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

Tel: 0203 928 2000
Email: nhsr.appeals@nhs.net

11 December 2024

REF: SHA/26271

APPEAL AGAINST NHS BIRMINGHAM & SOLIHULL ICB DECISION TO REFUSE AN APPLICATION BY RAZI GROUP LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT SUITE 2, LOWER GROUND FLOOR, MORGAN REACH HOUSE, 136 HAGLEY ROAD, BIRMINGHAM, B16 9NX UNDER REGULATION 25

1 Outcome

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

1.2 The Committee determined that the application should be refused.

A copy of this decision is being sent to:

Gordons Partnership on behalf of the Applicant
Office of the West Midlands on behalf of the Commissioner

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1 The Application

By application dated 6 December 2023, Razi Group Ltd ("the Applicant") applied to NHS Birmingham & Solihull ICB ("the Commissioner") for inclusion in the pharmaceutical list at Suite 2, Lower Ground Floor, Morgan Reach House, 136 Hagley Road, Birmingham, B16 9NX 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 made no comment.

1.2 In response to why the application should not be refused pursuant to Regulation 31 the Applicant made no comment.

1.3 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant made no comment.

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

1.4 In response to "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" the Applicant stated:

1.5 "The online pharmacy will have at least one Responsible Pharmacist (RP) at the premises at all times during the contracted hours. Patients will be able to order their medication online via the NHS app or via repeat requests to their GP and have it delivered to their doorstep the same day/next day, ensuring that they can receive the essential services they need, without any disruption. In addition, the online pharmacy will have a robust system in place to handle any potential issues or emergencies. Patients will be able to contact a qualified pharmacist directly through our online/email/video and phone service, and we will have measures in place to ensure that medication can be delivered quickly in the event of an urgent need. Urgent medications such as antibiotics or end-of-life will be stocked in advance and will be delivered the same day unless there is a supply issue in which case the patient will be signposted to their nearest pharmacy. We will make sure adequate staffing levels meet the demand for Essential Services during the opening hours. Staff members will be trained in providing uninterrupted essential services, including how to handle

unexpected events and emergencies. All staff members will have read and signed the comprehensive list of standard operating procedures (SOP). All staff will be allocated time for training and courses from the 'centre for pharmacy postgraduate education (CPPE)'.

1.6 Patients will not be provided face-to-face NHS essential services inside or within the vicinity of the premises. Patients attending for advanced services will be reminded by staff that we only provide medication delivered to patient's home addresses and no collection is allowed at the pharmacy. There will also be a large sign at the entrance of the premises door to remind patients of "consultation by appointment only and no public access". Inside the pharmacy, the dispensary door will be closed to prevent patient access."

1.7 The Applicant intends to provide:

1.7.1 Essential services

1.7.2 Advanced and Enhanced services:

1.7.2.1 New Medicine Service (NMS)

1.7.2.2 Community Pharmacy Seasonal Flu Vaccination

1.7.2.3 Community Pharmacist Consultation Service (CPCS)

1.7.2.4 Care Home Service

1.7.2.5 Home Delivery Service

1.7.2.6 Medication Review Service

1.7.2.7 Patient Group Direction Service

1.7.2.8 Emergency Supply Service

1.8 The Applicant's proposed core opening hours are:

1.8.1 Mon to Fri - 09:00 to 17:00

1.8.2 Sat - Closed

1.8.3 Sun - Closed

1.9 The Applicant's proposed total opening hours are:

1.9.1 As above.

2 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 5 July 2024 states:

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:

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

Decision report

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

"Distance Selling Premises – excepted application

2.3 Razi Group Limited – ME2953 / CAS-253230-X9S4V9 Suite 2, Lower Ground Floor, Morgan Reach House, 136 Hagley Road, Birmingham, B16 9NX

Decision:

2.4 The committee decided that the application is refused. Regulation 25 and all subsections of this regulation are not met as per the report. Regulation 31 is met. Regulations 31(i),31(ii) are met.

2.5 **Regulation 25(2)(a)** – 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.

2.6 **This regulation is deemed to have been met.**

2.7 **Regulation 25(2)(b)(i)** – The application provides very little detail to assure committee that the standard required to satisfy the regulatory requirements have been me.

2.8 **This regulation is deemed to have not been met**

2.9 **Regulation 25(2)(b)(ii)** – The pharmacy procedures do not meet the standard required to satisfy the regulatory requirements of the provision of essential services without face to face contact and the delivery of the services across whole of the England.

2.10 **This regulation is deemed to have not been met**

Regulation 31

2.11 Must be refused where paragraph 2 applies- (2) This paragraph applies where-

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

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

(ii) adjacent premises, and

(b) The NHSCB 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).

2.12 **This regulation is deemed to have been met**

2.13 **Regulation 31(2)(i)** No previous pharmaceutical services have been provided from these premises.

2.14 **This regulation is deemed to have been met.**

2.15 **Regulation 31(2)(ii) There are no premises adjacent.**

2.16 **Appeal Rights**

2.17 Razi Group Limited"

3 **The Appeal**

In a letter dated 3 August 2024, Gordons Partnership Solicitors appealed on the Applicant's behalf against the Commissioner's decision. The grounds of appeal are:

3.1 "We act for Razi Group Ltd, intending to trade as Razi Meds. Our client wishes to appeal against the decision by the Birmingham and Solihull ICB to refuse its application for inclusion in the pharmaceutical list for a distance selling pharmacy at Suite 2, Lower Ground Floor, Morgan Reach House, 136 Hagley Road, Birmingham, B16 9NX.

3.2 The application is made under regulation 25 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

The Decision

3.3 The Pharmaceutical Services Regulations Committee meeting for Birmingham and Solihull ICB refused the application on the following basis:

3.3.1 Regulation 25 and all subsections of this regulation were not met. (However the body of the report states the applicant has met reg 25(2)(a))

3.3.2 Regulation 25(2)(b)(i) – the application provides very little detail to assure committee that the standard required to satisfy the regulatory requirements have been met. This regulation is deemed to have not been met.

3.3.3 Regulation 25(2)(b)(ii) – the pharmacy procedures do not meet the standard required to satisfy the regulatory requirements of the provision of essential services without face-to-face contact and the delivery of the services across whole of the England. This regulation is deemed to have not been met.

The Appeal

3.4 Our client wishes to appeal on the grounds that the ICB has not given adequate reasons for refusal and the committee misdirected itself by saying that the regulatory requirements would not be met.

3.5 We set out below how Razi Group Ltd will provide essential services in accordance with regulation 25(2)(b) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 including:

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

3.5.2 (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.

3.6 The pharmacy has comprehensive Standard Operating Procedures (SOPs) which are part of its intellectual property. We attach our client's key SOPs and an index of all SOPs.

3.7 It is confirmed that there will be a registered pharmacist on site throughout the opening hours. All services will be available to persons anywhere in England. Public health services, signposting and support for self-care will be provided through the applicant's web interface, telephone systems and by materials delivered through post and delivery drivers.

3.8 The applicant's robust working practices and operating procedures will ensure safe and effective provision of essential services without face-to-face contact between a patient or any person receiving services on a patient's behalf and the applicant's staff.

GPhC Guidance and NHS Clinical Governance requirements

3.9 The applicant will operate the pharmacy in accordance with relevant legislation, standards and guidance. In this letter, particular reference is made to the updated GPhC document "Guidance for Registered Pharmacies Providing Pharmacy Services at a Distance, including on the Internet," ("GPhC guidance") and the Terms of Service for NHS pharmacists as the framework which underpins the safe and effective provision of essential services.

3.10 Focusing on the elements that are discussed under:

Standard 1 of the GPhC Guidance and Paragraph 28 of the Schedule 4 of the Regulations:

Governance Arrangements

3.11 Razi Meds is committed to providing high quality, safe and effective distant selling pharmacy services. As such, the Pharmacy adapts/implements the NHS clinical governance framework to ensure principles of good governance are built into all areas of its work.

3.12 The Pharmacy's Clinical Governance SOP sets out how the applicant is accountable, takes professional responsibility, and ensures the right systems and processes are in place.

Risk Assessment

3.13 The applicant will have in place a risk assessment document which will identify risks and set out how they will be managed for each service, medicine and medical device provided.

3.14 The risk assessments and risk management plans will be reviewed quarterly and also when there are significant business or operational changes.

3.15 The risk assessments and management plans will include:

3.15.1 how staff tell people about the pharmacy services they will receive, and how they get their consent, staff communication throughout the team and with third parties.

3.15.2 arrangements for stock handling and procurement,

3.15.3 incident reporting

3.15.4 safeguarding

3.15.5 processes for receiving prescriptions, including records of decisions to make or refuse a supply, exemption checking etc.

3.15.6 how medicines are supplied, including counselling and delivery

3.15.7 the business's capacity to provide the proposed services; staff levels, Health and Safety at work, training and skills including the use of any new technology (for example; if an App is introduced)

3.15.8 business continuity plans, including for the website, data security and information governance generally and equipment

3.15.9 record keeping

3.15.10 any information about pharmacy services on the website

3.15.11 assessment of how the pharmacy adheres to the information security procedures and identity checking

3.15.12 an assessment of how the pharmacy complies with the Equality Act 2010

Audit

3.16 Regular audit programmes will be in place and the process will be set out in the Razi Meds business compliance documents. The audit will be part of the evidence which gives assurance that the pharmacy continues to provide safe pharmacy services to patients. Any issues identified will be subject to a reactive review.

3.17 Key areas the audit will cover are those set out in the risk assessment listed above.

3.18 The areas for audit will also include feedback, including complaints, from patients and people who use the pharmacy.

3.19 The audits will also be compliant with NHS England audit requirements.

Reactive Review

3.20 A reactive review will take place if an audit identifies a problem, or if there is a change in the law affecting any part of the pharmacy service or a significant change in any part of the pharmacy service provided including a change in technology.

3.21 There will also be a reactive review if there are other concerns. Examples include a data security breach, receipt of complaints or matters arising from a review of near misses and error logs.

Accountability

3.22 The pharmacy will operate from only one location. During opening hours there will always be a responsible pharmacist (RP) on site. Each staff role will have clear lines of accountability that will be set out by the superintendent pharmacist. There will also be clear lines of accountability in relation to third party providers of delivery services. The SOPs require "dispensed by" and "checked by" boxes to be completed prior to supply.

Record Keeping

3.23 Pharmacy staff will maintain records about online/telephone consultations and medicines supplied which are sufficient to guard against risks of abuse or misuse.

3.24 A verifiable audit trail from the initial request for a medicine through to its delivery to the patient will exist. The pharmacy will keep records of:

3.24.1 The identity of customers (i.e. name and address) who have been supplied with medicines via the DSP;

3.24.2 Details of the medicines requested and supplied;

3.24.3 Details of any consultation with the patient or prescriber, interventions made and/or advice given;

3.24.4 The information upon which decisions to supply were made

3.24.5 The identity of the pharmacist who has assumed professional responsibility for supply of a medicine following an email/online request to purchase;

3.24.6 All relevant records must be maintained for a period of not less than 5 years.

3.25 Focusing on the elements that is discussed under:

Standard 2 of the GPhC Guidance and Paragraph 28 of the Schedule 4 of the Regulations:

Staff

3.26 Staff will be trained on provision of services without face-to-face contact.

3.27 The pharmacist will be available during the pharmacy's opening hours to monitor dispensing and/or offer advice and other essential services.

3.28 The applicant will undertake an approved workforce survey annually.

3.29 There will be a staff management programme. This will include induction, checking of qualifications, the professional development of staff. Staff rights to make protected disclosure will be supported. Performance management frameworks will be put in place.

3.30 Focusing on the elements that are discussed under:

Standard 3 of the GPhC Guidance and Paragraph 28 of the Schedule 4 of the Regulations:

Premises

3.31 The physical environment of the pharmacy will support provision of essential services without face-to-face contact between a patient or any person receiving services on a patient's behalf and the applicant's staff.

3.32 The pharmacy will have video conferencing facilities, telephone and fax lines available during normal working hours.

3.33 The premises has been carefully chosen to ensure it does not have the appearance of a standard High Street pharmacy. It is located in a commercial business centre away from retail or residential areas. The access to the car park firstly is via an electronic gate, persons require clearance via intercom or fobs to be able to enter the site, after which a further buzzer system is in operation to allow you to enter the building. A final

barrier to entry is the access door to the pharmacy itself within the building. This is kept locked at all times unless opened to allow access by the staff inside.

3.34 Pharmacy signage will be minimal but will ensure that the public are aware that there can be no face-to-face provision of essential pharmaceutical services. There will be no shop front.

3.35 Access to the building will be restricted to pharmacy staff only. Windows are secured with shutters and security bars.

3.36 The pharmacy will have a dedicated website https://razimeds.com The website will be available for access to health information at all times. It will also provide signposting and self-care and healthy lifestyle advice which are further discussed below.

3.37 A pharmacy leaflet will be available on the website and in hard copy to be posted out if required.

Websites and health promotion zones

3.38 The pharmacy will ensure its website complies with applicable regulations and guidance, including:

3.38.1 Ensuring website design reflects available guidance and provides an easy-to-follow layout. The website landing page will be an interactive page that is clearly promoted when patients and the public first access the website.

3.38.2 Website content will be compliant with the NHS guidance terms of service in relation to Healthy Living Pharmacy requirements with a reasonable range of up-to-date materials that promote healthy lifestyles by addressing a reasonable range of health issues.

3.38.3 All relevant logos will be displayed.

3.39 To ensure website content contains up-to-date materials that promote healthy lifestyles, a designated and trained staff member will update the website on a regular basis.

3.40 Focusing on the elements that are discussed under:

Standard 4 of the GPhC Guidance and Paragraph 28 of the Schedule 4 of the Regulations:

Safeguarding the Health, Safety and Wellbeing of Patients and the Public

3.41 Staff will be trained on provision of services without face-to-face contact.

3.42 The pharmacist will be available during the pharmacy's opening hours to monitor dispensing and/or offer advice and other essential services.

Transparency and Choice

3.43 The pharmacy will operate from only one site and information about the identity of the company providing services and the responsible pharmacist will be provided on the website.

Managing and supplying medicines safely

3.44 The supply of medicines will be done in such a manner as to minimise risk to patients. The SOPs cover the relevant standards.

3.45 Basic information will initially be collected from the patient, including name, date of birth, NHS number and the patients will be informed of the identity verification process. Prescriptions will then be cross-referenced against details provided by the patient.

3.46 Identity verification is two-fold and will include an initial verification of the patients' NHS number against the NHS database. Then the patient must provide either a copy of a government-issued ID, proof of address, GP confirmation and a previous prescriptions.

3.47 High-risk medications will require two-verification medications and a pharmacist will verify the patients' identity.

3.48 For on-line orders thepharmacycentre.com software will be integrated into the website – the user will upload a form of official photographic ID.

3.49 The software integrates with NHS login and has apps that patients could use to track their orders.

Supplying medicines safely

3.50 The suitability of the delivery service will be assessed prior to dispatch.

3.51 Communication channels for the Responsible Pharmacist with patients include telephone, email, live-chat, video calls and leaflets.

3.52 Delivery arrangements are discussed further below.

Essential Services

Paragraphs 3 to 22 of schedule 4 of the Regulations ("Terms of Service")

3.53 Safe and effective provision of essential services will be provided without face-to-face contact but in a way that fulfils the requirements of Part 2 of Schedule 4 of the Regulations.

3.54 Should a patient attend in person for essential services they will be advised that the Pharmacy and its staff cannot assist them on a face-to-face basis as it is a distance-selling pharmacy.

3.55 They will not be admitted into the site or premises as access is controlled by electronic gate and intercom. Communication will be though the intercom or though the non – face to face modes of communication already described. Staff will, if required and through the above modes of communication, assist the patient in finding appropriate providers for the service the patient needs by using the NHS web service.

Dispensing services and dispensing of drugs and appliances

Paragraphs 4 and 5

3.56 The Pharmacy has in place detailed SOPs to ensure safe and effective dispensing.

3.57 The Pharmacy additionally has in place specific SOPs for dealing with EPS prescriptions, private prescriptions and the sale of OTC (GSL) items and P medicines.

3.58 In summary, prescriptions will be received via the Electronic Prescription Service, sent to the pharmacy in the post or in situations where the patient is registered with a local GP, the prescriptions will be collected by staff from surgeries. Details about advice and delivery are given below.

Urgent Supply without a Prescription

Paragraph 6

3.59 The Pharmacy has an SOP in place to deal with urgent supply requests from both patients and prescribers.

3.60 Requests for supply can be received though post, website, telephone and email.

3.61 Where requested by a patient the pharmacist will consider the immediate need for the medicine and the practicability of obtaining a prescription, whether there has been an appropriate time interval if there has been a previous supply, the details of the medication and will only supply a maximum of 30 days' (or 5 days' for Schedule 4 or 5 CDs) worth of medication (or the smallest pack where appropriate).

3.62 Where requested by a prescriber the pharmacist will satisfy themselves that the supply is requested by a prescriber but that they cannot supply a prescription immediately, that the prescriber will supply a prescription within 72 hours, record the prescriber's and patient's details and those of the medication, follow up with the prescriber if the prescription is not received and update the prescription register as necessary.

3.63 Records will be kept of the emergency supply.

3.64 The pharmacy would prioritise urgent requests and will offer the quickest route possible via a reputable courier if it is deemed that an urgent supply is appropriate.

Preliminary matters before providing ordered drugs or appliances

Paragraph 7

3.65 The Pharmacy will ask patients to provide evidence as to exemption from charges. This certificate data will be uploaded to the PMR. If no proof is available, the patient should complete this when the prescription is delivered. All prescriptions will be signed, and indication given whether it is an exemption category or what the amount is to pay.

3.66 NHS fees for prescriptions will be taken remotely from the patient prior to handing over the prescription at delivery. The payment status on the prescription will need to be updated as 'PAID'. Staff will be trained as to which items incur double charges or have an unusual payment regime.

3.67 Private prescriptions can only be paid for once the items have been dispensed. Private prescriptions will therefore be labelled with a 'TO PAY' note. The patient will be advised if the item is cheaper to buy as an OTC item.

3.68 The evidence will be scanned or posted, and records will be kept of the exemption with alerts for expiry of evidence previously seen. Razi Meds will be building a method of submitting exemption details via the website, registered patients will require to update this at least every 6 months or upon expiry of provided evidence.

3.69 Patients who do not qualify for an exemption, could either make a payment for their prescription via the telephone or on a secure page on the pharmacy website.

Providing ordered drugs or appliances

Paragraph 8

3.70 The Pharmacy will provide ordered drugs or appliances by delivery to the patient's address. The pharmacy will take adequate steps to ensure that the delivery mechanism used is secure and that medicines are delivered to the intended user promptly, safely and in a condition appropriate for use; The delivery method will be appropriate for the item(s) provided and location of the patient.

3.71 Methods will include delivery by staff of the Pharmacy, Royal Mail and other approved couriers.

3.72 For local deliveries (up to 30 miles radius, but may be extended at the discretion of the RP) the trained delivery driver will deliver medication. Outside this area, Royal Mail will be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier will be used, or the items are fridge lines, in which case the cold chain courier should be used (see below).

3.73 The Pharmacy has SOPs in place to ensure appropriate delivery services are used for all items including cold-chain items and CDs.

3.74 The pharmacy will also ensure that medicines are packed, transported and delivered in such a way that their integrity, quality and effectiveness are preserved. It will be ensured that the package is suitable for the method of delivery and for the end-user. The pharmacy will use discrete packaging, leak proof containers for liquids and sift proof for solid material. Items will be packed in suitable cardboard boxes and filled with Styrofoam material or such material to avoid damage to the contents. Glass bottles or any fragile items will be bubble wrapped and packaged with 'fragile' stickers and the couriers will be advised of such parcels. For all local deliveries, regular pharmacy prescription bags will be used and packaged securely.

3.75 All deliveries will be tracked and delivery will only be made to the patient or their nominated representative. Deliveries must be signed for and, as stated below, ID will be checked in the case of CDs. The delivery mechanism used will provide a verifiable audit trail for the medicine from the initial request for a medicine through to its delivery to the patient or carer, or its return to the pharmacy in the event of a delivery failure;

3.76 The applicant will ensure that delivery mechanisms safeguard confidential information about the individual patient's medication.

3.77 Systems will be in place to inform a patient who is not at home that delivery was attempted.

Cold chain

3.78 Care will be exercised with thermo-labile products. Local delivery drivers will deliver local fridge lines. The medicine will be bagged up appropriately, labelled as a fridge line and will be delivered in a cold chain transportation bag. The patient will be called before the delivery driver leaves to ensure they are able to accept delivery. If delivery is unsuccessful the medicine will be returned to the pharmacy as soon as possible, staff will store it appropriately ensuring the cold line is maintained. In the event of a breach of cold chain with the local delivery driver; the pharmacy will arrange for immediate re-delivery of a new supply of medicines and the driver will return the medicines to the pharmacy where cold chain has been breached. These items will not be re-used and will be segregated from the pharmacy stock.

3.79 For courier deliveries, a Cold Shipping Package will be used for patients who require a refrigerated environment of 2-8°C for their deliveries. The delivery driver and the courier will both use cold pack arrangements which maintains "cold ship" temperature requirements.

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

3.81 The courier will ensure that:

3.81.1 Vehicles are equipped with heat & cool refrigeration equipment

3.81.2 Dual evaporators independently control the temperature of the front & rear compartments of the vehicle hold.

3.81.3 For MHRA compliance the courier vehicles and storage facilities are temperature mapped on a regular basis and installed with monitoring equipment to provide temperature readings throughout the day.

3.81.4 Temperature data for transit is collected from transporting vehicles.

3.82 If despite these safeguards a breach does occur the courier will ensure the breach is notified to the pharmacy and they will then follow the failed delivery process where the courier is instructed to leave a 'Missed Delivery' card.

3.83 The pharmacy will 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.

3.84 The courier is accredited with the MHRA for the storage of temperature critical pharmaceuticals & medicines and employs a permanent Responsible Person to ensure compliance with the regulatory requirements. Drivers are GDP trained and the operating procedures have been ISO9001 certified for quality.

Controlled drugs

3.85 There will also be specific procedures for the delivery of Schedule 2 & 3 CDs.

3.86 A robust audit trail will be in place. The delivery driver/courier will check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative.

3.87 A Controlled Drugs Delivery Sheet must also be filled in for CD deliveries in addition to the Delivery Log sheet. CDs should be in a separate bag to any other medication being delivered and the bags should be attached together.

3.88 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.

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

3.90 The couriers used for Controlled Drugs Deliveries will have the following UK Licenses and Standards:

3.90.1 MHRA Wholesale Dealer

3.90.2 GAMP 4 Systems Validation

3.90.3 MHRA IMP License

3.90.4 MHRA Manufacturer's "Specials" License

3.90.5 ISO 9001: 2000 Certified

3.91 They will Meet all Home Office safe custody and record keeping requirements.

Pandemic services

3.92 The pharmacy will provide medicines properly requested under any Pandemic Treatment Protocol arrangements and will comply with service specifications and regulations in place to supply, deliver and if appropriate, refuse to supply medication.

3.93 A new SOP will be written every time a new pandemic arises.

Refusal to provide drugs or appliances ordered

Paragraph 9

3.94 Pharmacy staff will be aware of the circumstances in which the pharmacy must or may refuse a prescription.

3.95 For private prescriptions, the dates and quantities of previous supplies will be checked first. Schedule 2 or 3 on FP10PCD will not be permitted under repeat supply. Repeat supplies of POMs and Schedule 4 CDs may be clinically inappropriate due to elapsed time and prescriptions will be referred back to the prescriber if they are old.

3.96 The pharmacy will ensure that before the issue of a repeat prescription the pharmacist will contact the patient remotely and check whether:

3.96.1 They experienced any side effects with their last prescription

3.96.2 They experienced any issues with their last prescription

3.96.3 The last prescription arrived at the delivery address undamaged

3.96.4 There have been any changes to their health since the issuance of the last prescription which would lead to them no longer requiring it

3.97 If any of these questions are returned by the patient indicating a need, the Responsible Pharmacist will either telephone or video call the patient to ensure:

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

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

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

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

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

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

3.98 Any decisions to refuse supply or any interventions or referrals will be recorded on the Intervention and Referral Form.

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

Paragraph 10

3.99 The pharmacy will:

3.99.1 ensure that appropriate advice is given to patients about any drugs provided to them for general information and to enable then to use the drugs or appliances appropriately.

3.99.2 as set out in the intervention and problem-solving SOP, recognise that intervention or advice may be required during the prescription preparation process. These interventions will often be given by telephone, although other non- face-to-face channels would be available, and the intervention would be recorded.

3.99.3 provide appropriate advice to patients to whom they provide medicines on the safe keeping of the medicines, and returning unwanted medicines to the pharmacy premises for safe destruction

Paragraph 11

3.100 The Pharmacy will make information regarding EPS and nomination forms available on its website. It will be explained to patients how EPS 2 works, when it may or may not be appropriate and the patient's ability change and choose provider.

3.101 The patient will be offered a copy of the "Explaining the Electronic Prescription Service – Information for Patients and Carers in England" leaflet to reinforce the above messages.

3.102 The Pharmacy's SOPs forbid any inducements and make clear that explicit patient consent is required for nominations.

3.103 The Pharmacy will ensure that EPS prescriptions are properly and safely dispensed as with all prescriptions and also, specifically, that patients are informed if the Pharmacy cannot fulfil the prescription so that the patient may use another provider if they wish.

Additional requirements in relation to specified appliances

Paragraph 12

3.104 Appliances will not be supplied.

Disposal service in respect of unwanted drugs

Paragraphs 13 to 15

3.105 Patients wishing to return unwanted medicines to the pharmacy may do so by courier, which will be provided and paid for by the pharmacy. Patients in locality may contact pharmacy by phone or email to arrange collection of unwanted medicines from their home or work by pharmacy staff.

3.106 Appropriate packaging will be sent to patients in advance and details of the service and how to book a collection will be available on the Pharmacy website.

3.107 The disposal service will be advertised to patients on the website or verbally during patient contact over the telephone/internet.

3.108 Staff will be trained on the handling of waste medicines and appropriate protective equipment will be available to deal with spillages. The pharmacy will use a waste management company for the disposal of waste.

Promotion of healthy lifestyles and prescription linked intervention

Paragraphs 16 and 17

3.109 The Pharmacy will provide opportunistic healthy lifestyle advice and public health advice to appropriate patients. This may be provided where:

3.109.1 Prescriptions have been issued for conditions which can be alleviated by lifestyle changes, such as diabetes or hypertension. This is relevant especially to prescriptions for new items

3.109.2 Online requests have been made for certain conditions, for example, vitamin supplements

3.110 The Pharmacy will predominantly provide advice to patients over the telephone or by advising them to access information from a list of websites online. Where appropriate, the pharmacy will refer patients to other online services either provided by the pharmacy or signpost the patients to another practitioner or organisation.

3.111 If necessary, records will be made on the patient's PMR. These records will include the date, reasons for providing advice, the type of advice provided and the outcome (if any). At least 10 anonymised records of these interventions must be recorded annually.

3.112 Staff will be trained on all health promotion interventions and updated CPCF requirements.

Health campaigns

Paragraph 18

3.113 The Pharmacy will take part in all health campaigns where practicable. Campaign posters will be displayed online for the duration of the campaign and any leaflets available can be found online on the website. If required to do so, the pharmacy will record the number of people who have been given advice. Briefing packs supplied by the PCO will be used to brief all pharmacy staff at the start of each campaign.

3.114 Records will be maintained of health promotion activities and outcomes, as well as community engagement efforts and regular reports will be produced on service delivery effectiveness

Signposting

Paragraphs 19 and 20

3.115 The Pharmacy will inform or advise patients of other health and social care providers and support organisations, such as patient groups, when appropriate. The Pharmacy will also make referrals to other online services provided by the pharmacy or direct them externally.

3.116 The assessment of the appropriateness of the signposting will include recognising the need to minimise inappropriate use of health or social care services.

3.117 The Pharmacy will source contact details for relevant providers as required. The Pharmacy will make written referrals if appropriate. The Pharmacy will also provide links to a range of health and social care providers and support organisations on its website.

3.118 Records will be kept of information or referrals made in a way that facilitates auditing of the services and follow-up care.

Support for self-care

Paragraphs 21 and 22

3.119 Advice will be given to patients (and/or carers).

3.120 The Pharmacy will provide this advice in the same manner as for signposting patients. Lifestyle questionnaires will be available for all patients visiting the website.

3.121 The Pharmacy will also provide advice on the appropriate use of non-prescription medicines that can be used as part of a self-care regime.

3.122 Records will be kept of the advice given, including any medicines supplied

Discharged Medicines Service

Paragraph 22B to 22C

3.123 The pharmacy will provide advice, assistance and support to a patient—

3.123.1 recently discharged from hospital who is referred to Razi Meds 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

3.123.2 who is otherwise referred to the Pharmacy for advice, assistance and support in respect of the patient's medication regimen by the staff of an NHS trust or NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services

3.124 An SOP will be in place to require checking for referrals, ensuring compliance with each stage of the service specification and setting out a process when a new or unknown patient's referral is received. The SOP will also stipulate the conditions where stages of the service cannot be provided.

3.125 The DMS procedure will be reviewed annually, and an audit trail will be maintained of any changes made. Staff will be trained on the procedure and will record any changes on the patient's PMR, to additionally be relayed to the GP and patient if appropriate.

3.126 The advice will be provided via one of the channels of communication appropriate to a distance selling pharmacy to patients anywhere in England, either by telephone or video call.

3.127 Action following a referral will be taken within 72 hours and appropriate records will be kept.

Advanced or Enhanced Services

3.128 An index of SOPs is attached. Once our client has confirmation of the commission of services, any SOPs that are not completed will be put in place prior to the commissioning of the service.

Publicity

3.129 It is confirmed that nothing in Razi Meds practice leaflet, publicity material, in material published on behalf of Razi Meds publicising services provided at or from the listed chemist premises or in any communication (written or oral) from staff to any person seeking the provision of essential services from Razi Meds Pharmacy will represent, either expressly or impliedly, the essential services provided at or from the premises are:

3.129.1 only available to persons in particular areas of England, or

3.129.2 Razi Meds Pharmacy may refuse, for reasons other than those provided for in the terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients

3.130 The pharmacy has been entered into Part 3 of the General Pharmaceutical Council's (GPhC) register as Razi Meds. Premises number 9012491

3.131 Our client confirms that it has procedures in place that will ensure:

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

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

3.132 In the circumstances, we hope you will allow our client's appeal and grant our client's application.

3.133 We look forward to your response."

3.134 [The Applicant later informed NHS Resolution that it was sending in an updated Absence of Responsible Pharmacist Standard Operating Procedure.]

4 Summary of Representations

This is a summary of representations received on the appeal.

The Commissioner

4.1 "Further to the earlier receipt of Standard Operating Procedures in respect of the above case. West Midlands Pharmacy Services Regulations Committee make the following observations having particular attention to specific areas that the original application failed to address and therefore did not provide the necessary assurance required for the application to be granted.

4.2 The Standard Operating Procedures provided to NHS Resolution have been examined and submit the committee's view below.

4.3 The applicant has now provided detailed information against each of the GPhC Standards for Providing Pharmacy Services at a Distance, including on the Internet and has provided a range of Standard Operating Procedures which supports delivery against these Standards. The particular assurance required focused on:

4.3.1 the provision of essential services without face-to-face contact between a patient or any person receiving services on a patient's behalf and the applicant's staff.

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

4.3.3 arrangements to ensure the appropriate delivery for all items including cold-chain items and CDs, and procedures for failed deliveries

4.4 Committee can therefore confirm that the applicant has now provided all the necessary information to assure committee that the requirements of Regulation 25, in particular, of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 will be met if the application is granted.

4.5 Committee would request the applicant provide further detail in respect of the Delivery of Controlled Drugs :

4.6 *For unsuccessful deliveries sent with a courier:*

4.6.1 *Ensure CDs are returned to the pharmacy on the same day*

4.6.2 *Enter the returned CDs back into the CD register with an explanation*

4.6.3 *Secure the returned CDs in the CD cabinet where appropriate*

4.7 Finally please advise action in the circumstance the designated courier needs to return failed deliveries of CDs back to the pharmacy on the same day given that they may be required to deliver to addresses that are several hours drive away from the pharmacy site, or if the courier gets significantly delayed in traffic?

4.8 We look forward to receiving the response."

5 **Summary of Observations**

This is summary of observations received.

Gordons Partnership on behalf of the Applicant

5.1 "We write further to your letter of 23 September 2024. Our client notes the comments of the ICB and attaches his SOP covering delivery and unsuccessful delivery of controlled drugs. The cold chain delivery SOP has also been revised and the amended version is attached.

5.2 In the circumstances, we hope you will allow our client's appeal and grant our client's application.

5.3 We look forward to your response."

6 **Consideration**

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

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

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

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

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

6.6 The Committee noted that the Applicant had not provided any information in the application form on this point but the Committee noted that the wording of the application form only required the Applicant to include information in the relevant section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee considered it reasonable to determine that the lack of information in the application form on this point when read with the wording of the application form allowed it to be reasonably satisfied that the Applicant considered that the proposed premises were not adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee further noted that the Commissioner's decision letter includes "*Regulation 31(2)(i) No previous pharmaceutical services have been provided from these premises. This regulation is deemed to have been met. Regulation 31(2)(ii) There are no premises adjacent.*" The Committee noted that the above had not been disputed by any of the parties on appeal. The Committee determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

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

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

6.10 The Committee noted that the Applicant had not included any information in the relevant section of the application form that deals with this point. The Committee noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Commissioner, in its decision report stated that "*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.* ***This regulation is deemed to have been met.***" The Committee noted that none of the parties had raised this as a matter on appeal. Based on the information available to it, the Committee therefore determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

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

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

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

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

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

6.16 The Committee noted the Applicant's 'SOP for Operating in the Absence of a Responsible Pharmacist' (updated) under the heading 'Procedure' states:

6.17 "*To guarantee the uninterrupted provision of essential services and the safe and effective delivery, the usual working practice in Razi Meds is to have a second pharmacist onsite working under the RP. In the event, there are any breaks in working time taken by the RP it will be covered by the second pharmacist who will then assume the responsibility of the RP, after appropriate handover, clear communication and update any log as defined below.*"

6.18 The Committee considered whether the Applicant had provided information to show that essential services will be provided across England. The Committee noted the appeal letter includes *"All services will be available to persons anywhere in England. Public health services, signposting and support for self-care will be provided through the applicant's web interface, telephone systems and by materials delivered through post and delivery drivers."*

6.19 The Committee considered if the Applicant had shown that essential services will be provided without face to face contact. The Committee noted the Applicant's information at point 7 of the application form states: *"Patients will not be provided face-to-face NHS essential services inside or within the vicinity of the premises. Patients attending for advanced services will be reminded by staff that we only provide medication delivered to patient's home addresses and no collection is allowed at the pharmacy. There will also be a large sign at the entrance of the premises door to remind patients of "consultation by appointment only and no public access". Inside the pharmacy, the dispensary door will be closed to prevent patient access."* The Committee also noted the appeal includes *"The premises has been carefully chosen to ensure it does not have the appearance of a standard High Street pharmacy. It is located in a commercial business centre away from retail or residential areas. The access to the car park firstly is via an electronic gate, persons require clearance via intercom or fobs to be able to enter the site, after which a further buzzer system is in operation to allow you to enter the building. A final barrier to entry is the access door to the pharmacy itself within the building. This is kept locked at all times unless opened to allow access by the staff inside."*

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

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

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

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

6.23.1 Dispensing of drugs and appliances

6.23.2 Urgent supply without a prescription

6.23.3 Preliminary matters before providing ordered drugs or appliances

6.23.4 Providing ordered drugs or appliances

6.23.5 Refusal to provide drugs or appliances ordered

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

6.23.7 Disposal service in respect of unwanted drugs

6.23.8 Promotion of healthy lifestyles

6.23.9 Prescription linked intervention

6.23.10 Health campaigns

6.23.11 Signposting

6.23.12 Support for self-care

6.23.13 Discharge medicines service

6.23.14 Websites and health promotion zones.

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

Providing ordered drugs or appliances

6.25 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).

6.26 The Committee noted the appeal letter under the heading ‘Providing Ordered Drugs and Appliances’ states:

6.26.1 *"The Pharmacy will provide ordered drugs or appliances by delivery to the patient's address. The pharmacy will take adequate steps to ensure that the delivery mechanism used is secure and that medicines are delivered to the intended user promptly, safely and in a condition appropriate for use;*

6.26.2 *The delivery method will be appropriate for the item(s) provided and location of the patient.*

6.26.3 *Methods will include delivery by staff of the Pharmacy, Royal Mail and other approved couriers.*

6.26.4 *For local deliveries (up to 30 miles radius, but may be extended at the discretion of the RP) the trained delivery driver will deliver medication. Outside this area, Royal Mail will be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier will be used, or the items are fridge lines, in which case the cold chain courier should be used (see below).*

6.26.5 *The Pharmacy has SOPs in place to ensure appropriate delivery services are used for all items including cold-chain items and CDs.*

6.26.6 *The pharmacy will also ensure that medicines are packed, transported and delivered in such a way that their integrity, quality and effectiveness are preserved. It will be ensured that the package is suitable for the method of delivery and for the end-user. The pharmacy will use discrete packaging, leak proof containers for liquids and sift proof for solid material. Items will be packed in suitable cardboard boxes and filled with Styrofoam material or such material to avoid damage to the contents. Glass bottles or any fragile items will be bubble wrapped and packaged with 'fragile' stickers and the couriers will be advised of such parcels. For all local deliveries, regular pharmacy prescription bags will be used and packaged securely.*

6.26.7 *All deliveries will be tracked and delivery will only be made to the patient or their nominated representative. Deliveries must be signed for and, as stated below, ID will be checked in the case of CDs. The delivery mechanism used will provide a verifiable audit trail for the medicine from the initial request for a medicine through to its delivery to the patient or carer, or its return to the pharmacy in the event of a delivery failure.*

6.26.8 *The applicant will ensure that delivery mechanisms safeguard confidential information about the individual patient's medication."*

6.26.9 *"Systems will be in place to inform a patient who is not at home that delivery was attempted.*

Cold chain

6.26.10 *Care will be exercised with thermo-labile products. Local delivery drivers will deliver local fridge lines. The medicine will be bagged up appropriately, labelled as a fridge line and will be delivered in a cold chain transportation bag. The patient will be called before the delivery driver leaves to ensure they are able to accept delivery. If delivery is unsuccessful the medicine will be returned to the pharmacy as soon as possible, staff will store it appropriately ensuring the cold line is maintained. In the event of a breach of cold chain with the local delivery driver; the pharmacy will arrange for immediate re-delivery of a new supply of medicines and the driver will return the medicines to the pharmacy where cold chain has been breached. These items will not be re-used and will be segregated from the pharmacy stock.*

6.26.11 *For courier deliveries, a Cold Shipping Package will be used for patients who require a refrigerated environment of 2-8°C for their deliveries. The delivery driver and the courier will both use cold pack arrangements which maintains "cold ship" temperature requirements.*

6.26.12 *This means that the courier ensures temperature integrity throughout the supply chain, from point of collection & goods-in to pharmaceutical storage to final delivery.*

6.26.13 *The courier will ensure that:*

6.26.13.1 *Vehicles are equipped with heat & cool refrigeration equipment*

6.26.13.2 *Dual evaporators independently control the temperature of the front & rear compartments of the vehicle hold.*

6.26.13.3 *For MHRA compliance the courier vehicles and storage facilities are temperature mapped on a regular basis and installed with monitoring equipment to provide temperature readings throughout the day.*

6.26.13.4 *Temperature data for transit is collected from transporting vehicles.*

6.26.14 *If despite these safeguards a breach does occur the courier will ensure the breach is notified to the pharmacy and they will then follow the failed delivery process where the courier is instructed to leave a 'Missed Delivery' card.*

6.26.15 *The pharmacy will 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.*

6.26.16 *The courier is accredited with the MHRA for the storage of temperature critical pharmaceuticals & medicines and employs a permanent Responsible Person to ensure compliance with the regulatory requirements. Drivers are GDP trained and the operating procedures have been ISO9001 certified for quality."*

6.27 However, the Committee noted that the Applicant had not provided any information in relation to the monitoring of temperatures of cold-chain medicines during transit by the local delivery driver and how the driver would be alerted to any changes in temperature which could compromise medicines.

6.28 The appeal letter continues:

"Controlled drugs

6.28.1 *There will also be specific procedures for the delivery of Schedule 2 & 3 CDs.*

6.28.2 *A robust audit trail will be in place. The delivery driver/courier will check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative.*

6.28.3 *Controlled Drugs Delivery Sheet must also be filled in for CD deliveries in addition to the Delivery Log sheet. CDs should be in a separate bag to any other medication being delivered and the bags should be attached together.*

6.28.4 *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.*

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

6.28.6 *The couriers used for Controlled Drugs Deliveries will have the following UK Licenses and Standards:*

6.28.6.1*MHRA Wholesale Dealer*

6.28.6.2*GAMP 4 Systems Validation*

6.28.6.3*MHRA IMP License*

6.28.6.4*MHRA Manufacturer's "Specials" License*

6.28.6.5 *ISO 9001: 2000 Certified*

6.28.6.6*They will Meet all Home Office safe custody and record keeping requirements.*

Pandemic services

6.28.7 *The pharmacy will provide medicines properly requested under any Pandemic Treatment Protocol arrangements and will comply with service specifications and regulations in place to supply, deliver and if appropriate, refuse to supply medication.*

6.28.8 *A new SOP will be written every time a new pandemic arises."*

6.29 The Committee considered that the Applicant had not provided information sufficient to show that controlled drugs will be kept secure during delivery by the local delivery driver.

6.30 The Committee further noted that the updated SOP for 'Handling Unsuccessful CD Deliveries' contradicts itself. At 2.6 it says:

6.30.1 *"If the courier service is unable to return the CD on the same day, the CD shall be stored safely at their approved warehouse overnight"*.

6.31 However, at point 3 under 'Extended Distance Deliveries', it says:

6.31.1 *"If a delivery attempt is unsuccessful:*

a. The courier must immediately contact the pharmacy to report the failed delivery.

b. The courier must return the CDs to the pharmacy on the same day, regardless of the distance.

c. If returning during normal operating hours is not possible, a responsible pharmacist must remain on-site to receive the returned CDs".

6.32 The Committee considered that the inconsistency does to provide any assurance as to the Applicant's ability to meet this aspect of its terms of service.

6.33 The Committee was not satisfied that there would be compliance with paragraph 8(1) of Schedule 4.

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

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

6.35 The Committee noted under the heading 'Refusal to provide Drugs or Appliances ordered' :

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

6.36 In it's SOPs, the Committee also noted the following:

6.36.1 "*Check if a patient is aware of the repeat collection service and where appropriate, initiate the service.*"

6.37 The Committee was of the view that the Applicant had not explained how it will provide advice about the benefits of repeat dispensing. The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.

Summary

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

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

6.39.1 confirm the Commissioner's decision;

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

6.39.3 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.

6.40 The Committee has reached a different decision on the application. In those circumstances the Committee determined that the decision of the Commissioner must be quashed.

6.41 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.

6.42 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.

6.43 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 Accordingly, 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 proposed premises were not adjacent to or in close proximity to other chemist premises.

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

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

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

7.2.2.5 the Committee was not satisfied that all essential services were likely to be secured in a safe and effective manner,

7.2.2.6 the Committee was satisfied that all essential services were likely to be secured without face to face contact;

7.2.3 The application is refused.

Case Manager
Primary Care Appeals