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

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

REF: SHA/26950

APPEAL AGAINST BIRMINGHAM AND SOLIHULL ICB DECISION TO REFUSE AN APPLICATION BY STAG CHEMIST BIRMINGHAM LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT UNIT 11 FIRST FLOOR, 537-539 COVENTRY ROAD, SMALL HEATH, BIRMINGHAM, B10 0LL 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:

Rushport Advisory for Stag Chemist Birmingham Ltd
PCSE on behalf of Birmingham and Solihull ICB

NHS Resolution

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1 The Application

By application dated 19 June 2025, Stag Chemist Birmingham Ltd ("the Applicant") applied to Birmingham and Solihull ICB ("the Commissioner") for inclusion in the pharmaceutical list at Unit 11 First Floor, 537-539 Coventry Road, Small Heath, Birmingham, B10 0LL under Regulation 25. In support of the application it was stated:

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

1.2 "Drug Tariff Part IX - Except items which require measuring or fitting."

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

1.4 "Not applicable as the application is NOT adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises."

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

1.6 "Not applicable as the application is NOT on the same site or in the same building as the premises of a provider of primary medical services with a patient list."

Pharmacy procedures

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

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

(b) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on

their own or someone else's behalf, and the applicant or the applicant's staff.

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

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

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

1.11 “Please see attached further information.”

Additional information:

1.12 “Further information regarding the provision of essential services in accordance with regulations for distance selling pharmacies – chapter 18 annex 1 part 7.

1.13 The following information, approved by the applicant, explains how the pharmacy procedures used within the premises will secure:

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

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

1.14 The premises standards and particulars published by NHS England will be complied with by the pharmacy, however not all of these standards directly apply to distance selling pharmacies except where a patient is accessing non-essential services.

1.15 The pharmacy will operate as a Healthy Living Pharmacy (HLP) and will meet the applicable NHS England premises standards and comply with the change management and organisational development criteria, ensuring that facilities are fit for purpose and designed to promote health and wellbeing. While not all NHS premises standards apply to Distance Selling Pharmacies (DSPs), we will adhere to those relevant to our model of care.

1.16 Premises:

1.17 The pharmacy premises will be equipped to facilitate private and secure communication, including telephone and live audio links and secure video consultations.

1.18 These methods ensure high standards of patient confidentiality and accessibility from any location in England.

1.19 All operations will strictly follow the General Pharmaceutical Council (GPhC) standards for internet and distance pharmacy services, including:

1.19.1 Remote consultation protocols

1.19.2 Robust risk management and SOPs

1.19.3 Information security and patient confidentiality

1.19.4 Safe supply and delivery of medicines

1.20 Our approach has been designed to reflect GPhC expectations and will evolve in line with updated regulatory guidance.

1.21 The following will be in place prior to opening:

1.21.1 A comprehensive risk assessment and matrix will be in place prior to opening. This will identify potential risks to patient safety and service delivery, alongside the controls needed to mitigate them.

1.21.2 Reviews will take place quarterly or sooner if there are significant business, regulatory, or operational changes.

1.21.3 The goal is to ensure safe, continuous service for all patients accessing the pharmacy remotely.

1.22 A structured audit programme will help verify that services remain compliant, effective, and patient-centred.

1.23 Audits will cover, at a minimum:

1.23.1 Staffing levels and training adequacy

1.23.2 Website content accuracy and transparency

1.23.3 Communication systems (with patients, within teams, and with healthcare partners)

1.23.4 Prescription receipt and processing systems (including EPS)

1.23.5 Decision records for refusal or accepting a sale

1.23.6 Delivery protocols and secure handover mechanisms

1.23.7 Information security (including GDPR and PCI DSS compliance)

1.23.8 Feedback and complaints management

1.23.9 Third-party activity (e.g. couriers, IT providers)

1.24 Audit findings will guide service improvements and training enhancements.

1.25 In addition to regular audits, reactive reviews will be triggered in cases such as:

1.25.1 Major changes in law or service scope

1.25.2 Patterns observed in error logs or complaints

1.25.3 Concerns raised by patients or regulators

1.25.4 Data breaches or technology failures

1.26 These reviews ensure that the pharmacy can respond swiftly and responsibly to emerging issues.

1.27 The pharmacy will always have a Responsible Pharmacist (RP) present during operational hours. Clear lines of responsibility and accountability will be defined for all team members, under the leadership of the Superintendent Pharmacist. This ensures operational clarity and regulatory compliance at all times.

1.28 All records will be digitally stored in the pharmacy's secure IT system, including (but not limited to):

1.28.1 Dispensing records

1.28.2 Patient consent forms

1.28.3 Complaints and sale refusals

1.28.4 Communications and queries

1.29 Records will be retained for at least seven years, or longer where required by legislation.

1.30 All staff involved in the provision of pharmacy services will:

1.30.1 Receive structured training based on GPhC guidance

1.30.2 Be competent and confident in delivering remote services safely

1.30.3 Undergo regular performance and skills reviews

1.31 Training will be delivered via accredited providers and in-house sessions, with ongoing assessments to ensure high performance and patient safety.

1.32 The pharmacy premises will be registered with the GPhC prior to commencing operations and will meet all the regulatory requirements for a Distance Selling Pharmacy. Access to the premises by the general public will not be permitted, in line with DSP regulations.

1.33 The premises will be secure, with:

1.33.1 Controlled entry

1.33.2 Designated areas for storage, preparation, and dispatch

1.34 Facilities for confidential communications

1.35 The pharmacy website will comply with data protection laws and cybersecurity best practices. It will include:

1.35.1 Secure data entry for patient information and card payments

1.35.2 Clear service descriptions

1.35.3 Up-to-date health resources for the public

1.35.4 Interactive features promoting healthy lifestyles, as required by current NHS DSP regulations

1.36 It will also display:

1.36.1 GPhC registration details as follows:

1.36.1.1 GPhC pharmacy registration number

1.36.1.2 name of the owner of the registered pharmacy

1.36.1.3 name of the superintendent pharmacist

1.36.1.4 name and address of the registered pharmacy that supplies the medicines details of the registered pharmacy where medicines are prepared, assembled, dispensed and labelled for individual patients against prescriptions (if any of these happen at a different pharmacy from that supplying the medicines)

1.36.1.5 information about how to check the registration status of the pharmacy and the superintendent pharmacist

1.36.2 Contact details for feedback and complaints

1.36.3 Email address and phone number for the pharmacy

1.36.4 Information on services such as returns, emergency supply, exemption registration, and public health campaigns

1.36.5 Required logos, including the GPhC internet pharmacy logo (linked to GPhC register) and any UK-specific online medicine sale markings.

1.37 The pharmacy will provide access to its services through a dedicated website that includes a prominently displayed interactive page. This page, visible upon the user's first visit, will offer a broad selection of current resources promoting healthy lifestyles and addressing a wide range of public health topics.

1.38 In accordance with updated regulatory requirements, this provision applies solely to access via the website. The pharmacy will not offer face-to-face access to essential services at its premises.

1.39 We will clearly communicate:

1.39.1 The range and nature of services offered

1.39.2 Who is providing each service

1.39.3 Whether services are delivered by the main pharmacy site or another registered location

1.40 This promotes patient trust and enables informed decision-making.

1.41 Governance:

1.42 All processes related to the handling and supply of medicines will follow robust Standard Operating Procedures (SOPs) designed to:

1.42.1 Minimise risks to patients

1.42.2 Ensure compliance with legal and clinical standards

1.42.3 Support accurate and secure dispensing, packaging, and delivery

1.43 Staff will be trained to follow these procedures consistently, with oversight from the Responsible Pharmacist and Superintendent Pharmacist.

1.44 Medicines will be supplied using secure, traceable delivery methods, including:

1.44.1 The pharmacy's own delivery driver

1.44.2 Royal Mail or courier services for national coverage and cold-chain product supply.

1.45 Procedures will include:

1.45.1 Verifying patient identity upon delivery

1.45.2 Assessing the most suitable delivery method (e.g., tamper-evident or temperature controlled packaging)

1.45.3 Monitoring third-party providers through patient feedback and service audits

1.46 Every delivery will be handled in a way that ensures the integrity, safety, and confidentiality of the medicines.

1.47 All pharmacy equipment will be sourced from reputable manufacturers and will be fit for its intended purpose.

1.48 To ensure ongoing reliability and accuracy:

1.48.1 Annual performance checks will be conducted for general equipment

1.48.2 Monthly reviews will apply to specialised tools, such as temperature monitoring systems

1.48.3 IT infrastructure will use secure, encrypted connections for both wired and wireless access

1.48.4 Access to systems will be role-restricted, managed by the Superintendent Pharmacist to ensure data integrity and security.

1.49 A complete set of SOPs will govern all pharmacy operations, including the provision of NHS Essential Services. These SOPs:

1.49.1 Align with NHS regulations, GPhC standards, and data protection laws

1.49.2 Will be regularly reviewed and updated to reflect best practices and any regulatory changes

1.49.3 Where required, relevant SOPs will be provided to NHS England on request to demonstrate compliance and operational readiness.

1.50 All essential services will be delivered in accordance with:

1.50.1 Company SOPs

1.50.2 GPhC Guidance on Distance Selling

1.50.3 The Human Medicines Regulations 2012

1.50.4 The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

1.50.5 The NHS Act 2006

1.50.6 Applicable Data Protection legislation

1.51 This governance structure ensures that patients anywhere in England receive safe, effective, and uninterrupted care without requiring face-to-face contact.

1.52 Procedures:

1.53 To comply with Distance Selling Pharmacy regulations, all NHS Essential Services will be provided exclusively via remote channels. Members of the public will not be permitted to access services on-site.

1.54 Patients and their representatives will be able to access support and services using the following methods:

1.54.1 Telephone

1.54.2 Live video consultations

1.54.3 Secure website forms and interactive features

1.54.4 Email correspondence

1.54.5 Postal services

1.54.6 The website will be designed to provide clear, simple instructions for accessing services remotely. It will also include options for secure communication and information submission.

1.55 Essential Services will be delivered through a range of systems, including:

1.55.1 Electronic Prescription Service (EPS)

1.55.2 Telephone

1.55.3 Text messaging (where appropriate)

1.55.4 Courier and Royal Mail services for medication dispatch

1.55.5 Specialist cold-chain couriers for temperature-sensitive medicines

1.55.6 Waste management firms for collection of returned or unwanted medicines

1.56 All NHS services will be provided free of charge, in line with the NHS Act 2006.

1.57 This approach ensures that patients across England can access safe and reliable pharmacy services without any face-to-face contact.

1.58 Prescriptions will be received through the Electronic Prescription Service (EPS), by post, or, where appropriate and with informed patient consent, collected from GP surgeries.

1.59 Each prescription will be:

1.59.1 Clinically and legally reviewed by a pharmacist before dispensing

1.59.2 Followed up with the prescriber if any discrepancies or concerns arise (e.g. drug interactions, dosage issues)

1.60 Where pharmacist interventions take place such as drug interactions, the pharmacist will telephone the prescriber and patient to discuss the appropriate intervention before dispensing and dispatching the prescription.

1.61 The pharmacy will follow defined SOPs to resolve issues promptly and avoid delays in patient care.

1.62 Where patients have long-term, stable conditions requiring regular medication, we will:

1.62.1 Promote the benefits of repeat dispensing

1.62.2 Provide remote advice to patients to encourage discussions with their GP where appropriate

1.62.3 Collaborate with patients, carers, and prescribers to ensure continuity of supply and adherence

1.62.4 Offer additional telephone-based consultations if concerns arise during repeat dispensing.

1.63 We will also support patients requiring compliance aids (e.g., monitored dosage systems, blister packs) in line with the Equality Act 2010, following an individual needs assessment.

1.64 While less common in a DSP setting, the pharmacy will be equipped to manage urgent and emergency supply requests, either:

1.64.1 From a prescriber, where conditions for urgent supply are met (including a written prescription within 72 hours)

1.64.2 From a patient, following an appropriate clinical interview via phone or video (in place of face-to-face contact)

1.65 Key procedures include:

1.66 Ensuring the medication is allowed to be supplied in an Emergency Supply situation eg. emergency supply cannot be provided for a Schedule 1, 2 or 3 CD except for Phenobarbital used for epilepsy.

1.67 Full documentation in the POM register with “Emergency Supply” clearly indicated

1.68 Use of the emergency supply protocol if no valid prescription is present

1.69 Prioritised delivery, marked as “Urgent,” with no additional cost to the patient

1.70 Faxed or scanned prescriptions will not be accepted as legally valid and will not be used to dispense medication. Emergency supply procedures will be followed instead.

1.71 Service Provision:

1.72 Disposal of unwanted medicines:

1.73 Patients will have access to several secure, convenient options for returning unwanted medication:

1.73.1 Collection by a specialist waste management service from patients and care homes.

1.73.2 Prepaid courier return (cost managed by pharmacy), available for patients who prefer to send items back.

1.73.3 Home or workplace collection for patients in the local area by pharmacy staff, arranged by phone or email

1.74 Appropriate packaging and instructions will be sent in advance. Upon return, items will be sorted and safely stored for disposal in line with waste regulations.

1.75 Healthy Lifestyle Promotion:

1.76 The pharmacy will promote healthy living through both active and passive methods:

1.76.1 Active identification: Patients completing lifestyle questionnaires via the website or post will be assessed and, if appropriate, contacted for further support

1.76.2 Passive identification: Patients identified through other services (e.g. prescription for diabetic or hypertension medication) will receive tailored information

1.77 Health promotion materials will be delivered:

1.77.1 With medication (printed leaflets)

1.77.2 Via email, text, or website links

1.78 As part of targeted campaigns on conditions such as:

1.78.1 Diabetes

1.78.2 Weight management

1.78.3 Smoking cessation

1.78.4 Cardiovascular health

1.78.5 Asthma and COPD

1.79 National Health Campaigns:

1.80 The pharmacy will support national NHS health campaigns by:

1.80.1 Including campaign materials in prescription deliveries

1.80.2 Promoting relevant advice through the website

1.80.3 Directing patients to further resources via text, email, and web-based notifications

1.81 The pharmacy will participate in NHS-specified audit activities, including:

1.81.1 At least one clinical audit per year, compliant with NHSCB (NHS Commissioning Board) requirements

1.81.2 A policy-based audit, where specified, to inform NHS commissioning and improve service delivery

1.82 Audits will follow secure data-handling procedures and be compatible with NHS systems for data sharing and reporting.

1.83 Signposting and Self Care:

1.84 Pharmacists will assess each patient's needs and, where necessary, signpost them to appropriate services, including:

1.84.1 NHS or local authority health and social care services

1.84.2 Support organisations or helplines

1.84.3 Other pharmacies or healthcare providers

1.85 Advice will be offered remotely, based on an "active or passive" identification process. If the pharmacy cannot provide a specific service or product, patients will be supported in finding a suitable alternative provider.

1.86 Appliance Referrals:

1.87 If a prescription is received for an appliance or stoma product outside the pharmacy's usual scope:

1.87.1 With the patient's consent, the prescription will be referred to another NHS pharmacy or appliance contractor

1.87.2 If consent is not given, the patient will be provided with contact details for at least two alternative providers (where known)

1.88 All referrals and advice will be recorded, where appropriate, to ensure transparency and continuity of care.

1.89 Support for patients with disabilities:

1.90 The pharmacy is committed to fulfilling its obligations under the Equality Act 2010.

1.91 Reasonable adjustments will be made to support patients who have difficulty managing their medicines, including:

1.91.1 Offering compliance aids such as monitored dosage systems or blister packs

1.91.2 Conducting remote assessments with the patient, carer, or representative to determine support needs

1.91.3 Providing tailored solutions that promote medication adherence without requiring face-to face visits

1.92 Both Level 1 (patient responsible for taking medication) and Level 2 (carer responsible for patient taking medication) compliance aid services will be available, based on the outcome of the assessment.

1.93 Clinical Governance:

1.94 While not classified as an Essential Service, the pharmacy will implement full clinical governance processes to ensure high-quality care. This includes:

1.94.1 Use of SOPs and incident reporting systems

1.94.2 Participation in workforce surveys and clinical audits

1.94.3 Staff engagement in regular CPD (for registered professionals) and training

1.94.4 Procedures for drug recalls and risk management

1.94.5 A clear complaints procedure accessible via the website and on request by phone or post

1.95 All staff will either be fully qualified or enrolled in accredited training programmes, with annual appraisals and continuous development support.

1.96 Information Governance:

1.97 The pharmacy will fully comply with:

1.97.1 UK GDPR and the Data Protection Act

1.97.2 The Access to Health Records Act 1990

1.97.3 NHS data protection and confidentiality standards

1.98 Key information governance measures include:

1.98.1 Secure storage and handling of patient data

1.98.2 A published Freedom of Information Publication Scheme (available via the website or by request)

1.98.3 Role-based access controls for all digital systems

1.98.4 Regular updates and IT security checks

1.99 The NHSmail account will be monitored daily, including for Discharge Medicines Service (DMS) referrals and urgent communications.

1.100 Discharge Medicines Service:

1.101 Upon referral, the pharmacy will deliver the three-stage DMS to eligible NHS patients who are:

1.101.1 Recently discharged from hospital, or

1.101.2 Transferred between care settings, with updated medication regimens

1.102 The service will involve:

1.102.1 Reviewing discharge information

1.102.2 Providing clinical support to patients and, where appropriate, carers

1.102.3 Liaising with GPs or other providers if concerns arise

1.102.4 Ensuring continuity of care and safe medication use

1.103 Clinical judgement will guide the pharmacist's approach, always respecting patient confidentiality when involving third parties.

1.104 Pandemic Treatment Protocol (PTP):

1.105 If activated, the pharmacy will support NHS Pandemic Treatment Protocols by:

1.105.1 Supplying medications under approved emergency frameworks

1.105.2 Informing patients of estimated delivery times and dispatch updates

1.105.3 Clearly labelling medicines as supplied under the relevant PTP protocol

1.106 The pharmacy may refuse supply if:

1.106.1 The request appears illegitimate

1.106.2 It conflicts with the pharmacist's clinical judgement

1.106.3 Threats or abusive behaviour occur

1.106.4 The request is not compliant with the protocol

1.107 Any refusal will be documented in the pharmacy system.

1.108 Deliveries:

1.109 The Responsible Pharmacist (RP) will oversee the entire delivery process to ensure that medicines reach patients safely and promptly. Key delivery principles include:

1.109.1 Secure packaging with tamper-evident seals

1.109.2 Delivery tracking and audit trail, from dispatch to receipt

1.109.3 Signed-for receipt by the patient, their carer, or an authorised representative

1.109.4 Confidential packaging to protect patient privacy

1.110 Delivery methods:

1.111 Local deliveries: Conducted by the pharmacy's own driver

1.112 National deliveries: Via Royal Mail Tracked Delivery or trusted couriers

1.113 Cold-chain medicines: Delivered using pharma-grade, temperature-controlled couriers with full monitoring

1.114 If a patient is unavailable, a non-delivery notice will be left, and redelivery arranged at no extra cost.

1.115 Cold-chain Integrity:

1.116 Items will be packaged in styrofoam-lined boxes or other suitable packaging with temperature stability ensured.

1.117 Products will never come into direct contact with ice packs to prevent freezing damage.

1.118 Any breach in the cold chain will trigger a failed delivery protocol, and affected items will not be reused

1.119 Controlled Drugs:

1.120 CDs may be delivered by couriers as legislation covers instances where CDs may be temporarily handled by the third-party eg. Delivery driver or courier where the CD is being transferred from the pharmacy to the patient. Couriers will meet specific quality and validation requirements such as an appropriate Home Office authorisation and storage capabilities.

1.121 The pharmacy will maintain full compliance with CD delivery regulations, ensuring that custody of the medication remains within legally permissible bounds.

1.122 Returned CDs:

1.123 Patients will be provided with advance instruction on how to return unwanted CDs or where appropriate, signposted to another pharmacy if the patient prefers.

1.124 CDs will be denatured and destroyed promptly in accordance with SOPs

1.125 Destruction will be witnessed and recorded in a designated CD destruction register

1.126 Returned CDs will never be reused or re-entered into stock

1.127 Contingency Planning:

1.128 To ensure continuity of service during disruptions (e.g. medicine shortages, postal strikes, EPS downtime), the pharmacy will implement a robust contingency plan, including:

1.129 A second pharmacist who can assume the role of RP if the first pharmacist requires a break

1.130 Multiple accounts with full-line and short-line wholesalers

1.131 Direct supply arrangements with manufacturers

1.132 Alternative delivery routes and communication channels

1.133 These measures will help maintain safe, uninterrupted patient care under all circumstances.

1.134 Patient Prescription Exemption:

1.135 The pharmacy will follow all NHS requirements regarding the verification of prescription exemptions:

1.136 Patients (excluding those exempt by age) must complete the exemption declaration in black ink

1.137 Evidence of exemption can be submitted:

1.137.1 Via the delivery driver

1.137.2 By scanned copy through email

1.137.3 By post or prepaid courier, with return postage covered by the pharmacy

1.138 If original documentation is not provided, the pharmacist will assess whether the evidence is satisfactory. If not, the “Evidence Not Seen” box will be ticked.

1.139 Exemption type and expiry date will be recorded in the patient’s medication record (PMR)

1.140 Patients who are not exempt can pay securely via the website’s online payment portal and the prescription will be marked as paid.

1.141 Information Updates:

1.142 The pharmacy’s NHS Digital Directory of Services profile will be actively maintained and kept up to date

1.143 MHRA Central Alerting System emails will be monitored daily via the NHSmail account to respond promptly to recalls or alerts

1.144 GPhC Registration:

1.145 The pharmacy and superintendent pharmacist will be registered with the General Pharmaceutical Council (GPhC) following approval of the NHS contract. No services will begin until a premises inspection has been successfully completed.

1.146 Practice Leaflet:

1.147 The pharmacy’s practice leaflet, website, and promotional materials will:

1.147.1 Not suggest services are restricted to specific areas or patient groups

1.147.2 Avoid language implying any refusal to supply based on location or patient type

1.147.3 Emphasise that services are available to anyone in England, as required by regulations.

1.148 Advanced and Enhanced Services:

1.149 Only those services that can be safely delivered remotely will be offered. No service will require a patient to visit the premises in person.

1.150 Missing information regarding DSP application following NHS Regulations 2013 Regulation 25 amendment

1.151 All information in this document is in addition to the content submitted in our original “Further Information” document.

1.152 In accordance with the amended Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, we confirm that all pharmaceutical services, will be delivered exclusively via remote methods such as telephone, video consultation, or secure digital communication. There will be no face-to-face contact at or in the vicinity of the pharmacy premises.

1.153 The New Medicine Service (NMS) is the only Advanced Service the pharmacy currently plans to offer, and every stage of the service will be delivered remotely. At no point will this or any other service involve in-person access.

1.154 To fully comply with Regulation 25, the pharmacy will implement the following measures to prevent public access:

1.154.1 The premises location is in an area not routinely accessed by the general public and is away from areas such as high streets where the general public would easily have access to.

1.154.2 All entrances will remain locked with a controlled-access system; only authorised staff can enter.

1.154.3 No signage or promotional materials will be visible outside the pharmacy.

1.154.4 A “NO PUBLIC ACCESS” warning sign will be clearly displayed at the entrance.

1.154.5 All windows will be frosted or obscured to prevent visibility from outside.

1.154.6 CCTV surveillance will monitor all entry points, with recordings of any public approach.

1.154.7 The pharmacy has no reception area or waiting space.

1.154.8 Deliveries will be accepted through secure, scheduled procedures with no contact from the public.

1.154.9 Staff are trained and governed by SOPs to refuse access to any person attempting to visit the premises.

1.155 The pharmacy website will clearly communicate our DSP model:

1.155.1 It will not advertise or suggest that face-to-face services are available.

1.156 The site will state:

1.156.1 "We are a Distance Selling Pharmacy and do not offer face-to-face services. If you wish to visit a pharmacy in person, please use https://www.nhs.uk/service-search/pharmacy/finda-pharmacy."

1.157 The site will also provide:

1.157.1 Up-to-date contact information

1.157.2 A contact form available 24/7 (replied to during working hours)

1.157.3 Telephone number, answered by trained staff during opening hours

1.157.4 Email address, regularly monitored

1.157.5 A live video consultation booking system

1.157.6 NHS 111 information for urgent care outside opening hours

1.158 Website contact information will be reviewed regularly to ensure accuracy and usability.

1.159 All consultations, including for pharmaceutical services, will be conducted via telephone or video, from a private area within the pharmacy to ensure confidentiality.

1.160 The pharmacy will maintain open telephone lines during all opening hours, and emails will be monitored in real time to ensure safe, timely communication with patients. A stable internet connection with backup capability will be available on site to support uninterrupted remote consultations.

1.161 Consultations will not be conducted off-site or subcontracted to other providers.

1.162 There will be no physical or remote consultations off-premises.

1.163 All staff conducting consultations will be:

1.163.1 DBS-checked

1.163.2 Trained in safeguarding

1.163.3 Accredited or enrolled in appropriate clinical training

1.164 The pharmacy will implement Standard Operating Procedures (SOPs) covering:

1.164.1 Remote delivery of each pharmaceutical service

1.164.2 Patient ID verification using NHS-approved information (name, DOB, address)

1.164.3 Medicines will be dispatched via secure, auditable delivery methods, maintaining full confidentiality and patient safety

1.164.4 Obtaining and documenting electronic consent

1.164.5 Preventing public access and redirecting those who attend providing staff with clear guidance on how to respond should an individual attempt to access the premises

1.164.6 Data handling and sharing in line with GDPR

1.164.7 Signposting patients to other NHS services where appropriate

1.165 Staff will be trained on all relevant SOPs, with regular audits to ensure adherence. Only trained and accredited staff will deliver pharmaceutical services.

1.166 Prior to service delivery, verbal consent will be obtained and recorded in the pharmacy's system.

1.167 Consent will include:

1.167.1 Agreement to receive the service remotely

1.167.2 Permission to share information with the GP, NHS England, and NHSBSA

1.167.3 Understanding of the right to withdraw at any time

1.167.4 No incentives will be offered for service participation.

1.167.5 Only eligible patients will be enrolled, in line with NHSBSA criteria.

1.168 For NMS:

1.168.1 Records (consent, interventions, follow-ups) will be maintained for at least two years.

1.168.2 Quarterly summary reports will be submitted to NHSBSA.

1.168.3 If digital entry is unavailable during a session, NMS worksheets will be used, then digitised.

1.169 The pharmacy will not provide the following face-to-face or off-site services:

1.169.1 Vaccination services (flu, COVID-19)

1.169.2 Appliance Use Reviews (AUR)

1.169.3 Hypertension Case-Finding

1.169.4 Any in-person Essential, Advanced, or Enhanced Service

1.170 This multi-layered approach ensures full compliance with Regulation 25, and guarantees that all pharmaceutical services will be delivered safely, effectively, and entirely without face-to-face contact at or near the pharmacy.

1.171 To summarise:

1.171.1 No face-to-face services will be provided at or near the premises

1.171.2 All pharmaceutical services will only be offered remotely

1.171.3 Our SOPs, staff training, premises setup, and website protocols have been designed to fully comply with Regulation 25 and recent NHS England guidance.

1.171.4 We remain committed to operating a fully remote, secure, and patient-focused Distance Selling Pharmacy in line with all legal, clinical, and operational expectations."

2 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 5 March 2026 states:

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

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

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

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

Actions from the Pharmacy Services Regulations Committee 07th January 2026

2.4 **"Distance Selling Premises – excepted application**

2.5 CAS-370305-N3D2J1

2.6 **Stag Chemist Ltd** Unit 11 First floor, 537 -539 Coventry Road, B10 0LL

2.7 **Regulation 31 – refusal: same or adjacent premises**

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

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

2.10 As Regulation 31(2)(a) does not apply, the Committee is not required to consider Regulation 31(2) (b).

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

2.12 The Committee then went on to consider Regulation 25.

2.13 **Regulation 25 – Distance Selling Premises Applications**

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

2.15 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.

2.16 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.

2.17 This is confirmed with information available on the NHS.UK website where the nearest general practice is located 0.1 mile away.

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

2.19 **Regulation 25(2)(b)(i)** – The Pharmacy Procedures indicate that the service will be provided as uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.

2.20 **Therefore this regulation is deemed to have been met.**

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

2.22 The pharmacy procedures and detailed SOPs provided do not meet the standard required to satisfy this regulatory requirement. The applicant has provided information on pharmacy procedures in the supporting information

documents, as part of their application for the delivery of the services across the whole of the England, as per the SOPs.

2.23 However, the lack of details provided by the applicant does not provide assurance for provision of pharmaceutical services.

2.24 **Therefore this regulation is deemed to have not been met.**

2.25 **Regulation 66:** The applicant has undertaken to provide the following directed services if the application is granted. NMS (Remotely only).

2.26 **Regulation 66(4**) therefore applies if the application is to be granted, and the inclusion of the applicant and the pharmacy premises in the pharmaceutical list for the area of Herefordshire Health and Wellbeing Board would be subject to the condition set out in Regulation 66(5).

2.27 The Committee **refused** the application.

2.28 Regulations 25(2)(a) and25(2)(b)(i) are met.

2.29 Regulation 25 (2)(b)(ii) is not met.

2.30 The Committee determined that appeal rights are to the applicant.

2.31 “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 **Birmingham Health and Wellbeing board** in respect of the premises included in the application, that inclusion will be subject to the following conditions:

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

2.31.2 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.

2.31.3 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.

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

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

2.31.6 the safe and effective provision of pharmaceutical services without face-to-face contact at the proposed 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; and o 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:

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

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

3 The Appeal

In a letter dated 16 March 2026, Rushport Advisory LLP representing the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "I act for Stag Chemist Birmingham Ltd and have been instructed by my client to submit this appeal against the attached decision of the Commissioner to refuse the above application.

3.2 My client has submitted a number of applications under regulation 25 due to the short notice given for the removal of this exemption in June 2025 and is still determining which of the premises identified will be most suitable to operate from. As the Committee will be aware, there is no regulation that limits the number of applications that can be made, or approved, so long as the applications were properly submitted prior to the June 2025 deadline, which this application was.

3.3 The Commissioner refused my client's application as it considered that my client had not provided sufficient evidence to demonstrate that their application met the test under regulation 25. My client has noted the Commissioner's comments and has instructed me to provide the attached updated SOPs. These SOPs replace all previous evidence submitted and should be considered when assessing this appeal. The SOPs have been approved by my client for use in the proposed pharmacy. [Appendix A for Committee]

3.4 The Committee is asked to note that patients or their representatives will not be permitted to access the proposed premises in person and the premises will operate with a controlled entry system.

3.5 We submit that the information provided with this appeal satisfies the legal test in full and the appeal should be allowed and we look forward to hearing from you in due course."

4 Summary of Representations

This is a summary of representations received on the appeal.

4.1 THE COMMISSIONER

4.1.1 "The application failed to meet Regulation 25(2)(b)(ii) for the following reasons, hence the application was refused:

4.1.1.1 Lack of assurance with regard to delivery of NMS

4.1.1.2 Lack of assurance with regard to delivery of DMS

4.1.1.3 Lack of assurance for a failed CD delivery procedure

4.1.1.4 No clarification on procedure for what a failed delivery protocol would be for items requiring cold storage The suite of pharmacy procedures now provided from the applicant to NHS Resolution was not available to the Committee at the time the decision was made.

4.1.2 If that information had been available, the Committee may have come to a different decision."

5 Summary of Observations

This is summary of observations received.

5.1 THE COMMISSIONER

5.1.1 "PSRC are aware of a significant number of complaints raised with the GPhC by other pharmacies regarding changes to EPS nominations without patient consent. It is understood that these are being investigated and PSRC understand that these are unlikely to be considered as part of the DSP regulations, but it was felt that NHS Resolution should be made aware."

6 Consideration

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

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

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

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

6.5 The Committee noted that Commissioner had providing observations highlighting complaints made to the regulator regarding EPS nominations. The Committee took no view of this data or its relevance to the instant application.

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

6.7 The Committee noted the Applicant had stated "*Not applicable as the application is NOT adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises*" and the Commissioner had determined that *"… it was not required to refuse the application under the provisions of Regulation 31*." Given there was no dispute on the matter, the Committee was satisfied that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

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

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

6.11 As far as Regulation 25(2)(a) is concerned, the Committee had regard to the application form in which the Applicant states "*Not applicable as the application is NOT on the same site or in the same building as the premises of a provider of primary medical services with a patient list*". The Committee noted that this had not been disputed and that it had not been provided with any information to persuade it otherwise. The Committee was therefore satisfied that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

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

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

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

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

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

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

6.18 SOP 1: 'Introduction and Background to SOPs'

6.18.1 "*1.3 Overriding Provisions Applicable to All SOPs*

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

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

6.19 SOP 33: 'The Responsible Pharmacist'

6.19.1 "*33.9 Absence of the RP*

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

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

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

6.21 SOP 1: 'Introduction and Background to SOPs'

6.21.1 "*1.3 Overriding Provisions Applicable to All SOPs*

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

6.22 SOP 3: 'Procedures for NHS Pharmaceutical Services'

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

6.23 The Committee next considered how the Applicant would provide pharmaceutical services without face to face contact. The Committee noted the following information in the Applicant's SOPs:

6.24 SOP 1: 'Introduction and Background to SOPs'

6.24.1 "*1.3 Overriding Provisions Applicable to All SOPs*

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

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

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

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

6.25 SOP 3: 'Procedures for NHS Pharmaceutical Services'

6.25.1 "*3.1 Communication Channels*

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

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

6.25.2 "*3.2 Request for face-to-face service provision*

OUR PHARMACY OPERATES FROM SELF-CONTAINED PREMISES THAT USE A CONTROLLED ACCESS SYSTEM. MEMBERS OF THE PUBLIC ARE NOT ABLE TO ATTEND THE PREMISES TO RECEIVE ANY NHS SERVICES [Applicant's emphasis]

If any member of staff receives a query from any member of the public, or patient or their carers that requests the provision of any pharmaceutical service face to face on or in the vicinity of the premises then they must;

Inform the person that, we cannot provide any face to face NHS services

Refer the person to the Responsible Pharmacist if they require any further explanation."

6.26 The Committee was mindful of the regulatory changes as of 1 October 2025 and 31 March 2026, that distance selling pharmacies can no longer provide Directed services (Advanced, National Enhanced and Enhanced Services) face to face with the patient at the pharmacy premises. As a result of this

amendment, the Committee noted that the Applicant would not be able to provide any pharmaceutical services to patients present at its premises.

6.27 The Commissioner, in its decision had stated with regard to Regulation 25(2)(b)(ii) "*the lack of details provided by the applicant does not provide assurance for provision of pharmaceutical services*." In its representations, the Commissioner explained further stating " … *Lack of assurance with regard to delivery of NMS*" and with regard to the Applicant SOPs provided with the appeal "*If that information had been available, the Committee may have come to a different decision*."

6.28 In its application, the Applicant stated that "*NMS is the only Advanced Service the pharmacy currently plans to offer, and every stage of the service will be delivered remotely. At no point will this or any other service involve in-person access*".

6.29 The Committee noted SOP 3 'Procedures for NHS Pharmaceutical Services' states:

6.29.1 "*3.3 Provision of Advanced or Enhanced Services*

> *The Pharmacy does not provide advanced or enhanced services to patients on the premises. NMS will be conducted remotely with no patients accessing the service at the premises (see NMS SOP).*
>
> *Pharmacy First will be provided remotely if the pharmacy has been approved to provide the service (see Pharmacy First SOP).*"

6.30 The Committee noted SOP 7 'The New Medicine Service ("NMS")' which states "*The service must be provided remotely by phone or video call*" and also SOP 8 'The Pharmacy First Service' which states "*Patients may not attend the premises to receive the service and the service must be provided remotely*".

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

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

6.33 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

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

6.35 The Committee noted SOP 3 'Procedures for NHS Pharmaceutical Services' states:

6.35.1 "*…Patients who wish to send paper prescriptions to the pharmacy by post should be sent stamped addressed envelopes to enable them to do so.*"

6.36 SOP 6 'Prescription Receipt & Exemption Checking' states:

6.36.1 "*6.2 Scope*

All online services including the following:

… NHS Prescriptions."

6.36.2 "*6.7 Administration Checks*

Check all prescriptions received in the post against printed and written prescription reception forms. Check the corresponding prescription has been received in the post…"

6.37 SOP 19 'Order Delivery' states:

6.37.1 "*19.6 Choice of Delivery Method*

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

6.38 On the basis of the information supplied, 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.

6.39 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

6.40 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.

6.41 The Committee noted SOP 16 'Emergency Supply and Urgent Supply' which describes how the Applicant will process such a request. The Committee noted that the SOPs refer to pharmaceutical services being delivered by several means of non-face to face communication including telephone and email, and

considered that it was reasonable to infer that these methods would be used to receive requests from prescribers for the urgent supply of drugs.

6.42 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

6.43 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.

6.44 The Committee noted SOP 6 'Prescription Receipt & Exemption Checking states:

6.44.1 "*6.9 Exempt NHS Prescriptions*

Where evidence of exemption is required or provided by the patient it can be sent to the pharmacy for verification via the delivery driver and then returned to the patient. The PMR system should be updated to reflect that necessary check has been carried out and a note of when the next check is required should be entered onto the system. The Regulations require a patient to produce 'satisfactory evidence' to confirm exemption. Where appropriate (i.e., for deliveries made other than by the pharmacy's delivery driver), the patient may scan or fax copies of the evidence to the pharmacy (or use the postal / courier service, but see NOTE below) and the pharmacy can note that the evidence provided was not in original format. It is for the pharmacist in charge to determine if the evidence is satisfactory or not and, if not, then cross the 'Evidence not Seen' box."

6.45 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.

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

6.47 The Committee noted SOP 6 'Prescription Receipt & Exemption Checking' states:

6.47.1 "*6.12 Paid NHS Prescription*

Check the prescription to confirm how many charges are due.

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

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

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

6.48 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

6.49 The Commissioner, in its decision had stated with regard to Regulation 25(2)(b)(ii) "*the lack of details provided by the applicant does not provide assurance for provision of pharmaceutical services*." In its representations, the Commissioner explained further stating " … *Lack of assurance for a failed CD delivery procedure*" and "*No clarification on procedure for what a failed delivery protocol would be for items requiring cold storage.*" With regard to the Applicant SOPs provided with the appeal, the Commissioner stated "*If that information had been available, the Committee may have come to a different decision*."

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

6.51 The Committee noted SOP 19 'Order Delivery' states:

6.51.1 "*19.10 Transfer to the Delivery Driver*

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

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

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

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

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

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

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

6.51.2 "*19.11 Delivery of prescription to patient or representative address*

…Ask the patient/representative for their name and address.

Check the patient name and address against the prescription and the bag label. Patient confidentiality should be maintained at all times, especially if delivering to a representative.

Where appropriate ask the patient or representative to complete the reverse of the prescription.

Hand the medication to the patient or representative.

Ask the patient or representative to sign their details on the delivery sheet. If they are unable to sign the delivery sheet the delivery driver should sign on their behalf with their consent and write a note explaining the reason the patient or representative could not sign.

If necessary, collect any medication returns. Always use the Patient Returned Medication Tray that is available in the delivery vehicle. Refer to the Patient Returned Medicines SOP for further guidance."

6.51.3 "*19.12 Successful delivery*

Once the deliveries are completed, return the delivery sheets to the pharmacy on the same day. The delivery sheets must be scanned into the pharmacy IT system and kept for a minimum period of 7 years."

6.51.4 "*19.13 Unsuccessful Delivery*

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 must follow up the unsuccessful delivery by contacting the patient to arrange a second delivery time.

DO NOT:

Post the medication through the letter/post box.

Leave the medication in the porch or any other out building.

Leave the medication at an unauthorised address."

6.51.5 "*19.14 Delivery of a prescription via Royal Mail (Not for Cold Chain or CDs)*

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

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

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

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

Confirm details of all prescriptions to be delivered.

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

Ensure Royal Mail driver signs Delivery Log sheet for all prescriptions being accepted for delivery. The delivery sheets must be scanned into the pharmacy IT system and kept for a minimum period of 7 years.

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

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

6.51.6 "*19.15 Unsuccessful Delivery via Royal Mail*

In the event of an unsuccessful delivery, Royal Mail 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."

6.51.7 "*19.16 Cold chain delivery via courier*

All cold chain deliveries must be carried out by couriers with verified and approved cold chain procedures. A list of approved cold chain couriers is available within the Pharmacy and will be updated from time to time. Each approved courier meets stringent criteria to ensure a fully monitored and dedicated cold chain service.

Specialist cold chain courier service will ensure the integrity of the cold chain and the maximum stability of thermo-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.

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

… Ensure any items for cold chain delivery via courier are stored in the fridge and accompanying items are appropriately marked with a fridge line sticker. Accompanying items must include a note to explain that

fridge items will be delivered separately to the rest of their items to enable the cold chain to be maintained.

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

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

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

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

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

Confirm details of all prescriptions to be delivered.

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

6.51.8 "*19.17 Unsuccessful cold chain delivery via courier*

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

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

6.51.9 "*19.18 Breach of Integrity of Cold Chain*

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

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

Where such an event occurs, the courier is instructed to leave a 'Missed Delivery' card and also inform the pharmacy that the delivery was unsuccessful due to a breach of the cold chain. The pharmacy must arrange for immediate re-delivery of the items via courier and the return of the items that have failed to be delivered to the pharmacy by the

courier. items subject to a cold chain breach may not be re-used and must be segregated from the pharmacy stock."

6.52 SOP 23 'Controlled Drugs: Delivery' states:

6.52.1 "*23.5 Delivery of Schedule 2 & 3 CDs*

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

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

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

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

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

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

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

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

6.52.2 "*23.7 Successful Schedule 2 & 3 Delivery*

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

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

6.52.3 "*23.8 Unsuccessful Schedule 2 & 3 Delivery via pharmacy driver*

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

6.52.4 "*23.9 Unsuccessful Schedule 2 & 3 Delivery via courier*

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

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

6.52.5 "*23.10 Note re Use of Couriers for Controlled Drugs Deliveries*

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

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

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

6.55 The Committee noted that in the application form, in response to the question as to whether they were undertaking to provide appliances, the Applicant had stated *"Drug Tariff Part IX - Except items which require measuring or fitting".* The Committee noted the Applicant's SOPs state:

6.56 SOP 9 'Pharmaceutical & Legal Assessment':

6.56.1 "*9.9 Items Requiring Measuring and Fitting*

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

6.57 SOP 26 'Support for Self-Care, Signposting and Health Promotion':

6.57.1 "*26.14 Items Requiring Measuring and Fitting*

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

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

6.59 The Committee considered whether the Applicant had explained what containers will be "suitable" for posted/delivered items.

6.60 The Committee noted that SOP 18 'Bagging-Up' states:

6.60.1 "*18.7 Choice of Packaging*

Choice of packaging will depend on the nature of the items being delivered and the appropriate level of protection must be used to ensure that the item can withstand the normal rigours of the delivery process.

All packaging must have the tamper proof seals provided in the pharmacy attached to the packaging so that any tampering with the packaging will be evident.

Medicine for local delivery which is not fragile and to be delivered by the delivery driver can be packaged in the [sic] *using the pharmacy bags supplied for standard prescription items.*

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

For postal items, either:

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

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

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

Coldchain items should be bubble wrapped and placed in Styrofoam filled re-enforced cardboard boxes and kept in the DELIVERIES FRIDGE (rather than the storage fridge) with the "FRAGILE" and "FRIDGE LINE" stickers attached. The courier company will transport the boxes in vans with cold chain sections that protect the integrity of

the box ("cold ship" packaging) and are fully monitored – typically at 2 to 8 degrees Celsius range- (see delivery SOP). Pharmacy staff should be aware that some thermolabile products can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in medicines which is damaging to them and such items ***must not be used.***" [Applicant's emphasis]

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

Refusal to provide drugs or appliances ordered

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

6.63 The Committee noted SOP 34 'Repeat Dispensing' states:

6.63.1 "*34.10 Prescription Reception*

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

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

6.63.2 "*34.11 Pharmaceutical & Legal Assessment*

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

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

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

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

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

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

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

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

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

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

6.64 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

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

6.66 The Committee noted SOP 34 'Repeat Dispensing' states:

6.66.1 "*34.10 Prescription Reception*

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

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

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

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

On receipt of a repeatable prescription from the patient, the pharmacy staff should ensure that the patient fully understands the Repeat Dispensing Process and is provided with a patient information leaflet that outlines the benefits of the service. Contact the patient to discuss

the service and confirm if they wish to access the information leaflet online, by email or by post.

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

6.66.2 "*34.11 Pharmaceutical & Legal Assessment*

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

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

6.67 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

6.68 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.

6.69 The Committee noted SOP 24 'Controlled Drugs: Collection and Disposal of Patient Returns' states:

6.69.1 "*24.5 Patient Returned Medication*

This service is available to <u>all</u> patients living in England.

Patients or their representatives <u>may not</u> return and [sic] *medicines directly to the pharmacy and must follow the procedures set out in this SOP.* [Applicant's emphasis]

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

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

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

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

6.69.2 "*24.7 Return by Royal Mail*

The pharmacist must

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

Assess the items for suitability for return by Royal Mail

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

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

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

Contact the patient to ensure that the packaging has been received

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

6.69.3 "*24.8 Handling Patient-Returned CDs from Delivery Driver*

Drivers need to:

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

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

Pharmacy staff need to:

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

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

6.70 SOP 25 'The Safe and Effective Receipt and Disposal of Medicines' states:

6.70.1 "*25.6 Process for Patients to Return Medication*

Patient Returned Medication

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

This service is available to all patients living in England.

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

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

Patients may

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

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

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

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

Explaining the Process to Patients

Check which patient or patients the medication belonged to.

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

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

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

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

6.70.2 "*25.7 Process for accepting patient returns by the Driver*

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

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

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

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

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

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

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

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

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

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

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

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

6.70.3 "*25.9 Return by Royal Mail*

The pharmacist must

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

Assess the items for suitability for return by Royal Mail

If items are suitable for return by Royal Mail then make a note on the PMR and arrange to send the appropriate packaging to

the patient for safe return (refer to bagging up SOP for appropriate packaging)

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

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

Contact the patient to ensure that the packaging has been received

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

6.70.4 "*25.10 Disposal of returned medicines*

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

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

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

Promotion of healthy lifestyles

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

6.73 The Committee noted SOP 27 'Promotion of Healthy Living, Lifestyle & Health Campaigns' states:

6.73.1 "*27.3 Identification of patients for promotion of Healthy Lifestyles*

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

Active patients will be those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further information should be sent, or who should be called to follow up on the results and offer additional support and information. All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight and also lifestyle

questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.

Passive patients are those where the identification happens as part of another interaction with the patient, but where the patient does not appear to be actively seeking additional assistance. For example, the dispensing of a prescription which identifies the patient as having high blood pressure / diabetes etc.

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

Leaflets will be delivered to patients with their medication. Those identified as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns. The website, app and email newsletters will also be used to promote healthy lifestyles via the health promotion zone."

6.73.2 "*27.4 Health Campaigns & Community Engagement Exercise*

Terms of Service require participation in a maximum of 2 campaigns per financial year, but you should agree to take part in all campaigns where practicable.

The Pharmacy will take part in national health campaigns to promote public health messages to patients across England. This will be achieved by sending out leaflets with prescriptions during specific targeted campaign periods and providing additional advice and learning resources via the website on the health promotion zone.

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

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

Prescription linked intervention

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

6.76 The Committee noted SOP 27 'Promotion of Healthy Living, Lifestyle & Health Campaigns' states:

6.76.1 "*27.6 Long Term Conditions*

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

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

For specific groups of patients (those with diabetes, at risk of coronary heart disease, especially those with high blood pressure, and patients who smoke or who are overweight) the pharmacists must provide advice without face-to face interaction (eg telephone, Live video, via the website). Such advice should be backed up, as appropriate, by the provision of written material such as leaflets."

6.76.2 "*27.7 Identification of patients for Support with Long Term Conditions*

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

Active patients will be those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further information should be sent, or who should be called to follow up on the results and offer additional support and information. All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight and also lifestyle questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.

Passive patients are those where the identification happens as part of another interaction with the patient, but where the patient does not appear to be actively seeking additional assistance. For example, the dispensing of a prescription which identifies the patient as having high blood pressure / diabetes etc.

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

Leaflets will be delivered to patients with their medication. Those identified as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns. The website, app and email newsletters will also be used to promote healthy lifestyles."

6.77 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

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

6.79 The Committee noted SOP 27 'Promotion of Healthy Living, Lifestyle & Health Campaigns' states:

6.79.1 "*27.4 Health Campaigns & Community Engagement Exercise*

Terms of Service require participation in a maximum of 2 campaigns per financial year, but you should agree to take part in all campaigns where practicable.

The Pharmacy will take part in national health campaigns to promote public health messages to patients across England. This will be achieved by sending out leaflets with prescriptions during specific targeted campaign periods and providing additional advice and learning resources via the website on the health promotion zone.

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

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

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

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

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

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

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

6.80 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

6.81 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.

6.82 The Committee noted SOP 26 'Support for Self-Care, Signposting and Health Promotion' states:

6.82.1 "*26.10 Other Provider Organisations and Support Details*

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

6.82.2 "*26.12 Signposting*

Service Description

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

6.82.3 "*26.13 Patient Identification*

Identification can take place during any interaction that the patient has with the pharmacy staff. In particular, staff should consider the results

from the identification of patients for the promotion of healthy lifestyles and those who have filled in the Lifestyle Questionnaire on the website.

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

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

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

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

6.83 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

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

6.85 The Committee noted SOP 26 'Support for Self-Care, Signposting and Health Promotion' states:

6.85.1 "*26.8 Patient identification*

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

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

on changes to the patient's lifestyle."

6.85.2 "*26.9 Service outline*

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

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

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

6.86 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

6.87 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 regiment by the staff of an NHS trust and NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.

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

6.89 The Committee noted SOP 28 'Discharge Medicines Service ("DMS")' states:

6.89.1 "*28.3 Process*

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

6.89.2 "*28.4 Consent*

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

6.89.1 "*28.5 DMS Stages*

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

6.89.2 "*28.6 DMS Stage 1 (within 72 hours of referral excluding times when the pharmacy is not open)*

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

6.89.3 "*28.7 Considering the appropriateness of any medication changes prior to discharge*

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

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

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

For actions that are considered appropriate the pharmacist must;

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

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

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

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

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

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

REQUIRED ACTIONS AS PER NHS GUIDANCE"

6.89.4 "*28.8 DMS Stage 2*

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

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

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

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

Then the pharmacist must:

Review / perform a further review of any prescription

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

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

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

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

6.89.5 "28.9 DMS Stage 3

The NHS Discharge Medicines Service should also be used as an opportunity to engage with patients about their medicines on a shared decision-making basis. Whether the patient or their carer makes contact themselves for advice, a referral is received from an NHS trust on

discharge or a prescription is received following prescribing changes, the pharmacist or pharmacy technician should take the opportunity to establish the patient's understanding of their condition(s), their associated medications and how each medicine can be best administered to get optimum benefit and reduce unwanted side effects.

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

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

Websites and health promotion zones

6.91 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.

6.92 The Committee noted that SOP 26 'Support for Self-Care, Signposting and Health Promotion' states:

6.92.1 "*26.11 Health promotion zone on our website*

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

Explaining the Interactive Page to Patients

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

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

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

6.93 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

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

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

6.95.1 confirm the Commissioner's decision;

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

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

6.96 The Committee was mindful that it had been provided with additional information which was not available to the Commissioner at the time it made its decision. Given that it had reached a different decision to that of the Commissioner, the Committee determined that the decision of the Commissioner must be quashed.

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

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

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

7 Decision

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

7.2 The Committee:

7.2.1 quashes the decision of the Commissioner; and

7.2.2 redetermines the application as follows -

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

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

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

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

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

The application is granted.

Case Manager
Primary Care Appeals