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27 March 2025

REF: SHA/26422

APPEAL AGAINST NHS WEST YORKSHIRE ICB DECISION TO REFUSE AN APPLICATION BY MEDTIME PHARMA LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT UNIT 17 HOLROYD BUSINESS CENTRE, CARR BOTTOM ROAD, BRADFORD, BD5 9BP UNDER REGULATION 25

1 Outcome

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

1.2 The Committee determined that the application should be refused.

A copy of this decision is being sent to:

Medtime Pharma Ltd
Primary Care Support England (on behalf of West Yorkshire ICB)
Community Pharmacy West Yorkshire

NHS Resolution

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1 The Application

By application dated 1 July 2024, Medtime Pharma Ltd ("the Applicant") applied to West Yorkshire ICB ("the Commissioner") for inclusion in the pharmaceutical list at Unit 17 Holroyd Business Centre, Carr Bottom Road, Bradford, West Yorkshire, BD5 9BP 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 section blank.

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

1.2.1 "The pharmacy premises are located near bricks and mortar pharmacies and one online pharmacy, however this organisation has not dispensed medication since September 2023. We aim to support the ever-increasing demand for home delivery service and compliance aids which there is a current demand for nationwide. As we are an online pharmacy, we aim to meet the shortfall of medication dispensing nationwide."

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

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

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

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

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

1.5 "To ensure uninterrupted provision of essential services during core hours across England, a responsible pharmacist will be in charge and logged into the PMR system for auditing. The responsible pharmacist will ensure safe and effective services without face-to-face contact via a GPhC registered website. Services can also be accessed through telephone, fax, email, and postal services.

1.6 The internet pharmacy will operate without public access, secured by alarm and key-coded entry. Strict SOPs from the National Pharmacy Association will be followed to comply with regulation 25. The pharmacy's website, designed by specialists, will meet GPhC requirements and promote public health, offering advice on healthy living, smoking cessation, weight loss, and more. Customers can purchase GSL and P medicines online under pharmacist supervision. Self-care support and advice on minor illnesses will be available online or via telephone, with referrals made to local healthcare services as needed.

1.7 The pharmacy will dispense EPS prescriptions and those sent via post or fax in emergencies, ensuring medications are labelled according to healthcare professionals' directions. The pharmacist will conduct necessary checks before medicines are dispatched through a secure delivery service that complies with MHRA and NHS England regulations. Controlled drugs will be dispensed only with a prescription, and deliveries will require customer signatures. Thermo labile medicines will be transported in a temperature-controlled environment.

1.8 The pharmacy will also collected unwanted medicines via approved couriers and ensure their safe disposal per GPhC guidelines. A clinical governance lead will oversee policy adherence, with a complaints procedure accessible online, by phone, or by post. The pharmacy will comply with NHS confidentiality codes and the Data Protection Act, implementing risk management strategies for incident reporting, staff training, audits and SOPs."

2 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 20 November 2024 states:

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

2.1 "West Yorkshire 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.

2.2 You have a right of appeal to the Secretary of State against West Yorkshire ICB's decision. Should you choose to appeal then you should either complete the online form available on the NHS Resolution website or send a concise and reasoned statement of the grounds for your appeal within 30 days of the date of this letter to nhsr.appeals@nhs.net or:

2.3 Primary Care Appeals, NHS Resolution, 8th Floor, 10 South Colonnade, Canary Wharf, London, E14 4PU"

DECISION REPORT

2.4 "The Pharmaceutical Services Regulations Committees in Common (PSRC) at the meeting held on Wednesday 30th of October 2024 considered the following and REFUSED the Application for Inclusion in the Pharmaceutical List under Part 3, Regulation 25 of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 – Distance Selling Premises (Excepted Application).

WY – Medtime Pharma Ltd. Unit 17, Holroyd Business Centre, Carrbottom Road, Bradford, West Yorkshire, BD5 9BP

2.5 PSRC was presented with papers for a DSP. The address of the premises appears separate to an existing DSP located at Unit 20. Both sites are located within the same business centre and are accessed within the same building via the same main entrance.

2.6 A review of Companies House information makes no connection between the applicant and the pharmacy at unit/office 20. There is no evidence of any shared Directors (or any Directors linked via other companies) nor are there shared registered offices nor shared Superintendents. Therefore, PSRC determined that Regulation 31 does not apply.

2.7 With regards to Regulation 25, the following was noted:

2.8 Regulation 25(2)(a) – does not apply as no primary care provider with a patient list is present within the same premises as the proposed site.

2.9 Regulation 25(2)(b)(i) – is met as the applicant has mentioned in the application how services will be provided remotely, and without interruption throughout the given opening hours.

2.10 Regulation 25(2)(b)(ii) – is not met as the Committee determined that, applicant has not fully explained how the safe and effective provision of essential services will be carried out. The applicant has provided very limited information in the application form to assure PSRC.

2.11 Regulation 64 – sets out the specific conditions to be met by applications for Distance Selling Premises:

2.11.1 (a) X must not offer to provide pharmaceutical services, other than directed services, to persons who are present at (which includes in the vicinity of) the listed chemist premises;

2.11.2 (b) the means by which X provides pharmaceutical services, other than directed services, must be such that any person receiving those services does so otherwise than at the listed chemist premises;

2.11.3 (c) the listed chemist premises must not be on the same site or in the same building as the premises of a provider of medical services with a patient list;

2.11.4 (d) in the case of pharmacy premises, the pharmacy procedures for the premises must be such as to secure –

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

2.11.4.2 (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 X or X's staff, and

2.11.5 (e) nothing in X's practice leaflet, in X's publicity material in respect of the listed chemist premises, in material published on behalf of X publicising services provided at or from the listed chemist premises or in any communication (written or oral) from X or X's staff to any person seeking the provision of essential services from X must represent, either expressly or impliedly, that –

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

2.11.5.2 (ii) X is likely to refuse, for reasons other than those provided for in X's terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (for example, because the availability of essential services from X is limited to other categories of patients).

2.12 The applicant has provided very limited information in the application form to assure PSRC that Reg 64 condition (d)(ii) is satisfied i.e. the safe and effective provision of essential services. Although clear and concise top level statements are made in support of the application, limited detail or supporting information is provided to fully assure safe and effective service provision.

2.13 The Committee considered the representations that received from Gorgemead Limited, CPWY, and YOR LMC Limited. Gorgemead Ltd requested that the decision maker considers all criteria relating to regulation 25 and the conditions set out in Regulation 64. Representations made by CPWY refer to West Yorkshire ICB being assured that Regulations 25(2)(a) and 25(2)(b) are met and that the applicant will be able to provide pharmaceutical services throughout the proposed contracted hours. Representations made by Bradford and Airedale branch of YORLMC voicing general opinions regarding the increasing numbers of applications for internet /distance selling pharmacies and asks 'that PCSE (WY ICB) monitors closely the internet pharmacies in this area to ensure that they abide by the regulations'.

2.14 As Committee members agreed that the applicant had provided limited information and did not elaborate on the particulars where required, for example, there is no description to detail how the applicant would respond to failed deliveries. The Committee agreed that they were not assured that the applicant fulfilled the conditions set out in Regulation 2(b)(ii) [sic] and Regulation 64.

2.15 PSRC decision: Having considered all the information provided by the Contractor and the Regulations, the PSRC refused the application.

2.16 Right of Appeal: Medtime Pharma Ltd."

3 The Appeal

Using the NHS Resolution appeal form dated 16 December 2024, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "Medtime Pharma Ltd is appealing the decision made by NHS England. The grounds of appeal are:

3.2 In summary, NHS England refused the application because they were not assured that Medtime Pharma Ltd fulfilled the conditions set out in Regulation (2)(b)(ii) [sic] and Regulation 64 due to limited information being provided.

3.3 NHS England was wrong to reach such a determination. The application was clear that essential services would be provided without face-to-face contact.

3.4 NHS England's decision primarily arose from perceived deficiencies in the detail provided on the procedures, specifically concerning failed deliveries and uninterrupted service provision.

3.5 NHS England determined the application had met the requirements for Regulation 25(2)(b)(i). Regulation 25(2)(a) was not applicable.

3.6 At the time of submission, the guidance suggested that standard operating procedures were not required to be submitted.

3.7 Subsequently, had the procedures been provided initially, this would have satisfied the requirements of the Committee.

3.8 A comprehensive list of standard operating procedures have been provided alongside this appeal for the Committee of NHS Resolution. [Provided at Appendix A for Committee.]

3.9 Please find below additional information explaining how the standard operating procedures will ensure the following:

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

3.9.2 (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's staff.

3.10 Patients from anywhere in England may contact the pharmacy to request Essential Services by phone, email, website, fax and writing during the proposed opening hours, without face-to-face contact. The website will accessible 24 hours a day throughout the year.

3.11 All Essential Services shall be delivered in a safe and effective manner in accordance with the attached pharmacy procedures:

3.11.1 To persons anywhere in England who request these services, during the opening hours of the pharmacy, without interruption.

3.11.2 Without face-to-face contact between the patient or their representative and the Pharmacy owner or their staff.

3.12 Medtime Pharma Ltd will comply with Regulation 64 as follows:

3.12.1 The pharmacy shall not provide any services, other than directed services, to persons who are present at or in the vicinity of the pharmacy premises.

3.12.2 Patients receiving services, other than directed services, must be by means other than at the pharmacy premises.

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

3.12.4 The pharmacy will not produce any practice leaflet or publicity material or any other communication, which expressly or impliedly states that access to the NHS essential services provided by the pharmacy are only available to persons in the particular areas of England or that the pharmacy is likely to refuse to provide essential services or prescribed drugs or appliances to particular categories of patients.

3.13 When a query is received from a member of the public, a patient, or their carer requesting the delivery of any Essential Service in person or in the vicinity of the premises, they will be informed that face-to-face interaction between the patient or their representative and pharmacy staff is not permitted. Staff will also explain that, due to NHS regulations, the pharmacy cannot provide Essential Services in person. Instead, they will advise the individual to contact the pharmacy via phone, email, or written communication to have their request addressed.

3.14 All staff members will receive appropriate training to deliver pharmacy services, including CPD where appropriate. All staff members shall adhere to legislation, procedures and guidance set out in the standard operating procedures.

3.15 Listed below are concise statements summarising the provisions made to ensure the safe and effective delivery of Essential Services to anyone in England without face-to-face contact:

Dispensing Medications

3.16 Prescriptions can be received by the pharmacy through EPS 2, post, collection from the GP surgery with consent, or via fax. Dispensed prescriptions, including controlled drugs and refrigerated items, will be delivered directly to the patient's home using secure and confidential methods, such as in-house delivery staff or appropriate courier service such as Royal Mail.

3.17 When transporting Controlled Drugs, couriers and drivers will be notified that they are carrying a CD to ensure secure handling during transport, in line with guidance, such as using secure containers.

3.18 Courier/drivers will be informed that cold chain requirement must be maintained for fridge lines using suitable containers, and, when necessary, an auditable cold chain will be ensured in accordance with SOPs.

3.19 All deliveries containing Controlled Drugs and refrigerated items will be tracked throughout transit. If the pharmacy uses a courier service, auditing processes will be implemented to ensure that all medications can be tracked at all stages during transit.

3.20 If the exemption status is not signed by the patient or representative, pharmacy staff must verify the exemption via telephone or email and sign it accordingly.

3.21 Please refer to standard operating procedures 10, 11, 17, 20 and 21 for additional information.

Repeat Dispensing

3.22 Appropriate advice about the benefits of repeat dispensing will be given to any patient who:

3.22.1 (i) has a long term, stable medical condition.

3.22.2 (ii) require regular medication in respect of their medical condition including where appropriate advice that encourages the patient to discuss repeat dispensing of that medicine with the prescriber.

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

3.24 Please refer to standard operating procedure 33 for additional information.

Disposal of Unwanted Medications

3.25 Patients who wish to return unwanted medication to pharmacy can do so through the pharmacy's own driver/courier service, which will be provided and funded by the pharmacy.

3.26 Upon return to the pharmacy, unwanted medicines will be sorted and placed in disposal units, awaiting collection by a specialist waste management company.

3.27 Please refer to standard operating procedure 23 for additional information.

Discharge Medicines Service

3.28 The Discharge Medicines Service will be offered to all referred patients. All three stages of the service will be delivered remotely, using appropriate communication methods without face-to-face interaction. Pharmacists will apply their clinical judgement when determining their actions or recommendations within the service and will uphold patient confidentiality, particularly when involving a carer in discussions about the patient and their medications.

3.29 Please refer to standard operating procedure 26 for additional information.

Promotion of Healthy Lifestyles and Public Health Campaigns

3.30 All patients will be invited to complete a healthy lifestyle questionnaire, which can be submitted by post or completed online through the pharmacy's website. Once the completed questionnaires are received, pharmacy staff will review the results to identify and contact patients who may benefit from additional information and support.

3.31 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 and email newsletters will also be used to promote healthy lifestyles via the health promotion zone.

3.32 Please refer to standard operating procedure 25 for additional information.

Support for Self-Care, Signposting and Health Promotions

3.33 If the patient requires support or advice beyond what the pharmacy staff can provide, they should be directed to an appropriate health or social care provider capable of offering the necessary assistance. Wherever possible, provide the patient with contact information for at least two suitable providers.

3.34 Please refer to standard operating procedure 24 for additional information.

Clinical Governance

3.35 The pharmacy is dedicated to fulfilling the clinical governance requirements outlined in the NHS Pharmaceutical Services Regulations. This includes adhering to all aspects of clinical governance, such as maintaining standard operating procedures, conducting patient surveys and audits, reporting patient safety incidents and near misses, and ensuring the pharmacy practice leaflet is kept relevant etc.

3.36 Given the detailed SOPs and contingency plans submitted, Medtime Pharma Ltd has resolved all concerns made from the original decision made by PSRC. This includes

addressing failed deliveries and ensuring uninterrupted services, and adhering to safety protocols.

3.37 Medtime Pharma Ltd acknowledges the representations made Gorgemead Ltd, CPWY, and YOR LMC Ltd. We assure the Committee that our processes, including ongoing monitoring and adherence to NHS regulations, will address any concerns regarding compliance and service quality.

3.38 Given the above, Medtime Pharma Ltd asks that the appeal be allowed and the application granted, confident that the information provided meets all regulatory requirements under Regulation 25 and Regulation 64.

3.39 Medtime Pharma Ltd looks forward to hearing from NHS Resolution in due course."

4 Summary of Representations

This is a summary of representations received on the appeal.

4.1 THE COMMISSIONER

4.1.1 "Thank you for your notification of the appeal by Medtime Pharma Ltd and for the opportunity to submit a response.

4.1.2 The appellant is correct, there is no expectation for an applicant of a market entry application to submit Standard Operating Procedures. However, there is an expectation for the applicant to provide detailed information as to how the proposal meets the required regulations and, in the case of a distance selling pharmacy, how the applicant assures the safe and effective provision of essential services without face-to-face contact.

4.1.3 At the end of this letter, I have enclosed the applicant's supporting information provided within the original application (i.e. four concise paragraphs submitted as part of section 7). **No further supporting information was provided by Medtime Pharma Ltd.** The application was considered by the Pharmaceutical Services Regulations Committee (PSRC) at the meeting held 30th of October 2024. [Emphasis added by the Commissioner.]

4.1.4 Based upon the information provided by Medtime Pharma Ltd, the PSRC considered the application and determined that, although the application had stated the intention to meet the requirements, the application failed to detail **how** they would provide safe and effective services. Consequently, the PSRC was not assured and therefore, could not grant the application. [Emphasis added by the Commissioner.]

4.1.5 A copy of the papers considered by the PSRC and a copy of the PSRC's determination for this case have previously been provided to NHS Resolution therefore, I will not duplicate the information here.

4.1.6 Within the Appeal, [Mr F], on behalf of Medtime Pharma Ltd, states:

4.1.6.1 NHS England's [sic] decision primarily arose from perceived deficiencies in the detail provided on the procedures, specifically concerning failed deliveries and uninterrupted service provision.

4.1.7 The reference to failed deliveries was one example identified by PSRC as to the lack of assurance detailed within the application and was by no means the only issue acknowledged.

4.1.8 [Mr F] speculates in para 1.7 that had Standard Operating Procedures '…*been provided initially, this would have satisfied the requirements of the Committee*'. It is true that, within the provision of more comprehensive information by the application, the PSRC may have granted the application.

4.1.9 To conclude, as part of the appeal to NHS Resolution by Medtime Pharma Ltd, it was noted that a significant amount of additional information has been provided that was not part of the original application and therefore could not have been considered by the PSRC at the time of determining the application on the 30th of October 2024.

4.1.10 [enclosed information as recorded at 1.5 – 1.8 above]

4.2 COMMUNITY PHARMACY WEST YORKSHIRE

4.2.1 "Thank you for your letter dated 8 January 2025 concerning the above application.

4.2.2 Community Pharmacy West Yorkshire members still feel that their comments made in their letter to [SS] on 10 July 2025 are valid. These were as follows:

4.2.3 Community Pharmacy West Yorkshire members would like to make the following observations:

4.2.4 NHS England [sic] must be assured that Regulations 25(2)(a) and 25(2)(b) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 do not apply.

4.2.5 The applicant must give NHS England [sic] assurance that they will be able to provide pharmaceutical services throughout the contracted hours.

4.2.6 NHS England [sic] will be aware of the decision made by NHS Resolution with regard to the Pharmacy 2 U (P2U) application in Leicestershire (SHA/22233). CPWY are sure that NHS England [sic] will want to reflect on the areas where the P2U application was felt to be lacking and ensure that this application is not subject to the same or similar concerns.

4.2.7 NHS England [sic] makes reference to previous application for Distance Selling pharmacies that have been refused upon appeal including the West Yorkshire applications SHA/18299 – May 2016 and SHA/18727 – Sept 2017.

4.2.8 Members wish these comments to be taken into consideration by the Authority [sic] and wish to be notified of the decision."

5 Summary of Observations

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

6 Consideration

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

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

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

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

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

6.6 The Committee noted in its application, the Applicant states that, in reference to Regulation 31, "*the pharmacy premises are located near bricks and mortar pharmacy and one online pharmacy"* however the Applicant had not provided any clear statement that it believed that Regulation 31 did not apply to its application. The Committee further noted, however, that the Commissioner concluded that the application does not fail under Regulation 31 and that this had not been disputed by any party during the subsequent appeal. Therefore, the Committee was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

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

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

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

reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Commissioner in its decision report stated that "*Regulation 25(2)(a) does not apply as no primary care provider with a patient list is present within the same premises as the proposed site".* Based on the information available to it, the Committee therefore 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)

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

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

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

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

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

6.16 The Committee noted in the SOPs provided by the Applicant that SOP 1 'Introduction and Background to SOPs' states that the pharmacy must provide:

6.16.1 "*The uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.*

6.16.2 *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 owner of this pharmacy or any member of staff either on or in the vicinity of the premises."*

6.17 Further SOP 3, 'Procedures for NHS Essential Services', states:

6.17.1 "*NHS Essential Services will be provided to any patient living in the England who requests such services, this is made clear on the website and in the Practice leaflet.*"

6.18 In its SOP 31, 'The Responsible Pharmacist', the Applicant:

6.18.1 "*As a Distance Selling pharmacy, we must provide uninterrupted service throughout the opening hours of the pharmacy. For this reason, the RP is not allowed to leave the premises in the same way as an RP at a non-Distance Selling pharmacy is allowed to (for up to 2 hours per day)* ***unless another pharmacist is present****."* [emphasis added by the Applicant.]

and further

6.18.2 "*The Pharmacy will have a second pharmacist available during the core and any additional hours that it operates. If, for any reason, the RP is required to leave the premises or wishes to take a break (as per Working Time Directive) then the second pharmacist must sign in as the RP.*"

6.19 In SOP 32, 'Preparing for the Absence of the RP', it states:

6.19.1 "*During the absence of the RP*

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

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

6.20 The above extract at 6.19 raised some concerns for the Committee as it contradicted 6.18.1 and 6.18.2. The Committee noted SOP 31 states "*As a Distance Selling pharmacy, we must provide uninterrupted service throughout the opening hours of the pharmacy. For this reason, the RP is not allowed to leave the premises in the same way as an RP at a non-Distance Selling pharmacy is allowed to (for up to 2 hours per day) unless another pharmacist is present".* Whereas SOP 32 states "*Monitor the time that the RP has been absent… if the absence exceeds 2 hours… the second Pharmacist must assume the role of the RP and the Superintendent Pharmacist should be contacted and informed that there is only one pharmacist on duty"*. SOP 31 suggested to the Committee that the Responsible Pharmacist must not leave the premises unless another pharmacist is present to assume that role. However, SOP 32 outlines what would happen in the event that the Responsible Pharmacist would not be present, meaning the Applicant would be unable to provide all essential services in line with the Regulations.

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

6.22 The Committee went on to consider whether services would be available to persons anywhere in England.

6.23 The Committee noted that throughout the SOPs the Applicant states that essential services will be provided without face to face contact between any service users and the pharmacy staff. SOP 1 'Introduction and Background to SOPs' states:

6.23.1 "*All staff must be made aware that face to face contact between patients (or their representatives) is prohibited in respect of any and all Essential Services either on or in the vicinity of the premises.*

6.23.2 *Face to face contact with patients or their representatives either at the premises is only allowed in respect of the provision of services other than Essential Services.*

6.23.3 *Any reference to 'contact' with or 'contacting' a patient in relation to these SOPs means contact other than face-to-face contact either on or in the vicinity of the premises."* [emphasis added by the Applicant.]

6.24 The Committee noted, as per SOP 3 'Procedures for NHS Essential Services', that service users would be able to utilise multiple methods to contact the pharmacy that did not result in face-to-face communication. The SOP, under the heading 'Communication Channels', states:

6.24.1 *"All communication regarding NHS Essential Services should be carried out using the most suitable non face to face method for the patient and the service being provided with particular consideration to maintaining confidentiality. This may be telephone, email, video-conferencing or other types of non-face to face communications such as text messages."*

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

6.26 The Committee was satisfied that the provision of services would be without face to face contact and would be available to persons anywhere in England. However, based on the information provided, the Committee could not be satisfied that the provision of services would be without interruption.

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

6.28 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:

6.28.1 Dispensing of drugs and appliances

6.28.2 Urgent supply without a prescription

6.28.3 Preliminary matters before providing ordered drugs or appliances

6.28.4 Providing ordered drugs or appliances

6.28.5 Refusal to provide drugs or appliances ordered

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

6.28.7 Disposal service in respect of unwanted drugs

6.28.8 Promotion of healthy lifestyles

6.28.9 Prescription linked intervention

6.28.10 Health campaigns

6.28.11 Signposting

6.28.12 Support for self-care

6.28.13 Discharge medicines service

6.28.14 Websites and health promotion zones

6.29 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

6.30 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).

6.31 The Committee noted that SOP 17 'Order Delivery' stated:

6.31.1 "*Choice of Delivery Method*

*For items **other than** cold chain / "fridge line" items, local deliveries (up to 30 miles radius, but may be extended at the discretion of the RP) the delivery driver should deliver medication. Outside this area Royal Mail should be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier should be used (see SOP for Delivery of Controlled Drugs), or the items are fridge lines, in which case the cold chain courier should be used (see below).* [Applicant's emphasis.]

…

Delivery of a prescription via Royal Mail (Not for Cold Chain or CDs)

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

Ensure that the pharmacist on duty is available to supervise the handing over of all items for delivery.

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

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

Confirm details of all prescriptions to be delivered.

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

Ensure Royal Mail driver signs Delivery Log 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 their Tracking number when the prescriptions have left the premises.

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

…

Cold chain delivery via courier

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

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

Any breach of cold chain conditions will be notified to the driver and any affected delivery will be cancelled with the pharmacy informed of the cold chain breach.

…

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

Ensure that the pharmacist on duty is available to supervise the handing over of all items for delivery.

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

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

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

Confirm with the courier that the delivery will be maintained at the booked temperature range.

Confirm details of all prescriptions to be delivered.

The courier must scan a barcode sticker for each item. The pharmacy retains a copy of the barcode which is also the tracking number.

…

Unsuccessful cold chain delivery via courier

In the event of an unsuccessful delivery, the courier will leave a 'Missed Delivery' card, stating the date and time of the attempted delivery along with

details of how to contact the courier to arrange the redelivery. The patient can then rearrange delivery for a convenient time by telephone or Internet.

We operate to a 48 hour maximum window for cold chain deliveries and the courier will keep the cold chain intact until successful delivery for up to 48 hours. After 48 hours the items will be returned to the pharmacy and the pharmacy will contact the patient to rearrange delivery.

Breach of Integrity of Cold Chain

The courier ensures temperature integrity throughout the supply chain, from point of collection & goods-in to pharmaceutical storage to final delivery.

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

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

6.32 Whilst the Committee noted the information above indicated that cold chain items would be delivered by a specialist courier, it also had regard to SOP 17 under the heading 'Transfer to the Delivery Driver' which states:

6.32.1 *"Ensure that the pharmacist on duty is available to supervise the handing over of all items for delivery.*

Ensure that any special instructions for the delivery are included with the packaging.

Ask the delivery driver to check the details on the delivery sheet correspond to the deliveries.

Ensure the delivery driver completes all the sections on the delivery sheet including their name and the date.

Ensure that any deliveries for fridge items and CDs are taken out of storage when appropriate.

Ensure the delivery driver is notified of any messages for the patient or representative.

Make and retain a copy of the delivery sheet until the original has been returned by the delivery driver. The original must be returned to the pharmacy on the same day.

Ensure the deliveries are placed in the delivery vehicle and are stored securely and out of sight. The delivery vehicle must be locked at all times when left unattended."

6.33 The Committee was of the view that the above extract at 6.32 was specific to the Applicant's own local driver as there is a separate section for courier. The Committee

was concerned that the statement "*Ensure that any deliveries for fridge items and CDs are taken out of storage when appropriate"* indicated that the local delivery driver would be handling and delivering cold chain items.

6.34 The Committee noted that the Applicant, in its appeal, stated:

6.34.1 "*Dispensed prescriptions, including controlled drugs and refrigerated items, will be delivered directly to the patient's home using secure and confidential methods, such as in-house delivery staff or appropriate courier service such as Royal Mail.*

6.34.2 *When transporting Controlled Drugs, couriers and drivers will be notified that they are carrying a CD to ensure secure handling during transport, in line with guidance, such as using secure containers.*

6.34.3 *Couriers/drivers will be informed that cold chain requirement must be maintained for fridge lines using suitable containers, and, when necessary, an auditable cold chain will be ensured in accordance with SOPs."* [emphasis added by NHS Resolution.]

6.35 As the Committee must be satisfied that the Applicant had explained how drugs/appliances will be provided to the patient (to ensure that the 'cold chain' is maintained), the Committee considered that the statement in the appeal that the pharmacy's own delivery drivers will be delivering cold chain creates sufficient ambiguity as to the Applicant's intentions. The Committee noted that the Applicant had not provided any information on the process that would be followed for deliveries of cold chain items by its own driver.

6.36 Therefore, the Committee could not be satisfied, as it was required to be, that during transit, the cold chain would be monitored throughout, or what would happen in the event of a breach of cold chain or failed/missed delivery by the pharmacy's own driver.

6.37 Based on the information before it, the Committee was not satisfied that the Applicant had provided sufficient information to show that there would be compliance with paragraph 8(1) of Schedule 4.

6.38 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

6.39 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).

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

6.40.1 confirm the Commissioner's decision;

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

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

6.41 Although the decision reached by the Committee is ultimately the same as the Commissioner, it has reached that decision for different reasons. Therefore, the Committee determined that the decision must be quashed.

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

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

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

7 Decision

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

7.2 Accordingly, the Committee:

7.2.1 quashes the decision of the Commissioner; and

7.2.2 redetermines the application as follows -

7.2.2.1 the Committee was satisfied that 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