

4 March 2021

**REF: SHA/24452**

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**APPEAL AGAINST NORTH EAST & YORKSHIRE  
AREA TEAM, NHS COMMISSIONING BOARD "NHS  
ENGLAND" DECISION TO GRANT AN  
APPLICATION BY ANTYJO INTERNATIONAL LTD  
FOR INCLUSION IN THE PHARMACEUTICAL LIST  
AT 20 ABBEY LANE, WOODSEATS, SHEFFIELD,  
S8 0BL UNDER REGULATION 25**

## 1 Outcome

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

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## 1 The Application

By application dated 25 June 2020, Antyjo International Ltd ("the Applicant") applied to NHS Commissioning Board ("NHS England") for inclusion in the pharmaceutical list at 20 Abbey Lane, Woodseats, Sheffield, S8 0BL 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 stated:

1.1.1 None

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

1.2.1 The premises is not on the same site with any other existing provider of pharmaceutical services.

1.2.2 Also this pharmacy is not intending to provide any enhanced or advanced service that will involve face to face except for CPCS which can be done over the phone if applicable.

1.2.3 The standard operating procedure will satisfy requirements on Regulation 25 for the uninterrupted provision of essential services to anyone in England.

1.2.4 There will be no face to face service with any patient for any essential service.

1.2.5 All prescriptions will be received either by post, EPS or collected from surgery and once dispensed all will be delivered directly to patients in line with its standard operating procedure. All queries will be resolved either on phone, email or any other means without face to face on premises.

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

1.3.1 n/a

## 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 All pharmacy procedures including the essential services will have an SOP that prohibits any face to face contact within the premises or in the vicinity of the pharmacy, by pharmacist or pharmacy staff to patients.
- 1.6 Customers within 5 mile radius to the premises will receive their medication by a trained delivery driver who will do the deliveries in line with the pharmacy's standard operating procedure.
- 1.7 For customers who live outside the 5 mile radius, their medication will be delivered by a courier service that allows the pharmacy to be able to track their medication in-situ and able to also take signature upon delivery.
- 1.8 The courier service must have the ability to deliver controlled drugs and cold chain without compromising any legal requirement for such medications.
- 1.9 The pharmacy standard operating procedure will ensure that pharmacist and staff phones the patient prior to delivery to ensure that patient will be available to receive their medication on expected day and time (estimated).
- 1.10 Also with customers consent pharmacy will collect their prescriptions (for those local) that is FP10 prescriptions and if they have nominated the pharmacy the Applicant will receive electronically and dispense and deliver promptly.
- 1.11 For customers anywhere in England who have an FP10 prescription, they will have to post it to the pharmacy or if they consent to nominate the pharmacy for electronic prescription, the Applicant will dispense them and inform them of when they will receive them by post and all these will be done in a timely manner.
- 1.12 All the other essential services example sign posting, support for self-care, repeat dispensing collection of unwanted medicines etc. will all be available to any patient irrespective of where they live within England without face to face interaction or contact during its opening times. The Applicant will use phone calls, emails or letters and electronic means (repeat dispensing) to offer them the essential services, they will be advised to use courier to return unwanted medications if the Applicant cannot physically reach them.
- 1.13 A dedicated phone line will be available to advise the public on its pharmacy procedures during opening hours.

- 1.14 The pharmacy will have in its standard operating procedure that no essential service will be offered on a face to face basis and also for safe and effective delivery of service, the Pharmacist will phone patients before their deliveries arrive to them to explain how their medication should be taken and answer any questions from patients regarding side effects or any other concerns to ensure that patients are safe.
- 1.15 Also the pharmacy will have on their website information that tells patients how to arrange for the pharmacy to pick up their unwanted medication or for those outside the 5 mile radius how to post it to the pharmacy for disposal.
- 1.16 Deliveries of cold chain for customers outside the 5 mile radius will be done by couriers that have the ability to do this eg DHL, this will ensure medications of such are maintained at 2-8°C temperature until it reaches customer and signed for upon delivery.
- 1.17 Also controlled drugs will be taken by courier services that makes tracking of medicines possible for customers who live outside the 5 mile radius for delivery by the pharmacy driver.
- 1.18 Signatures must be obtained upon delivery. A delivery confirmation must be sent to the pharmacy by courier service to indicate successful delivery. The pharmacy will also call patient on expected date of delivery to ensure the controlled drug has successfully reached customer.
- 1.19 Delivery to local customers within the delivery radius will be done by the trained delivery driver and if for controlled drug he/she will also take a controlled drug delivery sheet to obtain signature upon delivery and file such documentation in line with pharmacy SOP.
- 1.20 Also for cold chain delivery of local patients a fridge in the delivery van maintained at 2-8°C will be used to maintain cold chain until medication reaches customer without breaking the cold chain temperature at any point until it reaches customer.
- 1.21 A dedicated phone line will be available to advise public and surgeries on how the pharmacy operates to deliver essential services without face to face contact.
- 1.22 The pharmacy does not intend to offer any enhance or advance service that will involve face to face contact. All its essential services will be done through phone calls, emails or electronically or via the delivery driver without the need for anyone to attend the pharmacy but where a patient suddenly arrives at the pharmacy to request an essential service, the pharmacist or staff will explain politely to the patient that the pharmacy has an NHS contract that does not allow it to offer such services face to face within the pharmacy or anywhere within the vicinity of the pharmacy premises, the pharmacist or staff will send the patient home and arrange for the service to be delivered at a distance. Example if they have a prescription the delivery driver will go and collect it and bring to pharmacy for dispensing and delivered back to patient. Also the pharmacy will offer the patient an opportunity to nominate the pharmacy if they wish so their prescriptions are received electronically to avoid visiting the pharmacy in future.

- 1.23 This pharmacy does not intend to offer an advanced service or enhanced service that will need a face to face [sic] as one of its requirements.
- 1.24 This means that no customer will be allowed in the pharmacy premises for either essential, enhance or advanced service until further notice to help avoid any risk of a face to face interaction with the public.

## 2 The Decision

NHS England considered and decided to grant the application. The decision letter dated 29 October 2020 states:

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

Extract from the Decision Report

- 2.2 The application has been granted on the grounds that the Applicant has met the requirements set out in Regulation 25 and Regulation 64 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.
- 2.3 The proposed premises 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 was satisfied that the pharmacy procedures for the premises would be such as to secure the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and the safe and effective provision of essential services without face-to-face contact between any person receiving the services and the Applicant or the Applicant's staff.
- 2.4 The Committee considered Regulation 31 and determined that it did not apply.
- 2.5 As the application is in respect of distance selling premises, by virtue of regulation 64(3) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, if the applicant is subsequently included in the pharmaceutical list for the area of Sheffield Health and Wellbeing board in respect of the premises included in the application that inclusion will be subject to the following conditions:
  - 2.5.1 The Applicant must not offer to provide pharmaceutical services to persons who are present at (which includes in the vicinity of) the proposed premises;
  - 2.5.2 the means by which the Applicant provides pharmaceutical services must be such that any person receiving those services does so otherwise than at the proposed premises;
  - 2.5.3 the proposed premises must not be on the same site or in the same building as the premises of a provider of primary medical services with a patient list;
  - 2.5.4 the pharmacy procedures for the premises must be such as to secure:

- 2.5.4.1 the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and
- 2.5.4.2 the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff; and
- 2.5.5 nothing in the Applicant's practice leaflet, in the Applicant's publicity material in respect of the proposed premises, in material published on behalf of the applicant publicising services provided at or from the proposed premises or in any communication (written or oral) from the applicant or the applicant's staff to any person seeking the provision of essential services from the applicant must represent, either expressly or impliedly, that:
  - 2.5.5.1 the essential services provided at or from the premises are only available to persons in particular areas of England, or
  - 2.5.5.2 the Applicant is likely to refuse, for reasons other than those provided for in the Applicant's terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (for example, because the availability of essential services from the applicant is limited to other categories of patients).

### 3 The Appeal

In a letter dated 27 November 2020, Lloyds Pharmacy appealed against NHS England's decision. The grounds of appeal are:

- 3.1 Insufficient information has been provided with regard to Regulation 25 and the conditions set out in Regulation 64. For example, reference is made to SOPs but these were not provided to it as part of the application. Limited information was also provided in the application with regard to the process for the return of unwanted medicines. The application states this process will be available on their website. For deliveries under 5 miles, the application only states this will be made by a trained delivery driver, no further details are provided.
- 3.2 Lloyds encloses a copy of the application circulated to it as part of the consultation. It also encloses a copy of the representations it sent to NHS England.
- 3.3 Lloyds would be grateful if Primary Care Appeals would reconsider the application and review the application in accordance with this Appeal.

In a letter to NHS England dated 13 August 2020 Lloyds Pharmacy stated:

- 3.4 It is noted this is application for Distant Selling. Insufficient information has been provided with regard to Regulation 25 and the conditions set out in Regulation 64. For example, reference is made to SOPs but these are not provided. There is also limited information with regard to the process for the return of unwanted

medicines. The application states this process will be available on their website. For deliveries under 5 miles, the application only states this will be made by a trained delivery driver, no further details are provided.

- 3.5 Regulation 25 and the conditions set out in Regulation 64 have not been met therefore Lloyds would submit the application be refused.

## 4 Summary of Representations

This is a summary of representations received on the appeal.

### 4.1 NHS ENGLAND

4.1.1 Regarding the matters to be considered, in relation to Regulation 31, NHS England was satisfied that paragraph (2) does not apply. The pharmacy contractor that is in closest proximity to the application location is 0.1 miles from the proposed premises.

4.1.2 In relation to Regulation 25, the premises in respect of which the application is made are not located on the same site or in the same building as the premises of a provider of primary medical services with a patient list. Abbey Lane Surgery is situated on the other side of Abbey Lane from the proposed pharmacy premises.

4.1.3 NHS England considered that the Applicant had provided sufficient information to be satisfied that the pharmacy procedures for the pharmacy premises are likely to secure –

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

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

4.1.4 The submission of SOPs is not required as part of the application process.

### 4.2 THE APPLICANT

4.2.1 The Applicant writes in response to [NHS Resolution's] letter dated 11 January 2021 which highlighted the concerns of Lloyds Pharmacy in relation to NHS England's approval of its application in respect of a distant selling Pharmacy.

4.2.2 First and foremost the Applicant agrees with Lloyds Pharmacy in their concerns to ensure that the safety of the public and the compliance to stipulated regulations surrounding a distant selling pharmacy is adhered to at all times by all pharmacies including the Applicant's.

4.2.3 In view of this, the Applicant would like to state that it has every intention just like Lloyds Pharmacy to put the safety of the public first and to

uphold all regulations that govern the opening and running of its pharmacy.

- 4.2.4 In [your] letter, it stated that insufficient information was provided in relation to regulation 25 and 64 and an sop was not provided for their perusal [sic].
- 4.2.5 Firstly, an SOP document was not a requirement to this application and the document will be ready and available at the time of inspection by the GPhC and NHS England when required. The application asked for an explicit written explanation that satisfies the NHSCB that the pharmacy procedures for the pharmacy and its premises are likely to secure the uninterrupted provision of essential services, during its opening hours to persons anywhere in England who request those services and 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 applicant's staff.
- 4.2.6 The Applicant believes NHSCB were satisfied with the answers provided to the above, but to further answer the other concerns about receiving unwanted medicines from patients who live outside the 5 mile radius delivery point, the process will be as follows.
  - 4.2.6.1 Patient will contact the pharmacy about their unwanted medication for disposal.
  - 4.2.6.2 The pharmacist will advise patient to secure medication in a safe container and keep in a safe place out of reach of children or pets, also the pharmacist will check the contents and the approximate quantity with the patient over the phone and inform patient that the pharmacy cannot collect used sharps. Also if there are controlled drugs, the pharmacist will help the patient to identify and count them. This will be noted for cross referencing upon arrival to the pharmacy.
  - 4.2.6.3 The pharmacy will then post an appropriately prepaid sized bag/envelope for bagging the waste.
  - 4.2.6.4 The pharmacy will confirm with the patient, the receipt of the appropriate bag and instruct patient on how to empty the medicines in the bag safely.
  - 4.2.6.5 The pharmacy will then make an arrangement with an appropriate courier service to collect the bag at a date and specified time which will be communicated and agreed with the patient.
  - 4.2.6.6 Once collected and returned to the pharmacy premises, the waste will be emptied safely in the appropriate doop bins marked as patient returned bins by trained staff following procedures in pharmacy that keeps them safe.
- 4.2.7 Trained delivery drivers will collect from patients within the 5 mile radius upon agreeing a date and time with the patient. The patient will be made

aware that the pharmacy cannot collect used unwanted sharps and check for the presence of controlled drugs which must be counted by patient and cross checked by the delivery driver at the point of collection and noted in his/her delivery information book. He/she must only do this while wearing gloves and any other necessary PPE as the case may be.

- 4.2.8 The returned medication will be dooped as stated above and any controlled drugs returned will be counted and recorded and destroyed by Pharmacist and a witness using controlled drug destruction kit and dooped in appropriate bin.
- 4.2.9 The Applicant has also attached a picture to show the limited access to this property or premises and also its position being in a storey building for [NHS Resolution's] perusal. This will help prevent random access to the premises as doors will be kept locked at all times. This was taken into consideration in choosing this premises for the purpose of a distant selling pharmacy [sic].
- 4.2.10 Also it will have on the pharmacy website all the essential services including the return of unwanted medicines that will help inform customers on what to do when they need this service.
- 4.2.11 The Applicant hopes this will help clear all doubts and establish confidence in all stakeholders that this pharmacy will have a robust procedure which will be available at the time of inspection and will put the safety of the public first in all its dealings.

#### 4.3 L ROWLAND & CO (RETAIL) LTD

- 4.3.1 L Rowland & Co (Retail) Ltd have no further comments to make at this stage.

L Rowland & Co (Retail) Ltd enclosed a copy of their letter to NHS England of 27 July 2020 in which they stated:

- 4.3.2 L Rowland & Co (Retail) Ltd notes this is a Distance Selling excepted application and should one be required would be willing to attend any oral hearing in relation to the above application to express their written comments verbally.

- 4.3.3 L Rowland & Co (Retail) Ltd wishes to make the following comments:

- 4.3.4 As the application is in respect of distance selling premises, by virtue of regulation 64 (3) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, approval is subject to the following conditions:

- 4.3.4.1 The applicant must not offer to provide pharmaceutical services to persons who are present at (which includes in the vicinity of) the proposed premises;

- 4.3.4.2 The means by which the applicant provides pharmaceutical services must be such that any person receiving those services does so otherwise than at the proposed premises;

4.3.4.3 The proposed premises must not be on the same site or in the same building as the premises of a provider of primary medical services with a patient list;

4.3.4.4 The pharmacy procedures for the premises must be such to secure –

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

4.3.4.4.2 The safe and effective provision of essential services without face-to-face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff; and

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

4.3.4.5.1 The essential services provided at or from the premises are only available to persons in particular areas of England, or

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

4.3.5 L Rowland & Co (Retail) Ltd wish to be assured that NHS England has sufficient governance procedures in place to ensure that the criteria for the excepted application are fulfilled and the SOPs provided with the application is sufficient to allow a determination. L Rowland & Co (Retail) Ltd also request that NHS England keep it informed of the outcome in due course.

## **5 Summary of Observations**

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

## **6 Consideration**

6.1 The Pharmacy Appeals Committee (“Committee”) appointed by NHS Resolution, had before it the papers considered by 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 As a preliminary matter, NHS Resolution must first consider whether it has jurisdiction to hear the appeal including whether the appellant has a right of appeal against the original decision.
- 6.5 Following receipt of the appeal from Lloyds Pharmacy, NHS Resolution noted that NHS England had not afforded appeal rights to any party; the decision report stated "*Rights of appeal: None*".
- 6.6 NHS Resolution therefore wrote to NHS England and Lloyds Pharmacy on 17 December 2020 and requested comments on whether Lloyds Pharmacy had a right of appeal against the original decision under paragraph 30 of Schedule 2 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 or otherwise.
- 6.7 On 31 December 2020 NHS England stated that "*Further to the decision report which stated that there were no third party rights of appeal, NHS England and NHS Improvement have reviewed this matter and now consider that Lloyds Pharmacy Ltd does have a right of appeal against the original decision under paragraph 30 of Schedule 2 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.*"
- 6.8 The Committee noted that when the appeal was circulated to parties for representations, NHS England's email of 31 December 2020 was also circulated and parties were given the opportunity to provide comments on this matter. The Committee noted that no party had sought to dispute NHS England's updated position.
- 6.9 Therefore, on the information before it, the Committee considered that Lloyds Pharmacy did have right of appeal under paragraph 30 of Schedule 2 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations") and therefore proceeded to consider the appeal in line with the Regulations.

### **Regulation 31**

- 6.10 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).*

- 6.11 The Committee noted in its application, the Applicant states “the premises is not on the same site with any other existing provider of pharmaceutical services”. NHS England further determined that Regulation 31 did not apply. The Committee noted that no party had sought to argue that the application should be refused pursuant to Regulation 31. Therefore on the information provided, the Committee was not required to refuse the application under the provisions of Regulation 31.

### **Regulation 25**

- 6.12 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."*

- 6.13 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.*
- 6.14 Pursuant to paragraph 9(1)(a) of Schedule 3 to the Regulations, the Committee may:
- 6.14.1 confirm NHS England's decision;
  - 6.14.2 quash NHS England's decision and redetermine the application;
  - 6.14.3 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)**

- 6.15 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)**

- 6.16 The Committee noted that the Applicant had stated "n/a" 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.

- 6.17 In its representations on the appeal, NHS England stated “In relation to Regulation 25, the premises in respect of which the application is made are not located on the same site or in the same building as the premises of a provider of primary medical services with a patient list. Abbey Lane Surgery is situated on the other side of Abbey Lane from the proposed pharmacy premises.” The Committee noted that this had not been disputed by any party.
- 6.18 Based on the information available to it, the Committee 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)**

- 6.19 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.
- 6.20 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.
- 6.21 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.
- 6.22 The Committee has asked itself whether it has sufficient information and documentation which would address the criteria in Regulation 25(2)(b). If the Committee is to be satisfied of the matters in that paragraph, the Committee must be provided with evidence to demonstrate these matters. In this case, that evidence put forward has taken the form of the original application and subsequent representations.
- 6.23 The Committee noted in the information provided, the Applicant refers to contacting patients via several methods, including phone, email and letter. The Applicant also states that *“this pharmacy does not intend to offer an advanced service or enhanced service that will need a face to face [sic] as one of its requirements.*
- This means that no customer will be allowed in the pharmacy premises for either essential, enhance or advanced service until further notice to help avoid any risk of a face to face interaction with the public.”*
- 6.24 The Committee was aware that when the pharmacy opens, it will be the responsibility of NHS England, in keeping with Regulation 64, to ensure that services are provided other than with face to face contact.
- 6.25 The Committee was satisfied that the provision of services would be without face to face contact.

- 6.26 The Committee noted the Applicant's comments that *"For customers anywhere in England who have an FP10 prescription, they will have to post it to the pharmacy or if they consent to nominate the pharmacy for electronic prescription, the Applicant will dispense them and inform them of when they will receive them by post and all these will be done in a timely manner.*
- All the other essential services example sign posting, support for self-care, repeat dispensing collection of unwanted medicines etc. will all be available to any patient irrespective of where they live within England".*
- 6.27 Based on the information provided, the Committee was satisfied that the provision of services would be available to persons anywhere in England.
- 6.28 Beyond its comment that the *"standard operating procedure will satisfy requirements on Regulation 25 for the uninterrupted provision of essential services"* the Committee noted that the Applicant had not provided any information to explain the procedures that will be in place to ensure the uninterrupted provision of essential services, should the Responsible Pharmacist be absent for any reason. Therefore the Committee could not be satisfied, as it is required to be, that the provision of services would be without interruption.
- 6.29 The Committee went on to consider whether safe and effective provision of essential services was likely to be secured.
- 6.30 The Committee considered each essential service in paragraphs 3 to 22 of schedule 4 of the Regulations ("Terms of Service") in turn.
- 6.31 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:
- 6.31.1 Dispensing of drugs and appliances
  - 6.31.2 Urgent supply without a prescription
  - 6.31.3 Preliminary matters before providing ordered drugs or appliances
  - 6.31.4 Providing ordered drugs or appliances
  - 6.31.5 Refusal to provide drugs or appliances ordered
  - 6.31.6 Further activities to be carried out in connection with the provision of dispensing services
  - 6.31.7 Disposal service in respect of unwanted drugs
  - 6.31.8 Promotion of healthy lifestyles
  - 6.31.9 Prescription linked intervention
  - 6.31.10 Health campaigns
  - 6.31.11 Signposting
  - 6.31.12 Support for self-care

6.31.13 Discharge medicines service

- 6.32 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:

**Preliminary matters before providing ordered drugs or appliances**

- 6.33 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.
- 6.34 The Committee noted that no information had been provided by the Applicant in this regard and therefore could not be satisfied that there would be compliance with paragraph 7(3) of Schedule 4.
- 6.35 The Committee considered whether information had been provided to explain how charges will be paid.
- 6.36 The Committee noted that no information had been provided by the Applicant in this regard and therefore could not be satisfied that there would be compliance with paragraph 7(5)(b) of Schedule 4.

**Providing ordered drugs or appliances**

- 6.37 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).
- 6.38 The Committee noted in its application, the Applicant states:
- 6.38.1 "The courier service must have the ability to deliver controlled drugs and cold chain without compromising any legal requirement for such medications."
- 6.39 And further:
- 6.39.1 *"Deliveries of cold chain for customers outside the 5 mile radius will be done by couriers that have the ability to do this eg DHL, this will ensure medications of such are maintained at 2-8°C temperature until it reaches customer and signed for upon delivery.*
- Also controlled drugs will be taken by courier services that makes tracking of medicines possible for customers who live outside the 5 mile radius for delivery by the pharmacy driver.*
- Signatures must be obtained upon delivery. A delivery confirmation must be sent to the pharmacy by courier service to indicate successful delivery. The pharmacy will also call patient on expected date of delivery to ensure the controlled drug has successfully reached customer.*

*Delivery to local customers within the delivery radius will be done by the trained delivery driver and if for controlled drug he/she will also take a controlled drug delivery sheet to obtain signature upon delivery and file such documentation in line with pharmacy SOP.*

*Also for cold chain delivery of local patients a fridge in the delivery van maintained at 2-8°C will be used to maintain cold chain until medication reaches customer without breaking the cold chain temperature at any point until it reaches customer.”*

- 6.40 The Committee noted the Applicant’s comment that for cold chain delivery to local patients, a fridge will be used in the delivery van to maintain temperatures during transit. However no information had been provided by the Applicant to explain what would be done in a situation where the cold chain was compromised during transit.
- 6.41 In relation to the delivery of controlled drugs, the Committee noted that no information had been provided by the Applicant to show how these would be kept secure during transit with its local delivery driver, for example being held in a lockable storage facility inside the delivery vehicle.
- 6.42 Further no information had been provided to explain the processes the Applicant will have in place for the unsuccessful delivery of cold chain medicines and/or controlled drugs.
- 6.43 Therefore the Committee could not be satisfied as it is required to be, that there would be compliance with paragraph 8(1) of Schedule 4.
- 6.44 The Committee considered whether the Applicant had explained what containers will be suitable for posted / delivered items.
- 6.45 The Committee noted that no information had been provided by the Applicant in this regard and therefore could not be satisfied that there would be compliance with paragraph 8(15) of Schedule 4.

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

- 6.46 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.
- 6.47 The Committee noted that no information had been provided by the Applicant in this regard and therefore could not be satisfied that there would be compliance with paragraph 10(1) of Schedule 4.

**Promotion of healthy lifestyles**

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

- 6.49 The Committee noted that no information had been provided by the Applicant in this regard and therefore could not be satisfied that there would be compliance with paragraphs 16 – 18 of Schedule 4.

#### **Prescription linked intervention**

- 6.50 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.
- 6.51 The Committee noted that no information had been provided by the Applicant in this regard and therefore could not be satisfied that there would be compliance with paragraph 17 of Schedule 4.

#### **Health campaigns**

- 6.52 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.
- 6.53 The Committee noted that no information had been provided by the Applicant in this regard and therefore could not be satisfied that there would be compliance with paragraph 18 of Schedule 4.

#### **Discharge medicines service**

- 6.54 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.
- 6.55 Further the Committee considered whether the Applicant had explained what procedures it has in place for checking referrals for the discharge medicines service.
- 6.56 The Committee noted that no information had been provided by the Applicant in this regard and therefore could not be satisfied that there would be compliance with paragraphs 22B and 22C of Schedule 4.
- 6.57 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.

#### **Additional considerations**

- 6.58 The Committee noted that the Applicant did not intend on providing appliances by way of inclusion of the word “none” in the relevant section of its application form.

6.59 The Committee noted in its appeal letter, Lloyds stated that limited information had been provided in relation to the process for the return of unwanted medicines. The Committee considered whether in the information now provided, the Applicant had explained or otherwise demonstrated how it will safely and effectively accept and dispose of unwanted drugs presented to it for disposal.

6.60 In its representations, the Applicant states:

6.60.1 *“Patient will contact the pharmacy about their unwanted medication for disposal.*

*The pharmacist will advise patient to secure medication in a safe container and keep in a safe place out of reach of children or pets, also the pharmacist will check the contents and the approximate quantity with the patient over the phone and inform patient that the pharmacy cannot collect used sharps. Also if there are controlled drugs, the pharmacist will help the patient to identify and count them. This will be noted for cross referencing upon arrival to the pharmacy.*

*The pharmacy will then post an appropriately prepaid sized bag/envelope for bagging the waste.*

*The pharmacy will confirm with the patient, the receipt of the appropriate bag and instruct patient on how to empty the medicines in the bag safely.*

*The pharmacy will then make an arrangement with an appropriate courier service to collect the bag at a date and specified time which will be communicated and agreed with the patient.*

*Once collected and returned to the pharmacy premises, the waste will be emptied safely in the appropriate doop bins marked as patient returned bins by trained staff following procedures in pharmacy that keeps them safe.*

*Trained delivery drivers will collect from patients within the 5 mile radius upon agreeing a date and time with the patient. The patient will be made aware that the pharmacy cannot collect used unwanted sharps and check for the presence of controlled drugs which must be counted by patient and cross checked by the delivery driver at the point of collection and noted in his/her delivery information book. He/she must only do this while wearing gloves and any other necessary PPE as the case may be.*

*The returned medication will be dooped as stated above and any controlled drugs returned will be counted and recorded and destroyed by Pharmacist and a witness using controlled drug destruction kit and dooped in appropriate bin. ...*

*Also it will have on the pharmacy website all the essential services including the return of unwanted medicines that will help inform customers on what to do when they need this service.”*

6.61 Therefore the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 13 – 15 of Schedule 4.

## **Summary**

6.62 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).

6.63 As the Committee has reached a different decision to that of NHS England, the Committee determined that the decision of NHS England must be quashed.

6.64 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.

6.65 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.

6.66 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.

**Rachel White**  
**Technical Case Manager**  
**Primary Care Appeals**

A copy of this decision is being sent to:

Antyjo International Ltd  
Lloyds Pharmacy  
L Rowland & Co (Retail Ltd)  
PCSE on behalf of NHS England – North East & Yorkshire Area Team