27 August 2020

REF: 23376

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APPEAL AGAINST NHS COMMISSIONING BOARD "NHS ENGLAND" DECISION TO REFUSE AN APPLICATION BY LILLYSPHARMA LIMITED FOR INCLUSION IN THE PHARMACEUTICAL LIST AT THE BRENTANO SUITE, 5 BRENT CROSS GARDENS, LONDON NW4 3RJ 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 granted.

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1 The Application

By application dated 13 November 2019, Lillyspharma Limited ("the Applicant") applied to NHS Commissioning Board ("NHS England") for inclusion in the pharmaceutical list at The Brentano Suite, 5 Brent Cross Gardens, London NW4 3RJ under Regulation 25. In support of the application it was stated:

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 Drug Tariff part IX*

1.2 *Except items that require measuring or fitting.

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

1.3 Not applicable as no other pharmacy in same or adjacent premises.

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

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

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 [SOPs provided to NHS England as part of its application]

2 The Decision

NHS England considered and decided to refuse the application. The decision letter dated 29 May 2020 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.

Extract from decision report

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

2.3 **Boots Comments**

2.4 Boots is grateful to NHS England for forwarding the SOPs for the proposed pharmacy along with the application, however, the way in which patients will access services from the pharmacy is not clear from the application (via website etc).

2.5 Boots would therefore like to respectfully request that when considering this application members of NHS England satisfy themselves that the applicant will be able to meet all the criteria for a distance selling pharmacy and the conditions specified in regulation 64.

2.6 Boots trusts that NHS England will ensure the proposed premises are not on the same site or in the same building as a provider of primary medical services with a patient list (regulation 25(2)(a)).

2.7 Furthermore, it would also ask that NHS England be satisfied that the applicant is able to provide uninterrupted provision of essential services throughout the opening hours without face-to-face consultation, to all persons in England wishing to access these services.

2.8 (Regulation 25(2)(b)(i)) and between any person receiving these services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff (Regulation 25(2)(b)(ii)).

2.9 **Lloyds Comments**

2.10 It is noted this is application for Distant Selling. Lloyds would ask the Committee to be mindful of all matters relating to Regulation 25 and the conditions set out in Regulation 64 as part of the determination of the application.

2.11 **NHS England Comments**

2.12 The application and comments have been reviewed. NHS England has also reviewed the additional information provided.

2.13 There are insufficient details from the applicant relating to parts of the essential services that should be provide by a distance selling pharmacy, in particular:

2.13.1 Paragraph 5(2)(3) of schedule 4

2.13.2 Paragraph 10(1) of schedule 4

With regard to Regulation 31

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

Distance Selling premises applications

2.15 Regulation 25 …

(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;

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

(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

2.17 The applicant provided information via their application and additional information.

2.18 NHS England is satisfied that pharmacy procedures for the pharmacy are likely to secure the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.

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.

2.19 The applicant provided information via their application and additional information.

2.20 After these were reviewed by NHS England, there were insufficient details from the applicant relating to parts of the essential services that should be provided by a distance selling pharmacy, in particular:

2.20.1 Paragraph 5(2)(3) of schedule 4

2.20.2 Paragraph 10(1) of schedule 4

2.21 The application does not satisfy the criteria as set out in the Terms of Service of Pharmacists for the safe and effective provision of all essential services without face to face contact.

2.22 Therefore, the PSRC have determined that NHS England is not satisfied that the pharmacy procedures for the pharmacy premises are likely to secure the safe and effective provision of essential services without face to face contact

between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

Decision

2.23 Regulation 31

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

2.25 Regulation 25(2)(1)(a)

2.26 The proposed site is not on the same site or in the same building as the premises of a provider of Primary Medical Services with a patient list. Therefore this regulation does not apply for this application.

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

2.28 NHS England is satisfied that pharmacy procedures for the pharmacy are likely to secure the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.

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

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

2.31 NHS England is not satisfied that the pharmacy procedures for the pharmacy premises are likely to secure the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff. Therefore, the application has been be refused.

3 The Appeal

In a letter dated 22 June 2020, the Applicant through its representative Rushport Advisory LLP appealed against NHS England's decision. The grounds of appeal are:

3.1 The basis of the appeal is as follows and the timeline, whilst not strictly relevant to the appeal, may be helpful to NHS England when considering their response.

3.1.1 On or around 16 October 2019 the Applicant submitted their application under regulation 25.

3.1.2 On 16 October 2019 PCSE contacted Rushport to confirm that NHS England were processing the application.

3.1.3 On 16 October 2019 Rushport replied to PCSE to state that it was **not** in fact instructed in this application, but had been in a previous application for a different company and that all correspondence should be sent directly to the Applicant.

3.1.4 By letter dated 22 October 2019, NHS England contacted the Applicant to seek “missing information”, which required amending the form to remove Rushport’s details as the contact.

3.1.5 On 24 October 2019 the Applicant replied to NHS England providing the updated forms.

3.1.6 By letter dated 29 May 2020 NHS England refused the application for the reasons set out in the decision report.

3.2 As a rule, Rushport does not permit any Applicant to use SOPs that have been produced by Rushport unless Rushport has been instructed to act in the case. It notes that there have been some instances where Applicants have used its work without consent and where it becomes aware of this it initiates legal proceedings.

3.3 In this case however, the Applicant sought and received an exception to this rule due to some personal circumstances that had meant that they were unable to proceed with the opening of a pharmacy under a previous application. It may have been helpful if Rushport had made this clear to NHS England when it was initially contacted about its involvement and it apologises to NHS England for not doing so. It appears that NHS England may not have had sight of the SOPs when their decision was made and this may have led to the application being refused.

3.4 As NHS England has refused the application, the Applicant has requested that Rushport assist with this appeal and Rushport is therefore acting for the Applicant in this appeal process.

3.5 It has attached updated copies of the relevant SOPs which it would ask the Committee to use when considering the appeal and it trusts that the appeal will be allowed as the SOPs cover not only the matters identified as deficient in the NHS England report but also all other requirements under the Regulations.

3.6 [SOPs provided as part of its appeal at Appendix A.]

4 Summary of Representations

This is a summary of representations received on the appeal.

4.1 NHS ENGLAND

4.1.1 NHS England has considered the additional information that the applicant has now provided with their appeal letter.

4.1.2 Had the information been provided originally, it would have approved this application as the additional information now provides the information that was missing, this answers the concerns that it had regarding this application.

4.1.3 NHS England has no further information to add to this response.

4.1.4 There are now no objections from NHS England to granting this application.

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 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 in its decision letter, NHS England concluded that "*there are no current pharmacies listed at the proposed premises or adjacent to the proposed premises. Therefore regulation 31 does not apply for this application*." The Committee noted that this had not been disputed by any party therefore based on the information provided, the Committee was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

(2) 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 As far as Regulation 25(2)(a) is concerned, the Committee noted in its decision letter, NHS England concluded that "*the proposed site is not on the same site or in the same building as the premises of a provider of Primary Medical Services with a patient list. Therefore this regulation does not apply for this application*." The Committee noted that this had not been disputed by any party. The Committee was therefore satisfied 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)

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

6.13 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.

6.14 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.

6.15 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 Standard Operating Procedures (SOPs) which the Applicant has prepared or commissioned.

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

6.17 The Committee noted SOP 28 'The Responsible Pharmacist' states:

6.17.1 *"Another pharmacist must always be present if the RP is going to leave the premises for any reason."*

6.18 and further

6.18.1 *"The pharmacy will have a second pharmacist available during the core and any additional hours that it operates. If, for any reason, the RP is required to leave the premises or wishes to take a break…. then the second pharmacist must sign in as the RP."*

6.19 Based on the information provided to it, the Committee was satisfied that the provision of services would be without interruption.

6.20 The Committee noted SOP 1 'Introduction and Background to SOPs' states that the pharmacy must provide:

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

6.21 The Committee also noted SOP 2 'Procedures for NHS Essential Services' which states:

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

6.22 The Applicant refers throughout its SOPs to the provision of services to all of England, using the Royal Mail special delivery and national couriers.

6.23 The Committee was therefore satisfied that the provision of services would be available to persons anywhere in England.

6.24 The Committee noted SOP 1 'Introduction and Background to SOPs' states:

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

6.25 The Committee also noted SOP 2 'Procedure for NHS Essential Services' under the heading 'Communication Channels', it states:

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

6.26 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.

6.27 Based on the information provided, the Committee was satisfied that the provision of services would be without face-to-face contact.

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

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

6.30 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:

Dispensing of drugs and appliances

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

6.32 In its decision letter, NHS England stated that the Applicant had not provided sufficient information regarding paragraph 5(2)(3) of Schedule 4.

6.33 However the Committee noted SOP 5 'Online Order Receipt & Exemption Checking' under the heading 'Scope' states:

6.33.1 *"Requests to collect and dispense NHS Prescriptions*

Requests to dispense a prescription received in the post.

Any requests from the "contact us" section of the website."

6.34 The Committee also had regard to SOP 15 'Order Delivery' which under the heading 'Choice of Delivery Method' states:

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

6.35 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 5(2)(3) of Schedule 4.

Urgent supply without a prescription

6.36 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 had regard to SOP 13 'Emergency Supply and Urgent Supply' which describes how the Applicant will process such a request. The Committee noted that the SOPs refer to Essential Services being delivered by several methods of non face-to-face communication including telephone and email, and considered that it was reasonable to infer that these methods would be used to receive requests from prescribers for the urgent supply of drugs.

6.38 SOP 13 under the heading 'Delivery of Urgent and Emergency Supply Items' also states:

6.38.1 *"Given the nature of a request of this type, the Pharmacy should prioritise delivery of the medication to the patient. For local deliveries the driver should be specially informed of the fact that the items are "URGENT" and for any items delivered by courier, the company must be informed that items must be delivered ASAP by the quickest route possible. The Pharmacy must not charge additional fees to the patient even if these are incurred in the delivery process."*

6.39 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.

Preliminary matters before providing ordered drugs or appliances

6.40 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.

6.41 The Committee noted SOP 5 'Online Order Receipt & Exemption Checking' under the heading 'Exempt NHS Prescriptions' states:

6.41.1 *"Where no satisfactory evidence of exemption has been provided patients should be informed that checks to prevent and detect fraud are routinely undertaken by the NHS.*

Where evidence of exemption is required or provided by the patient it can be sent to the pharmacy for verification via the delivery driver and then returned to the patient. The PMR system should be updated to reflect that necessary check has been carried out and a note of when the next check is required should be entered onto the system. The Regulations require a patient to produce 'satisfactory evidence' to confirm exemption. Where appropriate (ie for deliveries made other than by the pharmacy's delivery driver), the patient may scan or fax copies of the evidence to the pharmacy (or use the postal / courier service, …) and the pharmacy can note that the evidence provided was

not in original format. It is for the pharmacist in charge to determine if the evidence is satisfactory or not and, if not, then cross the 'Evidence not Seen' box."

6.42 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.

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

6.44 The Committee noted SOP 5 under the heading 'Paid NHS Prescription' states:

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

Contact the patient to arrange payment using the secure payments system using the "customer not present" option.

If no fees have been paid or there is a discrepancy between fees paid and those due, the patient should be contacted and directed to pay the appropriate fees via the online payment system."

6.45 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(5)(b) of Schedule 4.

Providing ordered drugs or appliances

6.46 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).

6.47 The Committee noted SOP 15 'Order Delivery' under the heading 'Transfer to the Delivery Driver' states:

6.47.1 *"Ensure that any special instructions for the delivery are included within the packaging.*

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

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

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

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

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

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

6.48 The Committee noted under the heading 'Delivery of a prescription via Royal Mail (Not for Cold chain or CDs)' SOP 15 states:

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

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

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

Confirm details of all prescriptions to be delivered.

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

Ensure Royal Mail driver signs Delivery Log sheet for all prescriptions being accepted for delivery. …..

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

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

6.49 The Committee noted under the heading 'Cold chain delivery via courier' SOP 15 states:

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

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

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

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

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

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

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

Unsuccessful cold chain delivery via courier

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

***Breach of Integrity of Cold Chain** …*

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

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

6.50 The Committee noted that SOP 19 'Controlled Drugs: Delivery' under the heading 'Delivery of Schedule 2 & 3 CD's' states:

6.50.1 *"A robust audit trail is essential when controlled drugs are involved. The delivery can be made to a person who is not the patient (the patient must have given authorisation for a representative to take receipt of CDs on their behalf). A Controlled Drugs Delivery Sheet must also be filled in for CD deliveries in addition to the Delivery Log sheet.*

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

The delivery van must be kept locked at all times when the driver is not in the vehicle.

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

The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative. A delivery cannot be left with anyone who is not the patient or their authorised representative.

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

The prescription should be retained in the pharmacy until the delivery driver returns the appropriate paperwork signed by the patient or representative to confirm successful delivery or the patient signature is confirmed online if delivered by courier.

***Successful Schedule 2 & 3 Delivery** …*

For all successful deliveries the Controlled Drug delivery sheet signed by the patient or online courier delivery record should be cross-referenced with the prescription and CD register prior to the prescription being processed as part of the end of day procedure.

Unsuccessful Schedule 2 & 3 Delivery via pharmacy driver

Unsuccessful deliveries sent with a pharmacy driver must be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate.

Unsuccessful Schedule 2 & 3 Delivery via courier

Unsuccessful deliveries sent with a courier should be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate. Where the time of attempted delivery means that the return cannot be made on the same day, the courier will store the drugs at their approved warehouse overnight.

When a failed delivery occurs, the tracking service will notify the pharmacy and the patient of the failed delivery so that delivery can be re-arranged for the patient at the next convenient time or returned to the pharmacy. …

The Courier has pharma grade specialist facilities to meet specific quality and validation requirements for healthcare products. This includes Home Office licensed controlled drug stores. …

Controlled Drugs will be delivered by the pharmacy driver or courier services with tracked and verifiable audit trails."

6.51 Based on the information before it, the Committee was satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

6.52 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.

6.53 In relation to appliances, the Applicant in its application form stated that it will undertake to provide:

6.53.1 *"Drug Tariff part IX**

Except items that required measuring or fitting".

6.54 SOP 6 'Pharmaceutical and Legal Assessment' under the heading 'Items Requiring Measuring and Fitting' states:

6.54.1 *"Where a prescription is received for an item that requires measuring or fitting the patient should be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients should be signposted to at least two other providers of the service in their area (see signposting SOP)."*

6.55 SOP 22 'Support for Self-Care, Signposting and Heath Promotion' under the heading 'Items Requiring Measuring and Fitting' states:

6.55.1 "*Where a prescription is received for an appliance or stoma appliance customisation or any item that requires measuring or fitting the patient should be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients should be signposted to at least two other providers of the service in their area. (see signposting SOP)*"

6.56 The Committee noted that the Applicant did not intend to provide appliances which require measuring or fitting. In the event that the application is granted, the Applicant would not therefore, be able to provide those appliances.

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

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

6.59 The Committee noted SOP 14 'Bagging-Up' under the heading 'Choice of Packaging' states:

6.59.1 *"Choice of packaging will depend on the nature of the items being delivered and the appropriate level of protection must be used to ensure that the item can withstand the normal rigours of the delivery process.*

All packaging must have the tamper proof seals provided in the pharmacy attached to the packaging so that any tampering with the packaging will be evident.

Medicine for local delivery which is not fragile and to be delivered by the delivery driver can be packaged in the [sic] *using the pharmacy bags supplied for standard prescription items.*

DO NOT use normal cardboard boxes. When cardboard boxes are required ALWAYS use the re-enforced boxes that are purchased for delivery purposes.

For postal items, either:

At the very least – padded envelopes even for non-fragile items as this will help to ensure the integrity of the manufacturers packaging.

*For most items – bubble wrap and where necessary, polystyrene filler, placed within a cardboard box. **use the enforced cardboard boxes***

Large or fragile medicines should be packed into the re-enforced cardboard boxes with bubble packaging and filling material to protect from damage.

Cold chain items should be bubble wrapped and placed in Styrofoam filled re-enforced cardboard boxes and kept in the DELIVERIES FRIDGE (rather than the storage fridge) with the "FRAGILE" and "FRIDGE LINE" stickers attached. The courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box ("cold ship" packaging) and are fully monitored (see delivery SOP). Pharmacy staff should be aware that some thermoliable products can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in medicines which is damaging to them and such items must not be used."

6.60 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

6.61 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.

6.62 The Committee noted SOP 31 'Repeat Dispensing' under the heading 'Pharmaceutical & Legal Assessment' states:

6.62.1 *"The pharmacist should telephone and speak with the patient before issuing a repeat and ensure:*

They are taking or using, and likely to continue to take or use the medicine or appliances appropriately

Advise the patient that they should only order items that they need

Check that the patient is not suffering any side effects which may suggest they need a review of their medication

Check that the patient's regimen has not been changed since the prescriber authorised the repeatable medication.

Check that there has not been any change to the patient's health since prescription was authorised

Provide advice and encourage patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber.

Any interventions, referrals (to the patient's GP or otherwise) or refusal to supply decisions which are deemed to be clinically significant should be recorded on the Intervention and Referral Form."

6.63 The Committee further noted SOP 31 under the heading 'Prescription Reception' states:

6.63.1 *"The pharmacy record card must be completed and attached to a RA and an entry made on each occasion a dispensing takes place.*

Any amendments to the RD, e.g. items not issued or change to expected interval must be recorded in the comment section of the pharmacy copy of the card."

6.64 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 9(4) of Schedule 4.

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

6.65 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.

6.66 In its decision letter, NHS England stated that the Applicant had not provided any information regarding paragraph 10(1) of Schedule 4.

6.67 However the Committee noted SOP 31 'Repeat Dispensing' under the heading 'Prescription Reception' states:

6.67.1 *"Appropriate advice about the benefits of repeat dispensing must be given to any patient who:*

has a long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term); and,

requires regular medicine in respect of that medical condition, including, where appropriate, advice that encourages the patient to discuss repeat dispensing of that medicine with a prescriber at the provider of primary medical services whose patient list the patient is on.

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

6.68 In addition the Committee noted under the heading 'Pharmaceutical and Legal Assessment' SOP 31 states:

6.68.1 *"Provide advice and encouragement to patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber."*

6.69 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.

Disposal service in respect of unwanted drugs

6.70 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.

6.71 The Committee noted SOP 20 'Controlled Drugs: Collection and Disposal of Patient Returns' under the heading 'Patient Returned Medication' states:

6.71.1 *"This service is available to <u>all</u> patients living in England.*

Patients or their representatives <u>may not</u> return and [sic] *medicines directly to the pharmacy and must follow the procedures set out in this SOP.*

Patients should be referred to the 'Returning unwanted medication' page on the website for information.

To arrange the return of unwanted medicines to the Pharmacy the patient must telephone and speak to a member of the dispensary team. For controlled drugs this should always be the pharmacist on duty.

The process for returning medication should be explained to the patient.

Each return will be made by booking an appointment for the pharmacy's driver to visit the patient's home to collect the returned medication or by sending the appropriate packaging to the patient to arrange for return by Royal Mail".

6.72 Under the heading 'Return by Royal Mail' SOP 20 states:

6.72.1 *"The pharmacist must*

Speak to the patient about the return and clarify the items being returned.

Assess the items for suitability for return by Royal Mail

If items are suitable for return by Royal Mail then make a note on the PMR and arrange to send the appropriate packaging to the patient for safe return (refer to bagging up SOP for appropriate packaging) …

Send the packaging to the patient along with the instructions for appropriate packing of the goods

Contact the patient to ensure that the package has been received

Provide signposting to other pharmacies where the patient prefers to dispose of unwanted medicines locally."

6.73 Under the heading 'Handling Patient – Returned CDs from Delivery Driver' SOP 20 states:

6.73.1 *"Drivers need to:*

Be aware that they cannot accept patient returns from patients without prior arrangement. The driver should notify the patient to follow the "returning unwanted medication" process as set out on the website.

Ensure that appropriate packaging is within the van prior to starting the journey as the patient may not have requested the correct type or there may be a requirement for additional packaging."

6.74 The Committee noted SOP 21 'The Safe and Effective Receipt and Disposal of Medicines' under the heading 'Process for Patients to Return Medication' states:

6.74.1 *"Patient Returned Medication*

Patients or their representative MAY NOT return and [sic] *medicines directly to the pharmacy and must follow the procedures set out in this SOP.*

This service is available to all patients living in England.

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

To arrange sending medication back to the Pharmacy the patient must telephone and speak to a member of the dispensary team.

Patients may

Arrange collection by the Pharmacy driver at an appointed time, or

Send unwanted medication back to the pharmacy via courier (at the pharmacy's cost), or

The Pharmacy can arrange for medication to be collected by our specialist waste management contractor

Advise patient of their other options to dispose of unwanted or expired medication if none of these options is suitable for them (signposting to local pharmacies).”

6.75 Under the heading ‘Process for accepting patient returns by the Driver’, SOP 21 states:

6.75.1 *“Confirm that a collection of unwanted medication for disposal has been booked. Returns without a booking should only happen in exceptional circumstances….*

Identify any controlled drugs (check with the pharmacist if necessary); segregate these and place in a labelled clear bag for the pharmacist for denaturing and disposal. For further guidance read SOP Controlled Drugs: Disposal of Patient returned medication’.

Identify any sharps and ask the customer to take these back if it safe to do so, signposting to the most appropriate route of disposal.

Identify any cytotoxic or other hazardous waste (check with the pharmacist where necessary).

Identify any flammable waste and store separately until this can be removed by the waste contractor. …

Complete the ‘Patients Returns Sheet’ detailing the patients name and address, also if relevant their representatives name.

Store returned medicines in the quarantine area of the van for transport.

The returnable items can be taken back to the pharmacy for destruction.”

6.76 Under the heading ‘Disposal of returned medicines’ SOP 21 states:

6.76.1 *“Use the specialist waste management company to provide safe and secure disposal of unwanted medicines by collection of unwanted medicines from patients and residential homes.*

Unwanted medicines collected by the driver must be sorted and placed in disposal units / containers provided by the NHSCB or a waste contractor retained by the NHSCB ready for waste management services to collect.”

6.77 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.

Promotion of healthy lifestyles

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

6.79 The Committee noted SOP 23 'Promotion of Healthy Lifestyle & Public Health Campaigns' under the heading 'Public Health Campaigns' states:

6.79.1 *"The pharmacy will take part in national health campaigns to promote public health messages to our patients across England. This will be achieved by sending out leaflets with prescriptions during specific targeted campaign periods and providing additional advice and learning resources via the website. …*

We will also offer help and support on our website and direct patients to appropriate links for the health campaigns. This will ensure that patients across the UK are able to easily access information about health campaigns at all times."

6.80 Further, in SOP 23 under the heading 'Identification of patients for promotion of Healthy Lifestyles' it states:

6.80.1 *"Leaflets will be delivered to patients with their medication. Those identified as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns. The website, app and email newsletters will also be used to promote healthy lifestyles."*

6.81 The Committee was 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

6.82 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.

6.83 The Committee noted SOP 23 under the heading 'Identification of patients for promotion of Healthy Lifestyles' states:

6.83.1 *"Identification can take three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process.*

***Active patients** will be those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further information should be sent, or who should be called to follow up on the results and offer additional support and information. All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight and also lifestyle questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.*

***Passive patients** are those where the identification happens as part of another interaction with the patient, but where the patient does not appear to be actively seeking additional assistance. For example, the*

dispensing of a prescription which identifies the patient as having high blood pressure / diabetes etc.

As part of repeat dispensing process (or during any other interaction with a patient) *staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from promotion of healthy lifestyles they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided.*

Leaflets will be delivered to patients with their medication. Those identified as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns. The website, app and email newsletters will also be used to promote healthy lifestyles."

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

Public health campaigns

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

6.86 The Committee noted under the heading 'Public Health Campaigns' SOP 23 states:

6.86.1 *"The Pharmacy will take part in national health campaigns to promote public health messages to our patients across England. This will be achieved by sending out leaflets with prescriptions during specific targeted campaign periods and providing additional advice and learning resources via the website.*

Patients will be directed to the learning resources via email, text and other non-face-to-face communication so that they are aware of the campaign….

We will also offer help and support on our website and direct patients to appropriate links for the health campaigns. This will ensure that patients across the UK are able to easily access information about health campaigns at all times. The Pharmacy will send out 'quit kits' to patients who are looking to stop smoking. Examples of campaigns that we will take part in are: Be Clear on Cancer, Stoptober, Change for Life, Make the Right Choice and Sexual Health campaigns.

The Pharmacy will use the opportunity when dispensing prescriptions for patients who have conditions such as diabetes, heart disease, obesity and high blood pressure, to offer health advice over the phone or provide them with leaflets about their conditions. Patients will also be able to speak to the pharmacist regarding information about the campaigns. Advice and help will be available to patients during opening hours of the pharmacy and patients can access information on our

pharmacy website at all times. This ensures the uninterrupted provision of services to patients across England."

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

Signposting

6.88 The Committee considered whether the Applicant had explained how it will provide information to users of the pharmacy about other health and social care providers and support organisations.

6.89 The Committee noted in SOP 22 'Support for Self-Care, Signposting and Health Promotion' under the sub heading 'Signposting' it states:

6.89.1 *"Patient Identification*

Identification can take place during any interaction that the patient has with the pharmacy staff. In particular, staff should consider the results from the identification of patients for the promotion of healthy lifestyles and those who have filled in the Lifestyle Questionnaire on the website.

Staff should always consider that in order to minimise inappropriate use of health and social care services and of support services and person who:

requires advice, treatment or support that we cannot provide; but

we are aware of another provider of health services who is likely to be able to provide that advice, treatment or support.

6.89.2 *We must provide the patient with contact details of that provider and, where appropriate, refer the person to the provider. At least two providers should be identified if this is possible."*

6.90 Under the sub heading 'Other Provider Organisations and Support Details' SOP 22 also states:

6.90.1 *"Details of local health and social care providers to whom patients can be referred as well as contact details for local patient and support groups can should be provided to patients via written mailshots, flyers sent with prescription deliveries, our website and by telephone or email.*

The following links will be available to patients on our website (to be updated on an annual basis)…"

6.91 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 19 – 20 of Schedule 4.

Support for self-care

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

6.93 The Committee noted SOP 22 under the heading 'Service outline' states:

6.93.1 *"Upon receipt of a request for help with the Support for Self-Care, including treatment of minor illness and long-term conditions, pharmacy staff should consider available resources and provide general information and advice on how to manage illness.*

Advice should be backed up, as appropriate, by the provision of written material such as leaflets.

When such a request is received, the pharmacist should be informed and a record kept of the request.

Advice (and requests for advice) must operate without face-to face interaction (e.g. telephone, Skype, via the website)."

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

Summary

6.95 On the information before it, the Committee could be satisfied that there are procedures likely to secure safe and effective provision of essential services as required by Regulation 25(2)(b).

6.96 Taking into account the additional information which had been provided by the Applicant, in the form of an updated set of SOPs which had not been provided to NHS England, the Committee determined that the decision of NHS England must be quashed.

6.97 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.

6.98 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.

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

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

7.2.2.5 the Committee was satisfied that all essential services were likely to be secured in a safe and effective manner,

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

7.2.3 The application is granted.

Rachel White
Technical Case Manager
Primary Care Appeals

A copy of this decision is being sent to:

Rushport Advisory LLP
NHS England