

21 February 2019

REF: SHA/21041

1 Trevelyan Square
Boar Lane
Leeds
LS1 6AE

**APPEAL AGAINST NHS COMMISSIONING BOARD
"NHS ENGLAND" DECISION TO REFUSE AN
APPLICATION BY APKSM-PHARM786 LTD FOR
INCLUSION IN THE PHARMACEUTICAL LIST AT SUITE
1A LAVENHAM BUSINESS CENTRE, PARSONS
STREET, OLDHAM, OL9 7AH UNDER REGULATION 25**

Tel: 0113 86 65500
Fax: 0207 821 0029
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1 Outcome

- 1.1 The Pharmacy Appeals Committee ("Committee"), appointed by NHS Resolution, quashes the decision of NHS England and redetermines the application.
- 1.2 The Committee determined that the application should be granted.

Advise / Resolve / Learn

NHS Resolution is the operating name of NHS Litigation Authority – we were established in 1995 as a Special Health Authority and are a not-for-profit part of the NHS. Our purpose is to provide expertise to the NHS on resolving concerns fairly, share learning for improvement and preserve resources for patient care. To find out how we use personal information, please read our privacy statement at www.nhs.uk/About-us/How-we-use-your-information---FHSAU.aspx



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UNIT 2003



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1 The Application

By application dated 1 August 2018, APKSM-PHARM786 Ltd ("the Applicant") applied to NHS Commissioning Board ("NHS England") for inclusion in the pharmaceutical list at Suite 1a Lavenham Business Centre, Parsons Street, Oldham, OL9 7AH under Regulation 25. In support of the application it was stated:

- 1.1 In response to "If you are undertaking to provide appliances, specify the appliances that you undertake to provide (or write 'none' if it is intended that the pharmacy will not provide appliances)" the Applicant stated:
- 1.2 Drug Tariff part IX
- 1.3 EXCEPT items that require measuring or fitting
- 1.4 In response to why the application should not be refused pursuant to Regulation 31 the Applicant stated:
- 1.5 Not applicable as no other pharmacy in same or adjacent premises.
- 1.6 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant stated:
- 1.7 Application is not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

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

- 1.8 The information contained within this document has been approved by the Applicant prior to submission.

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.

NHS England Premises Standards

- 1.9 NHS England has published (January 2018) 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.

GPhC Guidance

- 1.10 The Applicant will operate the pharmacy in accordance with the "Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet" issued in April 2015.

- 1.11 Specifically, but not exhaustively, the Applicant will have in place, prior to opening;

Risk Assessment

- 1.12 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. The risk assessment will include consideration of;

1.12.1 a. how staff tell patients and the public about the pharmacy services they will receive, and how they get their consent

1.12.2 b. how staff communicate between different locations (if applicable)

1.12.3 c. medicines supply, including counselling and delivery

1.12.4 d. The pharmacy's capacity to provide the proposed services, and

1.12.5 e. Business continuity plans, including website and data security

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

Audit Procedures

- 1.14 A regular audit programme will be in place with initial frequency of quarterly audits. 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.

- 1.15 The audit will, at the very least, consider;

1.15.1 staffing levels and the training and skills within the team

1.15.2 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)

1.15.3 use of specialised equipment and new technology

1.15.4 systems and processes for receiving prescriptions, including EPS records of decisions to make or refuse a sale (note that the Applicant's pharmacy SOPs will require more frequent analysis of refusals to sell)

1.15.5 systems and processes for secure delivery to patients

1.15.6 any information about pharmacy services on the website

- 1.15.7 review of how the pharmacy keeps to the information security policy, Payment Card Industry Data Security Standard (PCI DSS) and data protection law
- 1.15.8 feedback from patients and people who use the Applicant's pharmacy services
- 1.15.9 concerns or complaints received, and
- 1.15.10 activities of third parties, agents or contractors
- 1.16 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

- 1.17 A reactive review will take place if an audit identifies a problem, or if there is;
 - 1.17.1 a change in the law affecting any part of the pharmacy service
 - 1.17.2 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
 - 1.17.3 a data security breach
 - 1.17.4 a change in the technology the pharmacy uses
 - 1.17.5 concerns or negative feedback are received from patients or people who use the pharmacy services
 - 1.17.6 a review of near misses and error logs causes a concern about an activity

Accountability

- 1.18 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.

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.

Premises

- 1.20 Premises will be registered with the GPhC prior to entry to the pharmaceutical list and will therefore comply with GPhC requirements for pharmacy premises.

Website

- 1.21 The only website used to sell P medicines will be the website associated with the pharmacy. The website will be secure and follow information security management guidelines and the law on data protection. The website will use secure facilities for collecting, using and storing patient details and a secure link for processing card payments.

- 1.22 The website will display;
 - 1.22.1 the GPhC pharmacy registration number
 - 1.22.2 the name of the owner of the registered pharmacy
 - 1.22.3 the name of the superintendent pharmacist
 - 1.22.4 the name and address of the registered pharmacy that supplies the medicines
 - 1.22.5 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)
 - 1.22.6 information about how to check the registration status of the pharmacy and the superintendent pharmacist
 - 1.22.7 details of specific services available and how to use them, ie
 - 1.22.7.1 Return of unwanted medicines
 - 1.22.7.2 Patient Lifestyle Questionnaire
 - 1.22.7.3 How to register exemptions from NHS charges
 - 1.22.7.4 Promotion of Health Lifestyles and details of campaigns being undertaken
 - 1.22.7.5 Procedures for Emergency Supply
 - 1.22.7.6 Explanation of rules on non face to face contact
 - 1.22.7.7 Annual patient survey
 - 1.22.7.8 Patient Information Leaflet
 - 1.22.8 the email address and phone number of the pharmacy
 - 1.22.9 details of how patients and users of pharmacy services can give feedback and raise concerns
 - 1.22.10 GPhC internet logo (linked to register entry)
 - 1.22.11 The pharmacy will be registered with the Medicines and Healthcare products Regulatory Agency (MHRA) and to be on the MHRA's list of UK registered online retail sellers.
 - 1.22.12 EU common logo
 - 1.22.12.1 The pharmacy will display the new EU common logo on every page of the website offering medicines for sale, even if they are already displaying the GPhC voluntary logo. The registered EU common logo will also be linked to the entry in the MHRA's list of registered online sellers.

- 1.23 Patients will be asked to provide informed consent for any pharmacy services that the pharmacy provides to them. Patient consent forms for services will be stored as part of the PMR record created for all patients that use the pharmacy services.

Managing Medicines Safely

- 1.24 The pharmacy SOPs provide the procedures for all staff to follow to ensure that the sale and supply of medicines is done in such a manner as to minimise risk to patients. The supply or sale of any new medicine must be approved by the superintendent pharmacist as suitable for sale via distance selling.

Supplying Medicines Safely

- 1.25 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;
- 1.25.1 assess the suitability and timescale of the method of supply, dispatch, and delivery for all medicines and particularly refrigerated medicines and controlled drugs
 - 1.25.2 assess the suitability of packaging (for example, packaging that is tamperproof or temperature controlled)
- 1.26 Prior to contracting with any carrier the pharmacy will check the terms, conditions and restrictions of the carrier.
- 1.27 Where any recipient is outside the UK the pharmacy will check the laws covering the export or import of medicines from the UK to that country.
- 1.28 The pharmacy will monitor third-party providers, including analysis of patient feedback about deliveries and delivery times and processes.

Equipment and Facilities

- 1.29 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.
- 1.30 All equipment will be subject to annual performance testing and review, with specialist equipment (such as temperature monitoring) subject to monthly checks.
- 1.31 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

- 1.32 The Applicant has already developed a draft suite of operating procedures to cover all aspects of the operations of this distance selling contract. 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.
- 1.33 The Applicant has not provided all SOPs with this application as they contain commercially sensitive material.
- 1.34 It should be noted that NHS England's national policy document, "Policy for monitoring compliance with the terms of service for pharmacy and dispensing

appliance contractors" (published 5 April 2013) contains a section on SOPs that states:

1.34.1 -2.11

"The essential service and clinical governance specifications require pharmacies to have appropriate standard operating procedures for dispensing, repeat dispensing and support for self-care.

Monitoring compliance requires only the determination of whether the pharmacy has an appropriate SOP.

It does not require NHS England to carry out a detailed analysis of the content of the SOPs.

Indeed, it would be unwise for an NHS England employee to carry out any detailed examination because he or she will be unable to determine what is appropriate for the individual pharmacy concerned.

Any shortcomings not identified, or suggestions made which themselves cause problems in delivery of the services could lead to NHS England itself being involved in litigation."

- 1.35 The Applicant however notes that there may be occasions where NHS England would wish to see specific SOPs if particular concerns are raised and in any such instance the Applicant would be happy to provide a copy of any requested SOPs.

PHARMACY SYSTEMS AND PROCEDURES

- 1.36 All Essential Services will be delivered in accordance with:

1.36.1 Company Standard Operating Procedures

1.36.2 NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

1.36.3 NHS Act 2006

1.36.4 Human Medicines Regulations 2012

1.36.5 GPhC – Professional Standards and Guidance on Distance Selling Pharmacies

1.36.6 Relevant Data Protection laws

- 1.37 This will ensure that the Applicant 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. 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.

- 1.38 The Applicant's wholly Internet/Delivery Pharmacy will operate from secure premises, with a controlled entry system, to which members of the public will not have access.

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

1.39.1 Telephone

1.39.2 Website/ Pharmacy App on mobile phones

- 1.39.3 The 'E Commerce' 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.
- 1.39.4 Email
- 1.39.5 Postal services
- 1.40 All NHS services will be delivered free of charge in accordance with the NHS Act 2006.
- 1.41 Essential Services will be delivered by using:
 - 1.41.1 Telephone, including text messaging where appropriate
 - 1.41.2 Electronic Prescription Service (EPS)
 - 1.41.3 Website
 - 1.41.4 Email
 - 1.41.5 Royal Mail postal service
 - 1.41.6 Courier service
 - 1.41.7 Specialist Waste Management Services
 - 1.41.8 The Applicant also intends to promote the use of free video-conferencing services such as Skype so that patients have a better chance of getting to know their pharmacy staff. Such services do not constitute 'face-to-face' contact under the Regulations and can be a particularly efficient way of interacting with patients and gaining rapport, as they are more personal than a basic telephone service. Many people now have the ability to use services like this via their mobile phones at any location where they can find a wireless internet signal.
 - 1.41.9 Specialist cold chain courier service will ensure the integrity of the cold chain and the maximum stability of thermo-labile 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.

Provision of NHS Essential Services

- 1.42 The Applicant will provide all the Essential Services as outlined in the NHS contractual framework.

Dispensing Services

- 1.43 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.
- 1.44 In the event that they are not clinically or legally correct, pharmacists will follow Standing Operating Procedures to resolve clinical or legal issues before dispensing

items. This may involve contacting the prescriber as soon as possible to make sure the patient receives their medication without delay.

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

Repeat Dispensing Services

- 1.46 Terms of Service require the Pharmacy to ensure that appropriate advice about the benefits of repeat dispensing is given to any patient who—
- 1.46.1 (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
- 1.46.2 (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.
- 1.47 Such advice will be provided by the Pharmacy using its permissible methods of non face-to-face contact with patients.
- 1.48 Dispensing of repeat NHS prescriptions including those dispensed in dosette boxes as may be required under the Disability Discrimination Act will be done 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. 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.

Urgent Supply and Emergency Supply

- 1.49 Whilst the Distance Selling nature of the pharmacy is such that 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.
- 1.50 The request may be received from a Prescriber (Urgent Supply) or from a Patient (Emergency Supply)
- 1.51 The following conditions must apply to the request made by a prescriber:
- 1.51.1 The Pharmacist must be satisfied that the request is from the appropriate authorised prescriber, see list above.
- 1.51.2 The Pharmacist is satisfied that a prescription cannot be supplied immediately due to an emergency.
- 1.51.3 The Prescriber agrees to provide a written prescription within 72 hours.
- 1.51.4 The medication is supplied in accordance with the prescriber's directions.
- 1.51.5 The medication is permitted to be supplied on an Emergency Supply basis.
- 1.51.5.1 An emergency supply cannot be provided for a Schedule 1, 2 or 3 CD except Phenobarbital for epilepsy by a UK registered prescriber.

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

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

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

Interview

1.54 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, Skype.

Records

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

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

Faxed Prescriptions

1.57 A 'faxed prescription' does 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 prescription can confirm that at the time of receipt a valid prescription is in existence.

1.58 Any pharmacist who decides to dispense a prescription only medicine against a faxed prescription without sight of the original prescription must ensure that adequate safeguards exist to ensure that the original prescription will be in their possession within a short period and not more than 72 hours. Any doubt as to the content of the original prescription caused by poor reproduction must be overcome before the medicine is supplied by contacting the prescriber.

1.59 Other than in emergency situations it is recommended that the pharmacist does not dispense against faxed prescriptions and instead uses the Emergency Supply procedures.

1.60 As it is possible to fax a prescription many times the pharmacist is advised to ensure that no dispensing against a fax takes place unless the system used for the sending or receipt of faxes is secure.

1.61 Schedule 1, 2, or 3 CDs (except Phenobarbital for the treatment of epilepsy) must not be supplied against a faxed prescription.

1.62 As detailed above the patient should be interviewed over the phone. Payment can be processed via the website or over the phone. The pharmacist may wish to consider the following before providing an emergency supply at the request of the patient:

Delivery of Urgent Supplies

1.63 Given the nature of a request of this type, the Pharmacy should 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 company must be informed that items must be delivered ASAP by the quickest route possible. The Pharmacy must 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

- 1.64 A Specialist Waste Management Services will provide safe and secure disposal of unwanted medicines by collection of unwanted medicines from patients and residential homes.
- 1.65 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/app and marketing leaflets.
- 1.66 Patients wishing to return unwanted medicines to the pharmacy may do so by courier, which will be provided and paid for by the pharmacy. Patients in locality may contact pharmacy by phone or email to arrange collection of unwanted medicines from their home or work by pharmacy staff.
- 1.67 Appropriate packaging will be sent to patients in advance and details of the service and how to book a collection will be available on the Pharmacy website.

Public Health (Promotion of Healthy Lifestyles)

- 1.68 Identification of patients for promotion of healthy lifestyles can take two forms, namely, passive or active.
- 1.69 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.
- 1.70 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.
- 1.71 All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight and also lifestyle questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.
- 1.72 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. The website, app and email newsletters will also be used to promote healthy lifestyles.

Public Health Campaigns

- 1.73 The Pharmacy will take part in national health campaigns to promote public health messages to our 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.
- 1.74 Patients will be directed to the learning resources via email, text and other non face-to-face communication so that they are aware of the campaign.
- 1.75 From 1 March 2015 patients should also be assessed for participation in at least one clinical audit and whichever of the following that the NHSCB specifies—
 - 1.75.1 (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

- 1.75.2 (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.
- 1.76 Signposting and Assessment of whether patients require advice to minimise inappropriate use of health or social care services.
- 1.77 Any help or advice that cannot be accessed on the website and app links will be available by telephoning the pharmacy and asking for advice. The patient will then be signposted to health and social care providers and/or any other assistance available. 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.
- 1.78 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—
- 1.78.1 (a) requires advice, treatment or support that the pharmacy cannot provide; but
- 1.78.2 (b) 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,
- 1.79 The pharmacy will provide contact details of that provider to that person and will, in appropriate cases, refer that person to that provider.
- 1.80 Where, on presentation 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—
- 1.80.1 (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; and
- 1.80.2 (b) 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.
- 1.81 Where appropriate, a referral can be made by means of a written referral note.
- 1.82 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 Self-Care

- 1.83 Information about support organisations, the treatment of common illnesses, minor ailments, long term medical conditions and appropriate usage of OTC medications will be available on the website, app and email newsletter. The pharmacist on duty can be contacted by telephone for more advice and drug interactions.
- 1.84 There will also be pharmacist selected web links and 'downloads' to print off.

Support for People with Disabilities

- 1.85 This service will be provided in accordance with the Disability Discrimination Act (DDA). The Applicant will make reasonable pharmaceutical adjustment to ensure that those who qualify for help under the DDA are provided with the right compliance aids.
- 1.86 The Applicant will conduct an initial assessment with the patient, care 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.
- 1.87 Compliance aid systems such as blister packs/dosette boxes will be provided in compliance with both service levels 1 & 2 respectively.

Clinical Governance

- 1.88 Note: Clinical Governance is not an 'essential service' and is therefore dealt with briefly in this submission.
- 1.89 The Applicant 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.
- 1.90 'How to Make a Complaint or compliment' will be displayed and downloadable from the pharmacy website or upon request by telephone or post a copy will be posted.
- 1.91 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.
- 1.92 All staff will have an annual appraisal, receive and provide feedback.
- 1.93 The Pharmacy will conduct an annual Patient Satisfaction Survey / Community Pharmacy Patient Questionnaire (CPPQ) based on the template recommended by the PSNC.
- 1.94 Details of the survey (as per PSNC website) can be found at <http://psnc.org.uk/contract-it/essentialservice-clinical-governance/cppq/>
- 1.95 The survey will be adapted to reflect the operation of a distance selling pharmacy, ie
 - 1.95.1 Distributed via email, post and with delivery drivers / couriers
 - 1.95.2 References to "visiting" the pharmacy changes to reflect non face to face contact methods used.
 - 1.95.3 Ratings for the pharmacy based on physical characteristics changed to reflect actual method of use, ie ease of use of website as opposed to "comfort and convenience of the waiting areas".

Information Governance

- 1.96 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.

Delivering Medicines

- 1.97 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.
- 1.98 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 done by the delivery driver. All other nationwide delivery will be delivered by special delivery and signed for by the patient, their notified carer or other patient authorised representative. Fridge Lines will be delivered by courier (see further below).
- 1.99 The patient will be provided with a tracking number to track the status of the delivery online. A text messaging system will inform the patient about their delivery.
- 1.100 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.
- 1.101 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.
- 1.102 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.
- 1.103 Medicine for local delivery which is not fragile and to be delivered by the delivery driver can be packaged in the using the pharmacy bags supplied for standard prescription items.
- 1.104 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.
- 1.105 This means that for postal / courier items, either:
- 1.106 At the very least - padded envelopes even for non-fragile items as this will help to ensure the integrity of the manufacturers packaging.
- 1.107 For most items - bubble wrap and where necessary, polystyrene filler, placed within a cardboard box. Cardboard boxes must be the re-enforced type.
- 1.108 Large or any fragile medicines should be packed into cardboard boxes with bubble packaging and filling material to protect from damage.
- 1.109 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.
- 1.110 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.

Controlled Drugs

Delivery of Controlled Drugs

1.111 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:

1.111.1 MHRA Wholesale Dealer License

1.111.2 MHRA Manufacturers Importers License

1.111.3 MHRA IMP License

1.111.4 ISO 9001: 2000 Certified

1.111.5 Meet all Home Office safe custody and record keeping requirements

Return and Destruction of CD

1.112 Appropriate packaging will be sent to patients in advance with instructions for packaging any returned medicines and this will be provided and paid for by the pharmacy. The Superintendent Pharmacist will specify the appropriate method of collection depending on the items being returned and the distance from the pharmacy. Patients may also be signposted to alternate pharmacies if they prefer to return medicines to a different pharmacy. Any 'returned' Controlled Drugs must not be re-used or entered into the CD register. The Applicant will denature and render them irretrievable as soon as possible in order to avoid storage problems and an increased security risk.

1.113 Destruction must be witnessed by another member of staff. If not immediately destroyed, they should be segregated from main stock, clearly marked 'Patient Returns' to minimise the risk of errors and inadvertent supply and stored securely in a CD Cabinet waiting to be denatured. A record of destruction will be recorded in a separate CD Destruction Register designated for this purpose and will be available in the pharmacy for inspection.

Cover for Breaks / Working Time Directive

1.114 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

1.115 The Applicant 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

- 1.116 The reverse of the prescription should be fully completed (other than age exempt patients) in black ink.
- 1.117 Where evidence of exemption is required or provided by the patient it can be sent to the pharmacy for verification via the delivery driver and then returned to the patient. The PMR system should be updated to reflect that necessary check has been carried out and a note of when the next check is required should be entered onto the system. The Regulations require a patient to produce 'satisfactory evidence' to confirm exemption. Where appropriate (ie for deliveries made other than by the pharmacy's delivery driver), the patient may scan or fax copies of the evidence to the pharmacy (or use the postal / courier service, but see NOTE below) and the pharmacy can note that the evidence provided was not in original format. It is for the pharmacist in charge to determine if the evidence is satisfactory or not and, if not, then cross the 'Evidence not Seen' box.
- 1.118 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.
- 1.119 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.
- 1.120 Payment for prescription charges will be received via the secure payment portal on the website (eg Sagepay) and when payment is received the prescription will be marked as paid.

Registration of the Premises with the GPhC

- 1.121 It is illegal to operate a Pharmacy without registering the premises and Superintendent Pharmacist with the GPhC. The Applicant will apply to register the premises with the GPhC following the grant of an NHS Contract application. The GPhC will send an inspector to inspect the premises for approval before commencement of any Pharmacy business. The GPhC has a team of inspectors who undertake the routine monitoring and inspection of premises.

Practice leaflet

- 1.122 Nothing in the Applicant's practice leaflet, or publicity material in respect of the listed chemist premises, in material published on behalf of the Applicant publicising services provided at or from the listed chemist premises or in any communication (written or oral) from the Applicant or the Applicant's staff to any person seeking the provision of essential services will represent, either expressly or impliedly, that—
- 1.122.1 (i) the essential services provided at or from the premises are only available to persons in particular areas of England, or
- 1.122.2 (ii) the Applicant is likely to refuse, for reasons other than those provided for in the Applicant's terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (for example, because the availability of essential services from the Applicant is limited to other categories of patients).

2 The Decision

NHS England considered and decided to refuse the application. The decision letter dated 14 December 2018 states:

- 2.1 NHS England has considered the above application and is writing to confirm that it has been refused.
- 2.2 Please see attached report.

Greater Manchester Health & Social Care Partnership, NHS England (Greater Manchester Office), Pharmaceutical Services Regulations Committee

Considerations

Regulation 31

- 2.3 The Pharmaceutical Services Regulations Committee (“the PSRC”) reviewed the proposed location of the pharmacy, and had regard to the dictionary definition of “adjacent”, which is “lying near, close, or contiguous; adjoining; neighbouring”. The address of the proposed premises is Suite 1a, Lavenham Business Centre, Parsons Street, Oldham OL9 7AH, which is within a small business/industrial estate just outside Oldham town centre. The nearest pharmacy is Lloyds Pharmacy, based at Werneth Primary Care Centre on Featherstall Road South OL9 7AY, 0.16km/0.1 miles from the proposed site (source: The NHS Site).
- 2.4 The PSRC was therefore satisfied that it was not appropriate to refuse the application under Regulation 31, as:-
 - 2.5 (a) there is no person on the pharmaceutical list (which may or may not be the applicant) already providing or undertaking to provide pharmaceutical services (“the existing services”), either from
 - 2.5.1 (i) the premises to which the application relates, or
 - 2.5.2 (ii) adjacent premises; and
 - 2.6 (b) the NHSCB is satisfied that it is not reasonable to treat the services that the applicant proposes to provide as part of the same service as the existing services provided by Lloyds Pharmacy (and so the premises to which the application relates and the existing listed chemist premises should not be treated as the same).

Regulation 25

- 2.7 The Regulations require the PSRC 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 either on or in the vicinity of the premises.
- 2.8 The PSRC considered the application in accordance with Regulation 25, and took into account all information provided by the applicant and interested parties. The PSRC also considered the following:-
 - 2.8.1 *are the premises listed in the application on the same site or in the same building as a GP practice?*
- 2.9 The location of the proposed pharmacy has been identified in the application as Suite 1a, Lavenham Business Centre, Parsons Street, Oldham OL9 7AH.

- 2.10 The nearest GP practices are all based within Werneth Primary Care Centre on Featherstall Road South OL9 7AY, which is 0.16km/0.1 miles from the proposed site (source: The NHS Site).
- 2.11 The PSRC was therefore satisfied that the application should not be refused by virtue of Regulation 25(2)(a).
- 2.12 The PSRC considered the evidence the Applicant provided in respect of the Terms of Service (ToS) Essential Services, and was mindful that the Applicant does not need to repeat every element of the ToS. However where an area of essential service delivery would usually require face to face contact, this should be explained in the context of how those services will be delivered in a distance selling pharmacy setting.

Is the applicant seeking to restrict the provision of essential services in any way?

- 2.13 The application is for a 40 core hour distance selling pharmacy, operating Monday to Friday 09:00 – 13:00 and 14:00 – 18:00, with no supplementary hours offered. The applicant intends to provide all essential services, and appliances. They do not intend to provide any advanced or enhanced services.
- 2.14 The Applicant has attempted to address each essential service individually, and specifically, the application provides some information regarding:-
 - 2.14.1 Pharmacy procedures, and the intention to operate in accordance with the Standard Operating Procedures (SOPs) that will be in place;
 - 2.14.2 Delivery of pharmaceutical services and the methods which will be used to achieve this; the applicant states that this will be done without face to face contact on the premises to patients anywhere in England;
 - 2.14.3 Dispensing;
 - 2.14.4 Repeat dispensing;
 - 2.14.5 Disposal of unwanted medicines,
 - 2.14.6 Promotion of healthy lifestyle;
 - 2.14.7 Self-care and signposting;
 - 2.14.8 Clinical governance;
 - 2.14.9 Delivery of medicines to patients;
 - 2.14.10 Patient declarations and prescription exemptions
- 2.15 The PSRC noted the content of the application, and that the Applicant had submitted a document entitled “Further Information in Relation to Provision of Essential Services in Accordance with the Regulatory Requirements for Distance Selling Pharmacies”, which contains some information about how a distance selling pharmacy would meet its essential services in respect to the following: Dispensing, Repeat Dispensing, Disposal of Unwanted Medicine, Promotion of Healthy Lifestyle, Signposting and Support for Self-Care. The PSRC noted that this is a generic document which does not contain any specific references to the Applicant, and considered that the level of detail contained within is insufficient in terms of explaining how services will be delivered safely and effectively, on a non-face-to-face basis, to persons anywhere in England.

- 2.16 Based on all available information, the PSRC was not satisfied that the application contained sufficient information or assurances that all aspects of essential service provision are likely to be secured through the Applicant's procedures.

Does any element of essential service provision involve face to face contact with the applicant or their staff, either on or in the vicinity of the premises?

- 2.17 The PSRC noted that the proposed premises are located within a small business/industrial estate setting. The premises are not "shop fronted" or in a prominent position. The Applicant has stated that they "will operate from secure premises, with a controlled entry system, to which members of the public will not have access."
- 2.18 Due to the nature and location of the proposed pharmacy premises in conjunction with the above statement, the PSRC was satisfied that provision of essential services would not involve face to face contact with patients either on, or in the vicinity, of the proposed premises.
- 2.19 The PSRC noted that all five respondents highlighted the relevant regulations to NHS England, but did not indicate either support nor objection to the application.
- 2.20 The Applicant did not respond to the interested party comments.

Decision

Regulation 31

- 2.21 The PSRC had regard to Regulation 31 and was satisfied that a refusal under Regulation 31 (same or adjacent premises) did not apply in this case, as there is no existing provider of pharmaceutical services based either at, or in the immediate vicinity of, the applicant's proposed premises address.

Regulation 25

- 2.22 The PSRC made a determination based on whether or not it considered that the application fulfilled the requirements of Regulation 25, which are set out below:-

2.23 *"Distance selling premises applications*

25.— (1) Section 129(2A) of the 2006 Act(c) (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 also 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) The NHSCB 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 the NHSCB 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."

- 2.24 The PSRC was satisfied that the Applicant's proposed premises are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list, and a refusal by virtue of Regulation 25(2)(a) does not apply in this case.
- 2.25 Taking into account all information provided, the PSRC was not however satisfied that the application fully meets the requirements of Regulations 25(2)(b)(i) or (ii); specifically in relation to the supporting information provided, which the PSRC concluded was insufficient in terms of explaining how all essential services would be delivered, safely and securely, on a non-face-to-face basis, to persons anywhere in England.
- 2.26 Therefore the PSRC's decision was to refuse the application.
- 2.27 The applicant APKSM-PHARM786 Ltd has a right of appeal against the PSRC's decision.

3 **The Appeal**

In a letter dated 14 December 2018 Rushport Advisory LLP representing APKSM-PHARM786 Ltd appealed against NHS England's decision. The grounds of appeal are:

- 3.1 Rushport Advisory LLP act for APKSM-PHARM786 Ltd (the Applicant) and have been instructed by the Applicant to submit this appeal against the attached decision of NHS England refusing the above application.
- 3.2 As NHS England has provided no reasons for refusing the application other than a statement which says that "the level of detailed contained within [the application] is insufficient in terms of explaining how services will be delivered safely and effectively, on a non-face-to-face basis, to persons anywhere in England", there are no specific points that the Applicant can address in this appeal.
- 3.3 In order to address NHS England's concern about the lack of sufficient detail the Applicant has asked its representative to submit their approved SOPs as part of this appeal and they ask that these are considered by Primary Care Appeals as part of the appeal process.
- 3.4 [SOPs provided – available for Committee]

4 **Summary of Representations**

This is a summary of representations received on the appeal.

4.1 **BOOTS UK LTD**

- 4.1.1 Boots have no further comments to make at this time but ask that NHS Resolution kindly inform Boots of the decision in due course.

Boots UK Ltd letter to NHS England

- 4.1.2 Boots UK Limited have the following comments to make.

- 4.1.3 Boots UK Ltd would like to respectfully request that when considering this application members of NHS England satisfy themselves that the applicant

will be able to meet all the criteria for opening a wholly internet/ mail order based/Distance selling pharmacy.

- 4.1.4 Boots trust that NHS England will ensure the proposed premises are not on the same site or in the same building as a provider of primary medical services with a patient list (regulation 25(2)(a)).
- 4.1.5 Furthermore, Boots would also ask that NHS England be satisfied that the Applicant is able to provide uninterrupted provision of essential services throughout the opening hours without face-to-face consultation, to all persons in England wishing to access these services. (Regulation 25(2)(b)(i)) and between any person receiving these services, whether on their own or on someone else's behalf, and the applicant or the applicants staff (Regulation 25(2)(b)(ii)).

4.2 GREATER MANCHESTER LPC

- 4.2.1 Greater Manchester LPC applications sub group has reviewed this application and is of the opinion that The NHSCB must ensure that the applicant has satisfied Regulation 25(2) of The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 by fully explaining how the pharmacy procedures will secure:
 - 4.2.1.1 the uninterrupted provision of essential services during opening hours to persons anywhere in England who request those services, we are particularly concerned that appropriate contracts are in place to allow the delivery of CD and Fridge lines at all times and the collection of waste medicines from patients; and
 - 4.2.1.2 the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own behalf or on behalf of someone else, and the applicant or the applicant's staff.
- 4.2.2 Greater Manchester LPC would like to receive any further correspondence regarding this application and wish to be kept informed of its progress.

4.3 NHS ENGLAND

- 4.3.1 NHS England writes to acknowledge the appeal received from APKSM-PHARM786 Ltd, against the decision of the Greater Manchester Pharmaceutical Services Regulations Committee ("the PSRC") to refuse the above-detailed Regulation 25 application.
- 4.3.2 NHS England notes from the appeal submissions that Rushport Advisory LLP has provided a full suite of generic distance selling pharmacy Standard Operating Procedures (SOPs) at this stage. NHS England is mindful that it does not approve the content of SOPs, however it does have a duty to consider whether the information contained within an application (which may or may not include SOPs) is sufficient and accurate to give assurances that robust procedures are in place to support the delivery of all essential services safely and effectively.
- 4.3.3 At the time the PSRC made its determination, it had before it the document entitled 'Further Information in Relation to Provision of Essential Services in Accordance with the Regulatory Requirements for Distance Selling Pharmacies', which the appellant had submitted in support of the application. The PSRC did not have sight of the SOPs now submitted as part of the appeal, and was not satisfied that the original document gave assurances that adequate procedures were in place.

4.3.4 Presenting the SOPs at the appeal stage indicates that the Applicant now acknowledges that the detail contained within original application was not adequate; and whilst there is no requirement to repeat every element of the Terms of Service (ToS) in an application, where a part of a service usually requires face to face contact this should be sufficiently explained in a distance selling context. The PSRC was of the opinion that the original application and supporting document did not offer adequate assurances that all essential services would be delivered safely and effectively to persons anywhere in England who wish to access those services, and on a non-face to face basis, as required by the Regulations.

4.3.5 In conclusion, NHS England is satisfied that the PSRC reached the correct decision based on the content of the original application; and noting that new information has now been introduced by the Applicant's representatives at the appeal stage, respectfully awaits the outcome of this appeal.

4.4 LLOYDS PHARMACY

4.4.1 Lloyds Pharmacy would like to submit the following response.

4.4.2 The proposed premise at Lavenham Business Centre (picture available) is opposite to a large health centre (Werneth Primary Care Centre). Lloyds Pharmacy would ask the Committee to ensure that as part of its review of the application there is no opportunity for face to face to contact in order to receive the provision of pharmaceutical services.

5 Unsolicited Comments

5.1 CHADDERTON PHARMACY

5.1.1 With regards to the distance selling application made by the company APKSM-PHARM786, as Chadderton Pharmacy has just become aware of this application it would like to raise a few critical points regarding this application which it feels should be taken into consideration by the Committee and the NHS resolution team.

5.1.2 The applicant Asima Khan is an independent prescriber working in Oldham for the Oldham GP federation and the second applicant Suleman Malik is also an independent prescriber who also operates in Oldham, working for the Oldham CCG. As their distance selling pharmacy application is also located in Oldham, Chadderton Pharmacy feels this is a conflict of interest and will potentially lead to direction of prescriptions to their own DSP for personal commercial gain as well as undermining the choice of patients.

5.1.3 Chadderton Pharmacy feels this vested interest of both the prescriber owners should have been declared to NHS England at the earliest opportunity, the applicant's intention to gain the DSP licence without declaring such significant interest gives rise to the points raised.

5.1.4 As both prescribing pharmacist owners (Asima and Suleman) are working alongside many GPs in the Oldham area, there is an obvious potential for the applicants in collaborating with fellow GPs, such collaboration would allow a significant amount of prescriptions to be directed to this pharmacy. As such practise has been evident in many distance selling pharmacies, especially in the Oldham area, where some local GPs have directed prescriptions to certain DSPs.

5.1.5 The above points also suggest the applicants intend to focus their pharmacy services mainly in the Oldham area therefore offering a more localized service rather than a nationwide service which is the main purpose of a DSP.

- 5.1.6 The location of the premises is directly opposite a very busy health centre, therefore it is highly likely many patients from the health centre will visit this DSP to have their prescriptions dispensed face to face, but there is no specific SOP available detailing how such patients from the health centre will not receive a face to face service, and also no SOP is available detailing how the patients arriving at the door requiring a face to face essential service will be redirected to another pharmacy where they could have their prescription dispensed face to face.
- 5.1.7 Chadderton Pharmacy feel the latter 2 points breach regulation 25 - Part 4 of the The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.
- 5.1.8 The SOPs have been purchased from Rushport Advisory LLP, these generic SOPs do not directly adapt to the model of this DSP application, being so close to a health centre.
- 5.1.9 The model of this DSP application, is similar to a few other DSPs models which are causing a major concern to the Department of Health (DoH), as a recent review (March 2018) published by DoH regarding DSPs found *"sudden drops in the dispensing volume at brick and mortar pharmacies following an opening of a DSP located nearby, with a corresponding spike in prescriptions at the new DSP, the vast majority coming from a single general practice."* The DoH stated this should not happen and is working to implement change to overcome such consequences in DSPs.
- 5.1.10 Therefore, Chadderton Pharmacy strongly feels APKSM-PHARM786 should NOT be granted the application, as their model directly relates to the concerns of DoH. As this application intends to open very near to the brick and mortar Lloyds pharmacy thus affecting their dispensing volume and the background of the both applicants points to prescription direction to this DSP, resulting in a localized service rather than a nationwide service.
- 5.1.11 If the application is granted, Chadderton Pharmacy feels NHS England will directly undermine the efforts of the Department of Health to prevent prescription direction and localised services by DSPs.

6 Summary of Observations

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

7 Consideration

- 7.1 The Pharmacy Appeals Committee ("Committee") appointed by NHS Resolution, had before it the papers considered by NHS England.
- 7.2 It also had before it the responses to NHS Resolution's own statutory consultations.
- 7.3 On the basis of this information, the Committee considered it was not necessary to hold an Oral Hearing.
- 7.4 The Committee had regard to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations").

Regulation 31

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

(1) A routine or excepted application must be refused where paragraph (2) applies

(2) *This paragraph applies where -*

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

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

(ii) adjacent premises; and

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

7.6 The Committee noted in its application form, the Applicant states that Regulation 31 is not applicable as "no other pharmacy in same or adjacent premises". NHS England, in its decision, noted that the nearest pharmacy was 0.16 kilometres away from the proposed site. The Committee noted that this had not been disputed by parties. Based upon the information before it, the Committee considered that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

7.7 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) *The NHSCB 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 the NHSCB is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure—

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

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

- 7.8 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 the NHSCB in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the NHSCB may need to make of the information or documentation when carrying out its functions.*

- 7.9 Pursuant to paragraph 9(1)(a) of Schedule 3 to the Regulations, the Committee may:
- 7.9.1 confirm NHS England's decision;
 - 7.9.2 quash NHS England's decision and redetermine the application;
 - 7.9.3 quash NHS England's decision and, if it considers that there should be a further notification to the parties to make representations, remit the matter to NHS England.

Regulation 25(1)

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

Regulation 25(2)(a)

- 7.11 As far as Regulation 25(2)(a) is concerned, the Committee had regard to the application form in which the Applicant states the "application is not on the same site or in the same building as the premises of a provider of primary medical services with a patient list." The Committee noted that Boots had requested that this be ensured. Lloyds also refer to the proposed premises being opposite Werneth Primary Care Centre. The Committee also noted that the Applicant's statement 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)

- 7.12 As far as Regulation 25(2)(b) is concerned, the Committee considered the information which had been provided by the Applicant in relation to its procedures for the provision of essential services, including its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.
- 7.13 The Regulations require the Committee to be satisfied as to a number of matters, including that essential services will be provided on an uninterrupted basis, in a safe and effective way, across England, and without face to face contact.
- 7.14 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicates that the obligation is only discharged if the information or documentation provided is sufficient to satisfy 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.
- 7.15 The Committee has asked itself whether it has sufficient information and documentation which would address the criteria in Regulation 25(2)(b). If the Committee is to be satisfied of the matters in that paragraph, the Committee must be provided with evidence to demonstrate these matters. In this case, that evidence put forward has taken the form of the original application and the Standard Operating Procedures (SOPs) which the applicant has prepared or commissioned.
- 7.16 It is not for the Committee to 'approve' or 'disapprove' of these SOPs (as they may contain matters not relevant to the Committee's consideration, and there are many ways an applicant can choose to organise itself in order to comply with the various requirements of the Regulations) and the Committee has not sought to do so. The Committee has sought evidence within the SOPs [and application] in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.
- 7.17 The Committee noted that parties in their representations had requested assurance that essential services would be provided without face to face contact, during the opening hours, anywhere in England and an unsolicited party had questioned how the Applicant would demonstrate this aspect of the regulations.
- 7.18 The Committee noted that throughout the application form, the Applicant states that essential services will be provided without face to face contact between anyone receiving the services and the pharmacy staff. This is reiterated throughout the SOPs provided with the appeal and in SOP 1 'Introduction and Background to SOPs' it states:
- 7.18.1 *"All staff must be made aware that face to face contact between patients (or their representatives) is prohibited in respect of any and all Essential Services either on or in vicinity of the premises."*
- 7.19 The Committee noted in the information provided, the Applicant refers on several occasions to contacting patients by phone, through the website, a pharmacy app on mobile phones as well as by email and postal services.
- 7.20 The Committee noted several references throughout the SOPs to the provision of services to all of England, using a delivery driver, the Royal Mail and national couriers. The Committee also noted SOP 2 'Procedures for NHS Essential Services' states:
- 7.20.1 *"NHS Essential Services will be provided to any patient living in England who requests such services, this is made clear on the website and in the Practice leaflet."*

- 7.21 The Committee noted in the information provided, the Applicant states that it will ensure it provides safe effective and uninterrupted provision of essential services to persons anywhere in England. In its SOP 28 'The Responsible Pharmacist', the Applicant states that:
- 7.21.1 *"...the RP is not allowed to leave the premises in the same way as an RP at a non-Distance Selling pharmacy is allowed to (for up to 2 hours per day) unless the second pharmacist is present"* and further
- 7.21.2 *"The Pharmacy will have a second pharmacist available during the core and any additional hours that it operates. If, for any reason, the RP is required to leave the premises or wishes to take a break... then the second pharmacist must sign in as the RP."*
- 7.22 The Committee was satisfied that the provision of services, would be without face to face contact; would be available to persons anywhere in England and would be without interruption. The Committee went on to consider whether safe and effective provision of essential services was likely to be secured.
- 7.23 The Committee considered each essential service in paragraphs 3 to 22 of schedule 4 of the Regulations ("Terms of Service") in turn.
- 7.24 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:

Dispensing of drugs and appliances

- 7.25 The Committee considered whether the Applicant had explained how non-electronic prescriptions will be presented by the patient and how products will be provided.
- 7.26 In its application form, the Applicant states that "prescriptions will be received by EPS, post and fax or where practicable, with the patient's informed consent, collected from a surgery". In its SOP 5 'Online Order Receipt & Exemption Checking' the Applicant states:
- 7.26.1 *"Requests to collect and dispense NHS Prescriptions.*
- Requests to dispense a prescription received in the post."*
- 7.27 The Committee also had regard to SOP 15 "Order Delivery" which states under "Choice of Delivery Method":
- 7.27.1 *"For local deliveries (up to 30 miles radius, but may be extended at the discretion of the RP) the delivery driver should deliver medication. Outside this area Royal Mail should be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier should be used..... or the items are fridge lines, in which case the cold chain courier should be used."*
- 7.28 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 5(2)(3) of Schedule 4.

Urgent supply without a prescription

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

7.30 The Committee had regard to SOP 13 entitled 'Emergency Supply and Urgent Supply' which describes how the Applicant would process such a request. The Committee also noted the SOPs state that essential services will be delivered by using telephone as well as email among other methods of non face to face communication, and considered that it was reasonable to infer that these methods would be used to receive requests from prescribers for the urgent supply of drugs.

7.31 The Committee further noted in SOP 13, it states:

7.31.1 *"Given the nature of a request of this type, the Pharmacy should 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 company must be informed that items must be delivered ASAP by the quickest route possible."*

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

Preliminary matters before providing ordered drugs or appliances

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

7.34 SOP 5 'Online Order Receipt & Exemption Checking' stated:

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

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

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

7.37 The Committee noted SOP 5 'Online Order Receipt & Exemption Checking' which states under the heading "Paid NHS Prescription":

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

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

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

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

Providing ordered drugs or appliances

- 7.39 The Committee noted that in its representations, the LPC expressed concern that appropriate contracts are in place to allow the delivery of CD and Fridge lines at all times. The Committee was mindful that the Regulations do not require that contracts should be in place at the time the application is made and proceeded with its consideration as below.
- 7.40 The Committee considered whether the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that (i) the 'cold chain' is maintained, where relevant, and (ii) that the requirements of the Misuse of Drugs Regulations 2001 and, in particular, Regulations 14 and 16, are met).
- 7.41 The Committee noted that in its application the Applicant states:
- 7.41.1 *"If the delivery to patients is local, this will be done by the delivery driver. All other nationwide delivery will be delivered by special delivery and signed for by the patient, their notified carer or other patient authorised representative. Fridge Lines will be delivered by courier."*
- 7.42 The Committee noted that SOPs had been provided with the appeal. The Committee noted SOP 15 'Order Delivery' under the heading "Preparation for Delivery" states:
- 7.42.1 *"Send a confirmation message to the patient via their preferred method of non face to face communication to let them know that their items are ready for delivery and confirm the estimated delivery time."*
- 7.43 SOP 15 'Order Delivery' under the heading "Choice of Delivery Method" states:
- 7.43.1 *"For local deliveries (up to 30 miles radius, but may be extended at the discretion of the RP) the delivery driver should deliver medication. Outside this area Royal Mail should be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier should be used....or the items are fridge lines, in which case the cold chain courier should be used."*
- 7.44 SOP 15 under the heading 'Transfer to the Delivery Driver' states:
- 7.44.1 *"Ensure that any special instructions for the delivery are included within the packaging.*
- Ask the delivery driver to check the details on the delivery sheet correspond to the deliveries.*
- Ensure the delivery driver completes all the sections on the delivery sheet including their name and the date.*
- Ensure that any deliveries for fridge items and CDs are taken out of storage when appropriate.*
- Ensure the delivery driver is notified of any messages for the patient or representative.*
- Make and retain a copy of the delivery sheet until the original had been returned by the delivery driver. The original must be returned to the pharmacy on the same day.*
- Ensure the deliveries are placed in the delivery vehicle and are stored securely and out of sight. The delivery vehicle must be locked at all times when left unattended."*

7.45 The Committee noted SOP 15 'Order Delivery' under the heading "Delivery of a prescription via Royal Mail (Not for Coldchain or CDs)" states:

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

.....

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

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

Confirm details of all prescriptions to be delivered.

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

Ensure Royal Mail driver signs Delivery Log for all prescriptions being accepted for delivery.

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

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

7.46 The Committee noted SOP 15 'Order Delivery' under the heading "Cold chain delivery via courier" states:

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

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

Cold chain management uses its own terminology. Several temperature ranges are specified in the relevant literature, the most common being controlled-room temperature or CRT (often defined from 15°C to 25°C), but also cool (from 8°C to 15°C), cold or refrigerated (from 2°C to 8°C), frozen (around -10°C) and cryogenic (around -150°C). There is, however, no general or universal glossary that is commonly accepted by all regulatory agencies. For courier deliveries, the Pharmacy will normally be advising the courier that delivery must be in the "cold or refrigerated" category.

The Cold Shipping Package is designed for customers that require a refrigerated environment of 2-8°C for their shipments and will be most commonly used in the pharmacy.

The packaging device maintains its exacting "cold ship" temperature requirements and is fully monitored to ensure that any breach is notified to the driver who will then notify the Pharmacy and follow the "failed delivery process".

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

Fully traceable transport of pharmaceuticals & medicines backed by the latest logistics technology provides consignment tracking, live ETA's and electronic proof of delivery. Temperature data for storage and transit is also recorded.....

Ensure any items for cold chain delivery via courier are stored in the fridge and accompanying items are appropriately marked with a fridge line sticker. Accompanying items should include a note to explain that fridge items will be delivered separately to the rest of their items to enable the cold chain to be maintained.....

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

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

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

Unsuccessful cold chain delivery via courier

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

Breach of Integrity of Cold Chain ...

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

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

7.47 The Committee noted that SOP 19 'Controlled Drugs: Delivery' which states under the heading of "Delivery of Schedule 2 & 3 CDs":

7.47.1 *"A robust audit trail is essential when controlled drugs are involved. The delivery can be made to a person who is not the patient (the patient must have given authorisation for a representative to take receipt of CDs on their behalf). The delivery driver/courier should check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative.*

A Controlled Drugs Delivery Sheet must also be filled in for CD deliveries in addition to the Delivery Log Sheet.

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

CDs and other medicines on that patients delivery must be stored in the lockable compartment of the delivery van and out of sight.

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

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

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

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

Successful Schedule 2 & 3 Delivery

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

Unsuccessful Schedule 2 & 3 Delivery via pharmacy driver

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

Unsuccessful Schedule 2 & 3 Delivery via courier

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

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

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

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

7.50 The Applicant states in its application form that it will undertake to provide:

7.50.1 "Drug Tariff part IX"

7.50.2 **EXCEPT items that require measuring or fitting.**

7.51 In its SOP 22 "Support for Self-Care, Signposting and Health Promotion" the Applicant states under the heading "Items Requiring Measuring and Fitting":

7.51.1 *"Where a prescription is received for an appliance or stoma appliance customisation or any item that requires measuring or fitting the patient should be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients should be sign posted to at least 2 other providers of the service in their area."*

7.52 The Committee note that the Applicant does not intend to provide appliances which require measuring or fitting. In the event that the application is granted, the Applicant would not therefore, be able to provide those appliances listed as excluded in the application form to patients.

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

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

7.55 The Committee noted SOP 14 'Bagging-Up' under the heading "Choice of Packaging" states:

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

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

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

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

For postal items, either:

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

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

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

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

monitored (see delivery SOP). Pharmacy staff should be aware that some thermoliable products can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in medicines which is damaging to them and such items must not be used."

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

Refusal to provide drugs or appliances ordered

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

- 7.58 The Committee noted SOP 31 'Repeat Dispensing' under the heading "Pharmaceutical & Legal Assessment" states:

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

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

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

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

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

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

Any interventions or referrals which are deemed to be clinically significant should be recorded on the Intervention and Referral Form."

- 7.59 The Committee further noted SOP 31 'Repeat Dispensing' under the heading "Prescription Reception" states:

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

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

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

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

- 7.61 The Committee considered whether the Applicant had explained how appropriate advice about the benefits of repeat dispensing is given to any patient who (i) has long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term), and (ii) requires regular medicine in respect of that medical condition.
- 7.62 The Committee noted SOP 31 'Repeat Dispensing' under the heading "Prescription Reception" it states:
- 7.62.1 *"Appropriate advice about the benefits of repeat dispensing must be given to any patient who:*
- has a long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term); and*
- requires regular medicine in respect of that medical condition, including, where appropriate, advice that encourages the patient to discuss repeat dispensing of that medicine with a prescriber at the provider of primary medical services whose patient list the patient is on.*
- Such advice will be provided by the Pharmacy using its permissible methods of non face-to-face contact with patients."*
- 7.63 In addition the Committee also noted under the heading "Pharmaceutical and Legal Assessment" in SOP 31 it states:
- 7.63.1 *"Provide advice and encouragement to patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber."*
- 7.64 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.

Disposal service in respect of unwanted drugs

- 7.65 The Committee noted that in its representations, the LPC requested assurance that appropriate contracts are in place to allow the collection of waste medicines from patients. The Committee was mindful that the Regulations do not require that contracts should be in place at the time the application is made and proceeded with its consideration as below.
- 7.66 The Committee considered whether the Applicant had explained how it will safely and effectively accept and dispose of unwanted drugs presented to it for disposal.
- 7.67 The Committee noted that SOPs had been provided with the appeal. For the return of controlled drugs, the Committee noted SOP 20 'Controlled Drugs: Collection and Disposal of Patient Returns' and in particular the section "Patient Returned Medication", which states:

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

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

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

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

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

Each return will be made by booking an appointment for the pharmacy's driver to visit the patient's home to collect the returned medication or by sending the appropriate packaging to the patient to arrange for return by Royal Mail ..."

- 7.68 The Committee further noted that SOP 20 goes on to state, under the heading "Handling Patient-Returned CDs from Delivery Driver":

7.68.1 *"Drivers need to:*

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

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

- 7.69 The Committee noted SOP 21 'The Safe and Effective Receipt and Disposal of Medicines' states, under the heading "Process for accepting patient returns by the Driver" it states:

7.69.1 *"Confirm that a collection of unwanted medication for disposal has been booked. Returns without a booking should only happen in exceptional circumstances..."*

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

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

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

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

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

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

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

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

- 7.70 The Committee was of the view that the Applicant expects patients to follow the instructions provided on its website in order to return unwanted medication so that the

pharmacy can arrange such returns and has given assurances as to how this is effected.

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

Promotion of healthy lifestyles

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

- 7.73 The Committee noted SOP 23 'Promotion of Healthy Lifestyle & Public Health Campaigns' under the heading "Identification of patients for promotion of Healthy Lifestyles" states:

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

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

Prescription linked intervention

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

- 7.76 The Committee noted SOP 23 'Promotion of Healthy Lifestyle & Public Health Campaigns' under the heading "Identification of patients for promotion of Healthy Lifestyles" states:

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

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

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

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

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

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

Public health campaigns

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

- 7.79 The Committee noted under SOP 23 ‘Promotion of Healthy Lifestyle & Public Health Campaigns’ under the heading “Public Health Campaigns” states:

7.79.1 “The Pharmacy will take part in national health campaigns to promote public health messages to our 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.

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

We will also offer help and support on our website and direct patients to appropriate links for the health campaigns. This will ensure that patients across the UK are able to easily access information about health campaigns at all times. The Pharmacy will send out ‘quit kits’ to patients who are looking to stop smoking. Examples of campaigns that we will take part in are: Be Clear on Cancer, Stoptober, Change for Life, Make the Right Choice and Sexual Health campaigns.

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

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

Signposting

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

- 7.82 The Committee noted under SOP 22 ‘Support for Self-Care, Signposting and Health Promotion’ under the heading “Patient identification” states:

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

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

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

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

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

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

Other Provider Organisations and Support Details

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

The following links will be available to patients on our website (to be updated on an annual basis)..."

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

Support for self-care

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

- 7.85 The Committee noted SOP 22 'Support for Self-Care, Signposting and Health Promotion' under the heading "Service outline" states:

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

Advice should be backed up, as appropriate, by the provision of written material such as leaflets.

When such a request is received, the pharmacist should be informed and a record kept of the request.

Advice (and requests for advice) must operate without face-to face interaction (eg telephone, Skype, via the website)."

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

Other Considerations

- 7.87 The Committee noted the unsolicited comments sent in by Chadderton Pharmacy. Chadderton Pharmacy has raised its concerns for the potential collaboration between the Applicant and local GPs for the direction of prescriptions. The Committee was of the view that this was not a matter that could be addressed on appeal and it would be

for NHS England to monitor the arrangements in place for the receiving of prescriptions should the application be successful.

- 7.88 The Committee noted the comments about the generic nature of the SOPs and was of the view that the SOPs as provided by the Applicant's representative are comprehensive, however the Committee would expect to see the name of the Applicant's pharmacy on the SOPs which, although not determinative, would have the potential to re-assure parties that the SOPs are owned by the Applicant.
- 7.89 The Committee is mindful that it does not have the power to interpret the aspirations of Department of Health and Social Care and has considered this application in line with the current Regulations as published.

Summary

- 7.90 On the information before it, the Committee could be satisfied that there are procedures likely to secure safe and effective provision of essential services as required by Regulation 25(2)(b).
- 7.91 The Committee noted that SOPs had been provided with the appeal, which NHS England had not seen prior to its deliberation of the application. In those circumstances, as the Committee has had additional information to consider and has reached different conclusions to NHS England, it determined that the decision of NHS England must be quashed.
- 7.92 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 NHS England) or whether it was preferable for the Committee to reconsider the application.
- 7.93 The Committee noted that representations on Regulation 25 had already been made by parties to NHS England, and these had been circulated and seen by all parties as part of the processing of the application by NHS England. The Committee further noted that when the appeal was circulated representations had been sought from parties on Regulation 25.
- 7.94 The Committee concluded that further notification under paragraph 19 of Schedule 2 would not be helpful in this case.

8 Decision

- 8.1 The Committee concluded that it was not required to refuse the application under the provisions of Regulation 31.
- 8.2 Accordingly, the Committee:
- 8.2.1 quashes the decision of NHS England; and
 - 8.2.2 redetermines the application as follows -
 - 8.2.2.1 the Committee was satisfied that the proposed premises were not adjacent to or in close proximity to other chemist premises,
 - 8.2.2.2 the Committee was satisfied that the premises of the Applicant are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list,

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

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

8.2.2.5 the Committee was satisfied that all essential services were likely to be secured in a safe and effective manner,

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

8.2.3 The application is granted.

Primary Care Appeals

A copy of this decision is being sent to:

Rushport Advisory LLP representing APKSM-PHARM786 (the Applicant)
NHS England
Boots UK Ltd
Greater Manchester LPC
Lloyds Pharmacy