharmacy website will feature a dedicated "Health Promotion Zone," an interactive page enabling patients to access pharmaceutical services and up-to-date materials promoting healthy lifestyles.

10.1. Interactive Page for Patients

The interactive page will be prominently promoted on the website, ensuring that new visitors are immediately directed to a range of relevant and current health information.

The Superintendent Pharmacist is responsible for curating a reasonable and diverse range of materials accessible through the interactive page, addressing a broad spectrum of health issues and aligning with public health campaigns promoted by UK health authorities.

The health promotion zone will also include details of current health campaigns, other information to encourage healthy lifestyle choices, and provide secure access to the Lifestyle Questionnaire, which is [sic]"

7.100 The Committee noted the reference in the SOP "Promoting Healthy Lifestyles and Managing Long-Term Conditions" which states "*Participation in national health campaigns involves sending leaflets with prescriptions during targeted periods and offering additional advice and learning resources on the website's health promotion zone."*

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

Summary

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

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

7.103.1 confirm the Commissioner's decision;

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

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

7.104 In those circumstances, as the Committee reached a different decision to that of the Commissioner, the Committee determined that the decision of the Commissioner must be quashed.

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

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

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

8 Decision

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

8.2 The Committee:

8.2.1 quashes the decision of the Commissioner; and

8.2.2 redetermines the application as follows -

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

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

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

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

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

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

8.2.3 The application is granted.

Case Manager
Primary Care Appeals