13 September 2024

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REF: SHA/26239

APPEAL AGAINST NORTHAMPTONSHIRE ICB DECISION TO GRANT AN APPLICATION BY JRAPHA CARE LIMITED FOR INCLUSION IN THE PHARMACEUTICAL LIST AT UNIT 73 ENTERPRISE CENTRE, MICHAEL WAY, WARTH PARK RAUNDS, WELLINGBOROUGH, NORTHAMPTONSHIRE, NN9 6GR 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 Solicitors on behalf of JRapha Care Limited
Rushport Advisory LLP on behalf of Jardines (UK) Ltd
PCSE on behalf of Northamptonshire ICB

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1 The Application

By application dated 19 October 2023, JRapha Care Limited ("the Applicant") applied to Northamptonshire ICB ("the Commissioner") for inclusion in the pharmaceutical list at Unit 73 Enterprise Centre, Michael Way, Warth Park Raunds, Wellingborough, Northamptonshire, NN9 6GR under Regulation 25. In support of the application it was stated:

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

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

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

Information in support of the application

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

7.1 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.

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

7.3 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.

1.4 "(A) Regular internal checks on prescription processing, customer feedback analysis and adherences to regulations will be done through audit procedures for quality assurance.

1.5 JRapha DSPs will provide round-the-clock customer support and any inquiries including prescription requests will be address promptly.

1.6 Trained staffs [sic] will be available to handle emergency procedure for situations such as adverse drug reactions, medication recalls or system failures. Easy access to patient record by authorised healthcare providers and patients themselves.

1.7 JRapha DSPs technology infrastructure will have 24/7 IT support system that is reliable and can minimise any downtimes due technical issues. JRapha DSPs will have a robust inventory management that will regulate stock checks and automated recording system that will prevent shortages and ensure that essential medicines are always available.

1.8 Patient privacy and data integrity will be protected by secured and encrypted communication methods between patients and healthcare providers.

1.9 To prevent serve interruptions, JRapha DSPs will put contingency plans in place, such as back up supply chains and remote working capability for staff in case of natural disaster, pandemic or other unexpected destructions.

1.10 Comprehensive medications counselling will be offered through remote channels. Also, patients will be educated by pharmacist on the proper usage , potential side effects and any precautions associated with their medicines.

1.11 (B) The procedure that will be followed; Greeting and Registration: as the patient arrives at JRapha DSPs premises, they will be received by the front desk staff with warm greetings. Appointment confirmation: any essential service sort for will be verified and appointment details will be confirmed. If the patient does not have a prior appointment, the need for immediate assistance or to schedule an appointment will be checked. The process for scheduling will be explained to the patient if necessary."

2 The Decision

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

The Commissioner considered and decided to grant the application. The decision letter dated 19 June 2024 states:

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

2.2 The report details the conditions that will be placed upon your inclusion in the relevant pharmaceutical list should a valid notice of commencement be received. Enclosed is a form confirming acceptance of these conditions. It should be completed by an authorised person and returned to me with your notice of commencement."

Extract from the decision report

2.3 "Fitness to practice was required for this application and was approved.

2.4 The proposed premises are not in a controlled locality.

2.5 The application will have no impact on those with protected characteristics under the Equalities Act 2010 and is in accordance with NHS England's Public Sector Equality Duty

2.6 Consider impact of decision on NHS England's duty on health inequality.

2.7 Regulations 25 – Distance Selling Premises Applications

2.8 The application meets the criteria for a distance selling application - Regulation 25

2.8.1 The proposed *premises in respect of which the application is made on the same site or in the same building as the premises of a provider of primary medical services with a patient List*. [sic]

2.8.2 The Committee is satisfied that the uninterrupted provision of essential services will be provided during the opening hours of the premises, to persons anywhere in England. In accordance with

2.8.2.1 Company Standard Operating Procedures

2.8.2.2 NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

2.8.2.3 Human Medicines Regulations 2012

2.8.2.4 GPhC – Professional Standards and Guidance on Distance Selling Pharmacies

2.8.2.5 Relevant Data Protection Laws.

2.9 JRapha Care Ltd will provide the following advanced service.

2.10 Advanced Services (National Services) Commissioned by NHSE

2.10.1 New Medicines Services

2.10.2 Flu vaccination service

2.10.3 CPCS (replaced by Pharmacy First Service)

2.10.4 Appliance Use Review

2.10.5 Stoma Appliance customisation

2.10.6 Hypertension Case Finding Service

2.10.7 Smoking Cessation

2.10.8 Supplementary Prescribing Service

2.11 Enhanced Serviced Commissioned by the ICB

2.11.1 On Demand Availability of Specialist Drugs Service (Palliative Care Drug Stockist Scheme) This is a closed service no new sign-ups can be undertaken at this time

2.11.2 Patient Group Direction Service (Extended Care Tier 1 and 2) this service is paused awaiting confirmation that the PGDs have been signed off.

2.12 Services not commissioned by the ICB or NHSE

2.12.1 Antiviral Collection Service

2.12.2 Care Home Service

2.12.3 Language Access Service

2.12.4 Medication Review Service

2.12.5 Home Delivery Service

2.12.6 Independent Prescribing Service

2.12.7 Medicines Assessment and Compliance Support Service

2.12.8 Prescriber Support Service

2.12.9 School Service

2.12.10 Screening Service

2.13 Expired Services detailed within the application.

2.13.1 Emergency Supply Service the enhanced service has been decommissioned and is part of the Pharmacy First National service. Pharmacy contractors can supply an emergency supply to walk in patients, but this is not an NHS service and therefore the patients will be changed for the medicines.

2.13.2 Hepatitis C Antibody Testing Service

2.13.3 Gluten Free Food Supply Service

2.14 Regulation 31 – Refusal; same and adjacent premises

2.15 No persons on the pharmaceutical list (which may or may not be the applicant) is providing or has undertaken to provide pharmaceutical services from

2.15.1 The premises to which the application relates, or adjacent premises and

2.15.2 The Integrated Care Board 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 chemists premises should be treated as the same site)

2.16 Regulation 64 – Distance selling premises: specific conditions

2.16.1 the committee deemed this regulation to have been met.

2.17 The Committee was satisfied that the applicant meets all of the criteria for opening a wholly, internet/mail order-based distance selling premises and therefore determined to grant this application.

2.18 Regulation 66

2.19 Regulation 66(4) applies and the inclusion of the applicant and the pharmacy premises in the pharmaceutical list for the area of Leicestershire Health and Wellbeing board would be subject to the condition set out in regulation 66(5).

2.20 The condition is that, at the pharmacy premises, the applicant must:

2.20.1 Provide the directed services mentioned in the application and

2.20.2 Not withhold agreement to a service specification for those services unreasonably

2.21 If the ICB commissions the services from the applicant within three years of the date of either the grant of the application or, if later, the listing in relation to the applicant of the

pharmacy premises, unless thereafter the ICB ceases to commission the services (if it has commissioned them).

2.22 The committee have requested that to satisfy the elements of regulation 66 the pharmacy must supply the East Midlands Primary Care Team with Signed SLAs for all enhanced services and complete MYS registration for those advanced services commissioned by NHS England that are detailed within the application within 8 weeks of the date of commencement.

2.23 The Committee determined to grant the application on the basis it met all the regulatory requirements and that Jardines UK should be given appeal rights."

3 **The Appeal**

In a letter dated 19 June 2024, Rushport Advisory LLP on behalf of Jardines (UK) Ltd ("the Appellant") appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "I act for Jardines (U.K.) Limited and have been instructed by my client to submit this appeal against the decision of the ICB to approve the above listed application.

3.2 We note that since my client's initial letter of objection the Applicant has ceased advertising NHS services on its website and is now a registered pharmacy with the GPhC.

3.3 The grounds of appeal are that the ICB failed to consider the legal test correctly. Specifically, the Applicant has failed to provide evidence that demonstrates how they will deliver essential services and additional services such as Appliance Reviews to any patient in England who requests such services.

3.4 For the above reason the appeal should be allowed."

4 After reviewing the paperwork provided by the Commissioner, it was noted that the Standard Operating Procedures (SOPs) provided by the Applicant to the Commissioner were not circulated prior to the application being considered. NHS Resolution applied its discretion under Schedule 3, Part 3, paragraph 7 and allowed all parties, including the Appellant, to make representations on the Applicant's SOPs (see Appendix A), given this provided further detail in relation to the application.

5 **Summary of Representations**

This is a summary of representations received on the appeal.

5.1 GORDONS SOLICITORS ON BEHALF OF JRAPHA CARE LIMITED

5.1.1 "We act for JRapha Care Limited, intending to trade as JRapha Pharmacy. Our client wishes to make representations on the appeal by Jardines (U.K. Limited).

5.1.2 In relation to the specific comment made in the appeal:

"The grounds of appeal are that the ICB failed to consider the legal test correctly. Specifically, the Applicant has failed to provide evidence that demonstrates how they will deliver essential services and additional services such as Appliance Reviews to any patient in England who requests such services."

5.1.3 The appeal raises specific concerns about the process for Appliance Use Reviews and the SOP for that service is attached [see Appendix B]. We also attach the SOP for the remote appliance service [see Appendix B]. The regulations discuss the provision of essential services to people anywhere in

England. Appliance Use Reviews are an advanced service so would not fall within this provision, but our client can confirm that all her services in relation to appliances would be available to persons anywhere in England.

5.1.4 It should be noted that the applicant corrected misstatements in the initial application in a response to the ICB in a letter dated 14 February 2024 as follows: "*Firstly, our client accepts that the application contains an inaccuracy where it refers to essential services and should have referred to directed services. Our client apologises for this. Jraphra Pharmacy has a full suite of distance selling SOPs and the directors are aware of the conditions under which services will be provided. As well as other condition, our client's directors are particularly aware that they will be responsible for the safe and effective provision of essential services without face-to-face contact between any person receiving the services and all personnel at Jraphra Pharmacy*."

5.1.5 It is confirmed that the pharmacy has comprehensive Standard Operating Procedures (SOPs) which are part of its intellectual property. These have been substantially updated since the application to the ICB and indexes are attached [see Appendix B]. Our client is happy to send SOPs to NHSR if required.

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

(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.

5.1.7 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.

5.1.8 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

5.1.9 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.

5.1.10 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

5.1.11 JRapha Pharmacy 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.

5.1.12 The Pharmacy's Clinical Governance SOP and Governance and Management SOP set out the importance of complying with NHS guidelines and GPhC standards and demonstrate how the applicant is accountable.

Risk assessment

5.1.13 The applicant will implement risk assessments which will identify all potential risks and set out how they will be managed, depending on their potential impacts.

5.1.14 These risk assessments will be reviewed annually, with an aim of continuous improvement in the management of these risks to ensure the risk control measures are effective audit

5.1.15 A regular audit programme will be in place and will be reviewed every 6 months 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.

5.1.16 The areas for audit will also include feedback, including complaints, from patients and people who use JRapha Pharmacy.

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

Reactive Review

5.1.18 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.

5.1.19 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

5.1.20 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 in the "Pharmacy Task" Matrix as set out by the Roles & Responsibilities of staff SOP. This Matrix will be reviewed every 2 years to ensure staff are aware of required responsibilities and accountability. Staff will be trained and informed of their confidentiality responsibilities and will sign a Staff Confidentiality Agreement.

5.1.21 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

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

5.1.23 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:

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

5.1.23.2 Details of the medicines requested and supplied;

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

5.1.23.4 The information upon which decisions to supply were made;

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

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

5.1.24 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

5.1.25 Staff will be trained on provision of services without face-to-face contact. This will be implemented through a comprehensive and structured training induction plan for new staff and ongoing training and professional developments for existing staff.

5.1.26 Training will include pharmacy policies, procedures and safety protocols and the Identify Verification and Authentication Standard for Digital Health and Care Services.

5.1.27 Regular competency assessments for staff will be conducted and recorded and subsequent training provided immediately for any gaps in training or competence.

5.1.28 Staff are encouraged to participate in Continual Professional Development (CPD) and are supported in achieving this by management and provided with access to CPD resources and opportunities. CPD will be monitored to ensure staff are up to date and fully trained.

5.1.29 Staff will be trained on the procedure to follow should the Responsible Pharmacist be absent from the pharmacy for any duration of time.

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

5.1.31 The applicant will undertake an approved workforce survey annually.

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

5.1.33 Focusing on the elements that are discussed under:

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

5.1.34 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.

5.1.35 The Pharmacy will implement controlled access measures, including locks and 24-hour CCTV.

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

5.1.37 The premises have 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.

5.1.38 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.

5.1.39 The Pharmacy will have a large poster of a notice informing patients in a clear format that walk-in and face-to-face essential services will not be provided at the pharmacy, and signposting patients to their website instead.

5.1.40 Access to the unit will be restricted to JRapha Pharmacy staff only. Premises are secured with a lock and alarm system.

5.1.41 Access granted to patients attending for enhanced and advanced services will be regulated by way of an appointment system.

5.1.42 The pharmacy will have a dedicated website, which is currently under development.

5.1.43 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.

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

Websites and health promotion zones

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

5.1.45.1 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.

5.1.45.2 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.

5.1.45.3 All relevant logos will be displayed.

5.1.45.4 To ensure website content contains up-to-date materials that promote healthy lifestyles, a designated staff member will update the website on a regular basis. A recognised provider, Digital Factorie, has been instructed to design this website.

5.1.46 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

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

5.1.48 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

5.1.49 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.

Transparency and Choice Managing and supplying medicines safely

5.1.50 The supply of medicines will be done in such a manner as to minimise risk to patients. Identity checking will be carried out by a recognised provider and the SOPs will cover the relevant standards. The pharmacy are currently working with a software developer to implement this identity check.

5.1.51 Upon receiving a prescription, a pharmacist will verify its validity and clinical appropriateness. The prescriptions will be received at the pharmacy via post (using pre-paid envelopes provided to patients) or via Electronic Transfer of Prescriptions (EPT) or Electronic Prescription Service (EPS) through patient nominations managed via the website or by telephone.

5.1.52 To enable patient nominations, the pharmacy requires the patient to provide personal information like the name, address, date of birth and contact details and verify their identify using their email or SMS verification. The patient must then create a secure account with a unique username and password.

5.1.53 Once an order has been received, the pharmacy technician will print out a summary. The order should be checked for errors. The medications will then be collected in one basket for each order. Each basket will contain the printed order form in order for the pharmacist to make a final check before dispatch. Orders for a prescription will also have a print out of the authorised prescription in the basket.

5.1.54 Signatures will be provided throughout the process, including of the person who collated the order and passed it to the pharmacist. Provenance of work performed on each order will be collected by adding signature boxes on each of the orders processed.

Supplying medicines safely

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

5.1.56 Communication channels for the RP with patients include telephone, email, livechat, video calls and leaflets.

5.1.57 Delivery arrangements are discussed further below.

Essential Services

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

5.1.59 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.

5.1.60 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

5.1.61 The Pharmacy has in place detailed SOPs to ensure safe and effective dispensing. SOPs covering the prescription receipt and delivery process have been updated and supplemented since the initial application.

Urgent Supply without a Prescription - Paragraph 6

5.1.62 The Pharmacy is aware of the process to deal with urgent supply requests from both patients and prescribers. Staff will be trained on the procedures to implement these.

Preliminary matters before providing ordered drugs or appliances - Paragraph 7

5.1.63 The Pharmacy will ask patients to provide evidence as to exemption from charges. The evidence will be scanned or posted, and records will be kept of the exemption with alerts for expiry of evidence previously seen. Digital Factorie will be building a method of submitting exemption details via the website.

5.1.64 Patients who do not qualify for an exemption will make payment via the secure payments system, completed either online or on the phone manually using the ‘customer not present’ functionality of the card processing provider.

5.1.65 If there are any discrepancies or outstanding fees, the patient will be contacted and directed to pay the correct fees via the online secure payment system.

Providing ordered drugs or appliances - Paragraph 8

5.1.66 Once a final check has been completed and the item has been packaged into a sealed dispatch bag, the Pharmacy will provide the ordered drugs or appliances by delivery to the patient’s address.

5.1.67 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. Items will be dispatched as per the order sheet, which contains details about what type of dispatch is required. The delivery method will be appropriate for the item(s) provided and location of the patient, for example, POMs should be dispatched by recorded delivery.

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

5.1.69 For local deliveries (within a 25-mile radius but may be extended at the discretion of the RP), delivery drivers will communicate delivery times and dates via text or email based on patient delivery preferences. These preferences are accommodated where feasible. Outside this area, discretely packaged medications will be sent via Royal Mail 24/48 services in appropriate packaging formats. Cardboard packaging is used by the pharmacy to ensure medications are durable and protected for transit.

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

5.1.71 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.

Cold chain

5.1.72 Care will be exercised with thermo-labile products. Where medication requiring refrigeration is delivered and staff are concerned regarding the maintenance of the cold chain and the length of time in transit, they are to refuse the order and return it to the supplier.

5.1.73 Where a product has been accepted, it must be placed within the temperature controlled, pharmacy grade refrigerator. When removed from this refrigerator, a visual inspection of the product must be conducted to ensure it complies with the described physical appearance.

5.1.74 The Pharmacy will use a regulated cold chain delivery firm to deliver these medicines and if unavailable, a cool pack/box may be used in conjunction with a validated minimum/maximum thermometer. Domestic cool boxes are not to be used.

5.1.75 Medicines will be kept in their original packaging and wrapped in bubble wrap or a similar insulation material and placed in the cool box with cool packs as recommended by the manufacturer, to prevent damage. Time spent transferring medicines from cool use will be kept to a minimum.

5.1.76 The Pharmacy have prepared procedures in the event of a suspected breach in the cold chain. A suspected breach will always be brought to the attention of the named person responsible for the storage of the medicines and will be reported in the hubnet.io error log. Where the minimum recording of the temperature is below 0^{C}, then the stock will be quarantined in a separate container or bag and labelled 'DO NOT USE'. The stock will then be disposed of in accordance with the Remote Disposal of Medicines SOP.

Controlled Drugs

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

5.1.78 These will be delivered via local delivery drivers for local deliveries or Royal Mail Tracked 24/48 service, which provides package tracking, delivery time options and signature verification by the pharmacy team post-delivery.

5.1.79 Written or verbal consent and a telephone number must be obtained from the patient and recorded on their PMR that they have requested delivery and given consent. This consent will be kept on record for 2 years. Exemption details and any delivery details to specified person other than the patient or carer must be recorded on the PMR. The pharmacist must clinically consider the appropriateness of each prescription.

5.1.80 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.

5.1.81 Controlled drugs must remain in the CD cabinet until delivery is imminent.

5.1.82 Checks will be completed to ensure that all medicines are labelled and that the name and address on the bag label corresponds to the prescription. A delivery slip will be attached to the bag to be signed by the patient upon delivery.

5.1.83 Patients will have their own drop sheet listing all required legal parameters, which can be found on the "Quick Form" section of the website. This will specify the name of the pharmacist, the item to be delivered and space for a signature. This drop sheet will also be given to the delivery driver. A signature must be obtained from the person receiving the item. Should the driver be unable to deliver the medication, the pharmacist at the pharmacy must be contacted. This can either be done by returning to the pharmacy with the drop sheet or calling the pharmacist.

5.1.84 A record will be made on the CD register by the RP.

5.1.85 Where there is a failed delivery, the driver should complete a Not at Home postcard and post through the letterbox and return to the pharmacy. Where the CD are returned subject to safe custody, these can be returned to the CD cabinet and for schedule 2 drugs, re-enter them onto the CD register with an explanation.

5.1.86 They will meet all Home Office safe custody and record keeping requirements.

Pandemic services

5.1.87 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.

Refusal to provide drugs or appliances ordered - Paragraph 9

5.1.88 Pharmacy staff will be made aware by the RP, through their training and induction, of the circumstances in which the pharmacy must or may refuse a prescription.

5.1.89 The pharmacy will ensure that before the issue of a repeat prescription the pharmacist will telephone and speak with the patient and check:

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

5.1.89.2 They are not suffering any side effects which may suggest they need a review of their medication,

5.1.89.3 Their medication regimen has not been changed since the prescriber authorised the repeatable medication.

5.1.89.4 There have not been any changes to the patient's health since prescription was authorised

5.1.90 Advice and encouragement will be provided to patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber.

5.1.91 Any interventions or referrals which are deemed to be clinically significant will be recorded.

Further activities to be carried out in connection with provision of dispensing services - Paragraph 10

5.1.92 The pharmacy will:

5.1.92.1 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.

5.1.92.2 provide appropriate advice to patients to whom they provide medicines on the safe keeping of the medicines via telephone advice or through leaflets provided to patients.

5.1.93 Through staff training, all pharmacy staff will understand the procedure when dealing with urgent supplies of a patient's medicine without a prescription.

5.1.94 The pharmacy has an SOP covering repeat dispensing which ensures that supply will only be made where the medication is required, and no changes have occurred that would require a referral back to the GP. This is ascertained by asking questions of the patient.

5.1.95 A pharmacy record card will be completed and attached to a RA and an entry made each time a dispensing taking place. Any amendments, such as items not being issued will be recorded in the comment section of the pharmacy copy of the card.

5.1.96 If the patient completes the questions and the Pharmacy ascertain a need, the Responsible Pharmacist will either telephone or video call the patient before issuing the repeat and providing and confirming the following:

5.1.96.1 if they are taking the medicine or appliances appropriately and will continue to do so

5.1.96.2 provide appropriate advice on the importance of only requesting those items which they actually need

5.1.96.3 if the patient is suffering any side effects which may require a review of their medication

5.1.97 Any interventions, referrals or refusal to supply decisions which are deemed clinically significant will be recorded on the Intervention and Referral Form.

5.1.98 The pharmacy has a procedure for notifying (by telephone or by other non-face-to-face method) a patient of medicines owed. This includes advice to the patient that they can take the prescription elsewhere when the shortfall in pharmacy stock is identified.

5.1.99 The procedure includes the provision of a written slip with the prescription delivery including details of the amount owed and when it would become available for delivery. Once the medication arrives, a cross can be marked on the owing slip to denote it has been completed. Records will be made of uncollected owings after 3 months.

Additional requirements in relation to specified appliances - Paragraph 12

5.1.100 The Pharmacy has a Remote Appliance SOP, which details this procedure, which applies to Part IXA, Part IXB or Part IXC prescription items.

5.1.101 Should a prescription for an appliance which needs fitting is received, the Pharmacy will review the patient's PMR to confirm the patient had the appliance before and confirm with the patient that there has been no change in required size.

5.1.102 Should the Pharmacy have received a new prescription, they will send an appliance measurement sheet electronically or physically to the patient, with instructions as to how to measure themselves. If this is not sufficient for the patient, a live video tele consult will be performed with the Responsible Pharmacist to assist the patient in their measurements.

Disposal service in respect of unwanted drugs - Paragraphs 13 to 15

5.1.103 Patients wishing to return unwanted medicines to the pharmacy may do so by giving waste to the drivers. The Pharmacy will obtain an upper tier 'Waste Carriers License' to transit this waste from the patient's home to the Pharmacy.

5.1.104 This waste carrier license will be renewed every 3 years. Patients in locality may contact the pharmacy by phone or email to arrange collection of unwanted medicines from their home or work by pharmacy staff.

5.1.105 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.

5.1.106 The disposal service will be easily accessible to patients on the website.

5.1.107 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

5.1.108 The Pharmacy will provide opportunistic healthy lifestyle advice and public health advice to appropriate patients.

5.1.109 Appropriate patients will be identified during another interaction such as dispensing where the patient is not actively seeking additional information but provides information which suggests advice would be beneficial or from a lifestyle questionnaire that will be available on the website. This is relevant to patients who have or are:

5.1.109.1 Diabetes

5.1.109.2 coronary heart disease

5.1.109.3 Smoking

5.1.109.4 Overweight

5.1.110 The Pharmacy will provide information on its website and via NHS leaflets.

5.1.111 Records will be kept of any advice given to patients.

Health campaigns - Paragraph 18

5.1.112 The Pharmacy will take part in all health campaigns where practicable, mostly through the website of when distributing NHS leaflets. This can be achieved by sending out leaflets with prescriptions during specific targeted campaign periods and providing additional advice and learning resources via the website.

Signposting - Paragraphs 19 and 20

5.1.113 The Pharmacy will inform or advise people of other health and social care providers and support organisations, such as patient groups, when appropriate.

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

5.1.115 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.

5.1.116 Records will be kept of information or referrals made on the Intervention and Referral Form.

Support for self-care - Paragraphs 21 and 22

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

5.1.118 The Pharmacy will provide this advice in the same manner as for signposting patients. A range of topics ranging from long-term conditions to minor ailments will be found on the website in the well-being section that provides information and advice. This will be linked to the NHS Choices website for further up-to-date information.

5.1.119 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.

5.1.120 Records will be kept of the advice given whether online or over the phone if deemed necessary.

Discharged Medicines Service - Paragraph 22B to 22C

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

5.1.121.1 (a) recently discharged from hospital who is referred to Pharmacy 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 who

is otherwise referred to the Pharmacy for advice, assistance and support in

5.1.121.2 (b) 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

5.1.122 An SOP will be in place to require checking for referrals and ensuring compliance with each stage of the service specification.

5.1.123 The advice will be provided via one of the channels of communication appropriate to a distance selling pharmacy to patients anywhere in England.

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

Advanced or Enhanced Services

5.1.125 An index of enhanced SOPs is attached [see Appendix B]. 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

5.1.126 It is confirmed that nothing in JRapha Pharmacy's practice leaflet, publicity material, in material published on behalf of JRapha Pharmacy 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 JRapha Pharmacy will represent, either expressly or impliedly, the essential services provided at or from the premises are:

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

5.1.126.2 JRapha 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

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

5.1.127.1The uninterrupted provision of essential services during the opening hours of the premises, to persons anywhere in England who request those services and

5.1.127.2The 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.

5.1.128 In the circumstances, we hope you will refuse this appeal and confirm the ICB's decision to grant our client's application."

5.2 RUSHPORT ADVISORY LLP ON BEHALF OF JARDINES (UK) LIMITED

5.2.1 "Thank you for your letter of 25 June enclosing the Applicant's SOPs.

5.2.2 These SOPs appear to suggest differing processes from those specified in the Applicant's original application form at section 7 which discussed greeting patients when they arrived at the pharmacy.

5.2.3 We note that the SOPs provided by the Applicant still do not address properly how they will deliver all essential services and additional services such as Appliance Reviews to any patient in England who requests such services.

5.2.4 We note that in relation to the fitting of Appliances, the Applicant proposes to carry this out by way of a video consultation. This does not appear to be appropriate for the "fitting" of an Appliance as it would require a physical process to be carried out.

5.2.5 In relation to delivery of cold chain products the Applicant proposes using a cool box with a validated minimum / maximum thermometer if a "regulated cold chain delivery firm" is not available. Such a procedure is clearly unsafe and impractical over long distances. The same SOP refers to moving "samples" to an alternate freezer if the temperature has deviated during the delivery process and again this does not appear appropriate in relation to the delivery of dispensed medication."

6 Summary of Observations

This is summary of observations received.

6.1 GORDONS PARTNERSHIP SOLICITORS ON BEHALF OF THE APPLICANT

6.1.1 "As you are aware, we act for JRapha Care Limited, intending to trade as JRapha Pharmacy. Our client wishes to make representations on the response by Jardines (U.K. Limited) dated 25 June 2024 to our response to Jardines appeal.

6.1.2 We have already clarified the error in the initial application form and said this in the letter to PCSE about the paragraph in the application that referred to greeting patients:

"our client accepts that the application contains an inaccuracy where it refers to essential services and should have referred to directed services. Our client apologises for this. Jraphra [sic] Pharmacy has a full suite of distance selling SOPs and the directors are aware of the conditions under which services will be provided. As well as other condition, our client's directors are particularly aware that they will be responsible for the safe and effective provision of essential services without face-to-face contact between any person receiving the services and all personnel at Jraphra [sic] Pharmacy."

6.1.3 To reiterate, we are instructed that patients will not attend the pharmacy to receive essential services.

6.1.4 In relation to the issues raised on appliances our client's comments are as follows: Most appliances can be supplied without seeing the patients; for example, catheter bags, syringes, needles, test strips, compression bandages, hosiery, Laryngectomy and Tracheostomy are all appliances that can be supplied to patients as prescribed. Furthermore, prescriptions for appliances usually have a specific order code.

6.1.5 Our client is aware of the obligation in the terms of service paragraph *8(4) "If the order is for or a product to be provided in accordance with a SSP is,] an appliance of a type requiring measuring and fitting (for example a truss), P must make all necessary arrangements for a registered pharmacist— (a) to measure the person named on the prescription form or repeatable prescription for the appliance; and (b) to fit the appliance"* and notes that provision does not specify the measurement and fitting must be in person.

6.1.6 Our client has given extensive thought to how measurement and fitting will be carried out if required and we attach a document which sets out how this will be achieved.

6.1.7 In relation to cold chain, Jardines refer to SOPs sent to PCSE and the letter of appeal explains that these have been updated. Please see the attached updated SOP [see below 6.1.17 – 6.1.40].

6.1.8 In the circumstances, we hope you will refuse this appeal and confirm the ICB's decision to grant our client's application."

Supporting information provided:

6.1.9 "Remote fitting of appliances that require precise measurement: The following methods will be used by the Pharmacist

6.1.10 Telehealth Consultations

6.1.10.1 Video Calls: The Pharmacists will use video conferencing tools such as Telehealth video calls, to guide patients through the measurement process. This allows the pharmacist to visually inspect and advise on the fitting.

6.1.10.2 Phone Calls: In some cases, the pharmacist will do phone consultations with the patient, especially if the patient can provide measurements or if they have prior experience with similar fittings.

6.1.11 Digital Measurement Tools

6.1.11.1 Smartphone Measurement Apps: such as Measure (iOS) and Google Measure (Android) apps guide the patient through taking measurements using a smartphone, providing step-by-step instructions and ensuring accuracy through the software algorithms. These measurements will then be reviewed by the Pharmacist on receipt.

6.1.12 Wearable Technology

6.1.12.1 Smart Wearables: Devices like smart bands or wearable sensors will be used by the patient to capture body measurements and other relevant data, which will be transmitted to the pharmacist for analysis.

6.1.13 DIY Measurement Kits

6.1.13.1 Home Measurement Kits: Patients will be provided with kits that include measuring tapes, instructions, and other necessary tools through post or delivery driver. They will follow the instructions to take their measurements and then share the data with the pharmacist.

6.1.13.2 Virtual Assistance: The Pharmacists will guide patients in real-time using augmented reality (AR) apps (Google Measure) to ensure correct use of DIY measurement kits.

6.1.14 Virtual Fitting Rooms

6.1.14.1 Online Platforms: Dedicated online platforms such as L&R Medical will be used, where patients can upload their measurements and receive fitting advice from the pharmacists.

6.1.15 Ensuring Accuracy and Compliance

6.1.15.1 Training and Support: The Pharmacist will ensure patients receive detailed instructions through post or delivery driver and support to ensure they take accurate measurements.

6.1.15.2 Follow-Up: The Pharmacist will follow-up consultations to verify the fitting and make any necessary adjustments.

6.1.16 Quality Assurance: The Pharmacist will regularly review and updates the remote fitting protocols/SOP to incorporate feedback and advancements in technology. By integrating these remote fitting methods, the pharmacists will provide accurate and effective fitting services while maintaining convenience for the patient. This approach leverages modern technology to deliver high-quality care even when in-person visits are not possible."

Cold Chain Deliveries Standard Operating Procedure ('SOP')

6.1.17 Receipt of Deliveries

6.1.18 Care will be exercised with thermo-labile products. Where medication requiring refrigeration is delivered and staff are concerned regarding the maintenance of the cold chain and the length of time in transit, they are to refuse the order and return it to the supplier.

6.1.19 Where a product has been accepted, it must be placed within the temperature-controlled, pharmacy grade refrigerator. When removed from this refrigerator, a visual inspection of the product must be conducted to ensure it complies with the described physical appearance.

6.1.20 Cold Chain Deliveries

6.1.21 Cold chain items are handled with strict adherence to verified procedures:

6.1.21.1 Local deliveries include packaging in polystyrene cool boxes with calibrated thermometers and ice packs.

6.1.21.2 Patients are notified of delivery timings; drivers confirm delivery times to minimize failures.

6.1.22 Integrity of Cold Chain

6.1.23 The pharmacy ensures maximum stability and integrity of thermo-labile drugs throughout packing, transportation, and delivery, monitored with temperature-controlled services.

6.1.24 Cold Chain Deliveries Beyond Local Radius via Royal Mail/courier

6.1.25 For all cold chain orders, only remove them from the fridge when ready to be packed and dispatched. Accompanying items should include a note to explain that fridge items will be delivered separately to the rest of their items to enable the cold chain to be maintained.

6.1.26 Cold chain parcels will be sent using Royal Mail. Cold Chain will ensure the integrity of the cold chain and the maximum stability of thermolabile drugs by packing, transporting and delivering in such a way that their integrity, quality and effectiveness is always preserved. This is a dedicated, fully monitored and temperature-controlled delivery service. The packaging should be the insulated Royal Mail insulated packaging which maintains a constant 2-8

degrees for up to 72 hours. Remove the checked order from the fridge, double check with the pharmacist before placing it in the insulated packaging. Push the activator button on the cooling pack to start the cooling process just before the order is to be collected. Ensure the box is sealed and attach the address label. A delivery should be booked using Royal Mail Cold Chain Services, selecting a delivery maintaining 2– 8°C. Confirm that the delivery will be maintained at 2 – 8°C with the courier and ask them to sign a log confirming receipt of the orders. Royal Mail insulated boxed cannot be reused once the activator button has been activated. The RP should make sure that all scheduled fridge line collections have been booked and collected before the end of the day.

6.1.27 Unsuccessful cold chain delivery via Royal Mail/courier

6.1.28 In the event of an unsuccessful delivery, Royal Mail Cold Chain Services will leave a 'Missed Delivery' card, stating the date and time of the attempted delivery. The patient can then rearrange delivery for a convenient time by telephone or Internet. Royal Mail Cold Chain Services will keep the cold chain intact until successful delivery.

6.1.29 Breach of Integrity of Cold Chain

6.1.30 The cold chain service is a dedicated, fully monitored and temperature-controlled delivery service. 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 Royal Mail/courier is instructed to leave a 'Missed Delivery' card and 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. To audit the cold chain delivery service, the pharmacy team will send dummy parcels to various locations with a recording temperature control device to check if cold storage has been maintained.

6.1.31 The pharmacist will arrange for the results to be recorded. This test will be carried out every month. The responsible pharmacist will ensure this is actioned monthly and the results recorded in the cold chain log. If there has been a breach of cold chain, the courier must be contacted, and an investigation carried out immediately. All further cold chain orders must be kept on hold until the courier can guarantee cold chain delivery. A member of the dispensary team will check if fridge lines have been delivered successfully from orders dispatched the previous day. If the delivery has not arrived within the scheduled time, the Royal Mail/courier must be contacted, and the issue investigated.

6.1.32 The Pharmacy may also use a regulated cold chain delivery firm to deliver these medicines if there is any disruption to the Royal Mail cold chain service.

6.1.33 Monitoring and Contingency

6.1.34 In all delivery methods packaging and delivery processes are tested and monitored to ensure temperature compliance. Specific examples of testing for the Royal Mail service is given above. Immediate action is taken in case of breaches, with patient notification and re-delivery arrangements.

6.1.35 Patient Communication

6.1.36 Upon prescription arrival, patients are contacted to confirm availability for cold chain medication delivery, with options for alternative delivery addresses or collection arrangements.

6.1.37 Missed Delivery Protocol

6.1.38 In case of missed deliveries, patients are informed to rearrange within 24 hours to maintain cold chain integrity. Packaging ensures temperature maintenance for up to 72 hours.

6.1.39 Cold Chain Breach

6.1.40 Immediate patient notification and re-delivery arrangements are made in case of cold chain breach. Affected items are segregated and returned to the pharmacy."

6.2 RUSHPORT ADVISORY ON BEHALF OF JARDINES (UK) LIMITED

6.2.1 "Thank you for you [sic] letter of 30 June enclosing what appears to be an updated version of the Applicant's SOPs.

6.2.2 The new SOPs are the third version that the Applicant has provided and still do not meet the legal requirements of regulation 25, however we note that the Applicant also refers to other SOPs that have not been provided.

6.2.3 In the new SOPs the Applicant focusses on GPhC standards and we appreciate that the Committee will not be considering those standards as part of the determination of this appeal.

6.2.4 The Applicant has attempted to address the concerns that we raised on behalf of our client with respect to the measuring and fitting of appliances and states that they have provided, "the SOP for the remote appliance service"

6.2.5 The Applicant then states;

"*The Pharmacy has a Remote Appliance SOP, which details this procedure, which applies to Part IXA, Part IXB or Part IXC prescription items.*

Should a prescription for an appliance which needs fitting is received, the Pharmacy will review the patient's PMR to confirm the patient had the appliance before and confirm with the patient that there has been no change in required size.

Should the Pharmacy have received a new prescription, they will send an appliance measurement sheet electronically or physically to the patient, with instructions as to how to measure themselves. If this is not sufficient for the patient, a live video tele consult will be performed with the Responsible Pharmacist to assist the patient in their measurements."

6.2.6 Whilst the SOPs starts by mentioning "*an appliance which needs fitting*", it does not in fact specify how fitting by the pharmacist would take place and instead discusses "appliance measurement". As a result, there is no safe and effective procedure for the fitting of appliances.

6.2.7 Similarly, the process to be used for measuring of Appliances requires the patient rather than the pharmacist to carry out the measuring process.

6.2.8 At page 14 of the Applicant's document there appears to be another SOP to deal with Appliance Use Review. This SOPs states that there will be a "planned face to face consultation between the pharmacist and the patient". As the Applicant uses the term "the pharmacist" rather than "a pharmacist", we assume that this consultation would take place at the pharmacy premises and this is reinforced by the Applicant stating that;

"Should a patient request an Essential Services (e.g. supply of medicine face to face or return of unwanted medicine to the pharmacy in person) during the advance service appointment, 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."

6.2.9 What is not clear is how the patient would be expected to attend the appointment if they lived in Cornwall or some other location that was a considerable distance from the Applicant's premises.

6.2.10 The Applicant then provides (at page 17 of the attachment) a "Remote Appliance Fitting Standard Operating Procedure", however, as the Committee will note, this SOP does not in fact deal with fitting at all and only deals with measuring. This SOP differs from the Appliance Use Review SOP in that it suggests that patients would not be invited to travel to the pharmacy for an appointment and would instead rely on video consultations. Clearly a pharmacist cannot fit an Appliance on a video consultation.

6.2.11 In relation to delivery of cold chain products the Applicant continues to propose using a "cool pack/box" with a "validated minimum / maximum thermometer" if a "regulated cold chain delivery firm is not available". Such a procedure is clearly unsafe and ineffective over long distances.

6.2.12 The Applicant refers to, but does not provide, "procedures in the event of a suspected breach in the cold chain" and it is therefore not possible to assess whether there are safe and effective procedures in place to deal with such circumstances.

6.2.13 In respect of the Discharged Medicines Service the Applicant simply states that they will have an SOP in place for the service but provides no detail.

6.2.14 In summary, the Applicant has still not provided sufficient information that would satisfy the Committee that all essential services will be provided in a safe and effective manner to any patient in England who requests them and the application should therefore be refused."

6.3 THE COMMISSIONER

6.3.1 "Thank you for your letter dated 30 July 2024; the East Midlands Primary Care Team (EMPCT) on behalf of Northamptonshire ICB would like to make the following representations.

6.3.2 Regulation 25(1) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended states that Section 129(2A) 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,

6.3.3 Regulation 25(2) states that in respect of pharmacy premises that are distance selling premises the commissioner must refuse the 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 the commissioner 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

6.3.4 The application by Jrapha Care Limited was for a distance selling premises and as such is an accepted application under regulation 25 of the National Health Services (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended.

6.3.5 The nearest provider of primary medical services with a patient list is a 3 minute drive from the proposed premises and therefore the application could not be refused on this element of regulation 25.

6.3.6 The applicant in not seeking to restrict the provision of essential services in any way. The applicant provided a list of Standard Operating procedures including the posting of meds and how returns will occur.

6.3.7 The applicant has explained how they will undertake appliance customisation through video link.

6.3.8 With regards to the essential service provision face to face with the applicant or their staff, the original application stated that the applicant would provide face to face essential services however, following representations made by Jardines UK and the BLMK and Northamptonshire LPC the applicant provided a letter for clarification and assurance that face to face essential services would not be provided.

6.3.9 The applicant provided representation through Gordons Partnership Solicitors in response to the representation received by Jardines UK and the BLMK and Northamptonshire LPC. A copy of the documents were shared with the committee as part of their decision making process.

6.3.10 This included a suite of SOPs.

6.3.11 With regard to the Cold Storage. The team are in agreement with the appellant in principle because the incorrect use of a cool box breaches Standards 4.2 and 4.3. However, some rewording of the SOP may address this.

6.3.12 The wording in the SOP may be ambiguous and it was felt that clarity is needed, rather than a specific change.

6.3.13 If a validated cool box manufactured for the transport of medicines is used as per manufacturer specifications in conjunction with a thermometer that has been calibrated to relevant cold change standards, and the box is only used for local deliveries expected to take no longer than time within the limits of the cool box, this would be suitable. The SOP does not state this though and it could be interpreted that a cool box could be used for deliveries by couriers that may take several days, which could be unsafe.

6.3.14 The SOP should be worded for clarity for when an approved cold chain carrier will be used and when a cool box will be used by pharmacy delivery staff i.e. cool box only for local deliveries as above.

6.3.15 A suitable thermometer would be one with a cold chain calibration certificate that is dated within the last 12 months and the calibration points include at least one within cold chain temperatures of 2°C to 8°C (e.g. a calibration certificate with 0°C, 5°C and 10°C points). A calibrated data logger is also an option.

6.3.16 The box should only be used for local deliveries that are well within the timeframe stipulated by the cool box manufacturer and deliveries should not be to more than a specified number of addresses (perhaps just 2 for safety). This is to limit the risk of exposure to temperature excursions outside of cold chain parameters when the box is opened.

6.3.17 The SOP should state that single use refrigerated packaging, without the use of a calibrated thermometer (or data logger) that accompanies the medicines throughout the transport process, will not be used.

6.3.18 Regarding the freezer, It appears this is copied from a previous version of the SOP. The team would expect more context and what the 'samples' relate to. Are they handling frozen samples and specimens? I would suggest that this is removed or amended if it does not accurately represent procedures.

6.3.19 In summary the contractor provided additional information to show compliance with all the elements of regulation 25. The application could not be refused with regards to regulation 31 as there are no persons on the pharmaceutical list (which may or may not be the applicant) is providing or has undertaken to provide pharmaceutical services from

6.3.19.1 The premises to which the application relates, or adjacent premises and

6.3.19.2 The Integrated Care Board is satisfied that it is reasonable to treat the services that the applicant proposes to provide as part of the service as the existing services (and so the premises to which the application relates and the existing listed chemist's premises should be treated as the same site)

6.3.20 The representation provided by Rushport on behalf of Jardines UK and BLMK LPC were sent prior to the contractor providing further information to support the application and therefore are out of date, the committee made the decision to approve the application based on the new evidence provided. Though there is some work to be carried out on the SOPs provided this is administration and would not have affected the application being approved. I would like to take this opportunity to respond to any further representations provided by Rushport Advisiory [sic]."

6.3.1 "Useful documents enclosed with the Commissioner observations (see Appendix C):

6.3.1.1 Representations received from the 45 day notification period from Jardines

6.3.1.2 Representations received from the 45 day notification period from BLMK and Northamptonshire

6.3.1.3 Reply following submission of representations from Jardines and BLMK."

7 Consideration

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

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

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

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

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

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

7.7 The Committee noted that it appeared that the Commissioner, whilst setting out Regulation 31, had not made a determination on Regulation 31. The Committee noted however that the application of Regulation 31 had not been disputed either on appeal or in subsequent representations.

7.8 Based on the information provided, the Committee was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

7.9 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."

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

7.12 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 it's decision report, whilst confirming that the application meets the criteria for a distance selling application had stated:

7.12.1 "*The proposed premises in respect of which the application is made on the same site or in the same building as the premises of a provider of primary medical services with a patient List.[sic]*"

7.13 The Committee considered the information before it and noted that, on appeal, it had not been argued that 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. Based on the information available to it, the Committee determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

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

7.15 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.

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

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

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

7.19 The Committee noted the initial references to "greeting patients", however the Committee noted the comments from the Applicant's representative that the Applicant has corrected the misstatements in the initial application form where it had referred to "essential services" when it should have referred to "directed services". The Applicant

had confirmed via their representative that "*our client's directors are particularly aware that they will be responsible for the safe and effective provision of essential services would be without face to face contact between any person receiving the services and all personnel at Jrapha Pharmacy*."

7.20 The Committee further noted the confirmation from the Applicant's representative that "*we are instructed that patients will not attend the pharmacy to receive essential services."*

7.21 The Committee noted the comments from the Applicant that the premises have been chosen so "*it does not have the appearance of a standard High Street pharmacy*" and further that "*it is located in a commercial business centre away from retail or residential areas."* The Committee also noted that the Applicant had confirmed that there would be further controls in place including locks and CCTV.

7.22 The Committee noted the confirmation from the Applicant that if a person did arrive at the premises then they would be advised that they would not be able to assist them with regard to essential services and were only able to assist through the prescribed methods of communication appropriate for a distance selling pharmacy, i.e. video conferencing facilities, telephone and fax lines as well as through the website. The Committee further noted the comments from the Applicant that if a patient did require a visit to the premises, for anything other than an essential service, then this would be by appointment only and they would be made aware that no essential services could be carried out.

7.23 Based on the information before it, including the revised SOPs and additional information from the Applicant's representative, the Committee was satisfied that the provision of essential services would be without face to face contact.

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

7.25 The Committee noted the various references throughout the application and supporting information to prescriptions being received by post as well as electronically and further confirmation from the Applicant that medications would be delivered by their own delivery driver, for local deliveries, and that they would also be making use of Royal Mail and courier companies. The Committee further noted that the Applicant had confirmed that they would have a fully functioning website and would be able to contact patients via telephone as well as using live chat functions. The Applicant had confirmed that they would be providing essential services to anyone anywhere in England.

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

7.27 The Committee noted the comments from the Applicant with regard to the Responsible Pharmacist and that "*during opening hours there will always be a responsible pharmacist (RP) on site*". The Committee noted the Applicant had gone on to state "*Staff will be trained on the procedure to follow should the Responsible Pharmacist be absent from the pharmacy for any duration of time."* The Committee noted that it had not been provided with any information as to what would happen in this situation and how the pharmacy would operate and ensure uninterrupted services in the absence of the Responsible Pharmacist.

7.28 The Committee was of the view that it was not clear, from the information provided how essential services would be provided, should they be required, during the absence of the Responsible Pharmacist. Therefore the Applicant would be unable to provide all essential services without the presence of a pharmacist on site.

7.29 Based on the information before it, the Committee was not satisfied that the provision of services would be without interruption.

7.30 The Committee went on to consider whether safe and effective provision of essential services was likely to be secured.

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

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

7.32.1 Dispensing of drugs and appliances

7.32.2 Urgent supply without a prescription

7.32.3 Preliminary matters before providing ordered drugs or appliances

7.32.4 Providing ordered drugs or appliances

7.32.5 Refusal to provide drugs or appliances ordered

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

7.32.7 Disposal service in respect of unwanted drugs

7.32.8 Promotion of healthy lifestyles

7.32.9 Prescription linked intervention

7.32.10 Health campaigns

7.32.11 Signposting

7.32.12 Support for self-care

7.32.13 Discharge medicines service

7.32.14 Websites and health promotion zones

7.33 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:

Urgent supply without a prescription

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

7.35 The Committee noted that the Applicant had stated that they are "*aware of the process*" and that "*staff will be trained on the procedures to implement these*" however the Committee had not been provided with any further information in subsequent representations that dealt with Urgent Supply without a prescription. The Committee was of the view that saying that they were aware of the process and listing a SOP as well as confirming that staff would be trained on the procedure was not sufficient to demonstrate compliance with the terms of service.

7.36 Given the lack of information the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.

Providing ordered drugs or appliances

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

7.38 The Committee noted the information contained in the Applicant's representations as well as the various SOPs, provided by the Applicant to the Commissioner provided with their representations and finally with their observations that covered the provision of drugs or appliances specifically with regard to "cold chain".

7.39 The Committee noted the statement from the Applicant "*Where medication requiring refrigeration is delivered and staff are concerned regarding the maintenance of the cold chain and the length of time in transit, they are to refuse the order and return it to the supplier."* The Committee was of the view that this process was concerned with the initial receipt of medications from suppliers, not from the pharmacy to patients, and, whilst it was important that the cold chain was maintained at all times in the supply chain, this was, in essence, no different to how a standard bricks and mortar pharmacy would deal with the receipt of medications and therefore took no view on this.

7.40 The Committee's focus was on how the Applicant would ensure that the cold chain was maintained for the drugs that it was responsible for delivering to patients.

7.41 The Committee noted that the Appellant had raised concerns regarding the use of a cool box in response to the representations and how the integrity of the cold chain would be maintained and monitored.

7.42 In response, the Committee noted that the Applicant had stated:

7.42.1 "*The Pharmacy will use a regulated cold chain delivery firm to delivery [sic] these medicines and if unavailable, a cool pack/box may be used in conjunction with a validated minimum/maximum thermometer. Domestic cool boxes are not to be used."*

7.43 The Applicant had gone on to state "*The Pharmacy have prepared procedures in the event of a suspected breach in the cold chain."*

7.44 The "Cold Chain Deliveries SOP" as provided by the Applicant with their observations states:

7.44.1 "*Cold Chain deliveries*

Cold chain items are handled with strict adherence to verified procedures:

- *Local deliveries include packaging in polystyrene cool boxes with calibrated thermometers and ice packs.*
- *Patients are notified of delivery timings, drivers confirm delivery times to minimise failures.*

Integrity of Cold Chain

The pharmacy ensures maximum stability and integrity of thermo-labile drugs throughout packing, transportation, and delivery, monitored with temperature controlled services.

Cold chain parcels will be sent using Royal Mail. Cold Chain will ensure the integrity of the cold chain and the maximum stability of thermolabile drugs by packing, transporting and delivering in such a way that their integrity, quality and effectiveness is always preserved. This is a dedicated, fully monitored and temperature-controlled delivery service. The packaging should be the insulated Royal Mail insulated packaging which maintains a constant 2-8 degrees for up to 72 hours. Remove the checked order from the fridge, double check with the pharmacist before placing it in the insulated packaging. Push the activator button on the cooling pack to start the cooling process just before the order is to be collected. Ensure the box is sealed and attach the address label. A delivery should be booked using Royal Mail Cold Chain Services, selecting a delivery maintaining 2– 8°C. Confirm that the delivery will be maintained at 2 – 8°C with the courier and ask them to sign a log confirming receipt of the orders. Royal Mail insulated boxed cannot be reused once the activator button has been activated. The RP should make sure that all scheduled fridge line collections have been booked and collected before the end of the day.

Unsuccessful cold chain delivery via Royal Mail/courier

In the event of an unsuccessful delivery, Royal Mail Cold Chain Services will leave a 'Missed Delivery' card, stating the date and time of the attempted delivery. The patient can then rearrange delivery for a convenient time by telephone or Internet. Royal Mail Cold Chain Services will keep the cold chain intact until successful delivery.

Breach of Integrity of Cold Chain

The cold chain service is a dedicated, fully monitored and temperature-controlled delivery service. 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 Royal Mail/courier is instructed to leave a 'Missed Delivery' card and 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. To audit the cold chain delivery service, the pharmacy team will send dummy parcels to various locations with a recording temperature control device to check if cold storage has been maintained.

The pharmacist will arrange for the results to be recorded. This test will be carried out every month. The responsible pharmacist will ensure this is actioned monthly and the results recorded in the cold chain log. If there has been a breach of cold chain, the courier must be contacted, and an investigation carried out immediately. All further cold chain orders must be kept on hold until the courier can guarantee cold chain delivery. A member of the dispensary team will check if fridge lines have been delivered successfully from orders dispatched the previous day. If the delivery has not arrived within the scheduled time, the Royal Mail/courier must be contacted, and the issue investigated.

The Pharmacy may also use a regulated cold chain delivery firm to deliver these medicines if there is any disruption to the Royal Mail cold chain service.

Monitoring and Contingency

In all delivery methods packaging and delivery processes are tested and monitored to ensure temperature compliance. Specific examples of testing for the Royal Mail service is given above. Immediate action is taken in case of breaches, with patient notification and re-delivery arrangements.

Patient Communication

Upon prescription arrival, patients are contacted to confirm availability for cold chain medication delivery, with options for alternative delivery addresses or collection arrangements.

Missed Delivery Protocol

In case of missed deliveries, patients are informed to rearrange within 24 hours to maintain cold chain integrity. Packaging ensures temperature maintenance for up to 72 hours.

Cold Chain Breach

Immediate patient notification and re-delivery arrangements are made in case of cold chain breach. Affected items are segregated and returned to the pharmacy."

7.45 The Committee noted that if the delivery had not been able to be made then a "Missed Delivery" card would be left and Royal Mail will keep the cold chain until successful delivery. The Committee noted that this can be maintained for up to 72 hours, although it was unsure why this could not be done so indefinitely given the use of a specialist service. Whilst delivery would continue to be monitored during this 72 hour period there was nothing provided by the Applicant for the Committee to be able to determine that if the delivery exceeded this time frame, what should happen to the medication.

7.46 With regard to local deliveries, the Committee noted that the Applicant was proposing to use their own delivery driver. The Committee noted that domestic cool boxes would not be used and the Applicant was proposing to use a "*cool pack/box in conjunction with a validated minimum maximum thermometer*". The Committee noted that whilst the Applicant had stated that they *"have prepared procedures in the event of a suspected breach in the cold chain*" no information was provided as to how the local delivery driver would audit and monitor the temperature whilst the medication was out for delivery.

7.47 The Committee further noted the comments from the Commissioner with regard to Cold Storage that "*The team are in agreement with the appellant in principle because the incorrect use of a cool box breaches Standards 4.2 and 4.3. However, some wording of the SOP may address this*."

7.48 The Committee further noted that the Commissioner had gone on to state:

7.48.1 *"Regarding the freezer, It appears this is copied from a previous version of the SOP. The team would expect more context and what the 'samples' relate to. Are they handling frozen samples and specimens? I would suggest that this is removed or amended if it does not accurately represent procedures."*

7.49 The Committee noted that the Commissioner had gone on to advise what the SOP should say in order for it to be compliant. The Committee was of the view that it is not the position of the Commissioner to be advising applicants what their SOPs or applications should say in order to meet the relevant criteria as set out in the Regulations.

7.50 Whilst the Committee noted the SOPs as provided for "Cold Chain", the Applicant had not chosen to provide SOPs for the delivery of "controlled drugs" but had confirmed that "*there will also be specific procedures for the delivery of Scheule 2 & 3 CDs"*.

7.51 The Applicant had confirmed that controlled drugs would be delivered via local delivery drivers as well as using the Royal Mail 24/48 service.

7.52 With regard to a failed delivery, the Applicant stated:

7.52.1 *"Controlled drugs must remain in the CD cabinet until delivery is imminent.*

Checks will be completed to ensure that all medicines are labelled and that the name and address on the bag label corresponds to the prescription. A delivery slip will be attached to the bag to be signed by the patient upon delivery.

Patients will have their own drop sheet listing all required legal parameters, which can be found on the "Quick Form" section of the website. This will specify the name of the pharmacist, the item to be delivered and space for a signature. This drop sheet will also be given to the delivery driver. A signature must be obtained from the person receiving the item. Should the driver be unable to deliver the medication, the pharmacist at the pharmacy must be contacted. This can either be done by returning to the pharmacy with the drop sheet or calling the pharmacist.

A record will be made on the CD register by the RP.

"Where there is a failed delivery, the driver should complete a Not at Home postcard and post through the letterbox and return to the pharmacy. Where the CD are returned subject to safe custody, these can be returned to the CD cabinet and for schedule 2 drugs, re-enter them onto the CD register with an explanation."

7.53 Whilst the Committee had been provided with information as to what would happen if there was a failed delivery by the pharmacy's own local delivery driver, it noted that it had no information as to what would happen if there was a failed delivery for those further afield whose medication was being delivered by Royal Mail.

7.54 Taking all of the information before it into account including the additional information from the Applicant in the form of revised SOPs, the Committee was not satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

7.55 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.

7.56 The Committee noted that the Applicant had not completed this section of the application form and therefore no appliances were specified, however the Committee noted the supporting information supplied with the SOPs entitled "Remote Appliance Fitting Standard Operating Procedure". The Committee further noted the additional information provided in response to the appeal entitled "Appliance Use Review" and "Remote Appliance Fitting Standard Operating Procedure".

7.57 The Committee noted the various comments from parties with regard to the Appliance Use Review being an advanced service and not an essential service and as such, the Committee was mindful that patients would be able to access the pharmacy for the review. However, the Committee was unsure as to how the pharmacist would be able to ensure that the appliances had been measured and fitted correctly for those that were not able to attend the pharmacy in person.

7.58 The Committee noted the comments from the Appellant that the information provided, with regard to the essential service of measuring/fitting the appliance, had set out how the pharmacist would help patients with the measuring for an appliance but that there was no information contained as to how the pharmacist would fit the appliance.

7.59 The Committee noted the information in the SOP, including the use of an appliance measurement sheet, various measurement apps, pre-recorded video and a teleconsult

as well as a "virtual fitting room". However the Committee was of the view that none of this was sufficient and a patient using a template for an appliance which requires measuring /fitting, even with guidance from a pharmacist, was not the same as the registered pharmacist measuring/fitting the appliance. Further the Committee concurred with the view of the Appellant that the information provided centred around the question of measuring and there was very little provided in the way of advising how the pharmacist was going to actual fit the appliance.

7.60 The Committee was therefore not satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(4) of Schedule 4.

Discharge medicines service

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

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

7.63 The Committee noted that the Applicant had confirmed that they will be providing the "Discharged Medicines Service" and also state "*An SOP [sic] will be in place to require checking for referrals and ensuring compliance with each stage of the service specification"*. The Applicant had further confirmed that any advice would be provided "*via one of the channels of communication appropriate to a distance selling pharmacy to patients anywhere in England*."

7.64 The Committee noted however it had not been provided with any further information either in the form of the supplementary information in representations or the SOP referred to in support of the process and how the Applicant will be providing the discharge medicines service. The Committee was of the view that saying that they had a SOP and confirming that they would be providing such a service was not sufficient to demonstrate compliance with the terms of service.

7.65 The Committee was therefore not satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

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

Summary

7.67 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).

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

7.68.1 confirm the Commissioner's decision;

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

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

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

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

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

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

8 Decision

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

8.2 Accordingly, the Committee:

8.2.1 quashes the decision of the Commissioner; and

8.2.2 redetermines the application as follows -

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

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

8.2.2.3 the Committee was not satisfied that all essential services were likely to be secured without interruption during the opening hours,

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

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

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

8.2.3 The application is refused.

Case Manager
Primary Care Appeals