

24 January 2019

REF: SHA/20002

1 Trevelyan Square  
Boar Lane  
Leeds  
LS1 6AE

**APPEAL AGAINST NHS COMMISSIONING BOARD  
"NHS ENGLAND" DECISION TO REFUSE AN  
APPLICATION BY TARIQ MUHAMMAD FOR  
INCLUSION IN THE PHARMACEUTICAL LIST AT  
UNIT 1, GROUND FLOOR, 442-450 STAPLETON  
ROAD, BRISTOL, BS5 6NR UNDER REGULATION  
25**

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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 refused.

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Advise / Resolve / Learn

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Accredited  
UNIT 2003



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## 1 The Application

By application dated 3 May 2018, Tariq Muhammad ("the Applicant") applied to NHS Commissioning Board ("NHS England") for inclusion in the pharmaceutical list at Unit 1, Ground Floor, 442-450 Stapleton Road, Bristol, BS5 6NR under Regulation 25. In support of the application it was stated:

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

- 1.1 As a dispensing pharmacy contractor, the Applicant intends to provide the full range of products that are presented on FP10 prescriptions, which include appliances, in line with its Terms of Service and in the normal course of the business.

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

- 1.2 N/A

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

- 1.3 N/A

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

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

- (a) the uninterrupted provision of essential services during the opening hours of the premises, to persons anywhere in England who request those services, and
- (b) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or someone else's behalf, and the applicant or the applicant's staff.

- 1.4 **In preparation of this application, the Applicant has written detailed Standard Operating Procedures for all aspects of the running of the pharmacy. A list of the titles of the SOPs is enclosed with the covering letter of this application. It is happy to provide any of these SOPs to the committee on request. The section below provides a summary of how the pharmacy will secure uninterrupted provision of essential services and the safe and effective provision of essential services without face to face contact. Each explanation refers to the relevant SOP.**
- 1.5 **The Uninterrupted provision of essential services**
- 1.6 The pharmacy procedures specify that a Responsible Pharmacist will be present in the pharmacy to secure the safe and effective running of the pharmacy at all times that the pharmacy is open for the provision of pharmaceutical services on request from persons anywhere in England (Ref SOP – Designating a Responsible Pharmacist).
- 1.7 The Pharmacy will create a website through which persons anywhere in England can access services offered by the pharmacy (Ref SOP – Patient Registration on Website).
- 1.8 **The Safe and Effective provision of Essential Services without face to face contact**
- 1.9 An explanation of how the pharmacy procedures ensure the safe and effective provision of services is described for each element of the essential service with reference to the relevant SOP. The SOPs are available on request.
- 1.10 Dispensing Medicines:
- 1.11 The procedures will specify that prescriptions will either be received electronically via the Electronic Prescription Service through the Pharmacy computer system or from the patient via the postal service. At no time will prescriptions be received directly from patients or their representative walking in to the premises. Persons anywhere in England will have the choice to have their prescriptions dispensed at the pharmacy through nomination of Electronic Prescriptions or by posting paper prescriptions or prescription tokens (Ref SOP – Receive Paper Prescriptions by Post and SOP – Receive EPS Prescriptions).
- 1.12 The procedures will ensure that pharmacy performs the appropriate legal, clinical and accuracy checks. The pharmacy will have safe systems of operation in line with clinical guideline requirements. The procedures will ensure there are systems in place to guarantee the integrity of products supplied. The pharmacy system will maintain a record of all medicines supplied which can be used to assist future patient care. The pharmacy system will also maintain a record of the advice given and interventions and referrals made, where the pharmacist judges it be clinically appropriate (Ref SOP – Pharmaceutical Assessment and Clinical Check).
- 1.13 The pharmacy procedures will also ensure the safe supply of appliances (Ref SOP – Appliance, Stoma and Incontinence). If the prescription asks for “measured and fitted”:

- 1.13.1 The pharmacist is to decide if he/she is competent to perform the measuring and fitting service for the appliance and if it is practicable to visit the patient in their own home to perform the measuring and fitting service.
  - 1.13.2 If the pharmacist is either not competent or it is not practicable to visit the patient to perform the measuring and subsequent fitting service, then two pharmacies near to the patient's address will be identified and telephoned to see if they are willing to provide the appliance and the service.
  - 1.13.3 Patients will then be contacted for consent to refer the prescription to one of the service providers. If a paper prescription is provided, then the prescription will be posted to the chosen alternative pharmacy. If the prescription is via the EPS service, this EPS prescription will be returned to the spine making it available for download by the chosen alternative pharmacy.
  - 1.13.4 If the patient does not consent to the prescription being referred to another provider, then the pharmacist is to provide the patient with the contact details of two providers of appliances for the patient to make direct contact. If a paper prescription is provided, then the prescription will be posted to the patient. If the prescription is via the EPS service, this EPS prescription will be returned to the spine making it available for download by another provider.
- 1.14 To ensure patients are able to use their medicines and appliances effectively, there are procedures for a pharmaceutical assessment and a clinical check. If the pharmacist deems that the patients require support in the use of medicines and appliances, the pharmacist will communicate with patients regarding "safe use of medicines" and "side effects and interactions" through the following non-face to face methods of communication which will be integrated with the PMR where records of advice are documented. (Ref SOP – Pharmaceutical Assessment and Clinical Check):
- 1.14.1 Written communication inserted in to the dispensed medicine packaging
  - 1.14.2 Telephone calls with patients
  - 1.14.3 E-mail communication
  - 1.14.4 SMS communication
  - 1.14.5 Via a patient app on a smart phone
- 1.15 Dispensed Medicines will be supplied to patients via secure postal service or in the case of "cold chain" or "controlled drugs" via a specialist couriers.
- 1.15.1 All standard items will be packaged into non-branded and discrete padded envelopes of appropriate size.
  - 1.15.2 For dispensed medicines that require maintenance of the cold chain, special packaging will be used that allows insertion of a "cold gel" away from the dispensed medicines. A specialist courier will be

selected for delivery to patients that can guarantee the maintenance of the cold chain, through its delivery vehicles and in storage at depots (Ref SOP – Cold Chain Medicines and SOP – Dispatch).

- 1.15.3 For dispensed medicines that are classified as CDs, a courier company will be selected that can ensure that during transit and in storage at depots, the packages will be segregated and securely stored away from other delivery packages (SOP – Controlled Drugs and SOP – Dispatch).
- 1.15.4 Requests for “urgent” supply from prescribers can be received by email, telephone or in the future by EPS message. The normal pharmacy model of supply will be explained and the following choices offered: same day supply via a specialist courier, details of two closest pharmacies which are local to the patient where the urgent supply can be collected or delivered, explanation of the NUMAS service and two closest pharmacies who provide this service (Ref SOP- Request for Urgent Supply by Prescribers).
- 1.15.5 Prescription charges will be collected electronically via the website using an electronic merchant service either at the point of informing the pharmacy that prescriptions items are expected for dispensing or at the point of preparation for dispatch of dispensed items (SOP – Patient registration on pharmacy website).
- 1.15.6 Evidence of Prescription charge exemptions will be requested at patient registration stage where if patients are exempt from prescription charges, they can upload copies of their evidence of exemptions such as pre-payment certificates or medical exemptions. (SOP – Patient registration on pharmacy website).
- 1.16 Repeat Dispensing / electronic Repeat Dispensing (Ref SOP – Repeat / Instalment dispensing)
- 1.17 The procedures will ensure that staff will complete the CPPE repeat dispensing e-learning and e-assessment.
- 1.18 The procedures ensure that Repeat dispensing prescriptions issued by GPs are dispensed.
- 1.19 The procedures will ensure that each repeat supply is required and seek to ascertain from patients that there is no reason why the patient should be referred back to their GP. The procedures will specify that for repeat prescriptions patients will be contacted and the relevant questions asked using the following non-face to face methods of communication:
  - 1.19.1 Telephone calls with patients
  - 1.19.2 E-mail communication
  - 1.19.3 SMS communication
  - 1.19.4 Via a patient app on a smart phone

- 1.20 The National Repeat Dispensing Scheme is promoted passively on the pharmacy website where there will be a section explaining the scheme and its benefits. The scheme is also promoted at the patient registration stage and at the point of inputting “usual” prescriptions and again at the point of giving consent to nominate the pharmacy to receive electronic prescriptions (Ref SOP – Patient Registration on pharmacy website).
- 1.21 Clinical Governance procedures will ensure that the pharmacy service is accountable, responsible and that there are the right systems and processes in place to continuously monitor and improve the services.
- 1.22 Incident reporting: The procedures will ensure that there is patient safety incident log which captures the appropriate information and reported to the NRLS.
- 1.23 Information Governance: The procedures will ensure that pharmacy complies with the required levels of Data protection as set out in the information governance toolkit.
- 1.24 Practice leaflet: an appropriate practice leaflet will be produced detailing the essential and advanced services provided from the pharmacy, the opening times and procedures for raising issues and complaints. These leaflets will be sent out upon the initial registration of the patient. In addition, the information contained in the leaflets will be displayed on the pharmacy website.
- 1.25 Patient Satisfaction Survey: An annual patient satisfaction survey will be conducted and sent out to patients with a pre-paid envelope, in addition a link to an electronic patient satisfaction survey will be present on the pharmacy website.
- 1.26 Premises: The procedures will ensure that there are appropriate areas for dispensing and supply of medicines. The procedures will also ensure that the premises are cleaned at regular intervals and there is good maintenance of any equipment used (SOP – Infection Control in the Pharmacy).
- 1.27 Promotion of Healthy Lifestyles (Public Health) will be carried out in the following way (Ref SOP – Promotion of Healthy Lifestyles):
  - 1.27.1 The procedures will ensure that there are leaflets available for download on 6 public health campaigns on the pharmacy website.
  - 1.27.2 The pharmacy PMR can also be programmed to send out automatic messages on the dispensing of certain types of medication. For example on dispensing of diabetes related medication or high blood pressure medication, automatic messages promoting smoking cessation and weight management with imbedded links to approved websites and literature can be sent. In this way the pharmacy can participate in local and national health promotion campaigns.
  - 1.27.3 Each message is automatically recorded against the patient’s record for future reference.
  - 1.27.4 In addition, prior to packaging dispensed items, appropriate leaflets will be proactively placed inside the package containing medicines.

- 1.28 Disposal of Unwanted Medicines: The pharmacy website will display the policy for disposal of unwanted medicines. The Procedures will ensure that if patients want to return unwanted or expired medicines, they will contact the pharmacy. The patients will be given the choice of returning unwanted medicines to their nearest pharmacy or to prepare the unwanted medicine for collection by a specialist courier with a waste collection license. Patients will be informed which items can be collected and returned for destruction and how to prepare the medicines for collection. Once received at the pharmacy, staff will follow procedures for separation of returned medicines and for placing in containers ready for destruction. (Ref SOP – Disposal of unwanted medicines).
- 1.29 Signposting: The Pharmacy website will have the appropriate links to NHS choices where patients / representatives can access the website and search for local services (Ref SOP – Signposting). In addition:
  - 1.30 Patients will message the pharmacy with specific request for advice.
  - 1.31 Where the pharmacist feels more specialist and appropriate advice and support can be provided by other health and social care providers, then the pharmacist will message the patient with links and contact numbers for the appropriate professional.
  - 1.32 A written referral note may be provided and attached to the message.
  - 1.33 A record of the advice or referral will be made on the patient's pharmacy record, when the pharmacist deems it to be of clinical significance.
  - 1.34 The CCG will provide pharmacies in the area with details of health and social care providers to whom patients can be referred
  - 1.35 The method of communication will be the following:
    - 1.35.1 Telephone calls with patients
    - 1.35.2 E-mail communication
    - 1.35.3 SMS communication
    - 1.35.4 Via a patient app on a smart phone
- 1.36 Self-care: The Website will have the appropriate links to NHS websites for self-care where patients / representatives can access the website and search for self-care advice (Ref SOP – Self-care). In addition
  - 1.36.1 Patients will message the pharmacy with specific request for advice.
  - 1.36.2 The pharmacist will message the patient and provide self-care advice which may include a recommendation for an OTC medicine to treat a minor ailment.
  - 1.36.3 A written referral note may be provided and attached to the message.
  - 1.36.4 A record of the advice will be made on the patient's pharmacy record, when the pharmacist deems it to be of clinical significance.

- 1.37 [The Applicant provided a set of Standard Operating Procedures dated March 2018, which the Committee had regard to at Appendix A.]

## 2 The Decision

NHS England considered and decided to refuse the application. The decision letter dated 28 September 2018 states:

- 2.1 NHS England has considered the above application and is writing to confirm that it has been refused. Please find enclosed a report detailing the refusal of the application.

Extract from decision report

### 2.2 **REGULATION 31 – same or adjacent premises**

- 2.3 There are no pharmacies at the proposed premises therefore NHS England was not required to refuse the application by virtue of Regulation 31.

### 2.4 **REPRESENTATIONS RECEIVED**

- 2.5 Responses were received from Boots and Lloyds.

- 2.6 Boots response was a standard letter requesting that NHS England ensure that it considers the application appropriately, including consideration of the applicant's previous application at the site which was refused earlier this year (24 January 2018).

- 2.7 Lloyd's letter stated that in the application as initially provided that the applicant "*has failed to properly explain how appliances will be provided on a national basis*" and "*has failed to explain how the applicant will identify various patient groups who may have a requirement for specific advice due to disease states or lifestyle issues*".

- 2.8 NHS England noted that Lloyds' letter was dated 23 November 2017 and gave a reference number correlating to a previous application by this applicant for a DSP at this site, however it had been confirmed that that letter had been sent to PCSE by Lloyds on 24 July 2018 in an email with the reference number for this application in the subject line.

- 2.9 The Applicant had responded to representations received, and in doing so noted the '*exhaustive*' SOPs supplied alongside his application.

- 2.10 The Applicant has stated his revised application addresses all comments of NHS England arising from the previous application, taking into account all representations made by interested parties.

### 2.11 **REGULATION 25(2) – requirements for distance selling pharmacies**

- 2.12 An application for distance selling premises is, by virtue of regulation 25(1), not subject to the market entry test. The requirements of regulation 25(2) were noted.

- 2.13 Reg 25(2)(a) – same site as a provider of primary medical services

- 2.14 There is no provider of primary medical services at the proposed address, so the application did not have to be refused by virtue of Regulation 25(2)(a).
- 2.15 Reg 25(2)(b) – the pharmacy procedures
- 2.16 Information about how the applicant would operate the proposed pharmacy was contained in:
  - 2.16.1 the ‘further information’ within the application, and
  - 2.16.2 the following SOPs supplied by the applicant in response to the representations,
    - 2.16.2.1 Patient Registration on Pharmacy website
    - 2.16.2.2 Receive Paper Prescriptions by Post
    - 2.16.2.3 Scan paper repeat slips
    - 2.16.2.4 Receive EPS prescriptions
    - 2.16.2.5 Appliance, Incontinence Appliance and Stoma Appliance
    - 2.16.2.6 Data Entry of Prescriptions
    - 2.16.2.7 Pharmaceutical Assessment & Clinical Check
    - 2.16.2.8 Batch dispense
    - 2.16.2.9 Collect Stock
    - 2.16.2.10 Scan and Label
    - 2.16.2.11 Check and Package
    - 2.16.2.12 Put on Shelf
    - 2.16.2.13 Prepare to dispatch
    - 2.16.2.14 Dispatch
    - 2.16.2.15 Marking off Packages as delivered
    - 2.16.2.16 Scan Prescriptions for Endorsing
    - 2.16.2.17 Ordering of stock items
    - 2.16.2.18 Repeat / Instalment Prescriptions
    - 2.16.2.19 Owings
    - 2.16.2.20 Emergency Supply
    - 2.16.2.21 Request for Urgent Supply by prescriber
    - 2.16.2.22 Promotion of Healthy Lifestyles

- 2.16.2.23 Sign Posting
  - 2.16.2.24 Self-Care
  - 2.16.2.25 Dealing with Complaints – NHS complaints procedure
  - 2.16.2.26 Accessible Information Standard (AIS)
  - 2.16.2.27 Support for People with Disabilities
  - 2.16.2.28 Supplying medicines in a compliance aid
  - 2.16.2.29 Cold Chain Medicines
  - 2.16.2.30 Controlled Drugs
  - 2.16.2.31 Legalities of Controlled Drug Prescribing
  - 2.16.2.32 Data entry, Clinical Check, Picking and Labelling of Controlled Drugs
  - 2.16.2.33 Stock Control and Record Keeping
  - 2.16.2.34 Disposal of Unwanted Controlled Drugs
  - 2.16.2.35 Recording Concerns on the Management of CDs
  - 2.16.2.36 Dealing with Near Misses and Errors
  - 2.16.2.37 Patient Safety and Drug-Device Alerts
  - 2.16.2.38 SCR Governance Person- Reconciliation of Summary Care Record alerts
  - 2.16.2.39 Information Governance and IT Security
  - 2.16.2.40 Summary Care Record
  - 2.16.2.41 Disposal of Unwanted medicines
  - 2.16.2.42 End of Month Prescription Submission
  - 2.16.2.43 Staff registration on Invalife, roles and responsibilities
  - 2.16.2.44 Designating a Responsible Pharmacist
  - 2.16.2.45 Designating a locum as the Responsible Pharmacist
  - 2.16.2.46 Absence of the Responsible Pharmacist from the pharmacy
  - 2.16.2.47 Stock Handling
  - 2.16.2.48 Date Checking for Dispensary Stock
- and

- 2.16.3 the applicant's response to the representations received.
- 2.17 NB: page numbers were added to the SOPs by NHS England to aid referencing.
- 2.18 *Services available without interruption*
- 2.19 The applicant had proposed total opening hours of 9am to 5pm, Monday to Friday (40 hours).
- 2.20 However in the SOP "Absence of the Responsible Pharmacist from the pharmacy", page 90, it states:
- 2.21 *"The Responsible Pharmacist can be absent from the pharmacy premises for maximum of 2 hrs during the operational working time of the pharmacy"*.
- 2.22 This is correct in terms of Responsible Pharmacist Regulations, but is not permitted under the NHS Terms of Service – if the Responsible Pharmacist is absent then NHS pharmaceutical services cannot be provided and the pharmacy is deemed to be closed. In such cases there would be an interruption.
- 2.23 On the basis of this, NHS England could not be satisfied that services would be provided without interruption.
- 2.24 *The essential services are provided without face-to-face contact*
- 2.25 Various methods of non-face-to-face communication were mentioned. Prescriptions will be received by post or electronically, and medicines will be supplied to patients via the Royal Mail or a courier.
- 2.26 NHS England noted that throughout the application that numerous references were made regarding 'technological innovations' that will support the provision of essential services without face to face contact (although some of these may still be under development), and in response to representations it was stated that the pharmacy has a software company which developed the various "patient apps" and systems.
- 2.27 Accordingly, NHS England was satisfied that services would be provided without face-to-face contact with patients.
- 2.28 *Services available to persons anywhere in England*
- 2.29 The application explicitly states that "The Pharmacy will create a website through which persons anywhere in England can access services offered by the pharmacy".
- 2.30 NHS England noted that both the application and SOPs routinely reference use of the website and the other proposed 'technological innovations'. It was noticeable that the SOP "Process of patient registration and set up on Website" did not seem to provide for patients to register for the pharmacy's service other than through the website. NHS England concluded that this may have the effect of denying the pharmacy's services to patients who do not use the internet.

- 2.31 Also noted within the SOPs were a number of suggestions that the pharmacy will encourage patients not to use the pharmacy for some pharmaceutical services, namely:
- 2.31.1 Regarding urgent prescriptions (see page 5 of the SOPs):
- 2.31.2 *10 ... The pharmacy website then gives a due date for the receipt of the supply. At this stage a message is displayed that if the prescription is required urgently on the same day, an alternative pharmacy should be sourced to supply the prescription.*
- 2.31.3 Regarding urgent supply without a prescription (see page 29 of the SOPs):
- 2.31.4 *“Explain the normal model of supply by internet pharmacies and give the prescriber the following choices:*
- 2.31.4.1 *The names and details of two pharmacies who would be close to the patient for delivery / collection of their required medicines.*
- 2.31.4.2 *To arrange for a same day delivery courier to deliver the medicines to the patient’s address*
- 2.31.4.3 *To Ring NHS111 and ask for the NHS urgent medicine supply advanced service.”*
- 2.31.5 Regarding unwanted medicines (see page 79 of the SOPs):
- 2.31.6 *“The patient will be given the choice of returning medicines to the nearest pharmacy or to having the medicines picked up by a specialist courier”.*
- 2.32 Additionally, NHS England noted that the SOP regarding appliances implies that appliances requiring measuring or fitting will only be available to patients close enough to the pharmacy for the pharmacist to visit them at home (see page 9 of the SOPs, emphasis added):
- 2.33 *“If the pharmacist is either not competent or **it is not practicable** to visit the patient to perform the measuring and subsequent fitting service, then two pharmacies near to the patient’s address will be identified...”*
- 2.34 On the basis of this, NHS England could not be satisfied that services would be available to persons anywhere in England.
- 2.35 *Safe and effective provision of services*
- 2.36 The information provided was checked against the particular issues checked by the Primary Care Appeals Unit in such cases.
- 2.37 NHS England was satisfied that the following issues were covered satisfactorily (paragraph numbers are the relevant paragraphs in the terms of service):

- 2.37.1 Para 5(2)-(3) (how prescriptions will be received): – SOP ‘Process of patient registration and set up on website’ on page 4 at para 5 includes that the patient / representative is required to indicate if their prescriptions are issued via EPS or as paper prescriptions by the GP surgery, and if paper then a free post address is provided. SOPs “Receive Paper Prescriptions by Post” and “Received EPS Prescriptions” otherwise covered the receipt of prescriptions by the pharmacy.
- 2.37.2 Para 7(3) (evidence of exemption from NHS prescription charge): the SOP “Patient Registration on Pharmacy Website” on page 5, para 7 states that evidence of exemption from the NHS prescription charge would be supplied by the patient during the registration process. A warning sign will be displayed advising that NHS checks are routinely undertaken to verify exemption entitlement.
- 2.37.3 Para 7(5) (how prescription charges will be paid): the SOP “Patient registration on pharmacy Website” on page 5, para 8 states that patient charges would be collected from debit/credit cards via an online payments system set up during the patient registration process.
- 2.37.4 Para 8 (delivery of cold chain medication):
- 2.37.4.1 appropriate means of despatch: SOP “Cold Chain Medicines” page 48, para 4d states that a specialist cold chain courier, Iglootherm, will be used (also mentioned in SOP “Dispatch”).
  - 2.37.4.2 how appropriate temperatures will be maintained during transit:
  - 2.37.4.3 SOP “Check & Package” on page 18, introductory paragraph mentions using a cold gel pack (in bubble wrap) to keep fridge items cool, and states that the PMR will flag if there are fridge items.
  - 2.37.4.4 SOP “Cold Chain Medicines” on page 48, paras 4b and 4d, again refers to the cold gel packs, and also to refrigeration equipment in vans.
  - 2.37.4.5 temperatures during transit being monitored
  - 2.37.4.6 SOP “Cold Chain Medicines” page 48, para 4d refers to temperature mapping of vehicles on a regular basis, and monitoring equipment to provide temperature readings throughout the day.
  - 2.37.4.7 procedures in event of non-delivery, including appropriate storage until redelivery:
  - 2.37.4.8 SOP “Cold Chain Medicines” on page 48, para 4d.v refers.
- 2.37.5 Para 10(1) (advice about the benefits of repeat dispensing):
- 2.37.5.1 SOP “Patient Registration on Pharmacy website” page 5 at para 9 states “*Patient / representative inputs the details of their*

*usual prescriptions. The national repeat dispensing scheme is promoted at this stage”*

2.37.5.2SOP “Repeat/Instalment Prescriptions” page 26 at the top states *“Please note that the pharmacy website will promote the use of the National Repeat prescription Service on its website and at the time of ordering”,* and also *“Patients who have regular supplies of medicines prescribed on prescriptions will be informed of the National Repeat Dispensing Scheme and encouraged to speak to their surgery regarding participating in this scheme”.*

2.37.6 Para 17 (assessing whether patients require advice because they have diabetes, CHD, etc): SOP “Promotion of healthy lifestyles” page 31 says that the PMR can be programmed to send out automatic messages upon the dispensing of specific items: *“For example on dispensing of diabetes related medication, automatic messages promoting smoking cessation and weight management with imbedded links to approved websites and literature can be sent”.* The SOP continues *“In addition, prior to packaging dispensed items, appropriate leaflets will be proactively placed inside the package containing medicines”.*

2.37.7 Para 18 (public health campaigns): SOP “Promotion of healthy lifestyles”, page 31, states that the PMR will be programmed to send out automatic Healthy Messages. In the application it is stated that leaflets will be available for download on the website relevant to each of the campaigns selected by NHS England.

2.37.8 Paras 20 and 22 (assessing whether patients require signposting or self-care advice to minimise inappropriate use of health or social care services):

2.37.8.1SOP “Signposting”, page 33, para 2 states referrals may be made to other providers where appropriate.

2.37.8.2SOP “Self-care”, page 34, includes the pharmacist messaging a patient who has requested advice with that advice, including recommendations for non-prescription medicines (if appropriate).

2.38 However, NHS England were not satisfied that the following issues were covered satisfactorily (as before paragraph numbers are the relevant paragraphs in the terms of service):

2.38.1 Para 6 (urgent supply without a prescription): the relevant SOP states (page 29);

*3. Explain the normal model of supply by internet pharmacies and give the prescriber the following choices:*

*a. The names and details of two pharmacies who would be close to the patient for delivery / collection of their required medicines.*

*b. To arrange for a same day delivery courier to deliver the medicines to the patient's address*

*c. To Ring NHS 111 and ask for the NHS urgent medicine supply advanced service.*

2.38.2 NHS England considered that whilst option b does seem to allow that the pharmacy may make an urgent supply, the other options indicated that the pharmacy would prefer to avoid providing this service if possible.

2.38.3 Para 8 (delivery of controlled drugs): No mention of checking the identity of or obtaining a signature from, the person receiving the package is identifiable from either the application or SOPs.

2.38.4 NHS England considered that while SOP "Data entry, Clinical Check, Picking and Labelling of Controlled Drugs" on page 57, para 9a states that if a patient is unable to receive packages containing CDs the specialist courier will "take the packages back to their depot where the packages will be stored safely away from other packages", that no other information was provided regarding the adequacy of these storage arrangements in either the application or SOPs.

2.38.5 It was noted that information is included in a number of other SOPs regarding other requirements relating to the delivery of controlled drugs, which were noted as follows:

2.38.5.1 SOP "Prepare to Dispatch" on page 21, para 4a, states that specialist couriers will be used for CDs, while SOP "Dispatch" on page 22, states that DX couriers "have a solution for CD items which ensures these packages are locked away".

2.38.5.2 SOP "Dispatch" on page 22, para 3c, records that the courier driver will be recorded on the reverse of prescription as the person collecting the CDs from the pharmacy

2.38.5.3 SOP "Data entry, Clinical Check, Picking and Labelling of Controlled Drugs" on page 57 states at para 8h that the pharmacy will telephone the patient "to ensure that they will be in to receive their packages which will contain CDs"

2.38.6 Para 8(15) (packaging): only limited information is provided regarding the packaging to be used for non-fridge/appliance items.

2.38.6.1 In the application, (section 7, under (b)1e) it states "All standard items will be packaged in to non-branded and discrete padded envelopes of appropriate size".

2.38.6.2 SOP "Check and Package" page 18 states "*Ensure that appropriate sized envelopes are used for packing*", and SOP "Prepare to dispatch" page 21 says the same at para 6.

2.38.7 NHS England considered that it would expect to see mention of:

2.38.7.1 specific padding such as bubble wrap or polystyrene for fragile items

2.38.7.2 tamper proof packaging.

2.38.8 Para 8(4) (how appliances will be measured and fitted if required): section 4 of the application states the intent to provide appliances, however within section 7 of the application, under b(1)c, it is stated (emphasis added):

*I. The pharmacist is to decide if he/she is competent to perform the measuring and fitting service for the appliance and **if it is practicable to visit the patient** in their own home to perform the measuring and fitting service.*

*II. If the pharmacist is either not competent or **it is not practicable** to visit the patient to perform the measuring and subsequent fitting service, then two pharmacies near to the patient's address will be identified and telephoned to see if they are willing to provide the appliance and the service.*

*III. Patients will then be contacted for consent to refer the prescription to one of the service providers. If a paper prescription is provided, then the prescription will be posted to the chosen alternative pharmacy. If the prescription is via the EPS service, this EPS prescription will be returned to the spine making it available for download by the chosen alternative pharmacy.*

*IV. If the patient does not consent to the prescription being referred to another provider, then the pharmacist is to provide the patient with the contact details of two providers of appliances for the patient to make direct contact. If a paper prescription is provided, then the prescription will be posted to the patient. If the prescription is via the EPS service, this EPS prescription will be returned to the spine making it available for download by another provider.*

2.38.9 NHS England noted that similar wording was contained in the SOP "Appliance, Incontinence Appliance and Stoma Appliance" (page 9, para 3c).

2.38.10 It was also noted by NHS England that this issue was raised by Lloyds in their representations and in response to these representations the above process was simply repeated.

2.38.11 NHS England considered that the above wording indicated that the pharmacy may decide that it is not practicable for the pharmacist to visit the patient, in which case the pharmacy would not provide the appliance, and instead direct the patient to alternative pharmacies.

2.38.12 As the terms of service require the pharmacy to make "all necessary arrangements" for a pharmacist to carry out the measuring and fitting, NHS England considered that the requirements of the Terms of Service would not be met.

2.38.13 Para 9(4) (checking it is appropriate to dispense against a repeatable prescription): SOP 'Repeat/Instalment Prescriptions' page 26, para 6, states that the pharmacist (at the point of the 'clinical check') will;

*“seek to ascertain from the patient that there is no reason why the patient should be referred back to their GP”.*

2.38.14 NHS England noted that no detail was provided as to the specific points which should be checked as listed in para 9(4) of the Terms of Service.

2.38.15 Slightly more detail in relation to appliance is given in the SOP “Appliance, Incontinence Appliance and Stoma Appliance” page 9 para 3b, but for the purposes of the terms of service NHS England considered that the requirements would not be met.

2.38.16 Para 14 (how unwanted drugs will be accepted for disposal):

2.38.16.1 The application, in section 7 at b5, states *“The pharmacy website will display the policy for disposal of unwanted medicines. The procedures will ensure that if patients want to return unwanted or expired medicines, they will contact the pharmacy. The patients will be given the choice of returning unwanted medicines to their nearest pharmacy or to prepare the unwanted medicine for collection by a specialist courier with a waste collection license.”*

2.38.16.2 SOP “Disposal of Unwanted medicines” includes similar wording.

2.38.17 NHS England considered that the wording again suggested that, whilst the pharmacy will accept unwanted medicines if it has to, its preference is to encourage patients to use other pharmacies – thereby avoiding providing this essential service.

2.38.18 NHS England also considered that the SOP included little detail on what information patients would be given about preparing their drugs for return to the pharmacy. Although it was noted that the application does state that *“advice will be given”* other SOP’s namely, “Disposal of Unwanted medicines” and SOP “Disposal of unwanted controlled drugs” page 62, contain adequate detail regarding the process for disposal.

2.39 Given the above, NHS England could not be satisfied that that there would be the safe and effective provision of essential services.

2.40 Therefore NHS England concluded that the requirements of Regulation 25(2)(b)(ii) had not been met.

## **CONCLUSION**

2.41 **NHS England accordingly refused the application because it could not be satisfied that:**

2.41.1 **services would be available during the opening hours of the premises without interruption**

2.41.2 **services would be available to all patients in England who might request them**

2.41.3 **there would be the safe and effective provision of the essential services.**

### 3 **The Appeal**

In a letter dated 17 October 2018 the Applicant appealed against NHS England's decision. The grounds of appeal are:

- 3.1 The Applicant had originally made an application for inclusion in the Pharmaceutical list on 17 October 2017 at the same location. The application was considered on 24 January 2018 and refused, citing lack of detail as the reason for refusal.
- 3.2 This second application, submitted on 3 May 2018, sought to address any and all the issues identified as the reasons for the refusal for the first application. This application set out a comprehensive overview of how the pharmacy is to operate. A detailed set of SOPs were provided in support, whilst making clear in the letter of 10 August 2018 that *"the SOPs provided with this application are in draft form and whilst they provide a good basis upon which the services can commence, there are likely to be ongoing refinements and improvements where necessary to enhance patient experience and services"*
- 3.3 The intention in providing an exhaustive set of SOPs, especially at this early stage where the pharmacy does not exist, was so that the NHS England would feel confident that it had given sufficient thought to all areas of practice that relate to "uninterrupted provision of services" and that these are "safe and effective".
- 3.4 Whilst NHS England has acknowledged that this application has in the majority of cases met the necessary requirements, they have misinterpreted many of the SOPs and consequently drawn incorrect conclusions to justify their refusal of this application.
- 3.5 The Applicant is enclosing its response to the issues NHS England has raised in their decision letter and trust that the Appeal Committee will carefully consider the facts of this application. It hopes the Appeal Committee will determine to overturn the decision by NHS England and grant of this application for inclusion in the Pharmaceutical List, on the basis that this application has demonstrated it has met the required test under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 for a Distant Selling Pharmacy.

Response to NHS England's Decision Letter

#### 3.6 **Services available without Interruption (12-15)**

- 3.7 NHS England has concluded that the presence of **SOP Absence of the Responsible Pharmacist from the pharmacy** could result in the pharmacy operating below the contracted hours. This conclusion is incorrect.
- 3.8 This SOP forms part of the pharmacy's legal and professional obligation that sets out the protocol which would be followed if in the event the RP has cause to leave the premises. The pharmacy fully intends to operate sufficiently in excess of the contractual minimum such that if there are any planned or unplanned absences by the pharmacist, this will not result in either service interruption or contravening its NHS Terms of Service. It is factually incorrect to conclude that any pharmacy simply by having this SOP in its possession, will, or is likely to, breach its Terms of Service.
- 3.9 **Services available to persons anywhere in England (19-23)**
- 3.10 NHS England has suggested that the application's extensive mentions of "websites" and "technological innovations" that the service would be restrictive to people who are unable to use the internet or such technologies. This suggestion is incorrect, and it wishes to confirm that the pharmacy will provide services and support to all patients via their chosen method of communication and this is covered in the **SOP Accessible Information Standard**.
- 3.11 NHS England has chosen to use SOPs relating to Urgent Prescriptions (Page 5), Emergency Supply (Page 29), Unwanted Medicines (Page 79) and Measured and Fitting (Page 9) to suggest that "*the pharmacy will encourage patients not to use the pharmacy for these services*" and therefore conclude "*services would not be available to persons anywhere in England*".
- 3.12 This conclusion by NHS England misrepresents the intentions behind these SOPs. The pharmacy fully intends to make the service available to all patients and will encourage them to do so. However, as is the case for all pharmacies, it is the Applicant's legal and professional responsibility to ensure patients and prescribers are given choice at all times. To be clear, it has set out accountable procedures that ensure patient's best interest and simply providing choice and options is not the same as actively refusing or 'encouraging' the patient to go elsewhere.
- 3.13 There is no evidence in the SOPs to suggest or indicate that the pharmacy will 'encourage' patients not to use the pharmacy for these services.
- 3.14 **Safe and effective provision of services (26)**
- 3.15 NHS England has concluded the pharmacy will not be able to provide Safe and Effective Services and based their conclusion on inferences they have made from a selection of SOPs. The points raised are dealt with as follows;
- 3.15.1 ***Urgent Supply without a prescription (26 i)***
- 3.15.2 A pharmacy operating under the NHS Terms of Service is under no obligation to provide prescription medicines without an NHS prescription, unless providing the advanced NuMAS service. The Terms of Service set out specific conditions where an "*P may provide a drug or appliance request before receiving a prescription*" and those will be adhered within the scope of this SOP.

### 3.15.3 ***Delivery of Controlled Drugs (26 ii)***

3.15.4 NHS England suggests that this SOP fails to mention how the pharmacy proposes to obtain a signature from the person receiving the package. However, **SOP Marking off packages as Delivered** already deals with obtaining signatures upon delivery.

3.15.5 NHS England suggests that this SOP fails to mention how the pharmacy deals with storage arrangements in the event of a non-delivery of a CD. However, **SOP Dispatch** states clearly that “*DX couriers have a solution for CD items which ensures these packages are locked away separate to other packages*”. In selecting DX Couriers, it is satisfied that they are compliant with Home Office Guidance for CDs in transit, and therefore have appropriate storage protocols in place for both outgoing items and those returned where delivery has not been possible. It is therefore not necessary to state this in the SOP.

### 3.15.6 ***Packaging (26 iii)***

3.15.7 NHS England suggests that this SOP fails to mention how the pharmacy proposes to package certain items and in particular the use of “bubble wrap/ polystyrene for fragile items” and “tamper proof packaging”. It is the Applicant’s view that it has given sufficient consideration to packaging and the clear reference to “padded envelopes of appropriate size” is sufficient to ensure safe and appropriate supply of medicines. The padded envelopes to be used at the pharmacy incorporate a ‘tamper-proof’ element as standard and therefore it is not necessary to state this description in the SOP.

### 3.15.8 ***Measured and Fitted (26 iv)***

3.15.9 NHS England has concluded that the proposed method for dealing with Measured and Fitted items is inadequate based on the use of the words “practicable” within the SOP. However, the use of this terminology does not imply that “all necessary arrangements” will not be made. For example, a patient may have a medical condition, such as Alzheimer’s, which means that a visit from a pharmacist could cause them undue stress. In such cases, it may ‘not be practicable’ to visit but the pharmacist would have made ‘all necessary arrangements’ by offering other options and therefore met their obligations under the Terms of Service.

### 3.15.10 ***Checking appropriateness of Repeatable Prescriptions (26 v)***

3.15.11 NHS England noted the lack of detail on the specific points of checking Repeat Prescriptions. However, NHS England has failed to acknowledge the extensive checks for all prescriptions which are covered in **SOP Pharmaceutical Assessments and Clinical Check**. Furthermore, it is clearly stated in **SOP Repeat/ Instalment Prescriptions**, that the pharmacist must have completed the necessary CPPE training and assessment. The combination of these factors will ensure that the pharmacy meets the necessary requirements under the Terms of Service.

### 3.15.12 *Unwanted Drugs (26 v)*

3.15.13 NHS England has once again inferred that by somehow providing choice to patients regarding their options, this suggests the pharmacy is seeking to avoid delivering on its obligations. There is no statement anywhere in the SOPs which suggests that the pharmacy's *preference* shall be to 'encourage' patients to use other pharmacies. This matter has also been dealt with in the previous section above "Services available to persons anywhere in England".

3.15.14 NHS England has noted lack of detail in the SOP on what information would be given to patients. However, such information is a matter for the website and not an SOP which governs the operating procedures within the pharmacy. It has stated in the application that the website, when built, will have the necessary patient facing information.

3.16 For the reasons stated above, the Applicant refutes NHS England's claims that any of these SOPs are evidence that the pharmacy will, or is likely to, fall short of its Essential Services under NHS Contract for safe and effective provision of services.

## 4 **Summary of Representations**

This is a summary of representations received on the appeal.

### 4.1 **BOOTS UK LTD**

4.1.1 Boots 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.

4.1.2 In accordance with regulation 25(2)(a) it trusts 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.

4.1.3 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)).

4.1.4 It would appear that the Applicant has gone some way to respond positively to the points made in the letter of refusal by NHSE

### 4.2 **LLOYDS PHARMACY LTD**

4.2.1 NHS England has documented a number of reasons why they considered the application did not meet the relevant requirements of the Regulations under Regulation 25 and the conditions set out in Regulation 64. These include:

4.2.2 **22. Additionally, the committee noted that the SOP regarding appliances implies that appliances requiring measuring or fitting will only be available to patients close enough to the pharmacy for the pharmacist to visit them at home (see page 9 of the SOPs, emphasis added):**

4.2.2.1 ***“If the pharmacist is either not competent or it is not practicable to visit the patient to perform the measuring and subsequent fitting service, then two pharmacies near to the patient’s address will be identified...”***

4.2.3 **23. On the basis of this, the Committee could not be satisfied that services would be available to persons anywhere in England.**

4.2.4 also

4.2.5 **26. However, the Committee were not satisfied that the following issues were covered satisfactorily (as before paragraph numbers are the relevant paragraphs in the terms of service):**

4.2.6 **i. Para 6 (urgent supply without a prescription): the relevant SOP states (page 29);**

***3. Explain the normal model of supply by internet pharmacies and give the prescriber the following choices:***

***a. The names and details of two pharmacies who would be close to the patient for delivery / collection of their required medicines.***

***b. To arrange for a same day delivery courier to deliver the medicines to the patient’s address***

***c. To Ring NHS111 and ask for the NHS urgent medicine supply advanced service.***

4.2.7 **The committee considered that whilst option b does seem to allow that the pharmacy may make an urgent supply, the other options indicated that the pharmacy would prefer to avoid providing this service if possible.**

4.2.8 **The appeal documentation does not provide any additional information to that provided in the original application therefore Lloyds would ask Primary Care Appeals to uphold the decision of NHS England.**

## **5 Summary of Observations**

This is summary of observations received.

### **5.1 THE APPLICANT**

#### **Boots letter 19 November 2018**

5.1.1 **It is pleased and encouraged that Boots have acknowledged in their letter that the *"appellant has gone some way to respond positively to***

*the points made in the letter of refusal by NHSE". It is grateful for Boots' recognition of the work that has gone into demonstrating that its application meets the necessary criteria for operating a Distant Selling Pharmacy.*

### **Lloyds Pharmacy letter 05 November 2018**

- 5.1.2 The representation by Lloyds Pharmacy appears to repeat the text of the original refusal letter relating to para 22, 23, 26(i) and goes on to state that the *"appeal documentation does not provide any additional information to that provided in the original application"*.
- 5.1.3 Its appeal letter of 17 October 2018 sets out a clear rebuttal to each of these points originally raised by NHS England and provided clarification on the interpretation of the SOPs where necessary. Lloyds Pharmacy have not contested its response and / or provided any explanation as to why they think the response is insufficient. The Lloyds Pharmacy letter, in the Applicant's view, therefore offers little substance.
- 5.1.4 Based on the two representations received, neither party has raised any viable objections to the appeal. It therefore kindly requests the Appeal Committee to overturn the decision by NHS England and grant this application.

## **6 Consideration**

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

### **Regulation 31**

- 6.5 The Committee first considered Regulation 31 of the regulations which states:
  - (1) A routine or excepted application 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).*

- 6.6 The Committee noted in its decision letter, NHS England states that “there are no pharmacies at the proposed premises therefore NHS England was not required to refuse the application by virtue of Regulation 31.” The Committee noted that this had not been disputed by any party therefore it was not required to refuse the application under the provisions of Regulation 31.

**Regulation 25**

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

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

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

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

*in respect of pharmacy premises that are distance selling premises.*

*(2) 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."*

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

***Additional information to be included with excepted applications***

8. *If the applicant (A) is making an excepted application, A must include in that application details that explain—*
- (a) *A's belief that the application satisfies the criteria included in one of the regulations in Part 4 which need to be satisfied if section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) are not to apply in relation to that application; and*
  - (b) *if the regulation includes reasons for which the application must be refused, why the application should not be refused for those reasons.*

***Nature of details to be supplied***

10. *Where, pursuant to this Part, a person is required to provide details, that obligation is only discharged if the information or documentation provided is sufficient to satisfy 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.*

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

6.9.1 confirm NHS England's decision;

6.9.2 quash NHS England's decision and redetermine the application;

6.9.3 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)**

6.10 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)**

6.11 As far as Regulation 25(2)(a) is concerned, the Committee noted in its decision letter, NHS England stated that "there is no provider of primary medical services at the proposed address, so the application did not have to be refused by virtue of Regulation 25(2)(a)." The Committee noted that this had not been disputed and that it had not been provided with any information to persuade it otherwise. The Committee was therefore satisfied that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

**Regulation 25(2)(b)**

- 6.12 As far as Regulation 25(2)(b) is concerned, the Committee considered the information which had been provided by the Applicant in relation to its procedures for the provision of essential services, including its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.
- 6.13 The Regulations require the Committee to be satisfied as to a number of matters, including that essential services will be provided on an uninterrupted basis, in a safe and effective way, across England, and without face to face contact.
- 6.14 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicates that the obligation is only discharged if the information or documentation provided is sufficient to satisfy 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.
- 6.15 The Committee has asked itself whether it has sufficient information and documentation which would address the criteria in Regulation 25(2)(b). If the Committee is to be satisfied of the matters in that paragraph, the Committee must be provided with evidence to demonstrate these matters. In this case, that evidence put forward has taken the form of the original application and the Standard Operating Procedures (SOPs) which the applicant has prepared or commissioned.
- 6.16 It is not for the Committee to 'approve' or 'disapprove' of these SOPs (as they may contain matters not relevant to the Committee's consideration, and there are many ways an applicant can choose to organise itself in order to comply with the various requirements of the Regulations) and the Committee has not sought to do so. The Committee has sought evidence within the SOPs and application in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.
- 6.17 The Committee noted in the information provided, the Applicant refers to contacting patients via several methods, including telephone, email, SMS, via a patient app and through written communication inserted into the dispensing medicine packaging. The Applicant also states that "at no time will prescriptions be received directly from patients or their representative walking into the premises". The Committee was therefore satisfied that the provision of essential services would be without face to face contact.
- 6.18 The Committee was aware that when the pharmacy opens, it will be the responsibility of NHS England, in keeping with Regulation 64, to ensure that services are provided other than with face to face contact.
- 6.19 The Committee noted the Applicant intends to create a website through which persons anywhere in England can access services offered by the pharmacy. The Applicant also refers to using the Royal Mail and couriers to provide medicines to patients. The Committee noted NHS England's concern that the pharmacy did not seem to provide for patients to register for the pharmacy's service other than through the website thereby denying the pharmacy's services to patients who do not use the internet. However the Committee noted in its appeal letter, the Applicant states that the pharmacy will provide

services and support to all patients via their chosen method of communication.

- 6.20 NHS England also highlighted several references throughout the SOPs provided which it contends suggests that the Applicant would encourage patients not to use the pharmacy for certain services, and therefore services would not be available to persons anywhere in England. However the Committee noted in its appeal letter, the Applicant states that “This conclusion by NHS England misrepresents the intentions behind these SOPs. The pharmacy fully intends to make the service available to all patients and will encourage them to do so. However, as is the case for all pharmacies, it is the Applicant’s legal and professional responsibility to ensure patients and prescribers are given choice at all times. To be clear, it has set out accountable procedures that ensure patient’s best interest and simply providing choice and options is not the same as actively refusing or ‘*encouraging*’ the patient to go elsewhere. There is no evidence in the SOPs to suggest or indicate that the pharmacy will ‘encourage’ patients not to use the pharmacy for these services.”
- 6.21 The Committee was therefore satisfied that the provision of services would be available to persons anywhere in England.
- 6.22 The Committee noted in its decision letter, NHS England concluded that it could not be satisfied that services would be provided without interruption.
- 6.23 In its application form, the Applicant states that “the pharmacy procedures specify that a Responsible Pharmacist will be present in the pharmacy to secure the safe and effective running of the pharmacy at all times that the pharmacy is open for the provision of pharmaceutical services”.
- 6.24 The Committee noted in its SOP titled ‘Absence of the Responsible Pharmacist from the pharmacy’ it states:

6.24.1 *“The Responsible Pharmacist can be absent from the pharmacy premises for a maximum of 2 hrs during the operational working time of the pharmacy (between midnight and midnight) ...*

*The Responsible Pharmacist should only be absent from the pharmacy if he / she is confident that the pharmacy can continue to run safely and effectively and should use their professional judgement as to what times are suitable to be absent.*

*The Responsible Pharmacist should ensure that he / she remains contactable e.g. leaving his / her phone number and completing the notice for pharmacy staff (available from the Royal Pharmaceutical Society). This notice indicates clearly where the Responsible Pharmacist has gone, mode of contact and how long approximately he/she will be. ...*

*If the Responsible Pharmacist is not contactable during the absence, then he/she will arrange for another Responsible Pharmacist to be available and that persons contact details will be available to pharmacy staff.*

*When the Responsible Pharmacist leaves the pharmacy he /she will complete the RP record on PMR which indicates the time and reason for absence.*

*The Responsible Pharmacist will only be absent from the pharmacy in relation to work commitments such as:*

- a. Seeing patients in a consulting room in the non-registered area of the pharmacy*
- b. Participation in a meeting with a local GP or at the CCG*
- c. Visiting patients in a care or residential home to undertake medicines advice*
- d. To participate in CPD*

*Before the Responsible Pharmacist leaves the premises he / she will ensure that all staff are aware of:*

- a. The notice for pharmacy staff*
- b. The contact details*
- c. That only GSL medicines may be sold or advice on GSL medicines may be given to any patients or customers and by which staff*
- d. That prescriptions may be taken in ready for the return of the pharmacist*

*Before the Responsible Pharmacist leaves the premises he / she will ensure that all staff are NOT legally allowed to:*

- a. Sell any Pharmacy only medicines [P] to customers*
- b. Hand out any pre-bagged prescriptions for delivery to the delivery driver*

*If the Responsible Pharmacist is absent for more than the 2 hours and there is no second pharmacist able to undertake the RP role, then he/she should ensure that:*

- a. staff DO NOT sell GSL medicines,*
- b. prescriptions are not prepared for dispensing*
- c. the individual personalised notice should be removed by a member of staff.*

*If the Responsible Pharmacist is absent and there is a second pharmacist within the pharmacy all normal duties and tasks can be undertaken by the staff within the Pharmacy.”*

- 6.25 However the Committee was of the view that it is not clear from the information provided, how essential services would be provided, should they be required, during the absence of the Responsible Pharmacist.
- 6.26 The SOP states that *“If the Responsible Pharmacist is not contactable during the absence, then he/she will arrange for another Responsible Pharmacist to be available and that persons contact details will be available to pharmacy staff”* and further that *“If the Responsible Pharmacist is absent and there is a second pharmacist within the pharmacy all normal duties and tasks can be undertaken by the staff within the Pharmacy.”* The Committee noted that it does not state that a second pharmacist will always be present at the pharmacy, should the Responsible Pharmacist be absent, simply that it's contact details will be available to staff. Therefore the Applicant would be unable to perform all essential services without the presence of a pharmacist on site.
- 6.27 Based on the information provided, the Committee could not be satisfied that the provision of services would be without interruption.
- 6.28 The Committee went on to consider whether safe and effective provision of essential services was likely to be secured.
- 6.29 The Committee considered each essential service in paragraphs 3 to 22 of schedule 4 of the Regulations ("Terms of Service") in turn.
- 6.30 The Committee paid particular attention to the following aspects of the essential services, which it considered were more difficult to provide safely and effectively in a distance selling context:
- 6.30.1 Dispensing of drugs and appliances
  - 6.30.2 Urgent supply without a prescription
  - 6.30.3 Preliminary matters before providing ordered drugs or appliances
  - 6.30.4 Providing ordered drugs or appliances
  - 6.30.5 Refusal to provide drugs or appliances ordered
  - 6.30.6 Further activities to be carried out in connection with the provision of dispensing services
  - 6.30.7 Disposal service in respect of unwanted drugs
  - 6.30.8 Promotion of healthy lifestyles
  - 6.30.9 Prescription linked intervention
  - 6.30.10 Public health campaigns
  - 6.30.11 Signposting
  - 6.30.12 Support for self-care

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

#### **Providing ordered drugs or appliances**

- 6.32 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 requirement of the Misuse of Drugs Regulations 2001 and, in particular, Regulation 14 and 16, are met).

- 6.33 In relation to the delivery of cold chain medicines, the Committee noted the SOP titled 'Cold Chain Medicines' under the title 'Delivery of Cold Chain medicines' states:

6.33.1 *"a. Refer to SOP checking and packaging, Ready for Dispatch and Dispatch. These SOPs ensure that Medicines that contain fridge lines are separated at dispensing and the cold chain is maintained.*

*b. Dispensed cold chain medicines are packaged together with a cold gel wrapped in bubble wrap. This is an additional precaution to ensure that the cold chain is maintained.*

*c. Packages are stored in a separate Dispatch fridge ready to be collected by the specialist courier.*

*d. A specialist cold chain courier (Igloothermo <http://www.igloothermo.com/services/pharmaceutical-courier> ) is to be used for the home delivery of all cold chain packages*

*i. All of the vehicles are equipped with heat & cool refrigeration equipment.*

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

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

*iv. Igloo offers Next Day delivery services for pharmaceuticals and medicines.*

*v. If the package can not be delivered, the package is returned to the van and back to the storage facility whilst ensuring cold chain is maintained. The pharmacy is contacted who will arrange for the re-delivery with the patient.*

*vi. The package is re-delivered to the patient."*

- 6.34 However, notwithstanding that it has proposed to use a specialist cold chain courier to deliver cold chain medicines, the Committee noted that no

information had been provided by the Applicant to explain what would be done in a situation where the cold chain was compromised during transit.

- 6.35 Therefore based on the information before it, the Committee was not satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.
- 6.36 The Committee considered whether the Applicant had explained the arrangements which ensure that, for appliances which require fitting/measuring, a registered pharmacist measures/fits them.
- 6.37 NHS England, in its decision letter, states that the wording in the application form, "indicated that the pharmacy may decide that it is not practicable for the pharmacist to visit the patient, in which case the pharmacy would not provide the appliance, and instead direct the patient to alternative pharmacies. As the terms of service require the pharmacy to make "all necessary arrangements" for a pharmacist to carry out the measuring and fitting, NHS England considered that the requirements of the Terms of Service would not be met."
- 6.38 The Committee noted in its application form, the Applicant states:

6.38.1 "The pharmacist is to decide if he/she is competent to perform the measuring and fitting service for the appliance and if it is practicable to visit the patient in their own home to perform the measuring and fitting service.

If the pharmacist is either not competent or it is not practicable to visit the patient to perform the measuring and subsequent fitting service, then two pharmacies near to the patient's address will be identified and telephoned to see if they are willing to provide the appliance and the service.

Patients will then be contacted for consent to refer the prescription to one of the service providers. If a paper prescription is provided, then the prescription will be posted to the chosen alternative pharmacy. If the prescription is via the EPS service, this EPS prescription will be returned to the spine making it available for download by the chosen alternative pharmacy.

If the patient does not consent to the prescription being referred to another provider, then the pharmacist is to provide the patient with the contact details of two providers of appliances for the patient to make direct contact. If a paper prescription is provided, then the prescription will be posted to the patient. If the prescription is via the EPS service, this EPS prescription will be returned to the spine making it available for download by another provider."

- 6.39 In its appeal letter, the Applicant states that the use of the terminology 'practicable' does not imply that 'all necessary arrangements' will not be made. The Applicant states "For example, a patient may have a medical condition, such as Alzheimer's, which means that a visit from a pharmacist could cause them undue stress. In such cases, it may 'not be practicable' to visit but the pharmacist would have made 'all necessary arrangements' by offering other options and therefore met their obligations under the Terms of Service."

- 6.40 However the Committee had initial concerns over what was meant by the term 'practicable'; it was not clear whether it meant in relation to a specialist appliance in which case the Applicant was not required/competent to measure and fit such appliances, or whether this in fact meant in relation to the location of the patient. The Committee also had concerns over the Applicants later explanation in its appeal letter, as it was unsure what would qualify another pharmacist to undertake the measuring and fitting of appliances for a patient with Alzheimer's.
- 6.41 Therefore the Committee was not satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(4) of Schedule 4.

*Additional considerations*

- 6.42 The Committee noted that NHS England had raised concerns in its decision letter, in relation to the following:

**Urgent supply without a prescription**

- 6.43 The Committee noted NHS England's concern over the wording in the Applicant's SOPs which it states "indicated that the pharmacy would prefer to avoid providing this services if possible."

- 6.44 The Committee noted the wording in the SOP titled 'Emergency Supply' states:

6.44.1 *"Give patient the following choices:*

*a. To Ring NHS111 and ask for the NHS urgent medicine supply advanced service.*

*b. The names and details of two pharmacies who would be close to the patient for delivery / collection of their required medicines.*

*c. To arrange for a same day delivery courier to deliver the medicines to the patient's address".*

- 6.45 However the Committee noted in its appeal letter, the Applicant states that "The pharmacy fully intends to make the service available to all patients and will encourage them to do so. However, as is the case for all pharmacies, it is the Applicant's legal and professional responsibility to ensure patients and prescribers are given choice at all times. To be clear, it has set out accountable procedures that ensure patient's best interest and simply providing choice and options is not the same as actively refusing or 'encouraging' the patient to go elsewhere.

There is no evidence in the SOPs to suggest or indicate that the pharmacy will 'encourage' patients not to use the pharmacy for these services."

- 6.46 Therefore the Committee was satisfied that it had been provided with sufficient information in this regard.

**Providing ordered drugs or appliances**

6.47 NHS England states that there is no mention of checking the identity of or obtaining a signature from, the person receiving the package. It also had concerns over the storage arrangements for undelivered items.

6.48 However the Committee noted in its SOPs, the Applicant refers on several occasions to CD items being delivered by specialist couriers. The SOP titled 'Dispatch', states:

6.48.1 *"DX couriers have a solution for CD items which ensures these packages are locked away separate to other packages. ...*

*For CD items the EDO device will ask the courier driver to sign to say they have collected the CD packages.*

*The courier driver is effectively the patient's nominated representative authorised to collect the CD on their behalf. The information on the back of the prescription will show the package was collected by the courier driver and this information is recorded in the CD register.*

*For CD items at this stage the items are marked as ready to input in to the electronic CD register*

*Watch them scan the courier generated barcode on each packs".*

6.49 The SOP titled 'Marking off Packages as Delivered' states:

6.49.1 *"For each package collected by couriers check delivery status on the courier's website. ...*

*If the delivery has not been made according to the due time, then investigate further with the courier company. If necessary, contact the patient directly to let them know."*

6.50 The Applicant also refers to its SOP titled 'Data entry, Clinical Check, Picking and Labelling of Controlled Drugs' which states:

6.50.1 *"Phone the patient to ensure that they will be in to receive their packages which will contain CDs.*

*Follow SOPs for marking off packages delivered*

*a. If the patient or their representative are not able to receive the package containing CD items, DX courier company, will take the packages back to their depot where the packages are stored safely away from other packages.*

*b. Another delivery date is arranged with the patient and the courier company."*

6.51 In its appeal letter, the Applicant states that in selecting DX Couriers, it is satisfied that they are compliant with Home Office Guidance for CDs in transit, and therefore have appropriate storage protocols in place for both outgoing items and those returned where delivery has not been possible.

- 6.52 The Committee was satisfied that it had been provided with sufficient information in this regard.
- 6.53 NHS England states that “only limited information is provided regarding the packaging to be used for non-fridge/appliance items”. NHS England states that it would expect to see mention of specific padding such as bubble wrap or polystyrene for fragile items and tamper proof packaging.
- 6.54 However the Committee noted in its application, the Applicant states that “all standard items will be packaged into non-branded and discrete padded envelopes of appropriate size.” Further in its appeal letter, the Applicant states that “the padded envelopes to be used at the pharmacy incorporate a ‘tamper-proof’ element as standard and therefore it is not necessary to state this description in the SOP.”
- 6.55 The Committee was satisfied that the information now provided is sufficient in this regard.

#### **Refusal to provide drugs or appliances**

- 6.56 NHS England did not consider there to be sufficient detail with regard to the specific points which should be checked as listed in paragraph 9(4) of the Terms of Service.

- 6.57 However the Committee noted in its application form, the Applicant states:

6.57.1 *“To ensure patients are able to use their medicines and appliances effectively, there are procedures for a pharmaceutical assessment and a clinical check. If the pharmacist deems that the patients require support in the use of medicines and appliances, the pharmacist will communicate with patients regarding “safe use of medicines” and “side effects and interactions”.*”

- 6.58 The Committee also noted the SOP titled ‘Pharmaceutical Assessment & Clinical Check’ under the heading ‘Purpose’ states:

6.58.1 *“The clinical check process to be carried out by the pharmacist*

*To ensure that the prescription is safe to supply to the patient*

*To ensure that the prescription is clinically appropriate*

*To ensure that the prescription is legally valid*

*To ensure that all items prescribed are reimbursable*

*To ensure patient concordance and appropriate use of medicines*

*To minimise medication errors”*

- 6.59 And under the heading ‘Key Steps’ states

6.59.1 *“Each item will have a set of clinical checks for review by the pharmacist including the following:*

- a. *Interactions and warnings*
- b. *If the dosage is within prescribed range*
- c. *If there are any medical conditions to consider*
- d. *Possible side effects and risks of adverse reactions*
- e. *Over ordering of medicines”*

6.60 The SOP then goes on to explain the necessary checks for specific medicines.

6.61 The SOP further states:

6.61.1 *“Pharmacist has the ability to leave notes against the prescription for future reference*

*Pharmacist to confirm that they have clinically checked the prescription*

*Pharmacist can write an advisory message to the patient at this stage which can either get emailed or appear on their messages section on the website, or on a patient app.”*

6.62 The Committee was satisfied that it had been provided with sufficient information in this regard.

**Disposal service in respect of unwanted drugs**

6.63 In its decision letter, NHS England states that the wording in the application form suggested that, “whilst the pharmacy will accept unwanted medicines if it has to, its preference is to encourage patients to use other pharmacies – thereby avoiding providing this essential service.”

6.64 NHS England also considered that the SOP included little detail on what information patients would be given about preparing their drugs for return to the pharmacy. Although it was noted that the application does state that “*advice will be given*”.

6.65 However the Committee noted in its application form, the Applicant states that “The pharmacy website will display the policy for disposal of unwanted medicines. The Procedures will ensure that if patients want to return unwanted or expired medicines, they will contact the pharmacy. The patients will be given the choice of returning unwanted medicines to their nearest pharmacy or to prepare the unwanted medicine for collection by a specialist courier with a waste collection license. Patients will be informed which items can be collected and returned for destruction and how to prepare the medicines for collection.”

6.66 The Committee again noted the Applicant’s argument in its appeal letter that “The pharmacy fully intends to make the service available to all patients and will encourage them to do so. However, as is the case for all pharmacies, it is the Applicant’s legal and professional responsibility to ensure patients and prescribers are given choice at all times. To be clear, it has set out

accountable procedures that ensure patient's best interest and simply providing choice and options is not the same as actively refusing or '*encouraging*' the patient to go elsewhere.

There is no evidence in the SOPs to suggest or indicate that the pharmacy will 'encourage' patients not to use the pharmacy for these services."

- 6.67 The Applicant also states that "the website, when built, will have the necessary patient facing information."
- 6.68 Therefore the Committee was satisfied that it had been provided with sufficient information in this regard.
- 6.69 In relation to all other essential services, the Committee was, on balance, satisfied that procedures adopted by the pharmacy (and general adherence to the Terms of Service) would be "likely to secure" safe and effective provision.

### *Summary*

- 6.70 On the information before it, the Committee could not be satisfied that there are procedures likely to secure safe and effective provision of essential services as required by Regulation 25(2)(b).
- 6.71 Although the Committee has reached the same conclusion to that of NHS England, it has done so for different reasons. Therefore the Committee determined that the decision of NHS England must be quashed.
- 6.72 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.
- 6.73 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.
- 6.74 The Committee concluded that further notification under paragraph 19 of Schedule 2 would not be helpful in this case.

## **7 Decision**

- 7.1 The Committee concluded that it was not required to refuse the application under the provisions of Regulation 31.
- 7.2 Accordingly, the Committee:
  - 7.2.1 quashes the decision of NHS England; and
  - 7.2.2 redetermines the application as follows -

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

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

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

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

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

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

7.2.3 The application is refused.

**Case Manager  
Primary Care Appeals**

A copy of this decision is being sent to:

Mr Tariq Muhammad  
NHS England  
Boots UK Ltd  
Lloyds Pharmacy Ltd