

21 January 2020

**REF: SHA/22233**

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**APPEAL AGAINST MIDLANDS (CENTRAL MIDLANDS) AREA TEAM, NHS COMMISSIONING BOARD "NHS ENGLAND" DECISION TO GRANT AN APPLICATION BY PHARMACY 2U LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT UNIT 3, MOUNT PARK BARDON, ROBSON WAY, LEICESTERSHIRE LE67 1FB 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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UNIT 2003



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## 1 The Application

By application dated 5 October 2018, Pharmacy 2U Ltd ("the Applicant") applied to NHS Commissioning Board ("NHS England") for inclusion in the pharmaceutical list at Unit 3, Mount Park Bardon, Robson Way, Leicestershire LE67 1FB 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: "*The Applicant will providing dispensing of appliances including ostomy and other products.*"
- 1.2 In response to why the application should not be refused pursuant to Regulation 31 the Applicant made no comment.
- 1.3 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant made no comment.

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 Please see the specification of the facility attached. This is a £10m investment into the most automated pharmacy facility in the UK.
- 1.6 There are significant processes and procedures in place and established in the Applicant's Leeds facility alongside business continuity to ensure systems are in place for the uninterrupted provision of essential services and safe and affective supply. This includes:

- 1.6.1 Range of staff with defined roles;
  - 1.6.2 Culture of openness;
  - 1.6.3 Effective SOPS and reporting of near misses;
  - 1.6.4 Strong information management;
  - 1.6.5 Secure premises;
  - 1.6.6 Highly automated systems and robots
  - 1.6.7 Systems in place to ensure delivery nationwide;
  - 1.6.8 Priority to the largest RM (Royal Mail) distributions hub and key suppliers;
  - 1.6.9 Ability to offer CD and fridge dispensing.
- 1.7 The Applicant intends to provide the following services:
- 1.7.1 Essential services
  - 1.7.2 Clinical governance
  - 1.7.3 The Applicant in tends to provide the following Enhanced and Advanced services:
    - 1.7.3.1 New Medicines Service – the applicant stated that there is no consultation area as NMS is done by telephone.
- 1.8 The Applicant’s proposed core opening hours are:
- 1.8.1 Mon to Fri 9 – 6
  - 1.8.2 Sat -
  - 1.8.3 Sun -
- 1.9 The Applicant’s proposed total opening hours are:  
(As above).

## 2 The Decision

NHS England considered and decided to grant the application. The decision letter dated 22 August 2019 states:

### Covering letter

- 2.1 NHS England has considered the application and is writing to confirm that it has been granted. Please see the enclosed report for the full reasoning.
- 2.2 The report details the conditions that will be placed upon the Applicant’s inclusion in the relevant pharmaceutical list should a valid notice of commencement be received. Enclosed is a form confirming acceptance of

these conditions. It should be signed by an authorised person and returned to NHS England with the Applicant's notice of commencement.

- 2.3 Also enclosed is a template of the notice of commencement which is the Applicant is required to submit to NHS England. Please note that if this is submitted before the end of the 30 day appeal period and a valid notice of appeal is then received by the Secretary of State, the notice of commencement will cease to have effect. This means that if the Applicant has opened its new premises then it will be required to close with immediate effect.
- 2.4 Please also note that the Applicant may only submit the notice of commencement up to 14 days before the date it intends to start service provision. If it is received more than 14 days in advance it is not a valid notice of commencement and will not be accepted by NHS England.

#### NHS England's Decision Report

- 2.5 NHS England agreed that there is no reason to decline the application and as the regulatory criteria has been met, the application is approved.
- 2.6 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 Leicestershire Health and Wellbeing Board in respect of the premises included in the application that inclusion will be subject to the following conditions:
- 2.6.1 The Applicant must not offer to provide pharmaceutical services to persons who are present at (which includes in the vicinity of) the proposed premises;
- 2.6.2 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;
- 2.6.3 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;
- 2.6.4 the pharmacy procedures for the premises must be such as to secure:
- 2.6.4.1 the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and
- 2.6.4.2 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
- 2.6.5 nothing in the Applicants practice leaflet, in the Applicants 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 Applicants staff to any person seeking the provision of

essential services from the Applicant must represent, either expressly or implied, that:

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

2.6.5.2 the Applicant is likely to refuse, for reasons other than those provided for in the Applicants 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 19 September 2019, Lloyds Pharmacy Ltd (“the Appellant”) appealed against NHS England’s decision. The grounds of appeal are:

3.1 The Appellant is writing to appeal the decision of NHS England to approve the application made by Pharmacy2U Ltd. The decision was communicated to the Appellant by letter dated 22 August 2019.

3.2 The Appellant’s grounds for appeal are that whilst NHS England has repeated the legal test (or at least part of it) in their decision letter, the entire reasoning provided by NHS England for reaching their decision is as follows;

3.2.1 *“NHS England agreed that there is no reason to decline the application and as the regulatory criteria has been met, the application is approved.”*

3.3 As the Committee will be aware, NHS England has applied the wrong test to this application. Instead of considering if the Applicant met all parts of the legal test and providing reasons for their decision, NHS England has instead reversed the legal test and found no reasons for refusal.

3.4 It is unclear what reasons NHS England could have had for refusal if they were looking for any as the Applicant provided virtually no information with their application that could be assessed against the legal test. In fact, there is no information to show how the Applicant would meet any part of the legal test and therefore it is not lawful for NHS England to have approved the application and nor is it possible for interested parties to provide any meaningful comments save to say that the information is missing.

3.5 In addition to the various parts of Regulation 25 that are listed in the NHS England decision letter, but which are not addressed in any meaningful way by the Applicant, the Appellant also notes the following;

3.5.1 The Applicant intends to provide full appliances if this application is approved. No information has been provided about how measuring or fitting will take place. The Appellant would be grateful if the Applicant would confirm how they currently manage this process in their existing distance selling pharmacy and confirm if this process will be replicated in the new facility?

- 3.5.2 The Appellant's opening hours are from 9am to 6pm Monday to Friday. The Appellant would be grateful if the Applicant would confirm if they intend to allow the pharmacist to take rest breaks and use the GPhC provisions that allow for the pharmacist to not be on the premises, or if the pharmacist will work all day without a break?
- 3.5.3 The Appellant understands that the Applicant will deliver cold chain items by Royal Mail, but this is not confirmed, and the Appellant would be grateful for more information as to how this process works.
- 3.5.4 The Appellant understands that the Applicant allows Royal Mail to deliver prescription items to a nominated "safe place", such as "leave in the porch" and would be grateful for more information on how this delivery process works.
- 3.5.5 It is unclear how the Applicant will comply with the Terms of Service requirements for contractors. The Appellant understands that the Applicant has SOPs that they use in another pharmacy and either may or may not use the same SOPs in this application, but as they have not been provided, the Appellant cannot comment further.
- 3.5.6 Regrettably some of the information that is handwritten on the application from to describe procedures is not legible. The Appellant would be grateful for a typed copy of these procedures so that it can comment further. However, as far as the Appellant can tell the points do not cover the regulatory requirements.
- 3.5.7 The Appellant notes that since the application was submitted, Mr ## has resigned as a director of the company and the Appellant presumes will not be the superintendent pharmacist. This information should be updated on the application form.
- 3.5.8 The Appellant would be grateful for more clarification on the Applicant's delivery processes including whether they use any of their own delivery drivers as no information has been provided about how medicines will be delivered. If the Applicant could provide details on their current delivery procedures and confirm if these will be replicated in the new facility, then this may be sufficient.
- 3.6 The Appellant believes that this application fails to meet the legal test and should be refused.

#### 4 **Summary of Representations**

This is a summary of representations received on the appeal.

##### **Pharmacy 2U Ltd (Applicant)**

- 4.1 In relation to Regulation 31, no person on the pharmaceutical list is already providing or has undertaken to provide pharmaceutical services from premises, or adjacent premises.
- 4.2 In relation to Regulation 25, the premises in respect of which the application is being made is not on the site or in the same building as the premises or a provider of medical services with a patient list; and the pharmacy procedures

for the pharmacy premises, as previously calculated, will 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 effective provision of essential services without face to face contact between any person receiving those services, whether on their own or someone else's behalf, and any Pharmacy 2U staff.

4.3 Please find below the Applicant's comments on the note made by Lloyds Pharmacy in their letter dated 19 September 2019 which NHS Resolution circulated with its letter:

4.3.1 *The Applicant intends to provide full appliances if this application is approved. No information has been provided about how measuring or fitting will take place. The Appellant would be grateful if the Applicant would confirm how they currently manage this process in their existing distance selling pharmacy and confirm if this process will be replicated in the new facility?*

4.3.2 The Applicant intends to supply appliances in the normal course of its business. The Applicant does this in its existing pharmacy. The Applicant is not permitted to offer essential NHS services on the premises so this has to be done remotely. The Applicant's current process is to contact patients wherever necessary and ask them to provide measurements; the Applicant guides them as to which measurements are necessary, how to take them, and how to send the details back to the Applicant promptly. If the Applicant assesses the patient as not being able or willing to provide accurate measurements, the Applicant will recommend that the prescriptions is returned to the spine to be dispensed elsewhere, or the Applicant will contact the patients surgery for assistance.

4.3.3 The Applicant believes that not offering to dispense appliances would significantly compromise the convenience of its service as these are often bulky items for which home delivery (distance selling) pharmacy is particularly well suited. The Applicant therefore intends to offer appliance dispensing whilst recognising that gathering measurements may be difficult in some circumstances; and the Applicant is fully committed to helping patients to obtain their measurements and appliances elsewhere if this is the best option for them, as the Applicant does in its existing pharmacy.

4.3.4 *The Applicant's opening hours are from 9am to 6pm Monday to Friday. The Appellant would be grateful if the Applicant would confirm if they intend to allow the pharmacist to take rest breaks and use the GPhC provisions that allow for the pharmacist to not be on the premises, or if the pharmacist will work all day without a break?*

4.3.5 The Applicant confirms that it intends to allow the pharmacist to take rest breaks. The pharmacist will not be expected to work all day without a break.

4.3.6 *The Appellant understands that the Applicant will deliver cold chain items by Royal Mail, but this is not confirmed, and the Appellant would be grateful for more information as to how this process works.*

- 4.3.7 The Applicant intends to dispense and dispatch cold chain items from this pharmacy. The Applicant's intended delivery processes are described in the SOP "BSOP1. Delivery of medicines and patient returns (version 1)" which has been circulated.
- 4.3.8 *The Appellant understands that the Applicant allows Royal Mail to deliver prescription items to a nominated "safe place", such as "leave in the porch" and would be grateful for more information on how this delivery process works.*
- 4.3.9 Royal Mail offer a "Safeplace" service. This is described in the following pages:
- 4.3.9.1 <https://www.royalmail.com/corporate/sending-receiving/uk/safeplace/>
- 4.3.9.2 [https://business.help.royalmail.com/app/answers/detail/a\\_id/13174/~/items-delivered-to-my-designated-safeplace](https://business.help.royalmail.com/app/answers/detail/a_id/13174/~/items-delivered-to-my-designated-safeplace)
- 4.3.10 Royal Mail's internal guidelines for this services state that:
- 4.3.10.1 Risk assessments of their service have been conducted;
- 4.3.10.2 Royal Mail photo ID is worn or carried by staff at all times;
- 4.3.10.3 Items can be left in the designated Safeplace only when the item is sent using a Tracked service, and when there is a Safeplace instruction;
- 4.3.10.4 If the Safeplace location is not considered to be secure, is open to the elements, is dangerous to access, and/or it may potentially be damaged or stolen, the item is not to be left in the Safeplace but taken back to the delivery office and a "Something for You" card is left for the occupier. An email and/or SMS notification may also be sent;
- 4.3.10.5 The location of the Safeplace used must match the one of the options on the staff member's handheld computer and this is then to be confirmed on the computer;
- 4.3.10.6 A photograph is taken of the Safeplace to provide an internal audit trail;
- 4.3.10.7 A "Something for You" card is left for the recipient after a parcel has been deposited successfully in the Safeplace;
- 4.3.10.8 Royal Mail may send an email and/or SMS notification to the recipient with information about specific Safeplace location the item was delivered to, and may also include a photograph of the Safeplace.
- 4.3.11 *It is unclear how the Applicant will comply with the Terms of Service requirements for contractors. The Appellant understands that the Applicant has SOPs that they use in another pharmacy and either may*

*or may not use the same SOPs in this application, but as they have not been provided, the Appellant cannot comment further.*

- 4.3.12 SOPs have now been provided as part of the most recent set of documentation. These detail how the Applicant intends to meet all of the Essential services of the NHS Contract without interruption and without face to face contact with patients or their representatives.
- 4.3.13 *Regrettably some of the information that is handwritten on the application form to describe procedures is not legible. The Appellant would be grateful for a typed copy of these procedures so that it can comment further. However, as far as the Appellant can tell the points do not cover the regulatory requirements.*
- 4.3.14 The Applicant has typed out the relevant sections and included these in the appendix to this document.
- 4.3.15 Since the application form has been submitted, the Applicant has provided to NHS England a copy of the proposed SOPs which demonstrate how pharmacy will operate safely and effectively to patients throughout England and without face to face contact.
- 4.3.16 *The Appellant notes that since the application was submitted, Mr ## has resigned as a director of the company and the Appellant presumes will not be the superintendent pharmacist. This information should be updated on the application form.*
- 4.3.17 The Applicant has already notified NHS England of the change of Superintendent pharmacist and it received a letter dated 11 July 2019 confirming their approval of the fitness information in respect of the appointment of ### as superintendent pharmacist of Pharmacy 2U Ltd. The Applicant provides a copy letter confirming that Pharmacy 2U Ltd remains a suitable person to be included on the pharmaceutical list.
- 4.3.18 *The Appellant would be grateful for more clarification on the Applicant's delivery processes including whether they use any of their own delivery drivers as no information has been provided about how medicines will be delivered. If the Applicant could provide details on their current delivery procedures and confirm if these will be replicated in the new facility, then this may be sufficient.*
- 4.3.19 The Applicant's intended delivery processes are described in the SOP "BSOP1 Delivery of medicines and patient returns (version 1)" which has been circulated.

Note

- 4.3.20 The Applicant's existing pharmacy in Leeds has been operating as a distance selling pharmacy since 1999 and has had many regulatory inspections from the General Pharmaceutical Council, NHS England and the Care Quality Commission in that time. The most recent full inspections from each of these bodies have found all aspects of the Applicant's delivery of NHS essential services to be satisfactory.

## **NHS England**

- 4.4 NHS England provided a copy of its Pharmaceutical Services Regulations Committee minute dated 23 July 2019 which includes:

4.4.1 *“The committee agreed that there is no reason to decline the application and as the regulatory criteria has been met, the application is approved.”*

- 4.5 NHS England provided copies of representations made to it in response to the application:

### **Masons Chemist**

4.5.1 It is noted this is an application for Distant Selling. Masons would ask the NHS England 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 and for NHS England to be fully satisfied that the Applicant has provided sufficient information and enclosures for it to be satisfied that the Applicant will meet obligations under Regulation 64.

4.5.2 In the application the Applicant has failed to provide evidence of how they intend to provide the safe and effective provision of all essential services without face to face contact nor how they will ensure these services are uninterrupted, particularly given a history of problems with their existing contract. It is also noted that the applicant seems to have referred to them currently operating a distance selling pharmacy in another part of the country as sufficient evidence that they meet the Regulations however whilst this may be the case, this does not in itself evidence the criteria for which this application should be considered.

4.5.3 Finally the application references building specifications for toilets which were not enclosed.

### **Well Pharmacy**

4.5.4 The AT must be assured that this application fully satisfies Regulation 25 and Regulation 64 of the NHS (Pharmaceutical Services) Regulations 2013 before it should be granted.

4.5.5 The AT should have regard to regulation 25(2) which states that the NHSCB must refuse the application unless it is satisfied that the procedures of the proposed pharmacy premises will allow the uninterrupted provision of essential services during the opening hours stated on the application form from anywhere in England. Furthermore, the safe and effective provision of essential services must be assured without face to face contact with the patient or the patient's representative.

4.5.6 Well respectfully draw the AT's attention to the fact that this application should not be approved automatically. In order to approve an application under the "distance selling premises" exemption, the application must wholly satisfy the Regulations rather than partially satisfy them.

## Leicestershire & Rutland LPC

- 4.5.7 The LPC have reviewed the application submitted to NHS England.
- 4.5.8 Applications for distance-selling premises must meet certain criteria and these are listed in regulation 25 and regulation 64.
- 4.5.9 The Applicant fails to provide evidence and supporting information to satisfy regulation 25 and the conditions set out in regulation 64.
- 4.5.10 Specifically, the application does not provide evidence of how they would provide safe and effective provision of uninterrupted essential pharmaceutical services without face to face contact (e.g. deliveries/assessments). The fact the Applicant may operate a distant selling pharmacy in another part of the country is not in itself evidence the criteria for this new application is met.
- 4.5.11 In addition, the LPC note that the application refers to building specifications for toilets which were not enclosed.
- 4.5.12 The LPC would request that the Area Team has satisfied themselves that this application fully meets the requirements of Regulation 25 of the NHS Pharmaceutical Regulations 2012. In particular, the Area Team should be satisfied that the Applicant has **clearly demonstrated** that they **have procedures in place**:
  - 4.5.12.1 in order 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
  - 4.5.12.2 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.
- 4.6 The Area Team should have particular regard to ensuring that the application or supporting documents clearly demonstrate that the Applicant had shown consideration towards:
  - 4.6.1 Effective contingencies in the event of a postal strike;
  - 4.6.2 Proposals for receiving patient waste medicine returns;
  - 4.6.3 Proposals for compliance with Public Health Campaigns;
  - 4.6.4 Procedures regarding the processing and delivery of prescriptions for Controlled Drugs.

## Lloyds Pharmacy Ltd

- 4.6.5 It is noted this is application for Distant Selling. The Applicant has provided no evidence to support the application in the context of Regulation 25 and the conditions set out in Regulation 64. The Applicant only relies that there are processes and procedures in place at their Leeds facility. No processes or procedures are provided as part

of this application. It cannot be assumed that because services are provided from another facility that they are met in this instance.

- 4.6.6 No details are provided about delivery of medicines and no evidence is provided with regards to processes in place for cold chain lines. Neither is evidence provided for where if assessments are required how this would be undertaken without face to face contact.
- 4.6.7 This application cannot be approved under Regulation 25 and therefore must be refused.

**Boots UK Ltd**

- 4.6.8 Very little information has been provided with the application. In section 7 of the application it states: "Please see the specification of the facility attached" however, no attachments have been circulated with the application.
- 4.6.9 Boots do not believe that the Applicant has submitted sufficient evidence for the deciding Committee to be satisfied that the Applicant will provide safe and effective provision of essential services.
- 4.6.10 Boots therefore request that the deciding Committee refuse this application.

**Charles Russell Speechlys LLP (on behalf of the Applicant)**

- 4.7 As NHS England will be aware, each of the interested parties makes essentially the same comment; whether the Applicant has provided sufficient information to NHS England to satisfy it that the requirements of Regulation 25 are met.
- 4.8 In fact, the Applicant has provided a significant amount to NHS England in respect of the provision of pharmaceutical services by the proposed pharmacy including supplying NHS England with SOPs on 1 February 2019 detailing how each essential service would be provided safely and effectively in the distance selling context.
- 4.9 The purpose of the Applicant submitting this information is to satisfy NHS England that the application meets the requirements of regulation 25. It is of course, not for NHS England to "approve" or "disprove" of the information provided. Regulation 25 does not require an Applicant to repeat every element of the Terms of Service and, indeed, it would be impossible for an Applicant to deal with every eventuality that may arise in any pharmacy.
- 4.10 The purpose of the information provided is to give NHS England an overview of the provision of each service so that it can be satisfied that the proposed pharmacy would be in a position to provide each essential service safely and effectively without face to face contact with a patient no matter where in England the patient lives. NHS England will be aware that the Applicant already operates the largest online pharmacy in the UK and therefore has a significant amount of expertise in providing pharmaceutical services remotely.
- 4.11 For the avoidance of doubt, in relation to the statutory test which must be met by the Applicant, it comments as follows:

#### Regulation 31

- 4.12 The premises to which this application relates are neither the same as, nor adjacent to, premises which are already included in the pharmaceutical list. Regulation 31 does not therefore apply to the determination of this application.

#### Are the premises on the same site or in the same building as the premises of a provider of primary medical services with a patient list?

- 4.13 The Applicant confirms that the premises to which this application relates 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.

#### Regulation 25

- 4.14 The pharmacy's procedures are likely to secure:

#### The uninterrupted provision of essential services during the opening hours of the premises

- 4.15 The applicant has detailed how essential services will be provided throughout the pharmacy's proposed opening hours. For the avoidance of doubt, the Applicant confirms that the responsible pharmacist will not be absent during the contractual or non-contractual opening hours as notified to NHS England. This will ensure the uninterrupted provision of pharmaceutical services during the opening hours of the premises.

#### To persons anywhere in England

- 4.16 The Applicant has provided information for each essential service explaining how it will be provided throughout England in the previously supplied SOPS.

#### Safe and Effective provision of essential services

- 4.17 The Applicant's procedures detail how essential service will be provided both safely and effectively.

#### Without face to face contact

- 4.18 The information provided by the Applicant in its SOPs confirms that there will be no face to face contact with patients and the pharmacist or the pharmacy's staff, not least since no patients will ever be present on the pharmacy premises.

- 4.19 In conclusion the Applicant has provided suitable and sufficient information to satisfy NHS England that its application meets the requirements of Regulation 25. For the reasons given above and on behalf of the Applicant, we request that NHS England grants this application.

#### **Leicestershire & Rutland LPC**

- 4.20 The LPC notes that the appeal centres around the possible incorrect interpretation of the regulatory test.

- 4.21 As this is an appeal and the entire application is considered afresh, it would expect NHS Resolution will look at this aspect in detail and apply the correct regulations.

- 4.22 It is also minded to query the circulation list, as the application has wider implications for an area not limited to the immediate vicinity of the proposed pharmacy, not least in terms of workforce retention and recruitment which may impact on the provision of pharmacy services in adjacent localities.
- 4.23 The LPC would be grateful if you could continue to keep the LPC informed and confirm that it would be more than happy to attend an oral hearing should one be required.

## 5 Summary of Observations

The following observations were received:

### Lloyds Pharmacy Ltd

- 5.1 Lloyds have now received from NHS Resolution a copy of the SOPs that Pharmacy2U have referred to and which Lloyds had not previously had sight of.
- 5.2 Lloyds have gone through both the Pharmacy2U response to its letter of appeal and the SOPs and it is clear that there are still significant shortcomings with the documents and evidence provided and the application does not meet the requirements of regulations 25.
- 5.3 The Applicant's response provides a number of reasons for refusing this application which include but are not limited to;
- 5.3.1 The Applicant confirms that they will provide a measuring and fitting service, but then states that they do not in fact offer this service at their existing NHS distance selling pharmacy and will not offer it at the proposed new premises and will instead ask patients to send measurements to them and if patients are not "able or willing" then these prescriptions are returned to the spine.
- 5.3.2 Asking patients to provide measurements if they are able and willing is not a measuring and fitting service. The Applicant appears to accept this and says that an inability to provide this service would "compromise the convenience of our service". As the Committee will be aware, this is not a ground for approving the application.
- 5.4 The pharmacist (singular) will be taking breaks during the contracted hours.
- 5.5 Cold Chain deliveries. Lloyds ask the Committee to consider whether the use of the Woolcool system is acceptable as a means of cold chain delivery. Lloyds should add that it does not object to the use of this type of packaging as it does appear to work well for this type of delivery and is MHRA approved. Lloyds would accept that temperature monitoring may not be required if the packaging used has been MHRA approved for the delivery of cold chain items over a limited time period. Lloyds would similarly accept that the MHRA is likely to be best placed to decide on the effectiveness or packaging used for deliveries given that it is one of their areas of expertise.
- 5.6 Royal Mail "safeplace" – Lloyds ask the Committee to consider whether leaving dispensed medication in a porchway or other chosen location outside a house is "safe and effective".

- 5.7 The Applicant states that the SOPs provided:
- 5.7.1 *“detail how we intend to meet all of the Essential services of the NHS contract without interruption and without face to face contact with patients or their representatives”*
- 5.8 Unfortunately the SOPs do not deal with all essential services. Almost all the SOP content (90 out of 93 pages) refers to controlled drugs in one way or another. No information is provided about even the most basic pharmacy functions, such as dispensing a prescription, other than for controlled drugs. Many essential services are simply not dealt with at all and Lloyds trust that the Committee will consider all the relevant Terms of Service and essential services when assessing this application.
- 5.9 The Applicant adds a “Note” which essentially asks the Committee to accept that because they are Pharmacy2U and have been operating a distance selling pharmacy since 1999 that their current application should in some way be treated more favourably. However, Lloyds note that the distance selling exemption has only existed since 2005 and it is therefore likely that the Applicant has never been properly assessed against the current Regulations.
- 5.10 In particular Lloyds ask the Committee to note that little or no information is provided in respect of;
- 5.10.1 Refusal to provide drugs or appliances ordered;
- 5.10.2 Process for payment of NHS charges;
- 5.10.3 Dispensing a repeatable prescription other than on the first occasion – side effects / changes;
- 5.10.4 Explaining the benefits of repeat dispensing;
- 5.10.5 Promotion of Healthy Lifestyles;
- 5.10.6 Prescription linked interventions;
- 5.10.7 Participation in public health campaigns;
- 5.10.8 Signposting;
- 5.10.9 Support for self-care;
- 5.10.10 Urgent supply;
- 5.11 Lloyds Pharmacy continues to believe that this application fails to meet the legal test and should be refused.

## 6 **Consideration**

- 6.1 The Pharmacy Appeals Committee (“Committee”) appointed by NHS Resolution, had before it the papers considered by NHS England. It also had before it the responses to NHS Resolution’s own statutory consultations.
- 6.2 On the basis of this information, the Committee considered it was not necessary to hold an Oral Hearing.

- 6.3 The Committee noted NHS England's decision letter included no information in support of its decision to grant the application. This was referred to by Lloyds Pharmacy on appeal. The Committee, mindful that it would be considering the application afresh, took no view on the content of the decision letter.
- 6.4 The Committee noted the LPC's comment on appeal: *"We are also minded to query the circulation list, as the application has wider implications for an area not limited to the immediate vicinity of the proposed pharmacy, not least in terms of workforce retention and recruitment which may impact on the provision of pharmacy services in adjacent localities."* The Committee was aware that NHS Resolution's distribution list for the appeal is in accordance with the regulations, based upon those parties who were notified by, and made representations to NHS England in response to the application. It was therefore, not a matter for NHS Resolution to circulate the appeal more widely for comment.
- 6.5 The Committee noted the appeal letter includes: *"Regrettably some of the information that is handwritten on the application from to describe procedures is not legible."* The Committee was satisfied that in response to the appeal, the Applicant had addressed this: *"I have typed out the relevant sections and included these in the appendix to this document."* The Committee noted that point 1 above, includes all of the previously illegible details.
- 6.6 The Committee further noted the appeal letter states: *"We note that since the application was submitted, Mr ## has resigned as a director of the company and we presume will not be the superintendent pharmacist. This information should be updated on the application form."* The Applicant responded: *"We have already notified NHS England of the change of Superintendent pharmacist and we received a letter dated 11 July 2019 confirming their approval of the fitness information in respect of the appointment of ### as superintendent pharmacist of Pharmacy 2U Ltd."* A copy letter from NHS England to the Applicant dated 11 July 2019, states: *"Further to previous correspondence all statutory fitness to practise checks in connection with the change of superintendent have been concluded. As a result I am pleased to confirm that NHS England has determined that Pharmacy 2U Ltd remains a fit and proper person to be included in the pharmaceutical list in respect of the area of Leeds Health and Wellbeing Board."* The Committee also noted a covering email from Primary Care Support England to the Applicant also dated 11 July 2019 confirms: *"NHS England have approved the fitness information in respect of the appointment of ### as Superintendent of Pharmacy2U Ltd. Please therefore find attached a letter confirming that Pharmacy2U Ltd remains a suitable person to be included on the pharmaceutical list."* Having regard to the above, the Committee was satisfied that the superintendent pharmacist currently associated with the application has been approved by NHS England.
- 6.7 The Committee noted Masons Chemist's representations on the application include: *"...the application references building specifications for toilets which were not enclosed."* The LPC stated: *"In addition, we note that the application refers to building specifications for toilets which were not enclosed."* The Applicant had not responded on appeal to any omission of building specifications. The Committee considered that the outcome of the appeal on this occasion, was unlikely to be influenced by that information.
- 6.8 The Committee had regard to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations").

**Regulation 31**

6.9 The Committee first considered Regulation 31 of the regulations which states:

*(1) A routine or excepted 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).*

6.10 The Committee noted that on its application form the Applicant made no comment regarding Regulation 31. The wording of the application form only required the Applicant to include information in the relevant section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee considered it reasonable to determine that the lack of information in the application form on this point when read with the wording of the application form allowed it to be reasonably satisfied that the Applicant considered that the proposed premises were not adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee noted NHS England's decision letter included no reference to any consideration by it of Regulation 31. However, in its representations on appeal, the Applicant stated: "*In relation to Regulation 31, no person on the pharmaceutical list is already providing or has undertaken to provide pharmaceutical services from the premises, or adjacent premises.*" The Committee having regard to the information provided to it including that the above had not been disputed on appeal, determined that it was not required to refuse the application under the provisions of Regulation 31.

**Regulation 25**

6.11 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."*

6.12 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.*

- 6.13 Pursuant to paragraph 9(1)(a) of Schedule 3 to the Regulations, the Committee may:
- 6.13.1 confirm NHS England's decision;
  - 6.13.2 quash NHS England's decision and redetermine the application;
  - 6.13.3 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)**

- 6.14 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)**

- 6.15 As far as Regulation 25(2)(a) is concerned, the Committee noted the Applicant had made no comment on its application form. The Committee further noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee noted that there is no reference in NHS England's decision letter to any consideration by it of Regulation 25(2)(a). However, when making representations on the appeal, the Applicant has stated: "*...the premises in respect of which the application is made is not on the same site or in the same building as the premises of a provider of medical services with a patient list*". The Committee having noted the information provided to it and noting that the above had not been disputed on appeal, was 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)**

- 6.16 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.
- 6.17 The Regulations require the Committee to be satisfied as to a number of matters, including that essential services will be provided on an uninterrupted basis, in a safe and effective way, across England, and without face to face contact.
- 6.18 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicates that the obligation

is only discharged if the information or documentation provided is sufficient to satisfy NHS England in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that NHS England may need to make of the information or documentation when carrying out its functions.

- 6.19 The Committee has asked itself whether it has sufficient information and documentation which would address the criteria in Regulation 25(2)(b). If the Committee is to be satisfied of the matters in that paragraph, the Committee must be provided with evidence to demonstrate these matters. In this case, that evidence put forward has taken the form of the original application and the Standard Operating Procedures (SOPs) which the Applicant has prepared or commissioned. The Committee was informed that these SOPs were not copied to interested parties on being notified of the application. This had led to the Appellant's comment on appeal:

*6.19.1 "...the Applicant provided virtually no information with their application that could be assessed against the legal test. In fact, there is no information to show how the Applicant would meet any part of the legal test..."*

- 6.20 The Committee was aware that prior to its circulation of the appeal, NHS Resolution had requested the Applicant to provide an up-to-date version of its SOPs in the knowledge that these would also be seen by the Appellant and interested parties. The Applicant responded in an email dated 9 October 2019. The Appellant submitted observations in respect of those SOPs. However, a further set of SOPs was provided by the Applicant following NHS Resolution's completion of its consultation process regarding the appeal. The Applicant stated that due to an earlier misunderstanding, the previous SOPs were not complete. Having reviewed the most recently provided SOPs, NHS Resolution decided that it could reach a decision on the appeal, without needing to circulate them to the parties for comment.

- 6.21 The Committee noted that in the appeal letter, prior to having had sight of any SOPs, the Appellant had stated:

*6.21.1 "It is unclear how the Applicant will comply with the Terms of Service requirements for contractors. We understand that the Applicant has SOPs that they use in another pharmacy and either may or may not use the same SOPs in this application, but as they have not been provided, we cannot comment further."*

- 6.22 The Committee noted the SOPs most recently provided to NHS Resolution by the Applicant, bear the proposed site in their title. Even if they had not done so, the Committee was of the view that in submitting the SOPs, the Applicant had indicated that these are the procedures against which it wished to have its application considered.

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

- 6.24 The Committee noted that in its representations on the application, Masons Chemist had stated: *“In the application the applicant has failed to provide evidence of how they intend to provide the safe and effective provision of all essential services ( a similar point was made to the LPC) without face to face contact nor how they will ensure these services are uninterrupted, particularly given a history of problems with their existing contract.”* In their response to the representations made on the application, Charles Russell Speechlys LLP then commenting on behalf of the applicant responded: *“Our client has detailed how essential services will be provided throughout the pharmacy’s proposed opening hours. For the avoidance of doubt our client confirms that the responsible pharmacist will not be absent during the contractual or non contractual opening hours as notified to NHS England. This will ensure the uninterrupted provision of pharmaceutical services during the opening hours of the premises.”*
- 6.25 The Committee whilst having regard to the above, considered from the information provided to it, whether it was satisfied that the provision of services would be without interruption.
- 6.26 The Committee noted that in its application form, the Applicant had stated: *“There are significant processes and procedures in place and established in our Leeds facility alongside business continuity to ensure systems are in place for the uninterrupted provision of essential services and safe and affective supply. This includes:*
- 6.26.1 *Range of staff with defined roles*
  - 6.26.2 *Culture of openness*
  - 6.26.3 *Effective SOPS and reporting of near misses*
  - 6.26.4 *Strong information management*
  - 6.26.5 *Secure premises*
  - 6.26.6 *Highly automated systems and robots*
  - 6.26.7 *Systems in place to ensure delivery nationwide*
  - 6.26.8 *Priority to the largest RM (Royal Mail) distributions hub and key suppliers.*
  - 6.26.9 *Ability to offer CD and fridge dispensing.”*
- 6.27 The Committee noted the Applicant’s SOP “Responsible Pharmacist regulations (version 1)” page 2, under the heading ‘Absence’ includes the following:
- 6.27.1 *“The legislation allows the Responsible Pharmacist to be absent for up to a maximum period of two hours during the pharmacy’s business hours between midnight and midnight.*
  - 6.27.2 *If there is more than one Responsible Pharmacist in charge of the pharmacy during the pharmacy’s business hours, the total period of*

*absence for all the Responsible Pharmacists must not exceed two hours.*

6.27.3 *If the Responsible Pharmacist is absent, the following arrangements must be in place:*

6.27.3.1 *Only be absent if the pharmacy can continue to run safely and effectively*

6.27.3.2 *Remain contactable with the pharmacy staff*

6.27.3.3 *Be able to return to the pharmacy with reasonable promptness*

6.27.4 *The law recognises that there may be circumstances when a Responsible Pharmacist cannot remain contactable. If this is the case, the Responsible Pharmacist must arrange for another pharmacist to be contactable and available to provide advice (this does not need to be another Responsible Pharmacist)."*

6.28 The Committee noted the assurances given on the Applicant's behalf at paragraph 6.24 above, that the responsible pharmacist: *"....will not be absent during the contractual or non-contractual opening hours as notified to NHS England."* In the Committee's view the Applicant's SOPs as also noted at points 6.26 and 6.27 above, do not necessarily support the inference that services would be provided without interruption. As regards the absence of the Responsible Pharmacist, the Committee considered that unforeseen circumstances may mean that he or she is not contactable, cannot return to the pharmacy if needed with reasonable promptness, and no arrangements have been made for cover by another responsible pharmacist. The Committee was not satisfied that the provision of services would be without interruption.

6.29 The Committee considered whether from the information provided to it, it could be was satisfied that the proposed provision of services would be without face to face contact. The Committee noted the application includes reference to:

6.29.1 *No consultation area as NMS done by telephone.*

6.29.2 *Secure premises*

6.30 As regards the means of communicating with the pharmacy, the committee noted the Applicant's 'SOP for Dispensary - Disposal of Unwanted Medicines' includes:

6.30.1 *"...as a distance selling pharmacy we are not able to offer NHS Essential services on the premises."*

6.31 The Committee further noted the Applicant's 'SOP for Dispensary- Clinical Governance –Premises Standards Programme (version 1)' includes:

6.31.1 *"Requirements*

*The parts of the premises from which NHS services are provided must be recognisable to patients as premises from which high quality NHS services are available, should be generally clean and look professional, and literature on health and social care issues that is available should*

*be up to date. Patients should be able to easily identify areas used for NHS healthcare, for example the prescription reception area and confidential consultation areas. Where practicable the areas used for NHS healthcare should be distinct from areas used for non-healthcare related services.”*

- 6.32 Whilst the same SOP does include reference to the premises with a note in bold indicating that certain parts of the SOP do not apply to Pharmacy 2U's provision of services, the Committee having reviewed the application, representations and SOPs, was provided with no unambiguous information to show that the nature of the building and arrangements to prevent access by patients.
- 6.33 The Committee considered from the information provided to it, that it could not be satisfied that the proposed provision of services would be without face to face contact.
- 6.34 The Committee considered from the information provided to it, whether it was satisfied that the proposed provision of services would be would be available to persons anywhere in England.
- 6.35 The Committee noted that the application refers to the Applicant's proposed use of Royal Mail to delivery dispensed medication. The Applicant's SOP 'BSOP1. Delivery of Medicines and Patient Returns (version 1)' includes under the heading 'Delivery of Medicines':
- 6.35.1 *“We send parcels primarily using Royal Mail tracked and/or signed-for services, depending on the nature of the items being dispatched and the patient's preferences. We always used tracked and signed-for services for any parcels containing controlled drugs, and medicines that require refrigerated storage in transit are packed in pharmaceutical grade WoolCool packaging and sent by a 24 hour tracked service, with the patient being kept informed about the date of dispatch and tracking information of all parcels on every occasion.”*
- 6.36 Whilst the SOP refers to the use of Royal Mail tracked and or signed for services, it does not provide confirmation that the service will be used to dispatch dispensed medication anywhere in England. The Committee having regard to the application, the Applicant's representations on appeal and SOP's found no reference to services being provided to anywhere in England. The Committee was therefore, not satisfied that the proposed provision of services be would be available to persons anywhere in England.
- 6.37 The Committee went on to consider whether safe and effective provision of essential services was likely to be secured.
- 6.38 The Committee considered each essential service in paragraphs 3 to 22 of schedule 4 of the Regulations ("Terms of Service") in turn.
- 6.39 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:
- 6.39.1 Dispensing of drugs and appliances

- 6.39.2 Urgent supply without a prescription
  - 6.39.3 Preliminary matters before providing ordered drugs or appliances
  - 6.39.4 Providing ordered drugs or appliances
  - 6.39.5 Refusal to provide drugs or appliances ordered
  - 6.39.6 Further activities to be carried out in connection with the provision of dispensing services
  - 6.39.7 Disposal service in respect of unwanted drugs
  - 6.39.8 Promotion of healthy lifestyles
  - 6.39.9 Prescription linked intervention
  - 6.39.10 Public health campaigns
  - 6.39.11 Signposting
  - 6.39.12 Support for self-care
- 6.40 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

- 6.41 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. The Committee noted that the Applicant's 'SOP for Dispensary–Repeat Dispensing (version 1)' includes under the heading 'Pharmacy2U specific workflow':
- 6.41.1 "Customer Care will enter patient details onto the CDB in the usual manner. If payment / exemption details are required, the operator will contact the patient to request these. Registration will not be completed until all payment / exemption details have been provided."*
- 6.42 The Committee noted that the application, the Applicant's representations or SOPs, do not include reference to any process by which evidence will be sought and provided about the patients' entitlement to exemption or remissions from NHS Charges.
- 6.43 The Committee was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.
- 6.44 The Committee considered whether the Applicant had explained how charges will be paid.
- 6.45 The Committee noted that the Applicant's 'SOP for Dispensary –Repeat Dispensing (version 1)' includes under the heading 'Pharmacy2U specific workflow':

6.45.1 *“Customer Care will enter patient details onto the CDB in the usual manner. If payment / exemption details are required, the operator will contact the patient to request these. Registration will not be completed until all payment / exemption details have been provided.”*

- 6.46 The Committee noted that the application, the Applicant’s representations or SOPs, do not include reference to any process by which NHS Charges will be paid by the patient.
- 6.47 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(5)(b) of Schedule 4.

#### Providing ordered drugs or appliances

- 6.48 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).

- 6.49 The Committee noted the Applicant’s ‘SOP for Dispensary BSOP1. Delivery of medicines and patient returns (version 1), page 1 includes: under the heading: ‘Delivery of Medicines’:

6.49.1 *“We send parcels primarily using Royal Mail tracked and/or signed-for services, depending on the nature of the items being dispatched and the patient’s preferences. We always used tracked and signed-for services for any parcels containing controlled drugs, and medicines that require refrigerated storage in transit are packed in pharmaceutical grade WoolCool packaging and sent by a 24 hour tracked service, with the patient being kept informed about the date of dispatch and tracking information of all parcels on every occasion.*

6.49.2 *“Box Size o LLT: Large Letter. A container which would fit through a standard sized letterbox.*

6.49.3 *B+: a box size larger than LLT, that can be packed automatically by the B+ packing machine.*

6.49.4 *Oversized: boxes that are larger than the B+ can pack, and which are packed and sealed by hand.*

6.49.5 *Priority*

6.49.6 *Premium: orders containing an item requiring refrigerated storage in transit; orders manually upgraded by our customer care team; or the back order component (owing) from an order that has been previously split.*

6.49.7 *Standard: all scenarios not listed above.*

6.49.8 *LLT Consent*

6.49.9 *If a patient has consented to receive parcels through their letterbox with no signature required, the parcel will be sent by a tracked service that does not require a signature. If an order is small enough to be packed into an LLT container, and the patient has given consent, it will be delivered through the patient's letterbox.*

6.49.10 *This has been risk assessed and cleared with the GPhC. Patients are asked to confirm that there are no children or pets at the address who could be harmed by this service.*

6.49.10.1 *If consent is not given, all parcels (including LLT containers) will be sent by a service that requires a signature on delivery."*

6.49.11 *Also on page 2 under the heading 'Controlled Drugs':*

6.49.11.1 *"Any order containing a controlled drug will always be dispatched using a service requiring a signature on delivery, regardless of LLT consent"*

6.49.12 *Also on page 2 under the heading 'Safe Place'*

6.49.12.1 *"If a patient provides consent for a parcel to be left in a "safe place" at their property if they are out, and it is packed into a B+ or oversized box, and does not contain a controlled drug, the parcel will be sent by a "Tracked Safeplace" service."*

6.49.13 *On page 2 under the heading 'Cold chain deliveries':*

#### **Cold chain deliveries**

6.49.13.1 *Medicines requiring refrigerated storage in transit are sent in WoolCool packaging which is designed specifically to keep pharmaceuticals within their target temperature range during delivery.*

6.49.13.2 *More information is available at <https://www.woolcool.com/pharmaceutical/>*

6.49.13.3 *We have conducted our own tests which show Woolcool maintains the temperature range below 8 degrees for 30-32 hours (see Appendix 1). Deliveries are always sent by 24 hour tracked or signed services, cold chain items are removed from refrigerated storage as late as possible before dispatch from the facility, and patients are kept updated on the progress and delivery date and time of such parcels via emails, texts, and visual information on our website and app to prevent failed deliveries.*

#### **Failed deliveries**

6.49.13.4 *Parcels returned to us by Royal Mail that were not delivered successfully to patients, or which were refused by them or returned to us after opening, are received by our customer service team each morning.*

*6.49.13.5 The customer service team have a process for checking each return at their earliest opportunity to confirm if the patient needs contacting, or if the contents of the parcels can be passed to the pharmacy team for destruction.*

*6.49.13.6 A full audit trail is kept of all steps taken and all medicines destroyed.*

*6.49.13.7 Controlled drugs are segregated and destroyed in the correct way (see CD SOPs).*

6.50 *A detailed SOP of this process is kept within the customer service team SOPs”*

6.51 The Committee noted the applicant’s comments regarding how drugs/appliances will be provided to the patient including ensuring that the cold chain is maintained. The Committee noted that the Applicant intends to rely on Royal Mail to transport the dispensed items. The Applicant has referred to the use of Woolcool packing sent via a 24 hour tracked service. However, the Committee was provided with no information to show how the Applicant would ensure that the cold chain packaging had not been breached at any point prior to its delivery to the patient. The Applicant has also referred in its SOPs to failed deliveries. The Committee was provided with no information to show if cold chain items can be stored pending a further delivery attempt and if so how the Applicant would ensure that the cold chain continues to be maintained. The Committee noted the Applicant’s reference to patients who give consent, to have their dispense items left in a safe place. Again the Committee had no information to show that the Applicant had demonstrated how the cold chain can be maintained.

6.52 The Committee further noted that the cold chain process does not include potential returns to the dispensary, Royal Mail storage and return being potentially outside of the limits of the materials the Applicant uses; let alone tamper proofing. The Committee was mindful that this potentially longer gap is more likely to render any temperature controlled drug unviable; a risk not addressed in the SOPs.

6.53 The Committee concluded that the Applicant had provided insufficient information regarding the delivery of cold chain items such that it could not be satisfied that the integrity of any items would be maintained throughout the delivery process.

6.54 As regards to Controlled drugs, the Committee noted no information had been provided to show how the security of dispensed items would be maintained. The Committee had concerns regarding the method of delivery chosen by the Applicant for the delivery of controlled drugs. The Committee noted the Applicant’s intention to use Royal Mail tracked services for the delivery of controlled drugs to patients. The Committee was provided with no information to indicate the conditions under which the controlled drugs are transported on leaving the pharmacy. Nor that items will be stored in a locked delivery vehicle, and will not be left unattended. The Committee noted there was no information regarding the tracking system and an explanation given as to how this would allow the Applicant to ensure that it is aware on a regular basis of the safe progress of the dispensed items to the patient, whether over short distances or to further afield in England.

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

Refusal to provide drugs or appliances ordered

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

- 6.57 The Committee noted that the Applicant had stated in their application form: *“The Applicant will providing dispensing of appliances including ostomy and other products.”*

- 6.58 The Committee further noted that in its representations on the appeal, the Applicant stated:

*6.58.1 “We intend to supply appliances in the normal course of our business. We do this in our existing pharmacy. We are not permitted to offer any essential NHS services on the premises so this has to be done remotely. Our current process is to contact patients wherever necessary and ask them to provide measurements; we guide them as to which measurements are necessary, how to take them, and how to send the details back to us promptly. If we assess the patient as not being able or willing to provide accurate measurements, we will recommend that the prescriptions is returned to the spine to be dispensed elsewhere, or we will contact the patients surgery for assistance.”*

*6.58.2 “We believe that not offering to dispense appliances would significantly compromise the convenience of our service as these are often bulky items for which home delivery (distance selling) pharmacy is particularly well suited. We therefore intend to offer appliance dispensing whilst recognising that gathering measurements may be difficult in some circumstances; and we are fully committed to helping patients to obtain their measurements and appliances elsewhere if this is the best option for them, as we do in our existing pharmacy.”*

- 6.59 The Committee noted Schedule 4, Part 2, Regulation 8 ‘Providing ordered drugs or appliances’ includes in sub-paragraph (4) *“If the order is for an appliance of a type requiring measuring and fitting (for example a truss), P must make all necessary arrangements for a registered pharmacist:*

*6.59.1 (a) to measure the person named on the prescription form or repeatable prescription for the appliance; and*

*6.59.2 (b) to fit the appliance.”*

- 6.60 The Committee considered that there is a clear obligation within the regulation above, for a registered pharmacist to measure the person and where necessary fit the appliance. The Committee noted the Applicant’s usual procedure as referred to above, would not involve a pharmacist measuring the person. Nor was any information given to show how a pharmacist would be fitting the appliance. The Committee noted whilst stating that prescriptions may need to be dispensed elsewhere seemingly because the patient is unwilling or unable to take the measurements themselves, the Applicant has not indicated how it

would make all necessary arrangements for a registered pharmacist to carry out the appropriate task(s).

- 6.61 Based on the information before it, the Committee was not satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(4) of Schedule 4.
- 6.62 The Committee considered whether the applicant had explained what containers will be “suitable” for posted/delivered items.
- 6.63 The Committee noted the Applicant’s ‘**SOP for Dispensary BSOP1**. Delivery of medicines and patient returns (version 1), page 1 includes: under the heading: ‘Delivery of Medicines’:
- 6.63.1 *“We send parcels primarily using Royal Mail tracked and/or signed-for services, depending on the nature of the items being dispatched and the patient’s preferences. We always used tracked and signed-for services for any parcels containing controlled drugs, and medicines that require refrigerated storage in transit are packed in pharmaceutical grade WoolCool packaging and sent by a 24 hour tracked service.”*
- 6.64 The Committee noted the Applicant had provided a link to WoolCool’s website where an explanation was provided for the various boxes pouches and envelopes is given:

#### Courier Boxes

- 6.64.1 *“Woolcool’s cardboard outer box is ideal for transporting a wide range of temperature controlled Pharma products and is available in six stock sizes. Offering a truly sustainable solution, our Courier Boxes are reusable and recyclable.”*
- 6.64.2 *“We can tailor our Courier Boxes to meet the requirements of your business, from offering different size options to creating bespoke designs”*

#### Insulated Envelopes

- 6.64.3 *“Woolcool’s Thermally Insulated Envelopes provide a robust and reliable way of delivering smaller quantities of Pharma products. Built in a classic envelope style with no gusset, Insulated Envelopes are available in three stock sizes.*
- 6.64.4 *The high-performance insulation – provided by the 100% natural wool fibres inside the Insulated Envelopes – provide up to 48 hours of performance.*
- 6.64.5 *Woolcool Thermally Insulated Envelopes can be tailored to your requirements, including alternative size options and bespoke design.”*

#### Insulated Pouches

- 6.64.6 *“Woolcool’s Thermally Insulated Pouches provide a superior way of delivering smaller amounts of Pharma products. Built as a Pouch with a Gusset and featuring a Sealable Lip, Insulated Pouches come in three*

*stock sizes. We can also create bespoke designs to suit your business needs*

*6.64.7 Thanks to Woolcool's pioneering high-performance insulation – provided by the 100% natural wool fibres inside – our Insulated Pouches provide up to 72 hours of performance.*

*6.64.8 Woolcool can tailor Insulated Pouches to meet the requirements of your business, from providing bespoke designs to alternative size options.”*

- 6.65 The Committee considered that although the Applicant had provided information regarding types of outer packing this was limited to temperature controlled products. The Committee was therefore not satisfied that it had been provided with information sufficient to show 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

- 6.66 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.
- 6.67 The Committee noted that the Applicant's 'SOP for Dispensary –Repeat Dispensing (version 1)' includes a link to a PSNC website includes information about Repeat Dispensing. The Committee noted a heading 'Patient Communication Materials' includes:
- 6.67.1 A template poster entitled: 'A new way to get your regular prescriptions'
- 6.67.2 A leaflet - Also entitled: 'A new way to get your regular prescriptions'
- 6.67.3 A patient flyer - to be ordered by the pharmacy from NHS England.
- 6.68 The Committee considered that the applicant had referred to information contained on the PSNC's website. The Committee considered it unlikely that patients would necessarily be familiar with the PSNC as an organisation in the same way that a pharmacist would be. Further, the Committee noted the availability of patient communication materials although the applicant had not described how these would be brought to the patients attention.
- 6.69 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.
- 6.70 In relation to all other essential services, the Committee was, on balance, satisfied that procedures adopted by the pharmacy (and general adherence to the Terms of Service) would be "likely to secure" safe and effective provision.
- 6.71 On the information before it, the Committee could not be satisfied that there are procedures likely to secure safe and effective provision of essential services as required by Regulation 25(2)(b).

- 6.72 The Committee noted that it had reached a different determination on the application from that of NHS England. In those circumstances, the Committee determined that the decision of NHS England must be quashed.
- 6.73 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.
- 6.74 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.
- 6.75 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 not 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 not satisfied that all essential services were likely to be secured without face to face contact;
  - 7.2.3 The application is refused.

**Case Manager**  
**Primary Care Appeals**

copy of this decision is being sent to:

Mr M Cox, Lloyds Pharmacy Ltd - Appellant  
Mr P Day, Pharmacy 2U Ltd - Applicant  
NHS England  
Ms S Hind – Leicestershire & Rutland LPC