

11 June 2021

REF: SHA/24562

Arena Point
Merrion Way
Leeds
LS2 8PA

**APPEAL AGAINST NHS COMMISSIONING BOARD
"NHS ENGLAND" DECISION TO REFUSE AN
APPLICATION BY MEDI PILLS LTD FOR INCLUSION IN
THE PHARMACEUTICAL LIST AT 60 CARTMEL DRIVE,
WOODLEY, READING, RG5 3NQ UNDER REGULATION
25**

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1 Outcome

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

A copy of this decision is being sent to:

Mr Sagarkumar Patel – Medipills Pharmacy
Boots UK Ltd
The Reading Pharmacy
Pharmacy Thames Valley

Advise / Resolve / Learn

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1 The Application

By application dated 28 September 2020, Medipills Ltd ("the Applicant") applied to NHS Commissioning Board ("NHS England") for inclusion in the pharmaceutical list at 60 Cartmel Drive, Woodley, Reading, RG5 3NQ 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 left this section blank.
- 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:
 - 1.4.1 (a) the uninterrupted provision of essential services during the opening hours of the premises, to persons anywhere in England who request those services, and
 - 1.4.2 (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 Applicant have Standard Operating Procedures in place to ensure safe and effective running of pharmacy with uninterrupted essential services and patient care [sic]. Being an Internet Pharmacy, people anywhere in the UK would be able to contact the Applicant via telephone, Email or Post where the Applicant's Pharmacist and qualified staff members are available to assist them with any queries they may have. With the help of Royal Mail, the Applicant have robust Medicine Delivery system in place all over the UK [sic]. The Applicant's delivery system ensures that patients receive their medicines promptly and without any breach of confidentiality. All the medicines including controlled drugs are delivered by Royal Mail tracked delivery. Any fridge lines are delivered without compromising "Cold Chain" with special delivery of fridge items. The Applicant will not have any customer / patient access at [its] premise and will not be providing any advanced services at the premises. Also, being an independent internet pharmacy contractor, grants the Applicant the flexibility needed to provide out of hours patient care.

2 The Decision

NHS England considered and decided to refuse the application. The decision letter dated 8 April 2021 states:

2.1 NHS England has considered the above application and [is] writing to confirm that it has been refused. Please see the enclosed report for the full reasoning.

NHS England South East (Thames Valley) Pharmaceutical Services Regulation Committee decision report.

2.2 Medipills Ltd – Distance Selling
60, Cartmel Drive, Woodley, Reading, RG5 3NQ
CAS-35745-Q8H9C2 / ME413
Wokingham HWB

2.3 The Application

2.4 An application from Medipills Ltd for a Distance Selling Premises Application was received on 17 August 2021. The Committee was now required to consider the application in accordance with Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended.

2.5 Consideration

2.6 The Committee considered the following:

2.7 The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended.

2.7.1 Department of Health guidance on Distance Selling Premises.

2.7.2 The application form provided by the Applicant.

2.7.3 Representations made by Boots UK Ltd, Thames Valley LPC, The Reading Pharmacy.

2.7.4 The Applicant's response to the representations received during the consultation period.

2.7.5 The Committee decided it was not necessary to hold an oral hearing before determining the application.

2.7.6 A map of the locality showing the nearest community pharmacies and GP Surgeries, in relation to the proposed premises for the Distance Selling pharmacy.

2.8 Regulation 31 – Refusal: same or adjacent premises

2.9 The Committee noted that it was required to refuse an excepted application, if the two conditions under paragraph 31(2) applied. These conditions are –

2.9.1 *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 the premises to which the application relates, or adjacent premises; and*

2.9.2 *The NHSCB is satisfied that it is reasonable to treat the services that the applicant proposes to provide as part of the same service as the existing*

services (and so the premises to which the application relates and the existing listed chemist premises should be treated as the same site).

- 2.10 The Committee was satisfied there is no pharmacy providing pharmaceutical services at the same or adjacent premises. The application did not therefore need to be refused in accordance with Regulation 31.
- 2.11 The Applicant stated on the application form that they intend to provide advanced services (MUR & NMS).
- 2.12 The Committee noted that the pharmacy intends to open for 42.3 core hours per week and would be staffed by a pharmacist.
- 2.13 In its consideration of the reasons supplied by the Applicant as to why the application should not be refused, the Committee noted that the Applicant had not detailed how they would comply with all essential services and gave no details of how they provide support for self-care element.
- 2.14 **Regulation 25(1)**
- 2.15 The Committee noted that as this was a distance selling application Regulation 25(1) indicates that section 129(2A) of the National Health Service Act 2006 does not apply, provided that Regulation 25(2) does not require the application to be refused.
- 2.16 **Regulation 25(2)(a)**
- 2.17 The Committee noted the proposed address and that it is not in the same site or building as a provider of primary medical services with a patient list. The Committee therefore did not have to refuse the application under Regulation 25(2)(a).
- 2.18 **Regulation 25(2)(b)**
- 2.19 The Committee noted that it had to be satisfied that services would be provided on an uninterrupted basis to patients anywhere in England and that essential services would be provided safely and effectively without face to face contact.
- 2.20 The Committee noted that there was minimal information provided within the application form to provide NHS England with assurance.
- 2.21 The Committee was not satisfied that there would be uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.
- 2.22 The Committee took the view that where compliance with the Terms of Service would ordinarily require face to face contact, the Applicant must explain how it is going to achieve compliance (and therefore safe and effective provision) without the face to face contact.
- 2.23 The Committee considered Schedule 4 to the Regulations having regard to the additional information supplied by the Applicant in support of the application.
- 2.24 **Schedule 4, paragraph 7** – the Committee considered whether the Applicant had explained how evidence would be sought and provided about the patient's entitlement to exemption from NHS Charges. The Committee noted the Applicant's had not provided any information or comments regarding how evidence would be sought and provided about the patient's entitlement to exemption from NHS Charges.
- 2.25 The Committee was not satisfied that paragraph 7 would be complied with effectively.

- 2.26 **Schedule 4, paragraph 14** - The Committee considered whether the Applicant had explained how it would accept unwanted drugs from patients. The Committee noted the Applicant had not provided any information or comments, indicating how the pharmacy will arrange for the unwanted medication to be collected from patients.
- 2.27 The Committee was not satisfied that the requirement of paragraph 14 would be complied with safely and effectively.
- 2.28 **Schedule 4, paragraph 16** – The Committee considered the Applicant had explained how it would promote public health messages to members of the public.
- 2.29 The Committee considered it had not been provided with sufficient information and was not satisfied that paragraph 16 would be complied with safely and effectively.
- 2.30 **Schedule 4, paragraph 19** - The Committee concluded the Applicant had not demonstrated how it would assess patients' need before signposting them in order to minimise inappropriate use of health or social care services.
- 2.31 **Schedule 4, paragraph 21** – The Committee concluded the Applicant had not demonstrated how it would provide advice or support for people caring for themselves or their families.
- 2.32 **Schedule 4, paragraph 28** - The Committee concluded the Applicant had not demonstrated how it would comply with all components of clinical governance element of the Terms of Service.
- 2.33 Decision
- 2.34 The Committee concluded that it was not required to refuse the application under the provisions of Regulation 31.
- 2.35 The Committee determined the application as follows –
- 2.35.1 the Committee was satisfied that the proposed premises were not adjacent to or in close proximity to other chemist premises.
 - 2.35.2 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,
 - 2.35.3 the Committee was not satisfied that all essential services were likely to be secured without interruption during the opening hours,
 - 2.35.4 the Committee was not satisfied that all essential services were likely to be secured for persons anywhere in England,
 - 2.35.5 the Committee was not satisfied that all essential services were likely to be secured in a safe and effective manner,
 - 2.35.6 the Committee was not satisfied that all essential services were likely to be secured without face to face contact;
 - 2.35.7 The Committee determined to refuse the application.
- 2.36 Third Party Rights of Appeal
- 2.37 The application is refused so the Applicant has the right to appeal.

- 2.38 The Committee decided not to grant third party rights of appeal to the decision of NHS England and Improvement to any of the parties that responded during the consultation period because the application had been refused.

3 The Appeal

In a letter dated 2 April 2021, Medipills Ltd appealed against NHS England's decision. The grounds of appeal are:

- 3.1 In response to refusal of Market Entry of Medipills Pharmacy as a Distance Selling Pharmacy, [the Applicant] would like to appeal the outcome by the NHS Market Entry team. Explanation is provided as below. Also, please find attached relevant "Standard Operating Procedures" of Medipills Pharmacy.
- 3.2 The Committee noted that the pharmacy intends to open for 42.3 core hours per week and would be staffed by a pharmacist. Pharmacist and Dispenser [sic].
- 3.3 In its consideration of the reasons supplied by the Applicant as to why the application should not be refused, the Committee noted that the Applicant had not detailed how they would comply with all essential services and gave no details of how they provide support for self-care element.
- 3.4 The Applicant states please refer to SOP 23 SOP 25.
- 3.5 Regulation 25(1)
- 3.6 The Committee noted that as this was a distance selling application Regulation 25(1) indicates that section 129(2A) of the National Health Service Act 2006 does not apply, provided that Regulation 25(2) does not require the application to be refused.
- 3.7 Regulation 25(2)(a). The Committee noted the proposed address and that it is not in the same site or building as a provider of primary medical services with a patient list. The Committee therefore did not have to refuse the application under Regulation 25(2)(a).
- 3.8 Regulation 25(2)(b) The Committee noted that it had to be satisfied that services would be provided on an uninterrupted basis to patients anywhere in England and that essential services would be provided safely and effectively without face to face contact.
- 3.9 The Committee noted that there was minimal information provided within the application form to provide NHS England with assurance.
- 3.10 The Committee was not satisfied that there would be uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.
- 3.11 [The Applicant states] there is no reason for any interruption in any essential services during opening hours. The Applicant would have Responsible Pharmacist and dispenser present during opening hours of the Pharmacy [sic]. Also, patients can contact the Applicant via telephone and email / website, from anywhere in UK.
- 3.12 The Committee took the view that where compliance with the Terms of Service would ordinarily require face to face contact, the Applicant must explain how it is going to achieve compliance (and therefore safe and effective provision) without the face to face contact.

- 3.13 As being a Distance Selling pharmacy, face to face contact is not possible. However, it doesn't stop the Applicant from communicating effectively with [its] customers. Patients can contact the Applicant via telephone or Email.
- 3.14 Also, [the Applicant] can provide information over the video call whenever necessary. This way, the Applicant can provide safe and effective service to [its] patients.
- 3.15 The Committee considered Schedule 4 to the Regulations having regard to the additional information supplied by the Applicant in support of the application.
- 3.16 Schedule 4, paragraph 7 – the Committee considered whether the Applicant had explained how evidence would be sought and provided about the patient's entitlement to exemption from NHS Charges.
- 3.17 The Committee noted the Applicant's had not provided any information or comments regarding how evidence would be sought and provided about the patient's entitlement to exemption from NHS Charges.
- 3.18 The Committee was not satisfied that paragraph 7 would be complied with effectively.
- 3.19 The Applicant states for this, please refer to SOP 8, related paragraph is highlighted.
- 3.20 Schedule 4, paragraph 14 - The Committee considered whether the Applicant had explained how it would accept unwanted drugs from patients. The Committee noted the Applicant had not provided any information or comments, indicating how the pharmacy will arrange for the unwanted medication to be collected from patients.
- 3.21 The Committee was not satisfied that the requirement of paragraph 14 would be complied with safely and effectively.
- 3.22 The Applicant states they do have information on [their] website regarding collection of unwanted medicines (website is not live yet as not allowed to make it live before getting NHS contract).
- 3.23 Please find attached document, which is also available on the Applicants website.
- 3.24 Attached file Name: "Unwanted medicine screenshot of website".
- 3.25 Attached file Name: "Unwanted-Medicines- Information"
- 3.26 Schedule 4, paragraph 16 – The Committee considered the Applicant had explained how it would promote public health messages to members of the public.
- 3.27 The Committee considered it had not been provided with sufficient information and was not satisfied that paragraph 16 would be complied with safely and effectively.
- 3.28 For the promotion of Public Health, the Applicant state they would use [their] website, Medipills.co.uk. The Applicant would review and update contents [their] website on regular basis [sic].
- 3.29 The Applicant would run various public health campaign related to diabetes, coronary heart disease, high blood pressure, for the people who smoke or are overweight on regular basis on [the Applicant's] website.
- 3.30 Schedule 4, paragraph 19 - The Committee concluded the Applicant had not demonstrated how it would assess patients' need before signposting them in order to minimise inappropriate use of health or social care services.

- 3.31 The Applicant states: please find attached SOP 24 for this.
- 3.32 Schedule 4, paragraph 21 – The Committee concluded the Applicant had not demonstrated how it would provide advice or support for people caring for themselves or their families.
- 3.33 The Applicant states: please refer to SOP 23 and SOP 25.
- 3.34 Schedule 4, paragraph 28 - The Committee concluded the Applicant had not demonstrated how it would comply with all components of clinical governance element of the Terms of Service.
- 3.35 The Applicant states they would follow Clinical Governance guidance from PSNC (Guidance from Pharmacy Contractors).
- 3.36 Please find attached documents.
- 3.37 Attached file Name: Clinical Governance Service Specification
- 3.38 Attached file Name: Clinical_Governance_guidance_updated_final

4 **Summary of Representations**

This is a summary of representations received on the appeal.

4.1 THE READING PHARMACY

- 4.1.1 This should not be allowed to pass, Woodley has more than enough provision for pharmaceutical provision including many pharmacies that deliver medication in person, NOT by royal mail unaudited and unmonitored post (no temperature regulation is in place). The Reading Pharmacy being one of those pharmacies that personally deliver using a CRB checked delivery driver, hence ensuring safe and accurate medication supply.
- 4.1.2 Providing pharmaceutical services from a residential premises should not be permitted and must be checked with the local council as this surely must be some sort of breach of regulations.

4.2 NHS ENGLAND

- 4.2.1 The application was refused on the basis that the Applicant had not provided evidence to assure NHS England with regard to Regulation 25(2)(b) i.e. that:
- 4.2.2 *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.*
- 4.2.3 The Applicant has provided some additional information that was not available to the Pharmaceutical Services Regulations Committee (PSRC) when it was making its decision. However, whilst the Applicant indicates they will comply with the requirements and provides some SOPs and a copy of guidance on Clinical Governance, they do not explain **how** they are going to implement those requirements such that the services are provided without face to face contact and to persons anywhere in England.

4.2.4 The PSRC respectfully requests that the decision made by NHS England to refuse the application is confirmed.

4.3 PHARMACY THAMES VALLEY LPC

4.3.1 Pharmacy Thames Valley LPC comments submitted within the 45 day consultation period still stand, and these are highlighted below. The local NHS team made the original decision based on their sound local knowledge and the LPC agree with the original decision to refuse the application.

4.3.2 An application for inclusion on the pharmaceutical list for a distance selling/ wholly internet pharmacy must be judged against the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 having particular concern to regulation 25 and 64. The following criteria must be taken into account when an application is considered and the LPC has considered these criteria and has included their comments on them:

4.3.3 **A distance selling pharmacy must not provide Essential services to a person who is present at the pharmacy, or in the vicinity of it. In addition, the pharmacy's SOPs must provide for the Essential services to be provided safely and effectively without face to face contact with any member of staff on the premises.** The documentation provided with the application does not include sufficient evidence of relevant SOPs and so the LPC would expect that NHS England would assure itself that there will be appropriate procedures in place.

4.3.4 **A distance selling pharmacy may provide Advanced and Enhanced services on the premises, as long as any Essential service which forms part of the Advanced or Enhanced service is not provided to persons present at the premises.** The application paperwork does not contain the relevant SOPs to allow the LPC to comment and so we would expect NHS England to seek further assurances.

4.3.5 **The pharmacy's procedures and SOPs must allow for the uninterrupted provision of Essential services during the opening hours of the pharmacy to anyone in England who requests the service.** The Applicant states that any breaks will be covered by a second pharmacist but gives no indication of how this would be managed or indication of likely levels of staff and the LPC would have concerns about sole working and the issues around sourcing pharmacist cover for short periods. The LPC would seek assurance of how NHS England will monitor compliance with contractual hours.

4.3.6 **Nothing in any written or oral communication such as a practice leaflet or any publicity can suggest, either expressly or impliedly, that services will only be available to persons in particular areas of England, or only particular categories of patients will (or will not) be provided for.** The Applicant includes a statement to this effect and the LPC would expect NHS England to check this if the contract is granted.

5 Summary of Observations

5.1 THE READING PHARMACY

5.1.1 The Reading Pharmacy confirm their previous response to the appeal that the contract should not be granted for the reasons mentioned in their first response.

6 Consideration

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

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

- 6.6 The Committee noted that the Applicant had not provided any information in the application form on this point but 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. Furthermore, the Committee noted NHS England’s comment in the decision report that the proposed premises were not adjacent to or in close proximity to other chemist premises. The Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

- (2) *The NHSCB must refuse an application to which paragraph (1) applies—*
 - (a) *if the premises in respect of which the application is made are on the same site or in the same building as the premises of a provider of primary medical services with a patient list; and*
 - (b) *unless the NHSCB is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure—*
 - (i) *the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and*
 - (ii) *the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff."*

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

Additional information to be included with excepted applications

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

Nature of details to be supplied

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

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

- 6.9.1 confirm NHS England's decision;
- 6.9.2 quash NHS England's decision and redetermine the application;
- 6.9.3 quash NHS England's decision and, if it considers that there should be a further notification to the parties to make representations, remit the matter to NHS England.

Regulation 25(1)

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

Regulation 25(2)(a)

- 6.11 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.
- 6.12 The Committee noted that NHS England's decision states "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". The Committee noted that this had not been disputed and that it had not been provided with any information to persuade it otherwise.
- 6.13 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)

- 6.14 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 certain Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.
- 6.15 The Committee considered whether the Applicant had explained the arrangements which ensure that, for appliances which require fitting/measuring, a registered pharmacist measures/fits them.
- 6.16 The Committee noted that that the Applicant has stated that they will not be providing any advanced services at the pharmacy premises. The Committee noted that the Applicant had not indicated on appeal that it would provide appliances. The Committee was therefore of the view that, if the application was to be granted, the Applicant would not be able to provide any appliances to patients.
- 6.17 The Regulations require the Committee to be satisfied as to a number of matters, including that essential services will be provided on an uninterrupted basis, in a safe and effective way, across England, and without face to face contact.
- 6.18 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicates that the obligation is only discharged if the information or documentation provided is sufficient to satisfy NHS England in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that NHS England may need to make of the information or documentation when carrying out its functions.

- 6.19 The Committee has asked itself whether it has sufficient information and documentation which would address the criteria in Regulation 25(2)(b). If the Committee is to be satisfied of the matters in that paragraph, the Committee must be provided with evidence to demonstrate these matters. In this case, that evidence put forward has taken the form of the original application, the appeal and certain Standard Operating Procedures (SOPs) which the applicant has prepared or commissioned.
- 6.20 It is not for the Committee to 'approve' or 'disapprove' of these SOPs (as they may contain matters not relevant to the Committee's consideration, and there are many ways an applicant can choose to organise itself in order to comply with the various requirements of the Regulations) and the Committee has not sought to do so. The Committee has sought evidence within the original application, appeal and SOPs in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.

Essential services will be provided on an uninterrupted basis

- 6.21 The Committee noted in the appeal letter, the Applicant states,
- 6.21.1 *“there is no reason for any interruption in any essential services during opening hours. The Applicant would have [a] Responsible Pharmacist and dispenser present during [the] opening hours of the Pharmacy. Also, patients can contact the Applicant via telephone and email / website, from anywhere in UK.”*
- 6.22 The Committee noted that whilst the Applicant has referred to the presence of trained staff including a Responsible Pharmacist and dispenser, it had not provided detail to show that a pharmacist would always be available at all times during the opening hours of the pharmacy. The Applicant has not provided information provided to show *how* the provision of services will be carried out without interruption.
- 6.23 Based on the information provided to it, the Committee was not satisfied that the provision of services would be without interruption.

Provision of services across England

- 6.24 The Committee noted from the application form that the Applicant states
- 6.24.1 *“Being an Internet Pharmacy, people anywhere in the UK would be able to contact [the Applicant] via telephone, Email or Post.”*
- and
- 6.24.2 *“[the Applicant] have robust medicine delivery system in place all over the UK [sic].”*
- 6.25 The Committee noted that the Applicant states in their appeal letter that,
- 6.25.1 *“patients can contact [the Applicant] via telephone and email / website, from anywhere in [the] UK.”*
- 6.26 The Committee also noted the Applicant had referred to the delivery of medicines to be undertaken by a delivery driver or by Royal Mail courier service.
- 6.27 The Committee was satisfied that the provision of services would be available to persons anywhere in England.

Without face to face contact

- 6.28 The Committee noted in the information provided, the Applicant refers to *“being an Internet Pharmacy, people anywhere in the UK would be able to contact [the Applicant] by telephone, Email or Post”*. The Committee further noted the Applicant states:
- 6.28.1 *“[The pharmacy] will not have any customer / patient access at [the] premise[s]”*
- and
- 6.28.2 *“As being a Distance Selling pharmacy, face to face contact is not possible. However, it doesn’t stop [the Applicant] from communicating effectively with [their] customers. Patients can contact [the Applicant] via telephone or Email. Also, [the Applicant] can provide information over the video call whenever necessary [sic]. This way, [the Applicant] can provide safe and effective service to [their] patients.”*
- 6.29 The Committee noted the Applicant has indicated that face to face contact is not possible, that there will be no patient access at the premises, that telephone, email or video may be used to communicate with customers. The Committee was satisfied that the provision of services would be without face to face contact.
- 6.30 For the reasons given above, the Committee was not satisfied that the provision of services would be without interruption. 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. The Committee went on to consider whether safe and effective provision of essential services was likely to be secured.
- 6.31 The Committee considered each essential service in paragraphs 3 to 22 of schedule 4 of the Regulations ("Terms of Service") in turn.
- 6.32 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:
- 6.32.1 Dispensing of drugs and appliances
- 6.32.2 Urgent supply without a prescription
- 6.32.3 Preliminary matters before providing ordered drugs or appliances
- 6.32.4 Providing ordered drugs or appliances
- 6.32.5 Refusal to provide drugs or appliances ordered
- 6.32.6 Further activities to be carried out in connection with the provision of dispensing services
- 6.32.7 Disposal service in respect of unwanted drugs
- 6.32.8 Promotion of healthy lifestyles
- 6.32.9 Prescription linked intervention
- 6.32.10 Health campaigns
- 6.32.11 Signposting
- 6.32.12 Support for self-care
- 6.32.13 Discharge medicines service

6.32.14 Websites and health promotion zones

Dispensing of drugs and appliances

- 6.33 The Committee considered whether the Applicant had explained how non-electronic prescriptions will be presented by the patient and how products will be provided.
- 6.34 The Committee noted the Applicant had indicated that the request for prescriptions could be done over the phone or online. However the Committee again remained concerned regarding the lack of information for the receipt of non-electronic prescriptions in the SOPs, for example by post or collection.
- 6.35 The Committee could therefore not be satisfied that there would be compliance with paragraph 5(2)(3) of Schedule 4.

Urgent supply without a prescription

- 6.36 The Committee considered whether the Applicant had explained how it proposes safely and effectively to receive requests from prescribers for urgent supplies of drugs and appliances.
- 6.37 The Committee could not see any reference to how the Applicant would manage requests from prescribers for urgent supplies of drugs.
- 6.38 6.36 The Committee was therefore not satisfied that there would be compliance with paragraph 6 of Schedule 4.

Providing ordered drugs or appliances

- 6.39 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).

- 6.40 The Committee noted SOP 8 Delivery of Medication to Patients states:

6.40.1 *“Place “Fridge” and “Controlled Drug” sticker next to bag label if any fridge or CD drugs to be delivered.*

Collect the medication bags (Checked) as per the delivery sheet and hand over to the delivery driver along with the Delivery Sheets. Also, hand over fridge and controlled drugs to delivery driver if any.

Make sure you put fridge lines in cool box before it leaves pharmacy in order to maintain cold chain. Cool box temperature needs to be maintained between 2 - 8 degrees Celsius.

Back of the prescriptions for controlled drugs needs to be signed by delivery driver before he leaves for delivery and hand over prescription to Pharmacist.

Upon receiving the medication, please make sure patient sign the appropriate box on delivery sheet. If any controlled drugs or fridge line, then patient needs to sign separate box for this as well on delivery sheet.

Signed delivery sheets should be kept for audit purpose for 3 months and one with

CD should be kept for 2 years.”

6.41 And further under the heading, Delivery By Royal Mail, SOP 8 states:

6.41.1 *“Make a list of patients who needs to be delivered by Royal Mail. Stick bag labels of all the patients on a delivery sheet.*

Collect the medication bags (Checked) as per the delivery sheet. Stick the bag label on designated courier bag and place the medication bag of that patient in that courier bag. Hand over the sealed courier bags to delivery driver to take these to Royal Mail post office for secure delivery. Keep the courier bags with controlled drugs inside separate, so Royal Mail can be informed and these only needs to posted as sign for.

Any fridge line should be posted separately via special courier as sign for delivery to make sure it gets delivered without compromising cold chain.

All the receipts and paper works of Royal Mail and courier company should be kept for 6 months for audit purpose and any receipts of Controlled Drug should be kept for 2 years.”

6.42 Whilst the Committee noted the information provided with regard to the cool box and the maintenance of temperature required for cold chain items, there was nothing provided by the Applicant to demonstrate that an audit process or appropriate system is in place which would highlight any items, which might have ceased to be refrigerated in transit and therefore be compromised, and how these would be prevented from being given to the patient. In addition, the Committee noted that no information had been provided by the Applicant as to what would happen should a failed delivery of a cold chain item occur. Further the SOPs that the Applicant had provided do not include a situation where the cold chain has been compromised in transit, and the SOPs do not set out how such a situation would be recognised and dealt with. The information provided by the Applicant contains a lack of information regarding storage if delivery has been unsuccessful. With regard to controlled drugs, the Committee noted it had been provided with insufficient information to show how the security of controlled drugs would be maintained during the delivery process. The Committee was not therefore confident, as it is required to be, that all dispensed cold chain and controlled drug products would be delivered in a safe and effective manner.

6.43 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.

Containers

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

6.45 The Committee could not see any reference to packaging and containers.

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

Refusal to provide drugs or appliances ordered

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

- 6.48 The Committee noted that the Applicant had not indicated how it would place itself in a position to assess the above.
- 6.49 The Committee was therefore not satisfied that there would be compliance with paragraph 9(4) of Schedule 4.

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

- 6.50 The Committee considered whether the Applicant had explained how appropriate advice about the benefits of repeat dispensing is given to any patient who (i) has long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term), and (ii) requires regular medicine in respect of that medical condition.
- 6.51 The Committee noted that the Applicant had not indicated how it would place itself in a position to assess the above. The Committee noted that the Applicant does not provide any information as to how they would support, manage and advocate the use of repeat dispensing or electronic repeat dispensing.
- 6.52 The Committee was therefore not satisfied that there would be compliance with paragraph 10(1) of Schedule 4.

Disposal service in respect of unwanted drugs

- 6.53 The Committee considered whether the Applicant had explained how it will safely and effectively accept and dispose of unwanted drugs presented to it for disposal.
- 6.54 The Committee noted the Applicant referred to the patient guidance leaflet for the Disposal of Unwanted Medicines that would be available on their website. The Committee was of the view that whilst the Applicant has referred to the availability of a disposal service to patients, insufficient detail was provided as to how patients should contact the pharmacy and subsequently prepare the waste to be disposed. Furthermore, insufficient detail was provided to show if the pharmacy could collect unwanted items from patients.
- 6.55 The Committee was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 13-15 of Schedule 4.

Promotion of healthy lifestyles

- 6.56 The Committee considered whether the Applicant had explained how it will safely and effectively promote healthy lifestyles.
- 6.57 The Committee noted the Applicant states on their appeal letter that:
- 6.57.1 *“For the promotion of Public Health, we would use our website, Medipills.co.uk. We would review and update contents our website on regular basis.*
- 6.57.2 *We would run various public health campaign related to diabetes, coronary heart disease, high blood pressure, for the people who smoke or are overweight on regular basis on our website.”*
- 6.58 The Committee noted SOP 24 - “Health Lifestyle”. The Committee noted that the Applicant does not provide any details as to how the promotion of healthy lifestyles activity will be actively undertaken to ensure that they comply with the terms of service or that patients can access materials, information and support in an effective manner. The Committee also noted that the Applicant has failed to provide specific information

as to how a patient would access promotion of healthy lifestyles information or be proactively identified as suitable patients to be directed to access this material.

- 6.59 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.

Prescription linked intervention

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

- 6.61 The Committee noted that SOP 23, Self Care of Patients and their Families states:

6.61.1 *“We have Pharmacist and support staff available to provide advice to people, including carers, requesting help with the treatment of minor illness and long-term conditions, including general information and advice on how to manage illness [sic].*

Pharmacy staff will advise on the appropriate use of the wide range of non-prescription medicines which can be used in the self-care of minor illness and long term conditions. Pharmacy staff will make healthy lifestyle interventions opportunistically when appropriate. Pharmacy staff will signpost patients to other health and social care providers, when appropriate.”

- 6.62 The Committee noted that although the Applicant does mention providing interventions to those patients with underlying health conditions, the Committee noted the information provided does not show how patients will be identified as being eligible for prescription linked intervention or specifically how this will be discussed with them.

- 6.63 The Committee was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

Health Campaigns

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

- 6.65 The Committee noted the Applicant states in their appeal:

6.65.1 *“For the promotion of Public Health, we would use our website, Medipills.co.uk. We would review and update contents our website on regular basis. We would run various public health campaign related to diabetes, coronary heart disease, high blood pressure, for the people who smoke or are overweight on regular basis on our website.”*

- 6.66 The Committee noted SOP 24 “Health Lifestyle” states:

6.66.1 *“When you are generally talking to your customers over the phone, note any habits that will affect their future well being and try to encourage them to make small changes that could make a big difference.*

Ways to increase their exercise without the expense of joining a gym like parking their car further away from the place they want to get to, always taking the stairs instead of the escalator or lift, having a short walk at lunchtime instead of sending somebody else for their sandwich.

Sell pedometers so people can see how many extra steps they have taken, and encourage them to increase their steps daily.”

and further

6.66.2 *“Encourage the customers to read the information online. The more you explain to customers the benefits of changing their lifestyles the more likely they are to attempt to. Tell them that it takes about 60 days to change a habit and the more you follow the new routine the more likely it is to become the new habit.”*

6.67 The Committee noted that although the Applicant has mentioned the promotion of healthy lifestyles, this was not considered sufficient information to suggest that the Applicant would participate in health campaigns and does not demonstrate how these messages would reach patients such as sending out leaflets with prescriptions during specific targeted campaign periods.

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

Discharge medicines service

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

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

6.71 The Committee noted that the Applicant had not indicated how it would be in a position to offer the above service.

6.72 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

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

6.74 The Committee noted that the Applicant had referred to its website in its appeal letter,

6.74.1 *“For the promotion of Public Health, we would use our website, Medipills.co.uk. We would review and update contents our website on regular basis [sic].*

6.74.2 *We would run various public health campaign related to diabetes, coronary heart disease, high blood pressure, for the people who smoke or are overweight on regular basis on our website.”*

- 6.75 Whilst the Committee noted the mention of the Applicant's website, that is "*not live yet as not allowed to make it live before getting NHS contract,*" there was no reference to any interactive page providing public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues.
- 6.76 The Committee was therefore not satisfied that there would be compliance with paragraph 28C of Schedule 4.
- 6.77 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

- 6.78 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).
- 6.79 Whilst the Committee had reached the same decision as NHS England, given its different reasons for doing so, the Committee determined that the decision of NHS England must be quashed.
- 6.80 The Committee considered whether there should be a further notification to the parties detailed at paragraph 19 of Schedule 2 of the Regulations to allow them to make representations if they so wished (in which case it would be appropriate to quash the original decision and remit the matter to NHS England) or whether it was preferable for the Committee to reconsider the application.
- 6.81 The Committee noted that representations on Regulation 25 had already been made by parties to NHS England, and these had been circulated and seen by all parties as part of the processing of the application by NHS England. The Committee further noted that when the appeal was circulated representations had been sought from parties on Regulation 25.
- 6.82 The Committee concluded that further notification under paragraph 19 of Schedule 2 would not be helpful in this case.

7 Decision

- 7.1 The Committee concluded that it was not required to refuse the application under the provisions of Regulation 31.
- 7.2 Accordingly, the Committee:
- 7.2.1 quashes the decision of NHS England; and
 - 7.2.2 redetermines the application as follows -
 - 7.2.2.1 the Committee was satisfied that the proposed premises were not adjacent to or in close proximity to other chemist premises,
 - 7.2.2.2 the Committee was satisfied that the premises of the Applicant are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list,
 - 7.2.2.3 the Committee was not satisfied that all essential services were likely to be secured without interruption during the opening hours,

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

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

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

7.2.3 The application is refused.

**Case Manager
Primary Care Appeals**