9 December 2024

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

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

REF: SHA/26339

APPEAL AGAINST NHS HUMBER AND NORTH YORKSHIRE ICB DECISION TO REFUSE AN APPLICATION BY SPINOFF LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT UNIT 1, 2 BRIDGE ROAD, STOKESLEY, TS9 5AA 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:

Spinoff Ltd
Boots UK Ltd
PCSE on behalf of Humber and North Yorkshire ICB

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1 The Application

By application dated 30 May 2024, Spinoff Ltd ("the Applicant") applied to Humber and North Yorkshire ICB ("the Commissioner") for inclusion in the pharmaceutical list at Unit 1, 2 Bridge Road, Stokesley, TS9 5AA under Regulation 25. In support of the application it was stated:

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

1.1.1 "Drug Tariff Part IX (except items that require measuring or fitting)".

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

1.2.1 "Not applicable. There are no other pharmacy [sic] on the same site or adjacent site or in the same building."

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

1.3.1 "The pharmacy premises is not located on the same site or in the same building as the premises of a provider of primary medical services with a patient list."

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

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

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

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

1.5 "NHS England has published premises standards that the Pharmacy will comply with, however, it should be noted that not all these standards apply directly to distance selling premises other than where a patient is accessing non-essential services.

1.6 The pharmacy will be a Healthy Living Pharmacy and comply with the change management and organisational development criteria, ensuring premises and facilities are fit for purpose and engaging with the community to deliver consistently high quality health and wellbeing services.

1.7 The pharmacy will be equipped with facilities to allow for both phone (or other live audio link) and live video communication with patients in a manner which maintains patient confidentiality.

1.8 The pharmacy will operate in accordance with the “Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet", the content of which is considered and replicated in part below but is not intended to exhaustively replicate the entirety of the GPhC guidance which will be followed.

1.9 Specifically, but not exhaustively, the pharmacy already has in place several procedures, which are GPhC requirements. The rest of the this [sic] document focuses on the procedures in place at the pharmacy.

1.10 It should be noted that any reference to ‘contact’ with or ‘contacting’ a patient in relation to these SOPs means contact other than face-to-face contact either on or in the vicinity of the premises.

Risk Assessment

1.11 A Risk Assessment document and risk matrix to help identify and manage risks. The risk assessment will look at what could cause harm to patients and people who use the pharmacy services, and what the pharmacy needs to do to keep the risk as low as possible.

1.12 The risk assessment will be reviewed quarterly and also when there are significant business or operational changes.

Audit Procedures

1.13 A regular audit programme will be in place. The audit will be an important 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.

1.14 The audit will, at the very least, consider;

1.14.1 staffing levels and the training and skills within the team;

1.14.2 suitability of communication methods with patients, and between staff and other healthcare providers, including between hubs and spokes and with collection and delivery points (if applicable);

1.14.3 use of specialised equipment and new technology;

1.14.4 records of decisions to make or refuse a sale;

1.14.5 systems and processes for receiving prescriptions, including EPS records of decisions to make or refuse a sale

1.14.6 systems and processes for secure delivery to patients;

1.14.7 any information about pharmacy services on the website;

1.14.8 review of how the pharmacy adheres to the information security policy,

1.14.9 Payment Card Industry Data Security Standard (PCI DSS) and data protection law;

1.14.10 feedback from patients and people who use the pharmacy services;

1.14.11 concerns or complaints received

1.14.12 activities of third parties, agents or contractors.

1.15 The Audit and review process will act as a Project Plan for the pharmacy to implement change and upgrades in service and training.

Reactive Review

1.16 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;

1.16.1 A significant change in any part of the pharmacy service provided, for example an increase in the number of patients the pharmacy provides services to, or an increase in the range of services the pharmacy intends to provide;

1.16.2 a data security breach;

1.16.3 a change in the technology the pharmacy uses;

1.16.4 concerns or negative feedback are received from patients or people who use the pharmacy services;

1.16.5 a review of near misses and error logs causes a concern about an activity.

Accountability

1.17 During opening hours there will always be a responsible pharmacist (RP) on site. Each area of work will have clear lines of accountability that will be set out by the superintendent pharmacist.

1.18 Record Keeping

1.19 Records in the pharmacy will be scanned in to the pharmacy IT system (including but not limited to, patient consent forms, queries, complaints, customer logs, sale refusals, and dispensing). Records will be kept for a minimum period of 7 years or longer if specific legislation requires.

Training

1.20 All staff will be properly trained and competent to provide medicines and other professional pharmacy services safely. The GPhC has produced guidance to ensure a safe and effective team and this will form the basis of the training.

Premises

1.21 Premises is registered with the GPhC and therefore complies with GPhC requirements for pharmacy premises.

1.22 The pharmacy website

1.22.1 The website will display;

1.22.2 GPhC pharmacy registration number;

1.22.3 name of the owner of the registered pharmacy;

1.22.4 name of the superintendent pharmacist;

1.22.5 name and address of the registered pharmacy that supplies the medicines;

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

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

1.22.8 Email address and phone number of the pharmacy;

1.23 The website will also provide details of specific services available and how to use them, such as:

1.23.1 Return of unwanted medicines;

1.23.2 Patient Lifestyle Questionnaire;

1.23.3 How to register exemptions from NHS charges;

1.23.4 Promotion of Health Lifestyles and details of campaigns being undertaken;

1.23.5 Procedures for Emergency Supply;

1.23.6 Explanation of rules on non-face to face contact;

1.23.7 Annual patient survey;

1.23.8 Patient Information Leaflet; details of how patients and users of pharmacy services can give feedback and raise concerns;

1.23.9 The website will be regularly updated, clear and accurate and follow the GPhC guidance on websites.

Transparency and Choice

1.24 The pharmacy website and materials will specify the nature and type of services it provides and who provides those services.

Managing Medicines Safely

1.25 The pharmacy SOPs provide the procedures for all staff to follow to ensure that the sale and supply of medicines in [sic] done in such a manner as to minimise risk to patients.

Supplying Medicines Safely

1.26 The SOPs for delivery of medicines contain detailed information on the safe and effective supply of medicines via the pharmacy's own driver, Royal Mail and courier firms, including;

1.26.1 assess the suitability and timescale of the method of supply, dispatch, and delivery for all medicines and particularly refrigerated medicines and controlled drugs;

1.26.2 ensuring that the prescriber has robust processes to check the identity of the person to make sure the medicines prescribed go to the right person - for example, by keeping to the Identity Verification and Authentication Standard for Digital Health and Care Services, which provides a consistent approach to identity checking across online digital health and care services;

1.26.3 assess the suitability of packaging (for example, packaging that is tamperproof or temperature controlled);

1.26.4 Ensure appropriate safeguards for all online supplies of medicines.

1.26.5 The pharmacy will monitor third-party providers, including analysis of patient feedback about deliveries and delivery times and processes.

Equipment and Facilities

1.27 All equipment used in the pharmacy will be sourced from manufacturers that have designed the equipment to be used in the manner in which the pharmacy intends to operate.

1.28 All equipment will be subject to annual performance testing and review, with specialist equipment (such as temperature monitoring) subject to monthly checks.

1.29 IT equipment will meet the latest security specifications and be regularly updated including the use of encrypted networks for wired and wireless communication. Access to records will be dependent on any given employee's level of authority and clearance which shall be determined by the superintendent pharmacist.

Standard Operating Procedures

1.30 A suite of operating procedures that cover the operations of this distance selling contract is available. If NHS England requires any further information about any aspect of the operation of the pharmacy then the relevant SOP will be provided upon request.

Pharmacy Systems And Procedures

1.31 All Essential Services will be delivered in accordance with:

1.31.1 Company Standard Operating Procedures;

1.31.2 NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013;

1.31.3 NHS Act 2006;

1.31.4 Human Medicines Regulations 2012;

1.31.5 Professional Standards and Guidance on Distance Selling Pharmacies;

1.31.6 Relevant Data Protection laws.

1.32 This will ensure that the pharmacy provides safe, effective and uninterrupted provision of all essential services to persons anywhere in England who request those services during the opening hours of the premises.

1.33 Essential Services will be provided without face to face contact between anyone receiving the services, whether on their own or someone else's behalf, and the pharmacy staff.

1.34 The Pharmacy will operate from secure premises with a controlled entry system, to which members of the public will not have access.

1.35 Any patient that requests essential services to be provided at the premises will be informed that the pharmacy is not permitted to provide those services at the premises.

1.36 Access to information about the provision of NHS Essential Services will be achieved by using:

1.36.1 Telephone;

1.36.2 The website will enable patients or their carers to communicate remotely but directly allowing quick and easy access and provide clear unambiguous details of how safe, efficient, uninterrupted NHS Essential Services will be provided by the Pharmacist and qualified, knowledgeable, experienced support staff on duty throughout the opening hours of the pharmacy premises without having 'face to face' contact with the patient or their representative.

1.36.3 Email;

1.36.4 Postal services.

1.37 All NHS services will be delivered free of charge in accordance with the NHS Act 2006. Essential Services may be delivered using:

1.37.1 Telephone, including text messaging where appropriate;

1.37.2 Electronic Prescription Service (EPS);

1.37.3 Website;

1.37.4 Email;

1.37.5 Royal Mail postal service;

1.37.6 Courier service;

1.37.7 Specialist Waste Management Services;

1.37.8 Live video services;

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

1.38 Provision of NHS Essential Services

Dispensing Services

1.39 Prescriptions will be received by the EPS, post, and fax or where practicable, with the patient's informed consent, collected from a surgery. Prescriptions will be clinically and legally assessed to determine if they can be dispensed.

1.40 In the event of any clinical or legal issues with the prescription the pharmacist will follow Standing Operating Procedures to resolve these issues before dispensing items. This may involve contacting the prescriber as soon as possible to make sure the patient receives their medication without delay.

1.41 When appropriate prescription interventions take place, for example drug/drug interactions, suspected over/under prescribing, etc. the pharmacist on duty will telephone and discuss with the prescriber and patient prior to dispensing or delivering the medication.

Repeat Dispensing Services

1.42 The Terms of Service require pharmacy contractors to ensure that appropriate advice about the benefits of repeat dispensing is given to any patient who –

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

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

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

1.44 Dispensing of repeat NHS prescriptions including those dispensed in dosette boxes as may be required under the Equality Act 2010 will be carried out in partnership with patients, carers, pharmacists and prescribers. It will cover requirements additional to those for dispensing, assessing the patients' need for repeat supply. Any clinical issues identified will be addressed to the prescriber.

1.45 Where considered necessary by a pharmacist, the patient may be contacted by telephone and given verbal advice in addition to information delivered with the repeat prescription.

1.46 Medicines will only be supplied where the pharmacist is satisfied that the patient is taking and is likely to continue to take the drug appropriately and is not suffering from any side effects which indicate the need or desirability to review the patient's treatment.

Urgent Supply and Emergency Supply

1.47 Whilst the Distance Selling nature of the pharmacy is such that Urgent Supply or Emergency Supply is unlikely to occur as often as in a retail pharmacy, all staff will be aware of the procedures to be followed in the event of such a request.

1.48 The request may be received from a Prescriber (Urgent Supply) or from a Patient (Emergency Supply).

1.49 The following conditions must apply to the request made by a prescriber: The Pharmacist must be satisfied that the request is from the appropriate authorised prescriber.

1.50 The Pharmacist is satisfied that a prescription cannot be supplied immediately due to an emergency.

1.51 The Prescriber agrees to provide a written prescription within 72 hours.

1.52 The medication is supplied in accordance with the prescriber's directions. The medication is permitted to be supplied on an Emergency Supply basis. An emergency supply cannot be provided for a Schedule 1, 2 or 3 CD except Phenobarbital for epilepsy by a UK registered prescriber.

1.53 EEA prescribers cannot request an emergency supply of any Schedule 1 - 5 CD.

1.54 Full records of the supply will be kept as per the relevant SOP.

1.55 The following conditions must apply to the request made by a patient:

1.56 The Pharmacist must interview the patient. The interview may not be by way of face to face contact and must be by other means, e.g., telephone, video call.

1.57 An entry must be made in the POM register on the day of supply and record all the relevant details.

1.58 The label for the dispensed medicine must contain the words "Emergency Supply".

Faxed Prescriptions

1.59 A 'faxed prescription' or other forms of scanned prescriptions do not fall within the definition of a legally valid prescription because it is not written in indelible ink, and has not been signed by an appropriate practitioner. A faxed / scanned prescription can confirm that at the time of receipt a valid prescription is in existence, but no medicines should be supplied until the original prescription is received.

1.60 The pharmacy will not dispense against faxed prescriptions and instead uses the Emergency Supply procedures.

Delivery of Urgent Supplies

1.61 Given the nature of a request of this type, the Pharmacy will prioritise delivery of the medication to the patient. For local deliveries the driver should be specially informed of the fact that the items are "URGENT" and for any items delivered by courier the courier will be informed that items must be delivered ASAP by the quickest route possible.

1.62 The pharmacy will not charge additional fees to the patient even if these are incurred in the delivery process. Other than noting the urgent nature of the delivery, normal delivery SOPs apply.

Disposal of Unwanted Medicines

1.63 As the pharmacy does not provide face to face essential services, patients will be advised to take their unwanted or out of date medication to a local brick and mortar pharmacy or GP surgery for disposal.

Promotion of Healthy lifestyles

1.64 Identification of patients for promotion of healthy lifestyles can take two forms, namely, passive or active.

1.65 Active patients will be those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further information should be sent, or who should be called to follow up on the results and offer additional support and information.

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

1.67 All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight and also lifestyle questions such as whether a patient is a smoker and how much exercise they normally on a weekly basis.

1.68 Leaflets will be delivered to patients with their medication. Those identified (Active or Passive) as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns to increase the patient's knowledge and understanding of health issues relevant to them. The website will also be used to promote healthy lifestyles.

Health Campaigns

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

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

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

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

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

Signposting and Support for Self-Care

1.72 Patient will be signposted to health and social care providers and/or any other assistance available whenever necessary. To assess whether patients require advice to minimise inappropriate use of health or social care services the pharmacist will use the same "Active and Passive" assessment tool already set out above.

1.73 Where it appears to the pharmacist, after reviewing the assessment and having regard to the need to minimise inappropriate use of health and social care services and of support services, that a person using the pharmacy would benefit from advice to help manage their medical condition then advice will be provided via non face to face methods of communication and this will include advice on both treatment options, nonprescription medicines and lifestyle advice.

1.74 If a patient; requires advice, treatment or support that the pharmacy cannot provide; but another provider, of which the pharmacy is aware, of health or social care services or of support services is likely to be able to provide that advice treatment or support, the pharmacy will provide contact details of that provider to that person and will, in appropriate cases, refer that person to that provider.

Referral for Certain Appliances

1.75 Where, on receipt of a prescription form or repeatable prescription, the pharmacy is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within the pharmacy's normal course of business, the pharmacist will -

1.75.1 if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; and

1.75.2 if the patient does not consent to a referral, provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the pharmacist.

1.76 In appropriate cases, the pharmacist will keep and maintain a record of any information given or referral made to facilitate auditing and follow up care.

Support for People with Disabilities

1.77 This service will be provided in accordance with the Equality Act 2010. The pharmacy will make reasonable pharmaceutical adjustment to ensure that those who qualify for help under the Act are provided with the right compliance aids.

1.78 The pharmacy will conduct an initial assessment with the patient, carer or representative to assess the support required to improve medication compliance. Such assessments will be carried out without patients having to access the pharmacy premises, so that no face-to-face contact at the premises will take place.

1.79 Compliance aid systems such as blister packs/dosette boxes will be provided in compliance with both service levels 1 & 2 respectively.

Clinical Governance

1.80 Note: Clinical Governance is not an 'essential service' and is therefore dealt with briefly in this submission.

1.81 The pharmacy will be involved in and comply with all the components of clinical governance including, but not limited to, compliance with standard operating procedures, patient safety incident and near miss reporting, demonstrating evidence of Pharmacists and Pharmacy Technician CPO, conducting clinical audits and patient satisfaction surveys, and drug recalls.

1.82 'How to Make a Complaint or compliment' will be displayed and accessible from the pharmacy website or upon request by telephone or post a copy will be posted.

1.83 All staff will be qualified or undergoing nationally accredited training. They will be competent to deliver the highest standards of Clinical Governance. All staff will receive individual and collective training, development and education provided in-house or from accredited external providers.

1.84 All staff will have an annual appraisal, receive and provide feedback.

1.85 The Pharmacy will conduct an annual Patient Satisfaction Survey / Community Pharmacy Patient Questionnaire (“CPPQ") based on the template recommended by the PSNC.

1.86 Details of the survey (as per PSNC website) can be found at http://psnc.org.uk/contract-it/essential-service-clinical-governance/cppq/

1.87 The survey will be adapted to reflect the operation of a distance selling pharmacy, i.e. Distributed via email, post and with delivery drivers/couriers. 2 References to "visiting" the pharmacy changes to reflect non face to face contact methods used.

1.88 Ratings for the pharmacy based on physical characteristics changed to reflect actual method of use, i.e. ease of use of website as opposed to "comfort and convenience of the waiting areas".

Information Governance

1.89 The pharmacy will be registered and comply with Data Protection Act and the General Data Protection Regulation (GDPR). It will also comply with the Access to Health Records Act 1990. It will publish its Freedom of Information Act Publication Scheme on its website and copies will be made available on request. All patient data will be kept private and confidential in accordance with NHS and legal obligations on data security, protection and confidentiality.

1.90 The pharmacy will receive support from the PMR provide [sic] to ensure that continuous access to the Electronic Prescription System is maintained.

1.91 Two members of staff will have the ability to login to the PMS system on all days (where there are 2 or more staff members working) and the NHS mail system will be checked every day for both general emails and also for any referrals under the Discharge Medicines Service.

Discharge Medicines Service ("DMS")

1.92 When NHS patients are discharged from hospital or there is, for other reasons, a transfer of care of them between different providers of NHS services, community pharmacies may be asked to perform a three stage service in respect of the patient, principally linked to changes in medication. The second and third stages of this service are linked to the first prescription presented post-discharge or post-transfer. Issues of concern may be raised by the pharmacy contractor not only with the patient or their carer but also with their general practitioner.

1.93 Under the DMS the pharmacy must provide assistance and support to, and in respect of, an NHS patient recently discharged from hospital who is referred to the 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 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.

1.94 The service allows and requires the pharmacy to help not only the patient directly, but also (within the bounds of confidentiality) their carers and also provide them with assistance and support.

1.95 The service is designed in 3 Stages, where each Stage builds on the last to provide additional support if required to the patient or, where appropriate their carer.

1.96 The pharmacist must use their clinical judgement when considering their actions and recommendations in respect of the service and consider the duty of confidentiality to the patient when involving a carer in discussions about the patient and their medication regimen.

1.97 If the DMS referral requesting that the pharmacy provides the DMS includes circumstances in which the pharmacy is not to provide, or is to cease to provide the DMS service, then the Pharmacy is not to, or is to cease to, provide the DMS in those circumstances (for example, X's or Y's admission or readmission to hospital).

Pandemic Treatment Protocol ("PTP")

1.98 The pharmacy will provide medicines properly requested under any PTP arrangements.

1.99 The RP should (and if requested to do so by the person being supplied must)

1.100 Provide an estimate of the time the drug will be ready and delivered. [sic]

1.101 If the drug is not ready by the time then provide a revised estimate of when the drug will be ready and continue to update the patient on this time should the estimate change.

1.102 Contact the patient to confirm dispatch of the medication.

1.103 In addition to the normal requirements, the dispensing label on the packaging of the product supplied must also contain the additional wording shown below; THIS PRODUCT IS BEING SUPPLIED IN ACCORDANCE WITH THE [INSERT NAME] PANDEMIC TREATMENT PROTOCOL

1.104 And insert the name of the relevant protocol.

Refusal to Supply under PTP

1.105 The pharmacy may refuse to provide an order for a drug that is or is purportedly in accordance with a PTP where—

1.105.1 the RP reasonably believes it is not a genuine order for the person who requests, or on whose behalf is requested, the provision of the drug;

1.105.2 providing it would be contrary to the RP's clinical judgement;

1.105.3 the RP or other persons are subjected to or threatened with violence by the person who requests the provision of the drug, or by any person accompanying (see footnote re "accompanying") that person; or

1.105.4 the person who requests the provision of the drug, or any persona accompanying (see footnote re "accompanying") that person, commits or threatens to commit a criminal offence.

1.106 The pharmacy must refuse to provide, pursuant to a PTP, an order for a drug that is or is purportedly in accordance with the PTP where P is not satisfied that it is in accordance with the PTP. Any refusal to supply must be noted on the patient and / or pharmacy record system.

Delivering Medicines

1.107 The Responsible Pharmacist (RP) has overall responsibility for ensuring the delivery of medicines to intended patients. Medicines must be delivered safely and with appropriate instructions.

1.108 The RP must take adequate measures 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. If the delivery to patients is local, this will be undertaken by the delivery driver except fridge lines which must be sent by courier. All other nationwide deliveries (other than fridge lines) will be delivered by Royal Mail special delivery or courier and signed for by the patient, their notified carer or other patient authorised representative. Fridge Lines will be delivered by courier (see further below).

1.109 Medicines will be packed, transported and delivered in such a way that their integrity, quality and effectiveness are preserved. The delivery mechanism used will provide a verifiable audit trail for medicine from the initial request through to its final delivery, or its return to the pharmacy in the event of a delivery failure. Packaging must maintain patient privacy and confidentiality.

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

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

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

1.113 Medicines classified as non-flammable or non-toxic must be securely closed and placed in a leak-proof container such as a sealed polythene bag (for liquids) or a sift proof container (for solids). Must be tightly packed in strong outer packaging and must be secured or cushioned to prevent any damage.

1.114 This means that for postal / courier items, either:

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

1.116 For most items - bubble wrap and where necessary, polystyrene filler, placed within a cardboard box. Cardboard boxes must be the re-enforced type.

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

1.118 The patient, carer or notified, authorised patient representative must always sign and date a receipt to prove safe receipt of the medicines.

1.119 A patient who is not at home when delivery is attempted will be informed using a non-delivery notice and an alternative delivery date will be arranged.

1.120 A list of the approved cold chain couriers is available within the Pharmacy. Coldchain items should be stored in styrofoam filled cardboard boxes prior to being passed to the courier and marked with the "FRAGILE" and "FRIDGE LINE" stickers. Additional packing will not be required as the courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box and are fully monitored.

1.121 Pharmacy staff should be aware that some thermolabile products can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in medicines which is damaging to them. The courier service is a dedicated, fully monitored and temperature controlled delivery service. Any breach of the cold chain is automatically notified to the driver who will then follow the failed delivery procedure and notify the pharmacy accordingly so that re-delivery can be arranged. Where the cold chain breach notice is issued items may not be re-used.

Delivery of Controlled Drugs

1.122 There is provision within controlled drugs legislation to cover occasions when a controlled drug (CD) may temporarily be in the possession of a third party, e.g. a delivery person or postal carrier, while it is being transferred from one authorised person to another authorised person who is entitled to be in possession of the drug.

1.123 Delivery of CD will be carried out by couriers with pharma grade specialist facilities to meet specific quality and validation requirements for healthcare products. This includes Home Office licensed controlled drug stores. The couriers will have the following UK Licenses and Standards:

1.123.1 1.109.1 MHRA Wholesale Dealer License;

1.123.2 1.109.2 MHRA Manufacturers Importers License;

1.123.3 1.109.3 MHRA IMP License;

1.123.4 1.109.4 ISO 9001: 2000 Certified;

1.123.5 1.109.5 Meet all Home Office safe custody and record keeping requirements.

Return and Destruction of CONTROLLED DRUGS

1.124 Patients will be advised to return unwanted controlled drugs to their local brick and mortar pharmacy

Cover for Breaks / Working Time Directive

1.125 Any breaks in working time taken by the RP will be covered by a second pharmacist who will then assume the responsibility of the RP.

Contingency Planning

1.126 The pharmacy will have accounts direct to pharmacy manufacturers and many full-line and short-line pharmaceutical wholesalers to try and increase the availability of stock and reduce Owings. A Contingency Plan will be in place to ameliorate the effects of any disruption to provision of pharmaceutical services such as medicines shortage, postal strike, EPS systems failure, etc.

Verification of Declarations of Prescription Exemptions

1.127 The reverse of the prescription should be fully completed (other than age exempt patients) in black ink.

1.128 Where evidence of exemption is required or provided by the patient it can be sent to the pharmacy for verification via the delivery driver and then returned to the patient.

1.129 The PMR system should be updated to reflect that necessary check has been carried out and a note of when the next check is required should be entered onto the system.

1.130 The Regulations require a patient to produce 'satisfactory evidence' to confirm exemption. Where appropriate (i.e. for deliveries made other than by the pharmacy's delivery driver), the patient may scan or fax copies of the evidence to the pharmacy (or use the postal / courier service, but see NOTE below) and the pharmacy can record that the evidence provided was not in the original format. It is for the pharmacist in charge to determine if the evidence is satisfactory or not and, if not, then cross the 'Evidence not Seen' box.

1.131 The type of exemption and date of expiry will be recorded in their Patient Medication Record. If they are not exempted prescription charge payments will be made using a secure on-line payment method.

1.132 Exemptions may be sent to the pharmacy by post and the pharmacy will pay for postage and return the exemption to the patient free of charge. Faxed and scanned email copies of exemptions are also acceptable. The nature of any exemption will be recorded on the PMR system with a copy attached to the patient's file.

1.133 Payment for prescription charges will be received via the secure payment portal on the website and when payment is received the prescription will be marked as paid.

Pharmacy Profile

1.134 The pharmacy profile will be regularly maintained and updated in the NHS Digital Directory of Services.

Central Alerting System

1.135 The pharmacy will maintain access to the MHRA Central Alerting System using the premises specific NHS mail email address which will be checked on a daily basis.

Registration of the Premises with the GPhC

1.136 The premises is registered with the GPhC

Practice leaflet

1.137 Nothing in the pharmacy's practice leaflet, or publicity material in respect of the listed chemist premises, in material published on behalf of the pharmacy publicising services

provided at or from the listed chemist premises or in any communication (written or oral) from the pharmacy or the pharmacy's staff to any person seeking the provision of essential services will represent, either expressly or impliedly, that –

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

(ii) the pharmacy is likely to refuse, for reasons other than those provided for in the

1.138 Pharmacy's terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (for example, because the availability of essential services from the pharmacy is limited to other categories of patients).

1.139 The Pharmacy will operate from secure premises with a controlled entry system, to which members of the public will not have access.

1.140 Any patient that requests essential services to be provided at the premises will be informed that the pharmacy is not permitted to provide essential services face to face at the premises. The customer will be advised that the pharmacy can only provide essential services via telephone or video call.

1.141 If the patient want to access [sic] essential services on a face to face basis, they will be referred to a local "brick and mortar" pharmacy.

1.142 Training will be provided to staff so they are aware that no essential services can be provided when a patient is on the premises.

1.143 All advanced services will be provided remotely via high quality video link or telephone.

1.144 Advance or enhanced services will be provided strictly in the consultation room, which is an area distinct from the dispensary and the general public areas of the pharmacy premises.

1.145 No element of essential services will be provided to the patient on-site in connection with the provision of advanced or enhanced services.

1.146 In the unlikely event that a patient makes a request for any essential service, the pharmacist or pharmacy team will explain to the patient the requested essential service can be accessed remotely. If the patient need [sic] pharmaceutical services urgently, they will be signposted to brick and mortar pharmacies in the area."

2 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 27 September 2024 states:

2.1 "NHS England has considered the above application, and I am writing to inform you that it has been refused for the following reasons:

2.1 This application was not supported by the committee [PSRC] due to some elements of essential services not being met and so they were not assured that all the regulations around a DSP application were met."

3 The Appeal

In the online appeal form dated 1 October 2024, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

3.1 “NHS England did not provide any reason for refusing the application other than stating "the application was not supported by the committee due to some elements of essential services not being met so they were not assured that all the regulations around a DSP application were met".

3.2 It would appear that the position of NHS England is they simply did not believe that Spinoff Limited will comply with DSP regulations.

3.3 This is an odd conclusion for NHS England to reach given that the application and extensive suite of SOPS provide clear demonstration of compliance with DSP regulations.

3.4 NHS England has also failed to comment on any of the SOP provided to them in any way which begs the question if the SOPs provided have been considered when determining the outcome of the application.

3.5 NHS England was wrong to refuse this application.

3.6 The committee is asked for the appeal to be allowed and the application granted.”

4 Summary of Representations

This is a summary of representations received on the appeal.

4.1 THE COMMISSIONER

4.1.1 “Thank you for your letter dated 7th October 2024.

4.1.2 This response will consider Regulation 31 and 25 as requested and submit evidence where necessary.

4.1.3 Just to note the point at the end of the first page which states "In relation to Regulations 25, and bearing in mind this is a reconsideration of the application …", we are not aware that this application has been considered previously at the Pharmacy Services Regulations Committee (PSRC). If this has been considered previously, please can the date of this be shared with us?

Regulation 31

4.1.4 Does not apply as there is not pharmacy at the same or adjacent premises.

Regulation 25(2)(a)

4.1.5 Does not apply as there is no primary care provider with a patient list present within the same premises as the proposed site.

Regulation 25(2)(b)(i)

4.1.6 The applicant did provide assurance in the Standard Operating Procedures (SOPs) that there would be uninterrupted provision of essential services throughout the opening hours of the proposed premises to patients throughout England who request services.

4.1.7 Regulation 25(2)(b)(ii) and Regulation 64

4.1.8 [I] would like to provide assurance to the contractor that the SOPs were submitted to PSRC and were used to consider the outcome of the application. This can be seen within the minutes of the meeting where on page 16 it states that " the application was good with lots of detail included in the SOPs and supporting information".

4.1.9 Contractor Application and SOPs

4.1.10 PSRC highlighted that on page 16 of the application, the contractor explicitly states:

4.1.11 Disposal of Unwanted Medicines

4.1.11.1 As the pharmacy does not provide face to face essential services, patients will be advised to take their unwanted or out of date medication to a local brick and mortar pharmacy or GP surgery for disposal.

4.1.12 This is repeated on page 77 of the SOPs.

4.1.13 On page 23 of the application, it states:

4.1.14 Return and Destruction of CONTROLLED DRUGS

4.1.14.1 Patients will be advised to return unwanted controlled drugs to their local brick and mortar pharmacy.

4.1.15 This is reiterated on page 103 of the SOPs which states:

4.1.16 Patient returned controlled drugs.

4.1.17 Procedure

4.1.17.1 If a person comes to the pharmacy to return medications for disposal, explain that as a distance selling pharmacy it is not possible to accept patient returns onsite.

4.1.17.2 Refer the patient to any non-DSP pharmacy or a GP surgery that offers this service Accepting controlled drugs waste by a delivery driver

4.1.17.3 If a person asks the driver to take back medications for disposal, the driver should refer the patient to a bricks-and-mortar pharmacy or GP Surgery that would be able to dispose of the unwanted medication.

4.1.18 Again, on page 129 of the SOPs, it states under Waste Handling that:

4.1.19 Procedure Accepting waste in the pharmacy.

4.1.19.1 If a person comes to the pharmacy to return medications for disposal, explain that as a distance selling pharmacy it is not possible to accept patient returns onsite.

4.1.19.2 Refer the patient to any non-DSP pharmacy who will be able to offer this service.

4.1.20 Accepting waste by a delivery driver

4.1.20.1 If a person asks the driver to take back medications for disposal, the driver should refer the patient to a bricks and mortar pharmacy who will be able to dispose of the unwanted medication.

4.1.21 Part of the Distance Selling Pharmacy (DSP) essential services is to dispose of unwanted medications and not re-direct patients to a bricks and mortar pharmacy. Although they cannot provide face to face services, there are other options that can be put in place to ensure patients can dispose of their

unwanted medications without having to be seen face to face to ensure the DSP meets its Terms of Service (ToS) safely and effectively.

4.1.22 It is Regulations 25(2)(b)(ii) and Regulation 64 that the PSRC refused the application as they were not assured that there had been met.

4.1.23 I acknowledge that this reasoning should have been made clearer when communicating the decision to the contractor and will take this learning on board going forward."

4.2 BOOTS UK LTD

4.2.1 "Thank you for your letter dated 7th October 2024 informing us of the above appeal.

4.2.2 We stand by our comments submitted to the NHS ICB that the premises that have been applied for are on the High Street and central shopping area of the town. The floor plan provided shows a clear and extensive patient seating/waiting area as well as what appears to be a large consultation room.

4.2.3 We ask that the SOP's provided by the appellant are carefully considered and that they satisfy the criteria set out in Regulation 25 and the conditions set out in Regulation 64.

4.2.1 We would be most grateful if you could notify us of the outcome of the appeal in due course."

In a letter dated 4 July 2024 addressed to PCSE Boots UK Ltd stated:

4.2.2 "Thank you for your letter dated 18th June 2024 informing us of the above application submitted under the NHS (Pharmaceutical Services) Regulations 2013 and inviting us to make representations.

4.2.3 We note that the name and address of the applicant is missing from the application form.

4.2.4 It is also of note that the premises that have been applied for are on the High Street and central shopping area of the town. We have not been provided with any evidence that the premises will not be accessible to patients for essential face-to-face services. The floor plan provided shows a clear and extensive patient seating/waiting area as well as what appears to be a large consultation room. The applicant is clearly proposing to provide services from these premises, and it is unclear as to how they will ensure that patients are not confused as to which services they can access. The application makes reference to providing flu vaccinations, these cannot be offered without the patient being present, clarification around this must be sought.

4.2.1 As the premises are withing the centre of the town, we ask how the applicant is proposing to ensure that the property is not made to look like a bricks and mortar pharmacy to avoid confusion and so patients are clear that they cannot walk in to have their prescriptions dispensed.

4.2.2 Boots UK Ltd do not believe that the deciding committee can be satisfied that this application fully meets the criteria set out in Regulation 25 and the conditions set out in Regulation 64 and it should therefore be refused.

4.2.3 We would be most grateful if you could notify us of the decision of the ICB in due course."

5 **Summary of Observations**

This is summary of observations received.

5.1 THE COMMISSIONER

5.1.1 “Thank you for your letter dated 14th November 2024.

5.1.2 In response to the points below in the email dated 14th November from NHS Resolution re the application being previously heard, I can clarify that the Pharmacy Services Regulations Committee (PSRC) was held on 25th September 2024 where this application was discussed, and a decision made.

5.1.3 Humber & North Yorkshire (HNY) Integrated Care Board (ICB) have nothing further to add and stand by the rationale previously provided to refuse the Distance Selling Pharmacy (DSP) application under Regulations 25(2)(b)(ii) and Regulation 64 as the PSRC were not assured that they had been met.

5.1.4 Part of the DSP essential services is to dispose of unwanted medications and not re-direct patients to a bricks and mortar pharmacy. Although they cannot provide face to face services, there are other options that can be put in place to ensure patients can dispose of their unwanted medications without having to be seen face to face to ensure the DSP meets its Terms of Service (ToS) safely and effectively.”

5.2 THE APPLICANT

5.2.1 “Thank you for your letter dated 14 November enclosing representations received in response to the notification under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

5.2.2 I note the representations were made by Humber and North Yorkshire ICB and Boots.

Part 1: Final observation in response to the Humber and North Yorkshire ICB.

5.2.3 The representation made by the Humber and North Yorkshire ICB has brought significant new information to light.

5.2.4 The information contained in the representation letter dated 25 October 2024 of the Humber and North Yorkshire ICB was not made available to Spinoff Limited until now.

5.2.5 It appears that the Humber and North Yorkshire ICB based on the judgement of its staff decided not to include the specific reason for rejecting Spinoff Limited's application. This is reflected in their rejection letter dated 27 September 2024 which they sent to the Market Entry Team and did not provide an explanation for their decision.

5.2.6 The decision to omit and withhold the reason why all regulations around a DSP application was not met is significant as it made it difficult for Spinoff Limited to make specific changes to its application prior to submitting an appeal to NHS resolution.

5.2.7 This lack of transparency on the part of the Humber and North Yorkshire ICB is particularly troubling.

5.2.8 Spinoff Limited has always been willing to comply with regulations and take on board the feedback of the ICB.

5.2.9 However, the Humber and North Yorkshire ICB should have made its reasoning clearer in its initial rejection letter dated 27 September 2024.

5.2.10 If a clear reasoning was given in their letter dated 27 September 2024, then Spinoff limited would have changed its SOPs and application to incorporate the feedback from the ICB before escalating to NHS resolution.

5.2.11 Unfortunately, clear reasoning by Humber and North Yorkshire ICB has only been provided at this stage of the appeal process and therefore changes to SOPs to ensure compliance can only be made at this stage.

5.2.12 Spinoff Limited has amended its Standard Operating Procedures (SOP) to incorporate the new feedback received from the Humber and North Yorkshire ICB. Additionally, the way the company will deal with requests by patients to return unwanted medication has been updated and enclosed as part of this letter.

5.2.13 The SOPs which have been updated are:

5.2.13.1 The Waste Handling SOP is now superseded by The Safe and Effective Receipt and Disposal of Medicines

5.2.13.2 The Patient returned controlled drugs SOP is now superseded by Controlled Drugs: Disposal of Patient Returns.

5.2.14 A copy of the updated SOPs are enclosed [see Appendix B].

5.2.15 It goes without saying that this application has not been treated fairly by the Humber and North Yorkshire ICB. Whether genuine ignorance on the part of the staff or deliberate and manipulative withholding and omission of information, the consequences are significant and it is Spinoff Limited that is bearing the brunt of it.

5.2.16 In a normal appeal process, no new matters should be raised at this stage.

5.2.17 However, this is not a normal appeal case.

5.2.18 In fact, the decision of the Humber and North Yorkshire ICB to withhold and omit information may be detrimental to Spinoff limited while the Humber and North Yorkshire ICB gets away with absolute impunity.

5.2.19 Therefore at this point, I ask the committee to treat the amended SOP with the full weight which would have been attributed to them if they were submitted at the initial stage of the appeal process.

5.2.20 PHS Group Healthcare Waste Management Services (or another similar company which may be appointed as required from time to time) will provide safe and secure disposal of unwanted medicines by collection of unwanted medicines from patients and residential homes. Upon return to the pharmacy unwanted medicines will be sorted and placed in disposal units ready for waste management services to collect. The disposal service will be advertised on the website and marketing leaflets.

Part 2: Final observation in response to Boots

5.2.21 I would like to comment on the points raised during representations made by Boots.

“It is also of note that the premises that have been applied for are on the High Street and central shopping area of the town. We have not been provided with any evidence that the premises will not be accessible to patients for essential face-to-face services.”

5.2.22 The door of the premises will be kept locked at all times which means access to the premises is controlled and patients will not be allowed in the pharmacy for NHS essential face to face services.

5.2.23 The Standard Operating Procedures of the pharmacy have also been designed to prevent any essential services from taking place face to face.

5.2.24 Staff will be fully trained to refuse any request to provide essential services face to face. Instead, the pharmacy team will explain to the patient how to access the essential service remotely. Staff training will be reviewed once a year or sooner if an incident arise.

"The floor plan provided shows a clear and extensive patient seating/waiting area as well as what appears to be a large consultation room. The applicant is clearly proposing to provide services from these premises, and it is unclear as to how they will ensure that patients are not confused as to which services they can access.

The application makes reference to providing flu vaccinations, these cannot be offered without the patient being present, clarification around this must be sought."

5.2.25 The purpose of the large consultation room is to provide private services which patients will need to pre-book.

5.2.26 Patients requesting NHS flu vaccinations (an NHS advanced service) will also need to pre-book an appointment before attending the pharmacy.

5.2.27 During the booking process, it will be clearly explained to the patient that no NHS essential services will be offered on the premises.

5.2.28 Moreover, patients will be made aware that the appointment will be strictly for the provision of the service they have pre-booked.

5.2.29 Internal signs within the pharmacy will highlight to patients that whilst they are attending the premises to receive private services/NHS flu jab no NHS essential services will be allowed face to face onsite.

5.2.30 The signs will be conspicuously displayed in the waiting zone, consultation room and reception area.

5.2.31 The Standard Operating Procedures of the pharmacy have also been designed to prevent any essential services from taking place face to face.

5.2.32 Staff will be fully trained to refuse any request to provide NHS essential services face to face. Instead, it will be explained to the patient how to access the essential service remotely. Staff training will be reviewed once a year or sooner if an incident arise [sic].

"As the premises are within the centre of the town, we ask how the applicant is proposing to ensure that the property is not made to look like a bricks and mortar pharmacy to avoid confusion and so patients are clear that they cannot walk in to have their prescriptions dispensed."

5.2.33 The premises of the pharmacy is not glass fronted and from the outside does not look like the typical building chosen by high street brick and mortar pharmacy operators.

5.2.34 It is intended that any signage for the pharmacy will be small and discrete. It should be noted that in this case, the purpose of signage is to facilitate delivery of medications from medicine wholesalers to the pharmacy.

5.2.35 To make it clear to patients that they cannot walk in to have their prescriptions dispensed, there will be a note on the door which will state that:

5.2.35.1 No medications can be handed out on the premises

5.2.35.2 No prescriptions can be accepted in person on the premises

5.2.35.3 No NHS essential services can be provided on the premises

5.2.36 The door of the premises will be kept locked at all times.

5.2.37 The dispensing area is separated from the rest of the pharmacy by an internal partition wall. Unlike most Boots Pharmacies which favours an open plan dispensary where patients can see what is going on, the dispensing area of Stokesley Pharmacy is not visible from outside the pharmacy and from the waiting area or the consultation room. We believe a secluded dispensary will make it less likely for patients to request essential services such as dispensing/collecting medications. Furthermore, operating an appointment based system for services such as flu vaccination will ensure patients are seen in the consultation room straight away. This will reduce the waiting time of patients on the premises and make requests for essential services less likely.

5.2.38 The pharmacy staff will be trained not to provide NHS essential services face to face. In the unlikely event that a patient presents to the pharmacy for any essential service, the pharmacist or pharmacy team will explain to the patient that the pharmacy is not allowed to provide such essential services on site face to face. It will also be explained to the patient that essential services are provided remotely by the pharmacy. Details how to access the essential services remotely will be provided to the patients.

5.2.39 Staff training will be reviewed once a year or sooner if an incident arise [sic].

5.2.40 The Standard Operating Procedures of the pharmacy have also been designed to prevent any essential services from taking place on site.

5.2.41 Stokesley Pharmacy has robust procedures in place to ensure that it operates safely and effectively without breaching NHS distance selling pharmacy regulations. I believe that the information presented in the application form and the response to the points raised by Boots demonstrate compliance with the NHS distance selling pharmacy regulations."

6 Consideration

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

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

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

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

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

6.6 The Committee noted that the Applicant had stated "N*ot applicable. There are no other pharmacy [sic] on the same site or adjacent site or in the same building*" as to why the application should not be refused pursuant to Regulation 31. The Committee noted that the Commissioner had not considered Regulation 31 in their decision letter, however the application of Regulation 31 had not been disputed either on appeal or in subsequent representations. Based on the information provided, the Committee was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

(ii) the safe and effective provision of essential services without face to face contact between any person receiving

the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff."

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

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

Regulation 25(2)(b)

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

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

6.13 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicates that the obligation is only

discharged if the information or documentation provided is sufficient to satisfy the Commissioner in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the Commissioner may need to make of the information or documentation when carrying out its functions.

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

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

6.16 The Committee noted the comments from Boots with regard to the location of the proposed pharmacy being on a "high street" and a "central shopping area of the town". The Committee noted that, in the application form, the Applicant had stated that "*the pharmacy will operate from secure premises with a controlled entry system, to which members of the public will not have access."* The Applicant in response to the comments from Boots had, in further representations, confirmed that the door would be kept locked and that access to the premises would be controlled and there would be no access for patients who were seeking essential services.

6.17 With regard to the comments in respect of the "large consultation room" the Committee noted that the Applicant was proposing to also provide private services as well as some advanced services, for which a consultation room was a necessity. The Committee again noted the assurances from the Applicant that "*the door to the premises will be kept locked at all times*" as well as:

6.17.1 *"No medications can be handed out on the premises*

No prescriptions can be accepted in person on the premises

No NHS essential services can be provided on the premises"

6.18 The Committee noted the application form which states "*any reference to 'contact' with or 'contacting' a patient in relation to these SOPs means contact other than face-to-face contact either on or in the vicinity of the premises"* and further states "*Essential services will be provided without face to face contact …*".and that "*The website will enable patients or their carers to communicate remotely but directly allowing quick and easy access … throughout the opening hours of the pharmacy premises without having 'face to face' contact with the patient or their representative.".*

6.19 The Committee also noted further information contained within the application form which sets out how the Applicant intends to provide essential services without face to face contact but using permissible methods of communication with patients, including communicating with patients by email, text, telephone and video calling.

6.20 However, the Committee noted the SOP "Owings" states:

6.20.1 *"The patient, carer or representative should be advised that if they do not collect the balance within a specified time it may not be possible to make the supply …"*

6.21 The Committee determined that reference to "*should be advised that if they do not collect the balance*" implied an option for patients which was not permitted under the Regulations.

6.22 Based on the information before it, the Committee was not satisfied that the provision of essential services would be without face to face contact

6.23 The Committee noted the various references throughout the SOPs and application form to prescriptions being received electronically and further confirmation from the Applicant that as well as medications being delivered by their own delivery driver they would also be delivered by Royal Mail and courier companies. The Committee noted that the Applicant would have a fully functioning website which would enable patients or their carers to communicate directly with the pharmacy. The Applicant would also be able to communicate with patients by email, text, telephone or video call. The Applicant confirmed, throughout the application form and SOPs that it would be providing all essential services to persons anywhere in England who request those services during the opening hours of the premises.

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

6.25 The Applicant confirmed in the application form that "*During opening hours there will always be a responsible pharmacist (RP) on site"* and further "*any breaks in working time taken by the RP will be covered by a second pharmacist who will then assume the responsibility of the RP"*. The Committee further noted the SOP "Responsible Pharmacist" which states:

6.25.1 "*RP Absence including lunch*

10. No pharmacist will leave the pharmacy unless there is a second pharmacist on site.

16. If the RP is absent and there is a second pharmacist within the pharmacy all normal duties and tasks can be undertaken by the staff within the Pharmacy.

…

RP not signed in

…

21. If an RP needs to leave the pharmacy and sign out as RP other than at the end of their shift they must obtain approval of either their line manager, or in extreme circumstances when the line manager cannot be contacted, the Superintendent."

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

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

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

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

6.29.1 Dispensing of drugs and appliances

6.29.2 Urgent supply without a prescription

6.29.3 Preliminary matters before providing ordered drugs or appliances

6.29.4 Providing ordered drugs or appliances

6.29.5 Refusal to provide drugs or appliances ordered

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

6.29.7 Disposal service in respect of unwanted drugs

6.29.8 Promotion of healthy lifestyles

6.29.9 Prescription linked intervention

6.29.10 Health campaigns

6.29.11 Signposting

6.29.12 Support for self-care

6.29.13 Discharge medicines service

6.29.14 Websites and health promotion zones

6.30 The Committee noted that the Applicant had stated "Drug Tariff Part IX (except items that require measuring or fitting)" in response to the question as to whether they were undertaking to provide appliances. The Committee noted the information contained within the application form with regard to "Referral for Certain Appliances" where the pharmacy is unable to provide the appliance. The Committee further noted the SOP "Appliance Dispensing" which confirmed that the Applicant was not dispensing any appliances which require measuring or fitting.

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

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

Providing ordered drugs or appliances

6.33 The Committee considered whether the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that (i) that 'cold chain' is maintained, where relevant and (ii) that the requirements of the Misuse of Drugs Regulations 2011 and, in particular, Regulations 14 and 16, are met).

6.34 The Committee noted in the information in the application form:

6.34.1 *Delivering Medicines*

The Responsible Pharmacist (RP) has overall responsibility for ensuring the delivery of medicines to intended patients. Medicines must be delivered safely and with appropriate instructions.

The RP must take adequate measures 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. If the delivery to patients is local, this will be undertaken by the delivery driver except fridge lines which must be sent by courier. All other nationwide deliveries (other than fridge lines) will be delivered by Royal Mail special delivery or courier and signed for by the patient, their notified carer or other patient authorised representative. Fridge Lines will be delivered by courier (see further below).

Medicines will be packed, transported and delivered in such a way that their integrity, quality and effectiveness are preserved. The delivery mechanism used will provide a verifiable audit trail for medicine from the initial request through to its final delivery, or its return to the pharmacy in the event of a delivery failure. Packaging must maintain patient privacy and confidentiality.

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

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

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

Medicines classified as non-flammable or non-toxic must be securely closed and placed in a leak-proof container such as a sealed polythene bag (for liquids) or a sift proof container (for solids). Must be tightly packed in strong outer packaging and must be secured or cushioned to prevent any damage.

This means that for postal / courier items, either:

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

For most items - bubble wrap and where necessary, polystyrene filler, placed within a cardboard box. Cardboard boxes must be the re-enforced type.

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

The patient, carer or notified, authorised patient representative must always sign and date a receipt to prove safe receipt of the medicines.

A patient who is not at home when delivery is attempted will be informed using a non-delivery notice and an alternative delivery date will be arranged.

A list of the approved cold chain couriers is available within the Pharmacy. Coldchain items should be stored in styrofoam filled cardboard boxes prior to being passed to the courier and marked with the "FRAGILE" and "FRIDGE LINE" stickers. Additional packing will not be required as the courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box and are fully monitored.

Pharmacy staff should be aware that some thermolabile products can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in medicines which is damaging to them. The courier service is a dedicated, fully monitored and temperature controlled delivery service. Any

breach of the cold chain is automatically notified to the driver who will then follow the failed delivery procedure and notify the pharmacy accordingly so that re-delivery can be arranged. Where the cold chain breach notice is issued items may not be re-used.

Delivery of Controlled Drugs

There is provision within controlled drugs legislation to cover occasions when a controlled drug (CD) may temporarily be in the possession of a third party, e.g. a delivery person or postal carrier, while it is being transferred from one authorised person to another authorised person who is entitled to be in possession of the drug.

Delivery of CD will be carried out by couriers with pharma grade specialist facilities to meet specific quality and validation requirements for healthcare products. This includes Home Office licensed controlled drug stores. The couriers will have the following UK Licenses and Standards: …"

6.35 In addition the Committee noted the SOP "Delivery of Prescriptions" which states:

6.35.1 *"The delivery driver is responsible for the physical delivery of medication within a 30-mile radius. The delivery driver should be trained in operating a safe system for the delivery of prescribed medicines and should be easily identified with the pharmacy (Uniform, name badge).*

Procedure

Identification of delivery patient

1. All deliveries within a 30 miles radius will be done by the pharmacy delivery driver.

2. Deliveries outside of a 30 miles radius will be done by Royal Mail. However, The pharmacist has the discretion to ask the pharmacy delivery driver to deliver medications outside the 30 miles radius such as for example in cases of emergencies.

3. All medications dispensed from an NHS prescription must be delivered to the patient free of charge.

…

Branch preparation of delivery by the pharmacy delivery driver (within 30 miles radius)

…

10. All dispensed CDs and fridge items must be stored in the appropriate storage area and taken out of this area when appropriate for delivery.

…

With the exception of controlled drug and fridge lines, medications can be:

a. Posted through the letter/post box

b. Left in a porch or any other out building or other suitable safe place provided the patient has given permission

Use of key safe and key codes

25. The use of key safes and key codes is permitted however the policy statement and guidance available on the intranet must be followed and the patient or carer must have given the permission to access a patient's home for this to occur. Never document the key code number onto any patient identifiable information.

Successful Delivery

26. Once deliveries are completed, return the delivery book to the pharmacy on the same day. All completed delivery books must be stored securely in the safe haven in accordance to the Pharmacy Documentation Asset Register.

Unsuccessful delivery

27. If the patient or representative is not able to receive the delivery of their medication and it is not possible to leave the medication in a safe place, complete the failed delivery slip and post the note through the letterbox.

28. The medication must be returned to the pharmacy on the same day and the Pharmacist informed about the unsuccessful delivery. The driver must annotate the label in the delivery book to indicate this.

29. The returned medication must be returned to the pharmacy and stored with prescriptions and sent out again the next day. If after a second attempt to deliver has failed, wait until the patient contact the pharmacy prior to delivering again.

Deliveries outside 30 miles radius (using Royal Mail)

Use Royal Mail Tracked 24 to deliver any item outside of a 30 miles radius.

Package all fridge lines using suitable thermal packaging."

6.36 The Committee noted the references in the application form to the cold chain being maintained and that "*additional packaging will not be required as the courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box and are fully monitored".* However, the Committee noted the above reference to deliveries outside 30 miles radius using Royal Mail and *"Package all fridge lines using suitable thermal packaging"* which suggested it would also be used for cold chain deliveries. With regard to cold chain couriers, it was noted that "*Any breach of the cold chain is automatically notified to the driver who will then follow the failed delivery procedure and notify the pharmacy accordingly so that re-delivery can be arranged. Where the cold chain breach notice is issued items may not be re-used*." However, the Committee noted that it had not been provided with a SOP for the delivery of cold chain by either courier or Royal Mail and it had not been provided with the "*failed delivery procedure*". The Committee considered that if there was a deviation in temperature outside of the recommended limits, there was nothing provided as to what the courier or Royal Mail should do once notified that the temperature had been compromised.

6.37 The Committee noted that whilst the Applicant had confirmed that controlled drugs would be delivered using a variety of methods, including their own delivery driver, courier and Royal Mail, the information provided in the SOP only appeared to relate to what would happen for a "missed delivery" if it was delivered by their own driver. The Committee noted the comment in the application form that "*A patient not at home when delivery is attempted will be informed using a non-delivery notice and an alternative delivery date will be arranged"* however, the Committee was unclear as to whether this was with regard to those items being delivered by the pharmacy's own delivery driver as well as those being delivered by courier or Royal Mail and whether this also referred to the delivery of controlled drugs. The Committee was of the view that there was

limited information provided by the Applicant as to what would happen if there was a failed delivery of controlled drugs by the either the courier or Royal Mail.

6.38 Taking all of the information before it into account, 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.

Other considerations

6.39 The Committee noted the comments from the Commissioner with regard to the return of unwanted medicine.

6.40 The Committee noted the original comments from the Applicant in their application form that "*As the pharmacy does not provide face to face essential services, patients will be advised to take their unwanted or out of date medication to a local brick and mortar pharmacy or GP surgery for disposal*" which had been reiterated in SOPs "Patient returned controlled Drugs" and "Waste Handling" however the Applicant had provided, with their observations, updated SOPs.

6.41 The Committee noted that the SOP "The Safe and Effective Receipt and Disposal of Medicines" had a sub heading of "Patient returned unwanted medication (incl medication return from private households, children's homes and residential care homes) stated:

6.41.1 *"This service is available to all patients living in England.*

The process for returning medication should be clearly explained to the patient. Medications can be returned to the pharmacy via Royal Mail at the pharmacy's expense. Patients should be informed that sharps and clinical/contaminated waste cannot be returned and must be disposed of according to local procedures. Additionally, cytotoxic and hazardous waste, as well as controlled drugs (CDs), should be separated where possible before being returned. If necessary, appropriate packaging should be provided for the safe return of hazardous medicines, as inadequate packaging may pose safety risks.

Patients may arrange collection by the Pharmacy driver (Note: Drivers must confirm that a collection of unwanted medication for disposal has been booked. Returns without a booking should only happen in exceptional circumstances).

Ensure the patient understands that any sharps and clinical/contaminated waste cannot be returned and they should follow local procedures for disposing of them. Ensure the patient knows that cytotoxic and hazardous waste, as well as CDs, must be separated if possible before returning to the pharmacy.

…

Advise patients of their other options to dispose of unwanted or expired medication if posting to the Pharmacy is inconvenient. They may return it to their local pharmacy whenever they are open.

…

Disposal of returned medicines

Patient returned medication must be collected and disposed of by a NHS approved waste collection contractor. Upon return to the pharmacy unwanted medicines will be sorted and placed in disposal units / containers provided ready for waste management services to collect. The disposal service will be advertised on the website and leaflets."

6.42 The Committee further noted the SOP "Controlled Drugs: Disposal of Patient Returns" which stated:

6.42.1 *"This service is available to all patients living in England.*

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

To organise sending medication back to the Pharmacy the patient must telephone and speak to the pharmacist.

Patients or their representatives MAY NOT return medicines directly to the pharmacy and must follow the procedures set out in this SOP. This service is available to all patients living in England.

The process for returning medication should be explained to the patient by the pharmacist – they may send it back to the Pharmacy via courier (at the pharmacy's cost) using the Special Delivery service. The pharmacist must clarify the items being returned and ensure the patient understands that any sharps and clinical/contaminated waste cannot be returned and they should follow local procedures for disposing of them. Ensure the patient knows that cytotoxic and hazardous waste, as well as CDs, must be separated if possible before returning to the pharmacy. Where necessary appropriate packaging should be sent to patients to return hazardous medicines – return of such medicines in inadequate packaging may be unsafe.

Returns of controlled drugs via the delivery driver

If a customer contacts the pharmacy asking for their unwanted medication to be collected, the process for returning medication should be explained to the patient by the pharmacist –The pharmacist must clarify the items being returned and ensure the patient understands that any sharps and clinical/contaminated waste cannot be returned and they should follow local procedures for disposing of them. Ensure the patient knows that cytotoxic and hazardous waste, as well as CDs, must be separated if possible before returning to the pharmacy.

Ask the patient to confirm the collection address.

Agree a mutually convenient date with the customer so that the driver can collect the unwanted medication.

Make a note on the PMR.

Attach the address label on the driver's sheet.

Mark the address label with the words "unwanted medication collection"

Place an empty waste disposal bag in the drivers delivery box.

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

Process for accepting patient CD returns by the Driver

If a customer presents unwanted medications to the driver:

Ask the customer if they have pre-booked a collection of unwanted medication.

The driver must confirm against the driver's sheet that a collection of unwanted medication for disposal has been booked and the address of collection match the location where they are being given the unwanted medication.

Drivers need to be aware that they cannot accept patient returns from patients without prior arrangement and the driver should notify the patient to follow the "returning unwanted medication" process as set out on the website. Returns without a booking should only happen in exceptional circumstances

Advise patients of their other options to dispose of unwanted or expired medication if posting to the Pharmacy is inconvenient. They may return it to their local pharmacy whenever they are open.

Process

Handling Patient-Returned CDs from Courier and pharmacy driver by dispensary staff:

If CDs have been identified as returned medicines, secure them in a bag, clearly marking on 'Patient-returned CDs for destruction' and include the date of return; place the bag in the CD cabinet away from pharmacy stock until they can be destroyed. Make an entry in the "Patient returned Controlled Drug Register" to record the Controlled Drug that require destruction."

6.43 The Committee was of the view that the Applicant had provided sufficient information for it to be satisfied that there would be compliance with paragraphs 13 – 15 of Schedule 4.

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

Summary

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

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

6.46.1 confirm the Commissioner's decision;

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

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

6.47 In those circumstances, given that the Committee had additional information which was not available to the Commissioner, the Committee determined that the decision of the Commissioner must be quashed.

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

6.49 The Committee noted that representations on Regulation 25 had already been made by parties to the Commissioner, and these had been circulated and seen by all parties

as part of the processing of the application by the Commissioner. The Committee further noted that when the appeal was circulated representations had been sought from parties on Regulation 25.

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

7 Decision

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

7.2 Accordingly, the Committee:

7.2.1 quashes the decision of the Commissioner; and

7.2.2 redetermines the application as follows -

7.2.2.1 the Committee was satisfied that there was not already a person on the pharmaceutical list providing pharmaceutical services from the proposed premises and the proposed premises were not adjacent to other chemist premises'

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

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

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

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

7.2.2.6 the Committee was not satisfied that all essential services were likely to be secured without face to face contact.

7.2.3 The application is refused.

Case Manager
Primary Care Appeals