NHS Resolution

8 May 2025

REF: SHA/26499

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APPEAL AGAINST NORTH EAST LONDON ICB DECISION TO REFUSE AN APPLICATION BY SPECIALS PHARMA LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT TC1-32 THE CUBE, YEWTREE AVENUE, DAGENHAM RM10 7FN 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:

Specials Pharma Ltd
North East London ICB

NHS Resolution

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1 The Application

By application undated, Specials Pharma Ltd ("the Applicant") applied to North East London ICB ("the Commissioner") for inclusion in the pharmaceutical list at TC1-32 The Cube, Yewtree Avenue, Dagenham RM10 7FN 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 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 "The Pharmacy is a distant selling pharmacy with the majority of contacts [sic] occurring either by phone or email. The product Medical Cannabis or CBPMs (Cannabis Based Products for Medicinal use in humans) is a "specials" or unlicensed medication and therefore subject to high levels of product safety issues. Currently prescription are private but the pharmacy via its PMR (Pharmacy Medication Record) system is validated for NHS use with all facilities such as repeat dispensing and others such as NMS etc. Our website will direct patient to our dedicated Patient Care Team who will sign post or pass to the pharmacist. Due to the medication communication to both clinics and doctors is extremely good. Health [sic] living is promoted namely around the use (Or in fact non use) of tabaco and the use of vaporisers as a healthier alternative.

1.6 The pharmacy and patients remain secure as

1.6.1 Prescriptions (Rx) are only from the Doctor or Clinic. There are no Rx direct from the patient

1.6.2 Patient information is received from the Dr and the patient is provided an introduction call to verify email and phone numbers, dr and clinic and to provide service information

1.6.3 There are SOPs in place for receiving Rx, Storing medication, assembly and dispensing and dispatch and returns

1.6.4 There are SOPs for Service Complaints, Product complaints and Adverse Events recording

1.6.5 There are SOPs for Controlled Drugs, unlicensed (Specials) medication and the chain of custody for CDs

1.6.6 There is dispensing error logs

1.6.7 There are SOPs for Drug Recalls, Quarantine and destructions

1.6.8 The Quality procedures also include qualifications, change control and non conformity

1.6.9 Deliveries are performed as signed only by an adult at the address by the logistics partner

1.6.10 All systems used are protected and backed up overnight

1.6.11 Pharmacy is fully staffed with a second pharmacist and 8 staff

1.6.12 There are 9 phone lines and 4 operators using a group email and an internal IT network."

2 **The Decision**

The Commissioner considered and decided to refuse the application. The decision letter dated 6 January 2025 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.

2.2 You have a right of appeal to the Secretary of State against North East London 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:

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

Extract from decision report

2.1 "Applicant's comments in the application

2.2 [See paragraphs 1.5 – 1.6.12 above]

2.3 LPC comments

2.4 North East London LPC have noted this application in respect of distance selling premises and as such is an accepted application under regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

2.5 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.

2.6 NEL LPC would like to be updated on any further communication on this application.

2.7 With regard to Regulation 31…

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

2.9 Regulation 25 [quoted]…

2.10 (a) 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.

2.11 (b) The applicant provided information via their application. This information has been assessed along with any comments provided.

2.12 The applicant needs to demonstrate that all the essential services can be provided without face to face contact to anyone in England that requests them. As there was very little additional information provided with this application, there is very little to make that assurance.

2.13 There is no clarity within the application that patients accessing essential services are not seen face to face.

2.14 There is information in the application regarding specials or unlicenced medicines which the pharmacy wishes to dispense, but little or no information about other services. The applicant needs to demonstrate that they are providing essential services to anyone in England who requests them but not face to face, a distance selling pharmacy should not just be providing limited services in one field.

2.15 The applicant also has not provided information regarding essential services as detailed below:

2.15.1 *Paragraph 5(2)(3) of Schedule 4 – no information provided.*

2.15.2 *Paragraph 6 of Schedule 4 - no information provided.*

2.15.3 *Paragraph 7(3) of Schedule 4 – no information provided.*

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

2.15.5 *Paragraph 8(1) of Schedule 4 – no information provided.*

2.15.6 *Paragraph 8(4) of Schedule 4 – no information provided.*

2.15.7 *Paragraph 8(15) of Schedule 4 – no information provided.*

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

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

2.15.10 *Paragraph 13 & 14 of Schedule 4– no information provided.*

2.15.11 *Paragraph 16 of Schedule 4– no information provided.*

2.15.12 *Paragraph 17 of Schedule 4– no information provided.*

2.15.13 *Paragraph 18 of Schedule 4– no information provided.*

2.15.14 *Paragraph 19 & 20 of Schedule 4– no information provided.*

2.15.15 *Paragraph 21 of Schedule 4– no information provided.*

2.15.16 *Paragraph 20(1) and Paragraph 22 of Schedule 4 – no information provided.*

2.15.17 *Paragraph 22B & 22C of Schedule 4 – no information provided.*

2.15.18 Pharmacy Website and health promotion zones – *limited information provided.*

2.16 It may be concluded that the London PSRC 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.

2.17 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.

2.18 Therefore, the PSRC have determined it 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.

2.19 Decision

2.20 Regulation 31.

2.21 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.

2.22 Regulation 25(2)(1)(a)

2.23 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.

2.24 Regulation 25(2)(1)(b)(i)

2.25 The London PSRC 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.

2.26 Regulation 25(2)(1)(b)(ii)

2.27 The London PSRC 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.

2.28 The London PSRC 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

Using NHS Resolution's online appeal form, submitted via email dated 5 February 2025, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "I believe that the PSRC are wrong in refusing this application for the following reasons set out in more details below

3.1.1 CBPM or Medical Cannabis has a number of restrictions due to the fact that they are controlled drugs and unlicensed. CBPMs are under further restrictions and regulation imposed by the MHRA, Home Office and the law regarding the classification of these medicines. It is a specialist area.

3.1.2 The supply chain is fragile and obtaining them can be difficult with a greater in depth understanding of the supply chain required. Something that the majority of retail pharmacies will avoid dispensing leaving only a few specialist providers. Currently there are only 10 or so in the UK.

3.1.3 An increasing number of NHS prescription for CBPMs is expected without there being many suppliers. The majority of suppliers, like Specials Pharma currently do not provide NHS services but private only. Patient will find an increasingly reduced access to medications. The PSCR Must take in consideration of how that may affect future NHS services as part of their report

3.1.4 Essential Services can be mainly provided where regulations permit. Services can be easily tailored to the unique group of people that take medical cannabis. Whilst we have no face to face as a DSP, patients are in regular contact via email or on the phone due to stock issues or the lack of product information. We have a patient care team that provides the customer relationship service.

3.2 Specials Pharma Ltd provides CBPMs or Medical Cannabis services only and our proposal is to continue to provide this specialist service. These drugs fall under the category of both a Schedule 2 controlled drug and an unlicensed (or "specials") medication and therefore service do not exactly fit what is expected of conventional medications. Allied to this there are few pharmacies that provide this service and outside of 2 private hospitals none in London. The provision of the service is therefore not met by NHS England and further access is required of which we are offering.

3.3 Medical Cannabis has mainly been dispensed as private medicine of which we have been dispensing for 4 years and is becoming more available through the NHS. Hence the application. Due to the fragility of the supply chain and the complexity of the various cultivars of this medication it can only be supplied by dedicated pharmacies who focus solely on this medication. Our prescribers and patients rely on up-to-date medication information which would be difficult if not impossible to provide via a normal pharmacy and can only be performed as a specialist service which we are. If all the listed pharmacies or even all pharmacies in London were asked if they knew what CBPMs

are and whether they intend to dispense them then the answer would be a resounding no on both counts.

3.4 The PSRC have determined that an oral hearing is not required, unfortunately this is not correct as the nature of these medication cannot be explained by a tick box form but would require further explanation. The PSRC is concerned that we may not be able to fulfil our obligation to provide essential services is incorrect as we have been operating privately and providing these services customed to the medication and the regulations applied to them.

3.5 Essential Services offered by Specials Pharma (SP)

3.6 Paragraph 5(2)(3) of Schedule 4 – SP offers the majority of these services and dispense within a reasonable time to non-EPS prescription for both medication and appliances. In the case of appliances SP has thus far only provides [sic] vaporisers for medical cannabis to be administered but are able to provide any conventional appliance. Currently the unlicenced CD are NOT available as part of the EPS and all prescriptions are provided with a wet signature as originals as per MHRA Guidance 14.

3.7 Paragraph 6 of Schedule 4 – These are schedule 2 and there is no regulations that allows repeats. SP does from time to time receive post dated prescriptions especially for those patient that are bad at managing their medication

3.8 Paragraph 7(3) of Schedule 4 – This would be performed for all NHS prescriptions received as part of the SOPs.

3.9 Paragraph 7(5)(b) of Schedule 4 – There is no prevision [sic] for unlicensed CD to be part of EPS. All prescriptions would be originals and sent as per the SOPs

3.10 Paragraph 8(1) of Schedule 4 – All prescriptions are checked by a registered pharmacist only as they are controlled drugs and can only be checked by one. This is part of the SOP and our practice for the last 4 years.

3.11 Paragraph 8(4) of Schedule 4 – As there is no face to face as per the regulations for a DSP this can only be performed by a pharmacist sending the relevant information to the patient and checking via zoom or by whatsapp. This is not currently in the SOPs but will be added.

3.12 Paragraph 8(15) of Schedule 4 – This can be performed easily with solutions but may not be for most dry flowers as they come sealed to reduce any issues especially mould as these are products with a water content and therefore susceptible to mould.

3.13 Paragraph 9(4) of Schedule 4 – There no provision for EPS for unlicensed controlled drugs. Should this change then SP will offer the service.

3.14 Paragraph 10(1) of Schedule 4– This is currently being performed. All new patient go through an introduction call followed by an email in which the following is stated “we are a registered pharmacy and can help with this or other medication. Ask if they wish to discuss their medication with a pharmacist.”

3.15 Paragraph 13 & 14 of Schedule 4– Currently we offer this services and have patient returns that are disposed of. We arrange uplift of the product, quarantine and then dispose of them in a CD disposal unit or doop bin for our clinical waste carrier to dispose of appropriately. The process requires a number of forms to be filled and is part of the SOPs

3.16 Paragraph 16 of Schedule 4– Where possible this is performed especially with tobacco as many of the patients come from the illicit market and need to be weaned off smoking. It is also explained to patient that using medical cannabis with tobacco will revert the drug from schedule 2 to schedule 1 status and thereby making it illegal to administer. Sign posting to their local pharmacy is offered.

3.17 Paragraph 17 of Schedule 4– We do not receive any information on any conventional medication. Patients do from time to time call about other illnesses and are put through to a pharmacist who will offer help, advice and signpost if necessary. In some cases where a patient care team member has picked up on issues this is transferred to the pharmacist to handle.

3.18 Paragraph 18 of Schedule 4– Currently we do not have a formalised system. However, as all patients receive email communications about there [sic] order any public health campaign can easily be added to the email template as a link to information. This can be added to our SOPs

3.19 Paragraph 19 & 20 of Schedule 4– Where necessary patients are referred to a patient advocacy group when they fall into any difficulties with housing, law etc. As these patients are under a consultant they are often referred back to their clinic as been [sic] best placed to offer health signposting.

3.20 Paragraph 21 of Schedule 4– Within the requirements for a consultant to provide medical cannabis, patient that cannot self-care would be excluded, and we have not had patients that fit this category. However, support can be given for information if needed. Should the situation change the SP will provide this service.

3.21 Paragraph 20(1) and Paragraph 22 of Schedule 4 – All incidents are recorded in an incidence form.

3.22 Paragraph 22B & 22C of Schedule 4 – There are no protocols for discharge medicines for medical cannabis. If the situation changes then this can provided for and the SOP amended."

4 Summary of Representations

This is a summary of representations received on the appeal.

4.1 THE COMMISSIONER

4.1.1 "I am writing in response to the above application where an appeal has been lodged against our decision to refuse the application.

4.1.2 The applicant has stated in their appeal that they *ONLY* provide CBPMs or Medical Cannabis services and propose to continue to provide this specialist service only.

4.1.3 An application to provide NHS services as a distance selling pharmacy (DSP) is to provide services to anyone in England that requests them, and a DSP should be providing a full NHS service and not just for a limited product group. That means that the pharmacy should be dispensing any NHS prescription that they are presented with. The response from the applicant makes this clear that this is not the case.

4.1.4 The applicant has provided more information regarding the essential services elements that we had identified as missing from their application but against a backdrop of only providing this limited product group related to medical

cannabis rather than across the whole range of services and dispensing any NHS prescription they may be presented with.

4.1.5 The information provided does not provide sufficient assurance that the pharmacy will be able to provide a full range of services, without face to face to anyone in England that requests them.

4.1.6 From the information in the original application and the appeal response, we believe that not all essential services will be provided, an updated assessment is given below:

4.1.6.1 *Paragraph 5(2)(3) of Schedule 4 – no information provided.*

4.1.6.2 *Paragraph 6 of Schedule 4 - no information provided.*

4.1.6.3 *Paragraph 7(3) of Schedule 4 – limited information provided.*

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

4.1.6.5 *Paragraph 8(1) of Schedule 4 – limited information provided.*

4.1.6.6 *Paragraph 8(4) of Schedule 4 – limited information provided.*

4.1.6.7 *Paragraph 8(15) of Schedule 4 – limited information provided.*

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

4.1.6.9 *Paragraph 10(1) of Schedule 4– limited information provided.*

4.1.6.10 *Paragraph 13 & 14 of Schedule 4– limited information provided.*

4.1.6.11 *Paragraph 16 of Schedule 4– limited information provided.*

4.1.6.12 *Paragraph 17 of Schedule 4– limited information provided.*

4.1.6.13 *Paragraph 18 of Schedule 4– no information provided.*

4.1.6.14 *Paragraph 19 & 2*0 *of Schedule 4– limited information provided.*

4.1.6.15 *Paragraph 21 of Schedule 4– no information provided.*

4.1.6.16 *Paragraph 20(1) and Paragraph 22 of Schedule 4 – no information provided.*

4.1.6.17 *Paragraph 22B & 22C of Schedule 4 – no information provided.*

4.1.6.18 Pharmacy Website and health promotion zones – *limited information provided.*

4.1.7 We would therefore request that this appeal be dismissed, and the application refused."

5 Summary of Observations

This is summary of observations received.

5.1 NORTH EAST LONDON LPC

5.1.1 “NEL LPC did not receive the initial communication regarding this application.

5.1.2 We are now responding to your email sent on 24th March 2025. The applicant has stated that they will only supply CBPMs or Medical Cannabis as a specialist service however this is not following the regulations of a distance selling pharmacy (DSP). There is no mention in the PNA of this specialist service being required. If a DSP is given permission to open it must provide a full DSP service. Any NHS prescription that they are presented with must be dispensed. This applicant has stated that they will only focus on Canabis [sic].

5.1.3 We cannot be reassured that this applicant will be meeting DSP regulations and therefore the appeal should be rejected.”

6 Late Observations

6.1 THE APPLICANT

6.1.1 “It is unfortunate, but not surprising, that the NHS has refused this application. This is a new branch of medication that is different from what is viewed as conventional. Over time, and I will include myself, there is a lot of prejudice against medical cannabis, and it's use as medicines. I was one but after seeing some of the amazing result, and yes some not so, I am convinced that this is a valid medication, and it has its use within the current portfolio of medicines used. We are not against dispensing "normal medicines" (Any that we are asked to by our patients) but were highlighting the need for specialist to provide a medical cannabis dispensing services to patients that require them.

6.1.2 Most of which are on conventional medicines and hence the application for a NHS license, as these medicines unlike medical cannabis are on NHS prescriptions. Neither are we against providing any essential services within this remit and for those that wish us to dispense there [sic] NHS medication. The evidence in other countries where medical cannabis is more established is that the supply is performed by specialist pharmacies dispensing this specialist medicines alongside the patients' regular medication. Currently we are providing medical cannabis on private prescriptions without view of any other medication. This is particularly difficult as many of our "pain" patients use medical cannabis to reduce their use of opiates and are in the processes of slowly reducing opiates and increasing their medical cannabis. This branch of medication will only increase over time with average estimates of 2.5 million patients within the next 10 years. As such we are on the frontier of proving [sic] a service (And probably a soon to be NHS one) and are looking to how best to serve the patient in a safe manner. I believe the NHS has attempted to fit a round peg in a square hole and not looked at the bigger picture of patient safety. Something that I would like to work in partnership with the NHS so that this service can be continuously improved for this set of patients.”

7 Consideration

7.1 The Pharmacy Appeals Committee (“Committee”) appointed by NHS Resolution, had before it the papers considered by the Commissioner.

7.2 It also had before it the responses to NHS Resolution’s own statutory consultations.

7.3 The Applicant challenges the Commissioner’s decision, not to hold an Oral Hearing. The Applicant states that *“the nature of these medication cannot be explained by a tick*

box form but would require further explanation". However the Committee considered that to determine the application by way of an Oral Hearing, there needs to be conflicting evidence provided by parties that it cannot resolve on the papers. The Committee did not consider that to be the case here. Therefore on the basis of this information provided, the Committee considered it was not necessary to hold an Oral Hearing.

7.4 The Committee noted the Applicant's comments that it "*provides CBPMs or Medical Cannabis services only and our proposal is to continue to provide this specialist service*." However, the Committee was mindful that the Applicant has applied under Regulation 25 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations") to open a distance selling pharmacy premises and as such must be considered against the relevant criteria in the Regulations.

7.5 Further in its application form, under the heading 'Pharmaceutical services to be provided at these premises', the Applicant ticked the box next to 'Essential Services are to be provided (paragraphs 3 to 22, Schedule 4)' which the Committee noted are the Terms of service of NHS pharmacists.

7.6 The Committee therefore proceeded to consider the application in line with the relevant Regulations.

Regulation 31

7.7 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).

7.8 The Committee noted that the Applicant had not provided any information in the application form on this point but the Committee 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. The Commissioner in its decision report concluded that "*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" which has not been disputed by any party.

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

Regulation 25

7.10 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."

7.11 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)

7.12 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)

7.13 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 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 *"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.*"

7.14 Based on the information available to it, which had not been disputed by any party, 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)

7.15 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.

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

7.17 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.

7.18 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. The Committee has sought

evidence within the application in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.

7.19 The Committee noted in the information provided, the Applicant refers to non face to face contact as well as contacting patients via email or phone. The Committee was aware that if 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.

7.20 Further the Committee noted the Applicant states that the "*Pharmacy is fully staffed with a second pharmacist and 8 staff*".

7.21 The Committee was therefore satisfied that the provision of services would be without interruption and would be without face to face contact.

7.22 However the Committee was not satisfied that the provision of services would be available to persons anywhere in England as the Applicant had not mentioned this anywhere in its application, on appeal or in its late observations.

7.23 The Committee went on to consider whether safe and effective provision of essential services was likely to be secured. The Committee considered each essential service in paragraphs 3 to 22 of Schedule 4 of the Regulations ("Terms of service") in turn.

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

7.24.1 Dispensing of drugs and appliances

7.24.2 Urgent supply without a prescription

7.24.3 Preliminary matters before providing ordered drugs or appliances

7.24.4 Providing ordered drugs or appliances

7.24.5 Refusal to provide drugs or appliances ordered

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

7.24.7 Disposal service in respect of unwanted drugs

7.24.8 Promotion of healthy lifestyles

7.24.9 Prescription linked intervention

7.24.10 Health campaigns

7.24.11 Signposting

7.24.12 Support for self-care

7.24.13 Discharge medicines service

7.24.14 Websites and health promotion zones

7.25 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:

Dispensing of drugs and appliances

7.26 The Committee considered whether the Applicant had explained how non-electronic prescriptions will be presented by the patients and how products would be provided.

7.27 Beyond its comments that it "*offers the majority of* [essential services] *and dispense within a reasonable time to non-EPS prescription for both medication and appliances",* the Committee noted that no information had been provided by the Applicant as to how any patient would present their non-electronic prescription to the pharmacy.

7.28 The Applicant also states that "*the unlicenced CD are NOT available as part of the EPS and all prescriptions are provided with a wet signature as originals as per MHRA Guidance 14*." However again, this information was not sufficient to enable the Committee to be satisfied that it will adhere to its Terms of service as set out in the Regulations.

7.29 Given the lack of information with regard to the receipt of non-electronic prescriptions, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 5(2)(3) of Schedule 4.

Urgent supply without a prescription

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

7.31 In its appeal, the Applicant states that it "*does from time to time receive post dated prescriptions especially for those patient that are bad at managing their medication*". However the Committee did not consider this to be sufficient to explain how the Applicant would safely and effectively receive requests from prescribers for urgent supplies of drugs and appliances.

7.32 The Committee was not therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.

Preliminary matters before providing ordered drugs or appliances

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

7.34 Beyond its comments that "*This would be performed for all NHS prescriptions received as part of the SOPs*" the Committee noted that the Applicant had not explained how evidence of any exemption would be obtained from the patient.

7.35 The Committee was not therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.

7.36 The Committee considered whether the Applicant had explained how charges will be paid and noted that no information had been provided in this regard.

7.37 Therefore the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(5)(b) of Schedule 4.

Providing ordered drugs or appliances

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

7.39 The Committee noted the Applicant's reference to SOPs being in place for "*dispatch*", "*Controlled Drugs, unlicensed (Specials) medication and the chain of custody for CDs*" however copies of these SOPs were not provided on appeal.

7.40 Further the Applicant states that "*Deliveries are performed as signed only by an adult at the address by the logistics partner*" and further "*All prescriptions are checked by a registered pharmacist only as they are controlled drugs and can only be checked by one. This is part of the SOP and our practice for the last 4 years.*"

7.41 However no information had been provided regarding the delivery of cold chain items, for example there was no information to explain how the Applicant would ensure the cold chain is maintained and monitored up to and including the point of delivery, what would happen to any items if the cold chain is not maintained during transit, or what would happen in the event of a missed/failed delivery. In terms of Controlled Drugs, no information had been provided as to how the Applicant would ensure Controlled Drugs are delivered securely, or what would happen in the event of a missed/failed delivery.

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

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

7.44 The Committee noted that the Applicant had not provided any information on the application form with regard to the provision of appliances and had left this blank. In its appeal, the Applicant states "*In the case of appliances SP has thus far only provides vaporisers for medical cannabis to be administered but are able to provide any conventional appliance*." and further *"As there is no face to face as per the regulations for a DSP this can only be performed by a pharmacist sending the relevant information to the patient and checking via zoom or by whatsapp. This is not currently in the SOPs but will be added."*

7.45 However, no information had been provided to explain how a registered pharmacist would measure / fit any appliances which required measuring / fitting, in a distance selling setting. For example, a pharmacist could not fit an appliance via zoom. It would need to happen in person, either at the patient's home or elsewhere, other than the pharmacy premises.

7.46 Therefore, based on the information provided, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(4) of Schedule 4.

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

7.48 Beyond its comments that "*This can be performed easily with solutions but may not be for most dry flowers as they come sealed to reduce any issues especially mould as these are products with a water content and therefore susceptible to mould*" the Committee noted that no information had been provided by the Applicant to explain what suitable containers it would use to post/deliver items.

7.49 Therefore the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(15) of Schedule 4.

Refusal to provide drugs or appliances ordered

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

7.51 The Applicant states that *"There no* [sic] *provision for EPS for unlicensed controlled drugs. Should this change then SP will offer the service."* The Committee was mindful that the Applicant has applied to provide all essential services as per the Terms of service set out in the Regulations.

7.52 As no information had been provided in this regard, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 9(4) of Schedule 4.

Disposal service in respect of unwanted drugs

7.53 The Committee considered whether the Applicant had explained or otherwise demonstrated how it will safely and effectively accept and dispose of unwanted drugs presented to it for disposal.

7.54 The Applicant states that "*Currently we offer this services and have patient returns that are disposed of. We arrange uplift of the product, quarantine and then dispose of them in a CD disposal unit or doop bin for our clinical waste carrier to dispose of appropriately. The process requires a number of forms to be filled and is part of the SOPs."*

7.55 However the Committee noted that no information had been provided to explain how patients will be able to return any unwanted items to the pharmacy, whether it's via pre-paid envelopes sent to patients upon request, or whether it's through a delivery driver or courier.

7.56 Therefore the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 13 – 15 of Schedule 4.

Promotion of healthy lifestyles

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

7.58 The Applicant states that "*Health* [sic] *living is promoted namely around the use (Or in fact non use) of tabaco and the use of vaporisers as a healthier alternative*" and further "*Where possible this is performed especially with tobacco as many of the patients come from the illicit market and need to be weaned off smoking. It is also explained to patient*

that using medical cannabis with tobacco will revert the drug from schedule 2 to schedule 1 status and thereby making it illegal to administer. Sign posting to their local pharmacy is offered." However, the Committee considered this was specific to those patients who smoke. There was no general information around how the Applicant would safely and effectively promote healthy lifestyles to all patients.

7.59 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 16 – 18 of Schedule 4.

Support for self-care

7.60 The Committee considered whether the Applicant had explained or otherwise demonstrated how it will provide advice and support for people caring for their families.

7.61 The Applicant states that "*Within the requirements for a consultant to provide medical cannabis, patient that cannot self-care would be excluded, and we have not had patients that fit this category. However, support can be given for information if needed. Should the situation change the SP will provide this service.*" However, no information has been provided regarding how it will provide advice and support for people caring for their families.

7.62 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 21 – 22 of Schedule 4.

Discharge medicines service

7.63 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 and NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.

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

7.65 The Applicant states that "*There are no protocols for discharge medicines for medical cannabis. If the situation changes then this can provided for and the SOP amended*." However, the Committee was mindful that the Applicant has applied to provide all essential services as per the Terms of service set out in the Regulations.

7.66 As no information had been provided in this regard, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

Websites and health promotion zones

7.67 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.

7.68 Beyond its comment that "*Our website will direct patient to our dedicated Patient Care Team who will sign post or pass to the pharmacist*" the Committee noted that limited information had been provided regarding its website, in particular whether there will be an interactive web page.

7.69 Therefore, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 28C of Schedule 4.

7.70 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

7.71 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).

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

7.72.1 confirm the Commissioner's decision;

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

7.72.3 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.

7.73 Although the Committee has reached the same conclusion to that of the Commissioner, the Committee has provided further reasoning for its decision. In those circumstances, the Committee determined that the decision of the Commissioner must be quashed.

7.74 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.

7.75 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.

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

8 Decision

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

8.2 Accordingly, the Committee:

8.2.1 quashes the decision of the Commissioner; and

8.2.2 redetermines the application as follows -

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

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

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

8.2.2.4 the Committee was not satisfied that all essential services were likely to be secured for persons anywhere in England,

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

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

8.2.3 The application is refused.

Technical Case Manager
Primary Care Appeals