30 November 2023

REF: SHA/26080

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APPEAL AGAINST NHS NORTH EAST LONDON ICB DECISION TO REFUSE AN APPLICATION BY MEDEXPRESS ENTERPRISES LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT UNIT 7 DATAPOINT, 6 SOUTH CRESCENT, CODY ROAD, LONDON, E16 4TL UNDER REGULATION 25

1 Outcome

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

1.2 The Committee determined that the application should be granted.

A copy of this decision is being sent to:

Temple Bright on behalf of the Applicant
PCSE on behalf of NHS North East London ICB

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1 The Application

By application dated 23 June 2022, MedExpress Enterprises Ltd ("the Applicant") applied to NHS England for inclusion in the pharmaceutical list at Unit 7 Datapoint, 6 South Crescent, Cody Road, London, E16 4TL under Regulation 25. In support of the application it was stated:

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

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

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

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

1.4 "MedExpress has a business continuity plan to ensure the safe, effective and uninterrupted provision of Essential Services to any person within England who requests these services during opening hours. This continuity plan is reviewed regularly (minimum annually) to ensure that it is fit for purpose.

1.5 All Essential Services will be delivered in accordance with Medexpress Standard Operating Procedures, the NHS Act 2006, NHS Regulations 2013 (and amendments 2020), RPSGB Professional Standards and Guidance for Internet Pharmacy Services, PSNC Guidance on Distance Selling Pharmacies and the GPhC standards.

1.6 Patients in England will be able to register to receive NHS Essential Services from MedExpress via the website or by contacting us directly via email, telephone, postal services, or social media.

1.7 At our premises, we will provide all Essential Services outlined in the NHS contractual framework, without face-to-face contact:

1.8 Our '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:

1.9 At our premises, we will provide all Essential Services outlined in the NHS contractual framework, without face-to-face contact. These are the dispensing of medication, repeat dispensing services, discharge medicines service, disposal of unwanted medicines, public health (promotion of healthy lifestyle), signposting, support for self-care, and clinical governance. Services will be delivered to patients via email (including email newsletter), telephone (including SMS where appropriate), Electronic Prescription Service (EPS), Royal Mail delivery (existing contracts in place), PHS Group Healthcare Waste Management Services (existing contracts in place) or equivalent, DHL Cold chain (or another equivalent cold chain courier service).

1.10 All NHS services will be delivered free of charge in accordance with the NHS Act 2006.

1.11 To ensure Essential Services are delivered safely without face-to-face contact, we comply with UK GDPR and the DPA 2018. We have a Data Protection Officer in place who ensures that all staff adhere to confidentiality agreements, and receive annual training in data protection and cyber security. Two step verification passwords are in place for all software containing patient data. We have an encrypted database (patient record) which is automatically backed every day which also has a rolling transaction log to restore or recover data. We also do routine restorations of our backups to ensure there are no recovery issues. All computers run the latest version of Windows 10, have antivirus installed and are kept up to date with the latest windows updates and patches. None of the live servers (holding patient data) are on site, and hence are not applicable to any internal security vulnerabilities. Each member of staff who has access to patient data has a unique 2FA login, and each request is logged. We also have a user access management system to assign and remove access roles instantly from staff. We use a password management tool for secure passwords and 2FA authentication wherever possible. All Wi-Fi access points and routers use unique administration passwords. We also have no removal/mobile devices holding any patient information.

1.12 We will demonstrate that our pharmacy meets the 10 principles of the National Data Guardian’s Data Security Standards by completing the Data Security and Protection Toolkit annually. This will show that we are meeting the leadership obligations set out by the standards, ensuring that patient data handling complies with NHS standards.

1.13 MedExpress does not advertise the pharmacy premises on the building, and as there is an intercom system, a patient will not be able to attend the premises directly. If a patient does attempt to contact the pharmacy via the intercom system to request one or more services, it will be explained that due to our Distance Selling Regulations we are unable to provide face-to-face NHS Essential Services. The patient will be signposted to other pharmacies who provide NHS services within the area.

1.14 We also intend 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. The pharmacy will also use Facebook, Twitter, Google, Email and postal service to communicate with the general public. This will include contact information, services available, public health advice, etc.

1.15 Prescriptions will be clinically and legally assessed to determine if they can be dispensed and we have the following Standard Operating Procedures in place to ensure we are able to deliver these services safely:

1.15.1 Procedures for NHS Essential Services

1.15.2 Online Order Receipt of NHS prescriptions

1.15.3 Selection, Labelling and Assembly of NHS prescriptions

1.15.4 NHS Prescription Owings

1.15.5 NHS Prescription Accuracy Check

1.15.6 Emergency Supply

1.15.7 Bagging-up NHS Prescriptions

1.15.8 NHS Order Delivery

1.15.9 Safe and Effective Storage of Medicine

1.15.10 The Safe and Effective Disposal of Medicine

1.15.11 Near Miss and Dispensing Errors

1.15.12 Customer Complaints

1.15.13 Dealing with an Incident

1.15.14 Repeat Dispensing

1.15.15 Supplying Medicines to Care Homes

1.15.16 Community Dosage Systems

1.15.17 Information Governance

1.15.18 Staff Training Policy

1.15.19 Record of Competence

1.15.20 EPS Nomination

1.15.21 EPS Dispensing Process

1.15.22 Support for Self-Care, Signposting and Health Promotion

1.15.23 Further SOPS for Controlled Drugs (Ordering, Receipt and Storage,

1.15.24 Dispensing, Delivery, Disposal of Patient Returns, Disposal of Pharmacy

1.15.25 Stock, Stock Balance Checks, Record Keeping, Requests for CDs using a requisition)

1.16 We have deliberately not provided all SOPs with this application as there are over 140 pages in the SOP folder and they also contain commercially sensitive material.

1.17 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.

1.18 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 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.

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

1.20 Healthy living 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. Signposting 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.

1.21 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. There will also be pharmacist selected web links and 'downloads' to print off.

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

1.23 Our superintendent and responsible pharmacist will be involved in all the components of clinical governance including 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. '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. 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. All staff will have an annual appraisal, receive and provide feedback. Information Governance The pharmacy will be registered and comply with Data Protection Act. It will also comply with the Access to Health Records Act. It will publish its Freedom of Information Act Publication Scheme on its website and copies will be made available on request. All patient data will be kept private and confidential in accordance with NHS and legal obligations on data security, protection and confidentiality.

1.24 To ensure safe and appropriate delivery of medicines: If the delivery to patients is local, this will be done by our own delivery driver. All other nationwide delivery will be delivered by recorded delivery and signed for by the patient, their notified carer or other patient authorised representative. 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. 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.

1.25 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.

1.26 Delivery of Controlled Drugs will be carried out by DHL. DHL has pharma grade specialist facilities to meet specific quality and validation requirements for healthcare products. This includes Home Office licensed controlled drug stores. They have the following UK Licenses and Standards: MHRA Wholesale Dealer License MHRA Manufacturer's Importers License GAMP 4 Systems Validation MHRA IMP License MHRA Manufacturer's "Specials" License ISO 9001: 2000 Certified Clinical trials audited to GMP Annexe 13 standards FDA

audited DHL meet all Home Office safe custody and record keeping requirements All Controlled Drugs will be delivered by the DHL Courier Services and tracked, with verifiable audit trails. Return and Destruction of CD 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. Returns will only be allowed via either collection by pharmacy staff from patient's homes, or via DHL (see above). 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.

1.27 Provisions such as DHL COLDCHAIN (or similar specialist cold chain courier service) will ensure the integrity of the cold chain and the maximum stability of thermo-liable drugs by packing, transporting and delivering in such a way that their integrity, quality and effectiveness is always preserved. This is a dedicated, fully monitored and temperature controlled delivery service.

1.28 We will will [sic] have accounts direct to pharmacy manufacturers and many full-line and shortline 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 .

1.29 Pharmacy staff will telephone the patient about their exemption status. If exempted, pharmacy staff will request evidence of exemption and ensure that the back of the prescription is completed and signed in black ink. If evidence of exemption is not seen, then the pharmacy staff will cross the 'evidence not seen' box. 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.

1.30 We have already obtained registration with the GPHC under registration number 9011509.

1.31 MedExpress is an online, distance-selling pharmacy registered with the General Pharmaceutical Council (GPhC registration number 9011509). The new premises are located on the first floor of a warehouse building. An intercom is located outside the building which prevents public access to the premises.

1.32 MedExpress does not advertise the pharmacy premises on the building, and as there is an intercom system, a patient will not be able to attend the premises directly. If a patient does attempt to contact the pharmacy via the intercom system to request one or more services, it will be explained that due to our Distance Selling Regulations we are unable to provide face-to-face NHS Essential Services. The patient will be signposted to other pharmacies who provide NHS services within the area.

1.33 If advanced services were to be carried out on the premises, it could only be by appointment, and no essential services could be provided at the same time as any such appointment. However, this is not applicable as we will not provide any advanced services."

2 The Decision

NHS North East London ICB considered and decided to refuse the application. The decision letter dated 14 August 2023 states:

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

Extract from report dated 2 August 2023

2.2 "The PSRC have determined that there is enough information to deal with this application without holding an oral hearing.

2.3 The comments received from parties is available to the PSRC panel to review.

2.4 Boots comments

2.5 Regulation 25(2)(b)(i) requires NHSE to be satisfied that the pharmacy procedures for the pharmacy premises are likely to secure the uninterrupted provision of services to persons anywhere in England who request those services.

2.6 Regulation 25(2)(b)(ii) requires NHSE to be satisfied that the pharmacy procedures for the pharmacy premises are likely to secure are the safe and effective provision of essential services.

2.7 We understand that an application from the same applicant for the same premises has previously been refused. We ask that NHS England are satisfied that this new application meets the requirements of Regulation 25(2). There is very little information included within the application, we refer to the limited information provided on the delivery and return of controlled drugs as an example.

2.8 We have no further comments to submit at this time but may wish to make further representations at a later stage and attend any oral hearing that may be held in relation to the application.

2.9 North East London LPC Comments

2.10 We would like to be reassured that NHSE&I will ensure that the DSP is following all the requirements and regulations that they are required to do so.

2.11 With regard to Regulation 31 …

2.12 The proposed pharmacy is not on the same site or adjacent to any other pharmacy, therefore this regulation is not engaged

2.13 [With regard to Regulation 25(2)(a)]

2.14 The premises in respect of which the application is made are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

2.15 [With regard to Regulation 25(2)(b)]

2.16 The applicant provided information via their application and during the application process. This has been reviewed.

2.17 There have been two comments as detailed above from Boots and the North East London LPC.

2.18 The applicant has provided some supplemental information and some SOPs from the application process, which has helped to answer some queries, however there is still some parts of the essential services that it is not clear how these will be provided. Whilst we appreciate that SOPs may be commercially sensitive, we do not require SOPs to be provided, just the information of how essential services will be provided. Listed below are the area where there is no information on how these will be provided.

2.19 *Paragraph 7(5)(b) of Schedule 4 – no information provided.*

2.20 *Paragraph 9(4) of Schedule 4 – no information provided.*

2.21 *Paragraph 10(1) of Schedule 4– no information provided.*

2.22 *Urgent supply without a prescription – no information provided.*

2.23 **It may be concluded that NHS North East London ICB is not satisfied that pharmacy procedures for the pharmacy are likely to secure the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.**

2.24 **It may also be concluded that the applicant is likely to not satisfy the criteria as set out in the Terms of Service of Pharmacists for the safe and effective provision of all essential services without face to face contact.**

2.25 **Therefore, the PSRC have determined that NHS North East London ICB is not satisfied that the pharmacy procedures for the pharmacy premises are likely to secure 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.**

2.26 **Decision**

2.27 Regulation 31.

2.28 There are no current pharmacies listed at the proposed premises or adjacent to the proposed premises. Therefore regulation 31 does not apply for this application.

2.29 Regulation 25(2)(1)[sic](a)

2.30 The proposed site 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. Therefore, this regulation does not apply for this application.

2.31 Regulation 25(2)(1) [sic](b)(i)

2.32 NHS North East London ICB is not satisfied that pharmacy procedures for the pharmacy are likely to secure the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.

2.33 Regulation 25(2)(1) [sic](b)(ii)

2.34 NHS North East London ICB is not satisfied that the applicant is likely to satisfy the criteria as set out in the Terms of Service of Pharmacists for the provision of all essential services without face to face contact.

2.35 NHS North East London ICB is not satisfied that the pharmacy procedures for the pharmacy premises are likely to secure 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. Therefore, the application has been refused."

3 The Appeal

In a letter dated 13 September 2023, the Applicant (through its representative, Temple Bright LLP) appealed against the ICB's decision. The grounds of appeal are:

3.1 "I act for Medexpress Enterprises Limited. On behalf of my client, I write to appeal a decision of NHS England to refuse my client's application for inclusion in the pharmaceutical list in respect of distance selling premises at Unit 7 Datapoint, 6 South Crescent, Cody Road, London, E16 4TL. The decision was notified to my client by letter dated 14th August 2023.

3.2 As NHS Resolution will be aware, this application must be determined in accordance with regulation 25 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

3.3 In support of its application, my client provided information explaining how its proposed pharmacy would have in place procedures which would be likely to secure the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services. My client explained how its pharmacy would provide safe and effective provision of essential services without face-to-face contact between any person receiving the service (whether on their own or on someone else's behalf) and the applicant or the applicant's staff.

3.4 My client's application form provided summary information, stating that detailed SOPs could be provided upon request. No request was made by NHS England for additional information in relation to the way in which my client would provide all essential services.

3.5 Representations were received on my client's application from Boots and the Local Pharmaceutical Committee. In response to the representations received, my client submitted additional information in relation to the supply of controlled drugs medication.

3.6 Notwithstanding that information, NHS England concluded that there was no information in relation to the following matters:

3.6.1 Paragraph 7(5)(b) of Schedule 4 (payment of the prescription charge)

3.6.2 Paragraph 9(4) of Schedule 4 (supplies against repeatable prescriptions)

3.6.3 Paragraph 10(1) of Schedule 4 (providing appropriate advice)

3.6.4 Paragraph 6 (Urgent supply without a prescription)

3.7 As NHS Resolution will appreciate, it is not necessary for an applicant to repeat every aspect of the terms of service within the information provided in support of application made pursuant to regulation 25. However, where compliance with a requirement of the terms of service would require specific steps to be taken in order for the service to be provided safely and effectively in the distance selling context, an applicant should explain how those steps would be achieved.

3.8 My client considered that it had provided sufficient information, in support of its application, to satisfy NHS England that the requirements of regulation 25 would be met by the proposed pharmacy.

3.9 However, my client notes the decision of NHS England and provides, with this appeal, a full copy of its current Standard Operating Procedures for the proposed pharmacy. [Copy provided to Committee at Appendix A.]

3.10 On behalf of my client, I will not repeat every element of the attached SOPs in this letter of appeal. However, as NHS Resolution will see from the attached, the SOPs:

3.10.1 Explain that there must be no face-to-face contact with patients (the premises will not be accessible to the public), and detail how the pharmacy staff will communicate with patients in the distance selling context

3.10.2 Confirm that all essential services are to be provided to patients anywhere in England who request those services

3.10.3 Provide for the uninterrupted provision of essential services throughout the pharmacy's contractual opening hours

3.10.4 Set out how patients will register to receive essential services

3.10.5 Detail how prescriptions will be received by the pharmacy, how the prescription charge will be taken and/or how exemption will be verified and recorded

3.10.6 Provide for relevant advice to be provided to patients, including in relation to:

3.10.6.1 Prescription linked interventions, including identifying patients with relevant health conditions who may benefit from further advice, and including backing up information with relevant literature

3.10.6.2 the likely delivery time of medication and any updates as necessary

3.10.6.3 advice in relation to the use and storage of medication, and the return of unused medication

3.10.6.4 the importance of only requesting medication that is needed

3.10.6.5 owings

3.10.6.6 the repeat prescription service, including identifying potentially eligible patients and advising them of the service and checking relevant matters with the patient, such as whether there have been any changes to their health since their last repeat medication supply

3.10.6.7 medication which is subject to a serious shortage protocol

3.10.6.8 The provision of pandemic services

3.10.7 Explain how emergency supplies may be made at the request of the prescriber

3.10.8 Provide for the packaging to be used for the delivery of medication, including cold chain medication

3.10.9 Explain how medication will be supplied to patients with reasonable promptness and free of charge, including the specific procedures in place for the delivery of controlled drugs and cold chain medication, how failed deliveries will be handled and the auditing of delivery services as appropriate

3.10.10 Set out how the pharmacy will dispose of unwanted drugs, including how unwanted drugs can be returned to the pharmacy for disposal and how the pharmacy will handle returned medication

3.10.11 Detail how the pharmacy will promote healthy lifestyles

3.10.12 Explain how the pharmacy will participate in health campaigns and how signposting and support for self-care services will be provided

3.10.13 Set out the provision by the pharmacy of the discharge medicines service

3.11 The information provided by my client explains how the pharmacy will have a functioning website which will have an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a range of up-to-date materials that promote healthy lifestyles by addressing a reasonable range of health issues. Nothing in the pharmacy's patient leaflet will suggest that services may be accessed by patients who are present at, or in the vicinity of, the pharmacy.

3.12 In conclusion, therefore, my client's application meets the requirements of regulation 25. NHS Resolution has sufficient information to be satisfied that the appropriate regulatory test would be met through the attached SOPs.

3.13 On behalf of my client, I therefore invite NHS Resolution to uphold this appeal and to grant the application."

4 Summary of Representations

This is a summary of representations received on the appeal.

4.1 NHS NORTH EAST LONDON ICB

4.1.1 "As detailed in the appeal it is for the applicant to provide the information in support of their application. Copies of SOPs are not required but the applicant should provide sufficient information so that the ICB can determine that all of the essential services can be made without face to face contact to anyone in England who requests services.

4.1.2 When the original application was made and there was a request for clarification, the missing information letter also contained the following statement: *"As the application is for a DSP, the applicant has to provide sufficient information to satisfy NHS England that they can provide all essential services to anyone in England without face to face. Whilst it is not prescribed what information is provided, this applicant has provided very little information and, on the information, provided it is highly likely that the application would be refused. The applicant may wish to review if they want to provide any additional supporting information for their application.*" In response the applicant did provide additional information on their application and through the notification stage of the process, in response to comments made on the application. However, there was still some missing information, hence the application was refused.

4.1.3 Through the appeal process a suite of SOPs has been provided and these have provided the missing information that we needed. Whilst we did not need all of the SOPs to make a determination, we needed slightly more than we had originally received.

4.1.4 With the information now provided, we would have granted this application, so we now have no objections to the application being granted."

5 Summary of Observations

This is summary of observations received.

5.1 TEMPLE BRIGHT LLP ON BEHALF OF THE APPLICANT

5.1.1 "Thank you for your email below and the attached correspondence.

5.1.2 My client does not have any further comment to make at this stage. It is noted that NHS England now supports the granting of my client's application in light of the further information provided by my client with its appeal, and Boots does not make any representations on this appeal."

6 Consideration

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

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

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

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

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

6.7 In its decision, the ICB concluded that "*There are no current pharmacies listed at the proposed premises or adjacent to the proposed premises*" which had not been disputed by any party.

6.8 The Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

(2) 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."

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

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

provided is sufficient to satisfy 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.

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

6.11.1 confirm the ICB's decision;

6.11.2 quash the ICB's decision and redetermine the application;

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

Regulation 25(1)

6.12 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)

6.13 The Committee noted that the Applicant had not included any information in the relevant section of the application form that deals with this point. The application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

6.14 In its decision, the ICB concluded that "*the proposed site 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. Therefore, this regulation does not apply for this application.*"

6.15 The Committee noted that this had not been disputed by any party, and therefore based on the information available, determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

6.16 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.

6.17 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.

6.18 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.

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

6.20 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.

6.21 The Committee noted SOP 13 titled 'Procedures for NHS Essential Services' states:

6.21.1 *"NHS Essential Services are provided to all patients living in England, this is made clear on the website and in the Practice leaflet.*

6.21.2 *All patients in England are able to register to receive NHS Essential Services from MedExpress via our website.*

6.21.3 ***Communication Channels***

6.21.4 *All communication regarding NHS Essential Services should be carried out over the telephone unless the customer has specifically requested to communicate via email.*

6.21.5 *All information relating to NHS Essential Services will appear on the website which will be regularly updated to reflect current campaigns. We are able to contact patients via email to confer public health campaigns.*

6.21.6 ***Request for face-to-face service provision***

6.21.7 *Establish where the person is located in England and which services they require.*

6.21.8 *Explain that due to our Distance Selling regulations we are unable to provide face-to-face provision of NHS Essential Services.*

6.21.9 *Use the 'Services Near You' application by NHS Choices to find suitable service providers near to the patient and offer them their details to contact them."*

6.22 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.

6.23 The Committee further noted SOP 12 titled 'Responsible Pharmacist' which states:

6.23.1 *"The RP must make an accurate contemporaneous record showing that they are the RP of a pharmacy for a particular day and time.*

6.23.2 *In certain situations the RP may need to be absent from the pharmacy to carry out their work. In this case they would still be the specific RP of the pharmacy however they will need to follow some specific guidance relating to their absence.*

6.23.3 *To ensure the provision of pharmaceutical services are provided, permitted time absent will be outside of the pharmacy's NHS contracted hours.*

6.23.4 *The RP must display a notice stating their name, GPhC registration number and a statement to show they are the RP at that pharmacy.*

6.23.5 *…*

6.23.6 ***During the absence of the RP***

6.23.7 *All of the pharmacy team must adhere to the pharmacy procedures set down by the RP.*

6.23.8 *Monitor the time that the RP has been absent.*

6.23.9 *If the absence exceeds 2 hours:*

6.23.9.1The pharmacy must close temporarily until a pharmacist assumes the duty of RP.

6.23.9.2The pharmacy must contact the RP for additional instructions and the estimated time of return.

6.23.9.3*If the RP is not contactable, the pharmacy team must contact the nominated advisory pharmacist for additional instructions."*

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

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

Dispensing of drugs and appliances

6.26 The Committee considered whether the Applicant had explained how non electronic prescriptions will be presented by the patient and how products will be provided.

6.27 SOP 14 titled 'Online Order Receipt of NHS prescriptions' states:

6.27.1 "*Requests to collect and dispense NHS Prescriptions from the surgery or patients' household.*

Requests to dispense a prescription received in the post."

6.28 Also the Applicant refers to delivering products using its own delivery driver, Royal Mail and specialist couriers throughout the application form and SOPs provided on appeal.

6.29 Therefore the Committee was 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

6.30 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.

6.31 The ICB in its decision referred to there not being any information provided in relation to paragraph 6 of Schedule 4 (of the Terms of Service). In its representations on the appeal, the ICB acknowledges the SOPs provided, stating that "*these have provided the missing information that we needed.*"

6.32 The Committee had regard to SOP 5 titled 'Emergency Supply' which describes how the Applicant will process such a request. The Committee noted that the SOPs refer to essential services being delivered by several means of non-face-to-face communication including telephone and email, 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.

6.33 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 6 of Schedule 4.

Preliminary matters before providing ordered drugs or appliances

6.34 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.

6.35 SOP 14 under the heading 'Exempt NHS Prescriptions' states:

6.35.1 *"Where evidence of exemption is required or provided by the patient, the PMR system should be updated to reflect that necessary checks have 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, the patient may scan or fax copies of the evidence to the*

pharmacy 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.

…

Where a patient uses the postal system to provide evidence of exempt status then the patient should be advised to use Tracked Delivery Postal Services or our own courier service. The pharmacy should cover the cost of any postal / courier for the patient."

6.36 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.

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

6.38 The ICB in its decision referred to there not being any information provided in relation to paragraph 7(5)(b) of Schedule 4 (of the Terms of Service). In its representations on the appeal, the ICB acknowledges the SOPs provided, stating that "*these have provided the missing information that we needed.*"

6.39 SOP 14 under the heading 'Paid NHS Prescription' states:

6.39.1 *"Check the prescription to confirm how many charges are due*

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

Use the secure, online, payment method to collect payments."

6.40 The Committee was therefore 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

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

6.42 In its application form, the Applicant states *"If the delivery to patients is local, this will be done by our own delivery driver. All other nationwide delivery will be delivered by recorded delivery".*

6.43 SOP 19 titled 'NHS Order Delivery' states:

6.43.1 *"Delivery of a NHS prescription via a courier (Royal Mail)*

Preparation for delivery:

Ensure that prescriptions for delivery are securely bagged and appropriately labelled.

Check every parcel is in the appropriate sized box and sealed on all sides and have a clearly labelled RM address label on it. The box should be secure and undamaged in any way.

Pack the prescription bag and any other items for delivery securely in the appropriate outer packing. Ensure that all relevant paperwork and any notes from the pharmacist are included.

Inclusion of Information On Storage and Return:

The pharmacy Terms of Service state that a pharmacy must provide appropriate advice to patients to whom drugs are supplied about the safe keeping of drugs and return of unwanted medicines.

For new patients, written information on safe storage and the returns process should be included with new deliveries. Patients should also be directed to the pages on the pharmacy website that provide details on the safe storage and return of unwanted medicines.

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.

Make a note of all Tracking numbers for prescriptions being delivered on the Delivery Log sheet. A dispenser checks the following day if the orders dispatched the day before have been delivered and makes a record in the audit log that the checks have been carried out. Any orders that have not yet been delivered are highlighted and rechecked the following day. If they are still not delivered, the customer is called to check and take action to arrange a resend or investigate with Royal Mail.

Ensure courier signs the Delivery Log sheet for all prescriptions being accepted for delivery. Store Delivery Log sheet for a minimum of 3 months from dispatch date.

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

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

Successful delivery

Once the deliveries are completed they are marked as Delivered in the Royal Mail Track and Trace website.

Unsuccessful Delivery via a courier (Royal Mail)

If the patient or representative is not able to receive the delivery of their medication, Royal Mail will leave a 'something for you' card stating the date and time of the attempted delivery and post it through the letterbox.

The patient can then either choose to collect and sign for their medicines at their local post office, or rearrange delivery for a convenient time by telephone or Internet.

The parcel will be held at the post office and then returned to the pharmacy if not called for.

In case of address incomplete or unknown, a person not known at the address or a refusal of delivery the parcel will be returned to the pharmacy as soon as possible.

Cold chain delivery via courier

For all cold chain orders, only remove them from the fridge when ready to be packed and dispatched.

Accompanying items should include a note to explain that fridge items will be delivered separately to the rest of their items to enable the cold chain to be maintained.

Cold chain parcels will be sent using FEDEX COLD CHAIN will ensure the integrity of the cold chain and the maximum stability of thermolabile drugs by packing, transporting and delivering in such a way that their integrity, quality and effectiveness is always preserved. This is a dedicated, fully monitored and temperature controlled delivery service.

The packaging should be the insulated FedEx insulated packaging which maintains a constant 2-8 degrees for up to 96 hours. Remove the checked order from the fridge, double check with the pharmacist before placing it in the insulated packaging. Push the activator button on the cooling pack to start the cooling process just before the order is to be collected. Ice packs are not needed. Ensure the box is sealed and attach the address label.

A delivery should be booked using FedEx Cold Chain Services, selecting a delivery maintaining 2– 8°C.

Confirm that the delivery will be maintained at 2 – 8°C with the courier and ask them to sign a log confirming receipt of the orders.

FedEx insulated boxed cannot be reused once the activator button has been activated.

The RP should make sure that all scheduled fridge line collections have been booked and collected before the end of the day.

Unsuccessful cold chain delivery via courier

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

Breach of Integrity of Cold Chain

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

Where such an event occurs, the 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.

To audit the cold chain delivery service, the pharmacy team will send dummy parcels to various locations with a recording temperature control device to check if cold storage has been maintained. A staff member will collect the parcel and record the results. This test will be carried out every month. The responsible pharmacist will ensure this is actioned monthly and the results recorded in the cold chain log. If there has been a breach of cold chain, the courier must be contacted, and an investigation carried out immediately. All further cold chain orders must be kept on hold until the courier can guarantee cold chain delivery.

A member of the dispensary team will check if fridge lines have been delivered successfully from orders dispatched the previous day. If the delivery has not arrived within the scheduled time, the courier must be contacted and the issue investigated."

6.44 In its application form, the Applicant states:

6.44.1 *"Delivery of Controlled Drugs will be carried out by DHL. DHL has pharma grade specialist facilities to meet specific quality and validation requirements for healthcare products. This includes Home Office licensed controlled drug stores. They have the following UK Licenses and Standards: MHRA Wholesale Dealer License MHRA Manufacturer's Importers License GAMP 4 Systems Validation MHRA IMP License MHRA Manufacturer's "Specials" License ISO 9001: 2000 Certified Clinical trials audited to GMP Annexe 13 standards FDA audited DHL meet all Home Office safe custody and record keeping requirements All Controlled Drugs will be delivered by the DHL Courier Services and tracked, with verifiable audit trails."*

6.45 SOP 23 titled 'Controlled Drugs: Delivery' states:

6.45.1 *"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 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 be filled in for CD deliveries (Appendix 2)

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

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

All CD orders should be sent using the Special Delivery service which delivers the next day.

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

A log should be filled in with the RP signing that they have given the CD orders to the courier. The log should have order numbers and RP signature against each entry and saved on the MedExpress folder on the google drive.

A daily audit should be carried out on the orders dispatched the day before to check if they have been delivered. Any orders that have not been delivered should be rechecked in the afternoon. If the order still has not been delivered, contact the customer to investigate. Inform the RP and investigate with RM.

The prescription should be retained in the pharmacy until the patient signature is confirmed online to acknowledge successful delivery by courier.

Successful Schedule 2 & 3 Delivery

For all successful deliveries the Controlled Drug 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 courier

Unsuccessful deliveries sent with a courier must be returned to the pharmacy and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate. The courier will return the CDs via the Special Delivery returns service."

6.46 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

6.47 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.

6.48 The Committee noted that in response to the question in the application form "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 did not complete this section of the form and left it blank. As with its finding on Regulation 25(2)(a) above, the Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that it did not intend to provide appliances, including those which require measuring or fitting. Therefore, in the event that the application is granted, the Applicant would not be able to provide such appliances.

6.49 The Committee considered whether the Applicant had explained what containers would be suitable for posted/delivered items.

6.50 SOP 18 titled 'Bagging-Up NHS Prescriptions' states:

6.50.1 *"Packaging to be used*

For small parcels, use cartons that fit appropriately, making sure the sides are sealed and no medication can come out of the parcel. For larger parcels use cartons that fit the order and can be sealed from all sides. Ensure all sides are sealed. The packaging should be discreet with no indication on the outside that medicines are being delivered in this parcel.

Small flat parcels - Small square cartons (Kite Packaging)

Medium and large flat parcels – medium and large Defender boxes

Small parcels - CD1 boxes

Medium parcels – Medium carton (7x5x5) (Kite Packaging)

Large parcels – C1 boxes

Select the appropriate packaging to ensure the medicine is packed securely. If needed plain brown paper can be used to stuff the box to ensure the medicines is protected during transport.

Make sure the Royal Mail address label is placed on the seal to prevent unauthorized opening of the parcel.

For fridge line orders, see NHS order delivery SOP and guidance on using the FedEx Cold Chain service.

All fridge line orders should be dispensed and labeled [sic] *in the same way as other medicines and replaced back in the fridge if the collection is not immediate.*

Fridge line orders should only be removed from the fridge just prior to being collected.

The prescription should stay attached to the fridge line until it has been packed and ready for dispatch in the Fedex insulated box.

Cold chain orders should have a fridge line sticker attached.

Accompanying medicines should have note to explain that fridge items will be delivered separately to the rest of their items to enable the cold chain to be maintained."

6.51 Based on the information provided, 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

6.52 The Committee asked itself how the Applicant will be satisfied that when dispensing a repeatable prescription other than on the first occasions, 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 to review the patients treatment.

6.53 The ICB in its decision referred to there not being any information provided in relation to paragraph 9(4) of Schedule 4 (of the Terms of Service). In its representations on the appeal, the ICB acknowledges the SOPs provided, stating that "*these have provided the missing information that we needed.*"

6.54 SOP 27 titled 'Repeat Dispensing' states:

6.54.1 ***"Pharmaceutical & Legal Assessment***

Terms of Service states that a pharmacy must, when providing drugs in accordance with a repeatable prescription, provide to the patient appropriate advice on the importance of only requesting those items which they need. Patients should be so advised either by phone or through the inclusion of written information with delivered medication.

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 the prescription was authorised.

Any interventions or referrals which are deemed to be clinically significant should be recorded on the Intervention and Referral spreadsheet. The prescriber must have signed the RA. The RDs will not

be signed but will be numbered as appropriate. The RA will detail the specific number of issues and, if appropriate, the dispensing interval."

6.55 The Committee was 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

6.56 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.

6.57 The ICB in its decision referred to there not being any information provided in relation to paragraph 10(1) of Schedule 4 (of the Terms of Service). In its representations on the appeal, the ICB acknowledges the SOPs provided, stating that "*these have provided the missing information that we needed.*"

6.58 SOP 27 states:

6.58.1 ***"Background***

Repeat dispensing is designed to make it easier for patients that receive regular repeat medication that are stable on their medication.

Repeat Dispensing

Repeat Dispensing is a process by which patients are able to obtain repeat medicines without the need to contact their GP on each occasion. The supplies of medicines are managed by the patient's pharmacy of choice and the patient or representative must visit the same pharmacy for each supply under the service.

The prescriber produces a master 'repeatable' authorising prescription (annotated with RA) on a standard FP10 form and a set of identical 'batch' prescriptions on a standard FP10 form (annotated with RD).

Both forms must be computer generated. Any handwritten amendments, including any additional medication added will invalidate the prescription.

…

To provide a framework for a safe on going repeat dispensing service which includes prompt attention to medication change or any other known changes in patient's needs.

…

Pharmaceutical & Legal Assessment

Terms of Service states that a pharmacy must, when providing drugs in accordance with a repeatable prescription, provide to the patient appropriate advice on the importance of only requesting those items which they need. Patients should be so advised either by phone or through the inclusion of written information with delivered medication.

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 the prescription was authorised.

Any interventions or referrals which are deemed to be clinically significant should be recorded on the Intervention and Referral spreadsheet. The prescriber must have signed the RA. The RDs will not be signed but will be numbered as appropriate. The RA will detail the specific number of issues and, if appropriate, the dispensing interval."

6.59 The Committee was therefore 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

6.60 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.

6.61 SOP 7 titled 'The Safe and Effective Receipt and Disposal of Medicines' states:

6.61.1 ***"Patient Returned Unwanted Medication (incl medication returned from private households, children's homes and residential care homes)***

Patients can be referred to the 'Returning unwanted medication' page on the website for information. To organise sending medication back to the Pharmacy the patient must telephone and speak to a member of the pharmacy or Customer service team.

Patients or their representatives MAY NOT return any medicines directly to the pharmacy and must follow the procedures set out in this SOP.

This service is available to all patients living in the United Kingdom.

The process for returning medication should be explained to the patient *– they may send it back to the Pharmacy via Royal Mail at the pharmacy's cost. Ensure the patient understands that any sharps and clinical/contaminated waste cannot be returned and they should follow local procedures for disposing of them. Ensure the patient knows that cytotoxic and hazardous waste, as well as CDs, must be separated if possible before returning to the pharmacy. Patients should be advised to mark the package of unwanted medication to "Z Returns" to allow them to be easily identified. Where necessary appropriate packaging should be sent to patients to return hazardous medicines – return of such medicines in inadequate packaging may be unsafe.*

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

Hazardous medicines

A list of medicines classed as hazardous that need to be handled with care and separated for disposal can be found at: https://www.cdc.gov/niosh/docs/2016-161/default.html

Controlled drugs

Controlled drugs should be segregated and appropriately denatured before disposal (refer Controlled Drugs: Disposal of Patient Returns SOP). A CD denaturing kit should be used, following the directions on the kit. Controlled drugs should be denatured as soon as possible and only be taken from their original container at the time of denaturing. The details should be recorded in the Patient Returned Controlled Drugs Register. This should be completed and witnessed at the time of denaturing and stored for two years.

Disposal of returned medicines

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

This SOP does not cover the topic of dealing with waste controlled drugs – these are dealt with in two separate SOPs.

Controlled Drugs: Disposal of Patient Returns SOP.

Controlled Drugs: Disposal of Pharmacy Stock SOP."

6.62 SOP 24 titled 'Controlled Drugs: Disposal of Patient Returns' states:

6.62.1 *"Patient Returned Medication*

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

the Pharmacy the patient must telephone and speak to a member of the dispensary team.

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

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

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

Process

Handling Patient-Returned CDs from Courier by Pharmacy

Pharmacy staff need to:

If CDs have been identified as returned medicines, secure them in a bag, clearly marking on 'Patient-returned CDs for destruction' and include the date of return; place the bag in the CD cabinet away from pharmacy stock until they can be destroyed. As soon as possible, refer to the Patient unwanted medicines form to make the entry in the "Patient unwanted medicines" and "Patient returned CD register" tab in MedExpress - Pharmacy issues log spreadsheet and on equivalent paper register, to record the CD that require destruction at a later date."

6.63 The Committee was therefore 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

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

6.65 SOP 8 titled 'Support for Self-Care, Signposting and Health Promotion' under the heading 'Healthy Lifestyle' states:

6.65.1 *"If it is appropriate to provide healthy lifestyle advice, the pharmacist should provide any advice necessary and within their area of competency. Where advice is provided it should be recorded as an*

intervention on the patient record. Where this advice includes information in a CCG campaign this should be recorded.

If it is not appropriate to provide advice the patient should be referred to the appropriate health or social care provider or support organisation. Where advice cannot be provided it should be recorded as an Intervention on the patient record along with the referral organisation."

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

Prescription linked intervention

6.67 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.

6.68 SOP 8 under the heading 'Long Term Conditions' states:

6.68.1 *"If it is appropriate to provide advice the pharmacist should provide any advice necessary and within their area of competency. Where advice is provided it should be recorded on the PMR. Any advice given should always aim to include counselling on a healthy lifestyle as well as management of the long-term condition.*

If it is not appropriate to provide advice to the patient or if the patient would benefit from a face to face consultation, the patient should be referred to the appropriate health or social care provider or support organisation. Where advice cannot be provided it should be recorded as an Intervention in the patient record along with the referral organisation.

For specific groups of patients (those with diabetes, at risk of coronary heart disease, especially those with high blood pressure, and patients who smoke or who are overweight) the pharmacist must provide advice without face-to face interaction (e.g. telephone, Skype, Zoom via the website). Such advice should be backed up, as appropriate, by the provision of written material such as leaflets."

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

Health campaigns

6.70 The Committee considered whether the Applicant had explained how it will safely and effectively participate in health campaigns, if and to the extent required by NHS England.

6.71 SOP 8 titled 'Support for Self-Care, Signposting and Health Promotion' states:

6.71.1 *"The scope of this SOP will include guidance for the provision of self-care to patients and their families, including signposting to appropriate*

supporting organisations, promotion of a healthy lifestyle and taking part in relevant health promotion campaigns. …

Objective

Implementing this SOP will ensure: …

Participation in relevant health promotion campaigns"

6.72 Further SOP 13 titled 'Procedures for NHS Essential Services' states:

6.72.1 *"All information relating to NHS Essential Services will appear on the website which will be regularly updated to reflect current campaigns. We are able to contact patients via email to confer public health campaigns."*

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

Signposting

6.74 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.

6.75 SOP 8 under the heading 'Signposting' states:

6.75.1 *"When signposting patients, use the 'Services Near You' application from NHS Choices to find suitable organisations in the locality of the patient. Please refer to "How to Navigate NHS Choices Website" document for guidance on how to use this application."*

6.76 The Committee was therefore 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

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

6.78 SOP 8 under the heading 'Support for self-care' states:

6.78.1 *"If it is appropriate advise the patient on different treatment options and potential changes to their lifestyle that may benefit their health. Patients should be advised on the correct use of the medicine they are using and if there is an opportunity advice promoting a healthy lifestyle should be given. Additional written information can be given to reinforce the message. A record should be made in the PMR."*

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

Discharge medicines service

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

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

6.82 SOP 35 titled 'Discharge Medicine Service' states:

6.82.1 *"Stage 1: Discharge referral received by pharmacy – actioned within 72 hours*

The pharmacy team check for patient discharge referrals at 9am, 12pm and 4pm. The systems can be PharmOutcomes, Refer to Pharmacy or NHSMail

Check the referral has the demographic and contact details of the patient and their GP, including their NHS number and hospital record number. There should be details of medicines used by the patient at discharge, including the name, strength, form, dose, timing, frequency and planned duration of treatment. There should be how the medicines are taken and the indication.

Check for the contact details of the referring clinician or hospital dept for pharmacy use

If the patient is new to the pharmacy, contact the NHS trust or patient to confirm the patient is happy to continue with the DMS service from MedExpress.

Carry out all clinical checks and identify any actions contained within the referral which need to be undertaken by the pharmacist within 72 hours

Undertake a comparison of the medicines the patient was taking at admission and those at discharge. Check the SCR if necessary but consent will need to be obtained from the patient first.

Raise any concerns or issues identified at clinical check with the NHS trust or general practice/ Primary Care Network pharmacist, if necessary

Make the appropriate notes on the patient medication record (PMR)

Check if any prescriptions for the patient previously ordered are in the dispensing or awaiting delivery process and need to be returned or adjusted

Submit data via Manage Your Service (MYS) Portal for Monthly Payment

Stage 2: First prescription is received post discharge –1 week –1 month post discharge

Check the first prescription received against discharge referral and PMR

Identify any issues or discrepancies and resolve these with the GP practice. Arange [sic] *for a new or amended prescription from the GP*

Make the appropriate records on the PMR

Stage 3 :Patient engagement to check their understanding of their medication regime –following 1st prescription received post discharge

The RP should contact the patient and/ or career to have a confidential discussion about their medication. If this isn't a convenient time, arrange another time that is suitable for the patient.

At the consultation, discuss the medicines prescribed with the patient/carer and provide appropriate advice and support.

Offer to dispose of any medication that are no longer needed if appropriate and send them a returns Royal Mail label.

Offer other services that may form part of the CPCF such as the new medicine service if the patient is eligible and it is clinically appropriate.

Makea record in the PMR and share details with the GP / PCN pharmacy team if clinically appropriate.

Submit the data via the MYS portal for monthly payment

Points to consider:

If the patient is uncontactable or withdraws consent following completion of Stage 1 in which case stage 2 cannot be completed

Patient is uncontactable or withdraws consent following completion of Stage 1 and 2 in which case stage 3 cannot be completed

If the patient switches to another pharmacy following completion of Stage 1, contact the patient's new pharmacy and offer to send them the referral information from the NHS trust and any other relevant findings from stage 1 of the service; patient consent should be obtained prior to sharing the details. The NHSmail account can be used to send a secure electronic message

If MedExpress receives a referral in error, the pharmacy should contact the NHS trust and request the referral is amended and sent to the correct pharmacy"

6.83 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C - 15 of Schedule 4.

Websites and health promotion zones

6.84 The Committee considered whether the Applicant had explained how it will ensure that it has a website for use by the public for the purpose of accessing pharmaceutical services from those premises, on which there is an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues.

6.85 SOP 8 under the heading 'Scope' states:

6.85.1 *"The MedExpress website will be available for use by the public for the purpose of accessing pharmaceutical services on which there is an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a range of up to date materials that promote healthy lifestyles by addressing a range of health issues."*

6.86 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 28C of Schedule 4.

Summary

6.87 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).

6.88 As the Committee has reached a different conclusion to that of the ICB, the Committee determined that the decision of the ICB must be quashed.

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

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

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

7 Decision

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

7.2 Accordingly, the Committee:

7.2.1 quashes the decision of the ICB; and

7.2.2 redetermines the application as follows -

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

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

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

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

7.2.2.5 the Committee was 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 granted.

Technical Case Manager
Primary Care Appeals